

# Examples of enforcement of GM food and feed legislation in EU Member States: the Italian case

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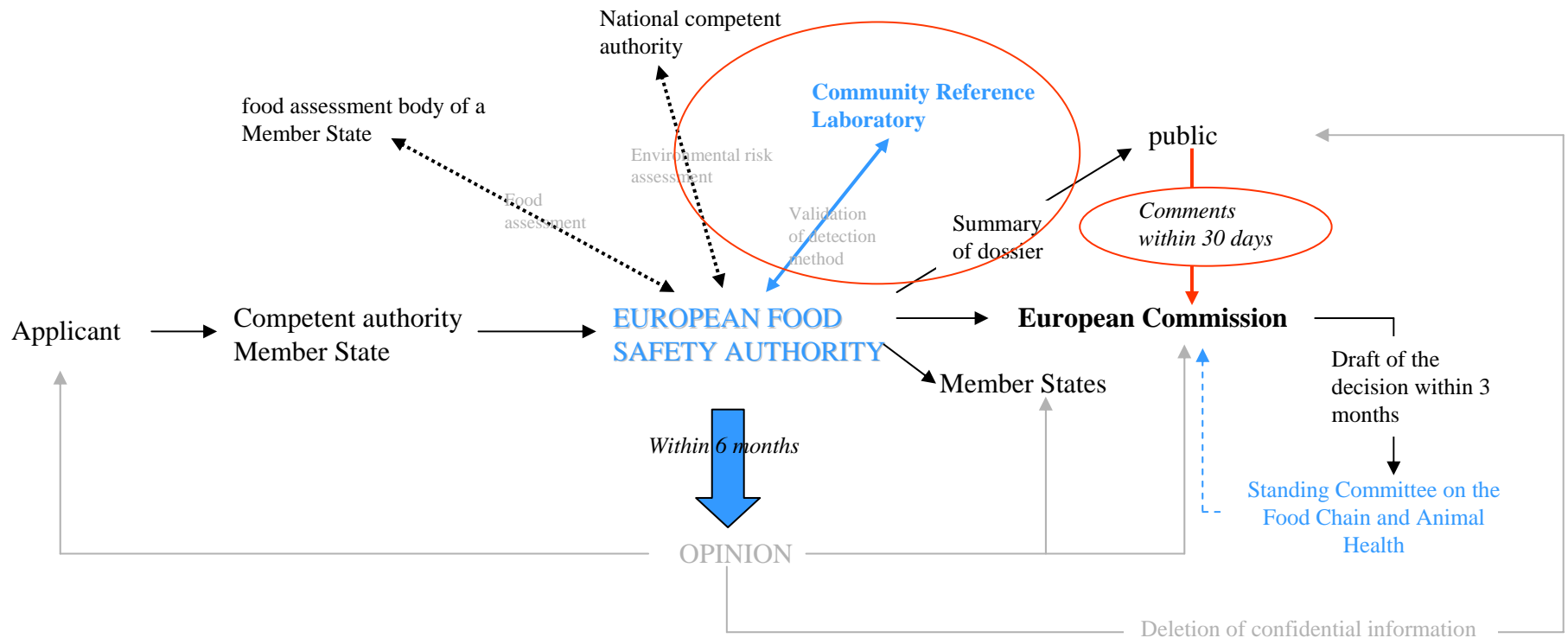


# Overview

- Legislative provisions
- Status of GM food and feed authorisation
- Official control of GM food and feed in Italy: planning and implementation
- The analytical control: achievements and challenges

# Reg. (EC) No 1829/2003

## Authorisation procedure





# Reg. (EC) No 1829/2003

## Labelling

- ☑ Specific labelling requirements when GM material  $> 0.9\%$  of the food/feed ingredient
- ☑ Labelling not compulsory when GM material  $< 0.9\%$ , provided that this presence is adventitious or technically unavoidable
  - ⇒ operators must be in a position to supply evidence to satisfy the competent authorities that they have taken appropriate steps to avoid the presence of such material

# Regulation (EC) No 1830/2003



## Traceability

### Information to be transmitted:

- ❑ products consisting of or containing *GMOs*:
  - that it contains or consists of *GMOs*
  - Unique identifier
- above the 0,9% threshold
- ❑ food and feed produced from *GMOs*:
  - an indication of each of the food ingredients which is produced from *GMOs*;
  - an indication of each of the feed materials or additives which is produced from *GMOs*;
  - in the case of products for which no list of ingredients exists, an indication that the product is produced from *GMOs*

# Regulation (EC) 834/2007

on organic production and labelling of organic products (repealing Regulation (EEC) 2092/91)

*published in the Official Journal L series 189,  
20/07/2007, p.1-23*

*in application since 1/1/2009*

- Prohibition of use of GMOs and products produced from or by GMOs
- 0.9%-tolerance threshold



# Status of authorisation of GM food and feed in EU: authorised events

Community Register of GM food and feed

[http://ec.europa.eu/food/  
dyna/gm\\_register/index\\_en.cfm](http://ec.europa.eu/food/dyna/gm_register/index_en.cfm)

# Status of authorisation of GM food and feed in EU: authorised events

Cotton

6 events



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

Updated  
24/04/2009



# Status of authorisation of GM food and feed in EU: authorised events

Maize  
12  
events



Transformation event	Authorised use		
	food	feed	other uses
Bt11	<ul style="list-style-type: none"> <li>containing, consisting or produced from</li> <li>additives produced from</li> </ul>	<ul style="list-style-type: none"> <li>containing, consisting or produced from (feed materials and feed additives)</li> </ul>	<ul style="list-style-type: none"> <li>products containing or consisting of (except cultivation)</li> </ul>
DAS1507	<ul style="list-style-type: none"> <li>containing, consisting or produced from</li> </ul>	<ul style="list-style-type: none"> <li>containing, consisting or produced from (feed materials and feed additives)</li> </ul>	<ul style="list-style-type: none"> <li>products containing or consisting of (except cultivation)</li> </ul>
GA21	<ul style="list-style-type: none"> <li>produced from</li> <li>additives produced from</li> </ul>	<ul style="list-style-type: none"> <li>produced from</li> </ul>	
MON810	<ul style="list-style-type: none"> <li>produced from</li> <li>additives produced from</li> </ul>	<ul style="list-style-type: none"> <li>containing, consisting or produced from (feed materials and feed additives)</li> </ul>	<ul style="list-style-type: none"> <li>cultivation</li> </ul>

Updated  
24/04/2009

# Status of authorisation of GM food and feed in EU: authorised events

Maize  
12  
events



Transformation event	Authorised use		
	food	feed	other uses
MON863	<ul style="list-style-type: none"> <li>containing, consisting or produced from</li> <li>additives produced from</li> </ul>	<ul style="list-style-type: none"> <li>containing, consisting or produced from (feed materials and feed additives)</li> </ul>	<ul style="list-style-type: none"> <li>products containing or consisting of (except cultivation)</li> </ul>
MON863 x NK603	<ul style="list-style-type: none"> <li>additives produced from</li> </ul>	<ul style="list-style-type: none"> <li>produced from (feed materials and feed additives)</li> </ul>	
MON863 x MON810		<ul style="list-style-type: none"> <li>produced from (feed materials)</li> </ul>	
NK603	<ul style="list-style-type: none"> <li>containing, consisting or produced from</li> <li>additives produced from</li> </ul>	<ul style="list-style-type: none"> <li>containing, consisting or produced from (feed materials and feed additives)</li> </ul>	<ul style="list-style-type: none"> <li>products containing or consisting of (except cultivation)</li> </ul>

Updated  
24/04/2009

# Status of authorisation of GM food and feed in EU: authorised events

## Maize 12 events



Transformation event	Authorised use		
	food	feed	other uses
NK603 x MON810	<ul style="list-style-type: none"> <li>containing, consisting or produced from</li> <li>additives produced from</li> </ul>	<ul style="list-style-type: none"> <li>containing, consisting or produced from (feed materials and feed additives)</li> </ul>	<ul style="list-style-type: none"> <li>products containing or consisting of (except cultivation)</li> </ul>
T25	<ul style="list-style-type: none"> <li>produced from</li> </ul>	<ul style="list-style-type: none"> <li>containing, consisting or produced from (feed materials and feed additives)</li> </ul>	<ul style="list-style-type: none"> <li>cultivation</li> </ul>
DAS1507 x NK603	<ul style="list-style-type: none"> <li>containing, consisting or produced from</li> </ul>	<ul style="list-style-type: none"> <li>containing, consisting or produced from</li> </ul>	<ul style="list-style-type: none"> <li>products containing or consisting of (except cultivation)</li> </ul>
DAS59122	<ul style="list-style-type: none"> <li>containing, consisting or produced from</li> </ul>	<ul style="list-style-type: none"> <li>containing, consisting or produced from</li> </ul>	<ul style="list-style-type: none"> <li>products containing or consisting of (except cultivation)</li> </ul>

Updated  
24/04/2009

# Status of authorisation of GM food and feed in EU: authorised events

Oilseed  
rape  
3  
events



Transformation event	Authorised use		
	food	feed	other uses
GT73	<ul style="list-style-type: none"> <li>• produced from</li> <li>• additives produced from</li> </ul>	<ul style="list-style-type: none"> <li>• containing, consisting or produced from (feed materials and feed additives)</li> </ul>	<ul style="list-style-type: none"> <li>• products containing or consisting of (except cultivation)</li> </ul>
MS8, RF3, MS8 x RF3	<ul style="list-style-type: none"> <li>• produced from</li> </ul>	<ul style="list-style-type: none"> <li>• containing, consisting or produced from (feed materials and feed additives)</li> </ul>	<ul style="list-style-type: none"> <li>• products containing or consisting of (except cultivation)</li> </ul>
T45	<ul style="list-style-type: none"> <li>• containing or produced from</li> </ul>	<ul style="list-style-type: none"> <li>• containing or produced from</li> </ul>	<ul style="list-style-type: none"> <li>• products containing (except cultivation)</li> </ul>

Updated  
24/04/2009

# Status of authorisation of GM food and feed in EU: authorised events

## Soya - 3 events



Transformation event	Authorised use		
	Food	feed	other uses
MON40-3-2	<ul style="list-style-type: none"> <li>containing, consisting or produced from</li> <li>additives containing, consisting or produced from</li> </ul>	<ul style="list-style-type: none"> <li>containing, consisting or produced from (feed materials and feed additives)</li> </ul>	<ul style="list-style-type: none"> <li>products containing or consisting of (except cultivation)</li> </ul>
A2704-12	<ul style="list-style-type: none"> <li>containing, consisting or produced from</li> <li>additives containing, consisting or produced from</li> </ul>	<ul style="list-style-type: none"> <li>containing, consisting or produced from (feed materials and feed additives)</li> </ul>	<ul style="list-style-type: none"> <li>products containing or consisting of (except cultivation)</li> </ul>
MON89788	<ul style="list-style-type: none"> <li>containing, consisting or produced from</li> <li>additives containing, consisting or produced from</li> </ul>	<ul style="list-style-type: none"> <li>containing, consisting or produced from (feed materials and feed additives)</li> </ul>	<ul style="list-style-type: none"> <li>products containing or consisting of (except cultivation)</li> </ul>

Updated  
24/04/2009

# Status of authorisation of GM food and feed in EU: authorised events



Sugar beet - 1 event

	Authorised use		
Transformation event	Food	feed	other uses
H7-1	• produced from	• produced from	

*Updated*  
24/04/2009

# Status of authorisation of GM food and feed in EU: authorised events

+ 2 GM microorganisms for feed uses

# Status of authorisation of GM food and feed in EU: authorised events

- 6 cotton events
- + 12 maize events
- + 3 oilseed rape events
- + 3 soya events
- + 1 sugar beet event
- + 2 GM microorganisms

27  
authorised  
events



# Status of authorisation of GM food and feed in EU

Events withdrawn from  
the market

# Status of authorisation of GM food and feed in EU: events withdrawn from the market

Products subject to Commission Decisions on withdrawal from the market:

- Bt176 maize
- GA21 x MON810 maize
- MS1, RF1, MS1xRF1 swede-rape
- MS1, RF2, MS1xRF2 swede-rape
- TOPAS19/2 swede rape

# Status of authorisation of GM food and feed in EU: events withdrawn from the market

Products subject to Commission Decisions on withdrawal from the market:

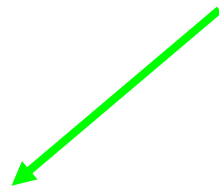
5 year-tolerance in food or feed products provided that the presence is:

- adventitious or technically unavoidable
- in a proportion no higher than 0,9 %

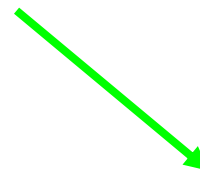
# Official control

Aim:

Verify the compliance to EU legislation on GM food and feed within the European market



Compliance to authorisation provisions



Compliance to labelling and traceability provisions

**Regulation (EC) n° 882/2004**  
on official controls performed to ensure the  
verification of compliance with feed  
and food law, animal health and animal welfare  
rules

in application since 1 January 2006

# Regulation (EC) n° 882/2004

## Official controls

### Purpose

- enforcing feed and food law, animal health and animal welfare rules and monitoring and verifying that the relevant requirements thereof are fulfilled by business operators at all stages of production, processing and distribution

### Method

- establishing at Community level a harmonised framework of general rules for the organisation, the implementation and the reporting of results of official controls

# Regulation (EC) n° 882/2004

Consideranda (15) e (16) ⇒ Title II, chapter II, art. 4, comma 3

- Competent authorities should ensure that where different control units are involved in carrying out official controls, appropriate coordination procedures are in place and effectively implemented
- Competent authorities should also ensure that, where the competence to carry out official controls has been delegated from the central level to a regional or local level, there is effective and efficient coordination between the central level and that regional or local level

# Regulation (EC) n° 882/2004

Title II, chapter III, art. 12, comma 1 e 2

□ Competent authority designate laboratories for the official control



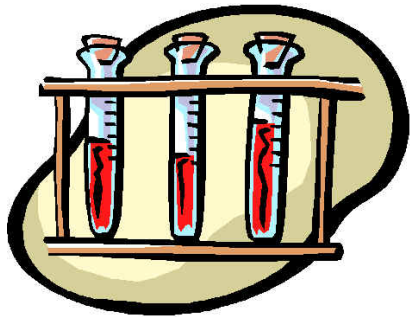
Operating, assessed and accredited in accordance with European standards:

- EN ISO/IEC 17025
- EN 45002
- EN 45003



# Regulation (EC) n° 882/2004

Title III, art. 32 e 33



Definition of duties and tasks and designation of Community Reference Laboratories and National Reference Laboratories

# Regulation (EC) n° 882/2004

Considerandum (34) ⇒ Title V, art. 41, 42 e 43

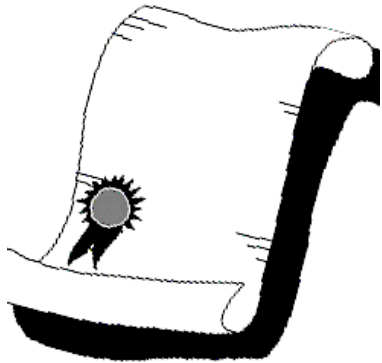
- each Member State shall prepare a single **integrated multi-annual national control plan**, in accordance with broad guidelines drawn up at Community level



**Definition of principles, requirements and priorities**

# Regulation (EC) n° 882/2004

## Title V, art. 44



- Every year, Member States shall submit to the Commission a **report** indicating relevant information



Any amendment to the plan, results of controls, type and number of cases of non-compliance identified, actions undertaken

# National control plans in Italy

National control plan of  
GM food 2009-2011



National control plan of GM  
feed 2009-2011

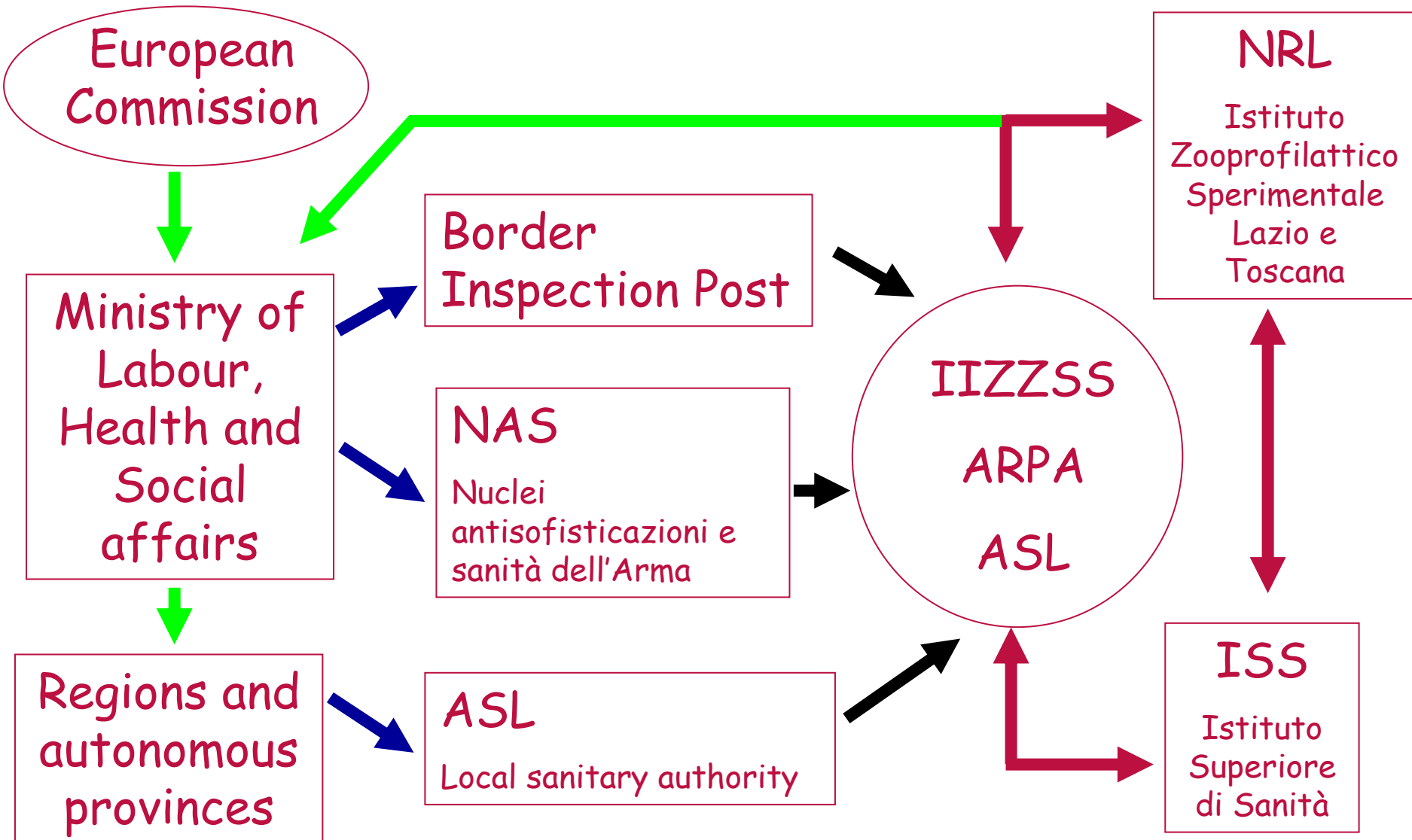


Regional plans

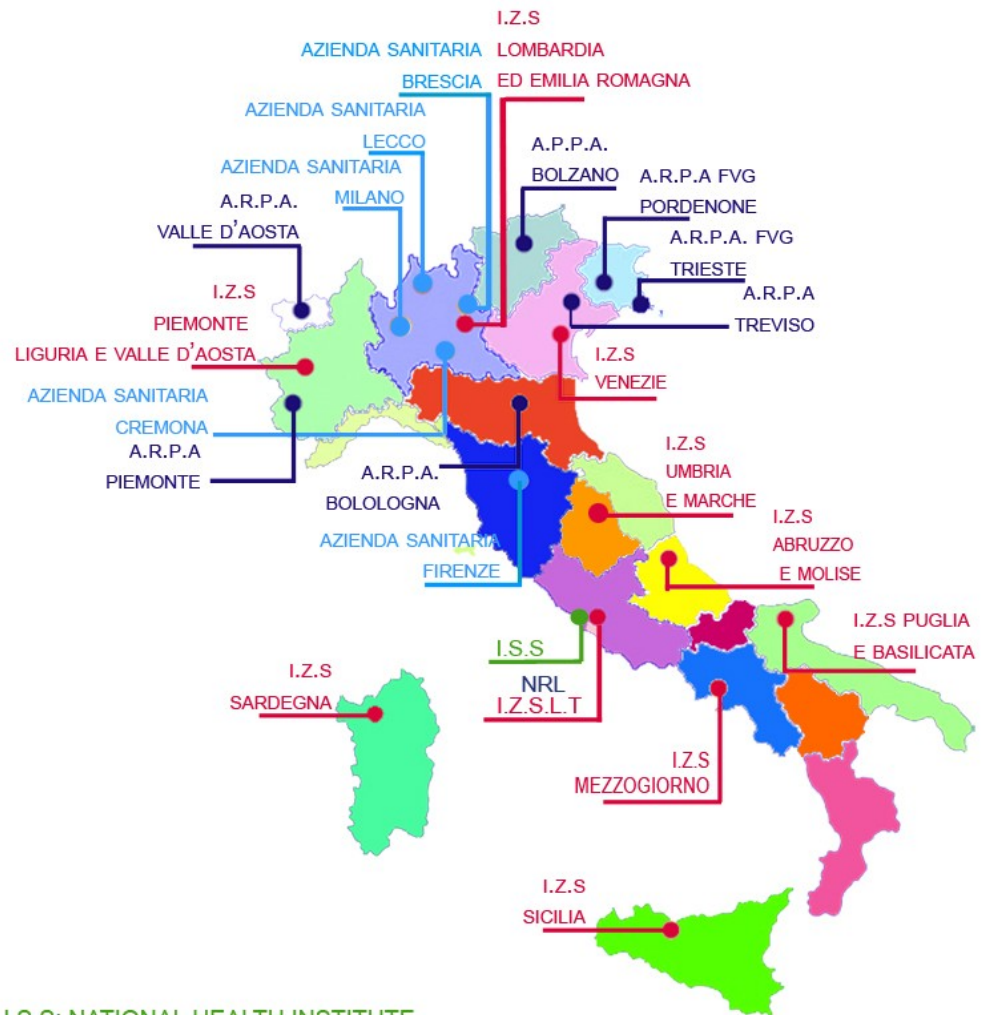
Plans for emergency cases:

- Maize Bt10 unauthorised from the USA
- Rice LL 601 unauthorised from the USA
- Rice Bt63 unauthorised from China

# Players of the official control



# The enforcement laboratories



I.S.S.: NATIONAL HEALTH INSTITUTE

NRL: NATIONAL REFERENCE LABORATORY

I.Z.S.: ISTITUTO ZOOPROFILATTICO SPERIMENTALE  
(VETERINARY PUBLIC HEALTH INSTITUTE)

A.P.P.A.: AGENZIA PROVINCIALE PER LA PROTEZIONE DELL'AMBIENTE  
(ENVIRONMENTAL PROTECTION AGENCY)

A.R.P.A.: AGENZIA REGIONALE DI PROTEZIONE AMBIENTALE  
(ENVIRONMENTAL PROTECTION AGENCY)



# The enforcement laboratories

## IIZZSS

- IZS Piemonte, Liguria e Valle d'Aosta
- IZS Lombardia ed Emilia Romagna
- IZS Venezia
- IZS Umbria e Marche
- IZS Lazio e Toscana
- IZS Abruzzo e Molise
- IZS Mezzogiorno
- IZS Puglia e Basilicata
- IZS Sardegna
- IZS Sicilia

## ARPA/APPA

- ARPA Piemonte
- ARPA Valle d'Aosta
- APPA Bolzano
- ARPA Friuli Venezia Giulia
- ARPA Veneto
- ARPA Liguria
- ARPA Emilia Romagna

## ASL

- ASL Brescia
- ASL Cremona
- ASL Milano
- ASL Lecco
- ASL Firenze

## ISS

# National Reference Laboratory art.33 Reg. (CE) 882/2004

Istituto Zooprofilattico Sperimentale  
delle Regioni Lazio e Toscana  
(Designated 14 November 2006)

Reference Centre for GMO analysis since 2002

CROGM





# Regulation (EC) 882/2004

## TITLE III REFERENCE LABORATORIES

### Article 33

#### National reference laboratories

- 2. These national reference laboratories shall:
  - a) collaborate with the Community reference laboratory in their area of competence;
  - b) coordinate, for their area of competence, the activities of official laboratories responsible for the analysis of samples in accordance with Article 11;
  - c) where appropriate, organise comparative tests between the official national laboratories and ensure an appropriate follow-up of such comparative testing;
  - d) ensure the dissemination to the competent authority and official national laboratories of information that the Community reference laboratory supplies;
  - e) provide scientific and technical assistance to the competent authority for the implementation of coordinated control plans adopted in accordance with Article 53;
  - (f) be responsible for carrying out other specific duties provided for in accordance with the procedure referred to in Article 62(3), without prejudice to existing additional national duties.

# Objectives and challenges of a National Reference Laboratory

- Coordination of the official control
- Harmonising procedures
- Support competent authorities
- Definition of plans and working programmes
- Collect interesting routine samples
- Training courses for operators
- Controlled circulation of confidential documents
- Link the national level to the european level

# Work in progress of the Italian NRL and network of labs

## Done

- ✓ Web based data collection system
- ✓ Proficiency test RRS
- ✓ National control plans
- ✓ Emergency plans (LL601, BT63)
- ✓ Harmonisation of endogenous reference gene method in real time PCR for maize events
- ✓ Collaborative study MON810

# Work in progress of the Italian NRL and network of labs

To be done in 2009:

- Website
- Collaborative studies MON863 and NK603
- Formalise the network

# Work of the Italian NRL and network of labs in the pipeline

Submission of a national research project to the Ministry of Health

## Main Objective:

- improving the national implementation of EU legislation on GM food and feed with respect to traceability and labelling requirements

# Work of the Italian NRL and network of labs in the pipeline

## Main secondary objectives:

- 1) developing guidelines for own-checking procedures and official control aimed at the verification of compliance to traceability and labelling requirements
- 2) improving (also in terms of practicability) and harmonising the implementation of sampling procedures
- 3) improving the efficiency and efficacy of the analytical control of GM food and feed
- 4) developing statistical models to be used for the definition and the implementation of surveillance and control plans of GM food and feed
- 5) improving communication, information and sharing of knowledge on issues related to traceability, own-check systems and official control of GM food and feed among official control authorities and stakeholders (business operators, consumers, etc.)

# National networks of enforcement laboratories: the power...

National networks of enforcement laboratories can provide:

- ☑ the necessary analytical capability and expertise for the implementation of the official control within the framework of food and feed legislation
- ☑ a valid support to the activity of the CRL, in particular with the aim of gaining in practicability and harmonization of analytical methods and GM food and feed control (implementation of Reg. 882/2004)

Reference systems

Screening methods

Sample collection

Training



## ... and the limits

National networks of enforcement laboratories require:

- ☑ a **harmonized** and **coordinated** system with respect to analytical procedures for the official control





Achievements and challenges of  
the official analytical control

# Evolution of the legal framework

Reg. 258/1997

Dir. 2001/18

Reg. 1829/2003

Reg. 1830/2003

Reg. 641/2004

Reg. 882/2004

No analytical tools

Provide very specific  
analytical tools

Focus on single event

Holistic approach to the  
official control

Focus on the whole system

Practicable and cost-effective

# Achievements and challenges of the official analytical control

## Achievements

- European Network of *GMO* laboratories
- CRL validations
- Development of CRMs
- Accreditation
- Measurement uncertainty
- ...

## Challenges

- Increasing n° species
- Increasing n° events
- Type of matrices
- Need to improve practicability
  - Reference gene methods
  - Screening methods
- Detection of unauthorised *GMOs*
- Accreditation system
- Harmonisation
- ...

# Type of matrices: raw material, ingredients, final products



# Achievements and challenges of the official analytical control

## Achievements

- European Network of *GMO* laboratories
- CRL validations
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- ...

## Challenges

- Increasing n° species
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- Harmonisation
- ...

# The GMO galaxy

