

GM Food & Feed, Traceability & Labelling

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NEW FRAMEWORK

- **Reg. 1829/2003** on GM Food & Feed
- **Reg. 641/2004** Detailed Rules for 1829/2003 Implementation
- **Guidance Document** of Scientific Panel on GMOs for the Risk Assessment of GM plants and derived food and feed
- **Reg. 1830/2003** on traceability and labelling of GMOs and F&F products produced from GMOs
- **Reg. 65/2004** on Unique Identifiers for Reg. 1830/2003

OLD ISSUES

‘A majority of Europeans do not support GM foods. These are judged not to be useful and to be risky for society.’

For GM crops, support is lukewarm, while they are judged to be moderately useful they are seen as almost as risky as GM foods....

For GM crops and GM foods support declined and opposition increased over the period 1996-1999. Between 1999-2002 there is no change in levels of support or opposition in Europe considered as a whole.’

(Europeans and Biotechnology in 2002 Eurobarometer 58.0)

How did we get here?

HOW DID WE GET HERE?

3 of the key regulatory stages:

1. *De facto* moratorium

2. White Paper on Food Safety

3. Commission Strategy on GMOs

de facto MORATORIUM ?

- **WTO Dispute** initiated by Argentina, Canada and USA *v* EU: alleging existence of measures affecting the approval and marketing of Biotech. Products (WT/DSB/M/155, panel established 29 August '03). Decision June / July; Appeal Autumn / Spring.
- **No authorisations of GMO products** between *October 1998 - May 2004 (except for Art. 5 NFR notifications - simplified procedure)*.

de facto MORATORIUM ?

- **Declaration by 11 Member States Env. Council June '99, discussions on revision of Dir. 90/220:**

Denmark, France, Greece, Italy & Luxembourg ‘...will take steps to have any new authorisations for growing and placing on the market suspended’.

Austria, Belgium, Finland, Germany, Netherlands & Spain ‘intend...not to authorise the placing on the market of any GMOs until it is demonstrated that there is no adverse effect on the environment and human health...’

de facto MORATORIUM ?

- “Safeguard Measures”:

Dir. 90/220 (Art.16)

(Dir. 2001/18 Art. 23)

• Austria, France,

• Germany, Greece, Luxembourg
& UK

Reg. 258/97 (Art. 12)

• Italy

- **Scientific Committee(s) concluded in all cases that no new evidence justifying overturning of the original authorisation.**
- **Half-hearted response from Commission.**

WHITE PAPER ON FOOD SAFETY

COM (1999) 719, January 2000: **FOOD**

Improve the ‘...procedure for **authorising the placing on the market of novel foods** (...in particular those containing or derived from genetically modified organisms)...in accordance with [principles in] Directive 90/220/EEC.’ (*Para. 76*)

‘...**labelling** of novel food, and, in particular, **products derived from genetically modified organisms...**’ (*Para. 103*)

‘**Regulation on the labelling of GMO free foodstuffs**. To give operators the possibility to use labelling claims referring to the **absence** of use of genetic engineering techniques for the production of foodstuffs.’ (*Action Item 15*)

Regulation on the labelling of food containing or derived from genetically modified organisms (*Action Item 52*)

WHITE PAPER ON FOOD SAFETY

COM (1999) 719, January 2000: **FEED**

‘The principles of food safety...should become applicable to the feed sector...’ (*No more Starlink*)

‘A legislative proposal for the evaluation, authorisation and labelling of novel feed, in particular of **genetically modified organisms and feeding stuffs derived therefrom**, will be put forward.’ (*Para. 69*)

‘Proposal for a Regulation on novel feed. To put into plan a **centralised system for the authorisation of** use in animal nutrition of non conventional products, **in particular of GMOs and GMO derived feedstuffs.**’ (*Action Item 6*)

COMMISSION STRATEGY

July 2000

- ‘Commission has a responsibility to ensure that legislation is properly enforced’
- ‘...there is currently no legal basis for a standstill on the authorisation procedure for GMO products...’
- Proposed a re-launch of authorisation procedure along with “package” of additional measures:
 - Labelling and traceability of GMOs
 - Environmental Liability
 - Addressing Possible Long-Term effects on Biodiversity
- ‘...start a process to facilitate a more reasoned debate on GMOs’

**How will the new regime
operate and can it
“work”?**

GENERAL PRINCIPLES

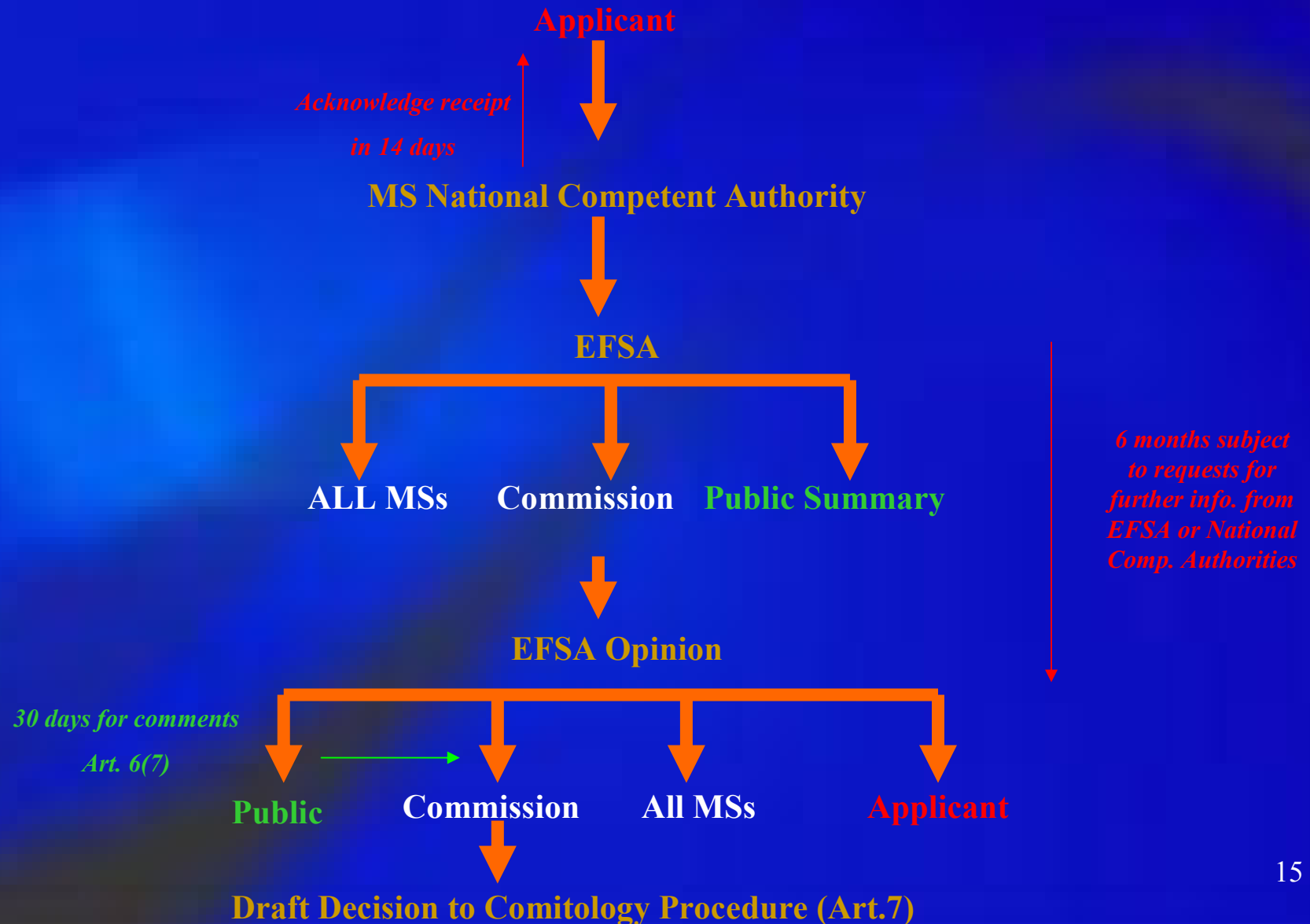
- **Food & Feed must be treated in one application where likely dual use.**
- **Possibility of filing single application for a GMO & All Uses (cultivation, importation, processing into food): ‘One door one key’.**

GENERAL PRINCIPLES

Dossier MUST demonstrate, Art.4(1):

- 1. NO adverse effects on human & animal health or environment**
- 2. NOT *'mislead consumer'***
- 3. NOT differ from food which it is intended to replace to such an extent that its normal consumption would be nutritionally *disadvantageous* for consumers.**

FOOD AUTHORISATION PROCEDURE: Art. 5

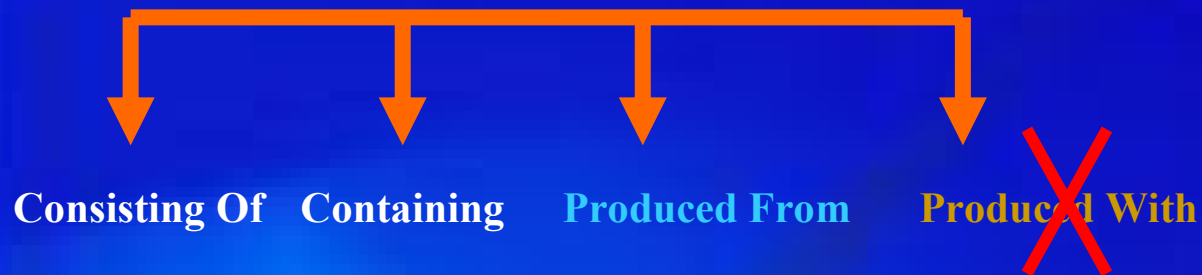


FOOD AUTHORISATION: SCOPE

Arts.3(1) **GMOs for Food Use**
& 4(4)
& Food ...

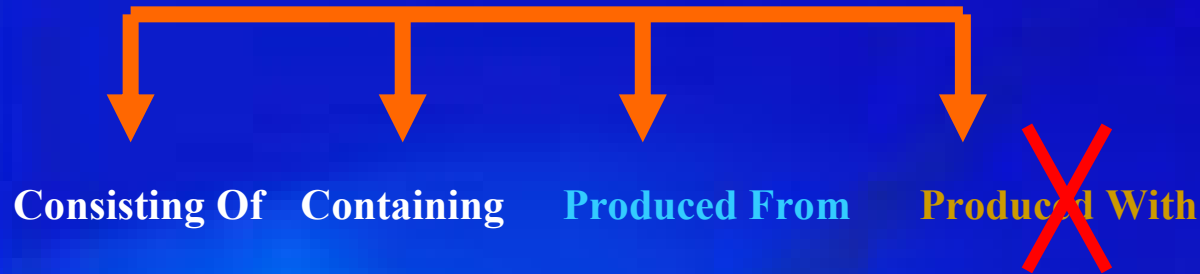


FOOD AUTHORISATION: SCOPE



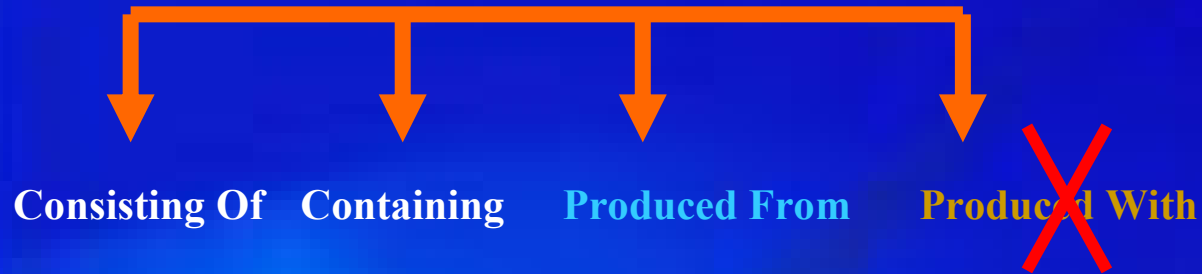
- **Produced From** ‘...means derived, in whole or in part from GMOs, but not containing or consisting of GMOs’ *Art. 2(10)*
- **Difference between ‘from’ and ‘with’**: ‘The determining criterion is whether or not material derived from the genetically modified source material is present in the food...’. *Rec. 16*
- Commission says Reg. ‘...is stricter than current legislation...It includes all foods **produced from GMOs, without making a distinction between those containing DNA...or protein resulting from genetic modification and those which do not...**’ (21 .Oct ‘03)

FOOD AUTHORISATION: SCOPE



- Commission says ‘**produced from**’ covers e.g. ‘highly refined soya or maize oil produced from GM-soya or GM-maize...’ (IP/03/1056, 22 July 2003)
- ‘Clear labelling, irrespective of the detectability of DNA or protein resulting from the genetic modification in the final product... precludes potential misleading of consumers as regards method of manufacture or production’ *Rec. 21 [No, actually irrespective or presence!]*
- Commission: ‘**produced with**’ is catalyst / processing aid.

FOOD AUTHORISATION: SCOPE



Produced “From” & “With”

- **BOTH have no GM DNA or Protein.**
- **BUT ONLY** former is subject to authorisation and bears labelling words “produced from genetically modified (name of ingredient)”. [Art. 13(1)(a)].
- Regulating Process NOT Product – if this is true, **is the “from” / “with” distinction: (i) logically defensible or (ii) capable of practical application?** [Comitology, Art. 35]

What justifies this level of inbuilt regulatory imprecision?

REG. 1829/2003: OBJECTIVES

What *higher objective* is being pursued through process labelling?

1. Free Movement in EU (Art. 95 EC)
2. Protect Human (& Animal) Health (Rec. 3)
3. Environmental Protection (Rec. 9)
4. Facilitate Informed Consumer Choice (Rec. 17) & Farmer Choice (Rec. 20).

REG. 1829/2003: OBJECTIVES

How is facilitating Consumer Choice expressed, more broadly, in the Reg.?

- Application, monitoring info. etc. all public. [Art. 29].
- EFSA Opinion is public – 30 day right to comment [Art. 6(7)].
- ‘It is recognised that, in some cases, scientific risk assessment alone cannot provide all the information on which a risk management decision should be based, and that other legitimate factors relevant to the matter under consideration may be taken into account.’ [Rec. 32 & Arts. 7(1) and 19(1)]
- Catch All - food must not ‘mislead the consumer’ [Article 4(1)(b)]. *Is “produced from” but excluding “produced with” misleading in itself? Assumption that more info. (of marginal value) is less misleading?*

REG. 1829/2003: OBJECTIVES

How is facilitating Consumer Choice expressed, more broadly, in the Reg.?

- **Dossier must include ‘reasoned statement that the food does not give rise to ethical or religious concerns’ [Art. 5(3)(g)] or labelling indicating that it may give rise to such concerns.**
- **Labelling that includes the words “genetically modified”, in the same font size as any list of ingredients / clearly on labelling or clear display when not packaged or smaller than 10cm² surface [Art. 13(1)].**
- **Labelling indicating differences in nutritional value/effects, health effects for certain parts of population etc. comp. with conventional counterpart [Art. 13(2)] and info. about it where no conventional counterpart.**

Apparent strong consumer-orientated focus.

REG. 1830/2003: TRACEABILITY

At first stage of placing on market operators must provide that the subsequent operator receives in writing:

- **that it is a GM products**
- **unique identifier**

At all subsequent stages operators must transfer info. above in writing.

All operators must hold info for 5yrs from *each* transaction (subject to exceptions).

THRESHOLDS

Already noted that GM F&F products cannot be placed on the market unless authorised: Arts 4(2) & 16(2).

2 EXCEPTIONS to this rule which turn on Adventitious or Technically Unavoidable Presence.

THRESHOLDS

Adventitious Presence Thresholds

0.5%

0.9%

Non-Authorized

Authorized

Art. 47

Arts. 12(2) & 24(2)

Only Until 18 Apr 2007

No Time Limit

**Review by 7 Nov 2005 (Art. 48)
or Before by Comitology**

Lowerable by Comitology

**No need to Authorize or Label
but must “trace” to show AP.**

**No need to label but must
“trace” to show AP.**

*Just 10 in this category -More
apparent than real?*

COEXISTENCE

A final gift...

Inserts by Art 43: New Art. 26a in Directive 2001/18

‘Member States may take appropriate measures to avoid the unintended presence of GMOs in other products.’

Spawned Art. 95 Notifications including: Upper Austria (ECJ & CFI litigation: cases C-492/03 and T-366/03) etc.

Standstill Directive notifications: Austria, Luxembourg, Denmark, Germany & Italy.

CONCLUSION

1. The new Regime is aimed at “healing” years of regulatory deadlock.
2. Major focus on consumer concerns.
3. This focus may have, unwittingly, produced a basic flaw in the system - distinction between “produced from” and “produced with” is hard to maintain or operate.
4. Where does this leave consumer confidence, MSs, the food chain?
5. Have we set ourselves up for a new round of battles in comitology on scope, AP and ultimately authorisations ?