FSA 22-09-17 Incidents and Resilience Annual Report 2021 to 2022

The paper outlines the work undertaken by the Incidents & Resilience Unit (IRU) in 2021/22 to ensure that the UK's food and feed incident detection, response and prevention capability is the best possible given the challenges related to Covid impacts, our exit from the EU and the changing global landscape in which we operate.

1. Summary

1.1 The paper outlines the work undertaken by the Incidents & Resilience Unit (IRU) in 2021/22 to ensure that the UK's food and feed incident detection, response and prevention capability is the best possible given the challenges related to Covid impacts, our exit from the EU and the changing global landscape in which we operate.

1.2 The Board are asked to:

Consider:

• the work of the IRU since the 2020/21 Incidents & Resilience Annual Report to the Business Committee.

Discuss and endorse:

- our incident and emergency response and our new ways of working
- the continued development of the IRU's capability and capacity to ensure we can deliver the best we can in the changing global landscape.

2. Introduction

2.1 This paper provides the annual report to the Board on the FSA's IRU activities in 2021/22, including incident response and areas supporting incident response.

2.2 The paper covers:

- Background and context
- Incidents and outbreaks 2021/22
- Incident detection / assurance
- Globally and domestically connected incident management
- Ongoing opportunities
- Preparedness and resilience
- Incident prevention and root cause analysis
- Conclusions

3. Background and context

3.1 The IRU's role is linked to the FSA's mission and is embedded in legislation.

3.2 Food Standards Agency's (FSA) incidents teams are in place in England, Wales and Northern Ireland (NI) and together with Food Standards Scotland (FSS) Scottish Food Crime & Incidents Unit (SFCIU), coordinate the response to food and feed (footnote 1) incidents and foodborne outbreaks, ensuring that products not in compliance with safety legislation are removed from the UK market.

3.3 Some of the incidents reported may involve food fraud or food crime. Where this is suspected, food crime leads (footnote 2) are engaged and there is day to day close working between FSA Incidents and food crime teams.

3.4 The main focus of this report is incidents related to England and supporting data from Northern Ireland and Wales.

3.5 The Incidents Team provides routine weekly updates to the FSA Executive Management Team and the FSA Board is updated on higher profile issues. Weekly reports which cover priority incidents and signals from the previous week are complimented by briefings on major incidents with significant UK impact/risks to consumer health.

4. Incidents and outbreaks during 2021/22

Figure 1: Total number of incident notifications received by FSA, by reporting year

4.1 In total, the FSA was notified of 2,336 food and feed safety incidents in England, Northern Ireland and Wales during 2021/22. This represents an 18% increase when compared to 2020/21 (see Figure 1) but is very similar to data in pre-pandemic years (2019/20, 2018/19).

4.2 Additional information relating to the types of incidents managed by the FSA are provided in Annex A. The top four hazard types for incidents notified to the FSA in 2021/22 were: pathogenic micro-organisms (615), allergens (320), poor & insufficient controls (296) and pesticide residues (209).

4.3 Of the top four incident types, incidents associated with pathogenic micro-organisms make up the highest proportion at 26% of the total; this is an increase in this category compared with

previous years, of 78% and 64% from 2020/21 and 2019/20 respectively. Coinciding with a doubling of poultry meat incidents since 2020/21 and 2019/20 this suggests the rise is linked to increased surveillance following a series of foodborne Salmonella outbreaks in breaded chicken products from Poland in 2020 & 2021, which affected more than 1000 people over multiple years with numerous products and brands affected. In response to the outbreak the FSA and the UK Health Security Agency (UKHSA) launched sampling surveys and highlighted the issue to industry and consumers. These focused activities led to affected products being removed from sale.

4.4 Levels of allergen notifications (320) are consistent with 2019/20 data (350) but higher than last year's data where levels dipped to 180. The drop in 2020/21 is thought to be due to the pandemic and changes in food industry operations over the period which altered people's access to food.

4.5 Poor and insufficient controls (296) is up from 95 in 2020/21 and 165 in 2019/20. The increase is due to Incidents Team assisting in a cross-agency response to manage possible food safety impacts of different border controls since EU Exit for a small number of imports transiting through the EU and avoiding sanitary and phytosanitary checks on entry into GB. Consignments were tracked and followed up with local authorities (LA).

4.6 There has been a doubling of pesticide notifications compared to the last 2 years which is due to a large-scale incident across the EU and the UK linked to the presence of non-permitted ethylene oxide in foods – this is discussed in Annex B - Case Study 1.

Figure 2: Total number of alert notifications issued by FSA by reporting year

4.7 The number of alerts issued increased from 141 in 2020/21 to 150 in 2021/22 which represents an increase of 6.4% but is below the average of 160 over the last 5 years. This included 84 Allergy Alerts, 66 Product Recall Information Notices and 0 Food Alerts for Action (see Figure 2).

5. Incident detection / assurance

5.1 The Receipt and Management team (RAM) function was established to help mitigate the loss of EU systems and was rated as providing 'substantial assurance' for 2021/22 by FSA Internal Audit. RAM receives alerts and proactively scans for incidents & emerging risks affecting the UK using a wide range of international data sources and prioritises signals of interest to determine UK risks.

5.2 During 2021/22, the RAM team processed a total of 12,376 signals, identifying 27 new incidents, making 99 referrals to LAs 'to investigate' and referring 371 signals 'for information' to other interested areas of the FSA. The team also identified 9 'complex signals' (emerging issues where further investigation is required to determine UK risks), these included two signals - 'listeria in enoki mushrooms' and 'salmonella in halva & tahini products from Syria' - which led to the removal of products from the market.

5.3 Annex C – Table C1 provides examples of the range of signals processed. Annex C - Figure C2 shows the types of signals processed and offers insight into food safety hazards being managed globally in 2021/22 which were broadly in line with UK incident types.

6. Globally and domestically connected incident management

6.1 Developing how we work with other UK agencies and authorities in other countries on food safety matters where the EU used to lead is essential, especially in areas such as foodborne illness outbreaks. Over the period there has been a closer working relationship with UKHSA, with a greater focus on methods for identifying & prioritising emerging outbreaks based on whole genome sequencing (WGS) capabilities. Collaborative assessment is carried out with FSA to ensure food chain investigations are prioritised based on areas of greatest risk. This rapid approach allows quicker detection and control of food safety risks & improved public health protection.

6.2 The Salmonella in Ferrero Kinder chocolate products case study (Annex B - Case Study 2) demonstrates the effectiveness of this rapid outbreak identification and prioritisation, which meant the UK was the first country to raise the alert of this multi-country outbreak (over 70 countries affected in total), potentially impacting the health of children. The case study also shows that during this outbreak the FSA was able to communicate effectively with other country authorities via the International Food Safety Authorities Network (INFOSAN), with the help of the World Health Organization (WHO)/Food and Agriculture Organization (FAO). This would have previously been managed via the EU Commission.

6.3 The feeder mice case study (Annex B – Case Study 3) highlights how FSA worked with Lithuanian Authorities & the EU Commission via Foreign Commonwealth & Development Office (FCDO), to manage a serious outbreak of Salmonella affecting over 1000 people, with a disproportionate impact on children. The FSA obtained agreement from Defra's Animal Disease Portfolio Group (ADPG) to a Lithuanian country-wide ban on these products which was introduced to prevent future cases.

6.4 Following EU Exit we have more reliance on INFOSAN for exchange of food safety information with other countries and some remaining limited third country access to EU Rapid Alert System for Food & Feed (RASFF), with FSA Northern Ireland notifying countries via manual RASFF notifications. The volume of activity using INFOSAN and EU RASFF has remained stable with 679 RASFF and INFOSAN notifications in 2021 compared to RASFF notifications in 2019 and 2020 which were 661 & 633 respectively.

6.5 The importance of close relationships with other countries when managing complex & large-scale incidents is demonstrated by the Ethylene Oxide (ETO) incident (Annex B – Case Study 1). Our relationship with the Food Safety Authority of the Republic of Ireland (FSAI) helped

manage this incident with hundreds of products recalled or withdrawn from UK & EU markets and with the potential for divergence of approach across the EU compared with the UK. Good communication with FSAI helped to broadly align our approach to protect consumers and provide advice to industry.

6.6 The FSA continued over the period to build on our already close relationships with industry to assist with detection, management, and prevention of incidents. We have established two industry forums: the Food Industry Liaison Group (FILG) and the Importers Working Group (IMPWG). Both forums primarily comprise food industry trade associations (TAs) who meet monthly to discuss food safety matters. Attendees' contributions cover live issues of mutual interest and industry have affirmed the benefit of these meetings continuing, to manage and improve food safety. These two forums played a significant part in handling incidents such as the case studies in Annex B and led to industry taking more rapid action to carry out activities and reduce risk to consumers.

6.7 Having a dedicated stakeholder engagement function within IRU since leaving the EU 'makes it easier for businesses to do the right thing' on issues relating to incidents. Industry trust the IRU team to consider concerns raised and they similarly take issues raised by FSA to their members. This continuing two-way dialogue features across the issues raised in the report, and levels of engagement are indicative of industry confidence in the process.

7. Ongoing opportunities

7.1 Work continues with INFOSAN to promote food safety, this includes:

- the FSA INFOSAN secondee has continued to help advance good/best food safety
 practice, and works within WHO to lead on areas of importance both globally and to the UK
- the delivery of the FSA funded upgrade of the INFOSAN Community Website has enhanced UK and other country food safety communications
- liaison with Canadian authorities on how food fraud / authenticity (where a food safety risk) can be managed on the INFOSAN website
- attending an INFOSAN group on Dietary and Food Supplements to share practice on how food supplements and associated risks are managed across global markets.

7.2 The FSA and FSS successfully hosted the first ever UK virtual Global Food Safety Incident and Emergency Response conference (GFSIER 2021) on 'how to enhance food safety and security in a changing world', with close involvement from INFOSAN and the network. Over six hundred (665) delegates from over 80 countries attended the three-day event. The conference programme included speakers from the UK industry and regulators as well as food safety experts and representatives from INFOSAN, WHO, FAO and Codex. Conference contributors encouraged greater collaboration, improved consistency of approach and more routine sharing of information to better manage the food safety issues facing food regulators and industry.

7.3 For future outbreak management we continue to refine procedures in key areas to ensure:

- procedures are in place to prioritise resource across authorities to allow urgent and rapid action needed for effective public health response
- guidance is developed on national/international definitions, especially 'weight of evidence' and 'outbreak definition in the genomic era' (with WGS making it easier to link cases and with more potential outbreaks identified, how do authorities focus resources on areas of greatest risk?)
- good practice and expertise are shared with global food safety and public health practitioner networks/communities, as a common global understanding and willingness to cooperate is key to resolution and future prevention.

7.4 How effective we are in our consumer-focused food safety communications was examined as part of an FSA/FSS evaluation project for the Efficacy of Recalls (EOR) programme undertaken in 2021/22. The original programme (2017-2019) aimed to improve food recalls and consumer protection relating to recalls. The evaluation showed good confidence in all the areas assessed but reported that consumer awareness of recalls, and their understanding of actions to take, remained low and unchanged. Additionally, there was little evidence of sharing of incidents learning across industry & regulators to improve standards. The outputs from the evaluation will be considered further and the full report will be published later in 2022.

7.5 We continue to adapt the systems to meet changing needs. The recent National Audit Office (NAO) report on 'Regulating After EU Exit', highlighted the average time spent to manage FSA incidents has increased since leaving the EU due to digital communication processes being replaced by manual processes. This was demonstrated by an assessment of 54 typical incidents which saw the average time spent on direct exchange of information increased by 67%, from 4.54 to 7.56 Full Time Equivalents (FTE). We therefore need to further optimise our new processes and develop digital solutions where possible with further investment & development planned for systems such as the Signals & Incident Management System (SIMS).

8. Preparedness and resilience

8.1 The FSA has robust arrangements in place to continually enhance and strengthen all aspects of our resilience and emergency preparedness. The work informs plans, procedures and resourcing to ensure we have sufficient capacity and capability to be able to respond to prolonged or multiple concurrent major incidents. To build and validate this capability and capacity the FSA delivers a comprehensive programme of training and exercises, at varying levels of complexity, both internally and with other organisations. Its impacts are measured through our increased capability and capacity to invoke our incident plans and protocols effectively and to deliver a proportionate and robust response.

8.2 Although the 2021-2022 programme was largely paused during live incident response activity, we designed and delivered 16 out of the 19 proposed activities that provided opportunities for over 540 staff from across the FSA. The activities focused on addressing gaps in capabilities that had been identified from previous lessons learned from live activities, including from our Covid-19 and Winter Plan responses, as well as allowing us to validate our updated incident management plans for example our Non-Routine Incident Management Plan that was published in December 2021. We are progressing with preparedness activities in 2022/23 that will include opportunities for staff across the agency, as well as the FSA Board, to support the Agency's response to incident management, ensuring we are continually learning and improving our response arrangements.

8.3 Our participation in multi-agency exercises remains invaluable as it enables the FSA to exercise its emergency response and incident plans and procedures at a cross-Government level, as well as the opportunity to reiterate to those involved the role and remit of the FSA, share best practice and build valuable resilience networks. We continue to identify opportunities where there is benefit for us to work and participate in multi-agency activities with other Government departments, agencies and stakeholders.

8.4 The FSA works across all 3 nations (England, Wales and Northern Ireland) and with Food Standards Scotland (FSS) to enhance and align our standard operating procedures and to ensure that we are sharing and adopting best practice in the management of food safety incidents and outbreaks across the four Nations.

9. Incident prevention and root cause analysis

9.1 The FSA continued to build root cause analysis (RCA) capability during 2021 particularly around sharing industry RCA learnings from incidents. A pilot project was undertaken on 'how' to disseminate RCA information and 'what' is the best format.

9.2 As part of the pilot, sanitised raw RCA data received from industry during 2021/22 was published on the FSA's data hub. The pilot involves working across industry and LAs to determine how the data can be improved to optimise our learning from incidents and reduce the risk of them recurring.

9.3 **Annex D** is a summary of the RCA data collected in 2021/22. We received a total of 286 RCAs over the period and as we only request RCA for i) those incidents when an alert is published, ii) for allergy incidents & and iii) micro incidents, the number of RCAs represents a third of total RCA requests. This number should increase as RCA becomes more established and recognised as being beneficial to industry. Almost half of the RCA responses received related to allergen incidents (44%), with the remainder associated with pathogenic micro-organisms (38%), foreign bodies (16%) and miscellaneous incidents (3%).

9.4 Although food safety benefits will not be fully realised until data sharing formats are decided by the pilot, industry are supportive of the current positive impacts of FBOs routinely undertaking RCA during an incident to prevent recurrence; this was reflected in the EOR evaluation findings (see section 7.4).

10. Conclusions

- consumers continue to be protected and the incident function has adapted well to the new requirements placed on it since leaving the EU
- some of these changes may be seen as opportunities in terms of increased speed of response and improved engagement with other countries
- further consideration of resource is needed by the Executive Management Team as part of ongoing development of processes and technology improvements.

Annex A

Figure A1: Incident notifications received during 2021 to 2022 reporting year, by incident type

Figure A2: Incident notifications received during 2021 to 2022 report year, by product type

Annex B - Case Studies

Case Study 1 – Ethylene oxide (ETO) and its derivative 2-chloroethanol in a range of products including sesame seeds, locust bean gum, noodles and calcium oxide (as a food supplements ingredient)

ETO (anti-microbial fumigant) is a genotoxic carcinogen and is not permitted in foods in the UK or EU. The issue which would normally fall to HSE as it involves pesticide residues, however, FSA took the lead as a food safety matter under General Food Law. Controlled use of ETO is permitted in some countries.

The issue started in September 2020 and is still ongoing in 2022. UK managed the incident through product withdrawals rather than published recalls.

The complexity of the incident related to use of EU pesticide law, whereby if an ingredient was in excess of permitted levels the whole product was considered unfit. This raised questions around methodologies of testing and whether pragmatic approaches should be adopted based on levels in the finished product. In total, there were 129 ETO incidents from 1 April 2021 until 31 March 2022. The main products affected in the UK were Dietetic Foods / Food Supplements / Fortified Foods (27% of the total ETO incidents), Food Additives & Flavourings (16%), Herbs & Spices (11%) and Ices & Desserts (9%), and Other Food product / mixed (14%) includes noodles. This has impacted incident numbers for these food types - for example 'dietetic foods, food supplements & fortified foods' category shows an increase to 229 compared with 150-160 for last 2 years.

Challenges of harmonisation of approach between UK and EU were aided by meeting FSAI and FSS on regular (weekly) basis, where exchange of information helped gain an overview of the situation and a better understanding of different approaches across different regulatory regimes. This included the managed divergence across EU countries – managed through 5 EU Crisis Coordinators meetings (4 in 2021 and 1 in Jan 2022). The incident is continuing, but notifications of affected products have reduced significantly since 2021 and industry agree that the situation is contained. A lessons-learnt exercise on the ETO incident, carried out with FSAI, evaluated communication across five nations. The review showed there was agreement across all teams involved that the incident response benefited from the communication mechanisms employed.

Case Study 2 - Salmonella Typhimurium outbreak linked to Ferrero Kinder chocolate products

The FSA, FSS and UK Health Security Agency (UKHSA) investigated an outbreak of Salmonella Typhimurium linked to chocolates manufactured in Belgium. Since March 2022, there were over 120 UK cases (as of 22 July 2022) and more than 300 cases (as of 18 May) across 16 countries; with affected products distributed to over 70 countries.

The UK was the first country to identify strong epidemiological and food chain links to the manufacturer in Belgium which led to a precautionary product (products 'may be' contaminated) recall in April 2022 to remove possible affected goods from the market. In addition, industry was informed and took action to investigate & remove affected products from the food chain. Making use of the strengthened relationship with INFOSAN, FSA and FSS shared evidence from the UK, with other countries which resulted in global product recalls being issued. At the same time authorities in Belgium closed the implicated manufacturing plant in order to contain the situation.

As part of the outbreak management UKHSA used their continuing relationship with European Centre for Disease Control to share information on human health investigations and whole genome sequencing for the UK cases, which helped develop the clearer global picture and contributed to the evidence base that subsequently led to further action taken by the UK. Further action included FSA and FSS issuing:

- three further recalls,
- a statement to Local Authorities for action
- press announcements for consumers to raise awareness and help ensure product recalls were observed.

The UK in liaison with other countries continues to be involved in the root cause investigations. We also continue to monitor with LAs and industry that recalled products are removed from sale and only safe products are on sale. The INFOSAN secretariat acknowledged the instrumental part played by the UK in this global multi-country incident.

Case Study 3 - Salmonella Enteritidis outbreak linked to feeder mice from Lithuania

The outbreak has been ongoing for several years and has involved over 1000 cases in the UK to date, with children disproportionately affected.

On 1 February 2022, the 4 Nations Animal Disease Policy Group (ADPG) accepted DEFRA's proposal to impose safeguard measures (footnote 3). Evidence presented included FSA feed safety risks and the impact on human cases from UKHSA.

On 17 February 2022 safeguard measures came into effect across UK, under TARP (The Trade in Animals and Related Products Regulations 2011), prohibiting all imports of feeder mice from Lithuania.

LAs were requested to contact suppliers of feeder rodents in their area to ensure that they are aware of the safeguard declaration.

A joint letter to the EU Commission was sent on 2nd December 2021, from the Defra Chief Veterinary Officer and the FSA's Chief Executive Officer, requesting action be taken to ensure reptile feeder mice supplied from the EU to the UK are both compliant and safe. The UK importer suspended supply of all Lithuanian mice as of Tuesday 7th December. The local authority undertook sampling of feeder mice and the results received on 9th December were positive for Salmonella.

A product recall was published on the same day. An updated recall was published on 11th December as the business extended the recall to include all batches. The recall was accompanied by a news story on the FSA website and via social media. A letter was issued to local authorities to verify the withdrawal and recall. A ministerial submission was issued by Defra on 13th December.

Annex C - Examples of signals impacting the UK

Example	Signal	Action
Example of early identification of incidents affecting the UK	Multi-country recall of various canned products because of defective packaging.	The Receipt and Management (RAM) team identified a number of signals over a short period of time concerning this recall. Investigations with local authorities showed food business operators (FBOs) in the UK were selling products subject to the recalls, even though no official distribution was confirmed via RASFF. Following confirmation of UK distribution, the signal was referred to the Incidents Team as an incident and following risk management advice, a Product Recall Information Notice (PRIN) was issued to recall the products from consumers.
Example of identification of trends / emerging issues	Significant increase in the number of signals concerning Listeria in enoki mushrooms originating in East & South-East Asia, following an outbreak in the US with links to cases in Canada and Australia.	RAM team flagged an increasing trend in the number of global alerts raised, particularly by the Canadian and US authorities. As a result of the RAM team raised as a potential emerging issue, enoki mushrooms were added to the Import Surveillance Plan for Q1 2022. The additional sampling undertaken under the imported foods sampling programme (mainly inland retail sampling) identified significant levels of non-compliance with a 90% failure rate for listeria contamination of the enoki mushrooms. Sampling failures were handled as individual incidents. The RAM team continue to monitor the issue to identify where further mitigations may be required to protect consumers.
Example of online marketplace referrals	Foreign body contamination (metal/plastic) of powdered soft drinks from the US widely available in the UK from online marketplaces.	Foreign body contamination (metal/plastic) of powdered soft drinks from the US widely available. Through the processing of daily signals, the RAM team identified that many of the products affected by the recall appeared to be widely available via online marketplaces for purchase by UK consumers. Investigations confirmed that products with matching lot and barcodes where available to purchase in the UK and RAM team liaised with Primary Authorities for the online platforms – a sweep of the listings was undertaken by the marketplaces and a total of 271 listings were removed from sale.ble in the UK from online marketplaces.

Annex C - Table C1

Annex C - Figure C2

The top 4 hazard types are reflective of the incident types for incidents reported during 2021/2022. High numbers of signals in relation to pesticide residues can be attributed to increased reporting of pesticides incidents associated with a Europe-wide incident relating to the detection of non-permitted ethylene oxide.

Top 10 Signal Hazard categories

Annex D - Root Cause Analysis Data Trends

Allergens

For allergen incidents, 'Labelling verification checks' (24%) is the major contributor, with an increase from 18% in 2020/21. 'Labelling declaration' (10%) and 'Procedures not followed' (10%) constitute the next largest categories, although both remain on the same prevalence figure when compared to the previous Reporting Year.

- Process: 33%
- Material: 9%
- Undetermined/Inconclusive: 1%
- Environment: 7%
- Equipment: 9%
- Method: 21%

Foreign bodies

For 'foreign body' incidents, the distribution of root causes associated is relatively widespread. 'Machinery' issues (19%) remains the highest category (24% in 2020/21) and procedural issues (8%) decreased from 13%. Contamination resulting from segregation failures (16%) were not identified as a root cause in 2020/21 and issues associated with 'Quality control checks' (5%) showed a significant decrease from the 24% previously reported.

- Process: 23%
- Material: 17%
- Environment: 9%
- Undetermined/inconclusive: 8%
- Method: 8%
- People: 11%
- Equipment: 22%

Pathogenic Microorganisms

For incidents caused by pathogenic micro-organisms, the distribution of root causes was widespread. 'Ingredient cross-contamination' (14%), 'Cleanliness or sanitation' (11%) and 'Ingredient Hygiene Controls' (8%) were the most prevalent root causes identified.

- Undetermined/Inconclusive: 25%
- Equipment: 18%
- Process: 11%
- People: 3%
- Environment: 4%
- Method: 15%
- Material: 24%

Miscellaneous RCAs

- Poor or insufficient controls 5
- mycotoxins 1
- not determined/other 1

Root cause categorisation:

- Environment: 33%
- Process: 23%
- Method: 11%
- Equipment: 11%
- Material: 11%
- People: 11%.
- 1. The term 'food' should be taken as meaning reference to 'food and feed' throughout this paper.
- 2. In England this is the National Food Crime Unit (NFCU), in Wales the Welsh Food Fraud Co-ordination Unit (WFFCU) and in Northern Ireland this is the FSA Food Fraud Liaison Officer.
- 3. Safeguarding measures are measures to restrict a product on a temporary basis where the product causes harm