IRELAND

Avosetta Meeting on GMOs (Siena, 29-30 September 2006)

ANSWERS TO QUESTIONNAIRE
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1) **Which is the national regulatory approach to GMO in the Member States? Is there a horizontal act on GMO or just sectoral regulations apply in the Member States?**

There are just sectoral regulations applicable in Ireland. The EU Directives and Regulations are transposed into Irish law by:

1. The Genetically Modified Organisms (Contained Use) Regulations 2001
2. The Genetically Modified Organisms (Deliberate Release) Regulations 2003
3. The European Communities (Feeding stuffs) (Genetically Modified Feed) Regulations 2004

All of these are available at www.balii.ie

Executive competencies in the Member States: which national authority is responsible for the area of Dir. 98/81 and Dir. 2001/18 and for the area of Reg. 1829/2003 and Reg. 1830/2003?

1. Directive 98/81 (OJ, L330, p13, 05/12/1998) of 26 October 1998 amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms.
Under the Genetically Modified Organisms (Contained Use) Regulations 2001, enacted pursuant to Council Directive 90/219/EEC and amended by Council Directive 98/81/EC, the Environmental Protection Agency (EPA) is the competent authority.

2. Directive 2001/18 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.

[1] I am most grateful for Rachel Walsh for her help in doing this paper.

The EPA is the competent authority for the purposes of the Genetically Modified Organisms (Deliberate Release) Regulations 2003[2] enacted pursuant to Directive 2001/18/EC.

The Department of Agriculture and Food and Food is also responsible for GM seeds, and the growing of GM crops alongside non-GM crops (co-existence). These issues are dealt with in Directive 2001/18

3. Regulation 1829/2003 (OJ L268, p1, 18/10/2003) of 22 September 2003 on genetically modified food and feed.
The Food Safety Authority of Ireland is responsible for the evaluation and authorization of GM food while the Department of Agriculture and Food is responsible for the evaluation and authorization of GM animal feed. These issues are dealt with in Regulation 1829/2003.

4. 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.
The competent authority in relation to food is the Food Safety Authority of Ireland, and in relation to feed is the Department of Agriculture and Food.

2) **Implementation and enforcement of Directive 2001/18/EC on the deliberate release into environment of GMO:**

a) **What about risk assessment, management and the concept of precaution?**

Risk assessment is dealt with in Article 14 of the Genetically Modified Organisms (Deliberate Release) Regulations 2003 Regulations, which requires notification to the competent authority and provision of a risk assessment in a prescribed form (see Second Schedule for the prescribed form). There is a requirement in Article 5 (2) (b) that such assessment give particular attention to the risks to human health or the environment posed by the deliberate release or the placing on the market of a genetically modified organism which contains one or more genes expressing resistance to antibiotics used in human or veterinary medicine.

Furthermore, a technical dossier containing specified information (see Third Schedule) on the proposed release may be required. It is important to note therefore that risk assessment is carried out by the notifier rather than by the competent authority, a mechanism which is analogous to Environmental Impact Assessment.

The objective of the environmental risk assessment is to identify and evaluate potential adverse effects of the GMO(s), direct or indirect, immediate or delayed. The cumulative and long-term effects the deliberate release of GMOs may have on human health and the environment must also be taken into consideration. The environmental risk assessment

[2] Hereafter the 2003 Regulations

looks specifically at how the GM product was developed and examines the potential risks associated with the gene products (for example toxic or allergenic proteins), and the possibility of gene-transfer (for example transfer of antibiotic resistance genes).

The risk assessment procedure is as follows:

- Identification of any characteristics of the GMO(s) which may cause adverse effects to human health or the environment;
- Evaluation of the potential consequences of each adverse effect;
- Evaluation of the likelihood of the occurrence of each identified potential adverse effect;
- Estimation of the risk posed by each identified characteristic of the GMO(s);
- Application of management strategies for risks from the deliberate release or placing on the market of GMO(s);
- Determination of the overall risk of the GMO(s). [3]

Risk Management is carried out by the competent authority making an informed decision on the basis of the information acquired at the risk assessment stage as to whether to consent to the deliberate release. Furthermore, it involves setting out relevant conditions to manage the release if necessary, and undertaking post-consent monitoring and any modification of authorizations required in light of the results of such monitoring. The EPA makes a determination of the notification within 90 days of its receipt having regard to compliance with the regulations, any observations or representations received and scientific evaluation of the risks posed by the proposed deliberate release for human health or the environment. Persons or bodies who made representations, the Commission and the local authority concerned must be informed of the decision.

The principle of precaution is evident throughout the regulations in this area, which require prior risk assessment, self-monitoring and authorization. The impact of the precautionary principle is particularly evident in the requirements for the Environmental Risk Assessment set out in the Second Schedule of the 2003 Regulations. There must be assessment of direct and indirect effects, immediate and delayed effects, as well as cumulative long-term effects. In accordance with the precautionary principle, some general principles are set out:

1. Identified characteristics of the GMO and its use which have the potential to cause adverse effects should be compared to those presented by the non-modified organism from which it is derived and its use under corresponding situations
2. The environmental risk assessment should be carried out in a scientifically sound and transparent manner based on available scientific and technical data;
3. The environmental risk assessment should be carried out on a case by case basis, meaning that the required information may vary depending on the type of the genetically modified organisms concerned, their intended use and the potential

[3] http://www.epa.ie/Licensing/GMOLicensing/FAQs/Answer,2051,en.html

receiving environment, taking into account *inter alia*, genetically modified organisms already in the environment

4. If new information on the genetically modified organism and its effects on human health or the environment becomes available, the environmental risk assessment may need to be re-addressed in order to determine whether the risk has changed determine whether there is a need for amending the risk management accordingly.

An analysis of what is involved in the assessment of risk was carried out in *Watson v. EPA*.[4] This case concerned the standard by reference to which the EPA must decide whether or not to grant consent for the deliberate release of a GMO. The applicant argued that the standard was that risks to the environment and health must be reduced to effectively zero, whilst the EPA and the recipient of the impugned consent contended that the standard was not so high or absolute. The conclusion reached by the EPA on the facts was that the risk was extremely low. (It should be noted that this decision was reached on the basis of older regulations, the Genetically Modified Organisms Regulations 1994)

The judge found in favour of the EPA and concluded that all possibility of risks did not have to be eliminated. Neither the Directive nor the regulations required the EPA to be satisfied that all risks have been reduced to an effectively zero level nor to be satisfied as a matter of certainty or beyond all reasonable doubt. The standard of judicial review applied was that of irrationality and it was held that as there was material before the EPA justifying their assessment that the risks were very low, the decision was not irrational.

b) **Which is the impact of the complex, multi-level EC law procedure for the release of GMO in domestic administrative systems and organizations? In particular, which are the procedures of authorization**?

It is submitted that the impact of the EC law procedure for the release of GMO's in Irish administrative systems and organizations is principally evident in the extra responsibilities which the procedures of authorization and post-consent monitoring have required existing administrative bodies to undertake.

The EPA is the competent authority that authorises deliberate releases following risk assessment. In so doing, it is advised by an Advisory Committee.
The first Advisory Committee on GMOs was set up in 1995, under Part VI of the Genetically Modified Organsims Regulations S.I. No 345 of 1994, (Articles 55-59) to advise the EPA in relation to any aspect of its functions under the Regulations. The Committee is appointed for a three-year term. It meets quarterly and advises the Agency on relevant GMO issues. The Committee consists of 14 members nominated by both Government and non-Government organisations (NGO's). Nominating bodies include:

- EPA
- Minister for the Environment, Heritage & Local Government

[4] *Watson v. Environmental Protection Agency,* [1998] IEHC 148, [2000] 2 IR 454

- Minister for Agriculture & Food
- Minister for Health & Children
- Minister for Enterprise, Trade and Employment
- Commissioners for Public Works in Ireland
- National Authority for Occupational Safety and Health
- Organisations which in the opinion of the EPA are representative of persons whose professions or occupations relate to biotechnology research or the biotechnology industry.
- Organisations which in the opinion of the EPA are concerned with environmental protection.
- Consumer interest groups [5]

Are the scientific bodies involved in such a process and what is their influence on the competent authority's decisions?:

This is left to the discretion of the EPA- scientific bodies must be included insofar as they are deemed by the EPA to be representative of persons whose professions or occupations relate to biotechnology research or the biotechnology industry or environmental protection.

c) What about self-monitoring and supervision by administrative bodies and public entities (NGOs, etc.)? How the safeguard clause is applied?

1. Self Monitoring

A monitoring plan must be contained in the risk assessment report. Article 66 of the ???2003 Regulations gives the agency the power to carry out or cause to be carried out any monitoring it considers necessary. Article 42 gives the agency power to adapt any monitoring plan in light of reports pursuant thereto. Article 54 provides that the agency can charge the consent holder for any monitoring it carries out. Any notification concerning the deliberate release of GMO's must contain methods for monitoring the effects of the releases, information as to the specificity, sensitivity and reliability of the monitoring techniques, techniques for detecting the transfer of donated genetic material to other organisms, information as to the duration and frequency of monitoring. Article 21 of the 2003 Regulations provides that where consent has been granted for a deliberate release, and subsequently

(a) there is any unintended change to the deliberate release, or
(b) new information relevant to the deliberate release becomes available, which could have consequences for the risks to human health or the environment, the notifier must

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- [5] http://www.epa.ie/Licensing/GMOLicensing/FAQs/Answer,2063,en.html and the relevant provisions of the act.

i. immediately take the measures necessary to protect human health and the environment;
ii. inform the EPA as soon as the unintended change is known or the new information becomes available; and
iii. inform the EPA as soon as possible of such further measures he or she has taken or proposes to take in relation to the matters concerned.

It is submitted that this provision places a significant degree of responsibility on notifiers for self-monitoring.

2. Supervision by Administrative Bodies and Public Entities

There does not appear to be any scope for supervision by NGO's under the 2003 Regulations, but there is extensive supervision by the EPA, which is an administrative body, through requirements for post-release reports and monitoring with power for the EPA to act on foot of the results of such supervision. For example, Article 22 of the 2003 Regulations provides that if, after granting consent in writing to a deliberate release, the EPA

(a) becomes aware of information which, in its view, could have significant consequences for risks to human health or the environment, or
(b) is notified of a proposed modification of the release by the notifier, or
(c) (c) is informed of an unintended change or new information in accordance with article 21, it may, following an evaluation of the matters concerned, require the notifier, in writing, to modify the conditions of, suspend, or terminate the deliberate release, not to be resumed without the written consent of the EPA.

However, conditions in authorisations could require holders of consents to keep the local community and NGOs informed of monitoring results.

3. Safeguard Clause

The safeguard clause in Article 23 of Directive 2001/18/EC provides that where a Member State, as a result of new or additional information made available since the date of the consent, has grounds for considering that a GMO, as or in a product which has been properly notified and has received written consent, constitutes a risk to human health or the environment, that Member State may provisionally restrict or prohibit the use and/or sale of that GMO as or in a product on its territory. The member state must give reasons to the Commission and other Member States and a decision on suspension, termination or alteration of consent is reached by the Commission.

Implementation:

Article 28 of the 2003 Regulations implements the safeguard clause on a domestic level. It provides that where on foot of new information or a reassessment of existing information, the EPA has detailed grounds for considering that the product constitutes a risk to human health or the environment, it may, by notice in writing to the notifier or

other person concerned, provisionally restrict or prohibit the use or placing on the market in the State of the product. Where the EPA thinks that the product constitutes a severe risk to human health or the environment it shall, by notice in writing to the notifier or other person concerned, require such measures to be taken as it considers appropriate (including suspension or termination of the placing on the market.)

Where the agency does so, it must immediately inform the commission, the competent authorities of other member states and the public by means of, at least, publication of a notice in a newspaper circulating in the state, of its decision and the reasons for the decision. It must provide a review of the environmental risk assessment, information as to whether or not it considers that the conditions of the consent should be amended and, if so, how, or whether the consent should be revoked, and any additional information on which it has based its action. The EPA will accept the decision made at a European level under the safeguard clause of the Directive and will communicate the decision to the notifier.

d) How are transparency and participation dealt with? What about the access to information on GMOs?

1. Access to Information

The European Communities Act, 1972 (Access to Information on the Environment) Regulations, 1998 address access to environmental information. The general principle is set out in Article 6, namely that public authorities will make available any information relating to the environment to any person who requests it, where such request is made in writing, stating the name and address of the person making the request and as specifically as possible, the information which is the subject of the request. This starting point is qualified in two respects: First, Article 8 (1) grants a public authority discretion to refuse to make available information where the information requested affects commercial or industrial confidentiality, or intellectual property. This discretion is referred to and developed in the GMO regulations. For example, Article 10 of the 2003 Regulations provides that:

(1) justification must be given by the applicant for consent for a request for confidentiality,

(2) The EPA cannot decide that any of the following are confidential information:

- **(a)** the name and address of the notifier and the location of a deliberate release proposed under, or granted consent in accordance with, Part II of the Regulations and the location of any genetically modified organisms grown in the State pursuant to a consent granted in accordance with Part C of the Directive insofar as that information is supplied to the Agency on foot of monitoring requirements specified in the consent,
- **(b)** The purpose of the deliberate release or placing on the market,
- **(c)** the description and intended uses of the genetically modified organism involved,
- **(d)** methods and plans for monitoring the genetically modified organism and for emergency response,
- **(e)** the environmental risk assessment, or
- **(f)** any information or other matter referred to in article 22(1), 28(1) or 28(2).

(Article 22 (1) refers to a situation where after granting consent to a deliberate release, the EPA (a) becomes aware of information which, in its view could have significant consequences for the risks to human health or the environment, or (b) is notified of a proposed modification or (c) is informed of an unintended change or new information. In such a case it may following an evaluation of the matters concerned, require the notifier in writing to modify the conditions of, suspend or terminate the deliberate release which constitutes a risk to human health or the environment**.** Article 28(1) provides that where, as a result of either (a) new or additional information made available since the date of a consent granted and affecting the environmental risk assessment in respect of the product or (b) a reassessment of existing information, the EPA has detailed grounds for considering that the product constitutes a risk to human health or the environment it may by notice in writing to the notifier or to any other person concerned provisionally restrict or prohibit the use or placing on the market in the state of the product. Sub article 2 provides that where in the circumstances described in sub article 1, the EPA considers that a product constitutes a severe risk to human health or the environment, it shall by notice in writing to the notifier or other person concerned require such measures to be taken as it considers appropriate (including suspension or termination of the placing on the market.)

Finally, if before the EPA has reached a decision as to whether information should be treated as confidential information or within 14 days of such decision, the notifier decides not to proceed with the deliberate release or placing on the market and informs the Agency accordingly, the Agency shall treat the information in respect of which the request was made as confidential information

Another factor limiting the scope of access to environmental information is the definition of "public authority" for the purposes of the regulation. It is defined as including a Minister of Government, the Commissioners of Public Works in Ireland, a local authority for the purposes of the Local Government Act 1941, a harbour authority within the meaning of the Harbours Act 1946, a health board established under the Health Act 1970, board or other body established by or under statute, a company in which all the shares are held by or on behalf of, or by directors appointed by, a Minister of the Government, or a company in which all the shares are held y a board, company, or other referred to in paragraph (vi) or (vii) definition. In each case, they must have public administration functions and responsibilities for the environment and possess information relating to the environment. Also encompassed by the definition is any person or body, other than a public authority as defined, which is under the control of a public authority and has public responsibilities for the environment and possesses information relating to the environment. It seems unlikely that this will in reality limit access to information on GMO's as the relevant competent authorities (EPA, FSAI and Department of Agriculture and Food and Food) seem clearly to come within the definition of public authority.

Article 9 of the 2003 Regulations requires the EPA to maintain a register, containing a prescribed minimum amount of information for each notification or record, for example:

- the name and address of the notifier,

- the location (including where necessary the name of the townlands) of the proposed deliberate release, or of any GMO grown with consent,
- the date of any deliberate release carried out, the date of any release onto the market,
- the description and intended uses of each GMO involved,
- the purpose of the deliberate release or placing onto the market,
- the date of receipt of a notification or amended notification,
- the date of publication of any relevant notices,
- the number, if any, of representations received,
- the date of any request and receipt by the EPA of further information, etc.

The register must be made available at the EPA's headquarters for inspection by any member of the public free of charge during office hours. Article 9 (4) and (5) prescribe further information to be made publicly available by the EPA, for example the environmental risk assessment, the conclusions of the EPA upon evaluating the risks, the method and plans for monitoring, the emergency response plan.

2. Transparency and Participation

Article 15 of the 2003 Regulations requires that a notice of an application for consent to a deliberate release must be placed in a newspaper circulating in the relevant area, conveying prescribed information such as, for example, the name and address of the notifier and the proposed period of deliberate release. A copy of the notice must be sent to the owner of the site on which it is proposed to carry out the deliberate release, and the relevant local authority. Article 16 provides that any person may, within 28 days of the publication of the notice, make representations to the EPA concerning the proposed release. Such representations must be in writing and accompanied by a prescribed fee. The EPA must acknowledge receipt of the representations, and consider them in making its decision. Article 17 provides that where there is a modification of the proposed release, or new information pertaining to the proposed release becomes available, which could have consequences for the risks to human health or the environment, the EPA must deal with the amended notification as if it were an entirely new notification, thereby allowing for public participation.

When BASF applied to carry out a field trial in Ireland of a genetically modified blight resistant potato, the EPA also placed information regarding the proposed field trial on their website to facilitate the engagement by interested parties in the public participation process.

Watson v. EPA[6] is informative in this context also. O'Sullivan J. upheld the view that an opportunity for public participation is not necessarily required where, after the period in

[6] *Watson v. Environmental Protection Agency,* [1998] IEHC 148, [2000] 2 IR 454

which the public are entitled to make submissions has elapsed, the notifier submits further information which the public do not have an opportunity to respond to. Specifically, such an opportunity is not required to be afforded where an initial objection was in general terms only which were not related to the specific notification. Furthermore, a newspaper notice required to be published under Article 31 (1) of the regulation within 14 days of the date of acknowledgement of receipt of a notification was actually published outside that period. However as the applicant had made submissions on foot of that notice it was held that she could not subsequently claim that the notice was invalid.

It was held that the location required to be stated in the register and in the published notice is a general indication of the location of a deliberate release, perhaps by reference to townland or townlands, rather than the identification of the site with pinpoint accuracy. It is submitted that *Watson v. EPA* suggests a relaxed approach to compliance with the public notice requirements in the 2003 Regulations, in contrast to the strict approach generally taken to compliance with public notice requirements in planning law in Ireland.

e) How is the court review? Ordinary JR Is the legal standing of third parties and associations allowed?Yes

f) **Which is the nature of the penalties fixed according to art. 33 (criminal, administrative, civil sanctions)?**

The Environmental Protection Agency Act 1992 provides in s. 8 that any person who contravenes any provision of the Act or of any regulation made under this Act or of any order made under this Act or of any notice served under this Act shall be guilty of an offence. The 2003 Regulations are made pursuant to sections 6 and sections 111 of the EPA act and therefore are caught by this provision. Section 8 (2) provides that where an offence under the Act is committed by a body corporate or by a person acting on behalf of a body corporate and is proved to have been so committed with the consent, connivance or approval of, or to have been facilitated by any neglect on the part of any director, manager, secretary or any other officer of such body, such person shall also be guilty of an offence. This may be of importance in the area of GMO's as many notifiers may in fact be corporations.

Section 9 of the EPA Act 1992 sets out the penalties which may be imposed for offences. Upon summary conviction, a guilty person may be liable to a fine not exceeding £1,000, or to imprisonment for any term not exceeding twelve months or, at the discretion of the court, to both such fine and such imprisonment, or on conviction on indictment, to a fine not exceeding £10,000,000 or to imprisonment for a term not exceeding ten years or, at the discretion of the court, to both such fine and such imprisonment. In imposing penalties the court is required to have regard in particular to the risk or extent of damage to the environment arising from the act or omission constituting the offence. Subsection 3 provides that where a person, after conviction of an offence under this Act, continues to contravene the provision, he shall be guilty of an offence on every day on which the contravention continues and for each such offence he shall be liable to a fine, on

summary conviction, not exceeding £200 or, on conviction on indictment, not exceeding £100,000

Article 58 of the 2003 Regulations provides that an offence under the Regulations, or an offence arising from the exercise of powers under the Act (defined as the Environmental Protection Agency Act 1992, thereby making it clear that the penalties are governed by that Act as well as the regulations themselves) by authorised persons appointed pursuant to Article 57 (which provides that the EPA may appoint such of its officers to be authorised persons as it considers necessary for the purpose of the Regulations) may be prosecuted by the EPA.

3) Authorisation of the placing on the market of GMOs

a) Authorisations for GMOs other than food and feed: what about risk assessment, management and the concept of precaution?

Under the Genetically Modified Organisms (Deliberate Release) Regulations 2003, no one can place a GMO on the market without consent from the EPA or the competent authority of another EU state (Article 26). According to Article 29, a person proposing to place a product containing or consisting of a genetically modified organism on the market for the first time must notify the EPA, pay the prescribed fee, and publish notice of its notification in a suitable newspaper, containing the information set out in Article 29 (4), such as his/her name and address, a description of the GMO etc. (see further public involvement below)

An Environmental Risk Assessment must be provided by the notifier, along with information on data and results obtained from any previous release of the organism or of organisms of the same description, which has been carried out by the notifier, whether inside or outside the European Community, and such information from any previous notification in connection with a release of the organism or of organisms of the same description, which the notifier has made to the Agency in accordance with these Regulations, or to the competent authority of another Member State of the European Communities for the purposes of the Directive, which satisfies the provisions of Part C of the Directive.

The notifier also must furnish a monitoring plan, and conditions for placing the product on the market, such as handling and use conditions, proposals for labelling and packaging etc. (Article 30). The notifier must give notice to the EPA of any modifications or new information which could have consequences for the risks to human health or the environment, prior to consent being granted. The EPA must forward a copy of the notification to the competent authorities of other Member States and to the Commission. The EPA must prepare an assessment report, and forward a copy to the notifier and to the Commission. If the assessment report favours placing the GMO on the market, the EPA must consider the comments of the Commission and the competent authorities of other Member States. Where there is opposition from other Member States, the European Food Safety Authority may furnish an opinion to a Regulatory Committee which makes the

final decision. Article 33 of the 2003 Regulations provides that the EPA shall grant consent to the notification where it has concluded a favourable assessment of the proposal and

(i) no reasoned objection to the favourable assessment has been made to the Commission or by a competent authority of a Member State,
(ii) a reasoned objection has been made but the matters have been resolved in accordance with the provisions of Article 15 (1) of the Directive, or
(iii) a reasoned objection to the favourable assessment has been made and the Commission has adopted a favourable decision in accordance with the provisions of Article 18(1) of the Directive.

(Article 15 (1) of the Directive provides for an opportunity for discussion between the competent authorities of Member States and the Commission within a 105 day period from the date to circulation of the assessment report. Article 18 (1) provides that in cases where an objection is raised and maintained by a competent authority or the Commission, a decision shall be adopted and published within 120 days by the Commission assisted by a Committee which makes decisions by a simple majority vote.)

The EPA shall within 30 days of the consent being granted, inform the competent authority of each Member State and the Commission that it has done so.

Risk Management is undertaken by the EPA. The EPA may consent to the placing on the market where there is a favourable assessment report and where any objections from the Commission or competent authorities of other member states have been resolved. The consent cannot be for more than 10 years. Conditions may be attached to the consent and must be complied with. Monitoring requirements are mandatory.

Is the benefit resulting from GMO use considered as a factor to be balanced against the expected risk? The law does not require this to be considered in any assessment but in this reality will surely be an important consideration in evaluating any application for consent.

Does the risk assessment take into account that the GMO may be released under very different climatic and geographical conditions?
Article 20 of the 2003 Regulations provides that the information provided by the notifier in the notification shall take into account the diversity of sites of use of the GMO concerned**.** Furthermore, in the Second Schedule, part C.1 provides that the environmental risk assessment, depending on the case, has to take into account the relevant technical and scientific details regarding characteristics of the potential receiving environment. Most clearly, however, in the Fourth Schedule, it is stated that a notification for placing on the market of a product containing or consisting of a GMO must describe the geographical areas(s) and types of environment where the product is intended to be used within the EC, including, where possible, the estimated scale of use in each area.

Is the public involved?

Yes-Article 29 of the 2003 Regulations provides that a person proposing to place a product containing or consisting of a genetically modified organism on the market must, not more than 14 days after the receipt by the EPA of the notification, cause to be published in a newspaper circulating in the State a notice of its proposal to place on the market a product containing or consisting of a genetically modified organism and must send a copy of the notice to the EPA within the 14 day period. The notice must have the heading "PROPOSED PLACING ON THE MARKET OF A PRODUCT CONTAINING/CONSISITING OF A GENETICALLY MODIFIED ORGANISM" and must contain the name and address of the notifier, the description of the GMO concerned, the fact that a notification has been submitted to the EPA, the fact that further information on the proposed placing on the market may be obtained from the EPA, the full title of the EPA and the full postal address of its headquarters, the full postal address of the Commission and its full title, and the fast that any person or body may make representations in writing to the Commission regarding the notification within 30 days beginning on the day that the Commission makes the summary of the notification received by it available to the public.

Do the authorities issue general authorisations, or do they restrict authorisations to specific climatic and geographical conditions?

The application for the consent must specify the location for the proposed release the conditions for the release. Article 20 of the 2003 Regulations provides that the information provided by the notifier in the notification shall take into account the diversity of sites of use of the GMO concerned**.** Furthermore, in the Second Schedule, part C.1 provides that the environmental risk assessment, depending on the case, has to take into account the relevant technical and scientific details regarding characteristics of the potential receiving environment. Most clearly, however, in the Fourth Schedule, it is stated that a notification for placing on the market of a product containing or consisting of a GMO must describe the geographical areas(s) and types of environment where the product is intended to be used within the EC, including, where possible, the estimated scale of use in each area. Therefore, any consent granted on foot of an application will be restricted to specfic climactic and geographical conditions.

Are there third party rights of standing to challenge an authorisation?
Yes via judicial review, see for example the challenge in *Watson. v. EPA*[7].

Authorisations for GM Food and Feed under Regulation 1829/03:
aa) What is the national practice in relation to the EC authorisation procedure?

1. Feed:

[7] *Watson v. Environmental Protection Agency,* [1998] IEHC 148, [2000] 2 IR 454

The provisions in Regulation 1829/03 relating to animal feed are implemented in more detail in Ireland by the European Communities (Feeding stuffs) (Genetically Modified Feed) Regulations 2004. The Department of Agriculture and Food is the competent authority. The general principle is set out in Article 4: No person can place a GMO on the market in feeding stuffs without complying with the requirements of Regulation 1829/03 and Regulation 1830/2003. Applications for authorisation must be made initially to the Minster for Agriculture, by submitting all of the information required under Regulation 1829/03, as well as any further information which the Minister may request. (Article 3). Regulation 1829/03 sets out the application process in Article 17. The application shall be sent to the national competent authority, which will acknowledge receipt in writing within 14 days. Furthermore, it shall inform EFSA and make the application and any supplementary information supplied by the applicant available to EFSA. EFSA will inform the other Member States and the Commission and make the application and information available to them, and make a summary of the dossier available to the public.

The information which must be supplied with an application is set out in Article 17 (3):

(a) the name and address of the applicant,
(b) the designation of the feed,
(c) its specification, including the transformation event(s) used;
(d) where applicable, the information to be provided for the purpose of complying with Annex II to the Cartagena Protocol;
(e) where applicable, a detailed description of the method of production and manufacturing;
(f) a copy of the studies, including, where available, independent, peer-reviewed studies, which have been carried out and any other material which is available to demonstrate that the feed complies with the criteria for consent;
(g) either an analysis, supported by appropriate information and data, showing that the characteristics of the feed are not different from those of its conventional counterpart, having regard to the accepted limits of natural variations for such characteristics and to the criteria specified in the Directive, or a proposal for labelling the feed;
(h) either a reasoned statement that the feed does not give rise to ethical or religious concerns or a proposal for labelling in relation to these concerns;
(i) where appropriate, the conditions for placing on the market the feed or feed produced from it, including specific conditions for use and handling;
(j) methods for detection, sampling (including references to existing official or standardised sampling methods) and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the feed and/or feeds produced from it;
(k) samples of the feed and their control samples, and information as to the place where the reference material can be accessed;
(l) where appropriate, a proposal for post-marketing monitoring regarding the use of the feed for animal consumption and
(m) a summary of the dossier in a standardised form.

According to the Department of Agriculture and Food:
"Authorisation of a genetically modified feed requires the preparation of a dossier setting out the reports of studies undertaken to demonstrate the efficacy of the product and its safety for animals, humans and the environment. The assessment of the dossier is then undertaken by the European Food Safety Authority following which a Community procedure involving all Member States comes into play. Products considered acceptable for both food and feed use are also authorised under a Community procedure involving all Member States subject if necessary to specified conditions of use.[8]"

2. Food:
There are no Irish implementing regulations relating to GM Food under Regulation 1829/03. The EC Regulation itself is directly applicable, and as such the authorisation procedure set out in the Regulation is applied in Ireland by the Food Safety Authority of Ireland as the relevant competent authority. Article 4 of Regulation 1829/03 provides that GMOs for food use; food containing or consisting of GMOs or food produced from or containing ingredients produced from GMOs cannot be placed on the market unless authorised. No authorisation can be granted unless it is shown that the food does not have adverse effects on human health, animal health or the environment and does not mislead the consumer and does not 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. The application for authorisation must be sent to the national competent authority, which shall acknowledge receipt in writing within 14 days, shall inform EFSA and shall make available to EFSA the application and any supplementary information supplied by the applicant. EFSA shall inform the other Member States and the Commission and make available to them the application and the supplementary information. Furthermore, it shall make a summary of the dossier available to the public.

Article 5 (3) sets out the information which must be supplied:

- **(a)** the name and address of the applicant,
- **(b)** the designation of the food,
- **(c)** its specification, including the transformation event(s) used;
- **(d)** where applicable, the information to be provided for the purpose of complying with Annex II to the Cartagena Protocol;
- **(e)** where applicable, a detailed description of the method of production and manufacturing;
- **(f)** a copy of the studies, including, where available, independent, peer-reviewed studies, which have been carried out and any other material which is available to demonstrate that the food complies with the criteria for consent;
- **(g)** either an analysis, supported by appropriate information and data, showing that the characteristics of the food are not different from those of its conventional counterpart, having regard to the accepted limits of natural variations for such characteristics and to the criteria specified in the Directive, or a proposal for labelling the food; either a reasoned statement that the food does not give rise to

[8] www.agriculture.gov.ie/feedingstuffs/leg2/Genetically_Modified_Feeds_31May05.pdf

ethical or religious concerns or a proposal for labelling in relation to these concerns;

(h) where appropriate, the conditions for placing on the market the food or food produced from it, including specific conditions for use and handling;

(i) methods for detection, sampling (including references to existing official or standardised sampling methods) and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food and/or foods produced from it;

(j) samples of the food and their control samples, and information as to the place where the reference material can be accessed;

(k) where appropriate, a proposal for post-marketing monitoring regarding the use of the food for human consumption and

(l) a summary of the dossier in a standardised form.

A technical dossier and risk assessment in accordance with Directive 2001/18/EC must also be supplied, along with a monitoring plan. EFSA then gives an opinion on the application, which it must forward to the Commission, which then submits a draft of its decision to the Standing Committee on the Food Chain and Animal Health, justifying any deviations from EFSA's opinion. The Committee decides finally by a simple majority vote. Commission Regulation 641/2004 provides detailed rules for the implementation of these general principles set out in Regulation 1829/2003 as regards the application for the authorization of new genetically modified food and feed**.**

How are transparency and participation dealt with?

There are no specific transparency and participation measures required in the Irish implementing legislation. Regulation 1829/03 requires the EFSA to make available a summary of the dossier to the public. EFSA itself does not received submissions from the public, but once it reports its opinion to the Commission, its opinion is made public and the public may make comments to the Commission within 30 days from such publication. (Article 6 (6) and Article 18 (7) of Regulation 1829/03/EC)

Are there national risk cultures expressed in the consultation procedure?

The Interdepartmental/Interagency Working Group established within the Department of Agriculture and Food and Food referred to certain factors peculiar to Ireland in the context of the coexistence of GMO and non-GMO crops[9]. They referred to:

The relatively small farm size (by comparison with some neighbouring continental tillage growers) and the regular changes in tenant-owner leases. These factors will require comprehensive monitoring and control in order to track crop changes between fields and thus enable coexistence measures to operate effectively. In addition, many Irish farm units are fragmented, thus adding to the requirement to establish comprehensive tracking procedures.

bb)Which is the legal standing in relation to the Commission authorization?

[9] Report available at www.agriculture.gov.ie

The standing to challenge a decision of the Commission is a matter of EU law. Article 230 of the EC Treaty provides that any natural or legal person may institute proceedings against a decision addressed to that person or against a decision which, although in the form of a regulation or decision addressed to another person, is of direct and individual concern to the former. The proceedings must be instituted within two months of the publication of the measure or of its notification to the plaintiff, or in the absence thereof, of the day on which it came to the knowledge of the plaintiff. Therefore, the person who has applied for authorization should have legal standing as any decision will be addressed to him or her.

However, the interpretation given to the requirement that a decision be of direct and individual concern to a person other than the addressee before they can challenge it means that potentially affected persons such as neighbours, NGO's etc are unlikely to have standing to challenge authorizations from the Commission relating to the placing on the market of GMO's (See for example case 25/62 Plaumann & Co. v. Commission, where the ECJ stated that "persons other than those to whom a decision is addressed may only claim to be individually concerned if that decision affects them by reason of certain attributes which are peculiar to them or by reason of circumstances in which they are differentiated from all other persons and by virtue of these factors distinguishes them individually just as in the case of the person addressed").

b) Role of the EFSA in providing the European scientific opinion on an application: should there not be a possibility for national scientific agencies, bodies etc. to comment on an application? Should EFSA be obliged to distribute that opinion together with its own opinion?

This is a recurring bone of contention between member states and EFSA, as Member States want more involvement in the process. Ireland's position, as articulated by the Minister for the Environment at an Environment Council in December 2005 is that Ireland recognises the independence and the expertise of EFSA and their role in dealing with the scientific aspects of questions posed and is of the view that it is too early to consider any changes to the regulatory framework given the limited expertise with the operation of the framework to date and the absence of clear knowledge on possible scenarios that might arise in the GMO approval system in the future. EFSA maintains that it welcomes contributions from competent authorities and scientific bodies in Member States.[10]

4) Coexistence:

a) what have MS done in order to protect non-GM agriculture/processing/trade/consumption? Focus on GM free zones, coordination of agricultural practices, liability, implementation of art. 31(3) of Dir. 2001/18

As of yet no steps taken in this regard according to the Department of Agriculture and Food. Article 26 a of Directive 2001/18/EC calls on Member States to take appropriate national measures on co-existence in order to avoid the unintended presence of GMO's in other products. In July 2003 the Commission adopted Recommendation 2003/556/EC on

[10] Department of Agriculture and Food and Food Briefing Note on GMO's

the guidelines for the development of national strategies and best practices to ensure the co-existence of gm crops with conventional and organic farming. The recommendation reaffirms that the Member States should develop measures for co-existence. The Department of Agriculture and Food says that Ireland is currently finalising its national strategies,

Have MS established a scheme ensuring GM free zones

The issue of co-existence and GM free zones arises under Regulation 1829/03, and therefore the competent authorities are the Department of Agriculture and Food and the FSAI. In August 2003, an interdepartmental/interagency Working Group was established within the Department of Agriculture and Food and Food to examine co-existence measures for Ireland. Their recommendations are divided between mandatory and voluntary measures. The mandatory measures would include obligations on farmers who wish to cultivate GM crops to :

- obtain prior approval from the Department of Agriculture and Food and Food,
- attend prescribed educational and training courses,
- maintain the crop separation distances as set out in the notification of approval, and
- obtain the signed written agreement of his/her neighbour where part of the neighbours farm is required to satisfy the necessary separation distance.

The voluntary measures would include:

- the cleaning of sowing and harvesting equipment,
- the segregation of transport and storage,
- the notification to adjacent landowners, over and above those which the farmer is obliged to notify of his/her intention to grow GM crops.

The recommendations also include the establishment of a fund for the redress of economic loss as a result of GM cultivation, if and when the necessity arises, with the fund initially supported by the State on a cost recovery basis and administered by and Independent Body. No final decision on such implementing measures has as of yet been reached as the consultation period was extended at the request of several interested parties. However, it seems clear that the calls by national interest groups such as the Irish Cattle and Sheep Farmers Association for the entire island of Ireland to be a GM free zone[11] will not be heeded in any way, as consent has already been granted for a field trial of genetically modified potatoes.

How does the special impact assessment based on Art. 6(3) Habitats Dir. work?
There are no special arrangements made in Irish legislation relating to GMOs in this context.

[11] News release from the ICSA dated 16th February 2005.

How GMO traceability and labelling issues are dealt with in the Member States' legislation

There is no Irish implementing legislation relative to labelling and traceability- Regulation 1829/03, Regulation 1830/2003 and Commission regulation 641/2004 are directly effective, implemented in large part by the Food Safety Authority of Ireland and by the Department of Agriculture and Food and Food as the two most relevant competent authorities, although the EPA is the competent authority for the purposes of release into the environment under Regulation 1830/2003.

The Food Safety Authority of Ireland has responsibility for tracing and labelling for foods, whilst the Department of Agriculture and Food and Food has responsibility for feed.

The FSAI is responsible for 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 Regulation 1829/03 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. 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:
(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 1830/2003/EC 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.

Traceability for products consisting of or containing GMOs
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 available.

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 Department of Agriculture and Food is the competent authority for labelling and traceability for feed. Again, Regulation 1829/03 and Regulation 1830/03 are directly effective.

Since April 2004 all genetically modified feed has to be labelled along the same principles as genetically modified food to give livestock farmers accurate information on

the composition and properties of feed. This meant that a large number of feedstuffs previously not subject to GM labelling requirements, such as GM soy meal in feed or compound feedstuffs and the genetically modified feed plants (e.g., soybean and maize) authorised under Directive 90/220/EEC had to be labelled. However, it does not require labelling of products such as meat, milk or eggs obtained from animals fed with genetically modified feed or treated with genetically modified medicinal products. [12]

In relation to Regulation 1830/2003, according to the Department of Agriculture, it applies to feed that consists of or contains GMO feed and feed produced from GMOs. The objective of the Regulation is to harmonize Community labelling procedures and risk management measures. Each operator within the chain must implement a system for recording the operators from whom they purchased GMO products and the operators to whom they supplied such products. However, when adventitious or unintentional contamination occurs in a food or feed below the thresholds set by Regulation 1829/2003 or Directive 2001/18, notification of each operator in the supply chain will not be necessary.[13]

The key provision of Regulation 1830/2003 is Article 4 which sets out traceability and labelling requirements for products consisting of or containing GMOs, requiring operators to inform the operator receiving the product that it contains or consists of GMOs and the unique identifier assigned to those GMOs. Operators must have in place systems and standardised procedures to allow the holding of this information for 5 years after each transaction. Operators must also ensure appropriate labelling of products as containing GMOs. Article 5 sets out similar requirements for food and feed produced from GMOs. Article 8 allows the Commission to establish a system for the development and assignment of unique identifiers to GMOs.

Directive 2001/18 is implemented via the Genetically Modified Organisms (Deliberate Release) Regulations 2003, which do not deal with labelling or traceability issues at all

5) <u>Do national systems of verification exist?</u>

6) Under the European Communities (Feedingstuffs) (Genetically Modified Feed) Regulations 2004, authorized officers may be appointed by the Minister. An authorized officer may, for the purposes of ensuring that the domestic and EC Regulations are complied with,

   (a) at all reasonable times enter any premises where he or she has reason to believe there is a product and inspect the premises,
   (b) require any person in charge of the premises connected with any equipment or other device at that premises to produce to

[12] http://www.epa.ie/Licensing/GMOLicensing/FAQs/Answer,2057,en.html
[13] http://www.agriculture.gov.ie/feedingstuffs/leg2/Genetically_Modified_Feeds_31May05.pdf

him or her any books, documents or records (and in the case of such information in a non-legible form to reproduce it in permanent legible form) relating to the product and to give to him or her such information as he or she may reasonably require in relation to the product,

(c) inspect and take copies of, or take extracts from, any such books, documents or records including in the case of information in non-legible form a copy of or extract from such information in permanent legible form in whatever form kept

(d) there or at any other place carry out such examinations, inspections or tests of the product, equipment or other device found on the premises or at the place as the officer considers appropriate and may remove or have removed from there any product, equipment or other device and retain it facilitate such examination, testing or inspection,

(e) examine any procedure connected with the manufacture, installation or maintenance of the product

(f) take, without payment, such samples of the product or of any other substance as the officer may reasonably require and carry out or have carried out on such samples there or elsewhere such checks and inspections as he or she considers necessary,

(g) secure for later inspection the premises or place or part of it,

(h) seize and detain the product

(i) dispose of or have disposed any product at the expense of the owner or any other person the Minister considers appropriate, where the authorized officer has reasonable belief that the product does not comply with the domestic or EC regulations and

(j) require the appropriate person to bring the product into compliance with the provisions of the EC Regulations at the cost of the owner or any other person the Minister considers appropriate. An authorized officer cannot, without the consent of the occupier, enter a private dwelling unless he or she has obtained a warrant from the District Court.

Penalties:

It is submitted that Ireland may be in breach of EU law in this respect in relation to food. Article 11 of Regulation 1830/2003 and Article 45 of Regulation 1829/2003 require Member States to lay down and implement rules for penalties for breaches of the provisions of the Regulation which are "effective, proportionate and dissuasive". The implementing regulations were required to be notified to the Commission no later than the 18th April 2004. In relation to food, there are no such implementing regulations. The European Communities (Feedingstuffs) (Genetically Modified Feed) Regulations 2004 deals with the penalties for breaches of Regulations 1829/2003 and 1830/2003 relating to feed. Article 9 provides that: A person guilty of an offence under the Regulations shall be liable on summary conviction to a fine not exceeding 3000 euros or up to six months

imprisonment. The offences created by the implementing regulations, in Article 8, are those of obstructing or otherwise interfering with an authorized officer in the performance of his or her duties, without lawful excuse, refusing or failing to comply with a request of an authorized officer, giving information to an authorized officer that the person knows to be false or misleading in a material respect, or (d) failing to comply with the provisions of the Regulations or the EC Regulations.

Subsection 3 provides that where an offence under the regulations is committed by a body corporate and is proven to have been so committed with the consent, connivance or approval of or to have been attributable to the wilful neglect on the part of any person being a director, manager, secretary or other officer of the body corporate or a person who purported to act in any such capacity, that person, as well as the body corporate, shall be guilty of an offence and shall be liable to be proceeded against and punished as if he or she was guilty of the offence.

Article 10 allows an authorized officer to serve notice of an on the spot fine of 100 euros where he/she has reasonable grounds to believe that an offence has been committed, (under the Irish implementing regulations or under EC Regulations 1829/03 or 1830/03), payment of which will prevent prosecution being brought in respect of the alleged offence. The onus of proving payment of the fine is on the person suspected of committing an offence.

7) How Member States implementing Directive 2004/35/EC on Environmental Liability with specific reference to GMOs? Ireland has not introduced any specific legislation to transpose this directive yet.

Siena, 29/05/06