

# Breve storia della valutazione del rischio OGM a livello internazionale

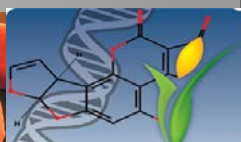
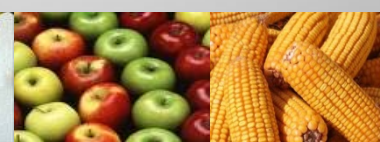
Roberta Onori

Dipartimento di Sanità Pubblica Veterinaria e Sicurezza Alimentare

Reparto OGM e xenobiotici di origine fungina

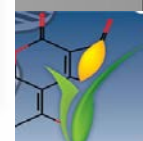
Email: [roberta.onori@iss.it](mailto:roberta.onori@iss.it)

**Analisi del rischio di alimenti e mangimi geneticamente modificati**



# Contenuto della presentazione

- **Breve panoramica delle linee guida elaborate dalle principali agenzie internazionali**
- **Principi generali sulla valutazione del rischio OGM**
- **Contesto normativo e autorità coinvolte**



# Obiettivi e principi della valutazione del rischio OGM

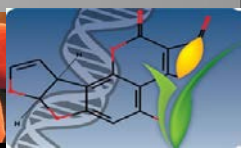
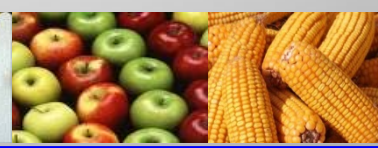
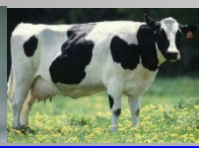
## Obiettivi

- Identificare e valutare i potenziali effetti avversi: diretti, indiretti, immediati e a lungo termine
- Individuare le necessità e le priorità dei gestori del rischio

## Principi generali

- Valutazione comparativa che utilizza appropriati comparatori per la definizione dei dati di riferimento
- Approccio caso-per-caso e progressivo step by step
- Approccio scientifico in grado di garantire la trasparenza delle conclusioni e cercando di valutare ogni possibile incertezza
- Aggiornamento delle conclusioni ogni 10 anni (rinnovo autorizzazione) o in base a nuove evidenze

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In 1990, the International Food Biotechnology Council (IFBC), a multidisciplinary team of scientists from academia and from industry, met and composed a draft titled "Biotechnologies and Food: Assuring the Safety of Foods Produced by Genetic Modification" (*Regulatory Toxicology and Pharmacology* 1990;12(3)).



## International Guidelines


➤ OECD Group of National Experts on Safety in Biotechnology, 1993, 1994, 1996

➤ OECD Task Force on the Safety of Novel Foods and Feed, 1998-present


➤ FAO/WHO Expert Consultations, 1991, 1996, 2000, 2001, 2003

➤ CODEX Task Force on Foods Derived from Biotechnology, 1999-2004

**CODEX ALIMENTARIUS COMMISSION**






Foods Derived from Biotechnology, 2009.




Foods Derived from Biotechnology, 2004. Incorporating:

- Principles for the Risk Analysis of Foods Derived from Modern Biotechnology, 2003;
- Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants, 2003;
- Guidelines for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms, 2003.


**JOINT FAO/WHO EXPERT CONSULTATIONS**




Safety Assessment of Foods Derived from Recombinant-DNA Animals, Feb-Mar 2007





Safety Assessment of Foods Derived from Genetically Modified Animals, including Fish, November 2003




Safety Assessment of Foods Derived from Genetically Modified Microorganisms, September 2001




Evaluation of Allergenicity of Genetically Modified Foods, January 2001


**ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT**




Considerations for the Safety Assessment of Animal Feedstuffs derived from Genetically Modified Plants (2003)



Report of the Task Force for the Safety of Novel Food and Feeds (2000)






Safety Considerations for Biotechnology Scale-up of Crop Plants (1993)



Recombinant DNA Safety Considerations (1986)

OECD "Blue Book"

**UN ENVIRONMENT PROGRAMME**



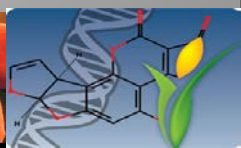
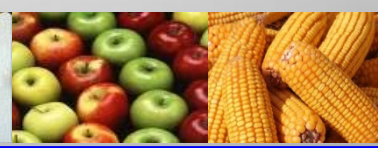
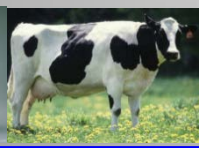
UNEP International Technical Guidelines for Safety in Biotechnology (1995)

**Analisi del rischio di alimenti e mangimi geneticamente modificati**  
Linee guida internazionali per la valutazione del rischio OGM

I concetti di ***familiarità e di equivalenza sostanziale*** sanciti nel 1993 *dall' OECD* e successivamente sviluppati da WHO/FAO nel 2000 sono alla base della metodologia per la valutazione della sicurezza d'uso per l'ambiente e per l'impiego alimentare degli OGM.

Il concetto di equivalenza sostanziale si basa sul presupposto che un organismo caratterizzato da **tradizione di sicurezza alimentare**, può essere utilizzato come elemento di paragone per la valutazione della sicurezza d'uso di alimenti e mangimi OGM.

Analisi del rischio di alimenti e mangimi geneticamente modificati



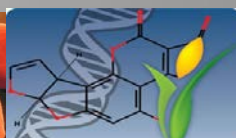
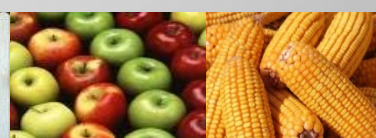


# Storia consolidata di sicurezza d'uso

“A substance may be considered to have a history of safe use as a food if it has been an ongoing part of the diet for a number of generations in a large, genetically diverse human population where it has been used in ways and at levels that are similar to those expected or intended in Canada”

Food Directorate, Health Products and Food Branch, Health Canada,  
June, 2006

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# *Equivalenza sostanziale - valutazione comparativa della sicurezza d'uso*

Il primo step di questo approccio è l'analisi delle caratteristiche molecolari, agronomiche morfologiche e relative alla composizione chimica dell'OGM basata sul confronto tra OGM e la sua controparte tradizionale coltivata nelle stesse condizioni agronomiche ed ambientali.

L'analisi comparativa permette di identificare le eventuali differenze tra la pianta OGM e non OGM, differenze su cui si basa la successiva valutazione.

La valutazione può prevedere successive analisi nutrizionali e tossicologiche specifiche al fine di dimostrare che la pianta GM ed i suoi prodotti derivati sono sicuri come la controparte tradizionale.

Analisi dei rischi di alimenti e mangimi geneticamente modificati



# Equivalenza sostanziale

L'equivalenza sostanziale non rappresenta di per se una valutazione della sicurezza d'uso ma è uno strumento utilizzato nella valutazione del rischio OGM

## Test di Differenza e di Equivalenza

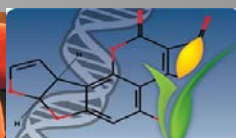
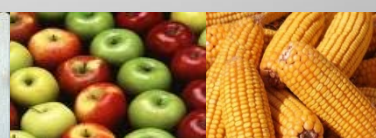
Per valutare se OGM è  
differente dal suo comparatore  
(identificazione del possibile  
pericolo)

Per verificare se OGM è  
equivalente alla specie di  
riferimento considerando le sue  
variazioni naturali

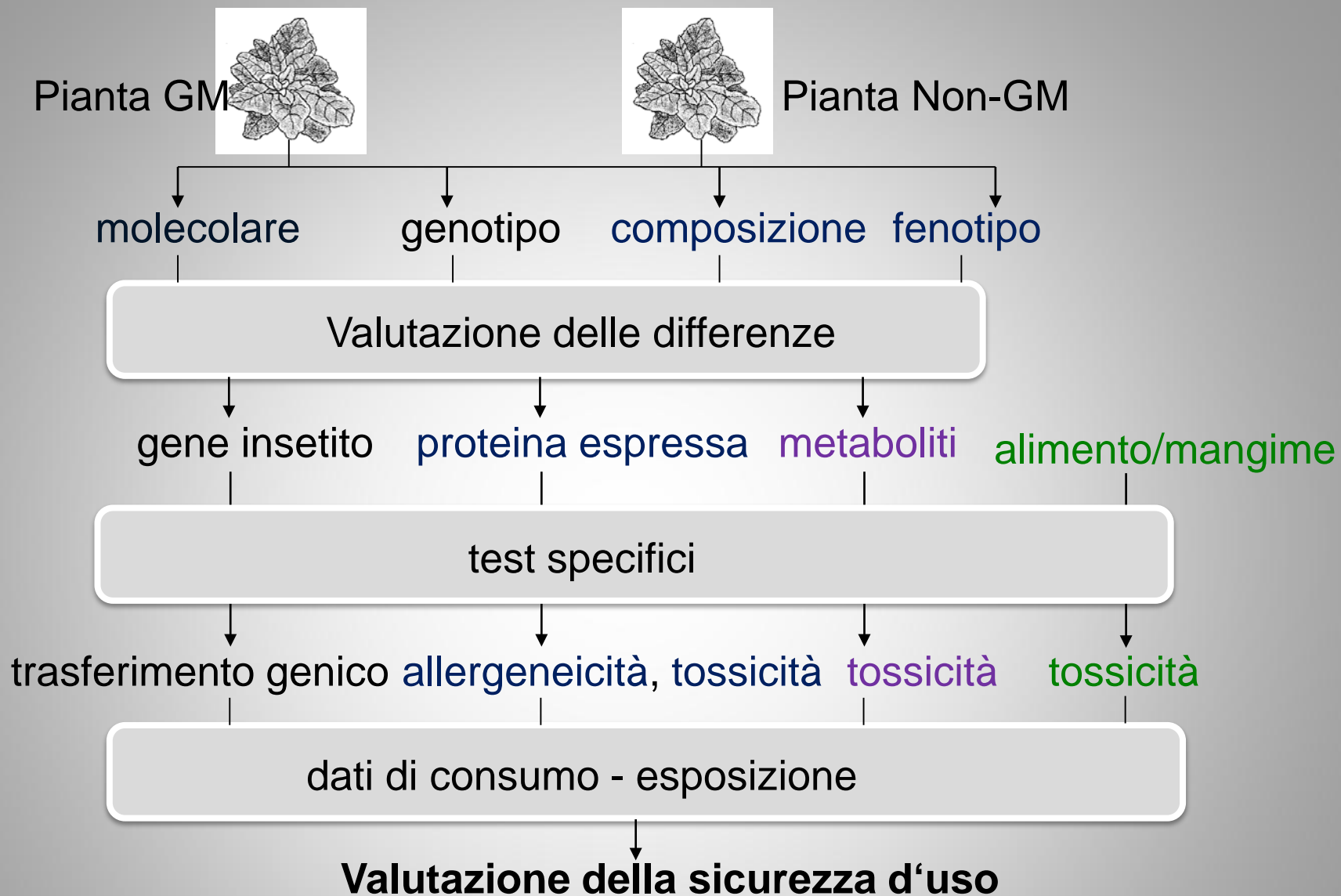
Se si riscontra differenza o assenza di equivalenza deve essere ulteriormente valutata la rilevanza biologica dei risultati ottenuti.

EFSA FF GD (2011) + EFSA Statistics Opinion (2010)

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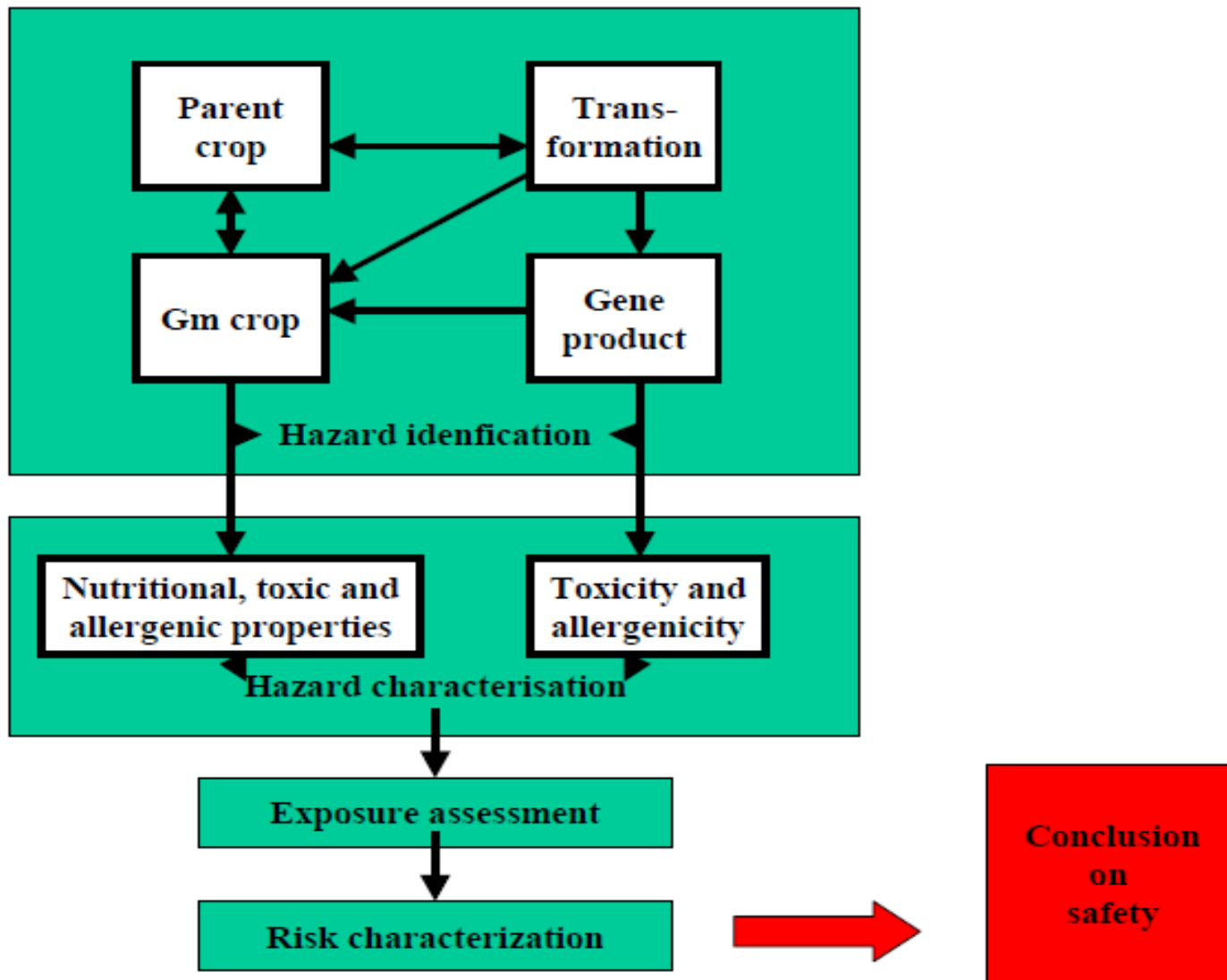






**Analisi del rischio di alimenti e mangimi geneticamente modificati**

# Risk Assessment Process for GM Crops



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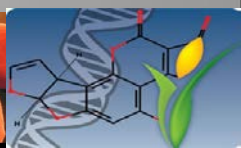
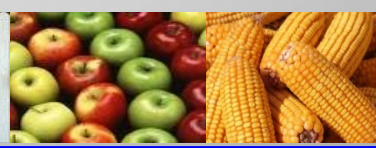
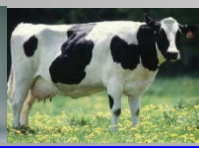


# OECD and Risk/Safety Assessment in Modern Biotechnology Food, Feed and Environmental Safety

**OECD's Biosafety Team**

**<http://www.oecd.org/biotrack/>**

**Analisi del rischio di alimenti e mangimi geneticamente modificati**

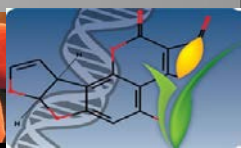
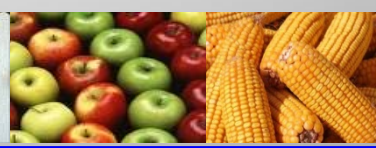


*organised in two programmes:*

- 1) OECD's Working Group for the Harmonisation of Regulatory Oversight in Biotechnology  
*(Environmental safety of transgenic organisms)*
- 2) OECD's Task Force for the Safety of Novel Foods and Feeds  
*(foods/feeds derived from transgenic organisms)*

ISS National Delegate

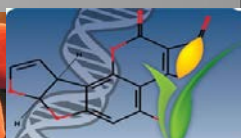
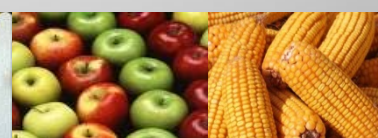
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# Who participates?

- **Working Group:** delegates from ministries/ agencies responsible for environmental risk assessment of transgenic organisms (competent authorities);
  - Observers and invited experts: UNEP, CBD Secretariat, UNIDO, other stakeholders.
- **Task Force:** delegates from ministries/ agencies responsible for risk assessment of novel foods and feeds (competent authorities);
  - Observers and invited experts: FAO, WHO, Codex secretariat, other stakeholders.

Analisi del rischio di alimenti e mangimi geneticamente modificati

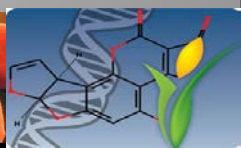
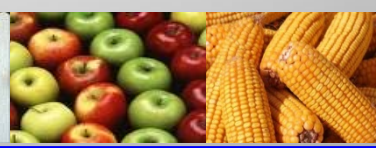
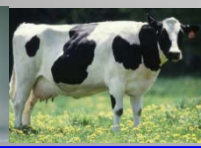




# The purpose of these programmes is threefold:

- To assist OECD countries evaluate the potential risks of transgenic products to ensure high standards of safety;
- To foster communication and mutual understanding of the regulatory processes in different countries; and
- To reduce the potential for non-tariff barriers to trade.

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# Task Force for the Safety of Novel Foods and Feeds

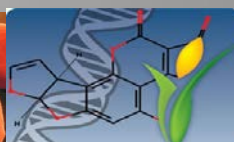
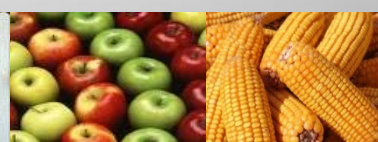
Since 1999, the Task Force addresses aspects of the safety assessment of foods and feeds derived from genetically engineered crops.

It develops **consensus documents** on food and feed compositional considerations. They compile information on the major components of specific crop plants, such as **key nutrients, toxicants, anti-nutrients and allergens** at the time of harvest (fresh) as well as once processed for food and feed uses.

This information is of value in the safety assessment of new (genetically engineered) varieties **for comparing their components with those of existing traditional varieties.**

**All consensus documents are electronically available on the OECD website at no charge**

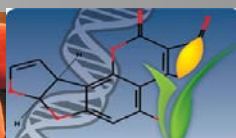
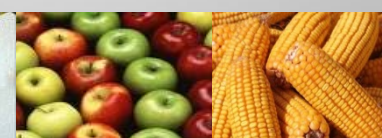
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# Food/ Feed Safety Consensus Documents

- Food/ feed risk/ safety assessment of transgenic varieties follows a comparative approach;
- In other words, is a new food as safe as a traditional counterpart?
- Include information (for use in food/ feed safety risk assessment of new varieties) on key:
  - Nutrients
  - Anti-Nutrients
  - Toxicants
  - Allergens
  - Secondary metabolites

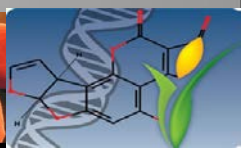
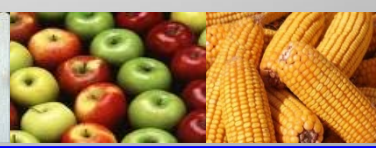
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# Some Published Food/ Feed Safety Consensus Documents

- Soybean (*under review*)
- Canola/ Oilseed Rape (*under review*)
- Potato
- Sugar Beet
- Maize
- Sunflower
- Alfalfa and Other Temperate Forage Legumes
- Bread Wheat
- Considerations for safety of animal feeds
- Rice
- Cotton
- Barley
- Cultivated mushroom *Agaricus bisporus*
- Tomato

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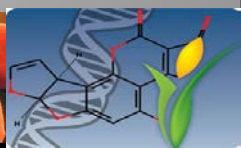
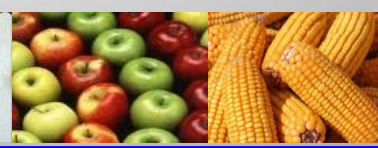
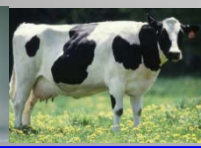




# Food/ Feed Safety Consensus Documents in preparation

- Cassava
- Sweet Potato
- Papaya
- Sugarcane
- Sorghum

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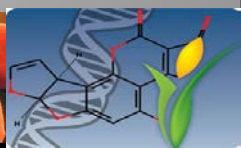
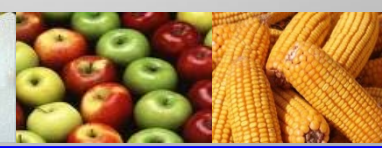
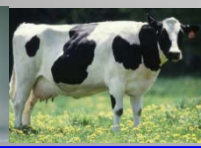


# Working Group

## Biosafety Consensus Documents

- Include a wealth of information (for use in risk assessment) on the **biology** of crops and traits:
  - The use of the crop/ trait in agriculture practice
  - Taxonomy
  - Reproduction
  - Wild relatives – hybridisation
  - Centre of origin and diversity
  - Weediness

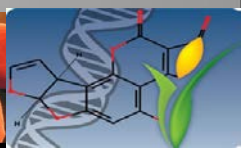
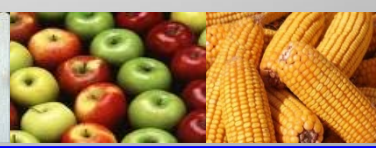
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# Some Published Biosafety Consensus Documents

- **Crops:** maize, oilseed rape, potato, bread wheat, rice, soybean, sugar beet, cotton, sunflower, peppers, papaya, etc.
- **Traits:** tolerance to glyphosate herbicide, tolerance to phosphinothricin herbicides, virus resistant through coat protein gene-mediated protection, Bt resistance, etc.
- **Trees:** Norway spruce, white spruce, poplars, Douglas fir, Sitka spruce, lodgepole pine, Eastern white pine, European white birch, larches, etc.
- **Micro-organisms:** *Acinobacter*, *Pseudomonas*, baculoviruses, Taxonomy in Risk Assessment, Detection methods, etc.
- **Unique identifier for transgenic plants:** Guidance used by many organisations and databases (OECD, CBD, industry...)

Analisi del rischio di alimenti e mangimi geneticamente modificati



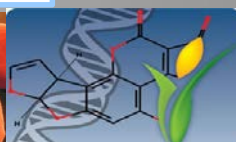
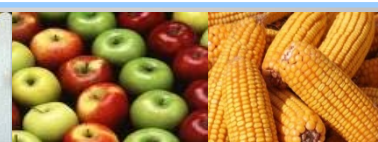
# Unique Identification System

An important achievement has been the development of a unique identification system for each transformation event of genetically engineered plants developed for commercial release and use. The unique identification provides an harmonised and practical “key” to access information in the OECD’s Database of products of modern biotechnology which have been approved for commercial application, as well as interoperable system (such as the CBD Biosafety Clearing House) and other databases.

The unique identifier is composed of three elements that must be separated by dashes (-). The total length is 9 digits, the last of which is a verification digit. The transformation event and the applicant designation should total 8 alphanumeric digits.

- 2 or 3 alphanumerical digits to designate the applicant;
- 5 or 6 alphanumerical digits to designate the “transformation event”;
- One numerical digit as a verification,

MON-04032-6 Roundup Ready™ soybean GTS 40-3-2 (40-3-2)



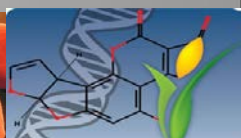
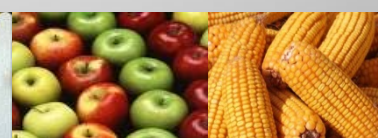
## Proposal for new consensus document

- Common Bean (*Phaseolus vulgaris*)
- Apple (*Malus domestica*) IT
- Call for animal composition data IT

## Proposal on Innovative novel feed ingredients

- *Algae*
- *Crop by-products obtained from processing of these crops for biofuel production* IT
- *Invertebrates*

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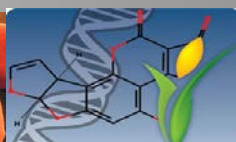
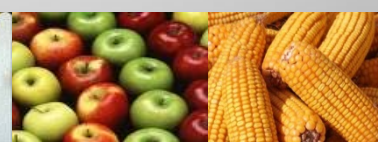


# Linee guida internazionali per la valutazione del rischio OGM

- Regolamenti e direttive Europee 1996-present
- ENTRANSFOOD, the EU Thematic Network on the Safety Assessment of Genetically Modified Food Crops, 2000-2003

**European Food Safety Authority, Guidance Documents GMO Panel**

**Analisi del rischio di alimenti e mangimi geneticamente modificati**





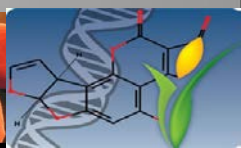
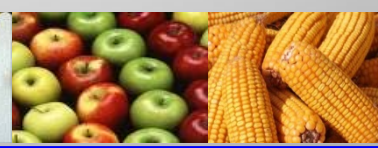
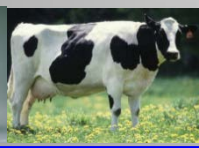
# Contesto normativo

- EU-Biosafety framework
  - Dir. 2001/18/EC, Reg. (EC) No. 1829/2003
- Normative nazionali
- Agreements Internazionali – Protocollo di Cartagena

## Autorità ed istituzioni coinvolte

- A livello europeo: EFSA (GMO Unit, Scientific Panel on GMOs)
- A livello nazionale : le autorità competenti per la valutazione del rischio

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# LEGAL FRAMEWORK FOR GMO RISK ASSESSMENT

EFSA's role is to carry out scientific Risk Assessment on GMOs under two regulatory frameworks:

17.4.2001 EN L 106/1

# 1

**DIRECTIVE 2001/18/EC** THE COUNCIL

**on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/269/EEC**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, affecting other Member States. The effects of such releases on the environment may be irreversible.

Having regard to the Treaty establishing the European Union, (5) The protection of human health and the environment

## Directive 2001/18/EC

### On the deliberate release into the environment of GMOs

(1) This Directive is a measure for the implementation of the scope of Directive 90/269/EEC and of the definitions therein.

(2) Directive 90/269/EEC has been amended. Now that new amendments are being made to the Directive, it is desirable, for reasons of clarity and rationalisation, that the provisions in question should be recast.

(3) Living organisms, whether released into the environment in large or small amounts for experimental purposes or as commercial products, may reproduce in the environment and cross national frontiers thereby affecting other Member States. The effects of such releases on the environment may be irreversible.

(4) The protection of human health and the environment

(5) The protection of human health and the environment

(6) For a comprehensive and transparent legislative framework, it is necessary to ensure that the public is consulted by either the Commission or the Member States during the preparation of measures and that they are informed of the measures taken during the implementation of this Directive.

(7) Placing on the market also covers import. Products containing and/or consisting of GMOs covered by this Directive cannot be imported into the Community if they do not comply with its provisions.

(8) Making GMOs available to be imported or handled in bulk quantities, such as agricultural commodities, should be regarded as placing on the market for the purpose of this Directive.

(9) The content of this Directive duly takes into account international experience in this field and international

18.10.2003 EN L 268/1

# 2

**REGULATION (EC) No 1829/2003** AND OF THE COUNCIL

**on genetically modified food and feed** (Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, (4) Differences between national laws, regulations and administrative provisions concerning the assessment and authorisation of genetically modified food and feed may hinder their free movement, creating conditions of unequal and unfair competition.

Having regard to the Treaty establishing the European Community,

## Regulation (EC) No 1829/2003

### On GM food and feed including derived products

feed is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.

(2) A high level of protection of human life and health should be ensured in the pursuit of Community policies.

(3) In order to protect human and animal health, food and feed consisting of, containing or produced from genetically modified organisms (hereinafter referred to as genetically modified food and feed) should undergo a safety assessment through a Community procedure before being placed on the market within the Community.

(4) The provisions of this Regulation should also apply to feed intended for animals which are not destined for food production.

(5) Feed consisting of or containing genetically modified organisms (GMOs) has so far been authorised, subject to the authorisation procedure provided by Council Directive 90/269/EEC of 23 April 1990<sup>(1)</sup> and Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms<sup>(2)</sup>; no authorisation procedure exists for feed produced from GMOs: a single, efficient and transparent Community authorisation procedure for feed consisting of, containing or produced from GMOs should be established.

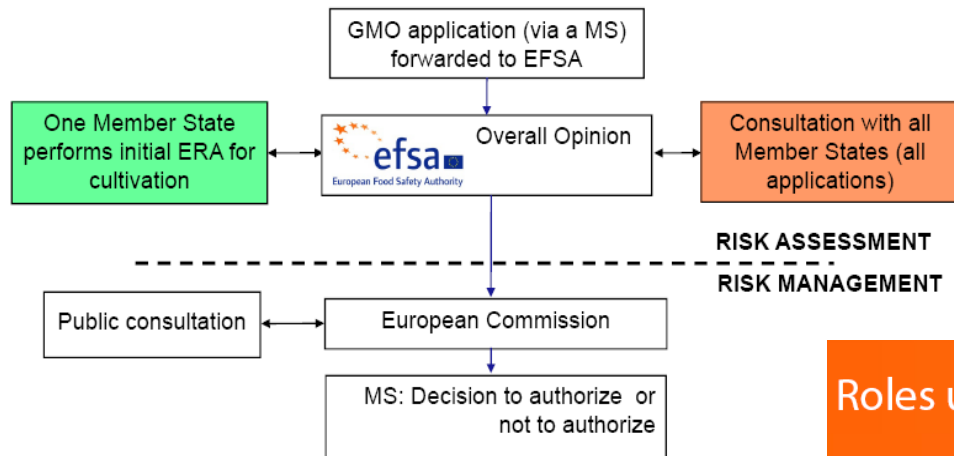
(6) The provisions of this Regulation should also apply to feed intended for animals which are not destined for food production.

(7) Feed consisting of or containing genetically modified organisms (GMOs) has so far been authorised, subject to the authorisation procedure provided by Council Directive 90/269/EEC of 23 April 1990<sup>(1)</sup> and Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms<sup>(2)</sup>; no authorisation procedure exists for feed produced from GMOs: a single, efficient and transparent Community authorisation procedure for feed consisting of, containing or produced from GMOs should be established.

(8) The provisions of this Regulation should also apply to feed intended for animals which are not destined for food production.

## Roles under Regulation (EC) No 1829/2003

Member States have access to all GMO applications and provide input through “EFSAnet”. One member State performs the environmental risk assessment



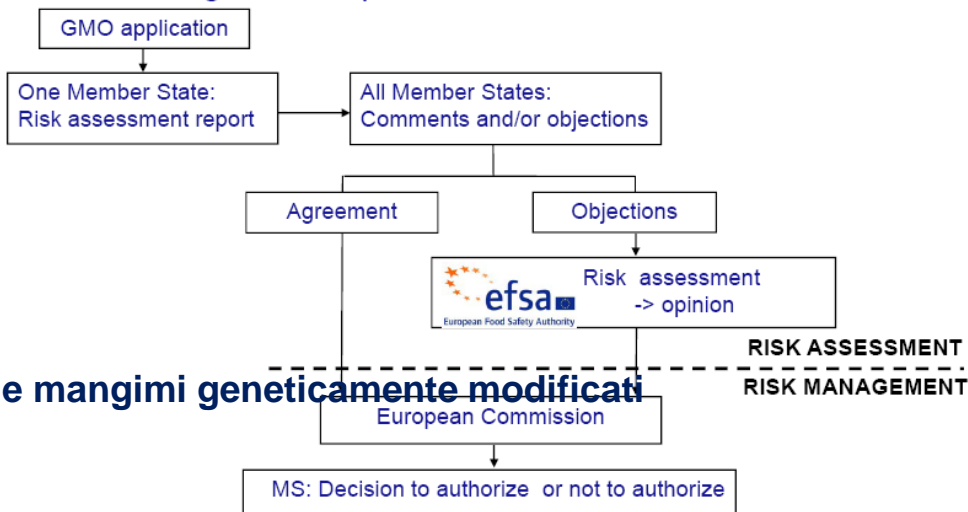
Il ruolo dell'EFSA è quello di effettuare una **valutazione scientifica del rischio** associato agli OGM nell'ambito:  
**Direttiva 2001/18**  
**Regolamento 1829/2003**

**Fornire pareri scientifici indipendenti alle Autorità responsabili della gestione del rischio**

**Analisi del rischio di alimenti e mangimi geneticamente modificati**

## Roles under Directive 2001/18/EC

Member States perform risk assessment. EFSA is consulted in case of divergence of opinion



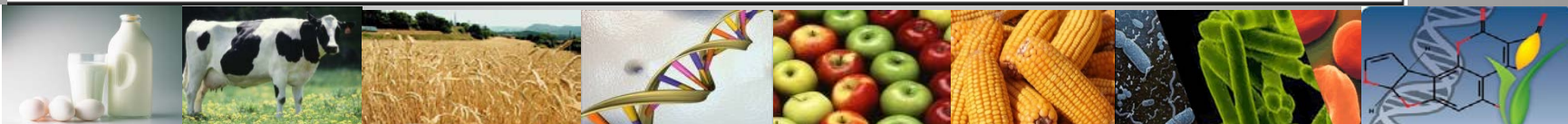
# Member State input

Consultation with all  
Member States (all  
applications)

Application EFSA-GMO-CZ-2006-33 (Maize MON 88017 x MON 810) Comments and opinions submitted by Member States during the three-month consultation period			ANNEX G		
Country	Organisation	Application EFSA-GMO-CZ-2006-33 (Maize MON 88017 x MON 810) Comments and opinions submitted by Member States during the three-month consultation period	ANNEX G		
Czech Republic	Ministry of Agriculture	Country	Organisation	Application EFSA-GMO-CZ-2006-33 (Maize MON 88017 x MON 810) Comments and opinions submitted by Member States during the three-month consultation period	
Denmark	Danish Forest and Nature Agency	Belgium	Belgian Biosafety Advisory Council	ANNEX G	
Finland	Gene Technology Board	Belgium	Belgian Biosafety Advisory Council	ANNEX G	
France	MINERDGO	Belgium	Belgian Biosafety Advisory Council	ANNEX G	
Germany	Federal Agency for Nature Conservation	Belgium	Belgian Biosafety Advisory Council	ANNEX G	
Country	Organisation	Reference	Comment	EFSA GMO Panel response	
Austria	Ministry for Health, Family and Youth, Dep. IVB/S	C. Information relating to the genetic modification	The molecular characterisation is based on an insert specific fingerprinting by Southern blotting employing a single restriction enzyme only. No additional analysis of the copy number and insert integrity in GM maize MON 88017 x MON 810 is presented in the dossier. Thus the identity of inserts in GM maize MON 88017 x MON 810 to the molecular situation in the parental GMO plants is only demonstrated on a gross level.	The identity of the inserts of MON 810 and MON 88017 in the parental lines have been sufficiently established in the respective applications previously assessed by the EFSA GMO Panel. Taking this into consideration, the EFSA GMO Panel considers that the Southern analysis provided sufficiently demonstrated that the structure of both MON 88017 and MON 810 inserts and flanking sequence is conserved in the hybrid. This analysis also demonstrates that both inserts are present in a single copy, as it is the case in the parental lines.	
			Critical issues for the assessment like the molecular identity of the inserts and the flanking regions at the sequence level are only assumed based upon the results of the gross characterisation by Southern blot. A more detailed analysis is needed to conclude the similarity to the molecular organisation of the parental GM lines before any further assessments of GM maize MON 88017 x MON 810 can be carried out. Furthermore the annotation of details of the presented data, like the identity of probes used for the Southern experiments, is incomplete and the references to sources of sequence data in the dossier are missing (pages 27-29, technical dossier).	The data provided by the applicant to support the molecular analysis are in line with the EFSA Guidance document on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed (EFSA, 2005a) and the EFSA GMO Panel considers the data sufficient.	
			In conclusion the information included in the technical dossier on molecular characterisation should be amended to include all relevant details for a demonstration that the molecular characteristics of genetic modifications in the parental GM events are preserved.		
Austria	Ministry for Health, Family and Youth, Dep.	D. 03 Information on the expression of the insert	1. Protein levels of Cry3Bb1, EPSPS and Cry1Ab were pooled across the 3 sites in the US, where GM maize MON 88017 x MON 810 was grown. Pooling of expression values is not adequate as there may be differences in site-specific expression levels. These values should therefore be indicated separately. Furthermore, data from	1. The data provided are sufficient to demonstrate that the ranges in protein expression levels observed are comparable between the stack and the single events. Furthermore, the protein levels do not raise any safety concern regarding the scope of this application.	
				2. The ranges of Cry3Bb1 expression in the stack and MON	

EFSA considers each and publishes all as part of each Opinion<sup>10</sup>

Analisi del rischio di alimenti e mangimi geneticamente modificati

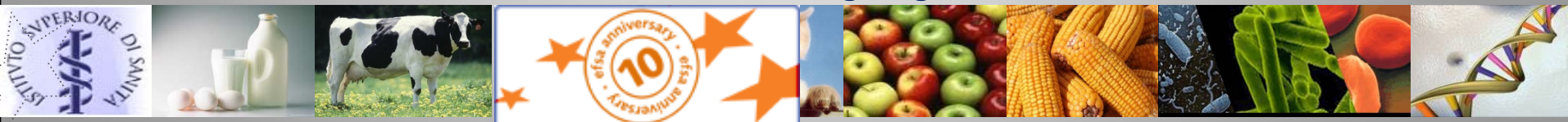




## WHAT EFSA CANNOT DO

- **Give authorisations** (for products such as GMOs, feed additives, food additives, pesticides etc)
- **Be responsible for food safety legislation** (sampling, labelling or other risk management issues such as co-existence measures)
- **Take charge of food safety/quality controls**

**Analisi del rischio di alimenti e mangimi geneticamente modificati**

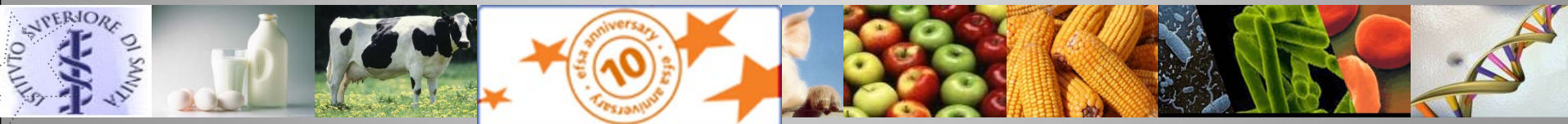




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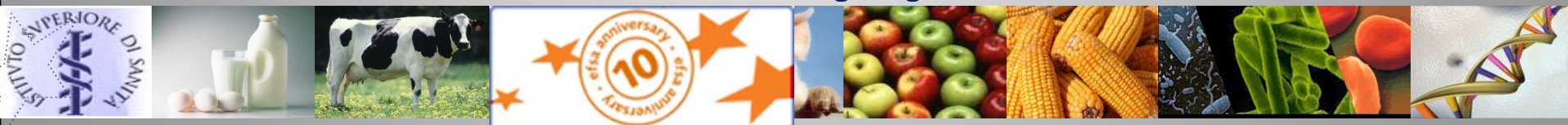
Analisi del rischio di alimenti e mangimi geneticamente modificati




## RISK ASSESSMENT PERFORMED BY

- ❑ **The GMO Panel (19 external experts) for a 3-y mandate**
  - elaborates guidance documents
  - delivers scientific opinions on applications for market authorisation regarding GMOs
- ❑ **40 Ad-hoc experts** support the GMO Panel in **Working groups** (4 standing WG and several temporary WGs)
- ❑ **15 GMO Unit scientists** provide support to the GMO Panel and its Working Groups

Analisi del rischio di alimenti e mangimi geneticamente modificati



## EFSA GMO PANEL EXPERTISE



**Ad-hoc experts**  
in new  
techniques,  
microbiology

### MOLECULAR CHARACTERISATION

- biochemistry
- molecular biology
- genetics
- plant breeding

**Ad-hoc experts**  
in food sciences,  
animal pathology

### FOOD FEED SAFETY

- toxicology
- immunology
- nutrition & animal feed
- food chemistry
- biotechnology

### ENVIRONMENTAL RISK ASSESSMENT

- plant biology
- ecology
- agronomy
- entomology
- biometrics & statistics

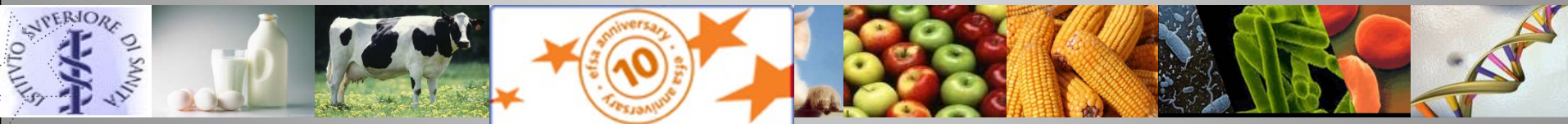
**Ad-hoc experts**  
in pesticides,  
natural toxins,  
environmental  
monitoring

- 15 EFSA **staff scientists**
- 40 ad hoc **experts**
- 210 **MS experts** from 108 organisations and authorities of EU member states

# SCIENTIFIC OPINIONS ON APPLICATIONS

GMO APPLICATIONS	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014 (till Dec)	TOTAL	
Adopted applications	10	5	5	6	9	7	5	8	10	7	72	{ 91
Adopted renewals	0	0	1	1	9	3	2	1	1	1	19	
Withdrawn applications	0	2	1	3	3	1	2	0	9	3	24	{ 30
Withdrawn renewals	0	0	1	0	0	2	2	1	0	0	6	

Analisi del rischio di alimenti e mangimi geneticamente modificati





## EFSA'S GUIDELINES TO APPLICANTS AND RISK ASSESSORS

### EFSA Guidance documents

- Provide guidance for applicants how to prepare and present the applications
- Detailed guidance needed as only full dossiers are considered
- Based on internationally agreed principles and protocols (Codex Alimentarius, OECD)
- Regularly updated
- Undergo public consultation



## SELECTED EFSA'S GUIDANCE DOCUMENTS ON GMOs

- Risk assessment of food and feed from GM plants (2011)
- Post-Market Environmental Monitoring (PMEM) (2011)
- **Environmental Risk Assessment (ERA) of GM Plants (2010)**
- Food and feed RA from GM animals and GM animal health and welfare (2012)
- Environmental Risk Assessment (ERA) of GM animals (2013)

All guidance documents are available at

<http://www.efsa.europa.eu/en/gmo/gmoguidance.htm>

# International Context

EFSA does not work in isolation!

- *European Commission*
- *OECD: Organisation for Economic Co-operation and Development*
- *FAO/WHO: CODEX Alimentarius*

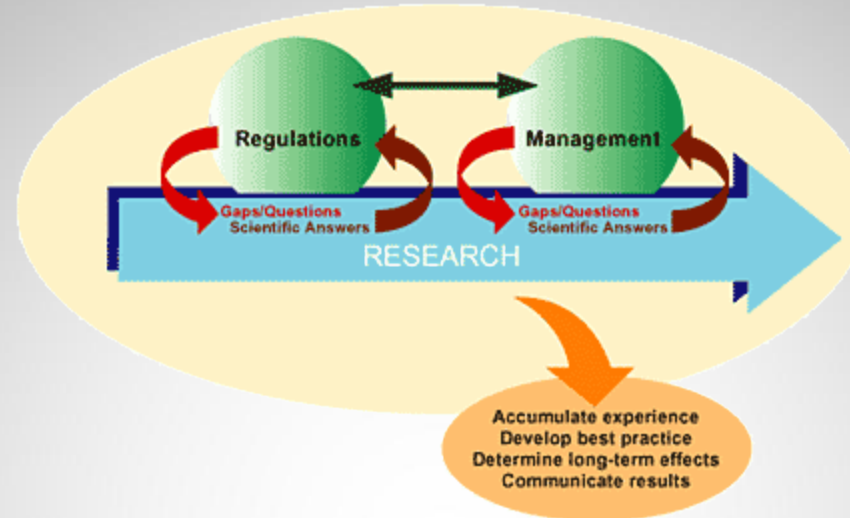


**Common foundation:**

the comparative approach (*Codex Alimentarius, 2003*)

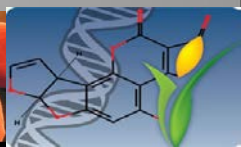
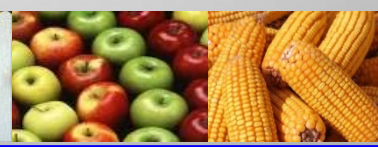
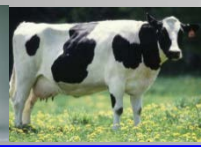
Different countries = different levels of requirements.  
EU has the most stringent ones!

## Relationship between GMO safety research, regulation and practice: synergy and feedback



Research results can resolve uncertainties and provide a sound basis for risk management and science-based regulation (where necessary), through pre-normative research, and lead to the establishment of best practice in a constantly evolving way. The overall result of this tripartite system has, of course, to be communicated to all concerned, particularly to the general public and to political groups, some of whom have shown sustained and sometimes critical interest in the development of GM technology and its applications in various sectors.

**Analisi del rischio di alimenti e mangimi geneticamente modificati**





Grazie per l'attenzione

Domande ?

**Analisi del rischio di alimenti e mangimi geneticamente modificati**





## Concept of substantial equivalence

The concept of substantial equivalence is based on the idea that an existing organism used as food/feed with a history of safe use, can serve as a comparator when assessing the safety of the genetically modified food/feed (OECD, 1993b; EC, 1997b). Application of this concept, also denoted as comparative safety assessment (Kok and Kuiper, 2003), serves the purpose of identifying similarities and potential differences between the GM crop-derived food/feed and the non-GM counterparts, which should subsequently be assessed regarding their toxicological and nutritional impact on humans and animals. The first step of the approach is the comparative analysis of the molecular, agronomic and morphological characteristics of the organisms in question, as well as their chemical composition.

Such comparisons should be made between GM and non-GM counterparts grown under the same regimes and environmental conditions. The outcome of this comparative analysis will further structure the second part of the assessment procedure, which may include further specific safety and nutritional testing. This approach should provide evidence on whether or not the GM crop-derived food/feed is as safe as the traditional counterpart. Where no appropriate comparator can be identified, a comparative safety assessment cannot be made and a comprehensive safety and nutritional assessment of the GM crop derived food/feed per se should be carried out. For instance, this would be the case where

a traditional crop is shown to differ from the comparator in a way that is likely to affect the safety or nutritional value of the food/feed. In such cases, a detailed safety and nutritional assessment of the GM crop derived food/feed should be carried out. For instance, this would be the case where a traditional crop is shown to differ from the comparator in a way that is likely to affect the safety or nutritional value of the food/feed.



## **Analisi del rischio di alimenti e mangimi geneticamente modificati**

