EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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**EN**

# WORKING DOCUMENT

## DRAFT

## GUIDANCE DOCUMENT ON THE APPLICATION OF ARTICLE 14 OF REGULATION (EC) N°178/2002 AS REGARDS FOOD CONTAMINATED WITH SHIGA TOXIN-PRODUCING ESCHERICHIA COLI (STEC)

## PURPOSE OF THIS DOCUMENT

This document is directed at competent authorities of Member States and aims to assist them when they are confronted with food with positive STEC results by providing them with guidance for a harmonised application of Article 14 of Regulation (EC) No 178/2002. This document does not intend to provide guidance on how STEC surveillance or monitoring should be conducted by Member States or food business operators.

## NOTE

This document is an evolving document and may be updated as necessary to take account of new scientific data, experiences and information from competent authorities and from the Commission's Health and Consumers Directorate General.

*The Court of Justice of the European Union constitutes the judicial authority of the EU and is the institution which interprets European Union law as last resort.*

## ABBREVIATIONS AND DEFINITIONS USED IN THE GUIDANCE DOCUMENT

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| CA | Competent authorities |
| EFSA | European Food Safety Authority |
| EURL | European Union Reference Laboratory |
| FBO | Food Business Operators |
| MS | Member State |
| RTE | Ready-to-eat |
| STEC | Shiga toxin-producing *Escherichia coli* |
| VTEC | Verocytotoxin-producing *Escherichia coli* |
| EAEC | Enteroaggregative *Escherichia coli* |
| *stx* gene | Shigatoxin-coding gene |
| *eae* gene | Intimin-coding gene |
| *aaiC* and *aggR* genes | Genetic markers characteristic for EAEC |

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## 1. BACKGROUND AND OBJECTIVES

Shiga toxin-producing *Escherichia coli* (STEC), also known as verocytotoxin-producing *E. coli* (VTEC), are one of the most common causes of gastrointestinal illness around the world. These food-borne pathogenic bacteria are frequently associated with severe forms of infection including hemorrhagic colitis and hemolytic uremic syndrome. As reported by the last edition of the European Union Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Food-borne Outbreaks[1], *E. coli* 0157 is the STEC serotype most often implicated in outbreaks although there are numerous other STEC serotypes that have caused serious human illness and outbreaks. These outbreaks are frequently associated with the consumption of fresh products, along with ready-to-eat (RTE) food.

The last major STEC outbreak occurred in 2011 from sprouts and, since then, most Member States (MS) have significantly increased the number of official controls aiming at detecting the presence of STEC in food placed on their market. These controls concern both imported and domestically produced foodstuffs.

The complexity of STEC relates to the difficulty of designating individual serotypes as pathogens. The plasticity of the genome, resulting in the acquisition of virulence or adherence properties from other organisms, normally by means of translocation on phages, means that new and unexpected strains are likely to appear in an unpredictable way over time. The major 2011 outbreak of E. coli O104:H4 is an example of the genomic variability referred to above and has seriously challenged the concept of STEC seropathogenicity, in particular the seropathotype approach proposed by Karmali and colleagues in 2003 (Karmali et al., 2003).

In April 2013, the European food safety authority (EFSA) published a scientific opinion[2] on "VTEC-seropathotype and scientific criteria regarding pathogenicity assessment". This opinion acknowledges that, even if it is still not possible to fully define human pathogenic STEC or identify factors for STEC that absolutely predict the potential to cause human disease, a molecular classification may give a first common approach which could assist the Competent Authorities (CA) of MS in conducting a risk assessment according to Article 14 of Regulation (EC) No 178/2002 when confronted with positive STEC results and in taking the appropriate measures to ensure that the risk for consumers is reduced as much as possible.

As no specific STEC food safety criteria have been laid down in Regulation (EC) No 2073/2005 on microbiological criteria of foodstuffs[3] (except for sprouts), the task of MS when managing STEC positive results can be challenging. It has to be noted that the application of the general principles of food hygiene at all steps of the food production chain is the main strategy for Food Business Operators (FBO) to prevent the food contamination by STEC.

[1] http://www.efsa.europa.eu/en/efsajournal/doc/3547.pdf
[2] http://www.efsa.europa.eu/en/search/doc/3138.pdf
[3] OJ L 338, 22.12.2005, P. 1

The purpose of the present document is to assist MS confronted with food with positive STEC results by providing them with guidance for a harmonised application of Article 14 of Regulation (EC) No 178/2002.

This document does not intend to provide guidance on how STEC surveillance or monitoring should be conducted by MS or FBO, nor has the ambition to recommend a sampling strategy for STEC in food.

The approach proposed in this document is applicable to all food commodities.

## 2. GENERAL RECOMMENDATIONS FOR A HARMONIZED APPLICATION OF ARTICLE 14 OF REGULATION (EC) NO 178/2002

Article 14 of Regulation (EC) No 178/2002 prohibits food being placed on the market if it is unsafe. Food is deemed to be unsafe if it is considered to be injurious to health or unfit for human consumption. Once a hazard is identified in food which might make it injurious to health, an assessment of the associated risk should be carried out, taking into account the potential exposure of consumers to this hazard. This exposure assessment should consider the normal conditions of use of the food, such as cooking, and the particular health sensitivities of specific categories of consumers where food is intended for that category of consumers.

Therefore, when confronted with food where a potential hazard has been detected, CA should always consider how serious the risk is before imposing any corrective measures. For this purpose, two key questions should be addressed:

- what harm might the contaminated food cause if directly ingested by consumers?

- how likely is it considering the intended use of this food?

## 3. STEC HAZARD CHARACTERIZATION

So far, according to the 2013 EFSA opinion, no single or combination of marker(s) has been found to define pathogenic STEC. Therefore, it is not possible to fully define human pathogenic STEC or to identify factors for STEC that absolutely predict the potential to cause human disease.

As scientific uncertainty in defining STEC pathogenicity persists, it seems prudent to consider the presence of the *stx* gene in an isolated *E. coli* strain ("presence of STEC") as a hazard entailing a high risk of causing a serious human disease if the contaminated food is directly ingested by consumers.

## 4. RECOMMENDATIONS FOR EXPOSURE ASSESSMENT

As different types of food are associated with different levels of risk for humans to become infected by STEC, MS should include information on the final destination or intended use of the food in the exposure part of their risk assessment.

For this purpose, when the laboratory results have confirmed the presence of the hazard (i.e. presence in an isolated *E. coli* strain of the *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 should include contaminated 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"). In order to help classify food in this latter category, MS should take into account domestic consumption habits on their territory (e.g. minced beef steak is often consumed undercooked or even rare in certain MS). Food profile 1 should be considered as the riskiest food as regards the possibility of human infection.

Food profile 2 should 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").

Under certain circumstances, MS may be confronted with contaminated food which is not yet at retail level and has different intended end uses (e.g. imported beef carcasses). In this case, MS cannot easily classify it in one of the two risk profiles and MS should base their classification decision on the FBO's ability to demonstrate, to the satisfaction of the CA, that the concerned product will be correctly labelled to inform successive FBOs and final consumers that a thorough cooking is needed before consumption. If this FBO's capacity cannot be demonstrated, the concerned food should be considered as a food with a risk profile 1 following a precautionary approach principle.

## 5. RECOMMENDATIONS FOR RISK MANAGEMENT MEASURES

Risk management measures should only be decided when the entire set of analytical results is available to confirm the hazard, i.e. the presence in an isolated *E. coli* strain of the *stx* gene.

For food with a risk profile 1, which should be considered as the riskiest food as regards the possibility of human infection, corrective actions, aiming at eliminating or reducing to an acceptable level the risk of infection by STEC, should be triggered as soon as the hazard has been confirmed.

Whereas for food with a risk profile 2, only STEC strains belonging to the serogroups most frequently associated with severe illnesses (i.e. serogroups O157, O26, O103, O145, O111, O104) should trigger corrective actions because of the risk of subsequent cross-contamination with RTE foods at retail or at consumer's kitchen level.

Corrective actions should differ depending on whether the contaminated food has already reached retail level or not:

- Food already at retail level should be withdraw or recall according to Article 19 of Regulation (EC) No 178/2002;
- Food not yet at retail level may be submitted to further processing by a treatment eliminating the STEC hazard.

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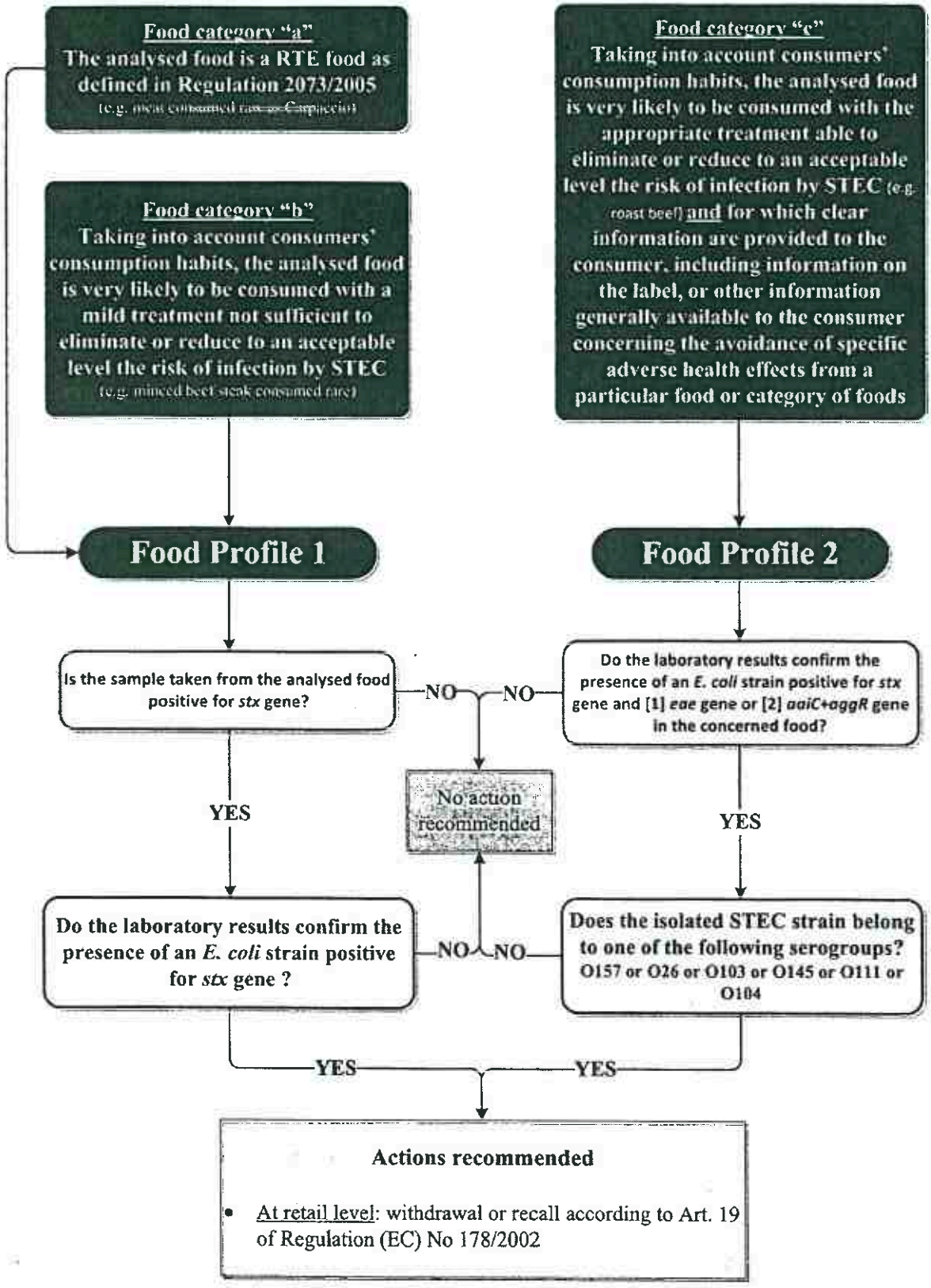
The flowcharts 1 and 2 summarise the recommendations described in this guidance document.

**Flowchart 1:** recommendations for a harmonized application of Article 14 of Regulation (EC) No 178/2002 as regards analysed foodstuffs contaminated by Shiga toxin producing E. coli sampled at retail level.



**Flowchart 2:** recommendations for a harmonized application of Article 14 of Regulation (EC) No 178/2002 as regards analysed foodstuffs contaminated by Shiga toxin producing E. coli sampled along the food chain (except at retail level).