

SIXTH FRAMEWORK PROGRAMME
THEMATIC PRIORITY 5
FOOD QUALITY AND SAFETY



ResistVir

Co-ordination of Research on genetic resistance to plant Pathogenic Virus,
and their Vectors in European Crops

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Summary

This report provides an in-depth review of the existing standards, legislation, ethical issues, codes of practice, regulations, and intellectual property issues, pertaining to the safe use of GM and traditionally-bred virus/vector resistant crops in the Republic of Ireland. The report provides the template for the reports currently being produced for selected other EU Member States. This report will feed into the work to be carried out under Task 4.2 and help in the production of the final report (D39).

Legislation, Technology Practices and Intellectual Property Rights Issues Report

Introduction

This report provides an account of the regulation of genetically modified and traditionally bred virus resistant crops in Ireland. As genetic modification of food crops is by far the more prominent public concern, this report has focussed on the regulations affecting the transport, use, distribution and marketing of genetically modified material.

EU legislation on Genetically Modified Organisms (GMOs) has been in place since the early 1990s and aims to ensure that GMOs and GMO-derived products that are grown, marketed and imported into the EC meet the strict standards of safety for the environment, as well as for human and animal health, whilst ensuring the effective functioning of the internal market. GMOs are defined in the legislation as “an organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination”¹.

Genetic Engineering in Ireland

Ireland has a strong biotechnology sector in which some 170 national and multinational companies are represented. Biotechnology is an important technology for industrial development, and is associated with traditional sectors such as brewing, distilling, agri-business and food, as well as with high-tech processes such as the manufacture of healthcare and diagnostic products, pharmaceuticals and fine chemicals. A significant level of expertise in higher level academic institutions has been built up since the 1980s, so that a skilled graduate workforce is available to attract inward investment.

The national biotechnology programme encourages research and assists in the transfer of biotechnology from third level academic institutions to industrial activity. BioResearch Ireland, established by the Government in 1987, works with Irish universities to assist in the commercial development and application of biotechnology research results. BioResearch Ireland now has five university based biotechnology centres around the country. These research and technical services to the food, diagnostic, agri-industry, pharmaceutical and other bio-related industries².

GMO Authorisations Under EU Law

What is the EU regulatory framework for GMO authorisation?

Genetically modified organisms (GMOs) and genetically modified micro-organisms (GMMs) can be defined as organisms (and micro-organisms) in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating or natural recombination.

Three main legal texts constitute EU framework on genetically modified organisms (GMO).

¹ http://www.fsai.ie/legislation/food/legislation_gmos.asp

² Department of the Environment and Local Government Consultation paper on a national policy position on the deliberate release of genetically modified organisms to the environment

1. The first one contains the rules regarding the deliberate release of GMOs into the environment (Directive 2001/18/EC, which replaces Directive 90/220/EEC). This Directive is applicable since 17 October 2002. 18 GMOs have been approved under Directive 90/220/EEC for different uses, some for cultivation, some for import and processing, some as feed, some as food. In terms of crops species, these GMOs include maize, oil seed rape, soybean and chicory.
2. The second is a Regulation on GM Food and Feed (Regulation (EC) No 1829/2003) which is in force since 7 November 2003 and will have to be applied after a transitional period as of April 2004. It replaces the GM part of Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients.
Already, products from 16 GMOs can legally be marketed in the EU. These are:
 - One GM soy and one GM maize approved under Directive 90/220/EEC prior to the entering into force of the Novel Food Regulation;
 - Processed foods derived from inter alia 7 GM oilseed rape, 4 GM maize and oil from 2 GM cottonseeds. These products have all been notified as substantially equivalent in accordance with the Novel Food Regulation.
3. The third is a Regulation on traceability and labelling of GMOs and traceability of food and feed produced from GMOs (Regulation (EC) No 1830/2003) laying down comprehensive traceability requirements for GMOs as well as food and feed produced from GMOs. The Regulation enters into force on 7 November 2003.³

Regulating GMOs in Ireland

The Department of the Environment, Heritage and Local Government along with the enforcement body, the Environmental Protection Agency (EPA) is responsible for the environmental aspects of GM technology including deliberate releases of GM crops in field trials and for the placing on the market of GM crops for general cultivation purposes. The seed certification division of the Department of Agriculture and Food (DAF) co- operates with the EPA in respect of GM seed regulation while the animal feed section of DAF regulates GM feed. The use of GMOs in medicines and pharmaceuticals is the responsibility of the Irish Medicines Board while the FSAI regulates the use of GMOs in food, including agriculture.

Approval of New GMO Products for Environmental Release and Placing on the Market

Twenty one applications for the placing on the market of GMOs have been submitted into the authorisation procedure under Directive 2001/18/EC, e.g. maize, oil seed rape, sugar beet, soy beans, cotton, rice, fodder beet. Eleven of these applications have scopes restricted to import and processing, while the remainder also include cultivation as a requested use. The procedure for authorisation as specified under Part C of Directive 2001/18/EC is divided into three main periods.

- (i) A national period where the lead Competent Authority (CA) has up to 90 days, from the date of receipt of the application, to prepare and submit an assessment report. During this 90-day period the 'clock' can be stopped if the lead CA is awaiting additional information from the notifier to complete the notification, thus extending the deadlines.

³ MEMO/03/221 Brussels, 7 November 2003

- (ii) A Community period, which comprises a 105-day period, which can be subdivided into two phases. During the first 60 days, the competent authorities of Member States can raise reasoned objections to the application. The final 45 days of the 105-day period is akin to a conciliation-type step, where the Commission, lead and objecting competent authorities can try and reach agreement.
- (iii) Consultation of the European Food Safety Authority (EFSA) if objections based on environmental or human health considerations are not withdrawn by all Member States at the end of the above 45-day period. The EFSA is required to provide an opinion within 90 days.

The most advanced of the above 21 applications in the procedure is the Monsanto NK603 GM maize, which is currently being reviewed by EFSA (step iii). This application is for import and processing. It does not include cultivation as a requested use. An EFSA opinion is expected on 4 December 2003 in line with the 90-day deadline.

Directive 2001/18/EC requires the Commission to adopt a Decision following consultation of the Member States in a Regulatory Committee. Taking account of the above EFSA deadline and the necessary administrative procedures, the Commission held a meeting of the Regulatory Committee in early February of 2004.

A further application (Monsanto GT73 oilseed rape) is shortly to be formally submitted to the EFSA for evaluation and an opinion is expected early in 2004. The scope of this application is also limited to import and processing. The remaining applications are currently being appraised by national authorities under periods (i) and (ii) above. It should be noted that the clock can be stopped at various stages in the procedure, where further information is requested from the applicant, effectively extending the deadlines and making it difficult to predict a time-scale for possible approval of these products⁴.

⁴ MEMO/03/221 Brussels, 7 November 2003

European Legislation Regulating GMOs in Ireland

Risk assessment

All EU regulatory requirements related to the release of GMOs are based on an environmental risk assessment specified in the Deliberate Release Directive. In all cases of releases of GMOs, this assessment is mandatory. It must be carried out by the notifier, i.e. the person or body seeking consent for a proposed release, and it must address potential risks to human health and the environment. The assessment and its evaluation by the competent authority are the core appraisal elements of a deliberate release notification from a safety point of view.

The main elements of risk assessment and evaluation as practised in Member States are as follows:

- 1 . Identify hazards associated with the GMO,
- 2 . Consider environment in which GMO(s) will be released and intended conditions of release; estimate extent of consequences for each hazard,
- 3 . Consider environment in which GMO(s) will be released and intended conditions of release; estimate likelihood that each hazard will occur,
- 4 . Use results of steps 2 and 3 to estimate risk for each hazard,
- 5 . Consider those hazards which cause risk; if risk is not at an acceptable level, adjust their impact by altering conditions of release or the GMO itself and repeat steps 2, 3 and 4, and
- 6 . Consider risks from all hazards and evaluate overall risk of adverse effects to human health and the environment. Where a specific risk or a degree of uncertainty exists, appropriate risk management techniques will be required to prevent adverse effects on people or the environment. In the event that available management techniques are incapable of protecting human health and the environment, consent may be refused by the competent authority.

The current proposal to amend the Deliberate Release Directive includes a measure to significantly strengthen the risk assessment process by making explicit provision for a common approach to be followed in each case. This approach, which will be formalised in an Annex to the amended Directive, will reflect international guidelines and consensus on safety in biotechnology⁵.

The following is a list of the significant European legislation concerning the regulation of GMOs in Ireland:

- Council Directive 90/219/EEC (OJ L117, p1, 08/05/1990) of 23 April 1990 on the contained use of genetically modified micro-organisms.

Amended by:

- Council Directive 98/81/EC (OJ, L330, p13, 05/12/1998) of 26 October 1998 amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms

⁵ Department of the Environment and Local Government Consultation paper on a national policy position on the deliberate release of genetically modified organisms to the environment

Supplemented by

- Council Decision 2001/204/EC (OJ L73, p32, 15/03/2001) of 8 March 2001 supplementing Directive 90/219/EEC as regards the criteria for establishing the safety, for human health and the environment, of types of genetically modified micro-organisms
- Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC
- Commission Regulation (EC) No 65/2004 (OJ L10,p5, 16/01/2004) of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms
- Directive 90/219/EEC, as amended, regulates research and industrial work activities involving genetically modified micro-organisms (GMMs) under conditions of containment. This includes work activities in laboratories.
- Directive 2001/18 on the deliberate release into the environment of genetically modified organisms is a ‘horizontal’ Directive, which regulates experimental releases and the placing on the market of GMOs.

Irish Statutory Instruments Regulating the Use of GMOs

The Deliberate Release Directive has been given effect in Irish law under the Genetically Modified Organisms (GMO) Regulations, 1994 and the Environmental Protection Agency (EPA) is the competent authority - essentially, the body responsible for administering the legislation at national level. However, certain functions under the Directive relate to matters which may ultimately entail decisions by the European Council of Environment Ministers, e.g., proposals to market genetically modified products on which the Member State competent authorities fail to agree. These limited but important functions are fulfilled by the Minister for the Environment and Local Government under the provisions of the directive.

The Regulations, *inter alia*:

- Express relevant provisions of the Directive in Irish law; in general these concern regulatory procedures,
- Designate the EPA as national competent authority,
- Introduce a control system for R&D releases of GMOs,
- Introduce procedures for processing notifications for consent to place genetically modified products on the EU market,
- Specify fees and other charges payable to the EPA,
- Provide for maintenance by the EPA of a public register of release notifications,
- Provide for enforcement action by the EPA, including powers to prosecute offences, and
- Enable the EPA to appoint an Advisory Committee on GMOs.

Under the provisions of the EU and national legislation already in place, a person or body cannot proceed with the deliberate release of a GMO in Ireland unless the

appropriate competent authority has granted prior consent. The current requirements are as follows:

In the case of proposed R&D releases (primarily field trials) in this country, consent must be obtained from the EPA under the GMO Regulations, 1994,

In the case of proposals to place products (other than food products) containing live GMOs on the open market, EU-wide consent must be obtained under the Deliberate Release Directive. In such cases, a notification seeking consent may be submitted to the competent authority of any Member State of the EU, and in the case of food products (including ingredients) containing live GMOs or produced using genetic modification techniques, consent must be obtained under the EU Regulation on novel foods for which the Department of Health and Children is responsible. Under the Deliberate Release Directive, consent to place a product containing or consisting of GMOs on the EU market can only be granted provided the product has satisfactorily completed the R&D stage or undergone an environmental risk assessment similar to the one provided for in the Directive. Procedures for the marketing of products operate at Community as well as national level, since consent granted by the competent authority of any Member State is valid for the whole Community. In these circumstances, consent by a competent authority must have the agreement of the competent authorities in all Member States. Where agreement is not reached at competent authority level, Member State procedures, which may involve reference to the EU Council of Environment Ministers, apply⁶.

The following is a list of the significant Irish Statutory Instruments concerning the regulation of GMOs in Ireland:

- *Genetically Modified Organisms Regulations, 1994* (S.I. No. 345 of 1994)
- *Genetically Modified Organisms (Amendment) Regulations, 1997* (S.I. No. 332 of 1997)
- *Genetically Modified Organisms (Contained Use) Regulations, 2001* (S.I. No. 73 of 2001)
- *Genetically Modified Organisms (Deliberate Release) Regulations, 2003* (S.I. No. 500 of 2003)

Regulating GMO Food in Ireland

In Ireland the Food Safety Authority is the competent authority for GM foods while the Department of Health and Children (DoHC) is responsible for policy matters. As competent authority, the FSAI enforces GM food regulations and in doing so monitors the Irish market to ensure that only EU-authorized GM foods are on the market and that they are labelled appropriately.

European Legislation Regulating GMO Food in Ireland

The following is a list of the significant European legislation concerning the regulation of food containing GMOs in Ireland:

Regulation 1829/2003 (OJ L268, p1, 18/10/2003) of 22 September 2003 on genetically modified food and feed. (Implementing measure)

⁶ Department of the Environment and Local Government Consultation paper on a national policy position on the deliberate release of genetically modified organisms to the environment.

Commission Regulation 641/2004 (OJ L102, p14, 07/04/2004) of 6 April 2004 on the detailed rules for the implementation of Regulation 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation.

Regulation 1830/2003 (OJ L268, p24, 18/10/2003) of the 22 September 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.

These Regulations applied from April 2004 and replaced parts of the novel food Regulation 258/97 and Regulations Regulation (EC) 1139/98, 49/2000 and 50/2000. Regulation 1829/2003 on genetically modified food and feed covers:

- (a) GMOs for food use/feed use
- (b) food/feed containing or consisting of GMOs
- (c) food/feed produced from or containing ingredients produced from GMOs

The Regulation lays down Community procedures for the authorisation and supervision of GMO food and feed and also lays down provisions for the labelling of GMO food and feed. The Regulation stipulates that GM food must not:

- Have adverse effects on human health, animal health, or the environment;
- Mislead the consumer;
- Differ from the food which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer

No person shall place on the market a GMO for food use or food unless it is covered by an authorisation granted in accordance with the Regulations and the relevant conditions are satisfied. The application procedure is set out in the Regulations. To date (May 04) food derived from 17 GM events have been approved in Europe, these are mainly products derived from oilseed rape, maize and cottonseed oil. A list of these GM foods can be found on the EU website at: http://europa.eu.int/comm/food/food/biotechnology/authorisation/list_author_gmo_en.pdf

There are a number of GMO foods pending authorisation at present and this list can be accessed at:

http://europa.eu.int/comm/food/food/biotechnology/authorisation/app_pend_en.pdf

Approval of New GMO Products as Food

Article 46(1) of the Regulation 1829/2003 on GM Food and Feed provides that applications for the authorisation of a GM food made under the Novel Foods Regulation which have received a final scientific assessment before the coming into application of the new Regulation are still to be processed under the Novel Foods Regulation. Authorisation for a GM food will include labelling and traceability

provisions as required by the new law. There are currently eight GM products pending authorisation under the Novel Food Regulation e.g. maize, soybean and sugar beet. The scientific risk assessment has been completed for two of the applications, a GM sweet maize from Syngenta (Bt11) and a GM field corn from Monsanto (GA21).

An opinion with regard to the draft decision to authorise Bt11 under the conditions as specified above could be expressed as early as Monday 10 November or at the next meeting in December by the representatives of the Member States in the Standing Committee of the Food Chain and Animal Health by qualified majority. If no qualified majority is obtained, the decision will be referred to Council. Council has three months to act and to adopt or reject the proposed decision with qualified majority. Council could also decide not to act. In this case it will be upon the Commission to take a decision. EFSA is currently evaluating an application from Monsanto concerning a GM maize line (NK603); the ESFA opinion is expected in December. The Commission is preparing the request for advice from the EFSA on two other maize lines from Monsanto (MON 863 and MON 810 X MON863). In both cases, the Commission has to await the advice from the EFSA before proceeding with these applications.

The four remaining applications are currently in the first stage of the authorization process and are still undergoing risk assessment by a competent authority in a Member State. It is therefore difficult to predict when these products would be ready for authorisation.

GMO PRODUCTS

APPROVED UNDER DIRECTIVE 90/220/EEC

Product	Notifier	Date of Commission Decision ¹ / Member State Consent ²
1. Vaccine against Aujeszky's disease	Vemie Veterinär Chemie GmbH	18.12.92
2. Vaccine against rabies	Rhône-Mérieux C/B/92/B28 & C/F/93/03-02	19.10.93
3. Tobacco tolerant to bromoxynil	SEITA C/F/93/08-02	08.06.94
4. Vaccine against Aujeszky's disease (further uses) ³	Vemie Veterinär Chemie GmbH C/D/92/I-1	18.07.94
5. Male sterile swede rape resistant to glufosinate ammonium (MS1, RF1) <u>Uses</u> : breeding activities	Plant Genetic Systems C/UK/94/M1/1	06.02.96
6. Soybeans tolerant to glyphosate <u>Uses</u> : import and processing	Monsanto C/UK/94/M3/1	03.04.96
7. Male sterile chicory tolerant to glufosinate ammonium <u>Uses</u> : breeding activities	Bejo-Zaden BV C/NL/94/25	20.05.96
8. Bt-maize tolerant to glufosinate ammonium (Bt-176)	Ciba-Geigy C/F/94/11-03	23.01.97
9. Male sterile swede rape tolerant to glufosinate ammonium (MS1, RF1) ⁴ <u>Uses</u> : import and processing	Plant Genetic Systems C/F/95/05/01/A	06.06.97 (not finally approved by F)

¹ where objections were raised by Member State authorities

² in the absence of objections by Member State authorities

³ linked to item 1 (same product, further uses)

⁴ linked to item 5 (same product, further uses)⁷

⁷ MEMO/03/221 Brussels, 7 November 2003

Product	Notifier	Date of Commission Decision ⁵ / Member State Consent ⁶
10. Male sterile swede rape tolerant to glufosinate ammonium (MS1, RF2) ⁷	Plant Genetic Systems C/F/95/05/01/B	06.06.97 (not finally approved by F)
11. Test kit to detect antibiotic residues in milk	Valio Oy C/F/1/96-1NA	14.07.97
12. Carnation lines with modified flower colour	Florigene C/NL/96/14	01.12.97 (MS consent)
13. Swede rape tolerant to glufosinate ammonium (Topas 19/2) <u>Uses</u> : import and processing	AgrEvo C/UK/95/M5/1	22.04.98
14. Maize tolerant to glufosinate ammonium (T25)	AgrEvo C/F/95/12/07	22.04.98
15. Maize expressing the Bt <i>cryIA(b)</i> gene (MON 810)	Monsanto C/F/95/12-02	22.04.98
16. Maize tolerant to glufosinate ammonium and expressing the Bt <i>cryIA(b)</i> gene (Bt-11) <u>Uses</u> : import and processing	Novartis (formerly Northrup King) C/UK/96/M4/1	22.04.98
17. Carnation lines with improved vase life	Florigene C/NL/97/12	20.10.98 (MS consent)
18. Carnation lines with modified flower colour	Florigene C/NL/97/13	20.10.98 (MS consent)

⁵ where objections were raised by Member State authorities

⁶ in the absence of objections by Member State authorities

⁷ this product is the result of a different transformation event to that of No. 9⁸

⁸ MEMO/03/221 Brussels, 7 November 2003

Labelling and Public Choice

The adequacy of the current labelling provisions under the Community regulatory framework on modern biotechnology, including the Deliberate Release Directive, has emerged as a major issue of concern for all interests. From a consumer point of view, the information currently being provided is inadequate to facilitate clear choices on whether or not to purchase products containing GMOs or products produced using genetic modification techniques. For businesses involved in the marketing of genetically modified products, current labelling requirements lack clarity and consistency.

The labelling provisions of the Deliberate Release Directive were improved in 1997 and products containing GMOs which are placed on the EU market on the basis of consent granted under this Directive must indicate the presence of GMOs.

However, in the case of mixed products, i.e. those containing genetically modified and conventional material, labelling to the effect that they "may contain GMOs" is adequate for the purposes of the Directive. There is a general level of dissatisfaction throughout the EU with the labelling of products on the basis that they "may contain GMOs". As a result, the further use of this labelling option was rejected by Member States in a decision on 26 May 1998 related to labelling requirements for certain genetically modified maize and soya products.

In its proposal to amend the Deliberate Release Directive, the Commission has proposed amending current labelling requirements to bring them into line with a general policy position on the labelling of genetically modified products, which it adopted in July 1997. The approach to labelling in the proposal to amend the Directive is based on the following three categories;

- Voluntary labelling ("this does not contain.....") for certified non-GMO products,
- Mandatory labelling ("this contains.....") for products known to be of GMO origin, and
- Mandatory labelling ("this may contain.....") in cases where material of GMO origin cannot be excluded but where no evidence of such material is available. However, the position taken by Member States on 26 May 1998 is likely to influence the debate on this aspect of the overall amendment proposal. The labelling debate is linked to the issue of whether or not it is necessary, feasible and viable to segregate genetically modified products from conventional (non-modified) products.

Ultimately, consumers should and will decide whether or not they wish to consume products either containing GMOs or produced using genetic modification techniques, provided they are given adequate and clear information to do so. The Minister for the Environment and Local Government has, on a number of occasions, stated his commitment to securing maximum transparency under the Deliberate Release Directive and this position will form the basis of his participation in the negotiations on this particular aspect of the current proposal to amend the Directive⁹.

⁹ Department of the Environment and Local Government Consultation paper on a national policy position on the deliberate release of genetically modified organisms to the environment

Legislation Regarding the Labelling of GM Food

Regulation 1829/2003 sets out specific labelling requirements for foods, which are to be delivered as such to the final consumer or mass caterers and which:

- (a) Contain or consist of GMOs; or
- (b) Are produced from or contain ingredients produced from GMOs

Specific GM labelling under 1829/2003 is not required if a food contains, consists of or is produced from GMOs in a proportion not higher than 0.9 per cent of the food ingredients considered individually, provided that this presence is adventitious or technically unavoidable. In order to establish that the presence of this material is adventitious or technically unavoidable, operators must be in a position to supply evidence to satisfy competent authorities that they have taken appropriate steps to avoid the presence of such material.

Without prejudice to the other requirements of Community law concerning the labelling of foodstuffs, foods which contain or consist of GMOs or which are produced from or contain ingredients produced from GMOs shall be subject to the following specific labelling requirements:

- (a) Where the food consists of more than one ingredient, the words ‘genetically modified’ or ‘produced from genetically modified (name of the ingredient)’ shall appear in the list of ingredients provided for in Article 6 of Directive 2000/13/ EC in parentheses immediately following the ingredient concerned;
- (b) Where the ingredient is designated by the name of a category, the words ‘contains genetically modified (name of organism)’ or ‘contains (name of ingredient) produced from genetically modified (name of organism)’ shall appear in the list of ingredients;
- (c) Where there is no list of ingredients, the words ‘genetically modified’ or ‘produced from genetically modified (name of organism)’ shall appear clearly on the labelling;
- (d) The indications referred to in (a) and (b) may appear in a footnote to the list of ingredients. In this case they shall be printed in a font of at least the same size as the list of ingredients. Where there is no list of ingredients, they shall appear clearly on the labelling;
- (e) Where the food is offered for sale to the final consumer as non-pre-packaged food, or as pre-packaged food in small containers of which the largest surface has an area of less than 10 cm², the information required must be permanently and visibly displayed either on the food display or immediately next to it, or on the packaging material, in a font sufficiently large for it to be easily identified and read.

In addition to the above labelling requirements, the labelling shall also mention any characteristic or property, as specified in the authorisation (the procedure for authorisation is set out in Articles 5, 6 & 7 of Regulation 1829/2003), in the following cases:

- (a) Where a food is different from its conventional counterpart as regards the following characteristics or properties:

- (i) Composition;
 - (ii) Nutritional value or nutritional effects;
 - (iii) Intended use of the food;
 - (iv) Implications for the health of certain sections of the population;
- (b) Where a food may give rise to ethical or religious concerns.

The labelling of foods falling within the scope of this Regulation, which do not have a conventional counterpart, shall contain appropriate information about the nature and the characteristics of the foods concerned.

Regulation (EC) 1830/2003 requires that 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.*

LABELLING OF GM-FOOD AND GM-FEED – EXAMPLES ⁸

GMO-type	EXAMPLE	Labelling Required at present	Labelling required in future
GM plant	Chicory ⁹	Yes	Yes
GM seed	Maize seeds	Yes	Yes
GM food	Maize, Soybean sprouts, Tomato	Yes	Yes
Food produced from GMOs	Maize flour ¹⁰	Yes	Yes
	Highly refined maize oil, soybean oil, rape seed oil ¹¹	No	Yes
	Glucose syrup produced from maize starch ¹¹	No	Yes
Food from animals fed on GM feed	Eggs, meat, milk	No	No
Food produced with the help of a GM enzyme	bakery products produced with the help of amylase	No	No
Food additive/flavouring produced from GMOs	Highly filtered lecithin extracted from GM soybeans used in chocolate ¹¹	No	Yes
GM Feed	Maize ¹²	Yes	Yes
Feed produced from a GMO	Corn gluten feed, Soybean meal	No	Yes
Feed additive produced from a GMO	Vitamin B2 (riboflavin)	No	Yes

⁸ The examples include foods, which have not been authorised for marketing in the EU.

⁹ One chicory has been approved for breeding purposes under Directive 90/220/EC, but not for food use

¹⁰ DNA or protein of GM origin detectable in the final product.

¹¹ DNA or protein of GM origin not detectable in the final product.

¹² The current labelling rules entered into force in 1997, and do not include four GMOs approved prior to that date.¹⁰

¹⁰ MEMO/03/221 Brussels, 7 November 2003

Traceability for Products Consisting of or Containing GMOs

Traceability requirements for food produced from GMOs is set out in Regulation (EC) 1830/2003 which requires that the labelling of such products is in accordance with the requirements of Regulation (EC) No 1829/2003 so as to ensure that accurate information is available to operators and consumers to enable them to exercise their freedom of choice in an effective manner as well as to enable control and verification of labelling claims.

Under Regulation 1830/2003 business operators must transmit and retain information about products that consist of or contain GMOs at each stage of the placing on the market of the product. Under Article 4, 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 of the Regulation

Where there is a lot identification system in place, except for the first placing on the market, the transmission of information is not necessary (see Article 6, 1830/2003) Operators shall have in place systems and standardised procedures to allow the holding of information and the identification of the operator by whom and the operator to whom the products have been made available¹¹.

Commission Regulation 65/2004 establishes a system for the development and assignment of unique identifiers for genetically modified organisms and applies to GMOs authorised for the placing on the market. The format for unique identifiers is set out in the Annex to this Regulation.

Scientific and Technical Issues of Public Concern

Based on practical experience in the operation of the Deliberate Release Directive since 1991, key scientific/technical issues of public concern regarding the deliberate release of GMOs to the environment have been identified as follows:

- (a) The use of antibiotic resistant genes as markers to identify organisms which have been successfully modified; concerns in this regard include:
 - The possibility of affecting the usefulness of antibiotics which are important in human and veterinary medicine, e.g. ampicillin;
 - A theoretical possibility of antibiotic resistant genes transferring from genetically modified plants to soil micro-organisms in nature, thus increasing the pool of antibiotic resistant micro-organisms in the environment, and the possibility of antibiotic resistant genes transferring to other (non-soil) organisms, including micro-organisms;

¹¹ http://www.fsai.ie/legislation/food/legislation_gmos.as

- The possibility of antibiotic resistant genes being transferred (accidentally or otherwise) into organisms, which are pathogenic to humans, animals or plants. Transfer to pathogenic micro organisms could compromise the effect of antibiotic therapy and is an area of particular concern;
 - Whether the use of such genes is necessary at all and, in cases where they are used, whether they could and should be deleted once they have served their primary function.
- (b) Releasing plants which have been genetically modified to make them resistant to specific herbicides; concerns in this regard include:
- The possibility that seeds shed during harvesting could grow as weeds in future crops and, apart from being a nuisance, would be difficult to control. The problem would be exacerbated if a subsequent crop also had tolerance to the same herbicide (e.g. through genetic modification) although this could be reduced through crop rotation;
 - The possibility that herbicide resistant crops could lead to the spread of resistance to other crops and/or related weed species or wild species, or that gene transfer between plants with tolerance to different herbicides could lead to plants, including weeds, developing multiple tolerance and creating serious control difficulties;
 - The commercialisation of herbicide tolerant crops could lead to an increased and/or more widespread use of candidate herbicides with associated environmental risks;
 - The possibility of creating new metabolites and residues;
 - The implications of specific herbicide resistance for the number of useful herbicides currently available;
 - The effect of this area of genetic modification in potentially contributing to continued use and dependence on chemicals for weed control.
- (c) Releasing plants with an introduced *Bt* toxin gene for the purpose of making them resistant to specific insects; concerns in this regard include:
- The possibility of insect resistance to the *Bt* toxins developing in species targeted by genetically modified crops and the consequent undermining of valuable natural pesticides;
 - Possible effects related to the expression of *Bt* toxins in all parts of genetically modified plants.
- (d) Toxicological and allergenic issues which include

- The possibility that introduced genes could have toxic properties, or could lead to the production of toxins in the GMO;
- The inadvertent reactivation of inactive pathways to toxic substances in the plant;
- The possibility that introduced gene(s) could alter the allergenic properties of crop plants intended for food or feed uses, or natural substances in the environment such as pollen¹².

¹² Department of the Environment and Local Government Consultation paper on a national policy position on the deliberate release of genetically modified organisms to the environment

Key Considerations for National Policy

Having regard to these principles, the range of considerations which may be addressed in this public consultation process include the following:

- (a) Best means of balancing environmental protection requirements associated with genetic modification and economic growth potential of the biotechnology sector;
- (b) Proportionality of regulatory systems/requirements to identified risks;
- (c) Issues arising in the context of the Commission proposals to amend the Deliberate Release Directive, e.g. scope of Directive, categorisation of research releases and simplified administrative procedures for certain marketing releases;
- (d) Appropriate national consultative/scientific mechanisms to advise on genetic modification and the environment;
- (e) Balancing environmental risks and benefits, including principles for environmental risk assessment, and long-term direct and indirect effects;
- (f) Scientific issues, including the use of genes conveying resistance to antibiotics, particularly valuable antibiotics in human and veterinary medicine terms, as selectable markers in genetically modified products;
- (g) Definition of adequate transparency, particularly labelling provisions; and
- (h) The provisions of the GMO Regulations, 1994, having regard to relevant Community legislation¹³.

Major Irish GMO Legislation

Contents

S.I. No. 345/1994: Genetically Modified Organisms Regulations, 1994
<http://www.irishstatutebook.ie/1994/en/si/0345.html>

S.I. No. 332/1997: Genetically Modified Organisms (Amendment) Regulations, 1997
<http://www.irishstatutebook.ie/1997/en/si/0332.html>

S.I. No. 73/2001: Genetically Modified Organisms (Contained Use) Regulations, 2001
<http://www.irishstatutebook.ie/2001/en/si/0073.html>

S.I. No. 500/2003: Genetically Modified Organisms (Deliberate Release) Regulations, 2003
<http://www.irishstatutebook.ie/2003/en/si/0500.html>

¹³ Department of the Environment and Local Government Consultation paper on a national policy position on the deliberate release of genetically modified organisms to the environment