GMO Authorisation Procedures under Regulation (EC) 1829/2003

TAIEX AGR 31411
Ohrid - 26 February, 2009

Leena Mannonen
Ministry of Agriculture and Forestry, Finland

Regulation (EC) 1829/2003

*Euroopan parlamentin ja neuvoston asetus
(EY) N:o 1829/2003,
annettu 22 päivänä syyskuuta 2003,
muuntogeenisistä elintarvikkeista ja rehuista

http://eur-lex.europa.eu/pri/fi/oj/dat/2003/l_268/l_26820031018fi00010023.pdf

*Kalvo lisätty/JT 27.11.2009

Regulation (EC) 1829/2003

Regulation in force as such in Member States

The MS (*Member State*) may need to

- ✓ Define organizational arrangements

  (VNa 910/2004 in Finland)

- ✓ Implement the Directive 2001/18/EC

  (In Finland the Gene technology Act 1995/377)

Organizational arrangements

- Contact point with EFSA and for submission of applications (Evira in Finland)
- Decision powers

  i.e. food, feed, cultivation, environment
- Coordination of the national opinion, if needed
- Scientific advice if regarded relevant
- GMO laboratories (participation in European Network of Gmo Laboratories, ENGL)
- Enforcement and control

Regulation (EC) 1829/2003

Article 1 – Objective

- Protection of human and animal health and the environment (established safety articles 4 and 16)
- Effective internal market
- Authorization procedures
- Labeling and consumer information provisions

Taking into account general provisions of the Regulation 178/2002 (“general food law”)

Scope - (EC) 1829/2003

Articles 3 (food) and 15 (feed) – Scope

(a) GMO's for food (feed) use

(b) Food (feed) containing or consisting of GMO's

(c) Food (feed) produced from or containing ingredients from GMO's

Recital (16) explaining what is covered / not covered

Comitology (article 35) for interpretations

Authorization Procedure

Steps and requirements indicated in articles (food/feed):

- Submission of applications in Articles 5/17
- Safety assessment by EFSA in Articles 6/18
- Authorization with Comitology in Articles 7/19
- Existing products in Articles 8/20
- Renewals in Articles 11/23
- Comitology in Article 35

Articles 5 and 17 Application – MS's role

- ✓ Application is sent to a MS's competent authority (CA)
- ✓ MS (CA) aknowledges the receipt (in 14d)
- ✓ MS (CA) sends the dossier to EFSA

MS does not check or comment the dossier

Articles 5 and 17 Application – EFSA's role

- ✓ EFSA informs the Commission and other MS
- ✓ EFSA makes the entire dossier available to CA's

  via EFSA's GMO ExtraNet and by weekly alerts

- ✓ EFSA makes the summary available to the public

  via EFSA's homepage - Register of Questions:

"The EFSA Register of Questions contains information on questions asked to EFSA by the EU regulatory authorities on food and feed safety issues within EFSA's remit. The Register of Questions provides information on the progress of a question as it moves through the risk assessment process. A question normally results in the publication of an opinion by one of EFSA's nine scientific panels or its scientific committee. "

Example of a weekly alert through Email:

Sender: HERNANDEZ VALERO Sonia [Sonia.HERNANDEZVALERO@efsa.europa.eu]
Sent: 18. February 2009 17:10
Subject: Info GMO EFSAnet: 18 February 2009 updates

NEW APPLICATIONS:

- Application **EFSA-GMO-NL-2005-22** (NK603 maize for CULTIVATION submitted by Monsanto): The section *correspondence and miscellaneous* has been amended with a letter EFSA to applicant – Clock remains stopped EFSA (6). This application is valid since 12/05/2006.
- Application **EFSA-GMO-UK-2007-43** (356043 soybean submitted by Pioneer): The section *correspondence and miscellaneous* has been amended with a letter JRC-CRL to EFSA – Validation of the Detection Method. The section *Overall opinion* has been updated accordingly. This application is valid since 28/09/2007
- Application **EFSA-GMO-NL-2008-53** (98140 maize submitted by Pioneer): See member States' comments. This application is valid since 12/11/2008.

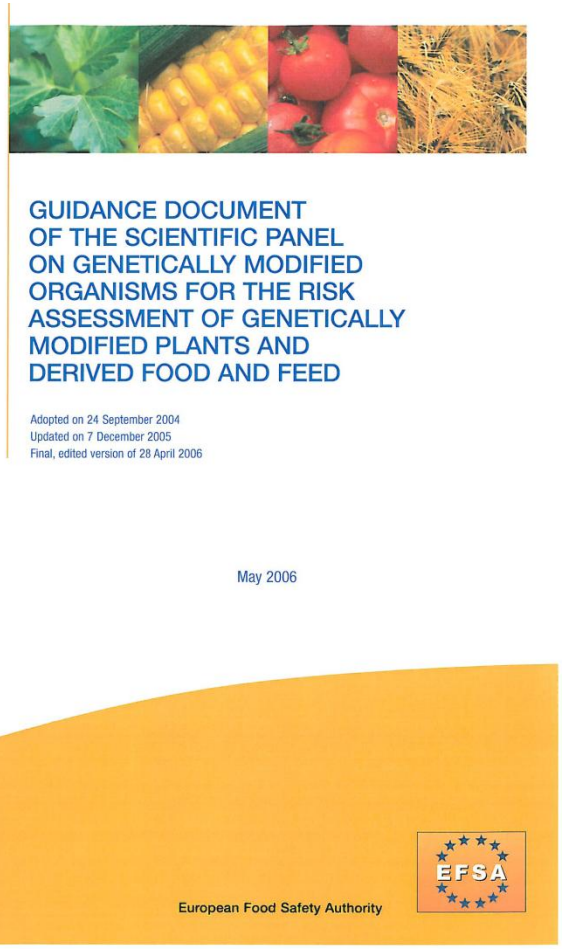
APPLICATIONS FOR RENEWAL:

- Application **EFSA-GMO-RX-Bt11** (Bt11 maize submitted by Syngenta): The section *Overall opinion* has been updated with the Overall opinion in accordance with Articles 6 and 18 of Regulation (EC) No. 1829/2003.
- Application **EFSA-GMO-RX-MON863xMON810** (MON863 x MON810 maize submitted by Monsanto): The section *correspondence* has been updated with a letter 2009-02-12_EFSA to appl_Clock remains stopped (2).This application is valid since 05/06/2008.

Articles 5 and 17 - Content of Application

Paragraph	
3	Provisions for food/feed containing, consisting of or produced from a GMO
5	Environmental considerations (dir 2001/18/EC)
6	For specific uses additional approvals might be needed
7	Implementing rules by the Commission
8	EFSA's guidance for preparation of applications

EFSA guidance for information



http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620775747.htm

Published in May 2006; Last updated 16 June 2008; ERA and allergy potential currently under review

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II Risk assesment strategy

- Comparative approach
- Incl. environmental risks (ERA)

III Information needed

A. General information

B. Information on recipient

C. Information on genetic modification

D. Information on GM plant

- traits and characteristics
- sequences, expression, gene-transfer
- difference to non-modified plant, stability
- toxicologicology, allergenicity, nutrition
- anticipated use, effect of processing …
- selection of material for comparison, statistics
- interaction with environment …
- environmental monitoring plan

etc .....

Articles 6 and 18 - EFSA's opinion

- Within 6 months from acceptance of valid application
- If cultivation requested a MS's competent authority (dir 2001/18/EC) may be asked to carry out the environmental assessment
- EU Joint Research Centre (JRC) validates the analysis method and reference material
- Clock stopped if additional information is required

Member States are working with EFSA

- ✓ If cultivation is requested a MS's competent authority (dir 2001/18/EC) may be asked to carry out the environmental risk assessment
- ✓ MS competent authorities (all) may comment the dossier within first 3 months
- ✓ MS GMO laboratories participate in validation of the analysis method

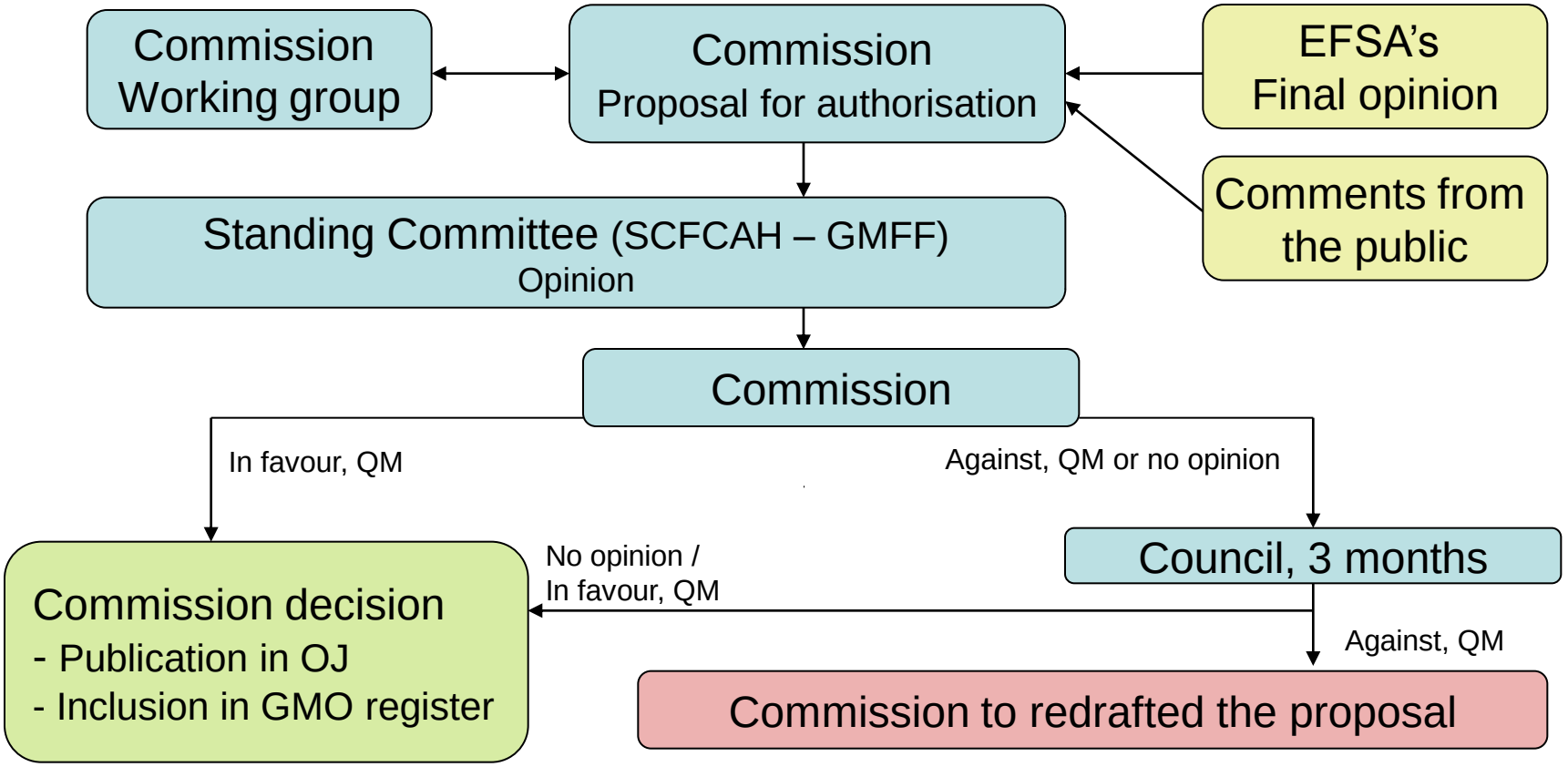
Articles 6 and 18 - EFSA's Final Opinion

Delivered via EFSANet for MS competent authorities

- ✓ Scientific safety assessment and possible assessment according to dir 2001/18/EC
- ✓ Labeling provisions
- ✓ Validated analysis method and availability of reference material
- ✓ Monitoring Plan(s)
- ✓ How MS's comments were considered

Scientific assessment published on EFSA's webpage

Authorization procedure
Articles 7 (food), 19 (feed) and 35



SCFCAH agrees with the proposal

- ✓ Qualitative majority i.e. 255 votes from 350, 62% of population or 14 MS out of 27
- ✓ Decision to be published in the Official Journal
- ✓ GM approval to be included in the Commission GMO Register (http://ec.europa.eu/food/dyna/gm_register/index_en.cfm)
- ✓ Approval for 10 years at time
- ✓ Authorization holder responsible for proper use, post market monitoring etc.
- ✓ Additional approvals for use as an additive, seed etc may be needed

Considerations on gmo authorisation - Finnish view

Authorisation of GMO's for food and feed may be approved if

- ✓ Safety has been established by EFSA and national experts confirm it
- ✓ Proper consumer information provisions fulfilled
- ✓ Enforceability i.e. analysis method validated and operational including the availability of reference material

Scientific advice for Finnish authorities

- The Novel Food Board

- Established as the food assessment body under the Novel Food Regulation (EC) 258/97
- Mandate renewed for gmo-food Reg. (EC) 1829/2003
- Expertise in food sciences, biotechnology, GMO's, medicine, allercology, toxicology, pharmacolocy, nutrition
- 20 individual scientific experts from universities and leading research centers in Finland
- Advisory body, no decision making power

Consumer information - labeling

Articles 12-13 (food) and 24-25 (feed)

- Products for final consumers (users) and mass caterers
- Food/feed contain, consist of, produced from gmo's
- Not if produced with gmo's
- 0,9% treshold for accidental, unavoidable presence
- Operators responsible of verification of presence
- Lower levels may be adopted
- In the list of ingredients
- Otherwise visible for non-pre-packed

National provision for gm-free labels and for menu's

Issues under discussion in EU

- ✓ Implementing measure for submission of applications
- ✓ Need for animal feeding trials, scientific approach
- ✓ Evaluation of the legislative framework for GMO's
- ✓ Interplay with pesticide legislation
- ✓ More effective environmental safety assessment
- ✓ EFSA's work load, trust in EFSA's work,
- ✓ More efficient MS participation in EFSA's work

Useful links for GMO's

Commission http://ec.europa.eu/food/food/biotechnology/index_en.htm

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

EU Joint Research Centre (JRC) http://gmo-crl.jrc.ec.europa.eu/

EFSA:

- GMO-panel http://www.efsa.europa.eu/EFSA/ScientificPanels/efsa_locale-1178620753812_GMO.htm
- GM-applications http://registerofquestions.efsa.europa.eu/roqFrontend/questionsList.jsf
- GMO Compass http://www.gmo-compass.org/eng/home/

Evira http://www.evira.fi/portal/fi/kasvintuotanto_ja_rehut/gmo/

Thank you!