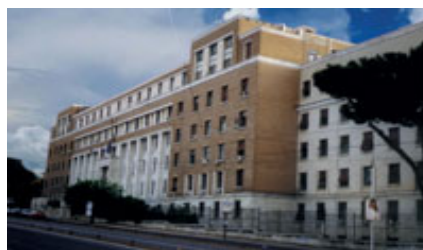


Valutazione del rischio VTEC negli alimenti: l'approccio europeo

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www.iss.it/vtec

www.iss.it/seu



EUROPEAN COMMISSION

HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions

C2 - Management of scientific committees; scientific co-operation and networks

OPINION OF THE

SCIENTIFIC COMMITTEE ON VETERINARY MEASURES RELATING TO

PUBLIC HEALTH

ON

VEROTOXIGENIC *E. COLI* (VTEC)

IN FOODSTUFFS

(adopted on 21-22 January 2003)



Istituto Superiore di Sanità - Dip. Sanità Pubblica Veterinaria e Sicurezza Alimentare
EU Reference Laboratory for *E.coli*



SCVMPH Opinion on VTEC, 2003

Requested from DG SANCO

Questions:

1. Identify categories of food where VTEC represents a hazard to public health;
2. Evaluate the appropriateness of setting microbiological criteria

CONCLUSION

Due to the sporadic occurrence and low prevalence of VTEC O157 found in food commodities representing a risk, applying end product microbiological standards for VTEC O157 is unlikely to deliver meaningful reductions in associated risk for the consumer. However, if there are reasons to suspect a high prevalence of a HP-VTEC, microbiological criteria and appropriate actions might be useful in controlling the risk. Finding HP-VTEC, in particular VTEC O157, in a foodstuff indicates a public health risk necessitating appropriate actions.

Monitoring of verotoxigenic *Escherichia coli* (VTEC) and identification of human pathogenic VTEC types¹

Scientific Opinion of the Panel on Biological Hazards

(Question No EFSA-Q-2007-036)

Adopted on 18 October 2007

Requested from EFSA

Questions:

- 1. Identify VTEC which are pathogenic to humans**
- 2. Advice on analytical methods to identify pathogenic VTEC**
- 3. Recommend the monitoring methods in animal populations and foodstuffs**

EFSA Opinion on VTEC, 2007

Recommendations

1. The **sero-pathotype** concept
2. VTEC sero-pathotypes selected using human surveillance data
3. Sero-pathotypes associated with **outbreaks and HUS; eae-positive: O157 + O26, O103, O111, O145 (Top 5)**
4. Targeted surveys on food: ruminant meat and minced meat products, fresh vegetable and salads, unpasteurised milk and dairy products derived therefrom.

SCIENTIFIC REPORT OF EFSA

Technical specifications for the monitoring and reporting of verotoxigenic *Escherichia coli* (VTEC) on animals and food (VTEC surveys on animals and food)¹

European Food Safety Authority^{2,3}

European Food Safety Authority (EFSA), Parma, Italy

Requested from EFSA

Questions:

1. Propose technical specifications for harmonised monitoring and reporting of VTEC in animals and food

EFSA technical specifications on VTEC, 2009

Recommendations

- 1. Monitoring in cattle and sheep at slaughter: VTEC O157 and (if possible) O26, O103, O111, O145**
- 2. Specific surveys on food categories at risk (see 2007)**
- 3. Methods:**
 - 1. ISO 16654 for O157**
 - 2. Draft ISO/TS 13136 for O26, O103, O111, O145**



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Office of
Public Health
Science

Laboratory QA/QC Division
950 College Station Road
Athens, GA 30605

Laboratory Guidebook Notice of Change

Chapter **new**, revised, or archived: MLG 5B.00

Title: Detection and Isolation of non-O157 Shiga-toxin Producing *Escherichia coli* Strains (STEC) from Meat Products

Effective Date: 10/01/10

Aimed at the so called “Top 7”

O157, O26, O45, O111, O121, O103, O145

MLG 5B.00 of the FSIS Microbiology Laboratory Guidebook

http://www.fsis.usda.gov/PDF/MLg_5B_00.pdf



Istituto Superiore di Sanità - Dip. Sanità Pubblica Veterinaria e Sicurezza Alimentare
EU Reference Laboratory for *E.coli*



Outbreak of Shiga toxin-producing *E. coli* in Germany

CORRIERE DELLA SERA*it*

2 June

**Batterio killer, oltre 2.000 casi in Europa
L'Oms: «Variante altamente tossica»**

*Le sequenze genetiche mostrano che si tratta di una
forma mutante di E.Coli. Morte sospetta in Francia*

Characteristics of the enteroaggregative Shiga toxin/ verotoxin-producing *Escherichia coli* O104:H4 strain causing the outbreak of haemolytic uraemic syndrome in Germany, May to June 2011

F Scheutz (fsc@ssi.dk)^{1,2}, E Møller Nielsen², J Frimodt-Møller^{1,3}, N Boisen^{1,2}, S Morabito⁴, R Tozzoli⁴, J P Nataro⁵, A Caprioli⁴

1. World Health Organization Collaborating Centre for Reference and Research on *Escherichia* and *Klebsiella*, Department of Microbiological Surveillance and Research, Copenhagen, Denmark
2. Food-borne pathogens and typing, Department of Microbiological Surveillance and Research, Statens Serum Institut, Copenhagen, Denmark
3. Department of Clinical Microbiology, Hillerød Sygehus, Hillerød, Denmark
4. European Union Reference Laboratory for *Escherichia coli*, Department of veterinary public health and food safety, Istituto Superiore di Sanità, Rome, Italy
5. University of Virginia School of Medicine, Charlottesville, United States

- ✓ Sierogruppo non “Top 7”
- ✓ *eae*-negativo



SCIENTIFIC OPINION

Scientific Opinion on VTEC-seropathotype and scientific criteria regarding pathogenicity assessment¹

EFSA Panel on Biological Hazards (BIOHAZ)^{2, 3}

European Food Safety Authority (EFSA), Parma, Italy

Requested from the Austrian Federal Ministry of Health

Questions:

1. Opinion on VTEC-seropathotype concept
2. Scientific criteria regarding pathogenicity assessment

EFSA Opinion on VTEC, 2013

Table 14: Proposed^(a) molecular approach for the categorisation of VTEC (*vtx* present)

Group	Genes ^(b)	Serogroups	Potential risk ^(c)	
			Diarrhoea	HUS/HC ^(d)
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

(a): As yet this proposed molecular approach must be regarded as provisional. This is because screening VTEC for the presence of *eae*, *aaiC* and *aggR* genes is not routinely undertaken by all laboratories reporting data to TESSy.

(b): Additional to the presence of *vtx* genes. *eae* = intimin-coding gene, *aaiC* = chromosomally-encoded gene encoding secreted protein of EAEC, *aggR* = plasmid-encoded regulator gene.

(c): Needs epidemiological studies for confirmation.

(d): HUS = haemolytic uraemic syndrome, HC = haemorrhagic colitis.

EFSA Opinion on VTEC, 2013

- It is not possible to fully define human pathogenic VTEC or to identify factors for VTEC that absolutely **predict the potential** to cause human disease.
- There is no single or combination of marker(s) that defines a „pathogenic“ VTEC
- The detection of verocytotoxins alone, or of genes encoding for such verocytotoxins **may not be a sound scientific basis for assessing the disease risk to the consumer**

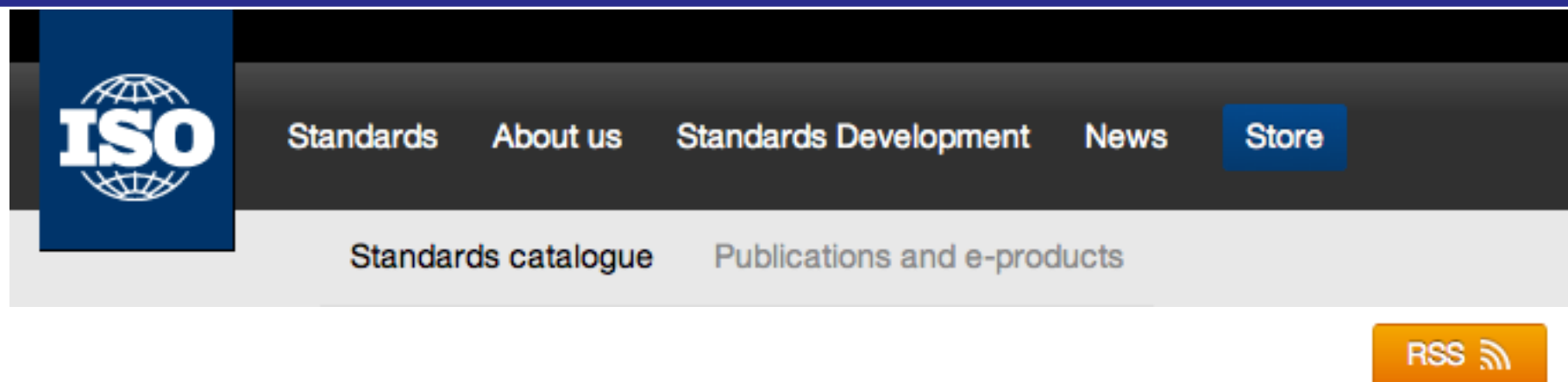
Nuovi Regolamenti UE sui germogli

Pubblicati il 1° Marzo 2013, in forza dal 1° Luglio

- ✓ **Reg. (UE) N. 208/2013:** rintracciabilità per i germogli e i semi
- ✓ **Reg. (UE) N. 210/2013:** riconoscimento degli stabilimenti di produzione (852/2004)
- ✓ **Reg. (UE) N. 211/2013:** certificazione per l'importazione di germogli e semi
- ✓ **Reg. (UE) N. 209/2013:** modifica il Reg. 2073/2005
 - ✓ **Assenza di VTEC O157, O26, O103, O111, O145, O104 in 25 gr**

Introduce per la prima volta un criterio microbiologico per i VTEC !

Reg. (UE) N. 209/2013 - Detection of VTEC in sprouts



ISO/TS 13136:2012

Microbiology of food and animal feed -- Real-time polymerase chain reaction (PCR)-based method for the detection of food-borne pathogens -- Horizontal method for the detection of Shiga toxin-producing Escherichia coli (STEC) and the determination of O157, O111, O26, O103 and O145 serogroups

+ Metodo EU-RL VTEC per O104
(www.iss.it/vtec)



*Presidenza
del Consiglio dei Ministri*

CONFERENZA PERMANENTE PER I RAPPORTI
TRA LO STATO, LE REGIONI E LE PROVINCE AUTONOME
DI TRENTO E BOLZANO

Intesa, ai sensi dell'articolo 8, comma 6, della legge 5 giugno 2003, n. 131, tra il Governo, le Regioni e le Province autonome di Trento e di Bolzano in materia di vendita diretta di latte crudo per l'alimentazione umana.

Rep. n. *5/CSR* del *25 gennaio 2007*

Allegato A - assenza patogeni

- *Listeria monocytogenes* Assenza in 25 ml
- *Salmonella* spp Assenza in 25 ml
- *Escherichia coli* O157 Assenza in 25 ml
- *Campylobacter* termotolleranti assenza in 25 ml
(n=5 e c=0)

VTEC nei prodotti carnei

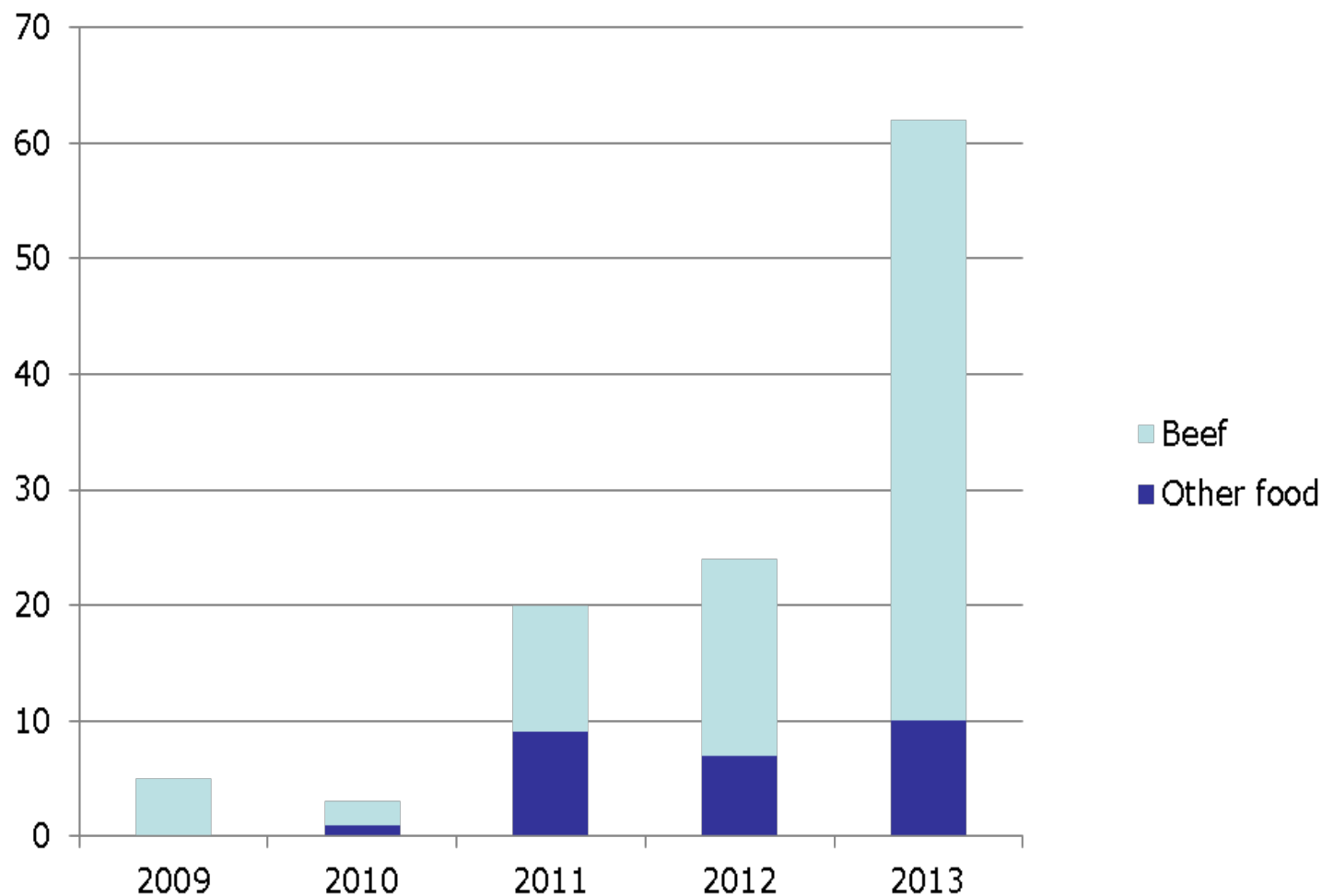
- **LEGISLATION**

- No VTEC criteria on meat
- Art. 14 of General Food Law
 - Reg 178/2004

- **RASFF**

- Increasing testing
- Increasing alerts and border rejections (mostly on beef)

RASFF notifications for VTEC



VTEC nei prodotti carnei

- Respingimenti di lotti di carne alle frontiere UE
 - Provenienti dal Sud America
 - Anche basati sulla presenza di VTEC NON appartenenti ai “top5”
 - Basati sull’ Art. 14 del Reg 178/2004 (analisi del rischio)
- Controversie con gli stati esportatori
 - Regole non chiare (possono variare con lo Stato Membro)
 - **Paradosso:** “top5” nei germogli (RTE), tutti i VTEC nella carne che in genere è destinata alla cottura !
 - Art. 14 del Reg 178/2004 è troppo indefinito

REGULATION (EC) No 178/2002

Laying down the general principles and requirements of food law, establishing the EFSA, and laying down procedures in matters of food safety

SECTION 4 - GENERAL REQUIREMENTS OF FOOD LAW

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.**

Problematiche aperte

- **Tipo di VTEC identificato**
 - Sierogruppo (Top5, Top5 + O104, Top7 USA,)
 - Combinazione di geni di virulenza (*vtx2*, *eae*, *EAgg*,)
- **Profilo di rischio dell'alimento**
 - Alto (RTE)
 - Basso (es. carcassa di pollo)
 - Intermedio (carne)
- **Tipo di risultato analitico**
 - PCR + isolamento
 - Solo PCR

2013- DG SANCO questionnaire on VTEC and beef

Purpose of the questionnaire

- Current MS approach?
- Improvement
- Reflexion... Harmonisation?

2013- DG SANCO questionnaire on VTEC and beef

Risultati

- Approcci e regole non omogenei
- Disponibilità ad armonizzare
- Richiesta di linee guida

Linee guida VTEC

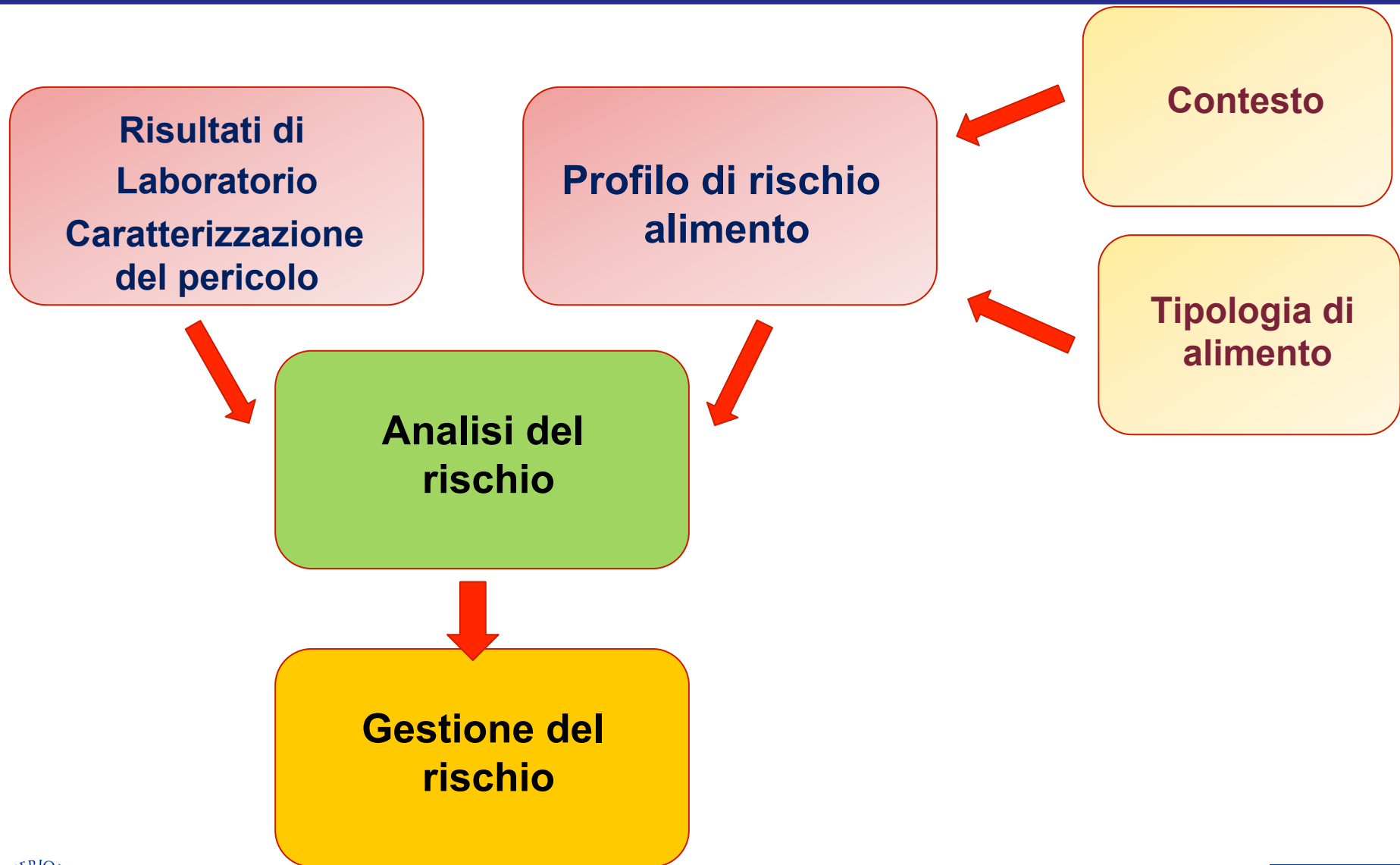
**Per l'applicazione dell'art. 14 del reg. 178/2002 agli
alimenti positivi per STEC**

In discussione alla

***Standing Committee on the Food Chain and Animal
Health (SCFCAH) Microbiological Criteria Working Group***



Linee guida VTEC



Riflessioni

- ✓ Il risultato di laboratorio “per se” non è un’analisi del rischio ma contribuisce a caratterizzare il “pericolo”
- ✓ Il risultato di laboratorio va considerato rispetto a:
 - ✓ Il tipo di alimento
 - ✓ Il contesto (*setting*) in cui questo si colloca: ulteriori processi, etichettatura, specifiche politiche di controllo o riduzione (vedi Reg. 178/2002)

Riflessioni

- L'analisi del rischio (almeno per le situazioni prevedibili) dovrebbe essere fatta quando si definisce un piano di controllo, non durante lo svolgimento del piano stesso
- Il processo di analisi dovrebbe coinvolgere i diversi soggetti coinvolti (tecnici e “*stakeholders*”)
- I “gestori” del rischio dovrebbero aver chiaro il tipo di risultato che può arrivare dal laboratorio (caratterizzazione del “pericolo”) e le relative misure da prendere