

European Commission - DG ENLARGEMENT - TAIEX
Libyan National Center for Standardization and Metrology
and Secretariat of Agriculture

*Workshop on Genetically Modified Organisms
and Food Additives*

AGR 41349

Tripoli, Libya

24 - 25 May 2010

ILARIA
CIABATTI

GMO authorisation procedures under Regulation (EC) 1829/2003



Centro di Referenza Nazionale per la ricerca di OGM

National Reference Laboratory for GMO analysis, Italy



Istituto Zooprofilattico Sperimentale delle Regioni Lazio e Toscana



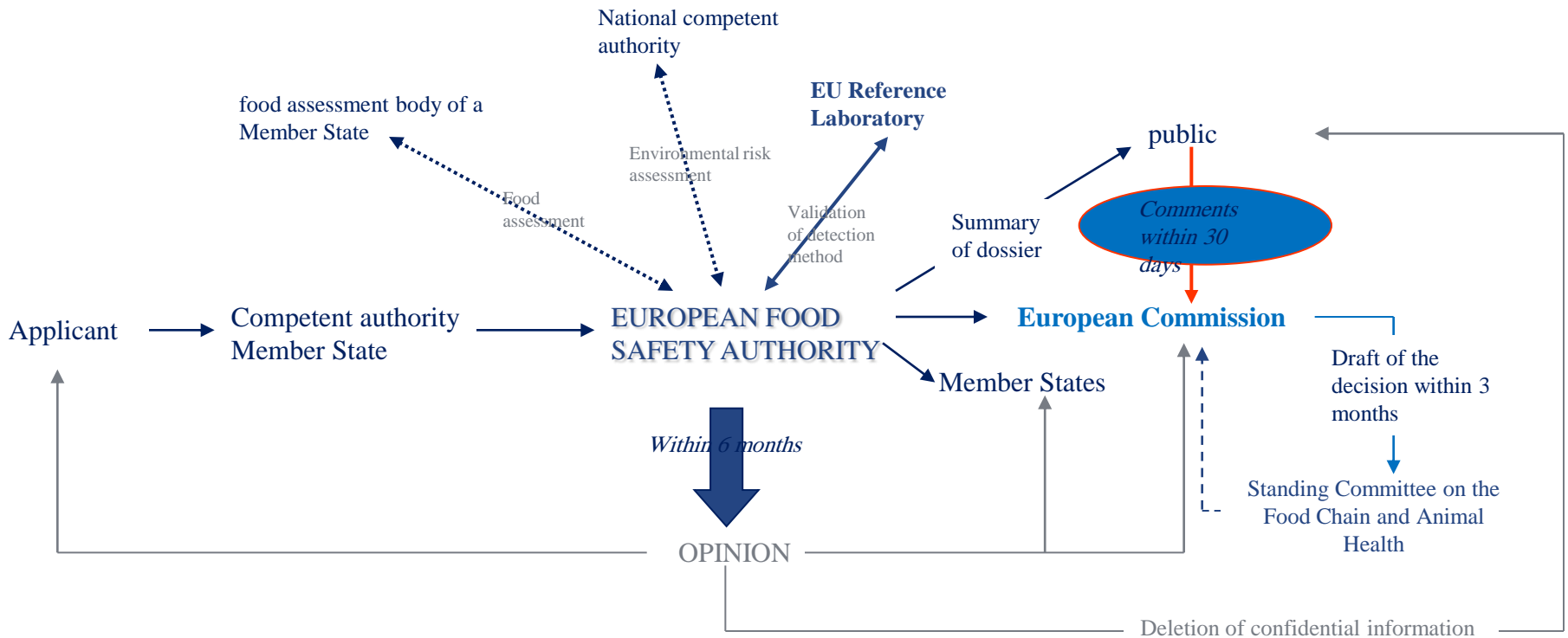
Reg. (EC) 1829/2003

Novelties

- © One door, one key principle \Rightarrow same application procedure for different uses
- © Authorisation granted for food and feed uses when both uses are expected

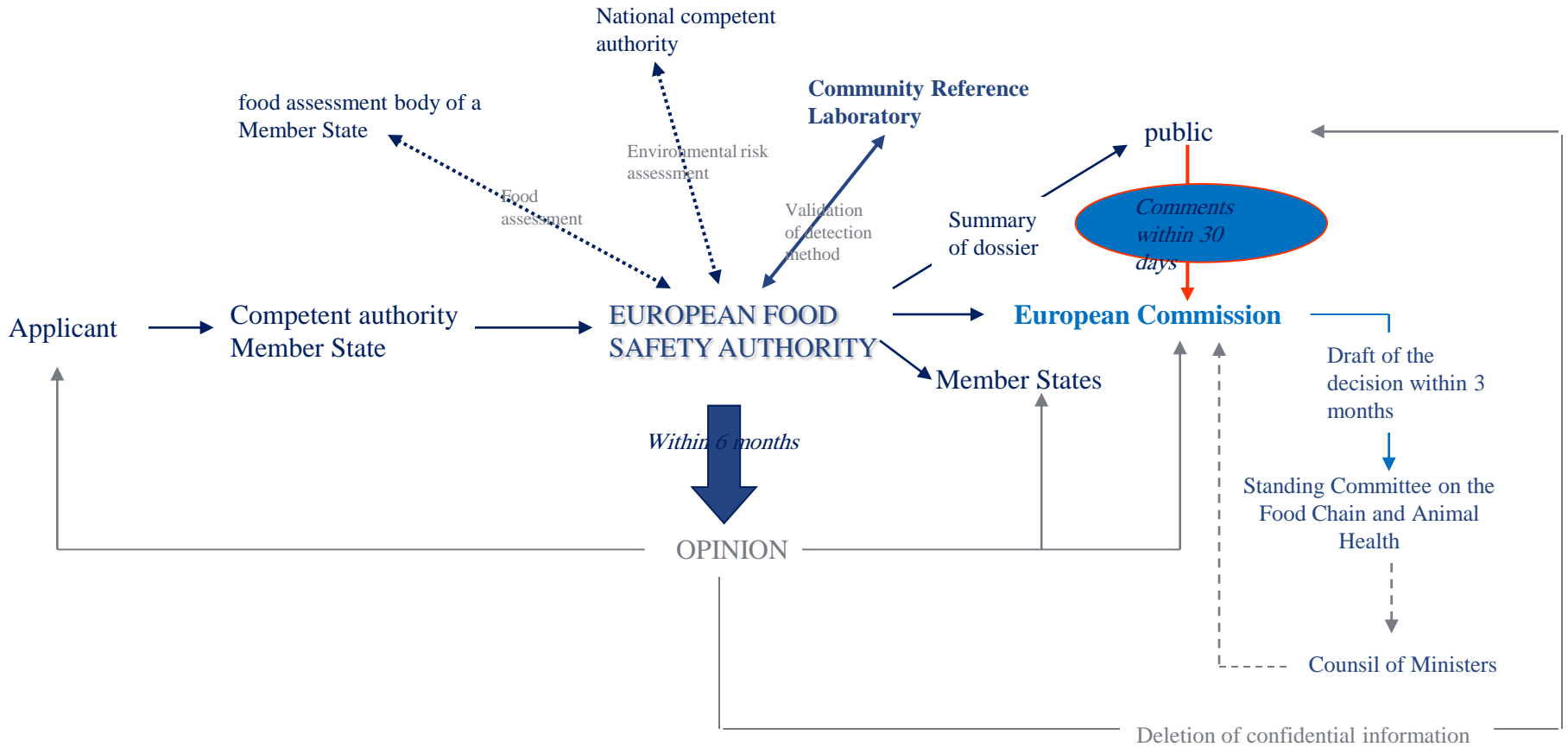
Reg. (EC) No 1829/2003

Authorisation procedure



Reg. (EC) No 1829/2003

Authorisation procedure





Reg. (EC) No 1829/2003

Application for authorisation

Accompanied by the following:

- ⦿ ...
- ⦿ studies and any other available material to demonstrate that the food does not have adverse effects
- ⦿ demonstration that the characteristics of the food are not different from those of its conventional counterpart or a proposal for labelling
- ⦿ a reasoned statement that the food does not give rise to ethical or religious concerns or a proposal for labelling
- ⦿ methods for detection, sampling and identification of the transformation event
- ⦿ samples of the food and their control samples, and information as to the place where the reference material can be accessed



Reg. (EC) No 1829/2003 Authorisation

- ⊙ valid throughout the EU for 10 years
- ⊙ renewable for 10-year periods
- ⊙ The authorised food shall be entered in the Community register of genetically modified food and feed available to the public
(http://ec.europa.eu/food/dyna/gm_register/index_en.cfm)
- ⊙ the unique identifier attributed to the GMO (as defined in Regulation (EC) No 65/2004)



CROGM

[http://www.gmo-
compass.org/eng/gmo/db/](http://www.gmo-compass.org/eng/gmo/db/)



Reg. (EC) No
1829/2003

Status of existing products

may continue to be placed on the market,
used and processed provided that

- ☑ they are notified with the same information and materials required in the application for non existing products
- ☑ the products be entered in the Community Register



Community Register of GM food and feed

EUROPA - Food Safety - Biotechnology - GM Food & Feed - Introduction - Windows Internet Explorer

http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

community register gm food

EUROPA - Food Safety - Biotechnology - GM Food & F...

Community register of genetically modified food and feed.

Genetically modified cotton

Transformation event/ Unique ID/ Company	Genes Introduced / Characteristics	Authorized use	Authorization Expiration Date	Details
Cotton (MON1445) <u>MON-Ø1445-2</u> Monsanto	Genetically modified cotton that contains: cp4 epsps gene inserted to confer tolerance to the herbicide glyphosate	Food produced from MON1445 cotton (cottonseed oil)	18/12/2011	
		Food additives produced from MON1445 cotton	Renewal of authorisation ongoing	
		Feed produced from MON1445 cotton (feed materials and feed additives)	Renewal of authorisation ongoing	
Cotton (MON15985) <u>MON-15985-7</u> Monsanto	Genetically modified cotton that contains: cry1Ac and cry2Ab2 genes inserted to confer insect-resistance highly selective in controlling Lepidopteran insects	Food additives produced from MON-15985-7 cotton	Renewal of authorisation ongoing	
		Feed produced from MON 15985 cotton (feed materials and feed additives)	Renewal of authorisation ongoing	
Cotton (MON15985 x MON1445)	Genetically modified cotton that contains: cry1Ac and cry2Ab2 genes inserted to confer	Food additives produced from	Renewal of	

Enlargement Agreements
EU - Russia: SPS issues

Menu
GM Register Introduction
Authorised products
Cotton (MON1445)
Cotton (MON15985)
Cotton (MON15985 x MON1445)
Cotton (MON531)
Cotton (MON531 x MON1445)
Cotton (LLCotton25)
Maize (Bt11)
Maize (DA S1507)
Maize (GA21)
Maize (MON810)
Maize (MON863)
Maize (MON863 x NK603)
Maize (MON863 x MON810)

Internet 100%

start EUROPA - Food Safe... regolamenti TAIEX Turchia 2010 Microsoft PowerPoint ... 14.46



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"> • 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)

Updated
1/04/2010

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

Maize

17
events



Updated
1/04/2010

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

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

Maize

17
events



Updated
1/04/2010

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

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

Maize 17 events



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

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

Maize 17 events



Transformation event	Authorised use		
	food	feed	other uses
MON89034	<ul style="list-style-type: none"> containing, consisting or produced from 	<ul style="list-style-type: none"> containing, consisting or produced from 	<ul style="list-style-type: none"> products containing or consisting of (except cultivation)
MON88017	<ul style="list-style-type: none"> containing, consisting or produced from 	<ul style="list-style-type: none"> containing, consisting or produced from 	<ul style="list-style-type: none"> products containing or consisting of (except cultivation)
59122 x NK603	<ul style="list-style-type: none"> containing, consisting or produced from 	<ul style="list-style-type: none"> containing, consisting or produced from 	<ul style="list-style-type: none"> products containing or consisting of (except cultivation)

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

Maize 17 events



Transformation event	Authorised use		
	food	feed	other uses
MIR604	<ul style="list-style-type: none"> containing, consisting or produced from 	<ul style="list-style-type: none"> containing, consisting or produced from 	<ul style="list-style-type: none"> products containing or consisting of (except cultivation)
MON863 x MON810 x NK603	<ul style="list-style-type: none"> containing, consisting or produced from 	<ul style="list-style-type: none"> containing, consisting or produced from 	<ul style="list-style-type: none"> products containing or consisting of (except cultivation)

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"> • produced from • additives produced from 	<ul style="list-style-type: none"> • containing, consisting or produced from (feed materials and feed additives) 	<ul style="list-style-type: none"> • products containing or consisting of (except cultivation)
MS8, RF3, MS8 x RF3	<ul style="list-style-type: none"> • produced from 	<ul style="list-style-type: none"> • containing, consisting or produced from (feed materials and feed additives) 	<ul style="list-style-type: none"> • products containing or consisting of (except cultivation)
T45	<ul style="list-style-type: none"> • containing or produced from 	<ul style="list-style-type: none"> • containing or produced from 	<ul style="list-style-type: none"> • products containing (except cultivation)

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"> containing, consisting or produced from additives containing, consisting or produced from 	<ul style="list-style-type: none"> containing, consisting or produced from (feed materials and feed additives) 	<ul style="list-style-type: none"> products containing or consisting of (except cultivation)
A2704-12	<ul style="list-style-type: none"> containing, consisting or produced from additives containing, consisting or produced from 	<ul style="list-style-type: none"> containing, consisting or produced from (feed materials and feed additives) 	<ul style="list-style-type: none"> products containing or consisting of (except cultivation)
MON89788	<ul style="list-style-type: none"> containing, consisting or produced from additives containing, consisting or produced from 	<ul style="list-style-type: none"> containing, consisting or produced from (feed materials and feed additives) 	<ul style="list-style-type: none"> products containing or consisting of (except cultivation)

Updated
1/04/2010



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
1/04/2010



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

Potato 1 event



Transformation event	Authorised use		
	Food	feed	other uses
EH92-527-1	<ul style="list-style-type: none">• adventitious or technically unavoidable presence	<ul style="list-style-type: none">• produced from• containing or consisting of adventitious or unavoidable presence	cultivation

Updated
1/04/2010



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
- + 17 maize events
- + 3 oilseed rape events
- + 3 soya events
- + 1 sugar beet event
- + 1 potato event
- + 2 GM microorganisms

33
authorised
events

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

33 authorised events:

- 24 single events
- 9 stacked events

Stacked event: *new products with more than one transformation event* (OECD guidance for the designation of a unique identifier for transgenic plants. Series on Harmonization of Regulatory Oversight in Biotechnology, No. 23 Available from [http://www.oilis.oecd.org/oilis/2002doc.nsf/LinkTo/env-jm-mono\(2002\)7](http://www.oilis.oecd.org/oilis/2002doc.nsf/LinkTo/env-jm-mono(2002)7))



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 %



Thank you