

Efficacy of Withdrawals and Recalls: How effective was the system redesign? (Objective 1)

6.1 What were the workstreams for delivery and their objectives?

6.1.1 Evidence from the desk review

Commencing in 2016, the system redesign was delivered by an overarching, multidisciplinary Food Recalls Steering Group (FRSG) and four main delivery workstreams that reported to the FRSG (shown in the figure below). This was overseen by the multi-stakeholder External Stakeholder Reference Group (ESRG). Workstreams 1, 2 and 4 were FSA/FSS led. Workstream 3 focused on developing enhanced trade-to- trade communications on withdrawals and recalls and was led by the industry body, the Federation of Wholesale Distributors (FWD). All workstreams developed multidisciplinary working groups to action their objectives.

Workstream 1: Roles and responsibilities

FSA/FSS Led: Development and implementation of guidance clarifying roles and responsibilities

Target audience: Food industry and Local Authorities

Output: Guidance on recalls and withdrawals

The focus of Workstream 1 was to develop and implement comprehensive UK guidance that clarified the roles and responsibilities of the key players involved in food withdrawal and recalls in the UK. This guidance took account of the principles detailed in The World Health Organisation (WHO) (2012) document "FAO/WHO guide for developing and improving national food recall systems" (footnote 1). Key objectives for Workstream 1 are contained in Appendix A.

Workstream 2: Accessible and consistent consumer information

FSA/FSS Led: Improvement of food recall communications to consumers

Target audience: Consumers and Food Industry

Output: Best practice to be included in the guidance

The purpose of the FSA/FSS-led Workstream 2 was to deliver a body of work to ensure that information to consumers on food recalls is consistent and accessible, based on proven best practice and underpinned by cross-industry sharing of approaches.

Practical actions undertaken by Workstream 2 included:

- research with industry to better understand current and possible future practices, and barriers to new approaches
- research with consumers to identify best practice (from the consumer's perspective) for recall notifications in terms of content and style; placement in- store and online and relevant channels for communication of alerts
- development of best practice that takes into account the above, which will form part of the guidance developed under workstream one.

Key objectives for Workstream 2 are contained in Appendix A.

Workstream 3: Improved trade to trade notifications

Industry Led: Development of enhanced trade to trade notifications including guidance and systems

Target audience: Food industry

Output: Enhanced trade to trade notifications included in guidance

Workstream 3 was an industry-led workstream that worked on trade-to-trade information on food recalls to ensure its consistency and accessibility, based on proven best practice and underpinned by cross-industry sharing of approaches. Key objectives for Workstream 3 are contained in Appendix A.

Workstream 4: Feedback loops and incidents prevention

FSA/FSS Led: Development and implementation of systematic root cause analysis procedures, e-learning and integration with guidance

Target audience: Food industry and Local Authorities

Output: Redevelopment and launch of an e-learning course

The purpose of FSA/FSS-led Workstream 4 was to develop and implement systematic root cause analysis procedures to be used by industry in the event of food withdrawals and recalls. These procedures included feedback loops to the FSA/FSS from industry (via enforcement authorities and/or businesses) identifying the chain of causal factors for a withdrawal/recall, the lessons learnt, and the measures taken by the businesses concerned to prevent recurrence. Outputs included:

- a redevelopment and launch of an e-learning course
- embedding RCA with LAs and the food industry.

Key objectives for Workstream 4 are contained in Appendix A.

Wider activities that supported the four key workstreams

It is important to recognise the role of other activities and workstreams which have contributed to the redesign and reform process, for example, the development of a Workstream 5. During the implementation phase, the communications strategy for the system redesign was coordinated by Workstream 5 (FSA and FSS staff). This workstream had the following objectives:

- to incorporate internal and external FSA/FSS communications about the system redesign
- to dovetail in with EU Exit messaging around incident management
- to incorporate consumer awareness-raising of the systems in place in the UK with respect to recalls, how to recognise a food recall and make informed choices.

This Workstream 5 was designed to complement the other four workstreams, and activities included recall communications around World Safety Day, discussions with major retailers around point of sale notices. Those involved in this workstream suggested that outputs were heavily impacted by Covid-19.

6.1.2 Insights from interviews with ESRG members

ESRG members interviewed by RSM highlighted that the overarching objective of the reforms was to better protect consumers. A formal review of the extent to which this objective has been met had not been carried out. Those interviewed were unable to specifically recall the objectives of each workstream, given the time lapse since the system redesign began.

Before the initiation of the reforms, ESRG members acknowledged that there was uncertainty about:

- how effectively recalls were being carried out;
- the reach of these to consumers; and
- the standardisation of the relevant processes.

6.2 How did evidence inform the redesign of the system?

As part of the system redesign, the FSA/FSS commissioned a number of research reports to draw out best practice and provide a solid evidence base. This section provides an overview of the key recommendations and findings from these reports (including Lynn Faulds Wood Review, Efficacy of Recalls, etc.).

6.2.1 Evidence from the desk review

Lynn Faulds Wood Review

The review was initiated in 2016 by the CEO and Executive Management Team (EMT) following publication of the Lynn Faulds Wood Review of the UK's systems for the recall of unsafe products. This Review explored the overarching theme of unsafe products, of which some elements applied to food.

The central recommendation of the Lynn Faulds Wood Review was to create a coherent system that would foster trust and an effective recall system with enhanced safety outcomes. Research showed that there was a strong consensus for a coordinating agency, with the necessary resources and competence, endorsed by central government to take the lead on this. The FSA was proposed to function in this role and were described as an example of a "national product safety agency" (footnote 2)

Other recommendations of the Lynn Faulds Wood Review included the need for:

- an official trusted website for businesses and the public
- a national injury database, with wider benefits beyond providing information and evidence for the recalls system
- improvement in funding, training, resources and procedures for enforcement officers
- mapping organisations involved in product recall, and better data sharing to prevent future incidents
- more reliable, detailed guidance on product recalls, developed in conjunction with industry

Externally commissioned research

In 2017, Kantar Public were commissioned by the FSA/FSS to conduct research with consumers and other stakeholders to establish the consumers' and stakeholders' views of the recalls process, to explore each step of the process in detail and where improvements might be made, and public awareness (footnote 3). Recommendations from the review included:

- clarification of what is expected of FBOs in terms of when and how to involve the FSA/FSS in withdrawals and recalls
- 2. increased assistance and guidance for smaller FBOs
- 3. processes and forums for sharing best practice should be developed, mindful to potential commercial implications
- a standardised industry recall notification template for FBOs, accompanied by best-practice procedures
- 5. a review of the points at which the FSA/FSS interacts with FBOs during the withdrawals and recalls process
- 6. post-recall reflections captured from all stakeholders

This was complemented by the 2CV and Community Research The Future of Food Recall Notifications report (footnote 4) commissioned by the FSA/FSS in 2018. This report explored the development of a recall notification template, and included UK-wide testing of existing recall notifications and the development of potential new designs and content. The research recommended the following principles when communicating with the public about food/allergy recalls:

Information principles

Recommendations

- What the problem is: Make it easy for customers to identify the issue/problem
- What they can do about it: Clearly communicate what consumers need to do next if the issue is relevant
- Exactly how to do it: Clearly communicate how consumers take next steps

Key design principles

Recommendations

- Clear and easy to read: Using a simple layout; large font; banners with clear headings and sub-headings
- Use colour and iconography to grab attention: Use of the colour red to denote risk; and use of iconography, banners, boxes and bordering to draw attention to crucial information
- Include a product image: Where feasible, using an image of the affected product to draw attention
- Concisely worded: Lay out information in a clear, simple and jargon-free manner, using bullet points or numbers to help organise information clearly.

Internally commissioned research

The above research was also supplemented by the research projects conducted internally by FSA colleagues in Science, Evidence and Research Division (SERD):

- 1. An analysis of FSA/FSS food alert data from 2013 to 2016, to broadly characterise major features and investigate trends over time.
- 2. Live case reviews that involved tracking ten food incidents resulting in a food alert to obtain in-depth information about how the recall process operated in practice.

- 3. An International Comparison of Guidance on Food Recalls Systems (footnote 5) (reported in 2017). A qualitative benchmarking exercise of the following countries' food recall systems: UK, Ireland, Australia, New Zealand, US, Canada. The specific elements examined included food recall procedures, traceability procedures and available guidance. The comparison identified that out of the six countries studied, the UK's guidance was the least comprehensive and focussed on interpretation of certain articles of Regulation (EC) No 178/2002 the conclusion being that there is scope for the UK to develop more comprehensive guidance to assist food businesses and local authorities on actions necessary in the event of unsafe food needing to be removed from the food chain. The areas identified for further consideration were:
- the creation of a new guidance document for FBOs to help ensure that they are aware of and fulfil their responsibilities
- FBOs to follow FSA provided templates during the recall process;
- FBOs to have food recall plans prepared and available to the Competent Authorities upon request
- the potential for implementing an 'urgency classification system' (based on the US and Canadian systems)
- the potential for developing a new central recalls database that is accessible to both FBOs and the FSA

The FSA also undertook a pilot study of a range of incidents resulting in food alerts to understand how familiar food businesses and enforcement authorities are with RCA, and how capable they were at performing it. The FSA Pilot study on RCA also looked at the variation in levels of understanding that existed between different sized businesses, to inform where education on RCA would most effectively be targeted. The study involved 20 FBOs that had recently experienced a food recall and they were asked, with the assistance of LAs, to revisit the incidents chosen, and complete the '5 Whys' RCA methodology in order to identify the relevant root cause. This study led to the following conclusions:

- not all businesses clearly defined the 'root cause' of their incidents
- the level of understanding across industry sectors was variable
- some businesses (and local authorities) required greater assistance from the FSA/FSS in reaching a satisfactory root cause than others
- a number of businesses were reluctant to share details of their findings with the FSA/FSS, as it is not mandatory
- some businesses did not see the importance of conducting RCA and indeed a number did not respond to the FSA/FSS request for RCA at all feedback relating to the use of the '5 Whys' and the usefulness of the e-learning course was generally positive
- patterns in RCA that related to human error, procedural faults and issues involving standard operating procedures were apparent.

In addition to the FSA commissioned research for the system redesign, the FSA delivered The Action Circle Project as part of broader FSA engagements. (footnote 6) The main aim of this project was to analyse the level of knowledge about RCA with specific knowledge at industry and LA levels, and also within the FSA. This project recommended that the e-learning course should be disseminated at industry level, as well as re- circulated at a local authority level.

Overall, the evidence base collected during the design phase informed the formulation of the four main planned outcomes for the system redesign and the subsequent creation of the workstreams. Then, during the delivery phase, some working groups collected further evidence base to produce the required outputs for their workstreams. The table below depicts how the evidence base informed the outcomes and the outputs of the project.

Table 6.1: The evidence base and the design phase of the system redesign

Outcomes and Outputs	Evidence base
Clear roles and responsibilities	Clear roles and responsibilities An International Comparison of Guidance on Food Recall Systems by SERD, FSA FSA/FSS Efficacy of Recalls by Kantar Public Case Review study
Accessible and Consistent Information	Case Review study An International Comparison of Guidance on Food Recall Systems by SERD, FSA FSA/FSS Efficacy of Recalls by Kantar Public
Increased consumer awareness	FSA/FSS Efficacy of Recalls by Kantar Public FSA/FSS Food Alert Data analysis
Feedback loops and a philosophy of continuous improvement	An International Comparison of Guidance on Food Recall Systems by SERD, FSA FSA/FSS Efficacy of Recalls by Kantar Public

Table 6.2: The evidence base and the delivery phase of the system redesign

Outcomes and outputs	Evidence base	
The Guidance on Food Traceability, Withdrawals and Recalls within the UK Food Industry (Workstream 1)	Consultation with the British Standards Institute	
Consumer notification templates (Workstreams 2 and 5)	The Future of Food Recall Notifications report by Community Research and 2CV Report	
RCA Package (Workstream 4)	FSA Pilot Study on RCA The Action Circle Project (internal research, not commissioned for this project)	

6.2.2 Insights from interviews with ESRG members

Reflections on the established evidence base

ESRG members involved in enforcing policy acknowledged the inadequacy of recall and withdrawal systems prior to the system redesign. There was a belief that FBOs had not been proactively engaging with FSA/FSS requests to recall products, and local authorities were not consistently checking whether organisations had satisfactory processes in place.

The comprehensiveness of the process of building the evidence base was noted by several ESRG members. The process of developing evidence was iterative and was peer-reviewed, which gave a high level of confidence in the findings and their ability to inform the process redesign. ESRG members were clear that the best practice drawn out in the evidence base was directly used to create the four planned outcomes for the system redesign.

From those ESRG members interviewed, several key activities were described to evidence the need for system redesign and inform how this would be developed. This included the contracting of an independent third-party organisation to investigate potential areas for improvement, as described by the research section 6.2.1.

Key evidence building activities described by ESRG stakeholders conducted ten live case study reviews to understand the existing withdrawals and recalls process

- analysed food alert data for four years and investigated trends over time
- qualitative international benchmarking, comparing six English speaking countries' systems
- completed 40 stakeholder interviews and a survey of the public

 workshops with consumer groups, where the template for the point of sale notices was coproduced.

Reflections on the involvement of stakeholder groups in building the evidence base

The majority of ESRG members agreed that the evidence base for the system redesign was sound, and that they had consulted with representatives from different stakeholder groups. These included:

- local authorities and councils
- consumer research groups
- food manufacturer organisations
- the FSA/FSS and other government departments.

When describing the role of the ESRG, members were positive about this group and suggested that the most appropriate stakeholders were represented.

ESRG members were positive about the co-design seen in the system redesign, referencing examples of evidence-based insights being applied and tested with industry to inform design and implementation. It was suggested that testing these ideas with industry gave a more realistic view about what might be achieved in terms of implementation, ensuring that the system redesign was practical rather than theoretical. For example, the proposal to display the point of sale notice on every till was dismissed by industry as this would be unrealistic for larger retailers to implement and it was suggested that if consumers saw large numbers of in-store notices, it could undermine consumer confidence in food.

Due to the extensive engagement and co-development with a range of stakeholders, interviewees suggested that there had not been a need to pilot the outputs of the system redesign.

6.3 What governance and management structures were in place, and were they effective?

6.3.1 Evidence from the desk review

During the design stage of the review, the system redesign and Senior Responsible officer (SRO) were supported by a Project Board, workstream-specific Working Groups and the ESRG was formed to ensure stakeholder engagement. Each group had its own Terms of Reference (TOR) document that detailed:

purpose and scope

Board membership, roles and responsibilities

frequency and format of meetings.

As the system redesign entered the delivery stage, these groups adapted their membership and scope to flex resources and skills required for the new tasks. This is denoted in Table 8. New terms of reference were developed for each of the newly formed governance layers within the programme.

Table 8: Governance structures

Structures	Design: Stages 1 and 2	Delivery: Stage 3 and 4	
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Project Board into Programme Board	The project and SRO were supported by a Project Board. The role of the Project Board was to provide a mechanism to review, challenge, direct and support delivery of the project. The Board met on a quarterly basis and through membership provided a high-level link with other departments within the FSA, and as the project operated at a UK level with colleagues from FSS.	As the project was entering Stage 3, it was suggested that the working title for the Project Board to be changed to Programme Board, to reflect the development of multiple workstreams and broader governance responsibility.
Working Group into Working Groups	The project has also received internal support through a Working Group, which played a key role in guiding the development of research and reviewing research findings. This group was made up of staff from both within the FSA and FSS.	As workstreams were developed within the programme, it was suggested that each workstream should be allowed to create its own Working Group. Each group was responsible for the delivery of the related workstream. The project working groups reviewed risks, dependencies, project plans and reported to the Programme Board.
ESRG into FRSG	To ensure the project connected with stakeholders, an External Stakeholder Reference Group (ESRG) was formed. This group allowed two-way communications between the project team and representatives from industry, regulators and consumers. The ESRG has played a key role in linking the project with stakeholders, providing a channel of communication with their members on project progress and providing input into the direction of research. Latterly it provided a key role in supporting the proposed outcomes and actions reported to the FSA Board.	As the project was entering Stage 3, it was suggested that ESRG should become the Food Recalls Steering Group (FRSG) and used to provide continued support for the project, particularly resourcing of workstreams. The Steering Group has concentrated on the technical development of the actions (suggested by the FSA/FSS Board) and was provided with updates from the Working Groups. Retention of the ESRG as the future Steering Group has ensured that industry, regulators and consumers continue to work together and cooperate on the delivery of improvements.

6.3.2 Insights from interviews with ESRG members

ESRG members interviewed were positive about the governance and management structures for the system redesign. The majority suggested that these were effective and were fit for purpose, providing good oversight and support for delivery of the system redesign.

Several aspects of governance and management structures that worked well and less well were highlighted by ESRG members, as outlined in the detail below.

Governance and management structures – what worked well and worked less well?

Worked well

- The programme was a corporate priority, so was assigned significant resource and support
- Oversight from the ESRG and FSRG kept the redesign on track and ensured that objects were being delivered
- Decision making was quick but thorough
- The FSA and FSS understood the need for consumer and industry input, and were committed to delivering this. There was also good representation of all the relevant stakeholders within workstreams
- Having four workstreams meant that delivery was divided into manageable sections

Worked less well

- Some changes in personnel within lower levels of governance part way through the programme meant that there was a learning curve for new members
- Due to the EU Exit and Covid-19, the system redesign became less of a priority after the research and design phase, meaning that some moment was loss
- It was a challenge for the steering group to meet face-to-face (pre-pandemic) as stakeholders were located across the UK
- Feedback from the FSA to stakeholders on their inputs could be slow to be delivered

- 1. Food and Agriculture Organisation of the United Nations and the World Health Organisation (2012) "FAO/WHO guide for developing and improving national food recall systems"
- 2. Wood.L. F. (2016) "<u>UK Consumer Product Recall Review</u>" Business Energy and Industrial Strategy
- 3. Kantar Public (2017) "FSA/FSS Efficacy of Recalls: Final Report" FSA
- 4. Community Research and 2CV (2018) "The Future of Food Recall Notifications" FSA
- 5. Food Standards Agency (2017) "An International Comparison of Guidance on Food Recall Systems" Advisory Committee for Social Science
- 6. A similar project was organised by the FSS