

AUDIT REPORT

Targeted Audit of Approved Establishments

MAY 2016



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1. GLOSSARY

DAFM	Department of Agriculture, Food and the Marine
EHS	Environmental Health Service
FSAI	Food Safety Authority of Ireland
HSE	Health Service Executive

2. EXECUTIVE SUMMARY

The Food Safety Authority of Ireland (FSAI) recently completed an audit of approved establishments utilising commercial cold stores, to assess compliance with food legislation. The audit had a particular emphasis on following up non-compliances identified during the audits of cold stores.

The programme consisted of seven on-site audits in approved establishments that were availing of the services of commercial cold stores to undertake additional activities on their products, e.g. to blast freeze product, collate orders, use of cold stores as dispatch depots, tempering of products, etc. Establishments were selected based on information that had been gathered during the audit of cold stores, which the FSAI carried out at the end of 2014. Each food business operator was provided with an individual report following the audit of their business and these reports were copied to the relevant supervising official agency. Verification of the implementation of corrective action to address audit findings is carried out by the official agencies as part of their official controls. The FSAI invited personnel from the relevant supervising official agencies to attend the audits. The Department of Agriculture, Food and the Marine (DAFM) attended the audits at establishments under their supervision, while the Health Service Executive (HSE) did not attend.

The wide variety of services now offered by commercial cold stores has meant that where traditionally processors sent their products to the cold store simply for storage, there is now a greater range and complexity of activities being undertaken by cold stores on behalf of processors. It is now also more common that the processors use the cold stores to store materials other than just finished products awaiting dispatch. While all of the processors audited were storing finished product in the cold stores, 43% were also storing raw materials, quarantined stock and rejected stock there, rather than at their own processing site.

All of the processors considered the cold stores they were using to be an approved supplier or sub-contractor. Documented agreements regarding the interactions between the processor and the cold store were in place in two of the processors audited. These documented agreements were in addition to the usual terms and conditions applied by the cold store relating to basic storage of product. The fact that only 29% of the processors had documented agreements regarding the activities undertaken on their behalf in cold stores, confirmed what was identified during the cold stores audit. That is, that systems and communications between processors and commercial cold stores were not adequately formalised or documented regarding these activities.

Three of the seven processors audited were operating as tenants in commercial cold stores. Each processor had dedicated space rented within the cold store and the processors' own staff worked there. During this audit at the processing establishment, the food safety management systems were assessed to ascertain whether the processor had included the activities being carried out by their staff in the cold stores. Only one of the three processors operating as a tenant in a cold store had documented the activities and controls on those activities as part of their food safety management system. The activities being undertaken in the cold stores by the other two processors' own staff had not been adequately incorporated into their food safety management systems.

In two of the processing establishments, incorrect information was being applied to products. During the traceability checks carried out, the audit team identified incorrect dates on labels, specifically the date of tempering being recorded on the label as the kill date and also an incorrect pack/freezing date. These incorrect dates had not been identified during supervisory checks during processing or checks on paperwork by the processor.

Only one of the seven processors audited had adequately described the procedures and controls in place in relation to returned product and in particular, the maintenance of traceability of such products. In the remaining six processors, the operational and documented controls regarding returns, re-work and tempering were not sufficiently detailed. Procedures developed by the processors relating to activities being carried out in the cold store on their behalf, did not include sufficient detail and failed to identify hazards and associated controls for the activities. In relation to returned product, procedures and operational controls did not adequately address product

which has been outside of the processor's direct control, e.g. product sent to a customer and rejected and returned. The procedures and controls relating to returned product and the re-work and/or re-labelling of such product require strengthening.

Traceability in the processors audited was maintained through the use of production management software systems. Each food business operator was requested to carry out traceability checks for products which had been observed by the audit team during the previous audit of cold stores. In five of the seven processors, the results of traceability checks on products which had been rejected by customers and returned to the processor were unsatisfactory and incomplete.

In two cases, reference to the dispatch to the original customer, the subsequent rejection and return to the processor, were excluded from the traceability information initially presented. When rejected product is scanned back into stock on return from the customer, the original traceability information is expunged from the traceability module of the production management system. The information regarding the initial sale and rejection was only available at the specific request of the audit team and required assistance from the processor's IT specialist to access the movement history of the product. The full information regarding the traceability within the 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.

The 15 breaches of legislation identified during the programme of audits highlight the need for processors to improve compliance with particular requirements of food law relevant to their business. This audit identified deficiencies in the manner in which food business operators control sub-contracted processes, such as those undertaken in cold stores on their behalf. It also identified that 66% of processors did not have adequate controls in place relating to activities being carried out by their own staff off-site.

In contrast, two examples of best practice were observed during the audits; one of the processors had integrated their production management system with their cold store's warehouse management system. This allowed the production information, such as batch numbers, production date, 'best-before' date, etc. to transfer across to the warehouse management system, when the product was scanned in to the cold store. It also allowed the processor to have visibility on their production management system of product while it was in the cold store. One of the processors had conducted a full audit of the commercial cold store as part of its supplier approval procedure; this included a full audit of the cold store's food safety management system as well as operational controls.

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

3. 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 approved establishments was undertaken as part of the FSAI's 2015 planned programme of audits; and was carried out as a follow-up to the audit of cold stores in 2014. The audit project focussed on approved establishments that were availing of the services of commercial cold stores to undertake additional activities on their products. These additional activities included sending products to commercial cold stores for blast freezing, collation of orders, for tempering of products or using the cold store as dispatch depots.

Establishments were selected based on information that had been gathered during a previous audit of cold stores.

3.1. Audit Objective

The objective of the audit was to assess food business operator compliance with food legislation applicable to their business; with particular emphasis on following up on non-compliances identified during the audits of cold stores.

3.2. Audit Scope

The scope of the audit was to assess food business operator controls in place in approved establishments where their products are being forwarded to commercial cold stores for storage, further processing or additional activities. During each audit, the team assessed whether food business operators were complying with the criteria against which the audit was being carried out.

3.3. Audit Criteria and Reference Documents

The principal audit criteria referred to during the audit were:

- <u>Regulation (EC) No 178/2002</u> 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
- <u>Regulation (EC) No 852/2004</u> on the hygiene of foodstuffs, as amended
- <u>Regulation (EC) No 853/2004</u> laying down specific hygiene rules for food of animal origin, as amended
- 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
- <u>Council Directive 2000/13/EC</u> on labelling, presentation and advertising of foodstuffs, as amended

- Regulation (EU) No 1169/2011 on the provision of food information to consumers, as amended
- Directive 2011/91/EU on indications or marks identifying the lot to which a foodstuff belongs
- <u>Regulation (EC) No 1069 of 2009</u> 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

3.4. 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.

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 approved establishments (processors) and was being carried out as a follow-up to the targeted audit of cold stores which took place at the end of 2014. During the audit, the interactions between processors and the commercial cold stores were examined. Documented agreements, activities being carried out on behalf of the processor, 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 in their approved establishment. These products had been identified by the audit team during the previous audit of commercial cold stores for a variety of reasons relating to labelling and traceability, or had been classified as rejected stock.

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 which were under the supervision of DAFM and one establishment which was under the supervision of the environmental health service (EHS) of the HSE. Inspectors from DAFM attended the audits of the establishments they supervised. The EHS did not attend the audit of the approved establishment supervised by the HSE. The audits were unannounced to the food business operators. Following audits in which non-compliances with legal requirements were identified, the food business operator is required to implement corrective actions which are reviewed by the supervising official agency.

The seven approved establishments audited as part of this programme of audits were meat processing establishments, all of which processed meat for the catering and retail sectors. Three of the processors also had cooking plants and produced meat products or meals which were ready-to-heat.

4. AUDIT FINDINGS

4.1. Services Availed of by Processors

The wide variety of services now offered by commercial cold stores has meant that where traditionally processors sent their products to the cold store simply for storage, there is now a greater range of activities being undertaken by cold stores on behalf of processors. It is now also more common that the processors use the cold stores to store materials, such as ingredients, other than just finished products awaiting dispatch. While all of the processors audited were storing finished product in the cold stores, 43% were also storing raw materials, quarantined stock and rejected stock there, rather than at their own processing site.

Services availed of in commercial cold stores by the processors audited included:

Table 1: Services Availed of by the Processors

Service Offered	Explanation
Product storage	Storage of product at chilled or frozen temperature
Goods receiving	Receipt of consignments of goods into the cold store
Goods dispatch	Dispatch of consignments of goods from the cold store at the instruction of the client
Traceability	Maintenance by the cold store operator of the traceability of consignments or products one step back and one step forward, on behalf of a client
Blast freezing	The freezing of product by means of a rapid current of cold air
Stock rotation	Managing rotation of consignments of products on behalf of a client. Many clients require that cold store operators dispatch their consignments on a first-in first-out basis
Stock control	The maintenance of stock to an agreed level. This can include ordering stock from a client's supplier by the cold store operator
Defrosting	The process whereby frozen product can be stored in a chilled area to allow the temperature to rise to between 0°C and 4°C in order to facilitate subsequent production at a client's establishment
Wrapping	The placing of a foodstuff in a wrapper or container in direct contact with the foodstuff concerned, and the wrapper or container itself
Re-packing/Re- wrapping	Changing or replacing the packaging or wrapping on a product
Labelling	The placing of labels onto the packaging or wrapping of a product
Decanting	The process of transferring product from one form of packaging into another, e.g. to decant meat frozen in plastic trays into boxes, or to remove frozen product from cardboard boxes and build it onto a plastic lined pallet, wrapped with a shroud
Splitting outer packs	The opening of outer packaging to facilitate the sale or distribution of smaller quantities of a product, e.g. opening an outer package containing 12 smaller packages, and removing a lesser number of packages to fulfil an order

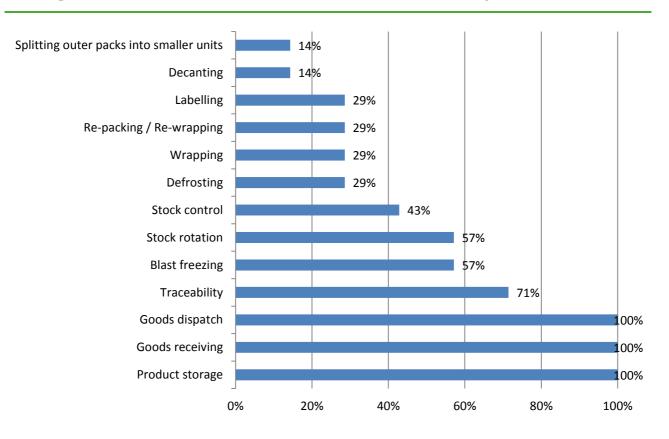


Figure 1: Services Availed of in Commercial Cold Stores by the Processors

4.2. Interactions between Processors and Cold Stores

The audit team assessed how the processors documented arrangements in regards to the activities undertaken on their behalf in the cold stores. All of the processors considered the cold stores they were using to be an approved supplier or sub-contractor. There was variety across the seven processors as to how this approval status was granted; ranging from completing a short questionnaire to carrying out an audit of the cold store, which included assessment of operational and documented controls.

Documented agreements regarding the interactions between the processor and the cold store were in place in two of the processors audited. These documented agreements were in addition to the usual terms and conditions applied by the cold store relating to basic storage of product. In the remaining five processors, there was no specific documented agreement relating to the activities being undertaken on the processors' behalf in the cold store. The fact that only 29% of the processors had documented agreements regarding the activities undertaken on their behalf in cold stores, confirmed what was identified during the cold stores audit, i.e. that systems and communications between processors and commercial cold stores were not adequately formalised or documented regarding these activities.

Three of the seven processors were carrying out audits or inspections of the commercial cold stores used by them. These varied in scope from simple customer visits to full audits of the cold stores' food safety management systems as well as operational controls.

During the audit of cold stores, it was noted that the practice of sub-letting cold store chambers or dedicated space within a chamber to tenants, has become common. These tenant operations varied from being an 'outpost' of a larger company to small food businesses using the space in the cold store as their sole premises. Three of the seven processors audited were operating as tenants in commercial cold stores. Each processor had dedicated space rented within the cold store and the processors' own staff worked there. The processors' own staff were responsible for movement of goods in and out of the cold store, management of traceability and any other activities undertaken, e.g. blast freezing, order picking, etc. Only one of the three processors operating as a tenant in a cold store had documented the activities and controls on those activities as part of their food safety management system. The activities being undertaken in the cold stores by the other two processors' own staff had not been adequately incorporated into their food safety management systems.

4.3. 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. Therefore, it is necessary to establish a comprehensive system of traceability within food and feed businesses so that, if necessary, targeted and accurate withdrawals can be undertaken.

Traceability in the processors audited was maintained through the use of production management software systems. Each of the food business operators were requested to carry out a traceability check for products which had been observed by the audit team during the audit of cold stores in 2014. In five of the seven processors, the results of this traceability check were not satisfactory.

During the previous audit of cold stores, the audit team identified products which had been rejected by a customer and were in transit back to the supplier, with no accompanying paperwork. A follow-up audit was conducted at the customer's approved establishment where traceability information was requested on these products. Satisfactory traceability information was available for one of these products, as the product had been entered into the production management system and copies of the paperwork were available. The other product, which was rejected at intake, had not been entered onto the production management system and therefore, it was not possible to trace. The audit team assessed the weight difference between what the supplier sent and what the processor paid for. The difference between these two weights corresponded with the weight of the product in the cold store. The processor agreed that this was a weakness in their system, and gave an undertaking to implement additional operational and documented controls on rejected products.

In another food business operator, traceability information for a product which had a kill date of 22/10/2014, a 'pack/freeze date' of 24/10/2014 was requested. This product had come to the attention of the audit team during the audit of cold stores, due to the fact that the 'freeze date' was not correct. The product had been received into the cold store on 12/11/2014 in its fresh state for blast freezing.

The traceability information presented regarding this product during the audit of the processor showed that the product was:

- Packed on 24/10/2014
- Dispatched to the cold store for blast freezing on 12/11/2014
- Dispatched by the cold store to a customer on 21/11/2014

The audit team requested further information regarding this product and its physical location between 24/10/2014 and 12/11/2014. The audit team informed the food business operator that this product had been seen in a cold store on 17/11/2014. At the request of the audit team, a number of 'movement' queries were run on the production management system by the processor's IT specialist, which yielded the following additional information, regarding this product.

- The product was dispatched fresh to Customer A in another Member State on 24/10/2014, from the processor's approved establishment.
- It was rejected by Customer A and returned to the processor's approved establishment, arriving on 07/11/2014, where it was scanned back into the production management system.
- This product was assessed and re-labelled on 12/11/2014 by the processor.
- It was then dispatched from the approved establishment on 12/11/2014 to the cold store for blast freezing
- The product, now frozen, was dispatched from the cold store to Customer B in another Member State on 21/11/2014.

While there were records for the re-labelling activity, including a copy of an original label and the new label, there was no indication from the new product label that it had been re-labelled. There was no reference in the initial traceability information provided by the processor to indicate that the product had been initially dispatched as fresh product, rejected by a customer and returned to the processor.

The initial traceability information provided by the processor was incomplete, in that reference to the dispatch of this product to Customer A, subsequent rejection by that customer, return to the processor and re-labelling were excluded from the traceability information presented to the audit team during the audit. The processor stated that the issue arose due to the rejected product being scanned back into stock on return from the customer, and this action expunges the original traceability information, from the traceability module of the production management system, and replaces it with the new destination information. Thus, the traceability presented for re-labelled products is not accurate or complete. Additionally, there is the possibility that this may happen several times, i.e. that the product may be rejected, returned, re-labelled and sent to a different customer more than once, resulting in the traceability of the product being incrementally lost with each rejection. The processor advised that following initial enquiries regarding this product in November 2014 as a result of the FSAI audit in the cold store, additional controls were implemented regarding the re-labelling of product. Those additional controls include the inclusion of the letter 'R' into the new product description, to denote that the product has been re-labelled. The freeze date and pack date have also been separated on the label. These additional controls, while useful, have no impact on correcting the fundamental issue regarding maintenance of the full traceability information for the product.

In another processor, a similar issue was identified whereby product was rejected by the first customer, returned to the processor, re-labelled and sold to a second customer. When the audit team requested traceability information for this product, it was presented by the processor without any reference to the first customer, the rejection by this customer or the re-labelling of the product. The information regarding the initial sale and rejection was only

¹ In production management systems, each time a product is moved from one location to another, it is recorded as a 'movement'. This can be achieved by entering information related to that product either manually or by scanning the information directly from the product, e.g. if a product moves from stock into production, it will be scanned and this change in the location of the product will be recorded in the production management system. Similarly, products are scanned into customer orders when that order is being assembled and this 'movement' is recorded in the system.

available with the assistance of the IT specialist at the specific request of the audit team, and required the IT specialist to write specific queries of the system. The production management system in place in this approved establishment was a bespoke system. It also expunged the original traceability information for rejected product, on scanning back into stock of that product, and replaced it with the new destination information.

The full information regarding the full traceability of these products which have been rejected by customers is not maintained as part of the product traceability within the food safety management system. A complete movement history should have been presented to the competent authority when requested, 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 relating to rejected products.

In one of the audits of cold stores, product labelled as 90VL minimum beef forequarter frozen in 15kg blocks but packed into 25kg boxes was seen by the audit team. This product had been rejected and was in storage in the cold store until it was to be returned to the supplier. During this audit of the food business operator who had processed and labelled the product, traceability for this product was requested. The processor advised that this product had been initially produced for a different customer but that the order had been cancelled. Following cancellation of that order, the product had been re-boxed from 15kg boxes into 25kg boxes and re-labelled for a second customer. It was at this stage that the audit team saw the product in the cold store, following its rejection by the second customer. On the day of the audit, some information was available but the processor was not able to provide a full explanation of the traceability for and movements of this product. It was not possible to establish quantitative traceability for the product which had been initially produced for the first customer, re-worked for the second customer who then rejected it and returned it to the processor. Following the audit, further information was provided by the processor to indicate that the product had been stored in a commercial cold store. This movement of the product back to the commercial cold store was not reflected on the electronic production management system. The processor advised that approximately 30% of the product was sold on to a third and fourth customer, while the remainder of the stock was still in the commercial cold store. The DAFM veterinary inspector with responsibility for the processor and the cold store, followed up on the quantitative traceability after the audit, and while certain information was provided, it was insufficient. The veterinary inspector then issued a corrective action request to the processor regarding the traceability of the specific rejected product and its movements since the rejection by the second customer. Further information was provided and the quantitative traceability was found to be satisfactory. The complete traceability and movement information for this rejected product was not provided on the day of the audit; which is not acceptable.

During the audit in another processor, the audit team identified that there was an issue in the recording of the label information for tempered products, which were subsequently being cooked by the processor to produce a ready-to-heat product. Traceability of these products was not adequate due to the date of tempering being recorded as the kill date. In addition, during other traceability checks at this processor, errors were identified in relation to the pack/freezing date being recorded. This could lead to incorrect product being recalled should an issue arise which related to specific kill dates or pack/freeze dates.

4.4. Pre-requisite Programmes and Food Safety Management Systems

Regulation (EC) No 852/2004 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 the food business operator ensures that all operations are carried out hygienically and in compliance with food law. Pre-requisite programmes ensure that operational and structural hygiene is maintained at an appropriate level for the nature and extent of the food business operators. 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.

Only one of the seven processors audited had adequately described the procedures and controls in place in relation to returned product, and in particular, the maintenance of traceability of such products. In the remaining six processors, the operational and documented controls around the area of returns, re-work and tempering were not sufficiently detailed. Procedures relating to activities being carried out in the cold store did not include sufficient detail and failed to identify hazards and associated controls for the activity. In relation to returned product, procedures and operational controls did not adequately address product which has been outside of the processor's direct control, e.g. product sent to a customer and rejected and returned. The procedures and controls relating to returned product and the re-work and/or re-labelling of such product require strengthening. Evidence of quantities re-worked or re-labelled as well as original and new labels should be maintained as part of the re-labelling process.

Of the processors operating as tenants within the cold stores, only one processor had described, as part of the food safety management system, the activities and controls relating to those activities carried out in the cold store by their own staff. Another processor had not documented the activities being carried out in the cold store; by the processors own staff, as part of the food safety management system. The third processor had documented procedures related to the activities being carried out in the cold store; however, they were not sufficiently detailed.

4.5. Food Information

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.

In two of the processors, incorrect information was being applied to products. One processor put a 'pack/freeze' date on indicating that the product was frozen on 24/10/2014; this would have been known to be incorrect at the time of application of the new label on 12/11/2014. During the traceability checks carried out, the audit team identified incorrect date related information on labels, specifically the date of tempering being recorded on the label as the kill date and also an incorrect pack/freezing date. These incorrect dates had not been identified during supervisory checks during processing or checks on paperwork by the processor.

4.6. Registration of Food Businesses within Cold Stores

Regulation (EC) No 852/2004 on the hygiene of foodstuffs, requires under Article 6 regarding official controls, registration and approval, that every food business operator shall notify the appropriate competent authority, in the manner that the latter requires, of each establishment under its control that carries out any of the stages of production, processing and distribution of food, with a view to the registration of each such establishment.

During the audit of cold stores at the end of 2014, activities were being carried out by a processor's own staff as part of a tenancy arrangement with the cold store. These included x-ray of rejected product, as well as re-labelling of product. Part of the re-labelling included the application of the identification mark belonging to the processor's approved establishment, which was located some distance away. This is not compliant with the requirements of Regulation (EC) No 853/2004. Furthermore, these activities had not been notified to the competent authority, by the processor, and were not subject to official controls at the time of the cold store audit. The audit team requested that a representative from the processor attend the cold store audit, when this was detected. The explanation given by the processor's representative at the time of the cold store audit was considered not to be adequate. The food business operator is a large meat processor with many approved establishments. During this follow up audit at the processor's approved establishment, the audit team requested further information relating to the activities being carried out in the cold store. The processor advised that they were working with the competent authority (DAFM) to seek registration of the room and activities in in the cold store.

4.7. Other Non-compliances

During the audits of the approved establishments, while attention was focused towards the follow up on noncompliances identified during the audit of cold stores, other non-compliances were also noted which related to the requirements set out in Annex II of Regulation (EC) 853/2004 on the hygiene of foodstuffs. These deficiencies related mainly to the structure of the establishment and operational hygiene within the approved establishment.

4.8. Breaches of Legislation

A total of 15 breaches of the following legislative requirements were observed during the programme of audits in the seven approved establishments:

- Five breaches of Article 18 of Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, relating to traceability
- Five breaches of Article 5 of Regulation (EC) No 852/2004 on the hygiene of foodstuffs, relating to hazard analysis and critical control points
- Two breaches of Article 8 of Regulation (EU) No 1169/2011 on the provision of food information to consumers, relating to responsibilities
- 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 Article 6 of Regulation (EC) No852/2004 on the hygiene of foodstuffs, relating to official controls, registration and approval

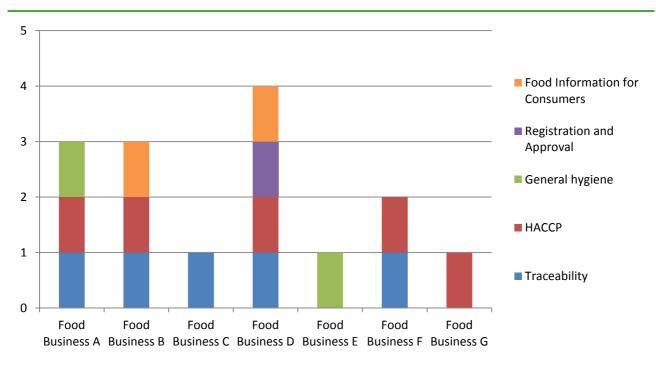


Figure 2: Legislative Breaches

5. POSITIVE PRACTICES OBSERVED DURING THE AUDIT

One of the processors had integrated their production management system with their cold store's warehouse management system. This allowed the production information, such as batch numbers, production date, 'best-before' date, etc. to transfer across to the warehouse management system when the product was scanned in to the cold store. It also allowed the processor to have visibility on their production management system of product while it was in the cold store.

One of the processors had conducted a full audit of the commercial cold store as part of its supplier approval procedure. This included a full audit of the cold store's food safety management system as well as operational controls.

6. CONCLUSIONS

The range of services being carried out in cold stores by or on behalf of processors extends significantly beyond the provision of temperature controlled storage. The lack of documented agreements as well as operational and documentary controls around the activities being undertaken in cold stores, confirmed the findings of the previous audit in cold stores. Communications surrounding the activities being carried out in the cold stores on behalf of or by the processors' own staff were not, in the opinion of the audit team, adequately formalised.

The 15 breaches of legislation identified during the programme of audits highlight the need for processors to improve compliance with particular requirements of food law relevant to their business. In five of the seven audits,

deficiencies relating to the basic management of product traceability, especially traceability of returned and reworked or re-labelled products, were identified. In many of these instances, production management systems were in place in order to manage traceability information. However, the manner in which they were set up for returned or re-worked products was not correct, leading to significant gaps in traceability information. The audit team identified that documented procedures relating to the activities being carried out in the cold stores on the processors behalf were not adequately detailed.

In the three cold stores where the processors' own staff were responsible for the activities being undertaken, only one of the processors had addressed those activities to a satisfactory degree as part of their food safety management system.

This audit identified deficiencies in the manner in which food business operators control sub-contracted processes, such as those undertaken in cold stores on their behalf. It also identified that 66% of processors did not have adequate controls in place relating to activities being carried out by their own staff off-site.

The full information regarding the traceability of rejected product is not maintained. A complete movement history should be presented to the competent authority on request, as part of the maintenance of the traceability information for products which have been quarantined, returned or rejected by customers.

7. RECOMMENDATIONS

- 1. Processors availing of services offered by commercial cold stores as part of their business activities, should document agreements to include operational and documentary controls around the activities being undertaken on their behalf.
- 2. Processors leasing part of a cold store must be registered as a food business operator at that establishment.
- 3. Processors must ensure that they maintain a complete and accurate record of the traceability of all products.
- 4. Processors must put procedures in place to ensure full compliance with all the relevant requirements of food law.
- 5. Processors 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.
- 6. Corrective action is required where non-compliances were noted with regards to structural deficiencies and poor hygiene practices.



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