Labelling of GMOs in the EU

Professor Michael Blakeney

Outline

- EU legislation
- European Food Safety Authority (EFSA)
- GM labelling

EU Legislation

EU-Regulation	**Directive on the Deliberate Release into the Environment of Genetically Modified Organisms (2001/18)**	**Regulation on Genetically Modified Food and Feed (1829/2003)**
Scope of application	Commercial use of a GM plant (that is able to reproduce); release into the environment involved with growing the plant or importing plant material	Food and feed that was made from or contains GM plants
In effect since	17 April 2001	19 April 2004

Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms

Article 2(1) and (2) organism means any biological entity capable of replication or of transferring genetic material, and genetically modified organism (GMO) means an organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

Article 11(5) in conjunction with Article 11(1), provides that no product containing GMOs may be released into the environment before the competent authority of the Member State in which the product is to be placed on the market for the first time has given its written consent following a notification made to it by the manufacturer or the importer into the Community.

Council Directive 90/220/EEC

Art.12.1. On receipt and after acknowledgement of the notification referred to in Article 11, the competent authority shall examine it for compliance with this Directive, giving particular attention to the environmental risk assessment and the recommended precautions related to the safe use of the product.

2. At the latest 90 days after receipt of the notification, the competent authority shall either:

(a) forward the dossier to the Commission with a favourable opinion, or

(b) inform the notifier that the proposed release does not fulfil the conditions of this Directive and that it is therefore rejected.

Council Directive 90/220/EEC, Article 13

1. On receipt of the dossier referred to in Article 12(3), the Commission shall immediately forward it to the competent authorities of all Member States together with any other information it has collected pursuant to this Directive and advise the competent authority responsible for forwarding the document of the distribution date.
2. The competent authority, in the absence of any indication to the contrary from another Member State within 60 days following the distribution date shall give its consent in writing to the notification so that the product can be placed on the market and shall inform the other Member States and the Commission thereof.

Council Directive 90/220/EEC, Article 13

4. Where the Commission has taken a favourable decision, the competent authority that received the original notification shall give consent in writing to the notification so that the product may be placed on the market and shall inform the other Member States and the Commission thereof.
5. Once a product has received a written consent, it may be used without further notification throughout the Community in so far as the specific conditions of use and the environments and/or geographical areas stipulated in these conditions are strictly adhered to.
6. Member States shall take all necessary measures to ensure that users comply with the conditions of use specified in the written consent.

Greenpeace & Ors [2000] EUECJ C-6/99 (21 March 2000)

- The French Minister for Agriculture, Fisheries and Food adopted, on 4 February 1997, a decree authorising the placing on the market of a genetically modified maize (*ZEA mays L.*) protected against corn borers and having increased tolerance to herbicides of the glufosinate-ammonium family, which constitutes the 'consent in writing provided for in Article 13 of Directive 90/220. On 5 February 1998, the same minister adopted a decree modifying the official list of plant species and varieties grown in France (maize seeds) (hereinafter 'the decree of 5 February 1998). The purpose of that decree was to authorise the marketing of seeds of certain varieties of genetically modified maize.
- Greenpeace applied to the Conseil d'État to have the decree of 5 February 1998 suspended or annulled.

the Conseil d'État decided to stay proceedings and to refer the following questions to the Court for a preliminary ruling:

'(1) Must the provisions of Council Directive 90/220/EEC be interpreted as meaning that if, after an application to place a genetically modified organism on the market has been forwarded to the Commission of the European Communities, no Member State has raised an objection as provided for in Article 13(2) of Directive 90/220, or if the Commission of the European Communities has taken a favourable decision pursuant to Article 13(4), the competent authority which forwarded the application to the Commission with a favourable opinion is obliged to give the consent in writing allowing the product to be placed on the market, or does that authority retain a discretion not to give such consent?

(2) Must the decision of the Commission of the European Communities of 23 January 1997 under which the French authorities are to authorise the placing on the market of the product ... notified by Ciba-Geigy Limited be interpreted as requiring the French Government to give its consent in writing?

47. Directive 90/220 is to be interpreted as meaning that, if, after an application for placing a GMO on the market has been forwarded to the Commission, no Member State has raised an objection, in accordance with Article 13(2) of the directive, or if the Commission has taken a 'favourable decision under paragraph (4) of that provision, the competent authority which forwarded the application, with a favourable opinion, to the Commission must issue the 'consent in writing, allowing the product to be placed on the market.

However, if in the meantime the Member State concerned has new information which leads it to consider that the product for which notification has been received may constitute a risk to human health and the environment, it will not be obliged to give its consent, provided that it immediately informs the Commission and the other Member States about the new information in order that, within the period laid down in Article 16(2) of Directive 90/220, a decision may be taken in the matter in accordance with the procedure provided for in Article 21 of that directive.

48. It is clear from the national court's file that, by its second question, it is asking essentially whether the Commission's 'favourable decision obliges the competent national authority to give its 'consent in writing, notwithstanding any irregularities which might be found by a court in the conduct of the examination of the notification by that authority and which are such as to call in question the legality of the decision to forward the dossier with a favourable opinion to the Commission.

49. As pointed out in paragraph 47 above, when the Commission has taken a 'favourable decision under Article 13(4) of Directive 90/220, the competent authority which forwarded the application with a favourable opinion to the Commission must, save in the circumstances mentioned at the end of that paragraph, issue the 'consent in writing allowing the product to be placed on the market.

57. ...where the national court finds that, owing to irregularities in the conduct of the examination of the notification by the competent national authority provided for in Article 12(1) of Directive 90/220, it was not proper for that authority to forward the dossier with a favourable opinion to the Commission as provided for in paragraph (2) of that provision, that court must refer the matter to the Court of Justice for a preliminary ruling if it considers that those irregularities are such as to affect the validity of the Commission's favourable decision, if necessary ordering the suspension of application of the measures for implementing that decision until the Court of Justice has ruled on the question of validity.

Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients

Art.1.2. This regulation shall apply to the placing on the market within the Community of foods and food ingredients which have not hitherto been used for human consumption to a significant degree within the Community and which fall under the following categories:

(a) foods and food ingredients containing or consisting of genetically modified organisms within the meaning of Directive 90/220/EEC;

(b) foods and food ingredients produced from, but not containing, genetically modified organisms;

Art.3.1, Regulation No 258/97

Foods and food ingredients falling within the scope of this regulation must not:

- present a danger for the consumer,
- mislead the consumer,
- differ from foods or food ingredients which they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for the consumer.

Article 8(1) ... the following additional specific labelling requirements shall apply to foodstuffs in order to ensure that the final consumer is informed of:

(a) any characteristic or food property such as:

- composition,

- nutritional value or nutritional effects,

- intended use of the food,

which renders a novel food or food ingredient no longer equivalent to an existing food or food ingredient.

A novel food or food ingredient shall be deemed to be no longer equivalent for the purpose of this article if scientific assessment, based upon an appropriate analysis of existing data, can demonstrate that the characteristics assessed are different in comparison with a conventional food or food ingredient, having regard to the accepted limits of natural variations for such characteristics.

the labelling must indicate the characteristics or properties modified, together with the method by which that was obtained;

- EC Recommendation 97/618/EC concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation No 258/97
- Section 3, point 3.3: the concept of substantial equivalence has been introduced by WHO and OECD with particular reference to foods produced by modern biotechnology. In the terminology of the OECD, the concept of substantial equivalence embodies the idea that existing organisms used as foods or as food sources can serve as a basis for comparison when assessing the safety of human consumption of a food or food component that has been modified or is new. If a new food or food component is found to be substantially equivalent to an existing food or food component, it can be treated in the same manner with respect to safety, keeping in mind that establishment of substantial equivalence is not a safety or nutritional assessment in itself, but an approach to compare a potential new food with its conventional counterpart.

- The application of the principle of substantial equivalence can be extended to the evaluation of foods from novel sources and processes. Substantially equivalent [novel foods and novel food ingredients] are thus comparable, in terms of safety, to their conventional counterpart. Substantial equivalence may be established either for the whole food or food component including the introduced new change, or it might be established for the food or food component except for the specific new change introduced. If a [novel food or novel food ingredient] has not been found to be substantially equivalent to an existing food or food component, this does not imply that it is unsafe. It just indicates that such a [novel food or novel food ingredient] should be evaluated on the basis of its unique composition and properties.

- In response to Commission Decision 98/292/EC of 22 April 1998 concerning the placing on the market of genetically modified maize (*Zea mays* L. line Bt-11 and Commission Decision 98/294/EC of 22 April 1998 concerning the placing on the market of genetically modified maize (*Zea mays* L. line MON 810), the French authorities and the UK authorities gave their consent for the placing on the market of genetically modified maize grain of the line Bt-11 - a genetic modification rendering the maize resistant to insects, and MON 810 - a genetic modification providing the maize with increased tolerance to a herbicide.

- On 10 December 1997, 30 January 1998 and 14 October 1998, notifications under the simplified procedure for placing novel foods or novel food ingredients on the market, laid down in Article 5 of Regulation No 258/97 were made to the Commission by or on behalf of certain companies.
- Those notifications related to the placing on the market of novel foods or novel food ingredients derived from the maize lines Bt-11, MON 810 and MON 809 (hereinafter the novel foods), such as cornflour.

- Those notifications were accompanied by opinions delivered in September 1996 by the Advisory Committee on Novel Foods and Processes (hereinafter the ACNFP), a competent body within the meaning of Articles 3(4) and 4(3) of Regulation No 258/97 established in the United Kingdom, and sent to the undertakings concerned by the United Kingdom authorities by letter of 14 February 1997. In the opinions, the ACNFP essentially concluded that the derived foods in question were substantially equivalent to products derived from conventional maize and were safe for use in food.
- Those notifications were subsequently forwarded to the Member States and published in summary form in the *Official Journal of the European Communities* (OJ 1998 C 200, p. 16 and OJ 1999 C 181, p. 22).
- The Commission and the Member States had agreed within the framework of the Standing Committee for Foodstuffs no longer to apply the simplified procedure to novel foods derived from GMOs which contain transgenic protein, with effect from January 1998.

- By letters of 23 November 1998, 4 February 1999 and 2 April 1999 to the Commission, the Italian health ministry alleged that the use of the simplified procedure for the purpose of placing on the market novel foods or novel food ingredients derived from maize lines Bt-11, MON 809 and MON 810 was improper. The ministry asked to see the documentation relating to that procedure, as well as the toxicological and allergenicity assessments.
- By letter of 23 December 1999 sent to the member of the Commission in charge of health and consumer protection the ministry, referring to a report by the association Verde Ambiente e Società and relying in addition on an opinion by the Consiglio superiore de sanità (Italian federal board of health) of 16 December 1999, again raised an objection to the use of the simplified procedure in the present case on the ground, *inter alia*, that the novel foods were not substantially equivalent to existing foods.

- According to that letter, preventive measures had to be taken to ensure that the novel foods were safe and that their potential health risks were rigorously assessed before they were placed on the market. The ministry also asked the Commission to reconsider allowing free circulation of those foods and, more generally, the adequacy of the simplified procedure for the purpose of excluding any risk to consumer health.
- By letter of 10 March 2000, the President of the Commission replied that it had been adequately established in the present case that the condition of substantial equivalence was satisfied and that recourse to the simplified procedure was therefore justified.
- By letter of 5 June 2000 to the President of the Commission and the competent Commissioner, the ministry repeated its objection to the use of the simplified procedure in the present case and, in addition, expressed the wish that the procedure no longer be used for transgenic foods because of the ambiguity of the concept of substantial equivalence.

Monsanto Agricoltura Italia & Ors [2003] EUECJ C-236/01 (09 September 2003) ECJ

Decree of the President of the Council of Ministers of 4 August 2000 on the precautionary suspension of the trade in and use of certain transgenic products within national territory under Article 12 of Regulation No 258/97 (GURI No 184 of 8 August 2000, p. 9) (hereinafter the Decree of 4 August 2000) states:

1. Trade in and use of the transgenic maize products Bt-11, MON 810 and MON 809 ... shall be suspended in accordance with the preamble.

The first question

49. By its first question, the national court essentially asks whether the first subparagraph of Article 3(4) of Regulation No 258/97 is to be interpreted as meaning that the presence in novel foods of residues of transgenic protein at certain levels precludes those foods from being considered substantially equivalent to existing foods and, consequently, use of the simplified procedure for placing those novel foods being placed on the market.

70. For the purpose of the simplified procedure, the condition of substantial equivalence set out in the first subparagraph of Article 3(4) of Regulation No 258/97 is assessed either on the basis of the available and generally recognised scientific evidence or, as was the case in the main proceedings, by scientific bodies which specialise in assessment of the risks generated by novel foods

The first question

71. This is a condition for applying that procedure which, if satisfied and in so far as the novel food concerned belongs to one of the categories of food which can be the subject of the procedure - a matter that is for the national court to determine as regards the foods at issue in the main proceedings - means that the risk assessment provided for under the normal procedure is not required.

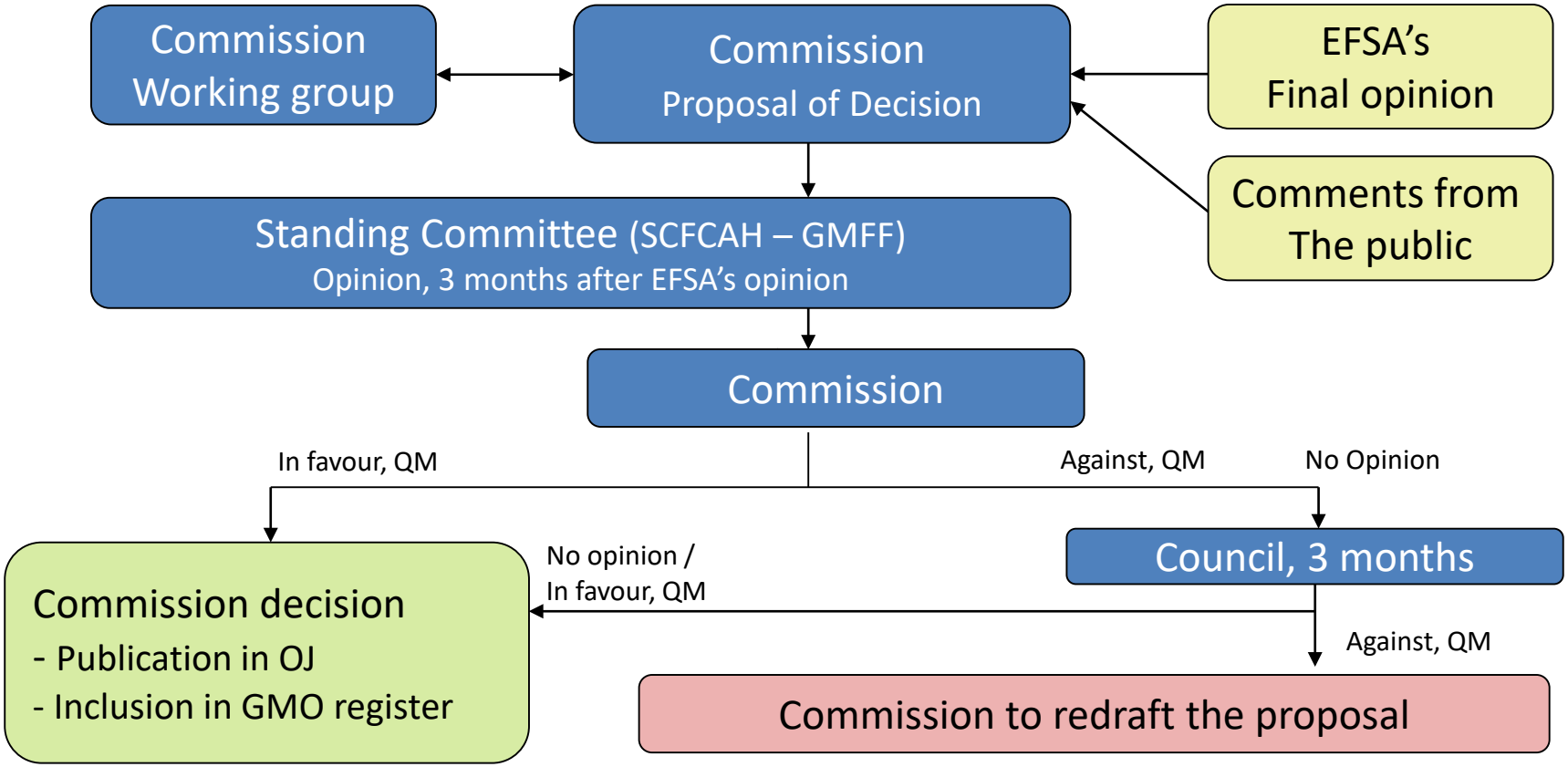
80. Since the protection of public health is a fundamental objective of Regulation No 258/97, the concept of substantial equivalence cannot be interpreted in such a way that the simplified procedure, which according to the wording of the first subparagraph of Article 3(4) of that regulation is in the nature of a derogation, amounts to a relaxation of the safety requirements which must be met by novel foods

81. As to the unpredictable effects on human health which the insertion of foreign genes may produce, if such effects were identifiable as a danger to human health according to available scientific evidence at the time of the initial examination by the competent body, they would have to be subject to a risk assessment, and a finding of substantial equivalence would therefore be excluded.

84. The answer to the first question must be that the first subparagraph of Article 3(4) of Regulation No 258/97 must be interpreted as meaning that the mere presence in novel foods of residues of transgenic protein at certain levels does not preclude those foods from being considered substantially equivalent to existing foods and, consequently, use of the simplified procedure for placing those novel foods on the market. However, that is not the case where the existence of a risk of potentially dangerous effects on human health can be identified on the basis of the scientific knowledge available at the time of the initial assessment. It is for the national court to determine whether that condition is satisfied.


EFSA: GMO Applications - Microsoft Internet Explorer fourni par Belgacom Skynet
Fichier Edition Affichage Favoris Outils ?
Précédente
Rechercher
Favoris
Média
Adresse
http://www.efsa.europa.eu
http://efsa.europa.eu
Panels & Units GMO
efsa
European Food Safety Authority
Committed to ensuring that Europe's food is safe
About EFSA
News
Scientific Documents
Panels & Units
GMO Applications
Home > Panels & Units > GMO > GMO Applications
AHAW
AMU
ANS
BIOHAZ
CEF
CONTAM
DATEX
EMRISK
FEEDAP
GMO
About us
Topics A-Z
Panel members
Panel meetings
Working Groups
Meetings with Member States
Scientific Documents
Guidance
GMO Applications
Requests & mandates
NDA
PLH
GMO Applications
Under European legislation, all GMOs and derived products must be evaluated by EFSA before they can
be authorised in the EU. For any GMO and derived food or feed to be authorised in the
must submit an authorisation application in line with European legislation. The Europ
forwards the application to EFSA and requests a scientific risk assessment. EFSA's G
out a detailed risk assessment to evaluate the safety of the GMO and derived food or f
independent scientific advice is then used by the Commission and Member States wh
decision on market approval.
Since 18 April 2004, Genetically Modified Food and Feed applications are regulated i
Community under Regulation (EC) 1829/2003. It provides for a single Community proc
authorisation. The European Food Safety Authority (EFSA) is responsible for the scient
genetically modified food and feed.
More detailed information on each application, including status, question numbers an
available through the Register of Question.
Page précédente
Page suivante
Enregistrer l'arrière-plan sous...
Établir en tant qu'élément d'arrière-plan
Copier l'arrière-plan
Définir comme élément du Bureau...
Sélectionner tout
Coller
Créer un raccourci
Ajouter aux Favoris...
Afficher la source
Codage
Imprimer
Actualiser
Exporter vers Microsoft Excel
Propriétés

Authorisation procedure after EFSA opinion



EUROPA - Food Safety - Biotechnology - GM Food & Feed - Introduction - Mozilla Firefox

File Edit View History Bookmarks Tools Help

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

Hotmail Personnaliser

EUROPA - Food Safety - Biotechn... er Acceptance of Genetically ....

http://eu.europa.eu/food

Food Safety - From the Farm to the Fork

English

EUROPA > European Commission > DG Health and Consumer Protection > Overview > Food and Feed Safet

Index | Mailbox

General Food Law Animal Nutrition Labelling & Nutrition Biotechnology Novel Food Chemical Safe

ersion

GM Food & Feed - Introduction

Biotechnology

GM Food & Feed

Community Register of GM Food and Feed

The search tool makes it possible to look for all products corresponding to a search criteria entered in the field. e.
all products containing *cotton* in their description. The search searches both in the Community register of GM produ
Regulation (EC) 1829/2003 and the Products subject to Commission Decisions on withdrawal from the market.

Search:

search

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) MON-Ø1445-2 **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) MON-15985-7 **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) MON-15985-7 x MON-Ø1445-2 **Monsanto**	Genetically modified cotton that contains: **cry1Ac** and **cry2Ab2** genes inserted to confer insect-resistance highly selective in controlling Lepidopteran insects **cp4 epsps** gene inserted to confer tolerance to the herbicide glyphosate	Food additives produced from MON15985 x MON1445 cotton	Renewal of authorisation ongoing	
		Feed produced from MON15985 x MON1445 cotton (feed materials and feed additives)	Renewal of authorisation ongoing	
Cotton (MON531) MON-ØØ531-6 **Monsanto**	Genetically modified cotton that contains: **cry1A(c)** gene inserted to confer insect-resistance	Food produced from MON 531 cotton (cottonseed oil)	18/12/2011	
		Food produced from MON 531 cotton (food additives)	Renewal of authorisation ongoing	
		Feed produced from MON 531 cotton (feed materials and feed additives)	Renewal of authorisation ongoing	

Resources
- Speeches
- Press Releases
- Health & Consumer Voice Newsletter
- Committees
- Links

International Affairs
- Organisations
- Codex
- OIE
- Import Conditions
- Pets and Animal Welfare
- Enlargement
- Agreements

Menu
- GM Register Introduction

Authorised products
- Cotton (MON1445)
- Cotton (MON15985)
- Cotton (MON15985 x MON1445)
- Cotton (MON531)
- Cotton (MON531 x MON1445)
- Maize (Bt11)
- Maize (DAS1507)
- Maize (GA21)
- Maize (MON810)
- Maize (MON863)
- Maize (MON863 x NK603)

http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=6

démarrer eMule v0... EUROPA ... 2 Explo... GMO Co... 2 Micro... VuePrint ... FR 18:25

Genetically Modified Organisms (Contained Use) Regulations 2000 (UK)

6.—(1) No person shall undertake any activity involving genetic modification of microorganisms unless, before commencing that activity, he has ensured that a suitable and sufficient assessment of the risks created thereby to human health and the environment has been carried out.

(2) The person carrying out an assessment required by paragraph (1) shall take into account the matters set out in Part I of, and include the steps set out in Part II of, Schedule 3.

Schedule 3 Part I, Matters to be taken into account in carrying out an assessment for the purposes of Regulation 6

(a) any potentially harmful effects, in particular those associated with—

(i) the recipient micro-organism,

(ii) the inserted genetic material (originating from the donor organism),

(iii) the vector,

(iv) the donor micro-organism (where that donor micro-organism is used during the activity involving genetic modification), and

(v) the resulting genetically modified micro-organism;

(b) the characteristics of the activity;

(c) the severity of the potentially harmful effects; and

(d) the likelihood of the potentially harmful effects being realised.

Schedule 3 Part I, Matters to be taken into account in carrying out an assessment for the purposes of Regulation 6

2. In paragraph 1, “potentially harmful effects” includes—

(a) disease to humans including allergenic or toxic effects;

(b) disease to animals or plants;

(c) adverse effects resulting from the inability to treat disease or offer an effective prophylaxis;

(d) adverse effects resulting from establishment or dissemination of the genetically modified microorganisms in the environment;

(e) adverse effects resulting from the natural transfer of genetic material to or from other organisms;

(f) adverse effects resulting from the likely interaction of the genetically modified micro-organism with other organisms at the premises where the activity involving genetic modification is to be conducted.

Risk assessment of activities involving genetically modified organisms other than microorganisms

7.—(1) No person shall undertake any activity involving genetic modification of organisms other than micro-organisms unless, before commencing that activity, he has ensured that a suitable and sufficient assessment of the risks created thereby to human health has been carried out.

(2) The person carrying out an assessment required by paragraph (1) shall take into account the matters set out in Part I of, and include the steps set out in Part II of, Schedule 4.

The Genetically Modified Food (England) Regulations 2004

The Secretary of State, in exercise of the powers conferred on him by sections 16(1)(a), (e) and (f), 17(2), 18(1), 26(1) and (3) and 48(1) of the Food Safety Act 1990 and now vested in him and having had regard in accordance with section 48(4A) of that Act to relevant advice given by the Food Standards Agency, and after consultation both as required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety and in accordance with section 48(4) and (4B) of that Act, makes the following Regulations:

Offences and Penalties

5. - (1) Any person who, after the date on which these Regulations come into force, contravenes or fails to comply with the specified Community provision referred to in Part I of the Schedule shall be guilty of an offence and liable -

(a) on summary conviction to imprisonment for a term not exceeding six months or to a fine not exceeding the statutory maximum; or

(b) on conviction on indictment to imprisonment for a term not exceeding two years or to a fine or to both.

THE SCHEDULE
SPECIFIED COMMUNITY PROVISIONS

PART I

Provision of Regulation 1829 /2003	*Subject Matter*
Article 4.2	Prohibition on placing on the market a food referred to in Article 3.1 unless it is covered by an authorisation and satisfies relevant conditions of the authorisation.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which apply to England, provide for the enforcement and execution of certain specified provisions (relating to food) of Regulation (EC) No. 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (OJ No. L268, 18.10.2003, p.1). Separate Regulations make provision for the enforcement of those provisions of Regulation (EC) No. 1829/2003 relating to animal feed.

In particular these Regulations -

(a) formally designate the Food Standards Agency as the national competent authority to receive applications for the authorisation of new genetically modified organisms for food use, food containing or consisting of genetically modified organisms, or food produced from or containing ingredients produced from genetically modified organisms *(regulation 3)*;

(b) provide for food authorities to enforce the provisions of these Regulations and Chapter II of Regulation (EC) No. 1829/2003 *(regulation 4)*;

(c) establish penalties for failing to comply with certain specified provisions of Regulation (EC) No. 1829/2003, once the Regulations are in force *(regulation 5 and the Schedule)*;

(d) apply various provisions of the Food Safety Act 1990 with some modifications in their application for the purposes of these Regulations *(regulations 6 and 7)*;

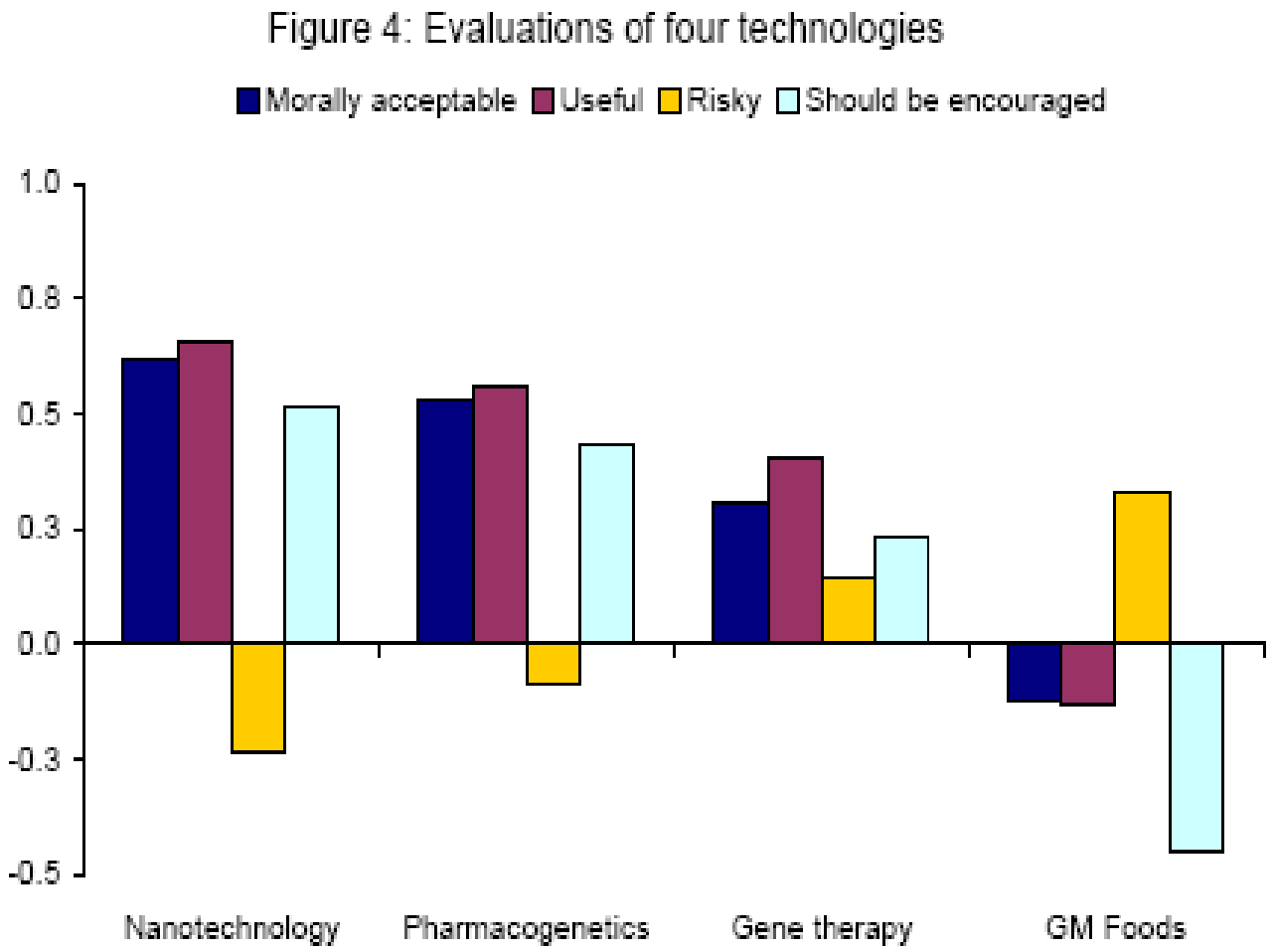
(e) revoke the Genetically Modified and Novel Foods (Labelling) (England) Regulations 2000 *(regulation 8)*;

(f) make consequential amendments to the Novel Foods and Novel Food Ingredients Regulations 1997 and to the Food (Provisions Relating to Labelling) (England) Regulations 2003 *(regulation 9)*.

A Regulatory Impact Assessment has been prepared and placed in the Library of each House of Parliament. Copies may be obtained from the Novel Foods, Food Supplements and Additives Division of the Food Standards Agency, Aviation House, 125 Kingsway, London WC2B 6NH.

The societal debate

Eurobarometer 64.3 (2006)



Greenpeace blasted for GM vandalism

Updated July 15, 2011 07:36:23

Scientists have condemned Greenpeace for destroying a trial crop of genetically modified (GM) wheat in Canberra.

Scientists say the destruction of the trial crop in Canberra's north yesterday is not only reprehensible, but also hypocritical.

CSIRO genetically modified the wheat to enhance its nutritional value, and it was to be used in the first human trials in Australia.

It was also Australia's first outdoor crop trial of the enhanced wheat.

Greenpeace protesters used string trimmers to destr
entire crop of GM wheat.

Related Story: Greenpeace destroys GM wheat
Map: Canberra

But Greenpeace says it took the dramatic action to destroy the crop using whipper-snippers because of health concerns, the risk of cross-contamination and the secrecy surrounding the trial.

Professor of Plant Science at the University of Adelaide Mark Tester says the technology is poorly understood and Greenpeace's attack was irresponsible.

Monsanto Plc v Tilly & Ors [1999] EWCA Civ 3044

In about June 1998 a number of people founded GenetiX Snowball (GXS).

GXS is an unincorporated association. The object of GXS is to campaign against GM plants and crops and those, like Monsanto, who are engaged in their research, development and production, to the end that in the first instance the Government should impose a five year moratorium on the growth of GM crops in Britain except in an enclosed environment from which there cannot be an escape of genetic material or pollen and eventually a banning of all such crops so that those who produce them must destroy them.

the central method of advancing GXS' campaign is by what is somewhat euphemistically called 'non-violent action' of pulling up the GM crops. GXS issue a 'Handbook for Action'. This is issued to those who ask for it for a price of £3.50. It runs to some one hundred pages and amongst other things describes how an attack on a particular site where GM crops are growing is to be carried out.

All farmers who grow the crops and all those like Monsanto who are responsible for their development are told of the campaign and that the crops are liable to attack; but they do not know when or where it will take place. One of the essential elements of the campaign is publicity; care therefore is taken to alert the press in advance that such an action will take place; they are invited to attend a rendezvous from where they are led to the site of the attack, where it is hoped that they will photograph and publicise the uprooting of the crops and any measures taken by the police to restrain those doing so.

Hitherto each person taking part in such an action has undertaken not to uproot more than 100 plants; but there is some indication in recent press releases that this limit is to be abolished.

The first such attack occurred on Saturday 4 July 1998 at a farm at Shirburn in Oxfordshire. The first six defendants attended and defendants one to five pulled up varying numbers of plants up to 100 each. The 6th defendant was present as media liaison officer, supporting the action of the other defendants.

- Monsanto issued a writ endorsed with a Statement of Claim complaining of the action at Shirburn. An interlocutory injunction was granted on the next day by Jowitt J.
- On 21 January 1999 Monsanto issued a summons under RSC Order 14 for summary judgment seeking to make permanent the interlocutory injunction on the grounds that there was no defence to the claim.
- This is an appeal to the Court of Appeal

- The arrangements between the farmer and Monsanto are governed by a standard form of agreement. The seed is the property of Monsanto; the drilling, spraying and co-ordination of the trial is done by Monsanto's contractor. More importantly it is provided that 'the crop resulting from the tests are all the property of Monsanto'. This is clearly sufficient to enable Monsanto to maintain the action for trespass both on sites which they do not own as well as those they do.
- The pleading of the public interest defence is exigious and lacking in particularity. The defendants were claiming to protect those in the vicinity of the crops, such as organic farmers whose crops might be cross-pollinated, thereby losing their organic status and organic bee-keepers who would be similarly affected if their bees sucked the GM crops. But they were also claiming to protect the wider public. Indeed the three respondents who appeared in person are convinced that the crops present a danger to mankind in general and farmers in the Third World in particular.

The respondents are anxious to have a full trial at which they desire to call experts who will support the various dangers alleged to exist. If they do establish them, presumably on a balance of probability, then it is said their actions are justified. But a moment's reflection shows that the issue is incapable of being tried in a court with our adversarial system of justice. Mr Gordon submitted that it would be necessary for the court to conduct some sort of balancing exercise to see whether the law breaking in question was proportionate to the danger. Thus pulling up a number of GM plants might be justified, but blowing up Monsanto's chemical plant might not. The law would be setting itself a task which no court could possibly answer nor could the outcome of the case possibly be predicted by lawyers. So that it would be impossible to advise in any case whether the defence of justification would succeed. The truth is in my judgment that the respondents wish to have the benefit of advancing their views in the forum of the court, with all its attendant publicity, not because it can amount to a defence, but because it is an admirable opportunity to proselytise their views.

GM SCIENCE REVIEW

SECOND REPORT

An open review of the science relevant to GM crops and food based on interests and concerns of the public

PREPARED BY THE GM SCIENCE REVIEW PANEL (JANUARY 2004)

The GM Science Review Panel's First Report was published on 21 July 2003 and attracted wide public and media interest, with over 20,000 copies downloaded from the Review website.

The second phase of the GM Science Review had three main purposes:

- to consider the issues raised in the Public Debate held in the summer of 2003 in the context of our First Report;
- to address new scientific developments that had taken place since the publication of our First Report, including the publication of the GM Herbicide-Tolerant Crop Farm-Scale Evaluations (FSEs) on 16 October 2003; and
- to consider reactions to the First Report received by letter and through the Review website and to consider to what extent these altered our conclusions.

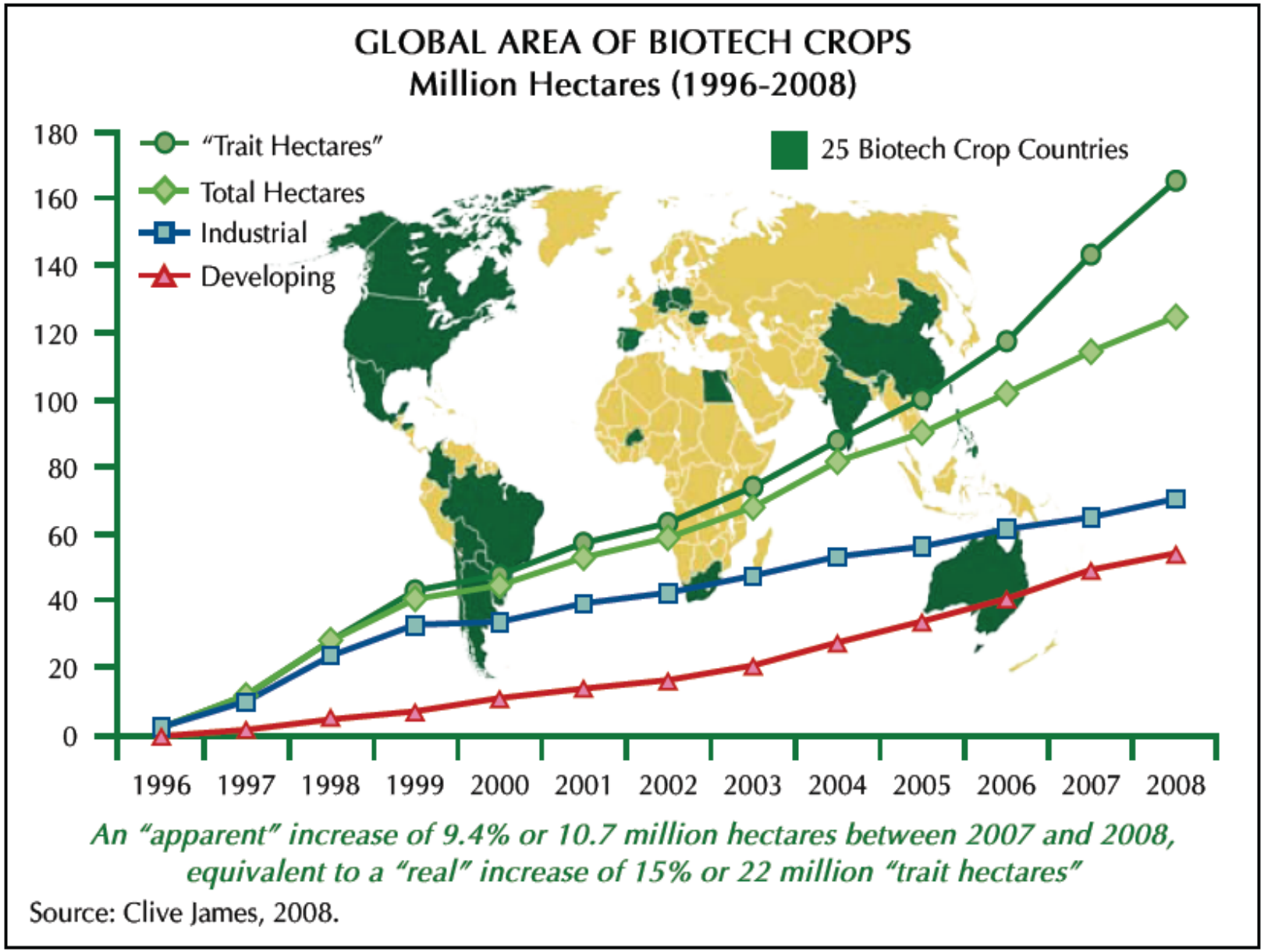
CHAPTER 5: THE SAFETY OF FOOD AND ANIMAL FEED DERIVED FROM GM CROPS

Possible nutritional and toxicological differences in GM food

Summary conclusions from First Report

'All novel food in the UK, which includes food produced by GM organisms, is subject to an EU-based and internationally determined regulatory regime, with procedures for safety assessment and risk analysis. The regime recognises that the consumption of food is not risk free and requires any novel (including GM) food to be at least as safe and nutritious as any traditional food it replaces or complements.

To date world-wide there have been no verifiable untoward toxic or nutritionally deleterious effects resulting from the cultivation and consumption of products from GM crops. However, absence of readily observable adverse effects does not mean that these can be completely ruled out and there has been no epidemiological monitoring of those consuming GM food.


GLOBAL AREA OF BIOTECH CROPS
Million Hectares (1996-2008)
"Trait Hectares"
Total Hectares
Industrial
Developing
25 Biotech Crop Countries
180
160
140
120
100
80
60
40
20
0
1996
1997
1998
1999
2000
2001
2002
2003
2004
2005
2006
2007
2008
An "apparent" increase of 9.4% or 10.7 million hectares between 2007 and 2008,
equivalent to a "real" increase of 15% or 22 million "trait hectares"
Source: Clive James, 2008.

European legislation concerning mandatory GMO labelling

Applicable regulatory provisions:

→ Regulation n°1829/2003: GM food and feed

→ Regulation n°1830/2003: Traceability and labelling of GMOs

Others:

→ Commission Report on the implementation of Regulation n°1829/2003 of the 25 Oct. 2006

→ Regulation n°1831/2003 on feed additives

→ Regulation n°834/2007 on organic production and labelling of organic products

Reg. No 1830/2003 of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms

Art.3.1. ‘Genetically modified organism’ or ‘GMO’ means genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex IB to Directive 2001/18/EC;

Directive 2001/18/EC
Definition of a GMO Art.2(2)

Genetically Modified Organism (GMO) means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination

The following techniques are **not considered to result in**

genetic modification:

- in vitro fertilisation;
- natural processes such as conjugation, transduction and transformation;
- polyploidy induction

Article 4 **Traceability and labelling requirements for products consisting of or containing GMOs**

[Art.3.3 3. ‘Traceability’ means the ability to trace GMOs and products produced from GMOs at all stages of their placing on the market through the production and distribution chains]

4.1. At the first stage of the placing on the market of a product consisting of or containing GMOs, including bulk quantities, operators shall ensure that the following information is transmitted in writing to the operator receiving the product:

(a) that it contains or consists of GMOs;

(b) the unique identifier(s) assigned to those GMOs in accordance with Article 8.

Article 5, **Traceability requirements for products for food and feed produced from GMOs**

1. When placing products produced from GMOs on the market, operators shall ensure that the following information is transmitted in writing to the operator receiving the product:

(a) an indication of each of the food ingredients which is produced from GMOs;

(b) an indication of each of the feed materials or additives which is produced from GMOs;

(c) in the case of products for which no list of ingredients exists, an indication that the product is produced from GMOs.

Article 8, **Unique identifiers**

...the Commission shall:

(a) prior to the application of Articles 1 to 7 establish a system for development and assignment of unique identifiers to GMOs;

(b) adapt the system provided for in point (a), as appropriate.

In so doing, account shall be taken of developments in international fora.

Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms

Article 2 1. Applications for the placing on the market of GMOs shall include a unique identifier for each GMO concerned.

2. Applicants shall, in accordance with the formats set out in the Annex, develop the unique identifier for each GMO concerned, following consultation of the OECD BioTrack product database, and the Biosafety clearing house, to determine whether or not a unique identifier has already been developed for that GMO in accordance with these formats.

Annex, Formats For Unique Identifiers

The Annex below defines the format for the unique identifier for plants in Section A and for micro-organisms and animals in Section B.

SECTION A

1. Overall format

This Annex provides details as to the format to be used for unique identifiers for GMOs pending or authorised for the placing on the market under Community legislation. The format consists of three components comprising a number of alphanumeric digits and providing reference to the applicant/consent holder, transformation event and a means for verification.

The format comprises nine alphanumeric digits in total. The first component represents the applicant/consent holder and comprises two or three alphanumeric digits. The second component comprises five or six alphanumeric digits and represents the transformation event. The third component provides for verification and is represented by a final numerical digit.

The following provides an example of a unique identifier developed using this format. >PIC FILE= "L_2004010EN.000802.TIF">

Labelling, Art.6

For products consisting of or containing GMOs, operators shall ensure that:

(a) for pre-packaged products consisting of, or containing GMOs, the words ‘This product contains genetically modified organisms’ or ‘This product contains genetically modified [name of organism(s)]’ appear on a label;

(b) for non-pre-packaged products offered to the final consumer the words ‘This product contains genetically modified organisms’ or ‘This product contains genetically modified [name of organism(s)]’ shall appear on, or in connection with, the display of the product.

This paragraph shall be without prejudice to other specific requirements in Community legislation.

C. EXEMPTIONS

7. Paragraphs 1 to 6 shall not apply to traces of GMOs in products in a proportion no higher than the thresholds established in accordance with Article 21(2) or (3) of Directive 2001/18/EC and in other specific Community legislation, provided that these traces of GMOs are adventitious or technically unavoidable.
8. Paragraphs 1 to 6 shall not apply to traces of GMOs in products intended for direct use as food, feed or for processing in a proportion no higher than the thresholds established for those GMOs in accordance with Articles 12, 24 or 47 of Regulation (EC) No 1829/2003, provided that these traces of GMOs are adventitious or technically unavoidable.

LABELLING RULES

Regulation n° 1830/2003

- Article 4: products **consisting** or **containing GMOs**:

  → mandatory indication that the product contains GMOs or consists in GMOs.

  EXCEPT if GMOs < 0.9 %

- Article 5: products developed **from GMOs** :

  → mandatory indication that each raw material or feed additive produced from GMOs

  EXCEPT if GMOs < 0.9 %

Commission report of 25 Oct. 2006 :

- § 11. **CLARIFICATIONS RELATED TO SOME ASPECTS OF THE LABELLING PROVISION OF THE REGULATION**

  GM free labelling scheme (p. 28)

  "*2)* Food products that can be genetically modified or not: Such food can be placed on the market without a GM label provided that they contain less than 0.9 % of GM material and that the presence of GM material is unintentional and technically unavoidable. **For these foods, a GM free labelling can not be excluded a priori**."

Council Regulation (EC) No 1139/98 of 26 May 1998 concerning the compulsory indication of the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC

Article 1.1. This Regulation shall apply to foods and food ingredients which are to be delivered as such to the final consumer (hereinafter referred to as 'the specified foodstuffs`) produced, in whole or in part, from:

- genetically modified soya beans covered by Decision 96/281/EC,
- genetically modified maize covered by Decision 97/98/EC.

. The additional specific labelling requirements shall be the following:

(a) where the food consists of more than one ingredient, the words 'produced from genetically modified soya` or 'produced from genetically modified maize`, as appropriate, shall appear in the list of ingredients provided for by Article 6 of Directive 79/112/EEC in parentheses immediately after the name of the ingredient concerned. Alternatively, these words may appear in a prominently displayed footnote to the list of ingredients, related by means of an asterisk (*) to the ingredient concerned. Where an ingredient is already listed as being produced from soya or maize the words 'produced from genetically modified` may be abbreviated to 'genetically modified`; if the abbreviated form of words is used as a footnote, the asterisk shall be directly attached to the word 'soya` or 'maize`. Where either form of words is used as a footnote, it shall have a typeface of at least the same size as the list of ingredients itself;

(b) in the case of products for which no list of ingredients exists, the words 'produced from genetically modified soya` or 'produced from genetically modified maize`, as appropriate, shall appear clearly on the labelling of the food;

(c) where in accordance with the provisions of the first indent of Article 6(5)(b) of Directive 79/112/EEC an ingredient is designated by the name of a category, that designation shall be completed by the words 'contains . . . (*) produced from genetically modified soya/genetically modified maize.

Codacons e.a. (Approximation of laws) [2005] EUECJ C-132/03

By judgment of 14 May 2002, the Tribunale amministrativo regionale del Lazio annulled Decree No 371/2001 to the extent to which it provided that the presence of GMOs in a proportion not exceeding 1% of the ingredients making up baby foods for infants and follow-on formulae, caused by adventitious contamination, need not be indicated on the labelling of such food and formulae.

Article 3(2) of Italian Decree No 128 of the President of the Republic of 7 April 1999 implementing Directives 96/5 and 98/36/EC on processed cereal-based foods and baby foods for infants and young children (GURI No 109, of 12 May 1999, p. 5, -Decree No 128/1999-) provides:

-- The foodstuffs in question - shall not contain pesticide residues in excess of 0.01 mg/kg nor shall they contain genetically modified substances.-

Article 4(1) of Decree No 500 of the Minister for Health of 6 April 1994 ... provides:

-Infant formulae shall be manufactured from protein sources defined in the annexes to Decree No 128/1999 and in accordance with the requirements which they contain, and from other food ingredients whose suitability for particular nutritional use by infants from birth has been established by generally accepted scientific data.-

31 Decree No 371/2001 added the following sentence to Article 4(1) of Decree No 500/1994:

-In any case, the use of products derived from [GMOs] is excluded, subject to any derogation provided for by Regulation (EC) No 49/2000.-

Codacons e.a

- taking the view that an interpretation of Regulation No 1139/98 of 26 May 1998 concerning the compulsory indication on the labelling of certain foodstuffs produced from genetically modified organisms of particulars was necessary in order for it to reach a decision in the main action, the Consiglio di Stato decided to stay the proceedings and to refer the following question to the Court for a preliminary ruling:
- Must Article 2(2)(b) of Regulation -? No 1139/98 -? apply also to baby foods for infants and for young children of up to three years of age, and, more specifically, in relation to such products, must the adventitious contamination by material derived from [GMOs] in a proportion of no more than 1% be indicated on the labelling?-?

49 Regulation No 1139/98 in fact applies only to certain foodstuffs, namely those obtained wholly or in part from certain genetically modified soya beans or certain genetically modified types of maize, referred to in Article 1(1) of the regulation.

50 As regards the Community legislation on foodstuffs intended for a particular nutritional use, more specifically use by infants and young children, it follows from Article 4 of Directive 89/398 that the Commission is responsible for adopting specific directives with, in particular, provisions regarding the labelling, presentation and advertising of certain products including infant formulae, follow-up milk and other follow-up foods and baby foods.

53 It follows from Article 7(1) and (4) of Directive 89/398, interpreted in keeping with the fourth recital in the preamble thereto, that labelling requirements such as those laid down by Regulation No 1139/98 apply in principle to foodstuffs intended for particular nutritional uses within the scope of the directive, namely those which are intended to meet a particular nutritional purpose in respect of certain categories of persons, unless it is necessary to provide for a derogation from those requirements in order to ensure that the particular nutritional purpose in question is attained.

55 Accordingly, in the absence of any indication to the contrary arising from the wording, the context or the purpose of Article 2(2)(b) of Regulation No 1139/98, that provision must be interpreted as meaning that the exemption for which it provides from the specific labelling requirements laid down by the regulation also applies to foodstuffs intended for the particular nutritional use of infants and young children, to whom Directive 89/398 refers.

56 That interpretation cannot be called into question on the basis of the precautionary principle.

63 The GMOs to which Regulation No 1139/98 refers can be placed on the market only if they have first been authorised following a risk assessment intended to ensure that, in the light of the conclusions of the assessment, they are safe for the consumer. The precautionary principle, where relevant, is part of such a decision-making process.

64 In view of all of the foregoing, the answer to the question referred must be that Article 2(2)(b) of Regulation No 1139/98 is to be interpreted as meaning that the exemption for which it provides from the obligation, laid down in Article 2(1) and (3) of that regulation, to state on the labelling of foodstuffs that material derived from certain GMOs is present, where such presence is the result of adventitious contamination and does not exceed a *de minimis* threshold of 1%, also applies to foodstuffs intended for the particular nutritional use of infants and young children.

UK Food Standards Agency (discussed in *Friends of the Earth, R (on the application of) v Food Standards Agency* [2007] EWHC 558)

- The FSA was created by the Food Standards Act 1999 in the wake of the BSE problem. Its functions are set out at sections 6 and 7:

6(1) The Agency has the function of- (a) developing policies (or assisting in the development by any public authority of policies) relating to matters connected with food safety or other interests of consumers in relation to food; and (b) providing advice, information or assistance in respect of such matters to any public authority." From section 7:

7(1) The Agency has the function of- (a) providing advice and information to the general public in respect of matters connected with food safety or other interests of consumers in relation to food; (b) providing advice, information or assistance in respect of such matters to any person who is not a public authority.

8(1) The Agency has the function of monitoring the performance of enforcement authorities in enforcing relevant legislation.

(2) That function includes, in particular, setting standards of performance (whether for enforcement authorities generally or for particular authorities) in relation to the enforcement of any relevant legislation.

...

(4) The Agency may make a report to any other enforcement authority on their performance in enforcing any relevant legislation; and such a report may include guidance as to action which the Agency considers would improve that performance.

(5) The Agency may direct an authority to which such a report has been made- (a) to arrange for the publication in such manner as may be specified in the direction of, or of specified information relating to, the report; and (b) within such period as may be so specified to notify the Agency of what action they have taken or propose to take in response to the report.

- The FSA published general objectives (Oct. 2000) Paras 14 and 15 deal with the Agency's approach to risk and encapsulated this case

14. We will develop and publish our approach to risk. In essence, we will maintain a policy based on the following principles. We undertake to adopt a consistent approach in all our decisions and actions. We will make decisions and take action that is proportionate to the associated risk.

In doing so we will take due account of the nature and magnitude of the risks involved, to the costs and benefits of proposed actions, to the information provided by the relevant independent advisory committees and to any other appropriate sources of expertise.

Decisions will be based on sound scientific advice, and we will commission programmes of research and surveillance specifically targeted to addressing our policy aims and objectives.

- "14. We will develop and publish our approach to risk. In essence, we will maintain a policy based on the following principles. We undertake to adopt a consistent approach in all our decisions and actions. We will make decisions and take action that is proportionate to the associated risk.
- In doing so we will take due account of the nature and magnitude of the risks involved, to the costs and benefits of proposed actions, to the information provided by the relevant independent advisory committees and to any other appropriate sources of expertise.

- “15. We recognise that there is often uncertainty in the science underlying our decisions and we shall explain these uncertainties and make sure it is clear how we have taken them into account. Where there is a risk of serious damage to public health, we will adopt a precautionary approach by acting quickly to implement appropriate measures to reduce health risks. Scientific certainty is rarely achieved in practice and we will not allow the absence of certainty to delay proportionate action. Equally, we will not use the absence of scientific certainty as an excuse for taking action other than that needed to protect public health and well being. Such action will be reviewed if new evidence becomes available.

This claim for judicial review by way of declaration against FSA concerns its lack of action following Emergency Decisions (ED) of the European Commission in respect of imported American long grain rice (LGR) which was found to be contaminated with a genetically modified organism (GMO) called LLRICE601.

It was claimed that, although immediate and sensible steps were taken by the FSA to stop rice coming into the country and to prevent distribution by the mills, there was a great deal of such imported rice already in circulation or on the market since the problem had in fact been discovered in the US as early as January of 2006.

Because rice has a two year sell-by date, there is, it is claimed, an ongoing risk that contaminated stocks may be on supermarket or other shelves or in restaurants, schools, prisons and the like. In particular, the claimant points to the fact that of the members of the European Union the UK took, in the last whole year recorded, 45% of the import of LGR from the US and had by a few months into last year taken some 41% of the total US import.

Per Calvert Smith J. ...in my judgment there must be a margin within which an agency such as the defendant has to be allowed to make its own decisions and even, to some extent, its own mistakes without attracting legal sanction.

The Rice Products from the United States of America (Restriction on First Placing on the Market) (Scotland) Regulations 2008

3.–(1) No person shall first place on the market any rice product unless-

(a)the conditions specified in Article 2(1) of the Commission Decision are complied with in relation to that product; and

(b)arrangements have been made to ensure compliance with the conditions specified in Article 2(2) of the Commission Decision in relation to that product.

(2) Any person who knowingly contravenes the prohibition in paragraph (1) is guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale, to imprisonment for a term not exceeding three months or to both.

Explanatory Note
(This note is not part of the Regulations)

These Regulations which extend to Scotland only, implement Commission Decision 2006/601/EC on emergency measures regarding the non-authorised genetically modified organism "LL RICE 601" in rice products (O.J. No. L 244, 7.9.2006, p.27) as amended by Commission Decision 2006/754/EC amending Decision 2006/601/EC on emergency measures regarding the non-authorised genetically modified organism "LL RICE 601" in rice products and by Commission Decision 2008/162/EC amending Decision 2006/601/EC on emergency measures regarding the non-authorised genetically modified organism "LL RICE 601" in rice products (O.J. No. L 52, 27.2.2008, p.25).

These Regulations provide (a) that no person shall first place on the market any "rice product" (defined in regulation 2(1)), except where it is accompanied by-

(a)a statement from the food business operator responsible for the consignment that the product only contains rice, from the 2007 or a subsequent harvest, that was subject to the plan of the USA Rice Federation aiming to remove "LL Rice 601" from the US export channels, and

(b)and the original of an analytical report issued by a laboratory referred to in Annex II to the Commission Decision confirming that the product does not contain the genetically modified rice "LL RICE 601"; that report must itself be accompanied by an official document issued by the Grain Inspection, Packers and Stockyards Administration of the United States Department of Agriculture in accordance with the protocol described in that Annex, and

(b)provide that a person who knowingly contravenes that prohibition is guilty of an offence and prescribe penalties for that offence (regulation 3(2))

The Feed (Corn Gluten Feed and Brewers Grains) (Emergency Control) (England) Regulations 2005

1. These Regulations, which apply in relation to England only, implement Commission Decision 2005/317/EC on emergency measures regarding the non-authorised genetically modified organism Bt 10 in maize products (OJ No. L101, 21.4.2005, p.14).
2. The Regulations –
(a) prohibit the first placing on the market of certain maize products originating from the United States of America (defined as "controlled products" in regulation 2(1)) unless, as required by Article 2 of Commission Decision 2005/317/EC, it can be demonstrated that the products do not contain Bt 10 maize or feed produced from Bt 10 maize (*regulation 3(1)*);
(b) make it an offence to breach that prohibition (*regulation 3(2)*);
.....

European regulation concerning **positive claims**

In the texts: NOTHING formally. Several indications though…

* * *

► Two difficulties to be solved :

- the issue of the **threshold** of adventitious or technically unavoidable presence of GMOs
- the use of feed additives and technological auxiliaries produced **with the help of GMOs**

► The THRESHOLD :

Commission report of 25 Oct. 2006 :

- § 11. **CLARIFICATIONS RELATED TO SOME ASPECTS OF THE LABELLING PROVISION OF THE REGULATION**

  GM free labelling scheme (p. 28)

  "*2)* Food products that can be genetically modified or not: Such food can be placed on the market without a GM label provided that they contain less than 0.9 % of GM material and that the presence of GM material is unintentional and technically unavoidable. **For these foods, a GM free labelling cannot be excluded a priori**."

The Genetically Modified Organisms (Traceability and Labelling) (England) Regulations 2004

2. - (1) In these Regulations -

"the Council Regulation" means Regulation (EC) No. 1830/2003 of the European Parliament and of the Council concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC;

Incorrectly labelled products

7. - (1) Where an inspector is satisfied that a product consisting of or containing genetically modified organisms has not been labelled in accordance with article 4(6) of the Council Regulation he may by notice in writing served on the operator -

(a) prohibit the placing on the market of the product until it has been correctly labelled;
(b) where the product has been placed on the market prior to the date of the notice, require the withdrawal of the product within such period as the inspector may reasonably believe to be necessary;
(c) prohibit the removal of the product from the premises described in the notice other than to enable the product to be labelled correctly; or
(d) require the product to be labelled in accordance with the Council Regulation within such period as the inspector may reasonably believe to be necessary.

Offences

8. - (1) It shall be an offence for a person -

(a) to contravene, or to fail to comply with, any specified Community provision;

....

(f) knowingly or recklessly to make a statement or furnish any information that is false or misleading in a material particular where the statement is made or the information is furnished in purported compliance with -

....

(2) It shall be a defence for a person charged with an offence under regulation 8(1)(a) to prove that he took all reasonable precautions and exercised all due diligence to avoid the commission of the offence by himself or by a person under his control.

Positive claims in member States

In GERMANY

"Gesetz zur Änderung des Gentechnikgestezes…"

► Adopted on the 1 April 2008 - came into force on 30 May 2008

THE CONTENT OF THE LAW

Article 2 § 3a:

► "Ohne Gentechnik" (without biotechnology) is the only mention allowed.

► For FOOD: no GM material at all (0.1% ? – level of quantification).

► For FEED: 0.9 % of adventitious or technically unavoidable presence.

► Additives and technological auxiliaries, if obtained with the help of GMOs: authorization delivered by the European Commission on ground of Regulation n° 834/2007 (on organic agriculture) is needed.

► Burden of proof of non-GMO content on economic operators.

► No restriction for veterinary medicines obtained with the help of GMOs.

6. Feeding periods without GMOs before transformation in foodstuff

Nr.	Race	Period
1	Horse family and steer for production of meat	12 months and, in any case, less than ¾ of their life
2	Small ruminants	6 months
3	Pigs	4 months
4	Milk producers animals	3 months
5	Poultry for production of meat	10 weeks
6	Poultry for production of eggs	6 weeks

OHNE GENTECHNIK!

“Bei Wiesenhof hat Gentechnik keine Chance”

“With Wiesenhof GMOs don’t have any chance”

AUSTRIA:
Richtlinie zur Definition der “Gentechnikfreien Produktion”

► Adopted the 6th of dec. of 2007 - Entry into force : the 6 of march of 2008

The CONTENT of the law

► **All kinds of claims are admitted** (bred without GMO, GMO-Free, without GMOs…)

►**THRESHOLD : 0,9%**

► **Supply chain operators must require mutual “confirmations” of the absence of GMOs from each other.**

► Full **segregation** of the branches of production (with or without GMOs)

► strong risk assessment (IP system with documented traceability)

► additives, technological auxiliaries, aromas, enzymes, etc. : special procedure (authorization of the “Codex Commission”)

► concerning stock breeding and aquaculture,
NO GMO from the birth.

BUT there are **exceptions** and **transitory provisions** (5 years):

- horse family and steer: 12 months before marketing
- pigs : total period of fattening
- milk producers animals : 2 weeks
- poultry for production of eggs : 6 weeks
- aquaculture: total period of fattening

Commission Recommendation 2004/787/EC of 4 October 2004

On technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003