

AUDIT
REPORT

Audit of Traceability
in Food and Food Products
of Animal Origin

SEPTEMBER 2017



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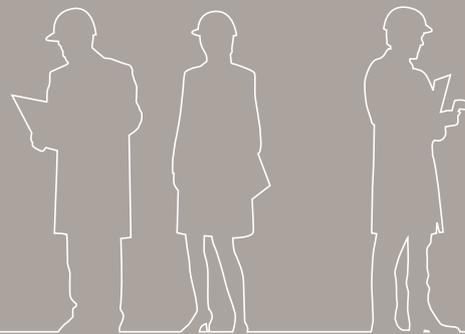


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The information in this report relates solely to the food businesses visited as part of the audit and is not necessarily reflective of the situation in other food businesses.

1. EXECUTIVE SUMMARY

The Food Safety Authority of Ireland (FSAI) has overall responsibility for the enforcement of food law in Ireland, which is predominantly carried out through service contract arrangements with official agencies. The FSAI carries out targeted audits of food businesses to determine the level of compliance with food law and the effectiveness of its implementation. This targeted audit of food businesses was undertaken as part of the FSAI's 2016 planned programme of audits, with eighteen audits conducted between May 2016 and May 2017 in sixteen food businesses. Two food businesses were subject to a follow-up audit to assess the implementation of corrective action arising from non-compliances identified in the first audit. The audit project focussed on the assessment of food business operator controls in place to ensure maintenance of traceability and labelling information along the food chain. Particular emphasis was placed on traceability and control of returned products which had been rejected by customers. Some of the food businesses were selected based on information that had been gathered during previous audits and others were selected in order to assess systems across different industry sectors and establishment size. Each food business operator was provided with an individual report following the audit of its business and these reports were copied to the relevant supervising official agency.

During the audit, operational controls, documented procedures and records relating to the food safety management system, internal audits and inspections, were examined. Twenty-seven breaches of legislation identified during the programme of audits highlight the need for food business operators to improve compliance with particular requirements of food law relevant to their business.

Sixty-eight traceability exercises were carried out by the audit team during the course of the eighteen audits. This included assessment of traceability back to suppliers as well as forward to customers for selected batches of products. Eighty-two per cent of the traceability exercises carried out were satisfactory. Twelve breaches of legislation relating to traceability were identified.

Nine of the sixteen food business operators had documented standard operating procedures relating to traceability that were satisfactory. The other seven food business operators had documented traceability procedures however, they were insufficiently detailed and did not accurately describe how traceability was managed in the food business. This is an area that has been identified in previous audits and it continues to be an area of non-compliance among food businesses.

During the traceability exercises, the audit team also assessed labelling of products for accuracy in relation to slaughter and cutting plant codes, batch codes, origin and other claims regarding the product. Non-compliant labelling was identified during seven audits. There were five occasions on which incorrect batch codes and plant codes were being recorded on traceability documents in processing areas which led to incorrect information being applied on the finished product label.

Quantitative traceability, i.e. reconciliation of quantities received, used, dispatched and in storage; was also assessed for batches of product which had moved out of the premises. In 61% (11) of the audits conducted, quantitative traceability exercises carried out were satisfactory. Some quantitative traceability exercises were not possible due to incomplete process records or errors being recorded in such records. Another reason why quantitative traceability exercises were not possible was that batch codes were not recorded on customer dockets, and therefore, quantities of the batch sold to particular customers could not be reconciled.

Food business operator controls related to product recall were assessed, and fourteen food business operators had documented recall procedures in place. Of the sixteen food businesses audited, nine had conducted a mock recall in order to test the effectiveness of their documented procedure. Those food business operators that had conducted a mock recall or had been subject to a product recall, had retained traceability, production and sales records as well as quantitative traceability records to demonstrate that the full batch of product was capable of being recalled.

As part of this audit project, particular emphasis was placed on traceability and control of returned or quarantined products, some of which had been rejected by customers. To this end, the audit team reviewed documented and operational controls in place by food business operators for such products. Eleven of the food businesses audited had addressed rejection of product by customers as part of their food safety management system. Ten food business operators audited accepted back rejected products from their customers. The remaining six food businesses did not accept product back from customers. Nine of the ten food business operators that accepted returned product had included controls for such product in their food safety management systems. These controls included determination of the designation of product, e.g. suitable for re-sale to another customer, down-grading/selling under concession or sending to waste. Procedures identified the function responsible for such a decision as well as detailing any additional checks to be performed on the returned product. Four of the six food businesses that re-sold products to another customer had electronic production management systems in place. When product was assessed and cleared for re-sale, it was then scanned back into stock using the electronic system. This scanning back into stock results in the original traceability information being expunged from the traceability records for the returned product. The full information regarding the traceability of these products which had been rejected by customers was not maintained as part of the product traceability within the production management system. A complete movement history should be available as part of the maintenance of the traceability information for these products. Amendments should be made to the electronic production management systems in processors to take account of the additional information which should be maintained in relation to rejected products. Only one of the two food business operators that were re-labelling returned product had adequate controls to ensure the accuracy and continuity of the information on the re-labelled product.

In contrast to the breaches of legislation identified during the audits, three food business operators demonstrated examples of best practice. These included one food business operator that carried out quantitative traceability for each consignment of incoming product using a spreadsheet-based programme. Another food business operator was using a web-based application as part of its incident management system. A third food business operator was using its accountancy package to facilitate forward traceability to customers.

Five recommendations are made to food business operators in order to strengthen controls in this area.

2. INTRODUCTION

The FSAI has overall responsibility for the enforcement of food law in Ireland, which is predominantly carried out through service contract arrangements with official agencies. The FSAI carries out targeted audits of food businesses to determine the level of compliance with current food law and the effectiveness of its implementation.

This targeted audit of food businesses was undertaken as part of the FSAI's 2016 planned programme of audits, with eighteen audits conducted between May 2016 and May 2017. The audit project focussed on the assessment of food business operator controls in place to ensure maintenance of traceability and labelling information along the food chain. Particular emphasis was placed on traceability and control of returned or quarantined products; some of which had been rejected by customers. Some of the food businesses were selected based on information that had been gathered during previous audits and others were selected in order to assess systems across different industry sectors and establishment size.

2.1. Audit Objective

The objective of the audit was to assess food business operator compliance with food legislation applicable to its business with particular emphasis on traceability and control of rejected, returned or quarantined products.

2.2. Audit Scope

The scope of the audit was to assess food business operator controls in place to ensure maintenance of traceability and labelling information along the food chain. Particular emphasis was placed on traceability and control of rejected, returned or quarantined products. During each audit, the team assessed whether food business operators were complying with the criteria against which the audit was being carried out.

2.3. Audit Criteria and Reference Documents

The principal audit criteria referred to during the audit were:

- [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
- [Regulation \(EC\) No 853/2004](#) laying down specific hygiene rules for food of animal origin, as amended
- [Regulation \(EU\) No 931/2011](#) on the traceability requirements set by Regulation (EC) No 178/2002 of the European Parliament and of the Council for food of animal origin
- European Communities (Food and Feed Hygiene) Regulations, 2009 ([S.I. No 432 of 2009](#)), as amended
- European Communities (Hygiene of Foodstuffs) Regulations, 2006 ([S.I. No 369 of 2006](#)), as amended

- European Communities (General Food Law) Regulations, 2007 ([S.I. No. 747 of 2007](#)), as amended
- [Regulation \(EU\) No 1169/2011](#) on the provision of food information to consumers, as amended
- European Union (Provision of Food Information to Consumers) Regulations, 2014 ([S.I. No. 556 of 2014](#))
- Health (Provision of Food Allergen Information to Consumers in respect of Non-Prepacked Food) Regulations, 2014 ([S.I. No. 489 of 2014](#))
- [Directive 2011/91/EU](#) on indications or marks identifying the lot to which a foodstuff belongs
- [Regulation \(EC\) No 1069 of 2009](#) laying down health rules as regards animal by-products and derived products not intended for human consumption
- European Union (Animal By-Products) Regulations, 2014 ([S.I. No. 187 of 2014](#))
- All relevant Statutory Instruments transposing the above legislation

2.4. Audit Methodology

This audit 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 and are in accordance with the requirements of Regulation (EC) No 882/2004 (including Article 6.1 of Commission Decision 677/2006) and Section 48 (9) of the FSAI Act.

Eighteen audits were conducted in sixteen food businesses, all of which were handling food of animal origin. Thirteen of the businesses audited were approved food businesses¹, and the remaining three were registered food businesses. Two food businesses were subject to a follow-up audit to assess the implementation of corrective action arising from non-compliances identified in the first audit.

At the opening meeting, the audit team provided an explanation of the audit to the food business operator, outlining that it was a targeted audit of food businesses, focused on assessment of controls regarding maintenance of traceability and labelling information along the food chain. Particular emphasis was placed on traceability and control of returned or quarantined products, some of which had been rejected by customers.

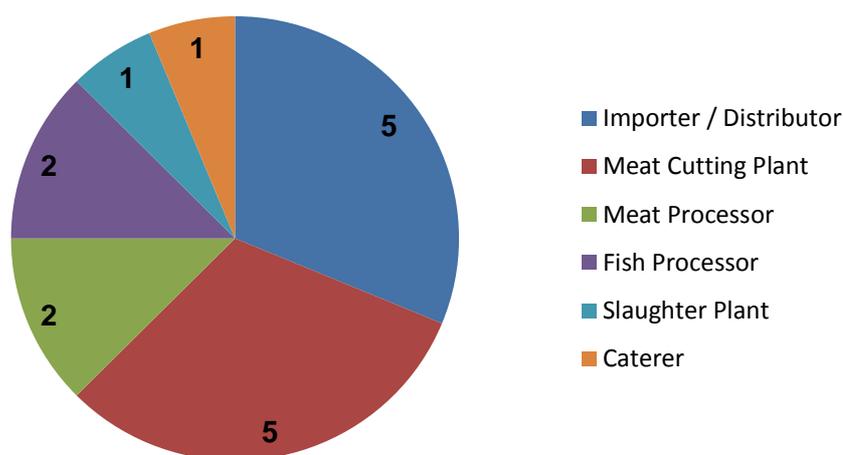
During the audit, operational controls, documented procedures and records relating to the food safety management system, internal audits and inspections were examined. The food business operator was requested to carry out a number of checks on traceability of products which had been processed or sold by it.

The supervising official agency was informed in advance of the audit so that the relevant inspector could accompany the audit team. There were six establishments under the supervision of the Local Authority Veterinary Services; four establishments under the supervision of the Department of Agriculture, Food and the Marine; three establishments under the supervision of the Environmental Health Service of the Health Service Executive and three establishments under the supervision of the Sea-Fisheries Protection Authority. Inspectors from each of the supervising official agencies attended the audits of the establishments they supervised. The audits were unannounced to the food business operators.

¹ Establishments handling products of animal origin for which hygiene conditions are laid down in [Regulation \(EC\) No 853/2004](#) must be approved by the relevant competent authority.

Following audits in which non-compliances with legal requirements were identified, the food business operator was informed of these and is required to implement corrective actions which are reviewed for close-out by the supervising official agency.

Figure 1: Types of Food Businesses Audited



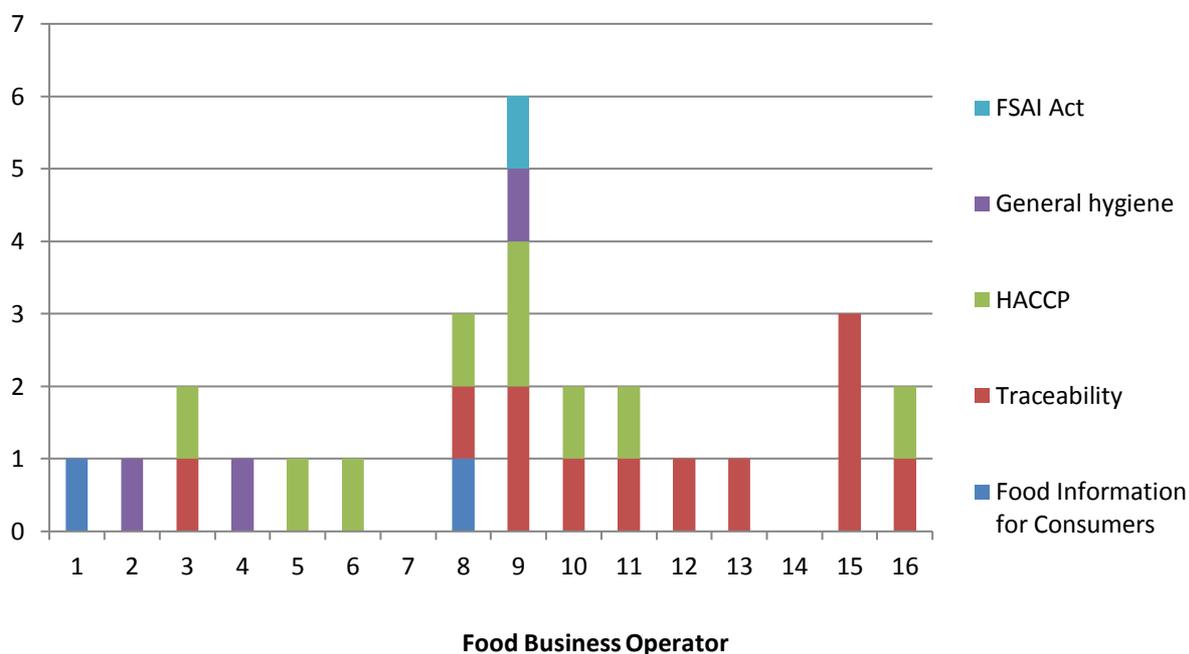
3. AUDIT FINDINGS

3.1. Breaches of Legislation

A total of 27 breaches of the following legislative requirements were observed during the programme of audits in the 16 food businesses:

- Twelve breaches of Article 18 of Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, relating to traceability
- Nine breaches of Article 5 of Regulation (EC) No 852/2004 on the hygiene of foodstuffs, relating to hazard analysis and critical control points
- Three breaches of Article 7 of Regulation (EU) No 1169/2011 on the provision of food information to consumers, relating to fair information practices
- Two breaches of Annex II of Regulation (EC) No 852/2004 on the hygiene of foodstuffs, relating to general hygiene requirements for all food business operators
- One breach of Section 50 of the Food Safety Authority of Ireland Act, 1998, as amended, relating to powers of authorised officers

Figure 2: Legislative Breaches



Three Compliance Notices were issued in three of the food businesses audited; all of which related to significant lack of traceability identified during the audits.

3.2. Traceability

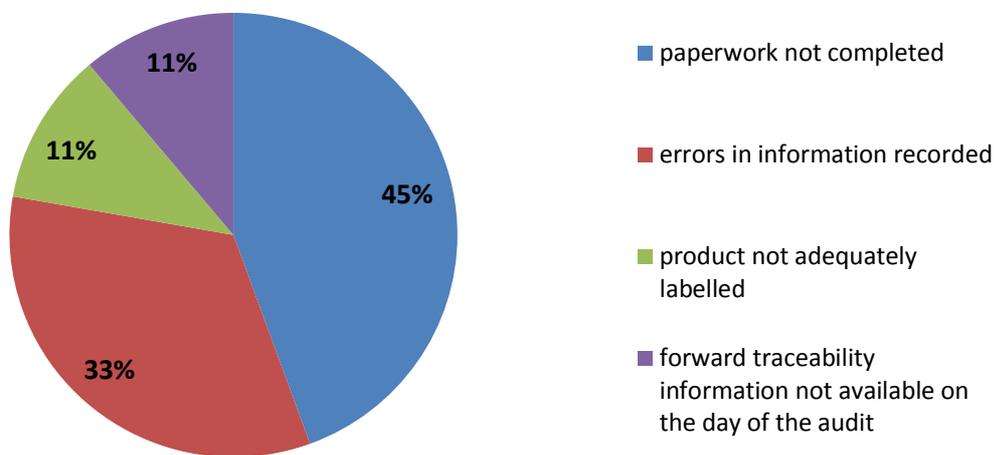
Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, requires under Article 18 that the traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed, shall be established at all stages of production, processing and distribution. To this end, such operators shall have in place, systems and procedures which allow for this information to be made available to the competent authorities on demand. It is therefore, necessary to establish a compliant system of traceability within food and feed businesses so that, if necessary, targeted and accurate withdrawals can be undertaken.

During the course of the eighteen audits, sixty-eight traceability exercises were carried out by the audit team. This included assessment of traceability back to suppliers as well as forward to customers for selected batches of products. Eighty-two per cent of the traceability exercises carried out was satisfactory. There were four main reasons that the remaining traceability exercises were unsatisfactory (Figure 3).

Nine of the sixteen food business operators had documented standard operating procedures relating to traceability that were satisfactory. The other seven food business operators had documented traceability procedures however, they were insufficiently detailed and did not accurately describe the how traceability was managed in the food business.

Significant improvement in compliance was noted during the second audit in the two establishments that were subject to a follow-up audit.

Figure 3: Reasons that Traceability Exercises were Unsatisfactory



3.3. Food Information to Consumers

Regulation (EU) No 1169/2011 on the provision of food information to consumers (FIC), under Article 8 relating to responsibilities, 8(2) requires that the food business operator responsible for the food information shall ensure the presence and accuracy of the food information in accordance with the applicable food information law and requirements of relevant national provisions. Additionally, Article 8(8) requires food business operators that supply to other food business operators food not intended for the final consumer or to mass caterers, shall ensure that those other food business operators are provided with sufficient information to enable them where appropriate, to meet their obligations under Paragraph 2.

During the traceability exercises, the audit team also assessed labelling of products for accuracy in relation to specific meat labelling legislation including, slaughter and cutting plant codes, batch codes, origin and other claims regarding the product. Non-compliant labelling was identified during seven audits. There were five occasions on which incorrect batch codes & plant codes were being recorded on traceability documents in processing areas, which led to incorrect information being applied on the finished product label. In one audit, an incorrect date of minimum durability was being applied. Had this product been subject to a recall, the wrong batch of product would have been recalled, as the incorrect date of minimum durability would have denoted a different production date. During another audit, a label was noted on poultry meat that had multiple countries of origin declared which is in breach of legislation.

3.4. Quantitative traceability

Quantitative traceability; that is, reconciliation of quantities received, used, dispatched and in storage; was also assessed for batches of product which had moved out of the premises. In 61% (11) of the audits conducted, the results of quantitative traceability exercises carried out were satisfactory. Three of the food business operators were not in a position to provide the full quantitative traceability information on the day of the audit, and provided further information following the audit. Two food business operators could provide quantitative traceability information for only some, but not all of the traceability exercises carried out. In the remaining two it was not possible for the food business operators to provide the audit team with quantitative traceability information for the selected batches. Some quantitative traceability exercises were not possible due to incomplete process records or errors being recorded in such records. Another reason was that batch codes were not recorded on customer dockets and therefore, quantities of the batch sold to particular customers could not be reconciled.

3.5. Product Recall

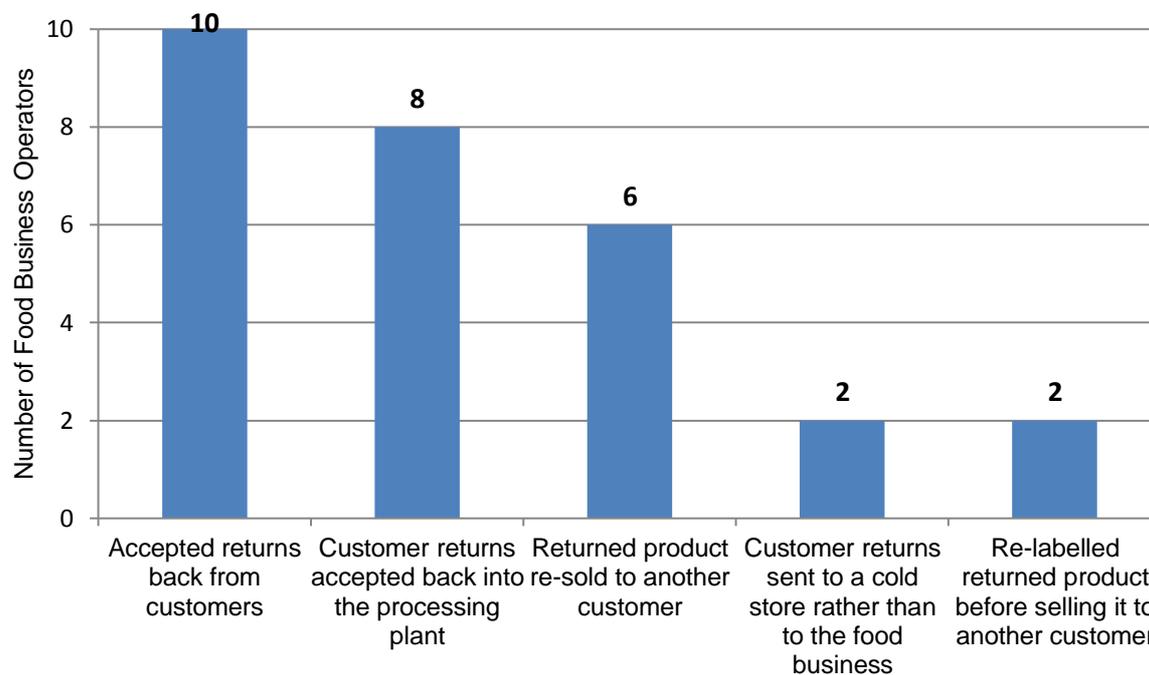
Food business operator controls related to product recall were assessed, and fourteen food business operators had documented recall procedures in place. Of the sixteen food businesses audited, nine had conducted a mock recall in order to test the effectiveness of their documented procedure. Those food business operators that had conducted a mock recall, or had been subject to a product recall, had retained traceability, production and sales records as well as quantitative traceability records to demonstrate that the full batch of product was capable of being recalled.

3.6. Management of Returned Products

Regulation (EC) No 853/2004 on the hygiene of foodstuffs requires under Article 5 that food business operators shall put in place, implement and maintain, a permanent procedure or procedures based on the HACCP principles. These procedures describe how food business operators ensure that all operations are carried out hygienically and in compliance with food law. Pre-requisite programmes ensure that operational and structural hygiene are maintained at an appropriate level for the nature and extent of the food business operation. When developing a food safety management system based on the HACCP principles, food business operators should, as part of the assessment of hazards, include the hazards associated with the return of products which have been rejected by customers. The procedures and controls in the business's food safety management system should clearly describe the controls in place at each stage of the process to maintain full traceability information and to ensure that such product is adequately controlled and identified.

As part of this project, the audit team reviewed documented and operational controls in place by food business operators for returned products. Eleven of the food businesses audited had addressed rejection of product by customers as part of their food safety management system. Ten food business operators audited accepted back rejected products from their customers. The remaining six food businesses did not accept product back from customers. Much of the product being returned from customers was fresh, and so assessment of the risks associated with the food being outside the food business operator's control, including maintenance of the cold chain, should be considered in detail as part of any assessment of suitability of the product for re-sale. Nine of the ten food business operators that accepted returns had included controls for such products in their documented procedures. These controls included determination of the designation of product, e.g. suitable for re-sale to another customer, down-grading/selling under concession or sending to waste, and the responsibility for such a decision as well as detailing any additional checks to be performed on the returned product.

Figure 4: Food Business Operators' Practices Regarding Returned Product



Four of the six food businesses that re-sold products to another customer had electronic production management systems in place. When product was assessed and cleared for re-sale, it was then scanned back into stock using the electronic system. This scanning back into stock, results in the original traceability information being expunged from the traceability records for the returned product. The full information regarding the traceability of these products, which had been rejected by customers, was not maintained as part of the product traceability within the production management system. A complete movement history should be available as part of the maintenance of the traceability information for these products. Amendments should be made to the electronic production management systems in processors to take account of the additional information which should be maintained in relation to rejected products. Only one of the two food business operators that were re-labelling returned product had adequate controls to ensure the accuracy of the information on the re-labelled product.

4. POSITIVE PRACTICES OBSERVED DURING THE AUDIT

One of the food business operators; an importer and distributor; had developed a system whereby quantitative traceability was carried out for each consignment of incoming product using a spreadsheet-based programme. This enabled any traceability or recall issues to be addressed in a very efficient and effective manner. Another food business operator was using a web-based application as part of its incident management system. This system was available on key personnel's mobile phones and facilitated immediate communication regarding any product recall. A third food business operator was using its accountancy package to facilitate forward traceability to customers. With minor amendments to the information being recorded as part of the billing process thereby enabling searches to be carried out by batch numbers, this system was very efficient in identifying which customers had received particular batches.

5. CONCLUSIONS

The 27 breaches of legislation identified during the programme of audits highlight the need for food business operators to improve compliance with particular requirements of food law relevant to their business. Twelve breaches of legislation relating to traceability were identified. Additionally, nine breaches of legislation were identified relating to the documented and operational controls as part of the businesses' food safety management systems. This is an area that has been identified in previous audits and it continues to be an area of non-compliance among food businesses.

6. RECOMMENDATIONS

1. Food business operators must put procedures in place to ensure full compliance with all the relevant requirements of food law.
2. Food business operators should ensure that food safety management systems cover the full range of activities relating to their business, and that such systems adequately address all relevant hazards or processes, including those relating to rejected, returned, re-worked or re-labelled products.
3. Corrective action is required where non-compliances were noted with regards to structural deficiencies and poor hygiene practices.
4. The FSAI has developed Guidance Note No. 10 on Product Recall and Traceability (Revision 3) and food business operators should consult this Guidance Note to help them develop effective traceability systems.
5. Food business operators should review traceability systems to ensure that the required level of traceability and accurate traceability records can be produced in a timely fashion. One way to achieve this is to conduct mock recalls on a regular basis, to test the effectiveness of the traceability system. While not a legal requirement, conducting mock recalls allows food businesses to identify any potential weaknesses in their system and strengthen the controls in place.



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