



# **EU draft guidance document on the application of Article 14 of Regulation (EC) No 178/2002 as regards food contaminated by STEC**

**EURL E. coli workshop  
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DDG2.G4.: Food, alert systems and training**

# Background

## Until 2010

- ❑ **Seropathotype approach:** in EU focus on **"Top 5" serogroups** (serogroups most frequently associated with severe illnesses in EU)

## 2011

- ❑ Sprouts outbreak: serotype O104:H4
  - **"new" pathogenic serogroup**
  - **food safety criteria for sprouts**

## 2013

- ❑ **Publication of EFSA Scientific Opinion on "VTEC seropathotype and scientific criteria regarding pathogenicity assessment":** EFSA revisited the 'seropathotype' concept of Karmali and colleagues (2003)



## 2013 EFSA opinion - STEC complexity

- ✓ Plasticity of the genome (e.g. *E. coli* O104:H4)
- ✓ Difficulty on designating individual serotypes as pathogens

The major 2011 outbreak involving *E. coli* O104:H4 has seriously challenged the concept of STEC seropathogenicity, in particular the seropathotype approach proposed in 2003

# 2013 EFSA opinion – Molecular approach

"It is not possible to fully define human pathogenic VTEC or identify factors for VTEC that absolutely predict the potential to cause human disease"

"A molecular approach, utilising genes encoding **virulence characteristics additional to the presence of vtx genes**, is proposed"

**Table 14:** Proposed<sup>(a)</sup> molecular approach for the categorisation of VTEC (*vtx* present)

Group	Genes <sup>(b)</sup>	Serogroups	Potential risk <sup>(c)</sup>	
			Diarrhoea	HUS/HC <sup>(d)</sup>
I	<i>eae</i> -positive or ( <i>aaiC</i> and <i>aggR</i> )-positive	O157, O26, O103, O145, O111, O104	High	High
II	<i>eae</i> -positive or ( <i>aaiC</i> and <i>aggR</i> )-positive	Any other	High	Unknown
III	<i>eae</i> -negative and ( <i>aaiC</i> plus <i>aggR</i> )-negative	Any other	Unknown	Unknown

# Article 14 of Regulation (EC) N°178/2002

## *Article 14*

### **Food safety requirements**

1. Food shall not be placed on the market if it is unsafe.
2. Food shall be deemed to be unsafe if it is considered to be:
  - (a) injurious to health;
  - (b) unfit for human consumption.
3. In determining whether any food is unsafe, regard shall be had:
  - (a) to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and
  - (b) to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.

# Managing the STEC risk: a multistep/factorial approach

## 1) Hazard characterisation:

- Strain isolated
- Presence of combined virulence genes/markers (stx, eae, aaiC/aggR)

## 2) Exposure assessment based on food profiling:

- Consumption Habits
- Type of food
- Traceability information

## 3) Recommendations for a harmonised application of Article 14 of GFL:

- Molecular approach
- Take account type of food
- Same rules for import and domestic production!

# 1) Hazard characterisation

## 2011 sprout outbreak and 2013 EFSA opinion: new approach desirable

EC Proposition: concomitant presence of [1] stx gene and eae gene (STEC causing the attaching and effacing lesion) **or** [2] stx, aaiC and aggR genes (Shigatoxin-producing EAEC) in an isolated E. coli strain = hazard entailing a high risk of causing a serious human disease if contaminated food directly ingested by consumers

## 2) Exposure assessment: food at retail level

**a) RTE food**



**Food profile 1**

**b) non-RTE food:  
treatment  
insufficient**



**c) non-RTE food:  
appropriate  
treatment to  
eliminate/reduce  
STEC risk**



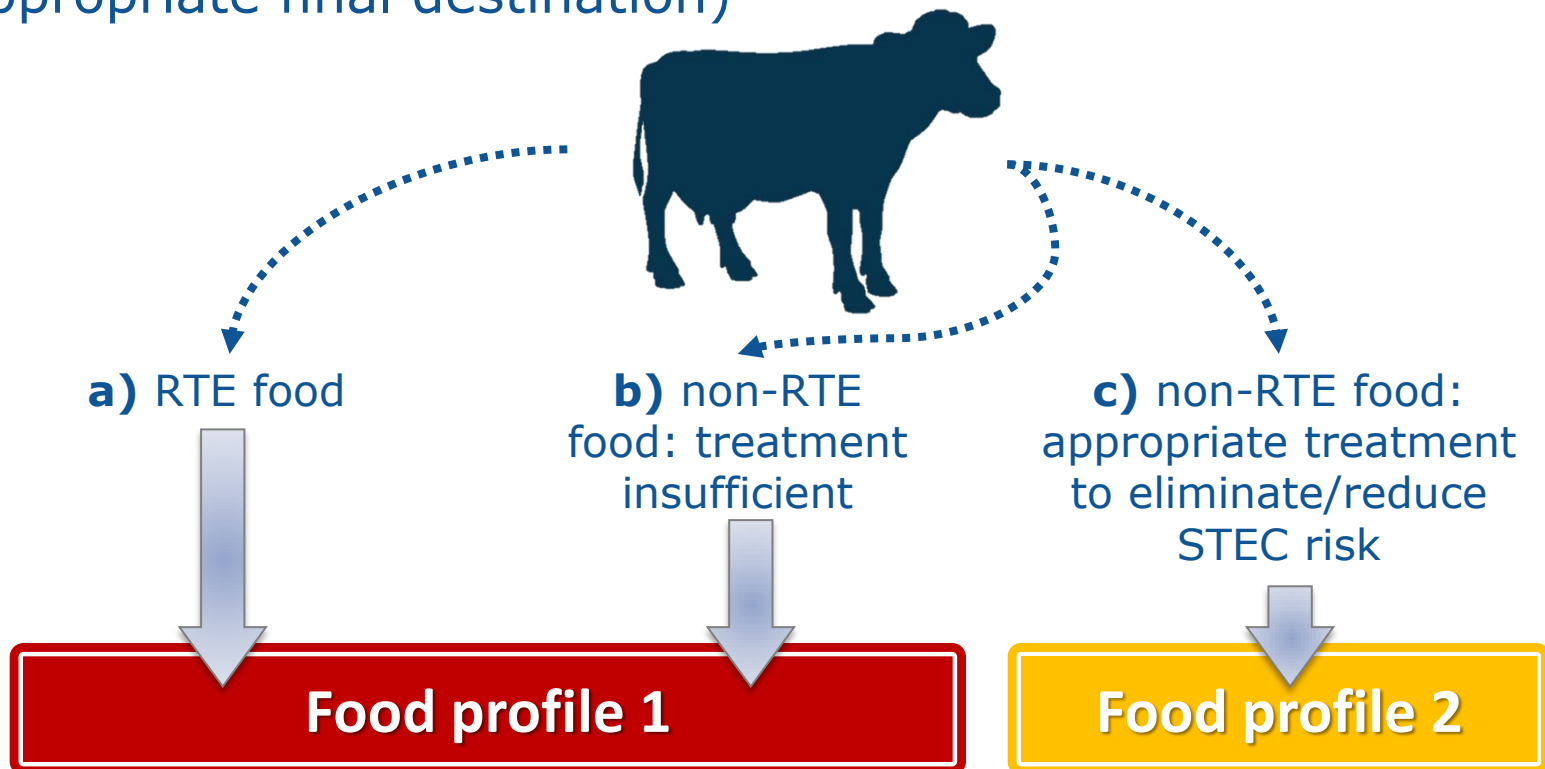
**Food profile 2**



## 2) Exposure assessment: food not yet at retail level

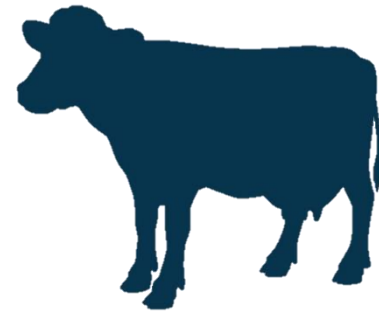
### Traceability information available and robust

(e.g. the FBO ability to correctly channel products to the appropriate final destination)



## 2) Exposure assessment: food not yet at retail level

Traceability information not available or not satisfactory

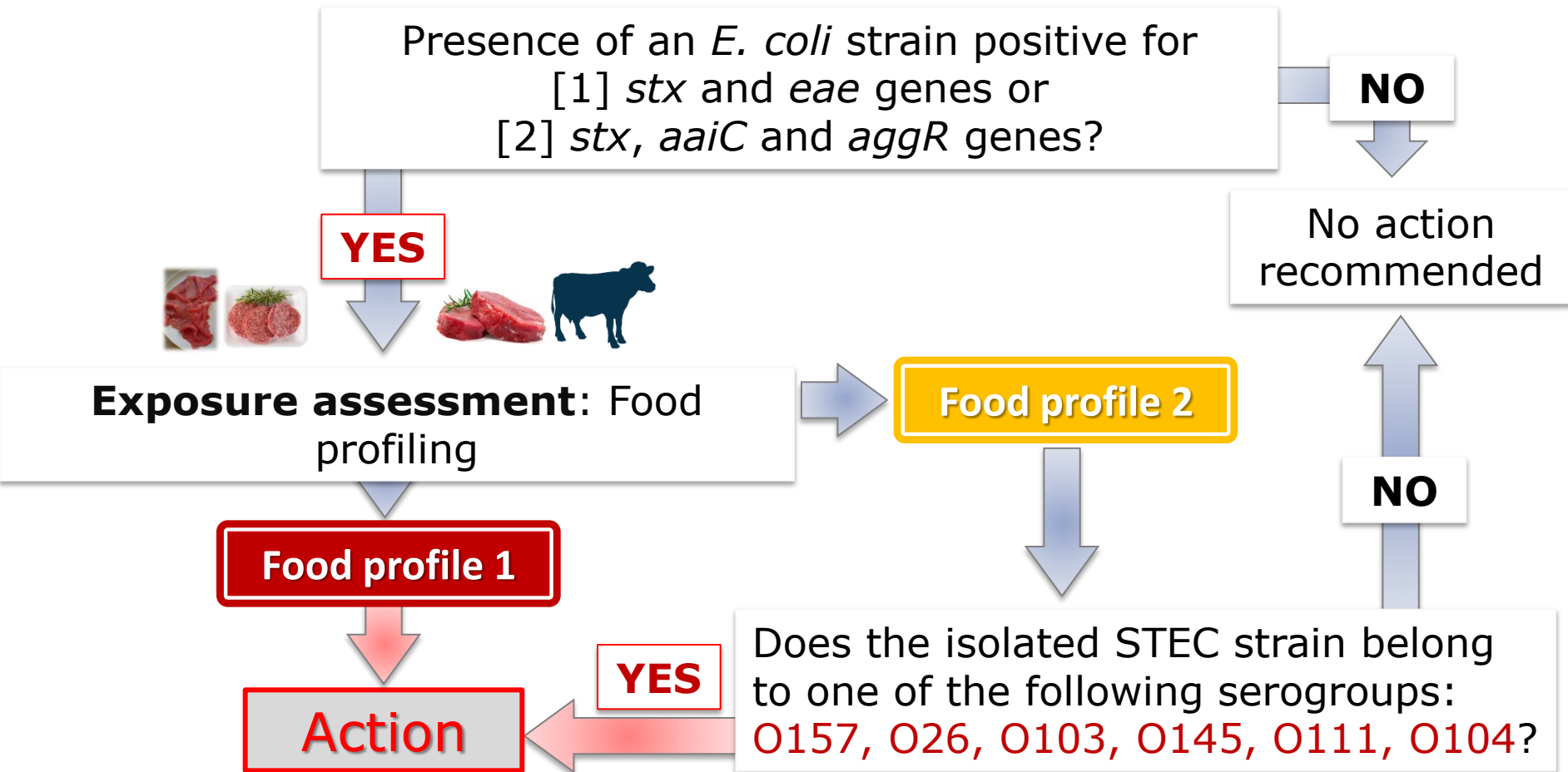


d) Food which may have different end uses and for which traceability information, provided by the FBO, is not available or is insufficient to classify the food in a, b or c



**Food profile 1**

### 3) Recommendations for a harmonized application of Article 14 of Regulation (EC) No 178/2002



# Questionnaire to MS - STEC draft guidance document

- Relevance of Karmali approach
- Hazard characterisation
- Exposure assessment recommendations
- Risk management recommendations
- Revision current food safety criteria
- Analytical methods applied (CA, FBO)
- MS past and current approaches



European  
Commission

# Questions?