

AUDIT
REPORT

Audit of official controls
carried out by the National
Standards Authority of Ireland

MARCH 2017



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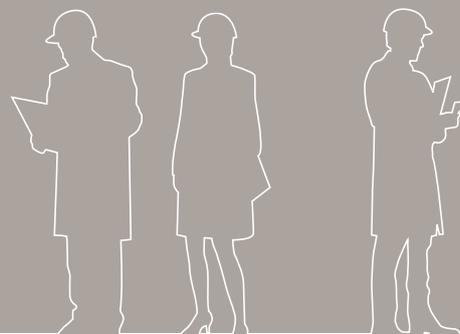


TABLE OF CONTENTS

1.	GLOSSARY	2
2.	EXECUTIVE SUMMARY	3
3.	INTRODUCTION	4
	3.1 Audit Objective	4
	3.2 Audit Scope	4
	3.3 Audit Criteria and Reference Documents	5
	3.4 Audit Methodology	5
4.	AUDIT FINDINGS	6
	4.1 Official Controls Performed in Accordance with Regulation (EC) No 882/2004	6
	4.1.1 Organisation and structure of official controls	6
	4.1.2 Coordination and planning	7
	4.1.3 Recognition and registration	7
	4.1.4 Prioritisation of official controls and risk categorisation	8
	4.1.5 Documented procedures	11
	4.1.6 Identification, follow-up and close-out of non-compliances	12
	4.1.7 Reports to food business operators	12
	4.1.8 Verification and review of official controls and procedures	13
	4.1.9 Staff performing official controls	14
	4.1.10 Contingency plans	14
	4.2 Food Business Operator Findings	14
5.	CONCLUSIONS	14
6.	AUDIT FINDINGS REQUIRING CORRECTIVE ACTION	15

1. GLOSSARY

FSAI	Food Safety Authority of Ireland
HSE	Health Service Executive
NSAI	National Standards Authority of Ireland

2. EXECUTIVE SUMMARY

The Food Safety Authority of Ireland (FSAI) is responsible for the enforcement of all food legislation in Ireland, which is carried out through service contracts with official agencies. The National Standards Authority of Ireland (NSAI) is responsible for official controls in relation to the initial and on-going recognition of natural mineral water at source and food contact materials in all non-food establishments throughout the supply chain, with the exclusion of retail establishments.

As part of its legal mandate, the FSAI is required to verify that the system of official controls is working effectively. Compliance by the NSAI with regard to relevant food legislation, adherence to the terms and requirements of the FSAI service contract, as well as conformance with relevant documented procedures, were assessed. Audits were carried out in the Limerick and Dublin offices of the NSAI, and on-site verification took place in three establishments.

The first part of the audit involved an examination of paperwork associated with official controls, reviewing 20 of the files the NSAI maintains on natural mineral water and food contact material establishments including related inspection reports. The second part involved an on-site verification audit of one natural mineral water and two food contact material establishments selected during the file review.

During the examination of the establishment files, the audit team reviewed the inspection reports and correspondence to establishments. The records of such inspections were detailed and non-compliances were addressed individually in the report. In many cases, advice and guidance were also provided to the establishment in relation to the corrective action required by them to ensure compliance with food law.

Many of the requirements within the service contract will need to be reviewed to closer align with the work of the NSAI under contract with the FSAI. The contract review process will need to incorporate better alignment of contract requirements with inspection activities and prioritise areas such as, determination of risk categorisation, inspection frequency, service plans, liaison meetings, contingency plans and sampling plans, which are not being fully met as written within the contract audited at the time of this audit.

3. INTRODUCTION

The FSAI is responsible for the enforcement of food legislation in Ireland. The FSAI carries out this enforcement function through service contracts with official agencies. These service contracts outline an agreed level and standard of food safety activity that the official agencies perform as agents of the FSAI. The NSAI has entered into a service contract with the FSAI and is responsible for enforcing food legislation for natural mineral water recognition and food contact materials. It is a requirement of the service contract and food legislation that the NSAI ensures official controls are carried out regularly, on a risk basis, and with the appropriate frequency.

The term 'natural mineral water' is legally defined and can only be used where the water complies with the specific source, compositional and labelling requirements of Directive 2009/54/EC. Natural mineral water is microbiologically wholesome water, originating in an underground source, protected from all risk of pollution and emerging from a spring tapped at one or more natural or bore exits. It is clearly distinguished from ordinary drinking water by its nature (mineral content and trace elements) and by its original state. Only very limited treatments are permitted. To be recognised as a natural mineral water, the water and source must be assessed and meet the requirements listed within the annexes of Directive 2009/54/EC.

Any material intended to come into contact with food, that is already in contact with food, or that can reasonably be expected to come into contact with food, is considered to be a food contact material. This includes packaging materials, cutlery, dishes, containers, processing machinery, cutting boards, etc. The general requirements for food contact materials are contained in Regulation (EC) No1935/2004 which requires that food contact materials are manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could: endanger human health; bring about an unacceptable change in the composition of the food; or bring about a deterioration in the organoleptic characteristics of the food.

3.1. Audit Objective

As part of its legal mandate, and in accordance with Schedule 5 of the service contract, the FSAI is required to verify that the systems of official controls put in place by the official agencies are working effectively. This audit was carried out to assess the effectiveness and appropriateness of the delivery of official controls by the NSAI. It determined whether the NSAI was in compliance with relevant official control legislation, and was adhering to the terms and requirements of the FSAI service contract. Conformance with relevant documented procedures was also assessed. The audit was carried out at two NSAI offices, in one natural mineral water manufacturer and two food contact material establishments.

This audit was undertaken as part of the FSAI's audit programme for 2016.

3.2. Audit Scope

The audit covered the organisation, planning, implementation and review of official controls of the NSAI in order to confirm compliance with the requirements of the FSAI Service Contract, Regulation (EC) No 882/2004, the Multi-Annual National Control Plan for Ireland, 2012 - 2016 and the NSAI's own documented procedures. As part of this audit, compliance with food law in the selected natural mineral water and food contact material establishments was also assessed.

The scope of this audit was the official controls carried out by the NSAI in relation to the recognition process of natural mineral water sources and the supervision of non-food contact material establishments that import, distribute or supply food contact materials in the supply chain, with the exclusion of the retail sector.

3.3. Audit Criteria and Reference Documents

- [Food Safety Authority of Ireland Act, 1998](#) (S.I. No. 29 of 1998) as amended.
- [Service Contract between the FSAI and the NSAI](#)
- [Multi-Annual National Control Plan for Ireland 2012-2016](#) (MANCP)
- [Regulation \(EC\) No 882/2004](#) on official controls performed to ensure verification of compliance with feed and food law, animal health and animal welfare rules, as amended
- [Regulation \(EC\) No 178/2002](#) laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, as amended
- [Regulation \(EC\) No 852/2004](#) on the hygiene of foodstuffs, as amended
- [Directive 2009/54/EEC](#) (S.I. No. 282 of 2016) on the exploitation and marketing of natural mineral waters
- [Regulation \(EC\) No 1935/2004](#) (S.I. No. 587 of 2007) on materials and articles intended to come into contact with food, as amended
- [Regulation \(EC\) No 2023/2006](#) on good manufacturing practice for materials and articles intended to come into contact with food, as amended
- [Regulation \(EC\) No 10/2011](#) on plastic materials and articles intended to come into contact with food, as amended
- [Directive 84/500/EEC](#) on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs, as amended
- [Regulation \(EC\) 282/2008](#) on recycled plastic materials and articles intended to come into contact with foods.
- [Directive 2007/42/EEC](#) relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs
- [Regulation \(EC\) No 450/2009](#) on active and intelligent materials and articles intended to come into contact with food
- [Regulation \(EC\) No 1895/2005](#) on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food
- [Directive 93/11/EEC](#) concerning the release of N-nitrosamines and N-nitrosable substances from elastomer or rubber teats and soothers
- Data supplied to the FSAI
- NSAI Documented Operating Procedures (DOPs)
- NSAI Database

3.4. Audit Methodology

This audit of official controls was undertaken using documented procedures which are included in the FSAI Quality Management System, namely the FSAI Audit Procedure and Charter. These procedures implement the FSAI audit obligations, defined in Schedule 5 of the service contract between the FSAI and the NSAI, and are in accordance with the requirements of Regulation (EC) No 882/2004 (including Article 6.1 of Commission Decision 2006/677/EC) and the FSAI Act.

A pre-audit questionnaire was forwarded to the NSAI, the purpose of which was to collate and confirm information regarding official controls and documented procedures within the NSAI which related to the scope of the audit. An evaluation plan was then developed which provided a detailed overview of the audit; including audit scope, objectives, criteria and team. The evaluation plan also included a proposed itinerary for on-site activity. The on-site activity took place over three days, 9th – 11th August, 2016.

The first part of the audit was office based; commencing with an opening meeting to explain the objective of the audit, the audit methodology and how the audit findings would be reported. The desktop element involved a review of the information provided as part of the pre-audit questionnaire. It also included an audit of paperwork associated with official controls from January, 2014 to the time of this audit. This evaluation included assessment of compliance with the requirements of the:

- Legislation
- Service contract between the FSAI and the NSAI and
- NSAI documented procedures

Establishment files with reports of inspections, including contemporaneous notes, were reviewed for evidence of official control activity.

The second part of the audit involved on-site verification in one natural mineral water establishment and two food contact material establishments.

A closing meeting was held at the end of the audit, the purpose of which was to outline the findings and to allow the NSAI staff an opportunity to provide clarification and/or additional information on the audit.

4. AUDIT FINDINGS

4.1. Official Controls Performed in Accordance with Regulation (EC) No 882/2004

4.1.1. Organisation and structure of official controls

Article 4 of Regulation (EC) No 882/2004 requires Member States to designate the competent authorities responsible for the purposes of the official controls set out in the Regulation. It also lays down operational criteria for the competent authorities.

Article 4 (2) of Regulation (EC) No 882/2004 requires the competent authority to ensure staff performing official controls are suitably qualified and experienced, that appropriate and properly maintained facilities and equipment are available; and that staff performing controls are free of any conflict of interest.

The NSAI has a service contract with the FSAI which outlines the agreed level and standard of official control activity it performs as the competent authority responsible for the implementation and enforcement of national and EU legislation for natural mineral water and food contact materials. These official controls specifically determine compliance with food legislation for the initial and on-going recognition of natural mineral water at source and food contact material legislation in all non-food establishments throughout the supply chain with the exclusion of the retail sector.

A structured approach for the organisation of staff for the performance of official controls was in place. There are three authorised officers currently conducting official controls in natural mineral water and food contact material establishments. One authorised officer conducts all official controls in the natural mineral water establishments. All three authorised officers carry out official controls in food contact material establishments. The authorised officers dedicate approximately 20-30% of their time to official controls related to natural mineral water and food contact materials.

At the time of the audit, there were two sites in Ireland recognised for the abstraction and subsequent bottling of natural mineral water and 111 food contact material establishments under the supervision of the NSAI. The NSAI has conducted official controls in food contact material establishments since 2012.

Procedures describing the organisation of official controls in natural mineral water establishments are documented in "DOP-38-01 Natural Mineral Water Recognition Scheme, Rev 2" and DOP-67-01 Food Contact Material Inspection, Rev 2 is used for food contact material businesses.

Legal powers and authorisations were in place for all staff conducting official controls.

4.1.2. Coordination and planning

Article 4(3) of Regulation (EC) No 882/2004 provides for efficient and effective coordination and cooperation between competent authorities.

Article 4(5) of Regulation (EC) No 882/2004 requires that, when, within a competent authority more than one unit is competent to carry out official controls, efficient and effective coordination and cooperation shall be ensured between the different units.

The NSAI business plan for 2016 was reviewed by the audit team and it included objectives in relation to scheduling and carrying out of official controls for natural mineral water and food contact materials. The NSAI team and manager responsible for these controls have quarterly meetings to review activities. The NSAI database used to manage all its certification/inspection schemes produces detailed reports on inspection activity. Due to the small number of staff conducting official controls, the audit team was advised that regular communications between the officers takes place to ensure consistency of approach. Documentary evidence was available to support this.

Schedule 2.2.2 of the service contract requires the NSAI to inform the FSAI of additions to or deletions from the list of natural mineral water premises without delay. Two natural mineral water establishments had their recognition suspended in 2016. Communication between the FSAI and the NSAI on the decision process was reviewed and found to be well documented. Following their suspension, the relevant section of the FSAI website listing all natural mineral water recognised establishments was updated.

The Health Service Executive (HSE) conducts official controls on natural mineral water from when it enters the manufacturing facility to the finished product. This means that the NSAI and the HSE, although conducting official controls on different parts of the natural mineral water process, are inspecting the same establishment. Sharing of inspection and sampling reports in cases of non-compliance between the agencies could enhance the effectiveness of official controls conducted in this establishment.

4.1.3. Recognition and registration

Article 31 of Regulation (EC) No 882/2004 requires Member States to establish procedures for the registration of food and feed business establishments. Article 6 (2) of Regulation (EC) No 852/2004 requires every food business operator to notify the appropriate competent authority with a view to the registration of each establishment.

The list of natural mineral water and food contact material establishments is maintained on the NSAI database.

Natural mineral water

The NSAI is the competent authority responsible for the recognition of natural mineral water at source. The scope of this recognition process includes the extraction point/bore hole and catchment area right up to the header tank as it enters the production facility. The official controls conducted on the production and bottling process from the header tank to the final product fall under the responsibility of the Environmental Health Service of the HSE.

The recognition process requires a minimum of two years of analytical data including hydrogeological reports, proposed extraction rates and microbiological, chemical and physical testing results demonstrating the stability of the source. A source specific "conditions of exploitation" document is drawn up by the NSAI (CN-38-01) and includes the details of the hydrogeologist's report, on-site inspections and sampling test results to confirm compliance.

A certificate of recognition is issued when the requirements within the conditions of exploitation are met. Directive 2009/54/EC (Article 1) and NSAI DOP 38-01 state that the validity of these certificates of recognition should not exceed a period of five years. The two natural mineral water establishments' files recognition certificates were reviewed with each exceeded this five year requirement. This breach had already been raised in a recent internal audit with corrective action agreed and a plan in place to address this.

Food contact material

There is no legal requirement for non-food establishments handling food contact material to register. It is therefore, through internet searches, industry and local knowledge, that new food contact material establishments are identified and then inspected by the NSAI. The current list of food contact material establishments entered onto the NSAI database with planned inspections totalled 111. The audit team noted that ceramic food contact material establishments were sampled in 2014. All samples tested within specification. Therefore, a decision was made and agreed between the FSAI and the NSAI not to conduct any further inspections in these establishments until further notice.

4.1.4. Prioritisation of official controls and risk categorisation

Article 3 of Regulation (EC) No 882/2004 requires that official controls are carried out regularly, on a risk basis and with appropriate frequency. In doing so, account must be taken of identified risks that may influence food safety, past records of food business operators, the reliability of own checks and any additional information on non-compliance.

Official control inspections are planned by the NSAI through the use of a database. This database outlines the official controls to be carried out in establishments which are under the supervision of the NSAI. It includes detailed descriptions of the types of official controls and associated tasks that are undertaken in the various establishment types.

The NSAI database sets up a unique entry for each establishment which is then assigned to an authorised officer. The frequency of inspection is pre-programmed into the database and the authorised officer is then guided by the database as to when inspections are due. Authorised officers schedule inspections up to three months in advance. If an inspection is not completed, the database highlights this to ensure it does not disappear off the inspection programme and is rescheduled.

The audit team confirmed that there was a structured and well organised approach for the co-ordination and planning of official controls. Twenty establishment files were reviewed during the audit, two for natural mineral water establishments and eighteen for food contact material establishments.

The review of food contact material establishment files focused on specific legislative requirements relating to declarations of compliance, labelling, traceability and good manufacturing practice. Details of suppliers, customers, follow-up on non-compliances and inspection reports were also assessed. The review of the natural mineral water establishment files included the examination of recognition certificates, the recognition process, conditions of exploitation, on-going recognition, compliance history and inspection reports.

Sampling plans and results were reviewed. Natural mineral water is sampled by the NSAI annually. Ceramics were sampled for compliance with food contact material legislation in 2014. The audit team noted that there is no routine or annual sampling plan for food contact materials.

Natural mineral water

Of the two natural mineral water establishment files reviewed, the audit team established that two full inspections and one sampling visit were conducted annually.

Table 1. Natural Mineral Water Establishment Inspection Summary

Establishment	2014	2015	2016
	No. of inspections	No. of inspections	(January – June) No. of inspections
1	2	2	1
2	3	3	1
3*	2	0	n/a
4*	3	0	n/a

*Establishment that had the natural mineral water recognition status suspended/withdrawn in 2016.

Inspection frequency is not specified in legislation or within the service contract.

Food contact material

The total numbers of food contact material inspections completed by the NSAI from 2014 to the audit date in 2016 are detailed in Table 2 below. No establishment was visited twice in one year. Therefore, the number of inspections each year also equals number of establishments inspected.

Table 2. Food Contact Material Establishment Inspection Summary

2014	2015	2016 January to June
42	44	28

Schedule 2.3.1 of the service contract as set out in Table 3, outlines the frequency following risk analysis, at which the NSAI will conduct official controls.

Table 3. Food Contact Material Inspection Frequency as per Service Contract

Establishment Type	Inspection Frequency
Producers of food packaging	Every year
Producers of other food contact materials	Every two years
Importers of food contact materials from Third Countries	Every year
Distributors (with no production) of food contact materials from Irish, EU or EFTA States	Every two years

Before January 2016, the NSAI authorised officers were completing inspections on all food contact materials establishments every 18 months. This was to get an understanding of the types, nature and extent of businesses in existence and in those inspected, determine the level of compliance with food contact material legislation. The initial risk model that was agreed at the start of the contract was comprehensive but proved unsuitable when implemented by the NSAI given the range in size, type and limited number of food contact material establishments. Based on 2014 and 2015 official control activities, the NSAI took the initiative at the beginning of 2016 in assigning a risk categorisation to each establishment. This new risk categorisation process includes risk category, establishment type and inspection frequency.

Table 4. Food Contact Material Establishment Risk Categorisation

Risk Category	Establishment Type	Inspection Frequency
Yes 1	Manufacturer/Producer	Every year
Yes 2	Convertor/Large distributor	Every two years
Yes 3	Small distributors	Every two years

The criteria used to assign risk are documented in procedure DOP-67-01, Section 3.2 “Inspections are performed at a frequency based upon risk giving due consideration to business type – manufacturer, convertor/large distributor, small distributor. Other factors which may be taken into consideration include b) product type and extent of contact with food, c) compliance history, d) external certifications and accreditations held by the business, e) extent of migration testing data available, f) product history/emerging issues”

In the establishment files reviewed, the audit team saw no evidence of the application of the factors listed from b) - f) being taken into account when assigning risk categorisation according to the amended procedure implemented in January, 2016. The current inspection frequency has been determined by business type.

Due to the complexity of official controls conducted by the NSAI, all inspections of food businesses are announced a couple of days in advance.

Eighteen food contact material establishment files were assessed by the audit team and since January, 2016. The frequency of official controls and the categorisation of business type are set out in Table 4. The Schedule 2.3.1 requirements of the service contract regarding risk categorisation and frequency of inspection are not being adhered to and the revised systems have not been agreed between the NSAI and the FSAI.

Finding

Food contact material

The Schedule 2.3.1 requirements of the service contract regarding risk categorisation and frequency of inspection are not being adhered to and the revised systems have not been agreed between the NSAI and the FSAI.

4.1.5. Documented procedures

Article 8 of Regulation (EC) No 882/2004 requires that competent authorities carry out their official controls in accordance with documented procedures containing information and instructions for staff, and must keep these procedures up-to-date.

Article 8(3) states that the competent authorities must have procedures in place to verify the effectiveness of official controls, to ensure corrective action is taken when needed, and to update documentation as appropriate.

The NSAI has a document management system called Q Pulse. This system maintains controlled procedures and provides access to internal audit reports, corrective actions and training records. Procedures are referred to as Documented Operating Procedures (DOPs) and are available to all NSAI staff electronically as 'read-only' documents.

There is a procedure for Document and Data control (DOP-01-06) which describes the controls over all documentation and data relating to the activities of the NSAI as well as the process for the review of existing or creation of new documents. All staff can request changes to a document however, these changes can only be approved by management or scheme champions.

During the review of the document control process, it was noted that different document headers were being used. DOP-22-01: Food Safety Management System (ISO 22000), DOP-38-01 (Revision 2): Natural Mineral Water Recognition Scheme and DOP-01-02: Training and Competence did not have an effective date and page control section as did all the other DOPs reviewed.

There is a standard template for conducting inspections for both natural mineral water and food contact material establishments. These templates were being used by all authorised officers and comprehensive contemporaneous notes were available to support all findings raised. However, an incorrect version of an inspection report template had been used for an inspection in one of the natural mineral water establishments.

Documented procedures for natural mineral water and food contact material official controls were amended prior to this audit. The audit team observed no consultation between the NSAI and the FSAI to agree the amendments made as required by the service contract.

Finding

Section 1.21 of the service contract specifies that documented procedures must be developed in agreement with the FSAI. Substantial changes to the natural mineral water and food contact material procedures were made shortly before the audit took place and were not made in consultation with the FSAI. It was noted also that some controlled documents and related records were not consistent in the template and header format used.

4.1.6. Identification, follow-up and close-out of non-compliances

Article 54 of Regulation (EC) No 882/2004 requires that when the competent authority identifies non-compliance, it shall ensure that the operator remedies the situation. When deciding which action to take, the competent authority shall take account of the nature of the non-compliance and that operator's past record with regard to non-compliance.

Article 8.3 (b) of Regulation (EC) No 882/2004 requires that competent authorities shall have procedures in place to ensure that corrective action is taken when needed.

Non-compliances are being identified and recorded in each inspection report. These are then followed up during the next inspection.

The audit team noted that some of the food contact material establishment reports included an update on the status of non-compliances from the previous inspection. As there can be two years between inspections, the inclusion of this update gives clear visibility to the establishment on progress or lack of between inspections.

From the assessment of natural mineral water and food contact material reports, the audit team noted that non-compliances were being addressed and closed out and there was an overall increase in compliance between inspections. In many cases, advice and guidance were also provided to the establishment in relation to the corrective action required by them to ensure compliance with legislation.

During the on-site visits, the audit team verified that the findings documented within the reports reviewed had been closed out. Minor non-compliances identified by the audit team had occurred since the last inspection.

The audit team noted that no enforcement action to date has been taken by the NSAI.

Three rapid alert notifications for food contact materials had occurred in the timeframe examined for this audit. There was evidence of the NSAI official control activity to follow up on all queries and evidence of communication with the FSAI to resolve the issue.

4.1.7. Reports to food business operators

Article 9 of Regulation (EC) No 882/2004 requires that competent authorities draw up reports on the official controls carried out, including a description of the purpose of official controls, the methods applied, the results obtained and any action to be taken by the business operator concerned. The competent authority shall provide the food business operator with a copy of the report on official controls carried out, at least in case of non-compliance.

It was noted during file review and on-site verification activities in both natural mineral water and food contact material establishments that detailed reports are sent to the establishment following inspections. These reports specified the aspects of official controls assessed during the inspection and the non-compliances identified. Every inspection, even in cases where no non-compliances were raised, resulted in a report being issued and circulated to the business in a timely manner.

Natural mineral water

The natural mineral water reports had three possible outcomes:

- Continue recognition
- Continue recognition based upon company response
- Suspended recognition

Food contact material

There is no overall outcome recorded on food contact material reports. The audit team did observe during the review of the food contact material establishment files, that 78% had non-compliances against the requirements for a declaration of compliance, 44% had non-compliances for labelling and 33% had non-compliances for traceability.

4.1.8. Verification and review of official controls and procedures

Article 4(2)(a) of Regulation (EC) No 882/2004 requires the competent authorities to ensure the effectiveness and appropriateness of official controls.

Article 4(4) of Regulation (EC) No 882/2004 requires the competent authorities to ensure the impartiality, consistency and quality of official controls at all levels and to guarantee the effectiveness and appropriateness of official controls.

Article 4(6) of the Regulation requires the competent authorities to carry out internal audits or have external audits carried out. These must be subject to independent scrutiny and carried out in a transparent manner.

All official control activities are recorded and submitted annually to the FSAI. These reports contain summary information on staffing, inspections numbers, sampling activities and training. The data within these reports are then inputted into annual reports and the Multi Annual National Control Plan. On review of the NSAI annual reports, the audit team noted variations in the information provided and the data verified during the audit process. Inspection numbers for food contact material establishments were higher than actually completed and training courses attended by authorised officers were not reported. Also, the NSAI annual reports indicated liaison meetings had taken place when in fact, they had not.

Follow-up inspections to resolve issues were completed promptly and effectively by the authorised officer for the natural mineral water establishments but these inspections were not recorded.

Inspection frequencies for food contact material establishments of up to three years were observed in the files reviewed by the audit team with no communication or update provided to the NSAI by the establishment between inspections.

The service contract specified that liaison meetings shall be held twice a year or more frequently as required by either party. The audit team noted that no liaison meetings occurred between the FSAI and the NSAI in 2015 or 2016 to date of this audit.

Finding

Some data provided by the NSAI in its 2014 and 2015 annual returns are incorrect.

4.1.9. Staff performing official controls

Article 4 (2) of Regulation (EC) No 882/2004 requires the competent authority to ensure staff performing official controls are suitably qualified and experienced, that appropriate and properly maintained facilities and equipment are available; and that staff performing controls are free of any conflict of interest.

Article 6 of Regulation (EC) No 882/2004 requires competent authorities to ensure that staff receive appropriate training and are kept up-to-date in their competencies.

The audit team found the staff in the NSAI to be very knowledgeable regarding both national and EU legislative requirements and they participated and co-operated fully with the audit. It was clear during the on-site verification visits to the establishments that good working relationships have been established between the establishment and the NSAI authorised officer. Additionally, the NSAI authorised officers have a good knowledge of the food business activities being carried out and the management structures in the establishments visited.

There is only one authorised officer conducting official controls in natural mineral water establishments.

Comprehensive training records are maintained and well documented.

4.1.10. Contingency plans

Article 13 of Regulation (EC) No 882/2004 requires the implementation of the general plan for crisis management referred to in Article 55 of Regulation (EC) No 178/2002, Member States shall draw up operational contingency plans setting out measures to be implemented without delay when feed or food is found to pose a serious risk to humans or animals either directly or through the environment.

Any issue of concern raised in relation to natural mineral water and food contact material under the supervision of the NSAI was seen by the audit team to be followed up thoroughly and efficiently by the authorised officers with good communication observed between the NSAI and the FSAI.

4.2. Food Business Operator Findings

During the on-site verification visits, a high level of compliance with the relevant food legislation was observed by the audit team. The business operators were advised of any minor findings observed by the team at the closing meeting on each site. These were noted by the businesses concerned and the NSAI authorised officer for follow-up at the next inspection.

5. CONCLUSIONS

The NSAI is responsible for official controls in relation to the initial and on-going recognition of natural mineral water at source and food contact materials in all non-food establishments throughout the supply chain with the exclusion of retail establishments. These duties are carried out under a service contract with the FSAI.

A structured approach for the organisation of staff for the performance of official controls was in place. The technical expertise of the authorised officers is very high and their knowledge of each establishment was very thorough. However, the risk categorisation assigned to each natural mineral water and food contact material establishment to determine inspection frequency will need to be reviewed and agreed in consultation with the FSAI to ensure all risk factors are considered.

A certificate of recognition is issued when the requirements within the conditions of exploitation are met. Directive 2009/54/EC (Article 1) and the NSAI's natural mineral water procedure DOP 38-01 state that the validity of these certificates of recognition should not exceed a period of five years. An NSAI internal audit report had raised the issue that both natural mineral water establishment files recognition certificates had exceeded this five year requirement and corrective actions were in place to address this.

The results of food safety official controls are being recorded in the NSAI database. Detailed inspection reports and contemporaneous notes are maintained and well documented. However, the summary data provided as part of the annual report submitted to the FSAI, which were reviewed as part of this audit, were found to be incorrect and will need to be amended.

Many of the requirements within the service contract will need to be reviewed to closer align with the work of the NSAI under contract with the FSAI. The contract review process will need to incorporate better alignment of contract requirements with inspection activities and prioritise areas such as, determination of risk categorisation, inspection frequency, service plans, liaison meetings, contingency plans and sampling plans, which are not being fully met as written within the contract audited at the time of this audit.

6. AUDIT FINDINGS REQUIRING CORRECTIVE ACTION

Audit findings requiring corrective action are listed in the corrective action plan. The findings identified during this audit should be disseminated nationally to ensure that corrective actions and opportunities for improvement identified are implemented across all areas.

[Audit of Official Controls carried out by the NSAI - Corrective Action Plan](#)



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