

Welsh Statutory Instrument 2002 No. 3188 (W.304)

The Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002

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STATUTORY INSTRUMENTS

2002 No. 3188 (W.304)

ENVIRONMENTAL PROTECTION, WALES

The Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002

<i>Made</i>	<i>18th December 2002</i>
<i>Coming into force</i>	<i>31st December 2002</i>

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The National Assembly for Wales, being designated^[1] for the purposes of section 2(2) of the European Communities Act 1972^[2] in relation to the control and regulation of the deliberate release of genetically modified organisms, 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) of the Environmental Protection Act 1990^[3], having consulted the Food Standards Agency in accordance with section 126(5) of that Act and of all other powers enabling it in that behalf, makes the following Regulations: -

Part I

General

Citation, commencement and application

1. - (1) These Regulations may be cited as the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002 and shall come into force on 31st December 2002.
- (2) These Regulations apply in relation to Wales.

Interpretation

2. - (1) In these Regulations -

"the Act" ("*y Ddeddf*") means the Environmental Protection Act 1990;

"the Advisory Committee on Releases to the Environment" ("*y Pwyllgor Ymgynghorol ar Ollyngiadau i'r Amgylchedd*") means the Committee appointed by the National Assembly for Wales under section 124 of the Act;

"antibiotic resistance markers" ("*marcwyr ymwrthedd gwrthfotig*") 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" ("*cais am ganiatâd i ollwng*") shall include any notification made under the First Simplified Procedure (crop plants) Decision;

"approved product" ("*cynnyrch wedi'i gymeradwyo*") means a product permitted to be marketed by a consent granted by the National Assembly for Wales 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(2) or (4) of the 1990 Directive;

"the Commission" ("*y Comisiwn*") means the European Commission;

"the Contained Use Directive" ("*y Gyfarwyddeb Defnydd Amgaeëdig*") means Council Directive 90/219/EEC[4] on the contained use of genetically modified micro-organisms as last amended by Council Decision 2001/204/EC[5];

"the Deliberate Release Directive" ("*y Gyfarwyddeb Gollwng Bwriadol*") means Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms[6];

"the 1990 Directive" ("*Cyfarwyddeb 1990*") means Council Directive 90/220/EEC[7] on the deliberate release into the environment of genetically modified organisms as amended by Commission Directive 1994/15/EC[8] and Commission Directive 1997/35/EC[9];

"electronic communication" ("*cyfathrebiad electronig*") means the same as in the Electronic Communications Act 2000[10];

"environmental risk assessment" ("*asesiad risg amgylcheddol*") means the environmental risk assessment required to be contained in an application for consent to release or market genetically modified organisms by regulation 12(1)(c) and regulation 17(2)(c) respectively;

"the First Simplified Procedure (crop plants) Decision" means Commission Decision 94/730/EC[11];

"genetically modified organisms" ("*organeddau a addaswyd yn enetig*") means a genetically modified organism or a combination of genetically modified organisms;

"higher plant" ("*uwchblanhigyn*") means a plant belonging to the taxonomic group

Spermatophytæ (Gymnospermae or Angiospermae);

"local authority" ("*awdurdod lleol*") means the council of a county or county borough;

"monitoring plan" ("*cynllun monitro*") means the plan required by regulation 17(2) (g);

"the register" ("*y gofrestr*") means the public register kept by the National Assembly for Wales under section 122 of the Act;

"the 1992 Regulations" ("*Rheoliadau 1992*") means the Genetically Modified Organisms (Deliberate Release) Regulations 1992[12].

(2) 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 in which that reference occurs.

Designation of competent authority

3. The National Assembly for Wales shall be the competent authority in relation to Wales for the purposes of the Deliberate Release Directive.

Purpose of Part VI of the Act and meaning of "genetically modified organisms" etc.

4. - (1) The amendments of section 106 of the Act (purpose of Part VI of the Act and meaning of "genetically modified organism" etc.) made by the Genetically Modified Organisms (Deliberate Release) Regulations 2002 have effect in relation to Wales as follows:

(2) The amendment made by regulation 3(2) of those Regulations, which substitutes for subsection (1) the following -

" (1) This Part has effect for the purpose of ensuring that all appropriate measures are taken to avoid damage to the environment which may arise from the escape or release from human control of genetically modified organisms.",

also has effect in relation to Wales.

(3) The amendment of subsection (4) made by regulation 3(3) of those Regulations, which substitutes for paragraph (a) the following -

" (a) have been artificially modified, or",

also has effect in relation to Wales.

(4) The amendment made by regulation 3(4) of those Regulations (which inserts subsections (4A) to (4D)) is modified by paragraph (5) and, as so modified, also has effect in relation to Wales.

(5) In subsection (4D), as inserted by that regulation, after "the Secretary of State" insert

"or, in relation to Wales, the National Assembly for Wales".

(6) The text of subsections (4A) to (4D), as inserted by that regulation and modified by paragraph (5), is -

" (4A) Genes or other genetic material in an organism are "artificially modified" for the purposes of subsection (4) above if they are altered otherwise than by a process which occurs naturally in mating or natural recombination.

This subsection is subject to subsections (4B) and (4C) below.

(4B) For the purposes of subsection (4) above -

(a) genes or other genetic material shall be taken to be artificially modified if they are altered using such techniques as may be prescribed for the purposes of this paragraph;

(b) genes or other genetic material shall not be regarded as artificially modified by reason only of being altered by the use of such techniques as may be prescribed for the purposes of this paragraph.

(4C) An organism shall be taken not to be a genetically modified organism for the purposes of this Part if it is an organism of a prescribed description.

(4D) In subsections (4B) and (4C) above "prescribed" means prescribed by regulations made by the Secretary of State or, in relation to Wales, the National Assembly for Wales."

(7) The amendment made by regulation 3(5) of those Regulations (which omits subsections (5) and (6)) also has effect in relation to Wales.

Meaning of "damage to the environment" etc.

5. - (1) The amendments of section 107 of the Act (meaning of "damage to the environment" etc.) made by regulation 4 of the Genetically Modified Organisms (Deliberate Release) Regulations 2002, as described in paragraph (2), also have effect in relation to Wales.

(2) The amendments referred to in paragraph (1) -

(a) substitute for subsection (2) (meaning of "environment") -

" (2) The "environment" includes land, air and water and living organisms supported by any of those media.",

(b) in subsection (3) (meaning of "damage to the environment") omit "to the living organisms supported by the environment",

(c) substitute for subsection (6) (meaning of "harm") -

" (6) "Harm" means adverse effects as regards the health of humans or the

environment.",

(d) substitute for subsection (9) (meaning of organism being under a person's "control") -

" (9) Organisms of any description are under the "control" of a person where he keeps them contained by measures designed to limit their contact with humans and the environment and to prevent or minimise the risk of harm.", and

(e) substitute for subsection (11) (meaning of organism being "marketed") -

" (11) Genetically modified organisms of any description are "marketed" by a person when products consisting of or including such organisms are placed on the market by being made available to other persons, whether or not for consideration.".

Techniques of genetic modification

6. - (1) Until the coming into force of the first regulations under section 106(4B)(a)[\[13\]](#) of the Act, genes or other genetic material shall be taken, for the purposes of subsection (4) of that section, to be artificially modified if they are altered using any of the following techniques:

- (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.

(2) Until the coming into force of the first regulations under section 106(4B)(b) of the Act, genes or other genetic material shall not be regarded, for the purposes of subsection (4) of that section, as artificially modified by reason only of being altered by the use of any of the following techniques:

- (a) in vitro fertilisation;
- (b) natural processes such as conjugation, transduction and transformation; and
- (c) polyploidy induction,

provided that such techniques do not involve the use of recombinant nucleic acid molecules or genetically modified organisms made by techniques or methods other than -

- (i) mutagenesis; or
- (ii) cell fusion (including protoplast fusion) of plant cells or organisms which can exchange genetic material through traditional breeding methods.

(3) Until the coming into force of the first regulations under section 106(4C) of the Act, an organism shall be taken, for the purposes of Part VI of the Act, not to be a genetically modified organism if it is yielded from the techniques or methods listed in paragraphs (2)(i) or (ii) provided that those techniques or methods did not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those made by techniques or methods listed in that paragraph.

Environmental risk assessment

7. - (1) 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; and
- (c) include any bibliographic reference and indications of the methods used where applicable.

(2) 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

8. - (1) 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 or she is required to submit that document in both a paper and in a commonly used electronic form.

(2) Wherever these Regulations require any communication from the National Assembly for Wales to the applicant for a consent or renewal of a consent to be in writing, "writing" shall include an electronic communication.

(3) 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.

Part II

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

Requirement for consent to release

9. The cases and circumstances prescribed for the purposes of section 111(1)(a) of the Act in relation to the release of any genetically modified organisms are all cases and

circumstances in which genetically modified organisms are intended to be released.

Exempt activities

10. The cases and circumstances prescribed for the purposes of section 111(7) of the Act in which persons are exempt from the requirements of section 111(1)(a) of the Act, insofar as those requirements apply to the release of genetically modified organisms, are all cases and circumstances in which release is in accordance with a consent to market genetically modified organisms given by the National Assembly for Wales under section 111(1)(a) of the Act or in which an approved product is released in accordance with the conditions and limitations to which the use of the product is subject.

Applications for consent to release - general provisions

11. - (1) An application for a consent to release genetically modified organisms must be made in writing to the National Assembly for Wales.

(2) Proposed releases of the same genetically modified organism or of a combination of genetically modified organisms 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, in the event of any inconsistency in the requirements as to information to be provided under that Decision and the requirements as to information to be provided under these Regulations, the provisions of that Decision shall prevail.

Information to be contained in application for consent to release

12. - (1) 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 pursuant to the Act or to another competent authority in accordance with Article 6 of the Deliberate Release Directive,

(c) an environmental risk assessment prepared in accordance with regulation 7,

(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.

(2) 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,

(b) an indication of the information submitted in the application, the disclosure of which might harm the competitive position of the applicant and which should therefore be treated as confidential, and

(c) any other information which the applicant considers is relevant.

(3) Any indication in accordance with paragraph (2)(b) must be accompanied by verifiable justification.

Advertisement of application for consent to release

13. - (1) 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) a statement 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) a statement 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 publications containing the advertisement to the National Assembly for Wales.

(2) 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.

(3) 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.

(4) 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, give to the following persons notice in writing that he or she has made the application and shall include in such notice 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[14],
- (d) the Association of National Park Authorities,
- (e) the Countryside Council for Wales[15],
- (f) the Environment Agency;

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

Transitional provisions for release

14. Where the National Assembly for Wales has received an application for consent to release genetically modified organisms before 31st December 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 17th January 2003;
- (c) the application shall be treated as having been sent to the National Assembly for Wales for the purposes of regulations 13(1) and (4) and as having been received by the National Assembly for Wales for the purpose of regulation 21 on submission of the information required by paragraph (b); and
- (d) if the information required by paragraph (b) has not been submitted by 17th January 2003, the National Assembly for Wales may refuse to proceed with the application.

Part III

PLACING ON THE MARKET OF ORGANISMS AS OR IN PRODUCTS

Requirement for consent to market

15. The cases and circumstances prescribed for the purposes of section 111(1)(a) of the Act in relation to marketing genetically modified organisms are all cases and circumstances in relation to the marketing of genetically modified organisms.

Exempt activities

16. The cases and circumstances prescribed for the purposes of sections 108(7) and

111(7) of the Act in which persons are exempt from the requirements of section 108(1)(a) of the Act (to carry out a risk assessment) and of section 111(1)(a) of the Act (to obtain consent), respectively, insofar as they relate to marketing genetically modified organisms, are all cases and circumstances in which -

- (a) an approved product is marketed for a use for which it has approval;
- (b) genetically modified micro-organisms are made available for activities regulated under the Contained Use Directive;
- (c) genetically modified organisms other than micro-organisms falling within paragraph (b) are made available 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;
- (d) genetically modified organisms are made available to be used exclusively for deliberate releases complying with the requirements laid down in Part II;
- (e) a genetically modified organism authorised under Council Regulation (EEC) No. 2309/93[16], as amended by Commission Regulation EC No. 649/98[17], is marketed; or
- (f) a novel food or novel food ingredient within the scope of Regulation EC No. 258/97 of the European Parliament and of the Council[18] is marketed in accordance with that Regulation.

Application for consent to market

17. - (1) An application for consent under section 111(1) of the Act must be made in writing to the National Assembly for Wales.
- (2) 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 has 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 in accordance with Article 6 of the Deliberate Release Directive;
 - (c) an environmental risk assessment prepared in accordance with regulation 7;

- (d) subject to paragraph (3), the information prescribed in Schedule 3;
- (e) the proposed 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;
- (j) a summary of the application in the format established by the Commission under Article 13(2)(h) of the Deliberate Release Directive.

(3) 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,
- (b) an indication of the information submitted in the application, the disclosure of which might harm the competitive position of the applicant and which should therefore be treated as confidential, and
- (c) any other information which the applicant considers relevant.

(4) The information provided in accordance with sub-paragraphs (2)(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.

(5) Any indication in accordance with paragraph (3)(b) must be accompanied by verifiable justification.

(6) Where the applicant can demonstrate in his or her application to the satisfaction of the National Assembly for Wales that, on the basis of the results of any release in pursuance of and in accordance with a consent granted 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

18. Where the National Assembly for Wales has received an application for consent to market genetically modified organisms before 31st December 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;
- (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 17th January 2003;
- (c) the application shall be treated as having been received by the National Assembly for Wales for the purposes of regulation 24 on submission of the information required by paragraph (b) above;
- (d) if, by 31st December 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 17th January 2003, the National Assembly for Wales may refuse to proceed with the application.

Applications for renewal of consent to market

19. - (1) 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 17th October 2006 where the consent was granted before 17th October 2002, and
- (b) no later than nine months before the expiry of the consent in all other cases.

(2) 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 29(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 new consent.

(3) Any consent to market genetically modified organisms granted by the National Assembly for Wales under section 111(1) of the Act before 17th October 2002 for which no application for renewal under paragraph (1) above has been received before 17th 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

20. - (1) The amendment of section 111 of the Act (consents required by certain persons) made by regulation 19(1) of the Genetically Modified Organisms (Deliberate Release) Regulations 2002, which inserts as a second sentence in subsection (6) the following -

" A notice under this subsection must state the reasons for requiring the further information specified in the notice.",

also has effect in relation to Wales.

(2) An applicant for a consent to release or to market genetically modified organisms who notifies the National Assembly for Wales of any information in accordance with section 111(6A) of the Act (requirement for applicant to notify new information regarding risks of damage to the environment) 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.

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

21. Following 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 person by means of a request placed on the register, to make representations to it relating to the release 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; and
- (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) 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).

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

22. - (1) The National Assembly for Wales shall not grant a consent to release genetically modified organisms under section 111(1) of the Act as it relates to the protection of human health without the agreement of the Health and Safety Executive[[19](#)].

(2) 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.

(3) 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.

(4) 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 21(b), provided that this consideration shall not prolong the 90 day period referred to in paragraph (3) by more than 30 days.

(5) 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.

(6) 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

23. 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 would 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 genetically modified organisms

24. - (1) Following 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 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 either -

- (i) send to the applicant an assessment report prepared in accordance with Schedule 4 which indicates that the genetically modified organisms should be permitted to 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 15 and no later than when it sends its assessment report in accordance with paragraph (d).

(2) 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 24(1)(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 24(1)(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.

(3) 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.

(4) Where the National Assembly for Wales intends to submit to the Commission an assessment report which indicates that the genetically modified organisms to which an application relates should be permitted to be marketed, the National Assembly for Wales shall first consult the Health and Safety Executive and shall not forward a favourable opinion on the application as it relates to the protection of human health where the Health and Safety Executive has informed the National Assembly for Wales that it does not fulfil the requirements of the Act and of these Regulations.

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

25. - (1) 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 permitted to 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 objection or objections have been raised by either a competent authority of a Member State or by the Commission but all 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.

(2) 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.

(3) 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.

(4) Subject to paragraphs (5) and (6), a consent to market genetically modified organisms may be given for a maximum period of ten years beginning with the day on which the consent is issued.

(5) For the purpose of granting consent to market a genetically modified organism or a progeny of that genetically modified organism contained in a plant variety where the plant variety is 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 2002/53/EC[20] and 2002/55/EC[21] as amended.

(6) 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[22].

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

26. - (1) Following 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.

(2) Where the National Assembly for Wales intends to submit to the Commission an assessment report which indicates that the genetically modified organisms to which an application relates should be permitted to be marketed, the National Assembly for Wales shall first consult the Health and Safety Executive and not forward a favourable opinion on the application as it relates to the protection of human health where the Health and Safety Executive has informed the National Assembly for Wales that it does not fulfil the requirements of the Act and of these Regulations.

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

27. - (1) 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 all 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.

(2) 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.

(3) The renewed consent to market genetically modified organisms may 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.

(4) 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

28. - (1) 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) 31st December 2004 in the case of marketing, and

(ii) 31st December 2008 in the case of release.

(2) Where prior to 31st December 2004 in the case of marketing and 31st 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

29. 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 in consents to release or market genetically modified organisms

30. - (1) The amendments of section 112 of the Act (consents: limitations and conditions) made by the Genetically Modified Organisms (Deliberate Release) Regulations 2002 have effect in relation to Wales as follows.

(2) The amendment of subsection (1) made by regulation 29(2) of those Regulations, which inserts at the end of that subsection "for the purpose of ensuring that all appropriate measures are taken to avoid damage to the environment which may arise from the activity permitted by the consent", also has effect in relation to Wales.

(3) The amendments of subsection (5) made by regulation 29(3)(a) and (b) of those Regulations, as described in paragraph (4), also have effect in relation to Wales.

(4) The amendments referred to in paragraph (3) are -

(a) in subsection (5)(b) -

- (i) after "Secretary of State" insert "forthwith",
- (ii) omit sub-paragraph (ii), and
- (iii) after that sub-paragraph insert -

" (iii) any unforeseen event, occurring in connection with a release by him, which might affect the risks there are of damage to the environment being caused as a result of their being released;", and

(b) substitute for subsection (5)(c) -

" (c) take such measures as are necessary to prevent damage to the environment being caused as a result of the release or, as the case may be, the marketing of the organisms;".

(5) The amendment of subsection (5) made by regulation 29(3)(c) of those Regulations, which inserts paragraphs (d) and (e), is modified by paragraph (6) and, as so modified, also has effect in relation to Wales.

(6) In paragraphs (d) and (e), as inserted by that regulation, after "the Secretary of State", in both places where it occurs, insert "or, in relation to Wales, the National Assembly for Wales".

(7) The text of paragraphs (d) and (e) of subsection (5), as inserted by that regulation and modified by paragraph (6), is -

- " (d) notify the Secretary of State or, in relation to Wales, the National Assembly for Wales of the measures (if any) taken as a result of new information becoming available or an unforeseen event occurring as described in paragraph (b) (iii) above; and
- (e) in a case where new information becomes available or an unforeseen event so occurs, revise the information contained in his application for a consent accordingly and supply the revised information to the Secretary of State or, in relation to Wales, the National Assembly for Wales.".

Proof of compliance with consent conditions

31. The amendment of section 119(1) of the Act ("Onus of proof as regards techniques and evidence") made by regulation 30 of the Genetically Modified Organisms (Deliberate Release) Regulations 2002, which after "the accused to prove" inserts "the matters described in subsection (1A) below.

" (1A) The matters referred to in subsection (1) above are -

(a) in the case of an offence under section 118(1)(c) above consisting in a failure to comply with the general condition implied by section 112(5)(c) above -

(i) that no measures, other than the measures taken by him, were necessary to prevent damage being caused to the environment from the release or, as the case may be, marketing of the organisms, or

(ii) in a case where he took no measures, that no measures were necessary; and

(b) in any other case,"

also has effect in relation to Wales.

New information on risks of damage to the environment

32. - (1) 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.

(2) Where an application for consent or for renewal of consent to market genetically modified organisms has been made to the National Assembly for Wales and the information referred to in paragraph (1) becomes available to it before the application has been determined, it 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.

(3) Where an application for consent or renewal of a consent to market genetically modified organisms has been made to the National Assembly for Wales and the information referred to in paragraph (1) becomes available to it after the consent has been granted or renewed, it shall ensure that an assessment report prepared in accordance with Schedule 4, 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.

(4) 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 objection or objections have been raised by a competent authority of any Member State or by the Commission but all outstanding issues have been resolved in accordance with Article 20(3) of the Deliberate Release Directive,

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

(5) The National Assembly for Wales shall only vary or revoke a consent to market

genetically modified organisms under section 111(10) of the Act -

- (i) where the information referred to in paragraph (1) has become available to it, and the procedure referred to in paragraphs (3) and (4) have been complied with, or
- (ii) in accordance with a decision adopted by the Commission in accordance with Articles 18(1) or 23(2) of the Deliberate Release Directive.

Part VI

SAFEGUARD

Safeguard

33. - (1) The National Assembly for Wales may serve a prohibition notice under section 110 of the Act to prohibit an act which is authorised by a consent granted by it under section 111 of the Act or by a 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.

(2) 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.

(3) 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.

(4) 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.

(5) 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 and shall at the same time withdraw any prohibition notice which is inconsistent with that decision.

(6) References in this regulation to the National Assembly for Wales exercising a function under section 110 of the Act shall, in any case to which section 126(3) of the Act applies, be treated as references to the National Assembly for Wales and the Food Standards Agency^[23] acting jointly.

Part VII

CONFIDENTIALITY

Confidentiality

34. - (1) 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,
- (e) the name and address of the holder of a consent to which a prohibition notice or other information relates.

(2) The amendments of section 123(7) of the Act (exclusion from register of certain information: particulars included even if commercially confidential) made by regulation 33(2) of the Genetically Modified Organisms (Deliberate Release) Regulations 2002, which -

- (a) after "section 122(1)(a)", inserts "(c)",
- (b) in paragraph (b) for "the description" substitutes "the general description", and
- (c) omits paragraphs (c) and (e),

also have effect in relation to Wales.

Part VIII

REGISTER OF INFORMATION

Information to be included on the register

- 35.** - (1) The register shall contain the particulars set out in paragraphs (2) to (10).
- (2) 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.
- (3) 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 notified to the National Assembly for Wales,
 - (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.

(4) 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.

(5) 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.

(6) The following information concerning the risk of damage being caused to the environment by genetically modified organisms -

(a) any information provided to the National Assembly for Wales in accordance with section 111(6A) or 112(5)(b)(i) of the Act,

(b) any information relating to an unforeseen event occurring in connection with a release of a genetically modified organism which might affect the risks there are of damage being caused to the environment notified to the National Assembly for Wales in accordance with section 112(5)(b)(iii) of the Act.

(7) A copy of any consent to market genetically modified organisms granted by a competent authority of another Member State.

(8) 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.

(9) Any decision adopted by the Commission in accordance with Article 18 of the Deliberate Release Directive.

(10) 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

36. - (1) The information prescribed in regulation 35(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 35(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 35(3)(h) shall be placed on the register within twelve days of the consent being granted or refused.

(4) The information prescribed in regulation 35(5)(a) shall be placed on the register within twelve days of the consent being granted.

(5) The information prescribed in regulation 35(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 35(5)(c) shall be placed on the register within fourteen days of the consent being revoked or varied.

(7) The information prescribed in regulation 35(6) and 35(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 35(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 35(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 35(9) shall be placed on the register within fourteen days of the decision having been notified to the National Assembly for Wales.

Publication of representations

37. - (1) 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 details of where and when paper copies of representations received may be inspected.

(2) 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.

Part IX

MISCELLANEOUS

Precautionary principle

38. In carrying out its functions under Part VI of the Act and these Regulations, the National Assembly for Wales is to take into account the precautionary principle.

Revocations

39. The regulations set out in Schedule 5 are revoked in respect of Wales to the extent specified in that Schedule.

Application of Part VI of the Act to the territorial sea

40. - (1) The amendment of section 127(2) of the Act (definitions etc: application to territorial sea) made by regulation 38(a) of the Genetically Modified Organisms (Deliberate Release) Regulations 2002 also has effect in relation to Wales.

(2) In section 127(2), as so amended, after "as it applies in England" insert "and applies to the territorial sea adjacent to Wales as it applies in Wales".

Application of Part VI of the Act to Wales

41. In consequence of the provision made by regulations 4, 5, 20(1), 30, 31, 34(2) and 40, section 163A of the Act ceases to have effect.

Signed on behalf of the National Assembly for Wales under section 66(1) of the Government of Wales Act 1998[24]

D. Elis-Thomas
The Presiding Officer of the National Assembly

18th December 2002

SCHEDULE 1

Regulations 12 and 17

**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 United Kingdom, 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 or any carrier or foreign DNA remaining in the genetically modified plant,
 - (b) the size and function of the deleted region or regions,
 - (c) the copy number of the insert, and
 - (d) the location or locations of the insert or inserts 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.

18. Any change to the ability of the genetically modified plant 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 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 and target organisms, if applicable.

22. The potential changes in the interactions of the genetically modified plant 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 12 and 17

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) pathogenicity, 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 functions in those organisms.
- 17. The frequency of mobilisation, 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 it or 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 selection.
- 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 organisms.

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

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

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

(c) the capacity of the organisms for colonisation,

(d) if the 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; and

(e) the other product hazards.

Part III

INFORMATION RELATING TO THE CONDITIONS OF RELEASE

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 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 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 organism or organisms.
66. The identification and description of the target organisms if applicable.
67. The anticipated mechanism and result of interaction between the released 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 potential 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 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

- 88. 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 17(2)(d) and (h) and (6)

**INFORMATION TO BE INCLUDED IN AN APPLICATION FOR CONSENT TO
MARKET GENETICALLY MODIFIED ORGANISMS**

Part I

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 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 24, 26 and 32

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 modification.

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.

SCHEDULE 5

Regulation 39

REVOCATIONS

<i>Regulations revoked</i>	<i>References</i>	<i>Extent</i>
The Genetically Modified Organisms (Deliberate Release) Regulations 1992	S.I. 1992/3280 as amended by the Genetically Modified Organisms (Deliberate Release) Regulations 1993 (S.I. 1993/152), the Genetically Modified Organisms (Deliberate Release) Regulations 1995 (S.I. 1995/304), the Genetically Modified Organisms (Deliberate Release and Risk Assessment-Amendment) Regulations 1997 (S.I. 1997/1900), and the Genetically Modified Organisms (Contained Use) Regulations 2000 (S.I. 2000/2831).	The whole Regulations
The Genetically Modified Organisms (Deliberate Release) Regulations 1993	S.I. 1993/152	The whole Regulations
The Genetically Modified Organisms (Deliberate Release) Regulations 1995	S.I. 1995/304	The whole Regulations

The Genetically Modified Organisms (Deliberate Release and Risk Assessment-Amendment) Regulations 1997	S.I. 1997/1900	Regulation 2
The Genetically Modified Organisms (Contained Use) Regulations 2000	S.I. 2000/2831	Regulation 31(2)

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which apply only to Wales, implement Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC ("the Deliberate Release Directive"). They revoke the Genetically Modified Organisms (Deliberate Release) Regulations 1992 (S.I. 1992/3280) and make amendments to Part VI of the Environmental Protection Act 1990 ("the 1990 Act"). The Regulations are divided into nine parts and have five Schedules.

The subject matter of the Directive and its predecessor is the control of the deliberate release into the environment and the marketing of genetically modified organisms by means of the imposition of a requirement to obtain consent for those activities and to comply with the conditions imposed on the consent. The changes introduced by the Directive strengthen the existing control regime, particularly in respect of post marketing monitoring.

Directive 1990/220/EEC was implemented partly by the (pre-existing) provisions of Part VI of the Act and partly by the Genetically Modified Organisms (Deliberate Release) Regulations 1992.

These Regulations apply in relation to Wales the amendments made to the Act by the Genetically Modified Organisms (Deliberate Release) Regulations 2002 which are required to implement the Directive. They also revoke the 1992 Regulations.

The statutory basis for the requirement to obtain consent for the release or marketing of genetically modified organisms is section 111(1) of the Act. The cases and circumstances in which consent is required are prescribed in these Regulations. A general requirement to obtain consent for the release or marketing of genetically modified organisms is imposed by regulation 9 (for release) and regulation 15 (for marketing). This general requirement is subject to the exemptions provided for in regulations 10 (for release) and 16 (for marketing).

The definitions used in the provisions relating to the control regime are contained in sections 106, 107 and 127(1) of the Act. Regulations 4 and 5 amend a number of these definitions to reflect the Directive. Regulation 4 also amends the power in section 106 for the National Assembly for Wales to prescribe techniques which result in organisms becoming "genetically modified". However, on coming into force of these Regulations, references in the Act to "genetically modified organisms" will be interpreted by reference to the modification techniques described in regulation 6.

Parts II and III of the Regulations impose requirements for applications for consent to release and market, respectively, genetically modified organisms (including transitional provisions).

Part IV lays down the procedure for dealing with applications from their receipt to their determination (and, in the case of consents to release, their subsequent variation or revocation). For release consents this includes provisions for public consultation and for marketing consents (and renewals of such consents) their agreement at European Community level.

Part V includes general requirements for marketing consents and amends section 112 of the Act (which imposes conditions on consents). It also provides for what should happen when new information becomes available which affects the risk assessment for the marketing of a genetically modified organism.

Part VI supplements section 110 of the Act insofar as it allows action to be taken to prohibit the marketing of a genetically modified organism which has consent so as to bring it into line with the taking of "safeguard action" under the Directive.

Part VII prescribes additional categories of information to be made public, notwithstanding that they may be commercially confidential, for the purposes of section 123(7) of the Act.

Part VIII includes the requirement for different categories of information to be included in the public register to be kept by the National Assembly for Wales under section 122 of the Act.

Part IX includes a requirement for the National Assembly for Wales to take the precautionary principle into account in carrying out its functions under the Act and these Regulations. The "precautionary principle" is a term derived from Article 174 of the Treaty Establishing the European Community. The preamble to the Directive states that the principle must be taken into account in the implementation of the Directive.

Schedule 1 sets out the information to be included in applications for consent to release or market genetically modified higher plants.

Schedule 2 sets out the information to be included in applications for consent to release or market genetically modified organisms other than genetically modified higher plants.

Schedule 3 sets out the information to be included in an application for consent to market genetically modified organisms.

Schedule 4 sets out the information to be included in an assessment report.

Schedule 5 specifies the Regulations revoked by these regulations.

A regulatory appraisal has been prepared for these regulations and is available on the National Assembly for Wales web-site (www.wales.gov.uk). Copies can be obtained from the Welsh Assembly Government, Plant Health and Biotechnology Branch, Crown Buildings, Cathays Park, Cardiff, CF10 3NQ.

Notes:

[1] S.I. 2001/3495.[back](#)

[2] 1972 c.68.[back](#)

[3] 1990 c. 43. The functions of the Secretary of State under these provisions (with the exception of section 156) were transferred to the National Assembly for Wales under Article 2 of and Schedule 1 to the National Assembly for Wales (Transfer of Functions) Order 1999 (S.I. 1999/672). The functions of the Minister of Agriculture, Fisheries and Food under these provisions were transferred to the National Assembly for Wales under Article 2 of and Schedule 1 to the National Assembly for Wales (Transfer of Functions) Order 2000 (S.I. 2000/253).[back](#)

[4] OJ No. L117, 8.5.1990, p.1.[back](#)

[5] OJ No. L73 ,15.03.2001, p.32 - 34[back](#)

[6] OJ No. L106, 17.4.2001, p.1.[back](#)

[7] OJ No. L117, 8.5.90, p.15.[back](#)

[8] OJ No. L103, 22.4.94, p.20.[back](#)

[9] OJ No. L169, 27.6.97, p.72.[back](#)

[10] 2000 c.7.[back](#)

[11] OJ No. L292, 12.11.1994, p.31.[back](#)

[12] S.I. 1992/3280. The functions of the Secretary of State under these regulations were transferred to the National Assembly for Wales under Article 3 and Schedule 1 to the National Assembly for Wales (Transfer of Functions) Order 2000 (S.I. 2000/253).[back](#)

[13] Section 106(4) is amended by regulation 3(3) and section 106(4A) to 106(4D) is inserted by regulation 3(4) of the Genetically Modified Organisms (Deliberate Release) Regulations 2002, and are given effect in Wales subject to further modification by regulation 4 of these Regulations.[back](#)

[14] S.I. 2000/2831.[back](#)

[15] *See* section 128 Environmental Act 1990 (c.43).[back](#)

[16] OJ No. L214, 24.8.1993, p.1.[back](#)

[17] OJ No. L88, 24.3.1998, p.7.[back](#)

[18] OJ No. L43, 14.2.1997, p.1.[back](#)

[19] *See* section 10 of the Health and Safety at Work etc. Act 1974 (c.37).[back](#)

[20] OJ No. L193, 20.7.2002, p.1.[back](#)

[21] OJ No. L193, 20.7.2002 p.33.[back](#)

[22] Council Directive 1999/105/EC on the marketing of forest reproductive material OJ No. L11, 15.1.2000, p. 17.[back](#)

[23] *See* section 1 of the Food Standards Act 1999 (c.28).[back](#)

[24] 1998 c.38.[back](#)

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