



Istituto Zooprofilattico Sperimentale
del Lazio e della Toscana *M. Aleandri*

7° Workshop dei laboratori del controllo ufficiale di OGM

11-12 Maggio 2015

Aula Zavagli

Istituto Zooprofilattico Sperimentale del Lazio e
della Toscana M. Aleandri

UGO
MARCHESI

Aggiornamento sull'applicazione del regolamento (UE) 619/2011



Centro di Riferenza Nazionale per la ricerca di OGM

Laboratorio Nazionale di Riferimento per gli alimenti e mangimi GM

Istituto Zooprofilattico Sperimentale delle Regioni Lazio e Toscana



CROGM

Reg. (UE) 619/2011

che fissa i metodi di campionamento ed analisi per i controlli ufficiali degli **alimenti per animali** riguardo alla presenza di materiale GM per il quale sia in corso una procedura di autorizzazione o la cui autorizzazione sia scaduta



Reg. (UE) 619/2011

Campo di applicazione

- ❑ materiale GM autorizzato in un paese terzo e per il quale è stata presentata nell'UE una domanda di autorizzazione e la cui procedura di autorizzazione sia durata più di 3 mesi, purché:
 - ✓ non sia stato classificato dall'EFSA come nocivo per la salute o per l'ambiente;
 - ✓ il metodo analitico quantitativo sia stato validato e pubblicato dall'EURL
 - ✓ sia disponibile il materiale di riferimento certificato
- ❑ materiale GM precedentemente autorizzato, la cui autorizzazione sia scaduta

Reg. (UE) 619/2011

- ❑ Procedura di campionamento (allegato I)
- ❑ LMRR (limite minimo di rendimento richiesto):
concentrazione minima di analita che può
essere rilevata e confermata in modo
riproducibile da un laboratorio ufficiale

⇒ **Fissato allo 0,1%**

Risultato $< 0,1\%$ ⇒ **campione conforme**

Risultato $\geq 0,1\%$ ⇒ **campione non conforme**

- ❑ Provvedimenti in caso di positività



Reg. (UE) 619/2011

Pending & expired



0,1%

Expired					
Name of the product	Unique identifier	Withdrawal decision	Date European Union Reference Laboratory method published	Location Certified Reference Material	Authorisation in a third country
Bt176 Maize Syngenta Crop Protection AG	SYN-EV176-9	2007/304/EC Official Journal L 117, p. 14 – 16 05/05/2007	17/07/2011	IRMM	Link
GA21 x MON 810 Maize Monsanto	MON-ØØØ21-9 x MON-ØØ81Ø-6	2007/308/EC Official Journal L 117, p. 25 - 26 05/05/2007	30/03/10 GA21, 14/03/06 MON 810	IRMM	Link
		2006-34	6/07/2007		

Reg. (UE) 619/2011

Incertezza di misura



Conforme

Non conforme

0,1%



Cosa è successo?

1° EPISODIO

- ⊙ campione di semi di cotone ad uso mangimistico prelevato (già nazionalizzato) dal Posto d'Ispezione Frontaliero di Ravenna in data 07/04/2014
- ⊙ Inviato all'IZSLER per competenza territoriale
- ⊙ Inoltrato al CROGM per approfondimenti analitici
- ⊙ Nel campione analizzato dal CROGM risulta presente cotone GM MON15985

State of the art of GMOs authorisation in the European Union: authorised events

Cotton 8 events



SITUAZIONE 2014

Transformation event	Authorised use		
	food	feed	other uses
MON1445	<ul style="list-style-type: none"> • produced from • additives produced from 	<ul style="list-style-type: none"> • produced from (feed materials and feed additives) 	
MON15985	<ul style="list-style-type: none"> • additives produced from 	<ul style="list-style-type: none"> • produced from (feed materials and feed additives) 	
MON15985 x MON1445	<ul style="list-style-type: none"> • additives produced from 	<ul style="list-style-type: none"> • produced from (feed materials and feed additives) 	
MON531	<ul style="list-style-type: none"> • produced from • additives produced from 	<ul style="list-style-type: none"> • produced from (feed materials and feed additives) 	
MON531 x MON1445	<ul style="list-style-type: none"> • additives produced from 	<ul style="list-style-type: none"> • produced from (feed materials and feed additives) 	
LL Cotton 25	<ul style="list-style-type: none"> • containing, consisting or produced from • additives produced from 	<ul style="list-style-type: none"> • containing, consisting or produced from (feed materials and feed additives) 	products containing or consisting of (except cultivation)



State of the art of GMOs authorisation in the European Union: authorised events

Cotton
8 events



Transformation event	Authorised use		
	food	feed	other uses
GHB614	containing, consisting or produced from	containing, consisting or produced from	products containing or consisting of (except cultivation)
281-24-236 x 3006-210-23	containing, consisting or produced from	containing, consisting or produced from	products containing or consisting of (except cultivation)



Reg. (UE) 619/2011

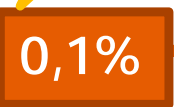
Pending GM COTTON EVENTS



SITUAZIONE 2014



0,1%



Transformation event	Authorised use		
	food	feed	other uses
MON15985	· containing, consisting or produced from	containing, consisting or produced from	products containing or consisting of (except cultivation)



EUROPEAN COMMISSION
JOINT RESEARCH CENTRE

Institute for Health and Consumer Protection
Molecular Biology and Genomics



**TECHNICAL GUIDANCE DOCUMENT FROM THE EUROPEAN UNION REFERENCE LABORATORY
FOR GENETICALLY MODIFIED FOOD AND FEED
ON THE IMPLEMENTATION OF COMMISSION REGULATION (EU) No 619/2011**

1. Background

The recently adopted Commission Regulation (EU) No 619/2011¹ lays down the methods for sampling and analysis for the official control of feed as regards to presence of genetically modified material for which an authorisation procedure is pending or the authorisation of which has expired (the so-called LLP, Low Level Presence Regulation). The requirements of this regulation are technically demanding because they set a non-compliance limit of 0.1% GMO (mass fraction).

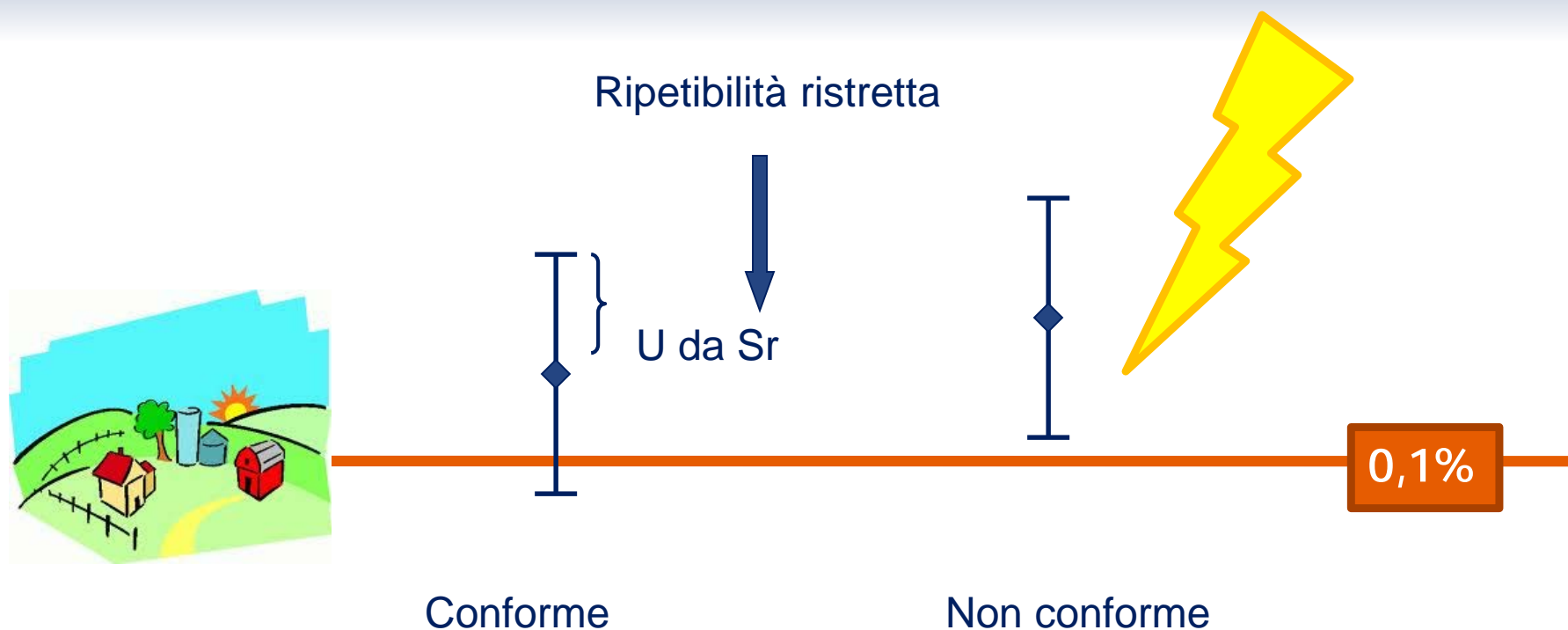
The European Union Reference Laboratory for Genetically Modified Food and Feed (EURL GMFF) plays a crucial role in the implementation of this regulation because only methods validated by the EURL that show a RSDr value of maximum 25% at the level of 0.1 % related to mass fraction of GM material can be used on GMOs falling under that regulation.

The aim of this document is to explain how this Regulation will affect the process of validation and how the laboratories need to operate under that Regulation.

This document may vary with time and therefore comments are welcome at:
enql-secretariat@jrc.ec.europa.eu

Reg. (UE) 619/2011

Incerteza di misura secondo linee guida EURL





Cosa è successo?

- ⊙ Nel 1° campione analizzato dal CROGM risulta presente cotone GM MON15985 in percentuale superiore allo 0,1%
- ⊙ Tra maggio e settembre 2014 il CROGM riceve diversi campioni di semi di cotone destinati all'alimentazione animale
- ⊙ In 6 di questi campioni risulta presente cotone GM MON15985 in percentuale superiore allo 0,1%

Cosa è successo?

Classification	Date of case	Country	Product Catego	Subject
border rejection	16/10/2014	Italy	feed materials	unauthorised genetically modified (MON 15985>LMRR) cotton seeds from Côte d'Ivoire
border rejection	23/07/2014	Italy	feed materials	unauthorised genetically modified (MON15985 and possibly MON831) cotton seeds from Côte d'Ivoire
border rejection	23/07/2014	Italy	feed materials	unauthorised genetically modified (MON15985 and possibly MON831) cotton seeds from Côte d'Ivoire
border rejection	23/07/2014	Italy	feed materials	unauthorised genetically modified (MON15985 and possibly MON531) cotton seeds from Côte d'Ivoire
information for attention	14/07/2014	Italy	feed materials	unauthorised genetically modified (MON15985 and possibly MON531) cotton seeds from Côte d'Ivoire
information for attention	14/07/2014	Italy	feed materials	unauthorised genetically modified (MON15985 and possibly MON531) cotton seeds from Côte d'Ivoire



Rapid Alert System for *Food and Feed*



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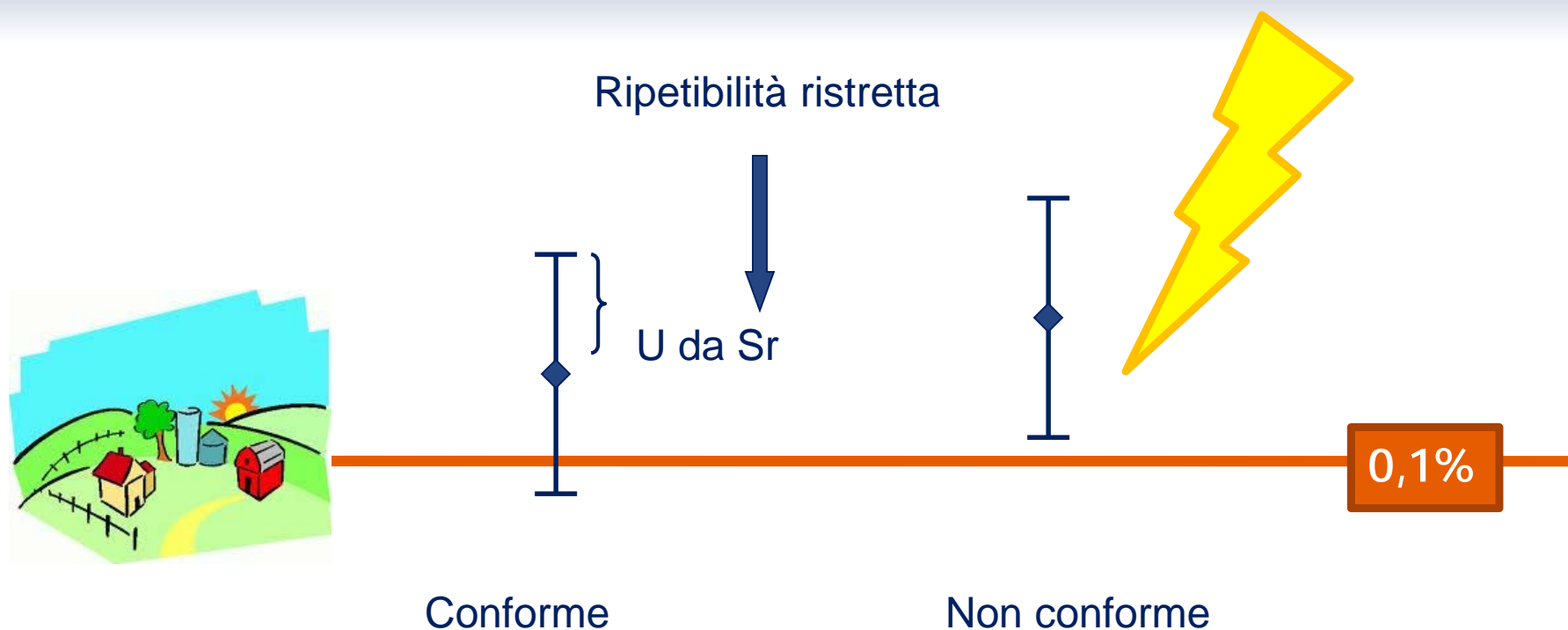
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Reg. (UE) 619/2011

Incertezza di misura secondo linee guida EURL



REGOLAMENTO (UE) N. 619/2011 DELLA COMMISSIONE

del 24 giugno 2011

che fissa i metodi di campionamento e di analisi per i controlli ufficiali degli alimenti per animali riguardo alla presenza di materiale geneticamente modificato per il quale sia in corso una procedura di autorizzazione o la cui autorizzazione sia scaduta

(Testo rilevante ai fini del SEE)

- (16) Ciascun laboratorio ufficiale deve definire l'incertezza di misurazione e confermarla nel modo descritto nel documento di orientamento sull'incertezza di misurazione destinato ai laboratori che provano OGM ⁽²⁾, redatto dal Centro Comune di Ricerca della Commissione (CCR).

⁽²⁾ http://www.irmm.jrc.be/html/reference_materials_catalogue/user_support/EUR22756EN.pdf



Reg. (UE) 619/2011

Incerteza di misura

JRC Scientific and Technical Reports



Guidance Document on Measurement Uncertainty for GMO Testing Laboratories

S. Trapman, M. Burns, H. Broll, R. Macarthur,
R. Wood, J. Zel





Reg. (UE) 619/2011

Incerteza di misura

JRC Scientific and Technical Reports

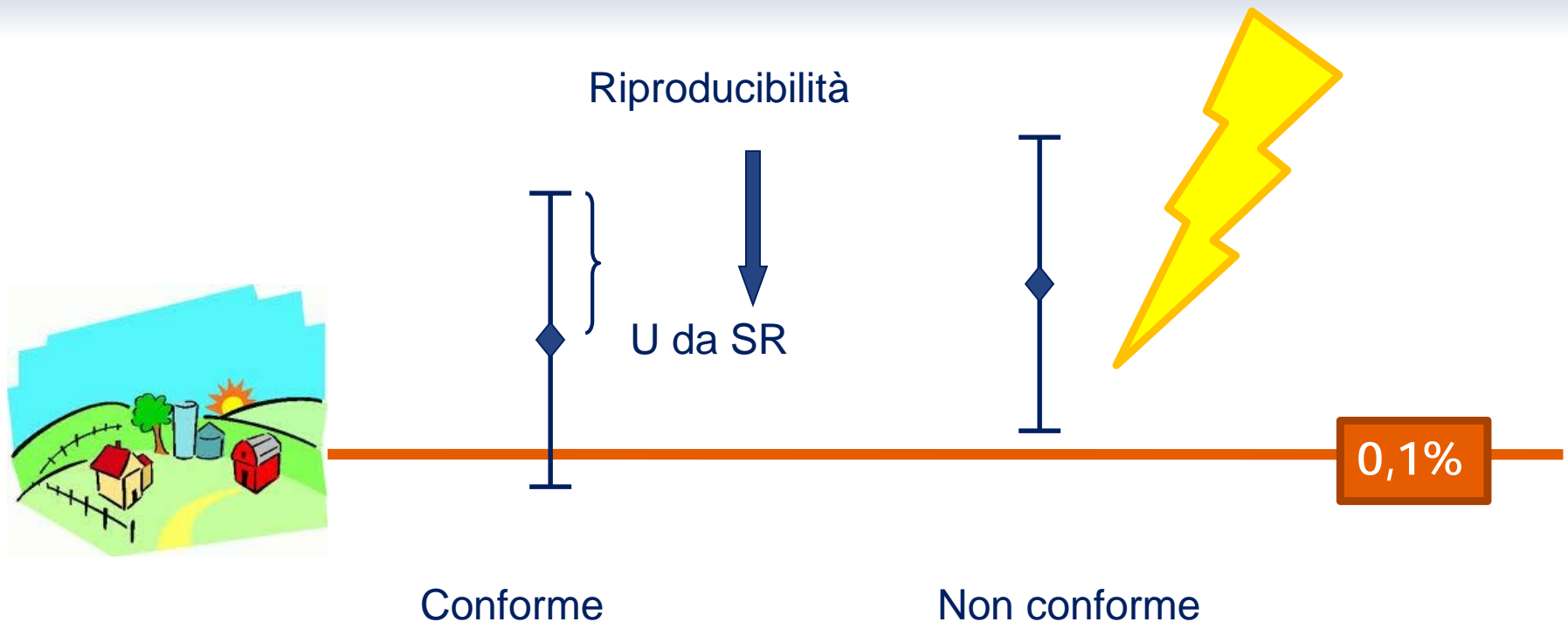
Guidance Document on Measurement Uncertainty for GMO Testing Laboratories

Pagina 12

In cases where no collaborative trial data are available, the MU can be estimated from analytical results measured within the laboratory concerned. Preference should, however, be given to data obtained through collaborative trials.

Reg. (UE) 619/2011

Incertezza di misura secondo linee guida IRMM



Guidance Document on Measurement Uncertainty for GMO Testing Laboratories

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0,2%

Conforme



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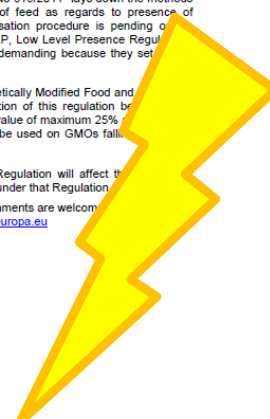
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engl-secretariat@irc.ec.europa.eu

0,2%

Non conforme

0,1%



Conclusioni

- ◎ Di fronte al dilemma su quale approccio adottare per la stima dell'incertezza di misura nel contesto del Reg. (UE) 619/2011, la Commissione Europea ha riconosciuto la validità di entrambi i sistemi
- ◎ A fronte tuttavia della coesistenza di due criteri entrambi validi la CE ha suggerito di preferire quello maggiormente favorevole all'importatore