Foodborne Disease Monitoring

FSA 25/03/05 - Report by Rebecca Sudworth

1. Summary

1.1 In March 2024 the Board were presented a paper on foodborne disease (FBD) in the UK. The Board agreed that a review of the current thresholds (footnote 1) for key pathogens should be undertaken and that this should be presented to the Board prior to the implementation of any changes.

1.2 This paper discusses the limitations of the current system of monitoring levels of FBD. It explains how the FSA has reviewed the reporting arrangements and puts forward an evidence-based approach to setting future thresholds.

1.3 The review concludes:

- Thresholds for individual pathogens remain a valuable tool to support monitoring population level foodborne diseases;
- Thresholds should be adjusted to ensure they are fit for purpose and consider the latest scientific evidence such as evolving detection methods; and
- Updated thresholds can be implemented by the next Annual Report and Accounts (ARA) publication, with periodic reviews (every 5 years, unless data suggests sooner).

1.4 In addition, the existing cross-government Epidemiology of Foodborne Infections Group (EFIG) (footnote 2)will be asked to provide intelligence on changes to testing and reporting and will be asked to provide evidence-based views on pathogens of interest.

The Board is asked to:

- **Discuss and comment on** the proposed arrangements for adjusting the approach to thresholds and the FSA activities to monitor trends in FBD.

2. Introduction

2.1 In March 2024 the FSA Board were presented an overview of foodborne disease in the UK and how the FSA and others throughout the food chain are mitigating the associated risks. That paper described our approaches to monitoring foodborne disease and the thresholds (Annex A, page 3) for key pathogens that were agreed by the FSA Business Committee in 2018. It also noted that a review of the FBD thresholds was underway, due to changes in sampling, laboratory testing and reporting arrangements, and there would be a further report to the Board once that

review was complete. This paper is reporting on the completed review.

Purpose of monitoring FBD

2.2 The FSA monitors levels of FBD to determine whether existing controls are working and identify appropriate actions and interventions to react when necessary. This could include using the latest evidence to understand root causes and consider updating controls, accordingly, through guidance and advice to consumers and businesses.

2.3 FBD monitoring is also used to horizon scan: by monitoring data and intelligence from a wide range of sources, the FSA can respond to new threats and take prompt risk management action when necessary.

2.4 If current controls are working well and no emerging threats are identified (for example from a new more virulent strain or change in consumer or industry practice), it would be expected that FBD rates would remain relatively steady (subject to normal year-to-year fluctuations).

Thresholds

2.5 Thresholds were established in 2018 as part of the FSA's population-level monitoring of FBD cases. They are used to ensure notable increases in FBD rates trigger action and were set for key foodborne pathogens at a level that would be considered outside of the expected range while taking into consideration year to year variation. A breach of thresholds would signal the need for investigation and, if necessary, action. The threshold level toolkit **(Annex 1)** sets out the agreed process on when and what action would be taken if levels rise outside of the expected range.

2.6 The current levels were based on analysis of data from 2000 to 2016 and are set for the following pathogens:

- Campylobacter,
- Salmonella (non-typhoidal),
- Shiga toxin-producing E. coli (STEC) O157,
- Listeria monocytogenes.

2.7 These four key pathogens are part of routine surveillance, most cases of illness associated with these pathogens are food related, and they are either responsible for a high number of cases of illness (*Campylobacter* and *Salmonella* (non-typhoidal), henceforth referred to as *Salmonella*) or are likely to cause more severe symptoms (*Listeria monocytogenes* and *STEC O157*).

2.8 Thresholds need periodic review to reflect changes in trends. For example, by managing food safety risks in the form of updating advice for businesses and/or consumers or the introduction of specific interventions in the poultry sector (such as the *Campylobacter* reduction strategy) long-term baseline levels could change. If there were sustained improvements, then we would reduce the thresholds in the periodic reviews to help us in our efforts to reduce foodborne disease to the lowest possible levels.

2.9 Alongside this, changes to sampling or diagnostic methods can impact on reported data. For example, if national laboratory services begin to use a more sensitive test, or the circumstances under which samples are routinely collected change, the reported number of laboratory-confirmed cases may change without any change in the underlying rates of

illness. Evidence of methodological changes, obtained through regular communication with other departments and agencies, form part of how reported data is interpreted.

2.10 The current review of thresholds was prompted by an FSA decision to include non-faecal isolates in our reporting (following discussions at EFIG). Previously, our analysis focused mainly on faecal only samples. However, as an increasing number of non-faecal samples (such as blood and urine) are now used to identify causes of illness, it is important to recalibrate the thresholds to account for their impact on the data. This is especially important in the case of *Salmonella*, which has seen an increasing proportion of cases identified from non-faecal isolates.

2.11 The review was expanded to take account of the latest knowledge on the epidemiology of the key pathogens and the current scientific opinion on the interpretation of foodborne disease data to develop a better long-term approach across all pathogens. Our objective is to update threshold levels to ensure they are more responsive and calibrated to evolving methods, and that any significant or unexpected changes to FBD incidence rates are promptly identifiable.

3. The Review

3.1 The review considered 4 key questions:

1. Is the concept of having thresholds still a sensible way to monitor levels and trigger action?
2. If thresholds are retained, how do we make sure those thresholds are meaningful and valid for each pathogen?
3. Is there a benefit to setting thresholds annually as we monitor trends on reported cases of foodborne disease, rather than maintaining a static threshold that is reviewed periodically?
4. What assurance mechanisms do we need to make sure thresholds and outputs of trend analysis are meaningful?

Consultation

3.2 A cross-government workshop was held with key stakeholders (footnote 3) in December 2024 to test our thinking and capture the latest expert opinion on monitoring levels of foodborne disease. This cross-government consultation reflects the multi-agency responsibilities across this area and continued the 4-nation collaborative approach that has been embedded to help the FSA manage FBD and develop risk reduction strategies.

3.3 The consensus from workshop attendees was that thresholds remain a sensible approach to help us achieve our objectives. The workshop also helped capture views on how to ensure thresholds are meaningful and our approach to setting them is robust.

4. Discussion

Setting meaningful thresholds

Salmonella and Campylobacter:

4.1 For both these pathogens, case numbers are unlikely to be unduly dominated by outbreaks (footnote 4). For *Campylobacter*, most infections from food occur in the home and are therefore isolated cases or very small, localised clusters. For *Salmonella*, while there are a number of outbreaks each year, these tend to make up a relatively small percentage of the overall number of laboratory-confirmed cases (7% for England in 2022). An increase in cases sufficient to cross the threshold would likely indicate a more systemic issue such as with the pathogen itself, our controls, or changes in consumer behaviour. A change would trigger an investigation, leading to action if necessary. For these reasons, having thresholds for both *Salmonella* and *Campylobacter* (pathogens with higher reported rates) and monitoring their rates provide us with

an effective warning system.

Listeria monocytogenes and STEC:

4.2 Both *Listeria* and STEC have a relatively low number of reported cases. One large or multiple smaller outbreaks can have a disproportionate impact on total cases, and lead to a breach of the threshold level. Incident investigations (footnote 5) and subsequent risk management interventions should identify and eliminate the root cause and so minimise future cases from a particular source, and learning would be applied to prevent similar incidents occurring. There is ongoing discussion among FSA/EFIG whether thresholds are appropriate for these pathogens, but no consensus has yet been reached. As thresholds are still useful as a benchmark and to trigger an investigation, it is recommended that they are retained at least until the next review period. However, breaches in thresholds for these pathogens should be interpreted cautiously for the reasons described above.

4.3 The FSA collects data on all known foodborne related incidents. This includes the date of notification, the type of incident, any suspected foods, the pathogens isolated and any specific data on the bacterial genetics. This is used to build a database to identify actions that can be taken to minimise any further incidents. It can help us understand how outbreaks impact on reported cases, especially where cases are relatively low, as with *Listeria monocytogenes* and STEC, and also provide information on causes/sources, changes in the aetiology of infections (such as a more virulent strain), and connect seemingly unlinked cases of illness through genetic testing of samples.

4.4 There is also a specific reason to change the STEC threshold. When the STEC threshold was established, diagnostics and reporting focussed on STEC O157. There is now widespread testing for non-O157 STEC which reflects the increased prominence of other STEC strains in outbreaks of foodborne diseases. Continuing with a threshold based solely on STEC O157 would result in an under-representation of the public health burden associated with STEC. It would also undermine our existing advice to stakeholders that food safety control plans should be validated and verified for all STEC strains known to cause severe disease where STEC is identified as a hazard. Therefore, the current threshold for STEC O157 will be expanded to include other relevant STEC serotypes.

4.5 It is proposed that each pathogen will be adjusted as follows:

- **Salmonella:** threshold to be recalculated to account for the impact of reporting isolates from all relevant sample types (faecal and non-faecal samples).

- **Campylobacter**: threshold will be recalculated (likely to remain unchanged (footnote 6))

- **Listeria monocytogenes:** threshold will be recalculated, to reflect a sustained decrease in case numbers since they were originally calculated

- **STEC:** threshold will be recalculated so that it is based on the main serotypes (footnote 7) of STEC related to human cases of FBD (rather than solely O157).

4.6 **Annex 2** (Figures 3 to 6) shows what new thresholds could look like for each of the four key pathogens. These have been calculated based on data from 2015 to 2023 (excluding the COVID years 2020 and 2021) using the upper 95% confidence interval. These will be discussed with EFIG before thresholds are finalised.

Determining the preferred technical approach to setting thresholds

4.7 As is appropriate for an evidence-based organisation, the review also considered the latest thinking and approaches to establishing and reviewing thresholds. It concluded that there were two approaches that could be applied. (A comparison of the outputs of the different approaches is provided in **Annex 2**).

Option 1 – Annual update:

- Setting threshold levels annually would recalculate the threshold automatically accounting for the addition of new figures each year. This would mean the thresholds will take account of more recent data. It would ensure longer term historical trends are incorporated into the threshold level.

Option 2 – Periodic review (preferred):

- A periodic review (5 years, unless data suggests sooner) of threshold levels would take account of the latest evidence on the epidemiology of key pathogens associated with foodborne disease and external factors which could affect the long-term trends, for example if evidence suggests the risk has changed (such as emerging strains with higher virulence).

4.8 While the use of annual thresholds has benefits in that it is based on the most recent data, there is the potential risk of masking slowly developing trends as the threshold might move in line with the trend. A periodic review that determines if there are known factors that require interpretation avoids this risk. Following our analysis of the evidence and consultation with experts on this, we have discounted Option 1 (annual update) and are therefore proposing to update the thresholds periodically (Option 2) based on consideration of the latest evidence by subject-matter experts. Ongoing expert analysis of emerging evidence (see section on EFIG below) will indicate when it is appropriate to review and adjust our thresholds.

Assurance of revised thresholds

4.9 We recognise the Board will want assurance that changes to thresholds are scientifically robust and that the sensitivity of identifying underlying changes is not compromised. The FSA proposes to continue monitoring FBD trends, review against the thresholds, and to report any significant changes to the FSA Board under normal reporting arrangements. Figures are included in the published Annual Report and Accounts (ARA) which is reviewed by ARAC who provide advice to the Board. Where breaches of the thresholds arise, the Board would be informed.

EFIG

4.10 To provide the necessary expert review and assurance, we are proposing to utilise a longstanding cross-government, FSA-led group to assess evidence and provide advice accordingly. This group is the EFIG and comprises expert representatives of all government departments and executive agencies who have an interest in FBD across the UK **(Annex 3)** . EFIG will examine the evidence on emerging factors that could impact on the effectiveness of thresholds and assess if they are still set at the appropriate level or require recalibration. They will also be able to advise on more fundamental changes such as whether thresholds for additional pathogens need to be established.

4.11 In addition to reviewing the thresholds, EFIG will review and comment on the latest data on reported cases of FBD which will be reflected in our routine reports. This would incorporate government intelligence across animal and human health into our monitoring systems and complement the data-driven threshold approach, providing. This will provide insight into possible

causes of changes in the data such as changes in virulence and transmissibility of pathogens, new sources, as well as whether these are likely to be foodborne, and advise on possible interventions.

5. Conclusion

5.1 The FSA has considered the review questions and has concluded:

- Individual pathogen thresholds remain a useful tool and continue to have a role in FSA monitoring activities for FBD.

- The current thresholds, set in 2018, need to be recalibrated to take account of developments in detection, reporting and our FBD interventions.

- The preferred approach is to update the individual thresholds to take account of changes in sampling and reporting and, in the case of STEC, our awareness of pathogen strains that are causing severe disease. Subject to the Board's agreement, the thresholds will be recalculated.

- Once agreed, data will be included in the published ARA which is reviewed by ARAC. Where breaches of the thresholds arise, the Board would be informed.

- Thresholds will then be reviewed every 5 years, unless data suggests sooner.

- There are opportunities to strengthen the governance around our approach to setting thresholds and routine monitoring of trends in FBD. This can be delivered through EFIG.

6. Recommendation

6.1 The Board is asked to:

- **Discuss and comment on** the proposed arrangements for adjusting the approach to thresholds and the FSA activities to monitor trends in FBD.

Annex 1 – Threshold Level Toolkit

The toolkit makes it easier to establish clear and timely investigations and actions to be taken when threshold (trigger) levels are breached or when the number of human cases of illness increase. A significant increase in cases or a breach of the threshold levels set by the FSA Board in 2018 will lead to investigation where appropriate action and/or intervention will then be considered.

1	The 4 key pathogens that are monitored by the FSA: • Campylobacter • Salmonella (non-typhoidal) • STEC O157 • Listeria monocytogenes
2	The trigger/thresholds levels set by the FSA Board in 2018 a) Campylobacter: Baseline 71,300 laboratory confirmed cases per year in UK (equivalent to 108.0 laboratory confirmed cases per 100,000 population) b) Salmonella (non-typhoidal): Baseline: 9,500 laboratory reports per year in UK (14.4 laboratory confirmed cases per 100,000 population) c) STEC O157: Baseline: 1,500 UK laboratory reports per year in UK (2.3 laboratory confirmed cases per 100,000 population) d) Listeria monocytogenes: Baseline: 250 UK laboratory reports per year in UK (0.4 laboratory cases per 100,000 population)
3	If threshold levels are not breached but cases are approaching the threshold level in any of the four major foodborne disease pathogens (*Campylobacter*, *Salmonella*, *E. coli O157*, *Listeria monocytogenes*), a review/investigation will be carried out by the FSA to inform if there is need for actions to be taken.
4	If no specific action is identified following the review/investigation, the FBD Policy Steering Group will continue to monitor changes/trends working with the cross-government Epidemiology of Foodborne Infections Group (EFIG) as required.

5	If threshold levels are breached in any of the four key pathogens (*Campylobacter, Salmonella, E. coli O157, Listeria monocytogenes*) the FBD Policy Steering Group will: • Investigate the reasons behind the increase, working in collaboration with Epidemiology of Foodborne Infections Group (EFIG), ACMSF and the FBD Research programme. This will be done by using information from social science outputs (such as Food and You) and other commissioned research to monitor consumer behaviour, inform interventions and risk communication. • Following investigations, could undertake further sampling of products/food associated with specific pathogen. In addition, determine the most appropriate response or action which might include further investigations including assessing likely impact of interventions, research and root cause analysis. • Consider if an action plan needs to be developed or reviewed (if there is an existing plan). Possible Options/Outcomes: • Update Executive Management Team and the FSA Board on the issue and recommend suitable interventions. • FBD Policy Steering Group will consider and recommend actions and/or intervention, including possible communications activity. • Identify where interventions or control measures could reduce FBD targeting key transmission pathways. • Identify which point in the food chain intervention is likely to have the biggest impact. • Select and target interventions for clear consumer benefit using rigorous evidence, analysis, and insight. • Influence consumer behaviours using tailored food safety messaging which is targeted to the intended population groups based on their particular risk, behavioural and demographic profiles.

Annex 2– A comparison of the current vs. potential new revised thresholds

Maintain current thresholds

1. The FSA monitoring for non-typhoidal Salmonella and Campylobacter was based on confirmed laboratory reports from faecal samples only, while public health agencies own reporting includes isolates from all samples, (also including blood and urine). For the last two years, the FSA has also been including non-faecal isolates when it reports trends in confirmed laboratory cases for non-typhoidal Salmonella and Campylobacter. At the same time, the FSA also changed from reporting absolute numbers to rates per 100,000 population.

2. This change in reporting impacts on the reported levels of individual pathogens to a different extent. For example, for Campylobacter this difference is relatively minor, with non-faecal sampled being less than 1% of the total in most years. Non-faecal isolates make up a larger proportion of reported isolates for non-typhoidal Salmonella and has been steadily increasing as a proportion of all samples (5.3% in 2015, 13.2% in 2021). This change does not impact STEC O157, where almost all samples are faecal, or Listeria, where few are and so reporting has always been based on all isolates.

3. In June 2022, the cross-government Epidemiology of Foodborne Infections Group (EFIG) (footnote 8) agreed that these should be included in the total. Including these isolates also brings the FSA in line with reporting elsewhere and avoids the risk of contradictory reporting between agencies (as happened in 2017). However, including non-faecal isolates means numbers will be higher than the previous threshold which was based on faecal isolates only. If we want to continue using the old threshold, we need to revert to reporting on faecal only isolates. In addition, advancements in scientific testing means that we are better able to detect pathogens within specimens and fewer samples are reported as unknowns. The practical impact of this is that there is an apparent increase in reported cases (see figures 1 and 2).

Figure 1: Rates of *Salmonella* laboratory confirmed cases (faecal vs all isolates)

4. This is less of an issue for Campylobacter where non-faecal isolates only make up around 1% of laboratory confirmed isolates, so there is no major need to adjust the thresholds. This is illustrated in figure 2 below where the lines for ‘faecal only’ isolates and ‘all isolates’ lines overlap and are difficult to distinguish.

Figure 2: Rates of *Campylobacter* laboratory confirmed cases (faecal vs all isolates)

Adjusted thresholds

5. Figures 3 to 6 show what new thresholds could look like for each of the four key pathogens. These have been set at the upper 95% confidence interval based on data from 2015

to 2023 (excluding the COVID years 2020 and 2021).

Figure 3: *Salmonella* laboratory confirmed cases (per 100,000 population)

Figure 4: *Campylobacter* laboratory confirmed cases (per 100,000 population)

Note: that for *Campylobacter* the potential new threshold is the same (to 1 decimal place) as the current threshold, so the two lines would be indistinguishable. Therefore, only the current threshold is given.

Figure 5: *Listeria monocytogenes* laboratory confirmed cases (per 100,000 population)

Figure 6: STEC O157 laboratory confirmed cases (per 100,000 population)

Figure 7: STEC laboratory confirmed cases (per 100,000 population)

Note: This graph shows a potential new all STEC threshold. This is based on data up to 2021 only and excludes Wales due to a change in the testing methodology in 2018. Before implementation it would need to be updated to account for later years when data becomes available, as well as including Welsh data.

Annex 3 - Epidemiology of Foodborne Infections Group (EFIG)

Background and Members

1. The group was first established in the early 2000s in response to the growing need for a coordinated approach to tackle foodborne diseases. The group brings together experts from various fields, to improve food safety and public health in the UK.

2. The group operates through a robust network of cross-government agencies, including the Food Standards Agency, UK Health Security Agency (UKHSA), Animal Plant Health Agency (APHA), Food Standards Scotland (FSS), and public health authorities (Public Health Wales (PHW) in Wales, and Public Health Agency Northern Ireland (PHANI) in NI (part of Health and Social Care Department for Northern Ireland (HSCNI)). Representation from these departments ensures that expertise from different sectors is harnessed to address the multifaceted nature of foodborne diseases.

Figure 1: Interdisciplinary cross government collaboration within the Epidemiology of Foodborne Infections Group

EFIG Aims and Role

3. EFIG meets twice a year (May and December) to discuss evidence-based insights by analysing new surveillance data and monitoring trends in foodborne illnesses. Each government department provides comprehensive updates for pathogens of concern (Salmonella, Shiga toxin producing Escherichia coli (STEC), Campylobacter and Listeria). APHA discuss the epidemiology in animal feed and livestock reports, as well as any National Control Program updates for Salmonella in poultry. Food surveillance data is presented by the FSA, APHA, UKHSA, and public health boards. Incidents of foodborne disease in humans are also presented by the FSA. Trends and concerns regarding human infection data and gastrointestinal hospitalisation rates are presented by the UKHSA and FSA. EFIG members can then identify key areas of concern, potential emerging trends, and knowledge gaps that need to be addressed with further research.

4. This information is useful for developing effective public health policies and interventions. For example, EFIG's involvement in One Health initiatives has influenced policies that consider the interconnectedness of human, animal, and environmental health. This holistic approach has been integrated into the UK Food Security report (UK FSR), ensuring that food safety policies are comprehensive and effective. This provides policymakers across the UK nations with the best possible information and analysis they need to maintain the UK’s food security.

5. EFIG data and information are shared with the Advisory Committee on the Microbiological Safety of Food (ACMSF). This group provides the FSA with independent expert advice on microbiological issues related to food safety. Therefore, this collaboration allows the ACMSF to receive up-to-date epidemiological data, which is crucial for assessing risks and providing informed advice to the UK Government.

Summary of EFIG aims and outputs:

- Interdisciplinary and cross-government collaboration
- Sharing Surveillance Data (across government and with ACMSF)
- Monitoring Foodborne Illness trends
- Identifying research priorities
- Supporting Risk Assessment and Policy Development
- Discussing and agreeing reports for One Health initiatives such as UK FSR

1. Thresholds were set above normal year-to-year variations to indicate a potential real increase in case numbers, prompting investigations by the FSA and other Health Agencies.

2. A cross-government group of scientific experts, who examine foodborne infection data, identifying emerging trends; chaired by the FSA

3. FSA (Wales, Northern Ireland, England), UK Health Security Agency (UKHSA), Public Health Wales (PHW), Public Health Scotland (PHS), Public Health Agency NI(PHANI), Food Standards Scotland (FSS)

4. Outbreaks are either: incidents where two or more people affected by the same infectious disease are linked by time, place, or common exposure, or; when a greater than expected rate of infection occurs (compared to the usual background rate for that place and time).

5. Incidents include: suspected, anticipated, or actual events involving contamination (such as. microbial in food) which would prompt investigation and management, or; a single case of a rare or high-consequence disease (such as botulism).

6. Changes in sample reporting do not materially affect the reported number of cases for Campylobacter as only a small proportion of non-faecal samples are included. The proposal is for the threshold to be recalculated to include non-faecal samples but, in practice, this is unlikely to have a major impact.

7. For the EU/UK this is currently Shiga toxin producing E. coli (STEC) O157, O26, O111, O103, O145 and O104:H4

8. A cross-government group of scientific experts, who examine foodborne infection data, identifying emerging trends; chaired by the FSA