

ADVISORY COMMITTEE ON THE MICROBIOLOGICAL SAFETY OF FOOD**DISCUSSION PAPER****Shiga Toxin Producing *E. coli* (STEC) in food****Issue**

In 2015, at the Agency's request, the Committee provided advice on risk assessment approaches for the handling of incidents involving STEC and food. The Committee provided risk-based advice on a draft EC guidance document which aimed to assist competent authorities of Member States when they are confronted with food with positive STEC results. Three years on, the Agency would like to bring this issue to the Committee's attention again, to ensure that its approaches to risk assessment remain appropriate. A summary of the main areas of relevance and recent developments in these areas has been prepared and attached as Annex A to this paper. The Committee is invited to review this information and in consideration with any other relevant information advise the Agency whether it considers current approaches to risk assessment remain appropriate or indicate whether any additional factors could be considered.

Background

1. In October 2015, the Agency requested the Committee's advice on the risks associated with STEC in food.
2. In 2015, the Committee was presented with paper ACM/1191¹ which outlined draft EC guidance on the application of article 14 of regulation 178/2002 as regards food contaminated with STEC. The guidance outlined approaches to be taken for different food types. Members were asked three specific questions relating to the guidance which are listed below. Based on this guidance, the Agency drafted a UK working policy document (Annex B, Members Use Only) which incorporated the views of the Committee and is used as a basis for handling STEC food incidents. Three years on, the Agency views it timely to revisit this subject with the Committee to ensure that its approaches to the risk assessment of foods contaminated with STEC remain appropriate.
3. A substantial amount of literature has been published in this area since 2015 and this paper is not intended to be an exhaustive review of this literature. Rather, this cover paper is intended to summarise the

¹ https://acmsf.food.gov.uk/sites/default/files/acm_1191_stec.pdf

Agency's and Committee's positions from 2015 and Annex A is intended to focus the committee's attention on some of the key issues relevant to the risk assessment of STEC in food and to highlight any changes in the evidence base since 2015 that are relevant to further developing approaches to STEC risk assessment, particularly for routine incidents.

Summary of draft EC guidance on handling STEC in food incidents

4. When laboratory results have confirmed the presence of the hazard (i.e. presence in an isolated *E. coli* strain of an *stx* gene), the contaminated food may be classified, for the ease of convenience, according to two risk profiles: **food profile 1** and **food profile 2**.
 - **Food profile 1** would include contaminated ready to eat (RTE) (food category "a") or non-RTE food frequently or usually consumed without a sufficient treatment able to eliminate or reduce to an acceptable level the risk of infection by STEC (food category "b"). To help classify food in this latter category, the domestic consumption habits in the particular MS should be taken into account (e.g. minced beef steak is often consumed undercooked or even rare in certain Member States). Foods in Food profile 1 should be considered as the riskiest as regards the possibility of human infection.
 - **Food profile 2** would include only contaminated food very likely to be consumed with the appropriate treatment able to eliminate or reduce to an acceptable level the risk of infection by STEC (e.g. food intended to be thoroughly cooked before consumption) and for which clear information is provided to the consumers, including information on the label, and possible other information generally available to consumers concerning the avoidance of specific adverse health effects from a particular food or category of foods (food category "c").
5. Food profile 1, should be considered as the riskiest category as regards the possibility of human infection and should be considered unsafe (and corrective actions triggered) as soon as the hazard (i.e. the presence of *stx* in an isolated *E. coli* strain) has been confirmed.
6. For food profile 2, while it is noted that serogroups of concern may change over time, the guidance notes that only the detection of STEC strains belonging to the serogroups most frequently associated with severe illnesses (i.e. O157, O26, O103, O145, O111, O104) with the relevant virulence markers *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). 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, provided that the FBO can demonstrate the product provides labelling instructions on safe cooking and handling, or that the product will be re-directed to an alternative use e.g. further processing to remove STEC

risk or provide evidence that the product will be further processed sufficiently to remove STEC risk. If none of these actions are taken, the product should be removed from the market.

Summary of the Committee's position in 2015

7. The Committee was asked three specific risk-related questions on the draft EC guidance. For ease, the Committee's response to these questions is provided below each question:

a) **Q: Whether it is appropriate to consider the presence of *stx* in an isolated *E. coli* strain ("presence of STEC") in RTE food (and foods that will not receive sufficient treatment to eliminate STEC) to present an unacceptable risk to health?**

The Committee considered that the presence of *stx* in an isolated *E. coli* strain in RTE food (and foods that will not receive sufficient treatment to eliminate STEC) presents an unacceptable risk to health. It was recognised that not all STEC strains are pathogenic but the magnitude of risk in relation to the presence of STEC in food is unclear.

b) **Q: If there is sufficient evidence to determine whether for food in non-RTE foods, the presence of *stx* in an isolated *E. coli* strain of serogroup O157, O26, O103, O145, O111, O104 with [1] *eae* or [2] *aaiC* and *aggR* presents an unacceptable risk to health particularly taking into account control measures by consumers and FBOs such as caterers?**

The Committee considered that there was insufficient evidence to determine whether presence of certain STEC strains in non-RTE foods present an unacceptable risk to public health. There was concern about the presence of STEC strains most likely to cause severe illness being present in non-RTE foods. The Committee agreed that the risks could be managed by application of food safety and hygiene controls by consumers and businesses but noted there is evidence that controls can break down and lead to outbreaks of severe illness.

c) **Q: Confirmation of an isolated *E. coli* strain in food samples that are positive for *stx* can involve practical issues. If analytical results are only available for the genetic results without confirming their presence in an isolated *E. coli* strain, would the Committee consider it possible to assess the potential risk to public health?**

The Committee concluded that if analytical results are only available for the genetic results without confirming their presence in an isolated

E. coli strain it would currently not be possible to assess the potential risk to public health.

The Committee is asked:

- Comment on the information available concerning STEC in food since the committee last considered this issue in 2015.
- If the committee wishes to change its response to the three questions (a-c above) as a result of this information.
- To review the general approach used by the Agency in dealing with foods contaminated with STEC and indicate whether this still remains appropriate or whether any improvements could be made.

Annexes – For Members’ Use Only

Annex A – Summary of some key areas to consider in STEC risk assessment (including some developments since 2015).

Annex B – Draft UK working policy on detection of STEC in food by official controls and food business operator sampling and testing.

Annex C - Strategy for testing STEC to discern level of health risk based on virulence genes. Source: FAO/WHO, 2018.