AGRICULTURE AND RURAL DEVELOPMENT COMMITTEE

Date of meeting: 19 June 2002

DRAFT REGULATIONS TO IMPLEMENT DIRECTIVE 2001/18 ON THE DELIBERATE RELEASE OF GENETICALLY MODIFIED ORGANISMS INTO THE ENVIRONMENT

Purpose

1. To inform the Committee and seek its views on draft subordinate legislation to implement Directive 2001/18 on the deliberate release of genetically modified organisms (GMOs) into the environment, prior to a public consultation on the legislation.

2. A copy of the draft regulations is at **Annex A**.

Summary

3. The paper summarises the key provisions in the regulations and how these fit in with the Directive.

Timing

4. The issue is being presented at this meeting because it is the first opportunity to bring a full draft of the regulations to the Committee. A public consultation on the draft regulations is due to start in July.

Background

5. At present controls on deliberate releases of GMOs into the environment are implemented through Directive 90/220/EEC. A replacement Directive, 2001/18/EC, has been agreed and the attached regulations implement that new Directive.

6. Directive 2001/18/EC sets out a harmonised and generic framework for the deliberate release into the environment of any genetically modified organisms (GMOs) within the European Union (EU). It is wide ranging and covers GMOs of all types, including plants, animals and micro-organisms . The only GMOs that are not covered by the Directive are GM novel foods and GM medicines. In both cases this is because specific sectoral legislation exists that provides for a level of protection to human health and the environment equal to that of the Directive.

7. The Directive covers two distinct types of GMO release – commercial/marketing (or Part C) releases,

and releases for any other purpose including research (or Part B) releases.

8. The Welsh Assembly Government conducted a public consultation on the broad thrust of the Directive and how it should be transposed last year. The results of which were reported to the Committee on 5 December. The paper, ARD 18-01(P4), can be viewed on the Internet at http://www.wales.gov.uk/newsite.dbs?37D6A43B000D32840000119B00000000+current+3C06358D000D020500006A0F00000000+cur_date+12_2001.

9. A summary of the main features of the deliberate release framework, and the major changes introduced by Directive 2001/18, are set out in Annex B. The Directive can be viewed in full on the EU web site at http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=32001L0018&model=guichett

More about implementation

10. Implementation of the Directive in Wales is made up of three main elements. These are:

- *the Directive itself* - this provides the legal foundation for implementing legislation in Member States, and provides for aspects of the new regime that take place solely at EU level.
- *Part VI of the Environmental Protection Act 1990 (EPA)* – primary legislation, which has been devolved to the Assembly, that gives the powers and responsibilities needed to implement the Directive in the UK.
- *the Regulations* – secondary legislation that supplements the EPA and the Directive to implement the new regime in Wales.

11. Taken together, the Directive, the EPA and the Regulations mark out the legislative rules and administrative procedures covered by the new regime

The regulations

12. The following paragraphs summarise the effect of each regulation, and where relevant, indicate which article of the Directive is being implemented. Please note:

- Part B = experimental or R&D release; and
- Part C = marketing release.

Part I - General provisions

13. *Regulation 1* - gives the title of the Regulations and provides that they only apply to Wales.

14. *Regulation 2* - provides definitions of the terms used in the regulations.

15. *Regulation 3* - amends some of the definitions contained in the EPA to bring them in line with the definitions used in the Directive, for example the definition of "harm".

16. *Regulation 4* - amends section 108 of the EPA to reflect the exclusions to the requirement to hold a consent which are specified in the Directive.

17. Regulation 5 - defines which techniques are, and are not, considered genetic modification for the purposes of the Directive. These are defined in Article 2(2) and Annex 1A of the Directive.

18. *Regulation 6* - requires an environmental risk assessment (ERA) to be submitted as part of an application to release or market a GMO. The regulation requires that an ERA must be prepared in line with the requirements set out in Annex II of the Directive.

19. *Regulation 7* - requires applicants to submit information in paper and electronic format.

20. *Regulation 8* - revokes the 1992 GMO deliberate release regulations.

Part II: deliberate release of GMOs for any other purpose than placing on the market

21. *Regulation 9* - sets out the process for making an application to release (Part B) a GMO into the environment. (Article 6 of the Directive)

22. *Regulation 10* - specifies what information should be contained in an application for consent to release under Part B. (Article 6 of the Directive)

23. *Regulation 11* - requires the applicant to place an advert in specified publications to inform the public about a proposed Part B release. It also requires that the applicant notify certain individuals and organisations about the release. (Article 9 of the Directive)

Part III: Placing on the market of organisms as or in products

24. *Regulation 12* - sets out activities that are not considered "marketing" of GMOs under the Regulations. For example, making available GMOs for activities regulated by the Contained Use Directive or the marketing of medicinal products for humans or veterinary use. (Article 12 of the Directive)

25. *Regulation 13* - specifies when a consent to market a GMO, which would be issued under section 111 (1) of the Environmental Protection Act, is required.

26. *Regulation 14* - specifies the information required in an application for a consent to market. (Article 13 of the Directive)

27. *Regulation 15* - puts in place transitional measures to handle applications for a marketing consent which are received before the Directive comes into force on 17 October. (Article 35 of the Directive)

28. *Regulation 16* - specifies how and when applications for the renewal of a consent to market should be made. (Article 17 of the Directive)

Part IV: Duties after making applications

29. *Regulation 17* - specifies how further information can be sought from applicants in connection with their application. It also sets out what an applicant must do if they become aware of new information about the risks posed by their application prior to a decision being issued. The regulation amends section 111 of the EPA and applies to Part B and Part C applications. (Article 13(6) of the Directive).

30. *Regulation 18* - introduces a mechanism for public consultation on Part B releases. The regulation also sets out the other steps in the process for coming to a decision on a Part B application, including seeking the views of the Commission and other competent authorities. (Article 6(5), Article 9 and Article 11(1) of the Directive)

31. *Regulation 19* - specifies the timetable for decisions on Part B applications. (Article 6(6) of Directive)

32. *Regulation 20* - specifies that a Part B consent can where varied where information becomes available about significant consequences with regard to risks for human health and the environment. (Article 8 of the Directive)

33. *Regulation 21* - specifies the administrative responsibilities of the Assembly when dealing with a Part C application. (Article 13 and Article 14 of the Directive)

34. *Regulation 22* - specifies the procedures the Assembly must follow to notify a Part C application to the Commission and other Member States and come to a decision on the application. It also specifies that consents will be time limited. (Article 15 and Article 18 of the Directive)

35. *Regulation 23* - specifies the duties of the Assembly in dealing with an application for the renewal of a consent to market. This includes acknowledging receipt of the application and preparing an assessment report in accordance with the requirements set out in Schedule 4. (Article 17 of the Directive)

36. Regulation 24 - specifies the procedures the Assembly must follow to notify an application to renew a Part C consent to the Commission and other Member States and come to a decision on the application. (Article 17 of the Directive)

37. Regulation 25 - phases out of GMOs containing antibiotic resistance marker genes (ARMs) that may have an adverse effect on human health and the environment. It requires that consents may not be issued for GMOs containing such ARMs from the end of 2004 in the case of Part C and 2008 in the case of Part B. Prior to these dates, when considering applications to release GMOs, the regulations require that special account of these ARMs is taken in assessing the risks posed by the application. (Article 4(2) of the Directive)

Part V: General provisions for consents

38. *Regulation 26* - specifies what a consent to market should contain. This includes how long the consent is valid for, any conditions placed on the consent and monitoring requirements. (Article 19(3) of the Directive)

39. *Regulation 27* - amends section 112 of the EPA to require consent holders to notify the Assembly of any new information that comes to light (e.g. through post-market monitoring or by other means) regarding risks posed by the GMO to human health or the environment. Consent holders are also required to inform the Assembly of any proposed alterations to releases, and take action to prevent damage to the environment. (Article 20 of the Directive)

40. *Regulation 28* - requires consent holders to submit a revised version of the original application for consent if they notify new information. (Article 20(2) of the Directive)

41. *Regulation 29* - sets out the responsibilities of the Assembly if new information on risks posed by a Part C GMO becomes available. (Article 8, Article 17 and Article 20 of the Directive)

Part VI: Safeguard

42. *Regulation 30* - alongside section 110 of the EPA, this regulation provides a mechanism for taking provisional safeguard action to prohibit or restrict the use of a GMO if new information emerges that it represents a risk to the environment or human health. (Article 23 of the Directive)

Part VII: Confidentiality

43. *Regulation 31* - modifies section 123 of the EPA to bring it into line with Article 25.4 of the Directive, which sets out information that - in the public interest - cannot be treated as confidential. This includes the location and intended uses of the GMO release, the environmental risk assessment, the methods and plans for monitoring the GMO, and any emergency measures. (Article 25 of the Directive)

Part VIII: Register of information

44. *Regulation 32* - supplements section 122 of the EPA by setting out information that must be placed on the public register. This includes for example:

- any application received for a Part B or a Part C consent,
- any Part B or Part C consent issued,
- a copy of any Part C consent issued by another Member State

(Article 8(2), Article 9, Article 20(4), Article 23, Article 24, Article 31 of the Directive)

45. *Regulation 33* - sets out the time limits by which information must be placed on the public register. (Article 8(2), Article 9, Article 20(4), Article 23, Article 24, Article 31 of the Directive)

Schedules 1 to 4

46. Schedules 1-4 - are taken directly from the Directive. They set out detailed information requirements that support various provisions of the Regulations.

- *Schedule 1* - sets out information to be contained in an application for a consent to release or market genetically modified higher plants.
- *Schedule 2* - sets out information to be contained in an application for a consent to release or market organisms other than genetically modified higher plants.
- *Schedule 3* - sets out information (in addition to Schedule 1 or 2) to be included in an application for consent to market GMOs.
- *Schedule 4* - sets out information to be included in assessment reports prepared by DEFRA in the case that they are leading on a Part C application.

The Environmental Protection Act 1990

47. Part VI of the Environmental Protection Act 1990 (EPA) is a key element in the regulatory system for the deliberate release of GMOs, for example it provides:

- the core principles and procedural elements of the new system - it sets out the purpose of the Act, key concepts, and establishes the requirement to have a consent to release GMOs;
- enforcement powers - this includes powers to appoint inspectors to ensure that conditions of consents are adhered to by consent holders;
- offences arising from persons contravening aspects of the deliberate release regime - this includes fines and prison sentences, as well as powers that can be used by a court to cause an offence under the EPA to be remedied by an offender.
- a system of fees and charges to recover the costs of processing applications and enforcement from applicants and consent holders.

48. The Advisory Committee on Releases into the Environment (ACRE), which provides on a case by case basis expert advice about the risks posed by GMOs, is established under section 124 of the EPA.

Compliance

49. The main powers that will enable the National Assembly to implement the Directive are contained at Part VI of the Environmental Protection Act 1990 and have been transferred to the Assembly by Transfer of Functions Order made under section 22 of the Government of Wales Act 1998. The Privy Council made a designation order at their meeting on 31 October to transfer of the remaining powers, under Section 2(2) of the European Communities Act 1972.

50. There are limited financial implications of making the regulations for the Assembly as the regulations build on an existing framework. There may be a small rise in administration costs because of the need to keep a more detailed public register and make available copies of applications. However, the costs are more than balanced by the improvement in public access to information.

51. There are no issues of regularity and probity.

Action for ARD

52. To give its views on the draft regulations.

Contact point

53. Plant Health and Biotechnology Branch – Countryside Division

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ANNEX A

DRAFT REGULATIONS

National Assembly for Wales

STATUTORY INSTRUMENTS

2002 No. (W.)

ENVIRONMENTAL PROTECTION, WALES

GENETICALLY MODIFIED ORGANISMS (DELIBERATE RELEASE)

(WALES) REGULATIONS 2002

EXPLANATORY NOTE

(This note is not part of the Order)

[To be completed]

STATUTORY INSTRUMENTS

2002 No. (W.)

environmental protection

GENETICALLY MODIFIED ORGANISMS (DELIBERATE RELEASE) (WALES) REGULATIONS 2002

Made [ ] 2002

Coming into force 2002

ARRANGEMENT OF REGULATIONS

Part I

INTERPRETATION AND GENERAL

Part II

[DELIBERATE RELEASE OF ORGANISMS FOR ANY OTHER PURPOSE THAN FOR PLACING ON THE MARKET]

Part III

[PLACING ON THE MARKET OF ORGANISMS AS OR IN PRODUCTS]

Part IV

DUTIES AFTER THE MAKING OF APPLICATIONS

Part V

GENERAL PROVISIONS FOR CONSENTS

Part VI

SAFEGUARD

Part VII

CONFIDENTIALITY

Part VIII

REGISTER OF INFORMATION

SCHEDULES

2. Information to be included in applications for consent to release or market organisms other than genetically modified higher plants

3. Information to be included in an application for consent to market genetically modified organisms

4. Information to be included in an assessment report

The National Assembly for Wales being designated()for the purposes of section 2(2) of the European Communities Act 1972() in relation to the control and regulation of the deliberate release of genetically modified organisms, in so far as concerns human health or environmental protection, acting in exercise of the powers conferred on it by the said section 2(2) and by sections 106(4) and (5), 107(8), 111(1), (4), (5), (7) and (11), 122(1) and (4), 123(7), [**and**] 126(1) [**and 156**] of the Environmental Protection Act(), and of all other powers enabling it in that behalf, hereby makes the following Regulations:—

PART I

General

Citation, Commencement and Extent

1. — These Regulations may be cited as the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002 and shall come into force on **[ ]** 2002.
    1. These Regulations extend to Wales only.

Interpretation

2. — In these Regulations –

"the Act" means the Environmental Protection Act 1990;

"the Advisory Committee on Releases to the Environment" means the Committee appointed by **[**the National Assembly for Wales**]** under section 124 of the Act;

"antibiotic resistance markers" means genes employed in the modification of an organism to

make that organism express resistance to a particular antibiotic or antibiotics;

"application for consent to release" shall include any notification made under the First Simplified Procedure (crop plants) Decision;

"approved product" means a product permitted to be marketed by a consent granted under section 111(1) of the Act or in accordance with Article 15(3), 17(6) or 18(2) of the Deliberate Release Directive or Article 13(4) of the 1990 Directive and "approval" in this context means approval for the use permitted by the consent;

"the Commission" means the Commission of the Communities;

"the Contained Use Directive" means Council Directive 90/219/EEC()on the contained use of genetically modified micro-organisms as amended by [Commission Directive 1994/51/EC**()** and Council] Directive 98/81/EC();

"controlled waters" has the meaning given by section 104 of the Water Resources Act 1991()

"the Deliberate Release Directive" means Council Directive 2001/18/EC() on the deliberate release into the environment of genetically modified organisms;

"the 1990 Directive" means Council Directive 90/220/EEC() on the deliberate release into the environment of genetically modified organisms as amended by Commission Directive 1994/15/ EC() and Commission Directive 1997/35/EC();

"electronic communication" means the same as in the Electronic Communications Act 2000();

"environmental risk assessment" means the environmental risk assessment required by regulation 6;

"The First Simplified Procedure (crop plants) Decision" means Commission Decision 94/730/EC ();

"the 1992 Regulations" means the Genetically Modified Organisms (Deliberate Release) Regulations 1992();

"genetically modified organisms" means a genetically modified organism or a combination of genetically modified organisms;

"Higher plant" means a plant belonging to the taxonomic group *Spermatophytae* (*Gymnospermae* or *Angiospermae*);

["local authority" means the council of a county or county borough;]

"monitoring plan" means the plan required by regulation 14(1)(g);

"the register" means the public register kept by the National Assembly for Wales under section 122 of the Act.

1. In these Regulations –
    a. any reference to a numbered regulation or to a numbered Schedule is a reference to the regulation or Schedule in these Regulations so numbered; and
    b. a reference to a numbered paragraph is a reference to the paragraph so numbered in the regulation or Schedule to which that reference occurs.

Purpose of Part VI of the Act and meaning of expressions used

3. — In section 106 of the Act (purpose of Part VI and meaning of "genetically modified organisms" and related expressions) –
    a. for sub-section 106(1) there shall be substituted –

        "This Part has effect for the purpose of ensuring that all appropriate measures are taken to avoid damage to the environment being caused by the escape or release from human control of genetically modified organisms.";

    b. for sub-section 106(4) there shall be substituted –

        "For the purposes of this Part an organism is "genetically modified", subject to sub-section (5) below, if any of the genetic material in the organism -

        (a) has been altered in a way that does not occur naturally by mating or natural recombination; or

        (b) is inherited or otherwise derived, through any number of replications, from other genetic material (from any source) which has been so altered.";

    c. for sub-section 106(5) there shall be substituted –

        "The National Assembly for Wales may prescribe by regulations techniques of modification (or any combination of such techniques), in each case, subject to such conditions as it shall think fit –

(a) through the use of which genetic modification at least occurs;

(b) which are not considered to result in genetic modification; or

(c) to which this Part shall not apply.";

d. Sub-section 106(6) is revoked.

1. In section 107 of the Act (meaning of "damage to the environment", "control" and related expressions in Part VI) –

a. for sub-section (2) there shall be substituted –

"The "environment" includes land, air and water and the living organisms supported by any of those media";

b. for sub-section (3) there shall be substituted –

""Damage to the environment" is caused by the presence in the environment of genetically modified organisms which have (or of a single such organism which has) escaped or been released from a person's control and are (or is) capable of causing harm.";

c. for sub-section (6) there shall be substituted –

""harm" means any adverse effects on human health or the environment.";

d. for sub-section (9) there shall be substituted –

"Organisms of any description are under the "control" of a person where he keeps them contained by specific measures used to limit their contact with and to provide a high level of safety for the general population and the environment"; and

e. for sub-section (11) there shall be substituted –

"Genetically modified organisms of any description are "marketed" when products consisting of or including such organisms are placed on the market by being made available to third parties, whether in return for payment [in money or money's worth] or free of charge, and "market" and "marketing" shall be construed accordingly.".

Reference to requirement for consent

4. In section 108 of the Act (risk assessment and notification requirements) for sub-section (2) there shall be substituted –

"Subsection (1) above does not apply to a person proposing to do any act in respect of which consent is required under section 111(1)(a) below or which is exempted from the requirement for consent by regulations made under section 111."

Techniques of genetic modification

5. — The following techniques are prescribed as artificial techniques for the purposes of section 106 (4) of the Act:
    a. recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation;
    b. techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation;
    c. cell fusion (including protoplast fusion) or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

1. The following are prescribed under section 106(5)(b) of the Act as techniques which are not considered to result in genetic modification on condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms made by techniques or methods other than those prescribed by paragraph (3) below as techniques of modification to which Part VI of the Act shall not apply–
    a. in vitro fertilisation,
    b. natural processes such as conjugation, transduction and transformation,
    c. polyploidy induction.
2. The following are prescribed under section 106(5)(c) of the Act as techniques of genetic modification to which Part VI of the Act shall not apply on condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those produced by one or more of the following techniques or methods -
    a. mutagenesis;
    b. cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods.

Environmental risk assessment

6. — An environmental risk assessment contained in an application for consent to release or market genetically modified organisms shall –
    a. identify and evaluate the potential damage to the environment, whether direct or indirect, immediate or delayed, which may arise from the release or marketing of genetically modified organisms,
    b. be carried out in accordance with Annex II of the Deliberate Release Directive and contain the conclusions required in section D of that Annex,
    c. include any bibliographic reference and indications of the methods used where applicable.

    1. Where the genetically modified organisms contain antibiotic resistance markers, the environmental risk assessment shall include an examination of the particular risks of damage to the environment which may be posed by the deliberate release or marketing of those genetically modified organisms.

Communication with applicant for consent

7. — Wherever an applicant for a consent or renewal of a consent to which these Regulations apply or a holder of such consent is required under these Regulations to submit any document in writing, whether before or after consent is granted, he is required to submit that document in both a paper and in a commonly used electronic form.
    1. Wherever these Regulations require any communication from the National Assembly for Wales to the applicant for a consent or renewal of a consent or renewal of a consent to be in writing, "writing" shall include an electronic communication.
    2. Any documents required by these Regulations to be in writing which do not fall within the provisions of paragraph (1) or (2) above must be in paper form.

Revocation

8. The 1992 Regulations are revoked in respect of Wales.

PART II

[DELIBERATE RELEASE OF ORGANISMS

FOR ANY OTHER PURPOSE THAN FOR PLACING ON THE MARKET]

Consent to release organisms

9. — The cases and circumstances prescribed under section 111(1)(a) of the Act in relation to the release of any genetically modified organisms are any cases and circumstances other than the release of an approved product in accordance with the conditions and limitations to which the use of the product is subject.
    1. An application for a consent to release genetically modified organisms must be made in writing to the National Assembly for Wales.
    2. The National Assembly for Wales may accept that releases of the same genetically modified organism on the same site or on different sites for the same purpose and within a defined period may be notified in a single application.
    3. Where an application for a consent to release genetically modified organisms is expressed to rely on the First Simplified Procedure (crop plants) Decision, the provisions of that Decision shall apply to the application in place of any provisions of these Regulations that are inconsistent with it.
    4. Where the National Assembly for Wales has received an application for consent to release genetically modified organisms before [17 October 2002] pursuant to the 1992 Regulations and has not yet determined the application –
        a. the application shall be subject to the provisions of these Regulations,
        b. the applicant shall submit to the National Assembly for Wales such further information, additional to that already provided in connection with the application, as is necessary in order to comply with the requirements of these Regulations by 17 January 2003,
        c. the application shall be treated as having been sent to the National Assembly for Wales for the purposes of regulations 11(1) and (4) and as having been received by the Secretary of State for the purposes of regulations 18 and 19 on submission of the information required by paragraph (b) above, and
        d. if the information required by paragraph (b) above has not been submitted by 17 January 2003, the National Assembly for Wales may refuse to proceed with the application.

Information to be contained in application for consent to release

10. — An application for a consent to release genetically modified organisms must contain –
        a. the information prescribed in –

i. Schedule 1 where the application is for consent to release any genetically modified higher plant, or
ii. Schedule 2 in any other case,

to the extent that such information is appropriate to the nature and scale of the release or application,

b. information on data or results from any previous release of the organisms, or of the same combination of organisms, which has been carried out by the applicant, and information from any previous application for the release of the organisms, or of the same combination of organisms, which the applicant has made to the National Assembly for Wales in accordance with the Act and these Regulations or to another competent authority [of any member State] in accordance with Article 6 of the Deliberate Release Directive, [or Article 6 of the 1990 Directive],
c. an environmental risk assessment ,
d. a summary, in the format established by the Commission under Article 11(1) of the Deliberate Release Directive, of the information contained in the application.

1. The application may contain -
   a. data or results from an application for consent to release genetically modified organisms previously made by some other person, provided that a copy of that person's agreement in writing is contained in the application, and
   b. any other information which the applicant considers is relevant.

Advertisement of application for consent to release

11. — Subject to paragraphs (2) and (3), a person who makes an application for a consent to release genetically modified organisms shall, not more than ten days after he or she sends that application to the National Assembly for Wales, cause to be published in publications to be specified by the National Assembly for Wales a notice containing the following information –
    a. the name and address of the applicant,
    b. the general description of the organisms to be released,
    c. the location and purpose of the release,
    d. the intended date or dates of the release,
    e. that information about the application will be placed on the register by the National Assembly for Wales within twelve days of the receipt of the application,
    f. the means by which that register can be inspected,
    g. that the National Assembly for Wales will consider any representations made to it relating to risks of damage to the environment posed by the release of the genetically modified organisms within a period which it shall specify in accordance with these Regulations.

and shall immediately send a copy of the newspaper containing the advertisement to the National Assembly for Wales.

1. A notice published under paragraph (1) above need not contain the information referred to in sub-paragraphs (c) and (d) of that paragraph insofar as the First Simplified Procedure (crop plants) Decision does not require that information to be submitted with the application and that information is not submitted with the application.
2. An applicant for consent shall ascertain from the National Assembly for Wales the level of detail on the location of the release which will be placed on the register and shall include the same level of detail in the notice to be published under paragraph (1) above.
3. A person who makes an application for a consent to release genetically modified organisms shall, not more than ten days after he sends that application to the National Assembly for Wales, give to the following persons notice in writing that he has made the application and the information prescribed in paragraph (1)(a) to (g), [save in so far as paragraph (2) permits such information to be excluded from the notice referred to in paragraph (1)] –
    a. the local authority and any [community] councils for the area or areas of each proposed release,
    b. the owner or owners of the site or sites of each proposed release, if a person other than the applicant,
    c. each member of the genetic modification safety committee established by the applicant under regulation 16 of the Genetically Modified (Contained Use) Regulations 2000(),
    d. the Association of National Park Authorities,
    e. the Countryside Council for Wales(),
    f. the Environment Agency;

and shall immediately send to the National Assembly for Wales copies of the notices.

Part III

[PLACING ON THE MARKET OF ORGANISMS AS OR IN PRODUCTS]

Excluded activities

12. — The cases and circumstances prescribed under section 111(1)(a) of the Act in relation to marketing genetically modified organisms shall not include -
    a. the making available of genetically modified micro-organisms for activities

regulated under the Contained Use Directive ,

b. making available genetically modified organisms other than micro-organisms referred to in paragraph (a) to be used exclusively for activities where appropriate stringent containment measures based on the same principles of containment as laid down in the Contained Use Directive are used to limit their contact with and to provide a high level of safety for the general population and the environment,
c. making available genetically modified organisms to be used exclusively for deliberate releases complying with the requirements laid down in Part II,
d. the marketing of a genetically modified organism authorised under Council Regulation (EEC) No. 2309/93.

Application for consent to market

13. — A consent to market genetically modified organisms under section 111(1)(a) of the Act is required -

a. where the product is not an approved product; and
b. to market an approved product for a use for which it does not have approval.

1. An application for consent under section 111(1) of the Act must be made in writing to the National Assembly for Wales.

Information to be contained in an application for consent to market

14. — An application for a consent to market genetically modified organisms which is not an application for renewal of consent must contain the following information –

a. the information prescribed in –
    i. Schedule 1 where the application is for consent to market any genetically modified higher plant, or
    ii. Schedule 2 in any other case,

to the extent that such information is appropriate to the nature and scale of the release which may result from the marketing,

b. information on data or results from any previous release of the organisms, or of the same combination of organisms which have been carried out by the applicant either inside or outside the European Community, and information from any previous application for consent to release the organisms, or the same combination of organisms which the applicant has made to the National Assembly for Wales in accordance with the Act and these Regulations or to another competent authority of any member State in accordance with Article 6 of the Deliberate Release Directive

[or Article 6 of the 1990 Directive],

c. an environmental risk assessment,
d. subject to paragraph 3, the information prescribed in Schedule 3,
e. the conditions for the marketing of the product, including specific conditions of use and handling,
f. a proposed period for the consent which shall not exceed ten years;
g. a monitoring plan prepared in accordance with [Annex VII of the Deliberate Release Directive] which shall include a proposal for the time period of the plan which may differ from the proposed period for the consent,
h. a proposal for labelling which shall comply with the requirements laid down in Schedule 3,
i. a proposal for packaging which shall comprise the requirements laid down in Schedule 3,
j. a summary of the application in the format established by the Commission under Article 13(2)(h) of the Deliberate Release Directive,

1. The application may in addition contain –
   a. data or results from an application for consent to release genetically modified organisms previously made by some other person, provided that a copy of that person's agreement in writing is contained in the application, and
   b. any other information which the applicant considers relevant.
2. The information provided in accordance with sub paragraphs (1)(a) and (d) shall take into account the diversity of sites of use of the genetically modified organism and shall include information on any results obtained from research and developmental releases concerning the impact of the release on human health and the environment;
3. Where the applicant considers, on the basis of the results of any release in pursuance of and in accordance with a consent [granted by the National Assembly for Wales] under section 111(1) of the Act under Part B of either the Deliberate Release Directive or the 1990 Directive, or on other substantive, reasoned scientific grounds, that the marketing and use of the product does not pose a risk of damage to the environment, he or she may propose not to supply part or all of the information prescribed in Part II of Schedule 3.

Transitional provision for marketing

15. Where the National Assembly for Wales has received an application for consent to market genetically modified organisms before [17 October 2002] pursuant to the 1992 Regulations and has not yet determined that application, or, in a case where the Commission is required to take a decision in accordance with Article 13(3) of the 1990 Directive, that decision has not yet been taken -
    a. the application shall be subject to the provisions of these Regulations, and
    b. the applicant shall submit to the National Assembly for Wales such further information, additional to that already provided in connection with the application, as is necessary in order to comply with the requirements of these Regulation by 17

January 2003.

c. the application shall be treated as having been received by the National Assembly for Wales for the purposes of regulation 21 on submission of the information required by paragraph (b) above,
d. if, by [17 October 2002], the National Assembly for Wales has forwarded to the Commission the information required by regulation 16(2) of the 1992 Regulations, it shall supplement it and, if it considers it to be necessary, revise it on receipt of the further information required by paragraph (b) above in the light of its obligations under these Regulations, and
e. if the information required by paragraph (b) above has not been submitted by 17 January 2003, the National Assembly for Wales may refuse to proceed with the application.

Applications for renewal of consent to market

16. — Where the National Assembly for Wales has granted a consent to market genetically modified organisms, under section 111(1) of the Act, any application to renew that consent shall be made in writing to the National Assembly for Wales -
    a. before 17 October 2006 where the consent was granted before [17 October 2002], and
    b. no later than nine months before the expiry of the consent in all other cases.
    1. The application shall contain –
        a. a copy of the consent to market the genetically modified organisms,
        b. where applicable, a report on the results of the monitoring carried out in accordance with the requirements of regulation 26(f),
        c. any other new information which has become available with regard to the risks of the product causing damage to the environment,
        d. as appropriate, a proposal for amending or adding to the conditions of the original consent, including the conditions concerning future monitoring and the time limitation of the consent.
    2. Any consent to market genetically modified organisms granted by the National Assembly for Wales under section 111(1) of the Act before 17 October 2002 for which no application for renewal under paragraph (1) above has been received before 17 October 2006 shall be treated as having expired on that date.

PART IV

DUTIES AFTER THE MAKING OF APPLICATIONS

Duty of the applicant after applying for consent to release or to market

17. In section 111 of the Act (Consents required by certain persons) for subsections (6) and (6A) there shall be substituted the following –

"(6) The National Assembly for Wales may by notice to the applicant require him to furnish such further information specified in the notice, for such reasons and within such period as shall be specified, as he may require for the purpose of determining the application; and if the applicant fails to furnish the information within the specified period the National Assembly for Wales may refuse to proceed with the application.

(6A) Where an applicant for consent for releasing or marketing genetically modified organisms becomes aware, before his application is either granted or rejected, of any new information with regard to any risks there are of damage to the environment being caused as a result of the organisms being released or marketed he shall -

(a) notify the National Assembly for Wales of that new information forthwith;

(b) if applicable, take the measures necessary to prevent any damage to the environment being caused as a result of their being released or, as the case may be, marketed and shall notify the National Assembly for Wales of those measures;

(c) revise the information and conditions specified in the application.

(6B) All documents required to be submitted to the National Assembly for Wales by sub-sections (6) and (6A) shall be submitted in both a paper and a commonly used electronic form."

Duties of the National Assembly for Wales on receiving applications for consent to release

18. On receipt of an application for consent to release genetically modified organisms the National Assembly for Wales shall –

    a. inform the applicant in writing of the date of receipt of the application,
    b. invite any interested persons by means of a request placed on the register, to make representations to it relating to any risks of damage being caused to the environment by the release (which it may require to be submitted in both a paper and in a commonly used electronic form) before the end of a period to be specified which shall not be less than sixty days from the date the application was received

by it;

c. ensure that within 30 days a summary of that application in the format established by the Commission under Article 11(1) of the Deliberate Release Directive is forwarded to the Commission,
d. examine the application for its conformity with the requirements of the Act and of these regulations,
e. evaluate the risks of damage being caused to the environment by the proposed release having regard to the environmental risk assessment,
f. take into account any representations relating to risks of damage being caused to the environment by the release made to it before the end of the period specified in accordance with paragraph (b) above and any comments made by a competent authority or authorities of other member States following the circulation to them by the Commission of the summary referred to in paragraph (c) above.

Decisions by the National Assembly for Wales on applications for consent to release

19. — The National Assembly for Wales shall not grant a consent to release genetically modified organisms as it relates to the protection of human health without the agreement of the Health and Safety Executive().
    1. The National Assembly for Wales shall not grant or refuse consent to release genetically modified organisms before the end of a period of sixty days beginning on the day on which the application for consent was received.
    2. The National Assembly for Wales shall communicate its decision on an application for a consent to release genetically modified organisms to the applicant and shall ensure that its decision is communicated to the Commission before the end of a period of 90 days beginning with the day on which the application was received and shall include in any refusal of consent the reasons for the decision.
    3. The period prescribed in paragraph (3) shall not include -
        a. any period beginning with the day on which the National Assembly for Wales gives notice in writing under section 111(6) of the Act that further information in respect of the application is required and ending on the day on which that information is received by the National Assembly for Wales, or
        b. a period of time during which the National Assembly for Wales is considering representations submitted by any persons in accordance with regulation 18(b), provided that this consideration shall not prolong the 90 day period referred to in paragraph (3) by more than 30 days.
    4. A consent to release genetically modified organisms shall require the applicant to send any information which might be relevant to assessing the risk of damage being caused to the environment, with, where appropriate, particular reference to any product which it is intended to market in the future, to the National Assembly for Wales after completion of

the release and thereafter, at such intervals as the National Assembly for Wales shall consider appropriate on the basis of the results of the environmental risk assessment.

5. The National Assembly for Wales shall send to the Commission the information submitted to it in accordance with paragraph (5).

Variation [or revocation] of a consent to release genetically modified organisms

20. The National Assembly for Wales shall only vary or revoke a consent to release genetically modified organisms under section 111(10) of the Act without the agreement of the holder of the consent where new information has become available to it which it considers could significantly affect the assessment of the risk of damage being caused to the environment by the release.

Duties of the National Assembly for Wales in relation to applications for consent to market

21. — On receipt of an application for consent to market genetically modified organisms the National Assembly for Wales shall –

    a. inform the applicant in writing of the date of receipt of the application,
    b. [ensure that a summary of that application in the format established by the Commission under Article 13(2)(h) of the Deliberate Release Directive is forwarded immediately to the Commission and to the competent authorities of each of the member States,]
    c. examine the application for its conformity with the requirements of the Act and of these Regulations and, if necessary, request the applicant to supply additional information,
    d. before the end of a period of 90 days beginning with the day on which it received the application –
        i. send to the applicant an assessment report prepared in accordance with Schedule 4 which indicates that the genetically modified organisms should be marketed and under which conditions, or
        ii. refuse the application, stating reasons for its decision, supported by an assessment report prepared in accordance with Schedule 4 which indicates that the genetically modified organisms should not be marketed.
    e. [ensure that a copy of the application is forwarded to the Commission when satisfied it conforms to the requirements prescribed in regulation 14 and no later than when it sends its assessment report in accordance with paragraph (d)].

1. The National Assembly for Wales shall ensure that –
    i. its assessment report,
    ii. any further information it has received from the applicant pursuant to the

service of a notice under section 111(6) of the Act,

iii. any additional information on which it has based its assessment report,

are forwarded to the Commission in the circumstances described in regulation 21(d)(i), before the end of a period of ninety days beginning with the day on which it received the application and, in the circumstances described in regulation 21(d)(ii), no sooner than fifteen days from the date it sent the assessment report to the applicant and no later than one hundred and five days from the date it received the application.

2. The ninety day periods prescribed in paragraphs (1) and (2) shall not include any period beginning with the day on which the National Assembly for Wales gives notice in writing under section 111(6) of the Act that further information in respect of the application is required and ending on the day on which that information is received by the National Assembly for Wales.

Decisions by the National Assembly for Wales on applications for consent to market

22. — The National Assembly for Wales may only grant an application for consent to market genetically modified organisms where it has prepared an assessment report which indicates that the genetically modified organisms should be marketed and either -

a. no objection has been raised by [a competent authority of] a member State or by the Commission during a 60 day period beginning on the day the Commission circulated the assessment report, or

b. an reasoned objection or objections have been raised by either a competent authority of a member State or by the Commission but outstanding issues have been resolved in accordance with Article 15(1) of the Deliberate Release Directive within a 105 day period beginning on the day the Commission circulated the assessment report, or

c. an objection has been raised by [a competent authority of] a member State or the Commission and the Commission has adopted a decision in accordance with Article 18(1) of the Deliberate Release Directive in favour of granting consent.

1. The National Assembly for Wales shall inform the competent authority or authorities of each member State and the Commission of its decision to grant consent to market genetically modified organisms within thirty days of its grant.
2. For the purpose of calculating the final forty-five day period of the one hundred and five days in sub-paragraph (1)(b) above no period during which further information is awaited from the applicant shall be taken into account.
3. Subject to paragraphs (5) and (6) below, a consent to market genetically modified

organisms shall be given for a maximum period of ten years beginning with the day on which the consent is issued.

4. For the purpose of granting consent to market a genetically modified organism or a progeny of that genetically modified organism intended only for the marketing of its seeds [under the relevant Community provisions] the period of the first consent shall end at the latest ten years after the date of the first inclusion of the first plant variety containing the genetically modified organism on an official national catalogue of plant varieties in accordance with Directives 70/457/EEC() and 70/458/EEC() as amended.
5. For the purpose of granting consent to market a genetically modified organism contained in forest reproductive material, the period of the first consent shall end at the latest ten years after the date of the first inclusion of basic material containing the genetically modified organism on an official national register of basic material in accordance with Council Directive 1999/105/EC().

Duties on the National Assembly for Wales on receiving applications for renewal of consent to market

23. — On receipt of an application for renewal of consent to market genetically modified organisms the National Assembly for Wales shall –
    a. inform the applicant in writing of the date of receipt of the application,
    b. examine the application for its conformity with the requirements of the Act and of these Regulations and, if necessary, request the applicant to supply additional information,
    c. either –
        i. send to the applicant an assessment report prepared in accordance with Schedule 4 which indicates that the genetically modified organisms should continue to be marketed and under which conditions, or
        ii. refuse the application, stating reasons for its decision, supported by an assessment report which indicates that the genetically modified organisms should not continue to be marketed,
    d. [ensure that a copy of the application and its assessment report is forwarded to the Commission.]

Decisions by the National Assembly for Wales on applications for renewals of consents to market genetically modified organisms

24. — The National Assembly for Wales may only grant an application to renew a consent to market genetically modified organisms when it has prepared an assessment report which indicates that the genetically modified organisms should continue to be marketed and either –
    a. no objection has been raised by a [competent authority of any] member State or by the Commission during a 60 day period beginning on the day the Commission has circulated the assessment report, or
    b. an objection or objections have been raised by either a [competent authority of any] member State or by the Commission but outstanding issues have been resolved in accordance with Article 17(8) of the Deliberate Release Directive within a 75 day period beginning on the day the Commission circulated the assessment report, or
    c. an objection has been raised by a [competent authority of any] member State or the Commission and the Commission has adopted a decision in accordance with Article 18(1) of the Deliberate Release Directive in favour of granting consent.

1. The National Assembly for Wales shall ensure that the competent authority or authorities of each member State and the Commission are informed of its decision to renew consent to market genetically modified organisms within thirty days of its renewal.
2. The [renewed] consent to market genetically modified organisms shall be given for a maximum of 10 years unless the National Assembly for Wales considers that a shorter or longer period is justified, in which case it shall give its reasons in writing.
3. The applicant may continue to market the genetically modified organisms under the conditions specified in the original consent until a final decision has been taken on the application.

Genetically Modified Organisms containing Antibiotic Resistance Markers

25. — The National Assembly for Wales shall not grant a consent to an application for the release or marketing of genetically modified organisms containing antibiotic resistance markers which may have adverse effects on human health and the environment after –
    i. 31 December 2004 in the case of marketing, and
    ii. 31 December 2008 in the case of release.

1. Where prior to 31 December 2004 in the case of marketing and 31 December 2008 in the case of release, an application is made for consent to release or market genetically modified organisms containing antibiotic resistance markers, the National Assembly for Wales shall evaluate the information in the environmental assessment accompanying the application, taking into particular consideration those antibiotic resistance markers in use for medical or veterinary treatment, with a view to identifying and phasing out the release

or marketing of the genetically modified organisms referred to in paragraph (1) within the time limits specified in that paragraph.

PART V

GENERAL PROVISIONS FOR CONSENTS

General provisions of consents to market genetically modified organisms

26. — A consent to market genetically modified organisms granted by the National Assembly for Wales under section 111(1) of the Act shall specify –

a. the scope of the consent, including the identity of the genetically modified organisms to be marketed, and their unique identifier,
b. the period of validity of the consent,
c. the conditions for the marketing of the product, including any specific conditions of use, handling and packaging of the genetically modified organisms, and conditions for the protection of particular ecosystems or environments or geographical areas as applicable,
d. that the applicant shall make control samples available to the National Assembly for Wales on request,
e. the labelling requirements, in accordance with paragraph 8 of Schedule 3, which shall include a requirement to notify the National Assembly for Wales of any new commercial name of the product after consent has been given,
f. monitoring requirements which shall be in accordance with the monitoring plan, and shall include the time period of the monitoring plan, an obligation that the applicant shall submit the reports of monitoring to the Commission and the competent authorities of the member States and, where appropriate, any obligations on any person selling the product or any user to provide information at an appropriate level on the location of the genetically modified organisms.

General Conditions on Consents to release or market genetically modified organisms

27. In section 112 of the Act (Consents: limitations and conditions) there shall be substituted –

a. for sub-section 112(1) –

"The National Assembly for Wales may include in a consent such limitations and

conditions as it may think fit for the purpose of ensuring that all appropriate measures are taken to avoid damage to the environment being caused by the activity permitted by the consent.";

b. for paragraph (b) of subsection (5) the following paragraph –

"(b) notify the National Assembly for Wales forthwith of -

i. any new information which becomes available with regard to any risks there are of damage to the environment being so caused;
ii. any proposed alteration of, or unintended change to, the release of a genetically modified organism which might affect the assessment of the risk of damage being caused to the environment; and

c. for paragraph (c) of subsection (5) the following paragraph –

"(c) take the measures necessary to prevent any damage to the environment being caused as a result of their being released, or, as the case may be, marketed, and notify the National Assembly for Wales of those measures."

Submission of revised application

28. A holder of a consent to release or market genetically modified organisms who notifies the National Assembly for Wales of any new information in accordance with section 112(5)(b)(i)() of the Act, shall submit in writing to the National Assembly for Wales a revised version of the original application for consent, amended to take account of the new information.

New information on risks of damage to the environment

29. — The National Assembly for Wales shall immediately forward to the Commission and the competent authority or authorities of each member State any new information which becomes available to it which it considers could affect the assessment of the risk of damage being caused to the environment by releasing or marketing genetically modified organisms.

1. Where an application for consent or for renewal of consent to market genetically modified organisms has been made and the information referred to in paragraph (1) becomes available to the National Assembly for Wales before the consent has been granted or renewed, the National Assembly for Wales may seek to reach agreement with the Commission and the other Member States pursuant to Articles 15(1) or 17(7) of the Deliberate Release Directive as applicable.
2. Where an application for consent or renewal of a consent to market genetically modified

organisms has been made and the information referred to is paragraph (1) becomes available to the National Assembly for Wales after the consent has been granted or renewed, it shall ensure that an assessment report, indicating whether the conditions of the consent should be varied, and, if so, how, or whether the consent should be revoked, is forwarded to the Commission within 60 days of the date of receipt of the new information.

3. Where the National Assembly for Wales has indicated that the consent should be varied and either-
    a. no objection has been raised by a competent authority of any member State or by the Commission during a 60 day period beginning on the day the Commission circulated the assessment report, or
    b. an reasoned objection or objections have been raised by a competent authority of any member State or by the Commission but outstanding issues have been resolved in accordance with Article 20(3) of the Deliberate Release Directive,

    it shall vary the consent as proposed and inform the applicant, and ensure that the competent authority or authorities of each member State and the Commission are informed that it has done so within 30 days thereof.

4. The National Assembly for Wales shall only vary or revoke a consent to market genetically modified organisms under section 111(10) of the Act either where the information referred to in paragraph (1) has become available to it, and the procedure referred to in paragraphs (3) and (5) have been complied with or in accordance with a decision by the Commission in the circumstances described in regulation 30(3).

PART VI

SAFEGUARD

Safeguard

30. — The National Assembly for Wales may serve a prohibition notice under section 110 of the Act to prohibit an act which is authorised by the consent granted in respect of an approved product only if its opinion that doing such an act would involve a risk of causing damage to the environment is based on detailed grounds as the result of either
    a. new or additional information made available since the date of the consent which affects the environmental risk assessment in respect of that product; or
    b. a reassessment of existing information in respect of that product on the basis of new or additional scientific information.

1. Where, in the circumstances described in paragraph (1) above, the National Assembly for Wales considers that the risk of damage being caused to the environment is severe it shall

serve a prohibition notice requiring such measures to be taken as it may consider appropriate and once any work required by the notice has been carried out it shall enter details of it on the register.

2. In cases to which paragraph (1) and (2) above apply, the National Assembly for Wales shall immediately inform the Commission and the other member States of its actions and shall at the same time provide them with –
    a. its reasons for taking such actions,
    b. the results of its review of the environmental risk assessment,
    c. its opinion as to whether the conditions of the consent should be varied, and, if so, how, or whether the consent should be revoked, and
    d. where appropriate, the new or additional information on which its decision to take action was based.
3. A prohibition notice served under section 110 of the Act in accordance with this regulation shall be subject to any decision adopted by the Commission in accordance with Article 23(2) of the Deliberate Release Directive.
4. Upon receipt of notification of a decision by the Commission to which paragraph (4) refers the National Assembly for Wales shall send a copy of it to the holder of the consent to which the decision relates.

PART VII

CONFIDENTIALITY

Confidentiality

31. — For the purposes of section 123(7) of the Act, the following descriptions of information are also information which the public interest requires to be included in the register notwithstanding that it may be commercially confidential –
    a. the location of the release of the genetically modified organism to which the information relates,
    b. the intended use of the genetically modified organism to which the information relates,
    c. the environmental risk assessment,
    d. the methods and plans for monitoring and for responding to an emergency in relation to the genetically modified organism to which the information relates.

1. For paragraph (b) of sub-section 123(7) of the Act there shall be substituted –

    "the general description of any genetically modified organisms to which the notice relates".

2. Paragraphs (c) and (e) of sub-section 123(7) of the Act are revoked.

PART VIII

REGISTER OF INFORMATION

32. — The register shall contain the particulars set out in paragraphs (2) to (10).

1. In relation to a prohibition notice served by the National Assembly for Wales under section 110 of the Act –
    a. the name and address of the person on whom the notice is served,
    b. the description of the genetically modified organisms in relation to which the notice is served,
    c. the location at which the genetically modified organisms are proposed to be released,
    d. the purpose for which the genetically modified organisms are proposed to be released or marketed,
    e. the reason for the service of the notice,
    f. any date specified in the notice as the date on which the prohibition is to take effect.
2. Subject to paragraph (4), in relation to an application for a consent under section 111(1) of the Act –
    a. the name and address of the applicant,
    b. a general description of the genetically modified organisms in relation to which the application is being made,
    c. the location at which the genetically modified organisms are proposed to be released, to the extent that this information is contained in the application for consent, or in relation to a consent to market, the location at which they are proposed to be grown,
    d. the purpose for which the genetically modified organisms are proposed to be released (including any future use to which they are intended to be put) or, in relation to a consent to market, the purpose for which they will be marketed,
    e. the intended dates of the release,
    f. the environment risk assessment,
    g. the methods and plans for monitoring the genetically modified organisms and for responding to an emergency, and
    h. [a summary of] any advice the National Assembly for Wales has received from the Advisory Committee on Releases to the Environment as to whether an application for release of genetically modified organisms should be granted or rejected, and either –
        i. the conditions or limitations in accordance with which that committee has advised that the consent should be granted, or
        ii. a summary of the reasons why that committee has advised that the consent should not be granted.
3. Where the National Assembly for Wales is or becomes aware that information regarding

the genetically modified organisms or the purpose for which they will be released or marketed has been published which is more detailed than that which would satisfy the requirements of paragraph (3) above, it shall enter so much of that more detailed information on the register as it shall consider appropriate.

4. In relation to consents granted under section 111(1) of the Act –
    a. a copy of the consent, and a reference to the application in respect of which it was granted,
    b. any information supplied to the National Assembly for Wales in accordance with conditions imposed on the consent,
    c. the fact that the consent has been varied or revoked, the contents of the notice by which the consent was varied or revoked, and a copy of the varied consent,
    d. [a summary of] any advice the National Assembly for Wales has received from the Advisory Committee on Releases to the Environment as to whether a consent to release genetically modified organisms should be varied or revoked.
5. The following information concerning genetically modified organisms released or grown pursuant to a consent –
    a. Any new information which becomes available with regard to any risks there are of damage being caused to the environment provided to the National Assembly for Wales in accordance with section 111(6A) or 112(5)(b)(i)() of the Act,
    b. Any proposed alteration of or unintended change to, the release of a genetically modified organism which might affect the assessment of the risk of damage being caused to the environment notified to the National Assembly for Wales in accordance with section 112(5)(b)(ii) of the Act,
6. A copy of any consent to market genetically modified organisms granted by a competent authority of another member State.
7. The location of any genetically modified organisms grown in [Wales] pursuant to a consent to market insofar as that information is applied to the National Assembly for Wales in accordance with the monitoring requirements imposed on the consent.
8. Any decision adopted by the Commission in accordance with Article 18 of the Deliberate Release Directive.
9. In relation to convictions for any offence under section 118 of the Act –
    a. the name and address of the person convicted,
    b. the description of any genetically modified organisms in relation to which the conviction was obtained,
    c. the offence which was committed,
    d. the penalty imposed and any order made by the court under section 120 of the Act.

Keeping the register

33. — The information on the register shall be made available to the public by such means as the National Assembly for Wales shall consider appropriate.

1. The information prescribed in regulation 32(2) shall be placed on the register within

twelve days of the prohibition notice being served.

2. The information prescribed in paragraphs (a) to (g) of regulation 32(3) shall be placed on the register within twelve days of the receipt by the National Assembly for Wales of the application for consent to release or market.
3. The information prescribed in regulation 32(3)(h) shall be placed on the register within twelve days of the consent being granted or refused.
4. The information prescribed in regulation 32(5)(a) shall be placed on the register within twelve days of the consent being granted.
5. The information prescribed in regulation 32(5)(b) and (d) shall be placed on the register within twelve days of its receipt by the National Assembly for Wales.
6. The information prescribed in regulation 32(5)(c) shall be placed on the register within fourteen days of the consent being revoked or varied.
7. The information prescribed in regulation 32(6) and (10) shall be placed on the register within fourteen days of its receipt by the National Assembly for Wales.
8. The information prescribed in regulation 32(7) shall be placed on the register within fourteen days of its receipt by the National Assembly for Wales.
9. The information prescribed in regulation 32(8) shall be placed on the register within fourteen days of its receipt by the National Assembly for Wales.
10. The information prescribed in regulation 32(9) shall be placed on the register within fourteen days of the decision having been notified to the National Assembly for Wales.

34. — The National Assembly for Wales shall, within a period of 28 days after granting consent to or rejecting an application for the release of genetically modified organisms, make available to the public by whatever means it shall consider appropriate a list of those persons who made representations to it in relation to the application, a summary of those representations and details of where and when [paper copies of] representations received may be inspected.

    1. Paragraph (1) shall not require copies of representations to be made publicly available where they contain confidential information and the person making the representations has asked the National Assembly for Wales to treat that information as confidential.

Signed on behalf of the National Assembly for Wales under section 66(1) of the Government of Wales Act 1998()

Date

The Presiding Officer of the National Assembly

SCHEDULE 1

Regulations 10 and 14

INFORMATION TO BE INCLUDED IN APPLICATIONS FOR CONSENT TO RELEASE OR MARKET GENETICALLY MODIFIED HIGHER PLANTS

PART I

GENERAL INFORMATION

1. The name and address of the applicant, and the name, qualifications and experience of the scientist and of every other person who will be responsible for planning and carrying out the release of the organisms, and for the supervision, monitoring and safety of the release.

2. The title of the project.

PART II

INFORMATION RELATING TO THE PARENTAL OR RECIPIENT PLANT

3. The full name of the plant –

(a) family name,

(b) genus,

(c) species,

(d) subspecies,

(e) cultivar/breeding line,

(f) common name.

4. Information concerning –

(a) the reproduction of the plant:

(i) the mode or modes of reproduction,

(ii) any specific factors affecting reproduction,

(iii) generation time; and

(b) the sexual compatibility of the plant with other cultivated or wild plant species [including the distribution in Europe of the compatible species].

5. Information concerning the survivability of the plant:

(a) its ability to form structures for survival or dormancy,

(b) any specific factors affecting survivability.

6. Information concerning the dissemination of the plant:

(a) the means and extent (such as an estimation of how viable pollen and/or seeds declines with distance where applicable) of dissemination; and

(b) any specific factors affecting dissemination.

7. The geographical distribution of the plant.

8. Where the application relates to a plant species which is not normally grown in the Member State or States, a description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.

9. Any other potential interactions, relevant to the genetically modified organism, of the plant with organisms in the ecosystem where it is usually grown, or elsewhere, including information on toxic effects on humans, animals and other organisms.

PART III

INFORMATION RELATING TO THE GENETIC MODIFICATION

10. A description of the methods used for the genetic modification.

11. The nature and source of the vector used.

12. The size, intended function and name of the donor organism or organisms of each constituent fragment of the region intended for insertion.

PART IV

INFORMATION RELATING TO THE GENETICALLY MODIFIED PLANT

13. A description of the trait or traits and characteristics of the genetically modified plant which have been introduced or modified.

14. The following information on the sequences actually inserted or deleted:

(a) the size and structure of the insert and methods used for its characterisation, including information on any parts of the vector introduced into the genetically modified plant [GMHP]or any carrier or foreign DNA remaining in the genetically modified plant [GMHP],

(b) the size and function of the deleted region or regions,

(c) the copy number of the insert, and

(d) the location of the insert in the plant cells (whether it is integrated in the chromosome, chloroplasts, mitochondria, or maintained in a non-integrated form) and the methods for its determination.

15. The following information on the expression of the insert –

(a) information on the developmental expression of the insert during the lifecycle of the plant and methods used for its characterisation,

(b) the parts of the plant where the insert is expressed, such as roots, stem or pollen.

16. Information on how the genetically modified plant differs from the parental or recipient plant in the following respects –

(a) mode or modes and/or the rate of reproduction,

(b) dissemination,

(c) survivability.

17. The genetic stability of the insert and phenotypic stability of the genetically modified plant [GMHP].

18. Any change to the ability of the genetically modified plant [GMHP] to transfer genetic material to other organisms.

19. Information on any toxic, allergenic or other harmful effects on human health arising from the genetic modification.

20. Information on the safety of the genetically modified plant [GMHP] to animal health, particularly regarding any toxic, allergenic or other harmful effects arising from the genetic modification, where the genetically modified plant is intended to be used in animal feedstuffs.

21. The mechanism of interaction between the genetically modified plant [GMHP] and target organisms, if applicable.

22. The potential changes in the interactions of the genetically modified plant [GMHP] with non-target organisms resulting from the genetic modification.

23. The potential interactions with the abiotic environment.

24. A description of detection and identification techniques for the genetically modified plant.

25. Information about previous releases of the genetically modified plant, if applicable.

PART V

INFORMATION RELATING TO THE SITE OF RELEASE

(Applications for consent to release only)

26. The location and size of the release site or sites.

27. A description of the release site ecosystem, including climate, flora and fauna.

28. Details of any sexually compatible wild relatives or cultivated plant species present at the release sites.

29. The proximity of the release sites to officially recognised biotopes or protected areas which may be affected.

PART VI

INFORMATION RELATING TO THE RELEASE

(Applications for consent to release only)

30. The purpose of the release of the genetically modified plant, including its initial use and any intention to use it as or in a product in the future.

31. The foreseen date or dates and duration of the release.

32. The method by which the genetically modified plants will be released.

33. The method for preparing and managing the release site, prior to, during and after the release, including cultivation practices and harvesting methods.

34. The approximate number of genetically modified plants (or plants per m2) to be released.

PART VII

INFORMATION ON CONTROL, MONITORING, POST-RELEASE AND WASTE TREATMENT

PLANS

(Applications for consent to release only)

35. A description of any precautions to –

(a) maintain the genetically modified plant at a distance from sexually compatible plant species, both wild relatives and crops.

(b) any measures to minimise or prevent dispersal of any reproductive organ of the genetically modified plant (such as pollen, seeds, tuber).

36. A description of the methods for post-release treatment of the site or sites.

37. A description of the post-release treatment methods for the genetically modified plant material including wastes.

38. A description of monitoring plans and techniques.

39. A description of any emergency plans.

40. Methods and procedures to protect the site.

PART VIII

INFORMATION ON METHODOLOGY

41. A description of the methods used or a reference to standardised or internationally recognised methods used to compile the information required by this Schedule, and the name of the body or bodies responsible for carrying out the studies.

SCHEDULE 2

Regulations 10 and 14

INFORMATION TO BE INCLUDED IN

APPLICATIONS FOR CONSENT TO RELEASE OR MARKET [GENETICALLY MODIFIED] ORGANISMS OTHER THAN GENETICALLY MODIFIED HIGHER PLANTS

PART I

GENERAL INFORMATION

1. The name and address of the applicant, and the name, qualifications and experience of the scientist and of every other person who will be responsible for planning and carrying out the release of the [genetically modified] organisms, and for the supervision, monitoring and safety of the release.

2. The title of the project.

PART II

INFORMATION RELATING TO THE [GENETICALLY MODIFIED] ORGANISMS

Characteristics of donor, parental and recipient organisms

3. Scientific name and taxonomy.

4. Usual strain, cultivar or other name.

5. Phenotypic and genetic markers.

6. The degree of relatedness between donor and recipient or between parental organisms.

7. The description of identification and detection techniques.

8. The sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques.

9. The description of the geographic distribution and of the natural habitat of the organisms including information

on natural predators, prey, parasites and competitors, symbionts and hosts.

10. The organisms with which transfer of genetic material is known to occur under natural conditions.

11. Verification of the genetic stability of the organisms and factors affecting that stability.

12. The following pathological, ecological and physiological traits -

(a) the classification of hazard according to existing Community rules concerning the protection of human health and the environment;

(b) the generation time in natural ecosystems, sexual and asexual reproductive cycle;

(c) information on survivability, including seasonability and the ability to form survival structures, including seeds, spores and sclerotia;

(d) pathogencity, including infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organisms and possible activation of latent viruses (proviruses) and ability to colonise other organisms

(e) antibiotic resistance, and potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy;

(f) involvement in environmental processes, including primary production, nutrient turnover, decomposition of organic matter and respiration.

13. The sequence, frequency of mobilisation and specificity of indigenous vectors, and the presence in those vectors of genes which confer resistance [to environmental stresses].

14. The history of previous genetic modifications.

Characteristics of the vector

15. The nature and source of the vector.

16. The sequence of transposons, vectors and other non-coding genetic segments used to construct the genetically modified organisms and to make the introduced vector and insert function in those [genetically modified] organisms.

17. The frequency of mobilisation, [and/or] genetic transfer capabilities and[/or] methods of determination of the

inserted vector.

18. The degree to which the vector is limited to the DNA required to perform the intended function.

Characteristics of the [genetically] modified organisms

19. The methods used for the modification.

20. The methods used –

(a) to construct inserts and to introduce them into the recipient organism;

(b) to delete a sequence.

21. The description of any insert and/or vector construction.

22. The purity of the insert from any unknown sequence and information on the degree to which the inserted sequence is limited to the DNA required to perform the intended function.

23. The methods and criteria used for selections.

24. The sequence, functional identity and location of the altered, inserted or deleted nucleic acid segments in question, and in particular any known harmful sequence.

Characteristics of the genetically modified organisms

25. The description of genetic [trait or] traits or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed.

26. The structure and amount of any vector or donor nucleic acid remaining in the final construction of the modified organisms.

27. The stability of the organisms in terms of genetic traits.

28. The rate and level of expression of the new genetic material in the organisms, and the method and sensitivity of measurement of that rate and level.

29. The activity of the gene product.

30. The description of identification and detection techniques, including techniques for the identification and detection of the inserted sequence and vector.

31. The sensitivity, reliability (in quantitative terms), and specificity of detection and identification techniques.

32. The history of previous releases or uses of the [genetically modified] organisms.

33. In relation to human health, animal health and plant health –

(a) the toxic or allergenic effects of the [genetically modified] organisms and/or their metabolic products,

(b) the comparison of the [genetically modified] organisms to the donor, recipient or (where appropriate) parental organisms regarding pathogenicity,

(c) the capacity of the [genetically modified] organisms for colonisation, and

(d) if the [genetically modified] organisms are pathogenic to humans who are immunocompetent-

(i) diseases caused and mechanism of pathogenicity including invasiveness and virulence,

(ii) communicability,

(iii) infective dose,

(iv) host range and possibility of alteration,

(v) possibility of survival outside of human host,

(vi) presence of vectors or means of dissemination,

(vii) biological stability,

(viii) antibiotic resistance patterns,

(ix) allergenicity, and

(x) availability of appropriate therapies.

(e) the other product hazards.

PART III

INFORMATION RELATING TO THE CONDITIONS OF RELEASE [AND THE RECEIVING ENVIRONMENT]

The release

34. The description of the proposed deliberate release, including the purpose or purposes of the release and any intention to use the genetically modified organism as or in a product in the future.

35. The intended dates of the release and time planning of the experiment including frequency and duration of releases.

36. The preparation of the site before the release.

37. The size of the site.

38. The methods to be used for the release.

39. The quantity of [genetically modified] organisms to be released.

40. The disturbance of the site, including the type and method of cultivation, and mining, irrigation or other activities.

41. The worker protection measures taken during the release.

42. The post-release treatment of the site.

43. The techniques foreseen for elimination or inactivation of the [genetically modified] organisms at the end of the experiment [or other purpose of the release].

44. Information on, and the results of, previous releases of the [genetically modified] organisms, and in particular, releases on a different scale or into different ecosystems.

The environment (both on the site and in the wider environment)

45. The geographical location and national grid reference of the site onto which the release will be made, or the foreseen areas of use of the product.

46. The physical or biological proximity of the site of the [genetically modified] organisms to humans and other significant biota.

47. The proximity to significant biotopes, protected areas or drinking water supplies.

48. The climatic characteristics of the region or regions likely to be affected.

49. The geographical, geological and pedological characteristics.

50. The flora and fauna, including crops, livestock and migratory species.

51. The description of the target and non-target ecosystems likely to be affected.

52. The comparison of the natural habitat of the recipient organisms with the proposed site or sites of release.

53. Any known planned developments or changes in land use in the region which could influence the environmental impact of the release.

PART IV

INFORMATION RELATING TO THE INTERACTIONS BETWEEN THE [GENETICALLY MODIFIED] ORGANISMS AND THE ENVIRONMENT

Characteristics affecting survival, multiplication and dissemination

54. The biological features which affect survival, multiplication and dispersal.

55. The known or predicted environmental conditions which may affect survival, multiplication and dissemination, including wind, water, soil, temperature and pH.

56. The sensitivity to specific agents.

Interactions with the environment

57. The predicted habitat of the [genetically modified] organisms.

58. The studies on the behaviour and characteristics of the [genetically modified] organisms and their ecological impact carried out in simulated natural environments, such as microcosms, growth rooms and greenhouses.

59. The capability of post-release transfer of genetic material -

(a) from the genetically modified organisms into organisms in affected ecosystems,

(b) from indigenous organisms to the genetically modified organisms.

60. The likelihood of post-release selection leading to the expression of unexpected [and/]or undesirable traits in the genetically modified organisms.

61. The measures employed to ensure and to verify genetic stability, the description of genetic traits which may prevent or minimise dispersal of genetic material, and methods to verify genetic stability.

62. The routes of biological dispersal, known or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact and burrowing.

63. The description of ecosystems to which the [genetically modified] organisms could be disseminated.

64. The potential for excessive population increase of the [genetically modified] organisms in the environment.

65. The competitive advantage of the organisms in relation to the unmodified recipient or parental [genetically modified] organisms.

66. The identification and description of the target organisms if applicable.

67. The anticipated mechanism and result of interaction between the released [genetically modified] organisms and the target organisms, if applicable.

68. The identification and description of non-target organisms which may be adversely affected by the release of the genetically modified organisms, and the anticipated mechanisms of any identified adverse interaction.

69. The likelihood of post release shifts in biological interactions or in the host range.

70. The known or predicted interactions with non-target organisms in the environment, including competitors, preys, hosts, symbionts, predators, parasites and pathogens.

71. The known or predicted involvement of the organisms in biogeochemical processes.

72. Any other potentially [significant] interactions of the organisms with the environment.

PART V

INFORMATION ON MONITORING, CONTROL, WASTE TREATMENT AND EMERGENCY RESPONSE PLANS

Monitoring techniques

73. Methods for tracing the [genetically modified] organisms and for monitoring their effects.

74. Specificity (to identify the [genetically modified] organisms, and to distinguish them from the donor, recipient or, where appropriate, the parental organisms), sensitivity and reliability of the monitoring techniques.

75. Techniques for detecting transfer of the donated genetic material to other organisms.

76. Duration and frequency of the monitoring.

Control of the release

77. Methods and procedures to avoid and/or minimise the spread of the [genetically modified] organisms beyond the site of release or the designated area for use.

78. Methods and procedures to protect the site from intrusion by unauthorised individuals.

79. Methods and procedures to prevent other organisms from entering the site.

Waste treatment

80. Type of waste generated.

81. Expected amount of waste.

82. Description of treatment envisaged.

Emergency response plans

83. Methods and procedures for controlling the [genetically modified] organisms in case of unexpected spread.

84. Methods, such as eradication of the [genetically modified] organisms, for decontamination of the areas affected.

85. Methods for disposal or sanitation of plants, animals, soils, and any other thing exposed during or after the spread.

86. Methods for the isolation of the areas affected by the spread.

87. Plans for protecting human health and the environment in case of the occurrence of an undesirable effect.

PART VI

INFORMATION ON METHODOLOGY

A description of the methods used or a reference to standardised or internationally recognised methods used to compile the information required by this Schedule, and the name of the body or bodies responsible for carrying out the studies.

SCHEDULE 3

Regulation 14(1)(d)(h) and (i)

INFORMATION TO BE INCLUDED IN AN APPLICATION FOR CONSENT TO

MARKET GENETICALLY MODIFIED ORGANISMS

PART 1

GENERAL INFORMATION

1. The proposed commercial name of the product and names of the genetically modified organisms in the product, and any specific identification, name or code used by the applicant to identify the genetically modified organism.

2. The name and address in the Community of the person who is responsible for the placing on the market, whether it be the manufacturer, importer or distributor.

3. The name and address of the supplier or suppliers of control samples.

4. A description of how the product and the genetically modified organism are intended to be used, highlighting any differences in use or management of the genetically modified organism compared to similar non-genetically modified products.

5. A description of the geographical area or areas and types of environment where the product is intended to be used within the Community, including, where possible, an estimate of the scale of use in each area.

6. A description of the intended categories of users of the product, such as industry, agriculture or consumer use by the public.

7. Information on the genetic modification for the purposes of placing on one or several registers modifications in organisms, which can be used for the detection and identification of particular products to facilitate post marketing control and inspection. This information should include where appropriate the lodging of samples of the genetically modified organism or its genetic material with the National Assembly for Wales, and details of nucleotide sequences or other type of information which is necessary to identify the product and its progeny, for example the methodology for detecting and identifying the product, including experimental data demonstrating the specificity of the methodology. Information that cannot be placed, for confidentiality reasons, in the publicly accessible part of the register should be identified.

8. The proposed labelling, which must include, in a label or an accompanying document, at least in summarised form, a commercial name of the product, a statement that "This product contains genetically modified organisms", the name of the genetically modified organism and the name and address of the person established in the Community who is responsible for the placing on the market, and how to access the information in the publicly accessible part of the register.

PART II

ADDITIONAL RELEVANT INFORMATION

9. The measures to be taken in the event of the escape of the [genetically modified] organisms in the product or misuse of the product.

10. Specific instructions or recommendations for storage and handling of the product.

11. Specific instructions for carrying out monitoring and reporting to the applicant and, if required, the National Assembly for Wales, which are consistent with Part C of Annex VII of the Deliberate Release Directive.

12. The proposed restrictions in the approved use of the genetically modified organism, such as where the product may be used and for what purposes.

13. The proposed packaging.

14. The estimated product in and/or imports to the Community.

15. Any proposed additional labelling, which may include, at least in summarised form, the information referred to in paragraphs 4 and 5 of Part I of this Schedule, or paragraphs 9 to 12 of this Part.

SCHEDULE 4

Regulations 21, 23, 24, 25 and 29

INFORMATION TO BE INCLUDED IN AN ASSESSMENT REPORT

1. An identification of the characteristics of the recipient organism which are relevant to the assessment of the relevant genetically modified organisms.

2. A description of the way in which the characteristics of the organisms have been affected by genetic modifications.

3. An identification of any known risks of change to the environment resulting from the release into the environment of the recipient non-modified organism.

4. An assessment of whether the genetic modification has been characterised sufficiently for the purpose of evaluating any risks to human health and the environment.

5. An identification of any new risks to human health and the environment that may arise from the release of the relevant genetically modified organisms as compared to the release of the corresponding non-modified organism, based on the environmental risk assessment.

6. A conclusion which addresses the proposed use of the product, risk management and the proposed monitoring plan, and states whether the relevant genetically modified organisms should be marketed and under which

conditions, or should not be marketed, including reasons for that conclusion, and whether the views of the competent authorities of the other member States and the Commission are being sought on specified aspects of the environmental risk assessment and what those aspects are.

ANNEX B

BACKGROUND ABOUT THE DIRECITVE

The existing deliberate release regime

In the EU, the regulatory framework for ensuring appropriate risk assessment and management of research and development (R&D) releases and the placing on the market of GMOs has been harmonised for about 10 years. This EU-wide framework is set out in Directive 90/220/EEC and its main features are:

- Common principles for decisions by individual Member States on proposed R&D releases of GMOs in their own territories (Part B releases).
- A single procedure enabling GMO products proposed for placing on the market in one Member State to be cleared for use on the whole EU market (Part C releases).
- Common information requirements for notifications of proposed Part B and C releases focused on the assessment of risks to human health and the environment.
- Common procedures for the exchange of risk assessment, and other, information between Member States, particularly as regards proposed Part C releases.
- A centralised procedure for resolving differences between Member States on Part C notifications and for reaching collective decisions on matters such as guidance.
- A specific mechanism by which Member States can provisionally restrict or prohibit the use and or sale of products (Article 16).

In Great Britain, Directive 90/220 has been implemented by Part VI of the Environmental Protection Act 1990 and the Genetically Modified Organisms (Deliberate Release) Regulations 1992, as amended in 1995 and 1997. Under the implementing legislation, a statutory expert advisory body, the Advisory Committee on Releases to the Environment (ACRE), advises the Welsh Assembly Government, and other responsible Ministers, on the scientific and risk assessment issues surrounding proposed releases.

The new deliberate release Directive

Directive 2001/18 strengthens the regime established by Directive 90/220. The main changes include:

- *Principles for environmental risk assessment* - Article 2.8 and Annex II set out a harmonised approach to risk assessment based on best practice in Member States. In particular, the new

Annex stresses the need for an approach that evaluates risks to human health and the environment "whether direct or indirect, immediate or delayed".

- *Post-market monitoring* - There are new provisions which require that a post-market monitoring plan be submitted as part of an application for a marketing consent (Article 13.2, Annex VII and Article 19.3).
- *Anti-biotic resistance markers* - In addition to their primary modifications, many GMOs have been modified to be resistant to certain antibiotics to make them easier to identify at the laboratory stage of their development. The new Directive sets target dates of 31 December 2004 and 31 December 2008, respectively for Part C and Part B, for the phasing out of antibiotic resistance markers in GMOs which may have adverse effects on human health and the environment (Article 4.2).
- *Traceability and labelling* - The Directive requires Member States to take measures to ensure "traceability" at all stages of the placing on the market of GMOs authorised under Part C (Article 4.6 and Annex IV). The Directive also requires that the words "This product contains genetically modified organisms" must be on a label or in a document accompanying any GMO product (Article 19.2 and Annex 4).
- *Consultation with the public* - The new Directive introduces a mandatory requirement for Member States to consult the public or groups on proposed releases under Part B of the Directive (Article 9.1). The precise form of consultation is a matter for individual Member States to decide, but the Directive requires that consultations should include "a reasonable time period".
- *Information to the public* - Member States are required to make available to the public information on all Part B releases of GMOs in their territory (Article 9.2) and establish public registers of information recording the location of GMOs (Article 31.3a and Article 31.3b).
- *Predictability and transparency of decision-making* - The Directive sets deadlines for each stage of the regulatory process. It also sets a maximum term for Part C marketing consents of ten years (Article 15.4). Consent holders will need to re-apply for consent when the limit is reached.
- *Differentiated and "simplified" procedures* - Directive 2001/18 retains the simplified procedure agreed in 1994. However, use of the procedure by Member States is optional. The Directive also allows Member States or the Commission to propose "differentiated procedures" (Article 7) for certain categories of GMOs under Part B.
- *Ethical and socio-economic issues* - The new Directive does not include ethical or socio-economic issues as specific factors to be taken into account when deciding applications to release or market GMOs. However, it does include provision for consulting ethical committees on matters of a general nature (Article 29) and for periodic reporting on the socio-economic implications of deliberate releases and the placing on the market of GMOs (Article 31.7(d)).