Efficacy of Withdrawals and Recalls: Case studies

Case study 1: Physical contamination of butter

Recall of butter due to the possible presence of metal:

A dairy Food Business Operator (FBO) was contacted by a consumer alerting them to the possible presence of a foreign object (small piece of metal) in a butter product. The FBO conducted an internal investigation and found that damage to a butter trolley was the likely source of the metal. After consultation with their local authority, the FBO decided to initiate a voluntary recall of the butter. This involved the FBOs themselves deciding to recall the products distributed via major UK supermarkets, online retailers and a small exporter as a precautionary measure.

Experience of the recent product recall

Following a second consumer notifying the business about the presence of a foreign object in the butter, the FBO consulted with the local authority regarding next steps. After this call with the local authority, the FBO then decided to initiate a voluntary recall of the butter. For the FBO, it was surprising that the decision to recall the butter was determined by their own judgement rather than direct instructions from the FSA/FSS to initiate a recall. On reflection the FBO agrees that a recall in this circumstance should remain the decision of the FBO.

How did the FBO communicate with retailers and consumers?

As part of the recall process, the FBO contacted retailers immediately via emergency contact details. They noted that they did not have up-to-date contact details for one retailer, which made the process slightly longer (i.e. over 24 hours). They also communicated with a small number of anxious consumers directly via their regular telephone line. They suggested that, in hindsight, they would have made more staff available over the weekend to respond to all consumers as soon as they contacted the business.

How did the FBO communicate with the local authority and FSA/FSS?

Throughout the incident, the FBO was in contact with the environmental health team within their local authority and the Incidents Team within the FSA/FSS, via emails and conference calls. A Root Cause Analysis (RCA) investigation was undertaken by the FBO, with the findings shared with the local authority and FSA/FSS. Both the local authority and the FBO acknowledged that this process was helped by having a good relationship prior to the incident.

Reflections on the new product withdrawals and recalls system

How clear were the roles and responsibilities?

The FBO reported that roles and responsibilities during the recall were clearly outlined by both the local authority and the FSA/FSS. The local authority reported that they had a good relationship with the FBO, which made the process straightforward.

The FBO praised the FSA/FSS for being responsive and available out-of-hours (given that the incident was around Christmas), and they welcomed the FSA/FSS ongoing communication and support during this stressful event (for example, responding to emails outside of regular working hours). They suggested that there was a perception within industry that interaction with the regulator could be “scary”, but they did not find that to be the case.

Learning and wider impacts of the improved product withdrawals and recalls system

As a result of the incident and corresponding RCA, the FBO removed the equipment in question and conducted fortnightly inspections of equipment. The FBO then redesigned the equipment to ensure no further issues could arise and following a risk assessment, they have chosen not to incorporate any other FSA/FSS guidance in their systems as they consider their current food safety incident protocol to be robust.

The FBO itself had not had any previous experience of a product recall, so were unable to comment on any differences with the previous withdrawals and recalls system.

Recommendations for the future

1. **Use a variety of consumer alert mechanisms** – as customer bases are often diverse, using a variety of methods to alert consumers (for example, social media, newspaper adverts) helps to alert different demographic groups.
2. **Consider developing a tailored recall message for website responses and regular out-of-hours monitoring during incidents** - the FBO suggested that other FBOs develop a tailored message to communicate with consumers affected by the recall.
3. **Consider developing more tailored withdrawals and recalls guidance for Small and Medium Enterprises (SME)** – these FBOs tend not to have the same levels of processes or experience as larger businesses, and may benefit from additional guidance aimed at SMEs.
4. **Ensure that FBOs keep up-to-date contact details for distributors** - this means that any withdrawal or recall decision can be communicated quickly, and products can be removed from shelves as son as possible.
5. **Consider developing a single form for a recall** - the FBO noted that both the local authority and FSA/FSS had separate forms, which were time consuming to complete. They suggested that a single form for both organisations would save time.
6. **Continue to ensure the recalls system continues to be flexible to cover the wide variety of FBOs** - a one-size-fits-all approach does not work in this diverse industry

Case study 2: Defective packaging of water bottles

Recall of water bottles due to production error (exploding/shattering bottles):

The FBO producing sparkling water received a complaint from a consumer claiming their glass bottle exploded. After receiving another complaint, the FBO initiated their internal process for an incident and contacted FSA/FSS. After a consultation with the local authority and the FSA/FSS, the FBO instigated a recall of the sparkling water because of a manufacturing fault that was causing the glass bottles to explode. This involved recalling products distributed via UK supermarkets and other businesses that were purchasing the bottles directly from the FBO. The product was also exported.

Experience of the recent product recall

How did the FBO communicate with retailers and consumers?

The recall notices were displayed in stores to notify the consumers. The FBO had several discussions with FSA/FSS to decide on the wording of the recall notice. They also posted the notice on their website.

How did the FBO communicate with the local authority and FSA/FSS?

For this FBO, it was their first time dealing with the FSA/FSS and they noted it was a “good learning experience”. The FBO suggested that having a named contact within the local authority would have been useful.

The FBO used the guidance and had no issues in taking the appropriate actions. They also had an internal colleague from their media team supporting them to share information with consumers during the recall process.

Reflections on the new product withdrawals and recalls system

How clear were the roles and responsibilities?

The FBO reported that roles and responsibilities during the recall were clearly outlined by the FSA/FSS. The FBO also praised their Incident Manager from the FSA/FSS for their effective communication. They also emphasised that contrary to their expectation of having a stressful recall, it was an easy and reassuring process.

Learning and wider impacts of the improved product withdrawals and recalls system

An RCA was undertaken, with an independent company assigned to undertake tests on the glass. The investigation findings support the likely root cause of bottles breaking as ‘Static Fatigue’ caused by a combination of: Increased pressure caused by HSG filler charge-up pressures and variable fill level control and increased ambient summer temperatures in the supply chain/consumers houses, affecting underlying micro- fractures within bottles which in some cases could cause the bottle to shatter. These findings were shared with the FSA/FSS as well as their bottle manufacturer.

As a result of this incident, the FBO and their supplier had to reconsider the design of certain bottles, and ultimately moved to another bottle design. They also increased the testing of their bottles and testing for overfills, to ensure the safety of the product.

Recommendations for the future

1. **Consumer notifications through social media** – the FBO suggested companies to share the recall notice on social media (for example, Facebook and Twitter) on their company accounts as this would potentially allow to reach more people.
2. **FBOs need improved education** – in some areas of their products, and use of packaging materials in production.
3. **Cross-industry sharing of learnings** - should be encouraged as learnings from the RCA can be applied more widely.

Case study 3: Salmonella incident

Recall of breaded chicken products due to contamination with salmonella:

The FBO issued a notification of a food incident after receiving a positive salmonella result for one of their supplied breaded chicken products. The sample was taken as part of the FSA/FSS Chicken Survey (footnote 1) By the time this incident was identified, the FBO confirmed that the batches were sold out and, therefore, no longer on sale.

Experience of the recent product recall

How did the FBO communicate with retailers and consumers?

The FBO issued email alerts, posted notices online, and displayed them in store.

Did the FBO undertake a Root Cause Analysis?

The FBO communicated with the supplier to check their process to identify the root cause, however, the RCA was unsuccessful in identifying the problem. The RCA contained an in-depth overview of the issue identifying the batch details, the level of risk, any communication made during the investigation, any potential root cause along with corrective and preventative actions that the supplier will implement.

Reflections on the new product withdrawals and recalls system

How clear were the roles and responsibilities?

The FBO agreed that the roles and responsibilities were clear.

How effective was the support and guidance?

The FBO used an online application form to complete an RCA, however, they noted that sometimes the FSA/FSS would ask the FBO to complete a separate form for an RCA in addition to the online one. The format of that MS Word version for the RCA document was remarked as “not user friendly”.

Moreover, the stakeholder interviewed indicated that the FSA/FSS guidance contains useful information, for example, contacts for allergy organisations. They also used the decision tree available in the guidance to decide whether the situation should be classed as a withdrawal or a recall. Overall, the stakeholder found the guidance supplementary to their own established internal processes and policies.

Learning and wider impacts of the improved product withdrawals and recalls system

The supplier of the breaded chicken products no longer sources chicken from certain companies where salmonella was detected. All products are also now fully cooked on site.

Recommendations for the future

1. **Improve the online forms to make them more user friendly** – the stakeholder suggested that an option to download the form and complete it offline would make this process easier.

Case study 4: Possible contamination with Hepatitis A

Recall of medjool dates due to possible contamination with Hepatitis A:

The UK Health Security Agency (UKHSA) discovered an outbreak of Hepatitis A related to the consumption of medjool dates. They notified the FSA/FSS who, in turn, notified the FBO. At the

time, the FBO had not received any complaints and all tests of sample dates were negative for Hepatitis A. However, the HSA advised the FSA/FSS and the FBO that there is strong epidemiological evidence linking this FBO to the medjool dates incidents in the community. Once the UKHSA shared their epidemiological report with the retailer, the FBO initiated a recall.

Experience of the recent product recall

How did the FBO communicate with retailers and consumers?

The FBO displayed notices in stores and emailed consumers via a loyalty scheme.

Did the FBO undertake a Root Cause Analysis?

The FBO undertook an RCA, however, even after thorough investigations, such as handling controls, and water control, they did not manage to establish the root cause.

Reflections on the new product withdrawals and recalls system

How clear were the roles and responsibilities?

The FBO reflected that the process was clear in terms of roles for each party involved and what the expectations were. Due to the nature of this incident, there was also involvement of the UKHSA. Going forward, the FBO suggested having direct communications with the UKHSA as opposed to via the FSA/FSS as it would speed up the information exchange and investigation, allowing action to be taken sooner.

How effective was the support and guidance?

The stakeholder said that the FSA/FSS guidance was “perfectly accessible”, and they used the templates online to create their recall notices.

Learning and wider impacts of the improved product withdrawals and recalls system

The FBO explained that they review their recall processes on an annual basis regardless of whether an incident had occurred or not. The FBO’s supplier follows the GLOBAL G.A.P. (an international food safety standard for farms) and as a result of this recall, they will challenge this standard as they followed all the requirements and the incident occurred anyway.

Recommendations for the future

1. **Industry-wide guidance on Whole Genome Sequencing (WGS)** – The stakeholder suggested that the power of WGS will help to identify more outbreaks than it was previously possible to. If the industry is going to be basing recalls on epidemiology and probabilities, there needs to be more online guidance for industry on understanding statistics and thresholds.
2. **Ensure the consistency of the guidance used** – while recognising that the quality of guidance is good, the FBO noted a lack of consistent enforcement of the guidance as they reflected some businesses would use “may contain” instead of “does contain” which affects how consumers perceive the significance of an incident.
3. **FSA/FSS should play a stronger role in enforcing recalls with brands** – the stakeholder stressed that retailers do not have any oversight over the technical processes of their branded suppliers, however, they have been asked to push their branded suppliers to recall on occasions. The stakeholder suggested that the FSA/FSS should be responsible for ensuring brands take the right action to protect the public whilst retailers take technical accountability for their own brand.

Case study 5: Incorrect allergen labelling on bread

Recall of bread due to the presence of undeclared sesame seeds:

A small Food Business Operator (FBO) was informed by their local authority during a routine inspection that the label on one of their loaves did not correctly declare the presence of sesame seeds. Sesame seeds are one of fourteen ingredients that are required to be declared as allergens by food law within the UK, to ensure that food is safe for consumers with food allergies. The label indicating that the product contained sesame seeds was applied to the front of the packaging rather than explicitly named in the ingredients list. The FBO undertook a recall of product following consultation with local authority and FSA/FSS.

Experience of the recent product recall

After being alerted to the incorrect labelling by the local authority, the FBO initiated the recall process. Slightly over 100 incorrectly labelled loaves were on supermarket shelves at the point at which the recall began. Although no ill effects were reported by consumers, the FBO took the decision to cease production of the sesame seed loaf.

How did the FBO communicate with retailers and consumers?

As there were relatively few shops selling this product, the FBO was able to inform retailers directly to remove the product. A point of sale notice was also placed in shops to alert consumers.

How did the FBO communicate with the local authority and FSA/FSS?

As the recall came through a routine local authority inspection, the local authority was involved from the outset, and also led on communication with the FSA/FSS. There was a high level of communication between the local authority and the FBO via email and telephone calls, which was useful to ensure that the recall was initiated quickly.

Reflections on the new product withdrawals and recalls system

How clear were the roles and responsibilities?

As a small business, the FBO indicated that the recall process was unfamiliar and slightly daunting, compounded by tight timeframes. This was the first time they had had to undertake a recall, so were unfamiliar with the process. The FBO reported some uncertainty around terminology used in the FSA/FSS guidance and Root Cause Analysis (RCA) document, and that they required some additional support from the local authority to complete this, who were able to explain the process.

Learning and wider impacts of the improved product withdrawals and recalls system

The FBO undertook an RCA following the incident. As a result of the recall, the FBO ensured that the labelling machine is now able to amend labels, and products are placed in transparent bags. The FBO analysed all other products to check that they were compliant, and that all allergens were noted on the labels. They also provided training to staff to ensure that they were aware of the potential allergy risks and how to prevent any future contamination.

The recall was described as a stressful experience for the FBO, and consequently they decided not to continue producing the sesame seed loaf, given the small quantities produced.

Recommendations for the future

1. **Provide tailored guidance for small FBOs** - only a limited number of small FBOs will have had experience of a previous recall, and many will not have specific staff to undertake this role. Therefore, small FBOs are more likely to require additional support to navigate the recalls process. Specific guidance (including common recalls case studies) could be provided for small FBOs, as well as a glossary of key terminology.
2. **Consider providing face-to-face training or webinars for small FBOs** - this would ensure that FBOs were aware of the steps required in any recall, as well as provide opportunities to share learning with other local businesses.

Case study 6: Chemical contamination of a food supplement

Recall of a food supplement due to the presence of Ethylene Oxide:

The FBO received a notification from their trade group that there had been an international contamination of calcium carbonate, an ingredient in the FBO's food supplement. The calcium carbonate had been contaminated by ethylene oxide, a pesticide which is not permitted in the UK. Correspondingly, after discussion with their local authority, the FBO decided to recall the product.

Experience of the recent product recall

As the product was on an introductory trial within the UK, the product was only available in a small number of retailers. However, an internal risk assessment conducted by the FBO suggested that in the unlikely event of a single consumer buying more than six products and any associated health risks with this quantity, a recall should be instigated. The FBO detailed this risk and the consequences in their incident report form which was then agreed with the local authorities.

The majority of the products were returned to the FBO from retailers, with a small number (less than ten) coming from consumers.

How did the FBO communicate with retailers and consumers?

Following the decision to recall the product, a point of sale notice was created, and the FBO communicated directly with the retailers.

How did the FBO communicate with the local authority and FSA/FSS?

The majority of communication was with the local authority, who co-ordinated with the FSA/FSS on the FBO's behalf.

Reflections on the new product withdrawals and recalls system

How clear were the roles and responsibilities?

Overall, the FBO described the process as "well done", with clear roles and responsibilities. The local authority was praised for being responsive. The FBO suggested that the guidance was extensive, but comprehensive, and answered all of their questions. They also found the annex and examples contained in the guidance to be particularly helpful. Interestingly, they suggested that, without the guidance, they would have been unlikely to follow the official process and reach out to their local authority first, and would have instead gone directly to the FSA/FSS.

Learning and wider impacts of the improved product withdrawals and recalls system

The FBO undertook an RCA investigation, and have adapted the FSA/FSS RCA template for mock recalls, as they found it “gold standard”.

Recommendations for the future

1. **Consider promoting the RCA e-learning module** - the FBO suggested that there was limited awareness of its existence within the industry, and it could be promoted via trade bodies.
2. **Periodically share the guidance flowchart amongst FBOs** - this was regarded as extremely helpful, as it was concise and alerted the FBO about next steps, so further awareness of this would be useful.

Case study 7: Allergen contamination of a Thai style sauce

Recall of a Thai style sauce due to undeclared allergen (milk):

A large supermarket chain was notified by one of their suppliers that milk was detected in routine testing of a product. Milk was not an intended ingredient in this product, therefore, not declared on the label. The FBO initiated an internal recall process and removed products from the stores. As the FBO had a previous recall experience, they directly got in touch with the FSA/FSS to initiate the wider formal process of a recall.

Experience of the recent product recall

How did the FBO communicate with retailers and consumers?

The FBO notified the consumers by putting a notice on their website, sending direct messages to online shoppers and sharing notices on social media. According to the FSA/FSS procedures, an allergy alert was issued as well.

Did the FBO undertake a Root Cause Analysis?

During the RCA, it transpired that supplier’s procedures for cleaning were not followed accurately and, thus, caused cross-contamination. However, as those procedures were not clear enough, an action plan was created and additional monitoring enforced. The learnings from the RCA were then shared with the FSA/FSS. The FBO felt this process was a standard response for them.

Reflections on the new product withdrawals and recalls system

How clear were the roles and responsibilities?

The FBO reported that roles and responsibilities were very clear across the FSA/FSS and the FBO. As the FBO had previous experience of dealing with recalls, they got in touch with the FSA/FSS directly without approaching local authorities first.

How effective was the support and guidance?

The FBO acknowledged that the guidance is very clear guidance and contains best practice examples and notice templates. The guidance is embedded in the FBO’s procedures as they followed the best practice examples and adapted it to their practices.

Learning and wider impacts of the improved product withdrawals and recalls system

As a result of this incident, the supplier updated their cleaning procedures. They carried out some refresher training on the procedures and there was supervision of cleaning procedures across all

shifts. The supplier also shared their learning with the FBO to identify gaps in similar procedures.

The FBO stakeholder noticed that the current recall system ensures standardised content of recall messages which is really important to ensure that consumers received all the key information about the recall process. They suggested that previously this level of information was not consistent. Moreover, the stakeholder noted improved clarity and improved messaging from the FSA/FSS. There are clear expectations for businesses regarding how and what should be communicated to consumers. Additionally, it was acknowledged that learnings on how to conduct RCA have also improved in the updated system of recalls.

Recommendations for the future

1. **Educate the consumer** – more information from the FSA/FSS on what consumers need to do in the recall situation, so it is handled safely in their homes.
2. **Introduce consumer notifications through social media** – the FBO shared that as consumer behaviour is changing with more consumers shopping online, they will not be using point of sale notices going forward. Instead, the focus will be on social media, direct communications to online shoppers via email and loyalty scheme members.
3. **Ensure consistent use of the guidance** – the FBO noted that retailers tend to follow the guidance and templates more closely compared to their suppliers.
4. **FSA/FSS should play a stronger role in coordination between the retailers and suppliers** – the FBO felt that the cascade of information from the branded supplier during the recall was not as fast as they would like to see which is a common issue for them when dealing with suppliers.

Case study 8: Allergen contamination of a pie

Recall of a baked scallop pie due to undeclared allergen (fish stock):

The FBO became aware that their production line had altered the contents of their frozen baked scallop pie, which now contained fish stock. This fish stock was not declared on the label, meaning a potential shellfish allergy issue. After discussion with their certification body, the FBO contacted the FSA/FSS to discuss the incident. Subsequently, the FBO decided to recall the product, and the FSA/FSS issued an allergy alert.

Experience of the recent product recall

Approximately 60 cases of the unlabelled product were retailing in different stores, including garden centres. The FBO ceased production of the pie, and any remaining cases in stock were not distributed to retailers.

How did the FBO communicate with retailers and consumers?

The FBO issued a point of sale notice for retailers to display. Where consumers had purchased the product directly from the FBO, they contacted these consumers individually via email.

How did the FBO communicate with the local authority and FSA/FSS?

The majority of communication was with the FSA/FSS, as the FBO found it challenging to find the contact details of their local authority, and communicate during Covid-19.

Reflections on the new product withdrawals and recalls system

How clear were the roles and responsibilities?

The FBO agreed that the roles and responsibilities were clear. They praised the FSS for uploading the notice on the website after-hours, and for helping them to navigate the process. They also found the point of saletemplate extremely helpful, as they were unsure of the type of details that should be included. The FBO stated that the recalls guidance was clear, as they were unaware of its existence prior to the incident. Interestingly, they suggested that they would have been unlikely to have notified allergy organisations to the recall without the input of the FSA/FSS.

Learning and wider impacts of the improved product withdrawals and recalls system

The FBO undertook an RCA, which identified that a change of recipe had altered the allergen content of the pie. Following the incident, the FBO required all staff to undertake in-house training on allergens, to ensure that staff were aware of the implications of altering recipes.

The FBO has also introduced new procedures as a result of the incident. These include a new labelling checklist for each product, as well as requirement for all products to be signed off by both Quality Assurance and the production manager before distribution.

Recommendations for the future

1. **Ensure that local authority contact details are kept up to date** - this is key in the event of personnel change, and speeds up the process. The FBO suggested to keep contact details up to date on local authority environmental health websites.
2. **Ensure that staff are aware of how alterations to recipes can affect the allergen content of products** - consider periodic in-house training so staff are aware of allergen implications.

Case study 9: Gluten contamination of sausages

Recall of pork sausages due to gluten contamination:

Sausages containing gluten had been incorrectly dispatched with sleeves of a different product that did not contain gluten in the ingredient list and was was specifically labelled as ‘gluten free’. A product recall was initiated by the business. The FBO had to get in touch with their distributors to remove the products from the shelves.

Experience of the recent product recall

How did the FBO communicate with retailers and consumers?

The FBO notified their retailers to remove products from the shelves. In some instances, it took around 12 hours to get in touch with retailers which was considered by the FBO as critical lost time. This was due to the FBO waiting for a response from the retailer. Additionally, the FBO contacted the Coeliac Society about this incident to notify gluten intolerant individuals and coeliacs through this channel.

How did the FBO communicate with the LA and FSA/FSS?

The FBO told that during this recall, there was a three-way communication between them, the FSA/FSS and the Environmental Health Officer (EHO). Reflecting on the process, the stakeholder noted that the conversation was duplicated many times as there was also a separate conversation between the FSA/FSS and EHO. This was perceived to be inefficient and slowed the decision making on the recall.

Did the FBO undertake a Root Cause Analysis?

The FBO concluded the root cause was a human error. A colleague inadvertently collected the wrong sleeves from the warehouse and supplied them to the production line. This meant that sausages containing gluten had been dispatched with sleeves of a new gluten-free product.

Reflections on the new product withdrawals and recalls system

How clear were the roles and responsibilities?

Whilst the FSA/FSS, FBO and EHO were involved in this incident, the FBO said the roles and responsibilities were quite clear and there was not much debate between the parties involved.

How effective was the support and guidance?

The FBO highlighted that they have a lot of in-house guidance, however, they use the FSA/FSS template for incident notification. During this incident, they drafted a template which was then approved by the FSA/FSS. The stakeholder noted that “it is useful to have an FSA/FSS template so you can quickly adapt it”.

Learning and wider impacts of the improved product withdrawals and recalls system

As a result of this incident, the FBO reviewed their internal procedures for label verification and started checking the presence of allergens in their products. Additionally, as a precautionary step, they have now updated their pallet signage, so all of the sides of the pallet contain notices alerting to the presence of gluten.

Recommendations for the future

1. **Quicker decision making from the FSA/FSS** as the FBO recalled it took almost 24 hours to confirm a recall even though they definitely knew that gluten- containing product has gone out advertised as being gluten-free.
2. The FBO suggested **an initial conference call between them, the FSA/FSS and EHO** once the decision to recall a product was made. This would reduce duplication of messages and speed the recalls process.

1. Survey of consumer practices with respect to coated frozen chicken products | Food Standards Agency