UK WORKING POLICY ON DETECTION OF STEC IN FOOD BY OFFICIAL CONTROLS AND FOOD BUSINESS OPERATOR SAMPLING AND TESTING

INTRODUCTION

1. The Food Standards Agency and Food Standards Scotland have reviewed the available evidence on Shiga toxin-producing *E. coli* (STEC) in foods with colleagues across Government, the independent expert Advisory Committee on the Microbiological Safety of Food (ACMSF) [1]and stakeholders to inform EU discussions and agree appropriate interventions following the detection of STEC in foods by Official Controls or Food Business Operator (FBO) sampling and testing programmes.

2. We recognise the risks associated with STEC in foods, particularly the ability of certain serogroups to cause severe disease. However, there is uncertainty in the evidence and gaps in our knowledge so risk management interventions must be considered carefully to ensure they are risk based and proportionate.

3. This paper proposes actions that should be taken by both local authorities and food business operators following detection of STEC in food and discusses the evidence supporting these proposals. A summary of the expected responses to unsatisfactory test results is provided at Table 1 in Annex I.

4. This policy is intended to help food business operators, their primary authority partners and local authorities to understand the proportionate and risk based actions that can be taken to manage the risks associated with detection of STEC in food based on the current evidence.

DETECTION OF STEC IN FOOD

General Principles

5. STEC are a group of *E. coli* characterised by their ability to produce toxins, designated Shiga toxins (*stx1* and *stx2* or their variants) because of their similarity with the toxin produced by *Shigella dysenteriae*. Shiga toxins are also known as verocytotoxins and the terms STEC and VTEC are synonymous.[1] The symptoms of STEC infection can include diarrhoea, abdominal pain, bloody diarrhoea, and haemolytic uremic syndrome (HUS), a serious condition that can lead to kidney failure and can be fatal. HUS develops in approximately 10% of patients infected with STEC O157 and is the leading cause of acute renal failure in young children.

6. The risk management action to be taken following the detection of STEC depends mainly on the following:

   - **Whether the microbiological test result is confirmed or presumptive positive**. FSA considers that the presence of STEC in food is confirmed when one or more of the *stx* genes are detected in an isolated *E. coli* strain.

[1] http://acmsf.food.gov.uk/sites/default/files/acm_1191_stec.pdf
http://acmsf.food.gov.uk/sites/default/files/acm_min_86.pdf

Identification of additional specific virulence genes in an isolate also provides more certainty of the strain's ability to cause severe disease but this information is not essential to determine the appropriate risk management action. If *stx* gene(s) are detected but have not been confirmed in an isolated *E. coli* strain, this is considered a presumptive positive result.

- **The treatment that will be applied to the food.** For this purpose, foods can be split into two food profiles:

Food Profile 1

Ready-to-eat (RTE) foods and foods consumed less than thoroughly cooked:

- Food defined in Regulation 2073/2005[2] as ready-to-eat (RTE)
- Food to be consumed with a mild treatment unlikely to remove the STEC risk[3]
- Food for which an FBO is not able to provide guarantees that a treatment that will remove the STEC risk will be applied before consumption[4]

Food Profile 2

Foods intended to be consumed following a treatment that will remove the STEC risk.

RISK MANAGEMENT INTERVENTIONS

FOOD PROFILE 1 - RTE foods and foods consumed less than thoroughly cooked

Presumptive Positive test result (detection of *stx* genes)

7. It is not possible to assess public health risks associated with the detection of *stx* gene(s) if their presence has not been confirmed in an isolated *E. coli* strain. The European Food Safety Authority (EFSA) opinion on 'VTEC-seropathotype and scientific criteria regarding pathogenicity assessment'[5] indicated that the detection of Shiga toxins alone, or of genes encoding for such toxins, is not a sound scientific basis for assessing the disease risk to the consumer. According to the opinion, the isolation of an STEC strain is needed to confirm the presence of *stx* gene(s) in addition to relevant virulence encoding genes in the same live cell rather than as free DNA or free *stx* phages in the enrichment culture.

[2] 'ready-to-eat' food means food intended by the producer or the manufacturer for direct human consumption without the need for cooking or other processing effective to eliminate or reduce to an acceptable level microorganisms of concern.
[3] This category would include for example minced meat used in burgers or other meat preparations that may be served less than thoroughly cooked.
[4] For example, if STEC is detected in carcass meat, trim or minced meat, the FBO would be expected to provide guarantees that the meat would only be consumed following thorough cooking. This could include labelling or information that would accompany the affected meat through the onward supply chain to the point of use.
[5] Scientific Opinion on VTEC-seropathotype and scientific criteria regarding pathogenicity assessment. EFSA Journal 2013;11(4):3138 https://www.efsa.europa.eu/en/efsajournal/pub/3138

The ACMSF also expressed a view that if the genetic results are available without confirming their presence in an isolated *E. coli* strain, it would currently not be possible to assess the potential risk to public health.[6]

8. Detection of *stx* gene(s) alone would therefore not generally require action to withdraw or prevent product being placed on the market. Confirmation of the presence of *stx* gene(s) in an isolated *E. coli* strain is generally required before such action is taken. However, if one or more *stx* genes are detected in foods included in investigations associated with outbreaks of illness, then this may, when taken with epidemiological information potentially linking the food to human illness, be sufficient to support action to withdraw product from the market.

9. Given the potential for STEC to cause severe disease it is appropriate for FBOs to respond to presumptive results by taking steps to ensure the business is prepared to take immediate action should the presence of STEC be confirmed. We would expect FBOs to include an appropriate response to presumptive results within their food safety management systems which should consider inclusion of the following steps:

- Retain affected batch(s) still within FBO control;
- Notify the local authority and/or FSA as appropriate via incident reporting channels;
- Collation of traceability and other information that would support immediate action should the result be confirmed;
- Notify onward supply chain and request retention of affected product still within their control.

We would welcome views on any practical issues arising from the proposed risk management advice in response to presumptive positive results including steps that should be taken at this stage to review HACCP in light of the detection of potential faecal contamination

Confirmed test result (detection of *stx* genes in an isolated *E. coli* strain)

10. The confirmed presence of STEC in a batch of food falling into Profile 1 is considered a serious risk to public health. Evidence indicates that some strains are not pathogenic, but a precautionary approach is appropriate given the uncertainty in the evidence and the potential for severe disease[7].

11. The Competent Authority should be notified through incident reporting procedures and action should be taken to withdraw affected batches from the market in accordance with Regulation (EC) 178/2002. Information on the onward supply of the product will be needed to determine whether a product recall from end users/ consumers would also be appropriate.

12. Follow up investigations should be initiated by the FBO to identify and remove the source of STEC contamination. The FBO should review the HACCP-based food safety

[6] See footnote 1
[7] See footnote 1

management system, to ensure that STEC is identified as a specific hazard and that effective procedures are in place to prevent STEC contamination in food that will not be processed sufficiently to remove the STEC risk.

<u>FOOD PROFILE 2</u> - Foods intended to be consumed following a treatment that will remove the STEC risk

13. The uncertainty in the evidence, characteristics of STEC and gaps in our knowledge make it difficult to assess the effectiveness of possible risk management interventions for Food Profile 2. We are most concerned about existing and emerging strains that could cause severe disease so further information on the strains present in Profile 2 foods is needed to determine the appropriate risk management action.

14. It is reasonable to expect the risks from STEC, including those *E. coli* strains capable of causing severe disease, to be managed, if foods are handled and cooked in accordance with instructions on the label provided by the supplier. It is important to acknowledge that incorrect application and break down of controls can lead to outbreaks of severe illness, however, with our current state of knowledge it is very difficult to identify proportionate control measures that would bring about public health benefits beyond those provided through provision and application of appropriate cooking and handling instructions provided by food businesses.

15. Proposed interventions therefore focus on providing proportionate measures that would help minimise the risks to consumers from foods within Profile 2 that contain strains of STEC capable of causing severe disease. They also take into account wider consumer interests, impact on business and wider government initiatives such as the need to reduce food waste.

Test results

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16. It is reasonable to wait for the completion of confirmatory tests before action is taken; therefore action would only be advised when an STEC strain capable of causing severe disease is isolated from a food within Profile 2. It should be noted that serogroups of concern may change over time due to the characteristics of STEC, particularly the plasticity of its genome and its ability to acquire and lose genetic characteristics.

    There are currently 6 serogroups[8] that are most frequently associated with severe human illness in Europe but we expect additional strains to emerge over time. Our knowledge of STEC will also develop so risk management intervention will need to take into account the latest evidence on STEC and effective controls.

17. If other virulence genes are detected, their presence should be taken into account to determine whether an STEC strain may be capable of causing severe human illness. Overall, an *E. coli* isolate of one of the STEC serogroups most frequently associated with human illness in combination with *stx* and [1] *eae* or [2] *aaiC* and *aggR* genes should be considered as presenting a potentially high risk for diarrhoea and Haemolytic Uraemic Syndrome (HUS)[9].

[8] O157, O26, O103, O145, O111, O104
[9] See footnote 1

18. In the majority of cases, isolation of an STEC strain capable of causing severe disease from a food within Profile 2 would not require a withdrawal or recall of product.

    Each incident should be considered on a case by case basis taking account of local factors that will determine appropriate action. There may, on occasion, be additional information that would lead to the food being withdrawn and recalled.

Action on confirmed test result

19. When sampling and testing confirms the presence of one of the STEC strains capable of causing severe disease, the following action should be taken by the FBO:

- FBO should confirm whether the affected batch(s) of food is labelled or accompanied by appropriate handling instructions to ensure it is cooked / treated before consumption sufficient to remove the STEC risk;

- If this instruction is not present, or insufficient to mitigate the risk, the affected product should be withdrawn and recalled from the market **OR**; if it is still within the control of the FBO, either redirected for further processing or for labelling in retrospect to ensure it is appropriately handled and adequately cooked before use;

- The FBO should initiate investigations to establish the source of STEC contamination and whether any other product is affected. Controls should be implemented to minimise the risk of contamination recurring in future;

- The FBO should review the HACCP-based food safety management system, to ensure that STEC is identified as a specific hazard and that effective and proportionate controls are in place to minimise the risk from STEC.[10]

We would welcome views on any practical issues arising from the proposed risk management advice for foods within Profile 2 found to contain a strain of STEC capable of causing severe disease.

FBO OBLIGATIONS

20. This policy position does not place additional obligations on FBOs to carry out testing over and above the existing requirements in Article 5 of Regulation 852/2004, however, FBOs have a legal responsibility to place safe food on the market, and must be able to demonstrate how this obligation is met, for example, by having appropriate corrective actions in place in response to unsatisfactory test results. FBOs are also required to

[10] This should draw on the latest evidence on the effectiveness of food safety management controls to prevent contamination of food by STEC. This would include experiences of FBOs in other countries that require absence of STEC in certain foods within Food Profile 2 and FBOs supplying foods that fall within Food Profile 1 (for example, minced meat used to produce burgers that are less than thoroughly cooked before consumption).

have appropriate monitoring in place as part of their HACCP-based approach in Article 5 of Regulation 852/2004.

21. FBOs may wish to take risk management action on a presumptive positive result using molecular methods which screen for the presence of certain genes without carrying out confirmatory testing using the Standard Reference method.[11] Ideally positive results from the screen would trigger further confirmatory tests as this will contribute to our knowledge of STEC and understanding of the limitations of current testing methods. However, we accept that businesses may wish to develop sampling and testing regimes based on molecular methodology and establish their own criteria that would trigger corrective action. We would expect such regimes to provide at least equivalent public health protection to the interventions proposed in this paper.

22. There is no explicit requirement for FBOs to report unsatisfactory test results from routine STEC sampling and testing programmes to the competent authority. Obligations for reporting results would however, be covered by the general requirements for placing safe food on the market in accordance with Regulation EC 178/2002 and FBOs would be expected to follow the usual processes for reporting test results when there is an indication that food placed on the market may be unsafe. **For Food Profile 1, FBOs therefore have an obligation to report unsatisfactory test results to the competent authorities, including presumptive positive results.**

23. For foods falling within Food Profile 2, since we advise that detection of one of the strains capable of causing severe disease requires intervention by FBOs, **we advise FBOs to report unsatisfactory test results to the competent authorities so that steps can be taken collaboratively to ensure the appropriate action is taken.** Sharing of information and testing data will also help develop our understanding of STEC and identify proportionate interventions that might be applied.

Third Country Export Requirements

24. Businesses wishing to export to third countries will need to meet the requirements of receiving countries. Given the different food safety and consumer cultures that exist, it is likely that different approaches may be applied. There are also differing opinions on pathogenicity of STEC and appropriate mechanisms for control.

25. Where the STEC testing requirements for third country exports are not met and FBOs wish to consider whether the product can be placed on the UK market, this should be assessed in accordance with this policy advice.

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[11] http://www.iso.org/iso/catalogue_detail.htm?csnumber=53328

ANNEX I

TABLE 1: SUMMARY OF ACTION REQUIRED IN RESPONSE TO UNSATISFACTORY TEST RESULTS FROM BOTH OFFICIAL CONTROLS AND FBO SAMPLING AND TESTING

	Presumptive test result	**Confirmed test result**
Definition	Detection of one or more *stx* gene(s) is considered a presumptive positive result if their presence has not been confirmed in an isolated *E. coli* strain	Presence of STEC is confirmed when one or more *stx* gene(s) are detected in an isolated *E.coli* strain.
Food Profile 1	**Action required by LA/FBO**	**Action required by LA/FBO**
Ready-to-eat (RTE) foods; **Foods to be consumed with a mild heat treatment unlikely to remove the STEC risk** **And** **Food for which an FBO is not able to provide guarantees that a treatment that will remove the STEC risk will be applied**	The Competent Authority should be notified through incident reporting procedures. FBOs should prepare to take immediate action in readiness for a confirmed test result: • Retain affected batch(s) still within FBO control; • Collate traceability information; • Notify onward supply chain and request retention of affected product still within their control; If presumptive results are not confirmed, held product can be released on to the market with no further action. There may be instances where a withdrawal or recall may be required by the competent authorities on the basis of detection of *stx* genes alone, if, for example, there is epidemiological or other information that links the food to cases of illness.	The Competent Authority should be notified through incident reporting procedures. The affected batch(s) of food must be withdrawn from the market in accordance with Regulation (EC) 178/2002. Information on onward supply of the product will be required to determine whether a product recall from end users/ consumers is required. Investigations should be initiated by the FBO to identify and eliminate the source of STEC contamination and any other batches or products affected. The FBO should review the HACCP-based food safety management system, to ensure that STEC is identified as a specific hazard and that the risk from STEC in food is minimised.

	Presumptive test result	Confirmed test result
Definition	Detection of certain genes[12] associated with severe disease is considered a presumptive positive result if their presence has not been confirmed in an isolated *E. coli* strain.	Presence of certain STEC strains associated with severe disease is confirmed i.e. when specific genes[13] are detected in an isolated *E.coli* strain.
Food Profile 2	**Action required by LA/FBO**	**Action required by LA/FBO**
Raw foods or foods intended to be consumed following a treatment that will remove the STEC risk	It is reasonable to wait for the completion of confirmatory tests before action is taken. FBOs may, according to their own risk assessments or commercial operations, take risk management action on the basis of a presumptive positive result.	Confirm the affected batch(s) is labelled or accompanied by appropriate cooking and handling instructions to ensure it will be treated or cooked sufficient to remove the STEC risk **OR** Re-label the affected batch(s) retrospectively or ensure it is accompanied by appropriate cooking and handling instructions as above. **OR** Product still within the FBO's control can be redirected to an alternative use e.g. further processing sufficient to remove the STEC risk; **OR** Provide evidence that the product will be further processed sufficient to remove the STEC risk. If none of the above actions are taken, the affected batch(s) must be withdrawn from the market. Investigations should be initiated by the FBO to identify and eliminate the source of STEC contamination and any other products affected. The FBO should review the HACCP-based food safety management system, to ensure that STEC is identified as a specific hazard and that effective and proportionate controls are in place to minimise the risk from STEC.

[12] genes for one of the top six STEC serogroups most frequently associated with serious human illness in Europe (O157, O26, O103, O145, O111, O104) in combination with *stx* and [1] *eae* or [2] *aaiC* and *aggR* genes

[13] See footnote 12