DRAFT:
DELIBERATE RELEASE OF GENETICALLY
MODIFIED ORGANISMS: A GUIDE

November 2002
Department for Environment, Food and Rural Affairs
CHAPTER 1 SUMMARY

This guide contains practical guidance on legislation controlling the deliberate release of genetically modified organisms (GMOs) in England. It replaces the previous DOE/ACRE Guidance Notes 1, [7 and 10]. [This guide is not a legally binding document, authoritative interpretation of the law is ultimately a matter for the courts.]

Summary

- This document sets out the purpose, scope and main aspects of the deliberate release regime as it affects England in terms of Part B (non-commercial) and Part C (commercial) releases of GMOs

- It explains the difference between Part B (non-commercial) releases and Part C (commercial) releases

- It explains the relationship between the three main pieces of legislation (Directive 2001/18, the Environmental Protection Act, and the Regulations) which together form the regulatory framework for deliberate release of GMOs in England

- It outlines, step-by-step, the regulatory process that must be complied with and who the key players are in England, in order to obtain the Secretary of State’s permission to deliberately release a GMO into the environment.
Chapter 2

INTRODUCTION

1. The Genetically Modified Organisms (Deliberate Release) Regulations 2002 have replaced the Genetically Modified Organisms (Deliberate Release) Regulations 1992. The 2002 Regulations are made, in part, under the powers of the Environmental Protection Act 1990 (EPA) which gives the Secretary of State certain powers and responsibilities regarding the deliberate release of GMOs. The Regulations supplement the EPA and implement other changes made by Directive 2001/18/EC.

2. The Scottish Parliament, the National Assembly for Wales, and the Department of the Environment in Northern Ireland will be introducing their own regulations and guidance covering aspects of the Directive for which they have devolved powers.

3. Directive 2001/18/EC represents EU legislation designed to protect human health and the environment across the EU from any adverse effects that may be caused by the deliberate release into the environment of genetically modified organisms (GMOs). It does this by setting out a system by which GMOs have to be approved on safety grounds before they are allowed to be released into the environment anywhere in the EU. It also requires that the national legislation and administrative provisions of all 15 Member States are brought into line with the Directive to ensure that the same safety standards are met across the EU.

Information box 1 – main aspects of the deliberate release regime

In essence, the regulatory process under Directive 2001/18/EC requires that:

(i) any GMO must be authorised before it can be released into the environment. Each application for a consent to release GMOs is judged on its own merits in terms of potential risks it poses to human health or the environment.

(ii) applications are scrutinised by independent scientific experts to see whether they meet the safety standards of Directive 2001/18, and a public consultation is held.

(iii) a decision is taken by regulators based on expert advice and public representations, and a consent is either granted or refused. If a consent is granted, conditions will be attached to it specifying how the GMO may be used (and how it may not be used).

(iv) any GMO that is released into the environment will be monitored. If new risks come to light regulators can amend or revoke a consent.
Scope of the Regulatory Framework

4. The Directive is wide ranging and covers GMOs of all types, including plants, animals and micro-organisms. Under the Directive the term “genetically modified organism” excludes human beings. GMO releases are not covered by the Directive if other sectoral legislation that provides for a level of protection to human health and the environment equal to that of the Directive applies (e.g. GM medicines).

Part B research release/Part C commercial releases

5. Directive 2001/18 deals with two distinct types of GMO release. Part B of the Directive sets out the process that a GMO must go through before it can be released for “any other purpose than for placing on the market” (including for the purposes of scientific research). Part C of the Directive sets out the process of scrutiny for the “placing on the market of GMOs as or in products”. Correspondingly, for the purposes of this guidance:

- “Part B” refers to non-commercial including research releases (see Information Box 3 which describes the main aspects of the process)
- “Part C” refers to commercial releases. (see Information Box 4)

6. The decision making processes for Part B and Part C GMOs are different. Responsibility for decision making on Part B applications lies at the Member State level and as such is fully implemented in national legislation. Responsibility for decision making on Part C applications lies primarily at EU-level, although it also involves action at the Member State level (in essence, a Part C application is made initially to one of the Member States, then a collective decision is made by all Member States and the Commission acting jointly). Accordingly, our national legislation only covers aspects of the Part C process that take place at the Member State level (e.g. action the Secretary of State must take if an application for a Part C consent is made to her). Other Member States are implementing similar legislation for dealing with Part C applications made to them. Aspects of the Part C procedure that take place at the EU level are covered by the Directive itself.

Directive/Environmental Protection Act/Regulations

7. Implementation of the Directive in England is made up of three main elements. These are:

- the Directive itself - this provides the legal foundation for implementing legislation in all 15 Member States. It also provides for aspects of the regulatory framework that take place solely at

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1 The Regulations and the Environmental Protection Act 1990 refer to powers granted to, and requirements on, the “Secretary of State”. In practice, administration and decision making under the deliberate release regime is delegated to Defra officials and Ministers.
EU level, for instance collective decision making by the European Commission and all Member States on the granting or refusal of Part C consents. A summary of the EU level decision making process is at Chapter 5.

- Part VI of the Environmental Protection Act 1990 (EPA) – primary legislation that gives the Secretary of State powers and responsibilities to control the deliberate release of GMOs in England, and to implement the Directive. (see Chapter 3)

- the Regulations – secondary legislation that supplements the EPA (e.g. the EPA sets the broad requirement that a person wanting to release a GMO in England must apply to the Secretary of State for a consent to do so – the Regulations set out the detail of how this must be done). The Regulations also directly implement aspects of the Directive in England. (see Chapter 4)

8. Taken together, the Directive, the EPA and the Regulations mark out the legislative rules and administrative procedures covered by the new regulatory framework as it regards England.

<table>
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<tr>
<th>Information box 2: key players in the regulatory process</th>
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<tr>
<td>• the applicant – a person or organisation who wishes to release a GMO, who must submit an application for a consent to do so</td>
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<td>• the public – who get a chance to comment on Part B and Part C applications before decisions are made</td>
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<td>• the Advisory Committee on Release to the Environment – a committee of independent scientific experts that assess GMOs for safety and advise Defra</td>
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<tr>
<td>• Defra – which decides whether or not proposed [R&amp;D] [non-commercial] GMO releases in England meet the safety criteria of the Regulations, and issues or refuses a Part B consent accordingly</td>
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<tr>
<td>• The European Community – the European Commission and the 15 Member States, which take collective decisions on whether or not to grant Part C consents (which would allow the GMO to be released commercially in the EU single market).</td>
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Information Box 3: “Part B” applications – main stages

Stage 1: application
- Applicant makes application and Secretary of State (SoS) informs applicant of date of receipt.

Stage 2: consultation
- Not more than 10 days after start of Stage 1, applicant advertises application, notifies prescribed bodies, and copies advertisement to SoS.
- Within 12 days of end of Stage 1, SoS puts information about application on public register and invites representations within not less than 60 days from end of Stage 1.
- Within 30 days of end of Stage 1, SoS sends summary of application to European Commission for circulation to other Member States.

Stage 3: assessment and decision
- Not less than 60 days from end of Stage 1, SoS takes into account any representations, comments from Commission or other Member States, and the advice of ACRE, including advice on any representations or comments received.
- Not less than 60 and not more than 90 days from the end of Stage 1, SoS tells applicant of decision on granting or refusal of consent.
- The 90-day period does not include any period while the SoS is either (a) awaiting further information from the applicant or (b) considering representations, provided consideration does not prolong Stage 3 by more than 30 days.
- The SoS places on register any more detailed and appropriate information about an application of which she has become aware.

Stage 4: information about decision
Within 12 days of end of Stage 3, SoS puts on public register advice of ACRE on the application and a copy of any consent granted.
Information Box 4: “Part C” applications made in England – main stages

Stage 1: application
- Applicant makes application and Secretary of State (SoS) informs applicant of date of receipt.

Stage 2: initial consultation
- SoS sends summary of application to other Member States and European Commission.
- Within 12 days of end of Stage 1, SoS puts information about application on UK register.
- Commission makes summary public and invites comments within 30 days, and sends any comments to SoS and other Member States.

Stage 3: initial assessment and decision
- Not more than 90 days from the end of Stage 1, SoS sends assessment report to applicant indicating whether the GMOs should or should not be marketed, taking account of ACRE’s advice, etc. If the assessment is negative, the SoS rejects the application.
- The 90-day period does not include any period whilst SoS is awaiting further information from the applicant. Any further relevant further information is placed on register.

Stage 4: further consultation
- SoS sends assessment report to Commission (a) if it is favourable, no more than 90 days from the end of Stage 1 or (b) if it is unfavourable, no sooner than 15 days from the date the report is sent to the applicant, and no later than 105 days from the end of Stage 1.
- No later than when the assessment report is sent to applicant, SoS sends application to Commission, which sends report and application to other Member State within 30 days.
- Commission circulates any comments or reasoned objections within 60 days.
- Commission makes assessment reports recommending that consent be granted available to the public and invites comments within 30 days, and sends any comments to SoS and other Member States.
- If consultation raises no outstanding issues, SoS issues final decision in favour of application.
Other Legislation

9. The Genetically Modified Organisms (Contained Use) Regulations 2000 (which implement in the UK the Contained Use Directive (90/219/EEC as amended by 98/81/EC) for genetically modified micro-organisms) applies to activities in which organisms are genetically modified or in which genetically modified organisms are cultured, stored, transported, destroyed, disposed of or used in any other way and for which physical, chemical or biological barriers, or any combination of such barriers, are use to limit their contact with, and to provide a high level of protection for, humans and the environment. Notification to the Competent Authority of all premises where genetic modification is to take place is required, as is prior notification of certain higher risk activities; consents are required for the highest risk activities. Further details can be found in HSE’s A Guide to the Genetically Modified Organisms (Contained Use) Regulations 2000.

10. GMO products may have to satisfy other regulatory procedures that apply to the commercial use of similar products, whether or not their production involves genetic modification. For example, for the main agricultural and vegetable species, new varieties may not be marketed unless they have been added to the UK National List or the European Common Catalogue (an amalgam of MS National Lists). This requires a series of tests and trials to demonstrate that new varieties are distinct, uniform and stable, and for agricultural varieties, that they have a value for cultivation and use in the UK. GM varieties must also have a marketing consent under GM legislation as well as Novel Foods approval where appropriate before they can be added to the National List.

11. Any use of pesticides on GM crops has to be approved under the Control of Pesticide Regulations 1986 (as amended) and the Plant Protection Products Regulations 1995 (as amended). In seeking any extension of approval of a pesticide to include GM crops, the necessary safety and efficacy data would have to be supplied by the applicant. The Pesticide Safety Directorate would evaluate the application against the considerations of human and environmental safety which have been established for all pesticide uses.

12. The Animals (Scientific Procedures) Act 1986, administered by the Home Office, regulates the production, possession and use of protected animals, living vertebrate animals and the invertebrate species octopus vulgaris, for experimental or other scientific purposes. The deliberate release of GM animals protected by the 1986 Act for an experimental or other scientific purpose will also require the express permission of the Secretary of State for the Home Department, unless the Secretary of State for the Home Department has specifically discharged them from the controls of the 1986 Act.

13. In addition at present any GM product to be used as or in food must be approved under European Commission Regulation 258/97 concerning

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novel foods and novel food ingredients. Applications or enquiries should be made to the Food Standards Agency which is the UK Competent Authority. Use of a GM product as an animal feed is currently covered under Directive 2001/18 as there is no specific sectoral legislation on GM animal feedingstuffs, but the Commission has issued proposals that would introduce new procedures for the pre-market approval of both GM food and feed products.

14. There are also separate regulatory procedures that any human or animal medicines containing GMOs have to go through before being allowed to be administered to humans or animals.

**NOTE:** This is not a complete list of all other legislation that may have a bearing on work with GMOs. It will be for an applicant to ensure that they comply with all the relevant Regulations.

**Administrative arrangements**

15. To apply for a consent for the deliberate release of genetically modified organisms (GMOs) it is necessary to submit a written application to the Department for the Environment Food and Rural Affairs (Defra). There are four different formats for applications and these can be found on the Defra website at [www.defra.gov.uk/environment/gm/formats/index.htm](http://www.defra.gov.uk/environment/gm/formats/index.htm). Once completed the application should be sent to

Chemicals and GM Policy Division  
Defra  
3/G9 Ashdown House  
123 Victoria Street  
London, SW1E 6DE
CHAPTER 3: ENVIRONMENTAL PROTECTION ACT 1990

Part VI of the Environmental Protection Act 1990

**Summary**


- EPA Part VI provides for:
  - **core principles and definitions of key terms** of the regime
  - **key procedural elements** - e.g. the requirement that any GMO must be authorised before it can be released
  - **enforcement powers** - e.g. for the Secretary of State to appoint inspectors to ensure that releases are being conducted in the manner authorised by the consent
  - **offences** - actions which are considered to be offences under the Act, and fines and prison sentences that may be imposed by a court if an offence is committed.
  - **fees and charges** by which the Government can recover the costs of processing applications and enforcement from applicants and consent holders.

1. Part VI of the Environmental Protection Act 1990 (EPA) is the primary legislation in England controlling the deliberate release into the environment of GMOs. The 2002 Regulations are a statutory instrument made, for a large part, under the EPA. In general terms, the EPA sets the broad purpose, principles and requirements of the deliberate release regime in England, whilst the 2002 Regulations go into detail on how this should be achieved. For instance, the EPA requires that any deliberate release of a GMO in England must be authorised by the Secretary of State – and the regulations describe in detail how an application should be made, timescales, how the public should be consulted and so on. The EPA also provides for enforcement powers and for offences and penalties stemming from non-compliance with the Act.

2. This chapter deals with broad concepts within the EPA that are necessary to understand the deliberate release regime in England. Specific provisions of the EPA are dealt with in the guidance on the 2002 Regulations themselves, in the context of how the EPA and the 2002 Regulations combine in practice, in Chapter 3.

**Purpose**

The purpose of Part VI of the EPA is to ensure that “all appropriate measures are taken to avoid damage to the environment being caused by the escape or release from human control of genetically modified organisms”\(^3\).

\(^3\) Section 106(1) of EPA Part VI, as amended by regulation 3(1)(a) of the 2002 Regulations
Scope and effect of provisions in force

3. EPA Part VI was introduced in 1990 in response to the emerging scientific and commercial activity on genetically modified organisms, and in anticipation of European legislation in this area. It contains broad provisions on the deliberate release of GMOs. Following the introduction of EC Directive 90/220 in 1991 (with which all national legislation was required to conform) only those aspects of the EPA that were necessary to implement the Directive were brought into force\(^4\). In practical terms this means that some parts of the EPA Part VI have been brought into force, and some have not. A summary of the provisions in force is at Annex H.

4. [List of amendments to the Act and website details of where to find them on the Parliamentary website to be included.]

Key terms and concepts

5. Sections 106 and 107 of the EPA define key concepts relating to the regime. Some are directly relevant to the purpose of the regime as described above including the definition of terms such as “environment”, “damage to the environment”, “harm”, “escape or release from human control”, and “genetically modified organism”. Others relate to the practical implementation of the purpose of the regime, such as the provisions defining when a GMO is “released” or “marketed”.

“Environment”, “damage to the environment” and “harm”

6. In terms of the deliberate release regime the “environment” includes land, air and water and the living organisms supported by any of those media\(^5\). [see amended definition] This definition covers all living things individually or collectively - including humans, animals, plants, fungi, micro-organisms, and whole ecosystems. It also covers inert aspects of the environment consisting of “land”, “air” or “water” – e.g. property such as buildings, physical aspects of landscapes and so on.

7. “Damage to the environment” is taken to mean the presence in the environment of genetically modified organisms which have (or of a single organism which has) escaped or been released from a person’s control and are (or is) capable of causing harm\(^6\). “Harm” is taken to mean any adverse effects on human health or the environment\(^7\). Under these definitions “damage to the environment” would occur if a GMO had an adverse effect on any living organism supported by the environment, or on an inert aspect of the environment itself.

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\(^4\) The relevant provisions were brought into force by two commencement orders – The Environmental Protection Act 1990 (Commencement No. 7) Order 1991 (Statutory Instrument 1991 No. 1042 (c.27)), and The Environmental Protection Act 1990 (Commencement No. 12) Order 1992 (Statutory Instrument 1992 No. 3253 (c.101)).

\(^5\) Section 107(2) of EPA Part VI, as amended by regulation 3(2)(a) of the 2002 Regulations.

\(^6\) Section 107(3) of EPA Part VI, as amended by regulation 3(2)(b) of the 2002 Regulations.

\(^7\) Section 107(6) of EPA Part VI, as amended by regulation 3(2)(c) of the 2002 Regulations.
“Release”, “control” and “escape”

8. The definitions of “release”, “control” and “escape” help define the scope of the deliberate release regime – in that releases of GMOs into the environment are covered by the deliberate release regime, and GMOs under control are covered by contained use legislation. Escapes from the defined conditions, whether from the deliberate release or contained use regimes are covered by the respective legislation.

9. Under the EPA a GMO is “released” if someone deliberately allows it to pass from their control into the environment.8 A GMO would “escape” if it passed unintentionally from a person’s control into the environment. GMOs are considered to be under “control” if they are contained by specific measures used to limit their contact with and to provide a high level of safety for the general population and the environment.9 Whether or not a GMO is considered to be under “control” will depend on the specific circumstances of each case, although in general terms “control” would involve a physical barrier that limits the possibility that a GMO can have contact with the outside “environment”.

[examples to be included]

“Marketed”

10. In terms of the EPA, GMOs of any description are “marketed” 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.10

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8 In terms of the deliberate release regime the term “released” is used to describe only non-commercial releases of GMOs (e.g. research trials). Releases intended to take place on a commercial basis are treated differently and are described as being “marketed”, as defined in paragraph 10.
9 Section 107(9) of EPA Part VI, as amended by regulation 3(2)(d) of the 2002 Regulations
10 Section 107(11) of EPA Part VI, as amended by regulation 4(6) of the 2002 Regulations to reflect the definition of “placing on the market” given by Article 2(4) of Directive 2001/18/EC.
“Requirement for consent”

11. Section 111(1) of the EPA imposes the basic requirement for consent for specified activities involving GMOs in circumstances and cases prescribed by the Secretary of State. Regulations 8 and 14 have the effect of imposing the requirement for consent in respect of all cases involving the deliberate release or marketing of GMOs. Regulation 15(a) excludes from the requirement for marketing consent GMOs already approved under Part C of the Directive. The remaining provisions of regulation 15 exclude specific cases from the requirement for consent, including GMOs which comply with the requirements of the contained use regime and products, such as GM novel foods or medicines which are covered by sector specific EU legislation.

Imports

12. Because of the way in which “marketing” is defined in the EPA the requirement for consent imposed by section 111 extends to the import of GMOs intended for commercial release in England. To illustrate, GM seeds imported into England from North America that are intended to be grown commercially as GM crops would have to be authorised under Part C of the Directive. Imports of GM products that are not intended to be released into the EU environment would not need to be authorised under Directive 2001/18, although they may fall under other EU legislation. For instance, GM maize imported into the EU intended only for use as a food ingredient may not fall under Directive 2001/18, provided that no release takes place (e.g. it is transported straight to a food processing plant under containment). However, the food and food ingredient would require approval under EC Regulation 258/97 on novel foods and novel food ingredients.

Exemptions

13. The Directive specifies some activities relating to exchanges of GMOs between parties that are not to be considered as “placing on the market”. These exclusions relate to GMOs that comply with the requirements either of the contained use regime or Part B of the Directive (which covers non-commercial releases of GMOs). They also exclude specific types of GMO products – GM novel foods and GM medicinal products - that are covered by sector specific EU legislation11. Other than these exclusions any GMO product that is released into the environment on a commercial basis in the EU must be authorised under Part C of Directive 2001/18/EC.

Conditions placed on consents

11 Exceptions to the regime’s definition of “marketed” are dealt with by regulation 12(1) of the 2002 Regulations. Guidance on this comes later in this document.
14. Section 112 of the EPA provides that any consent that is issued by the SoS may be subject to enforceable conditions. These enable her to control and regulate GMOs after they have been released into the environment under Part B or Part C consents. Conditions of consents are summarised in an explanatory memorandum attached to each consent, the format for which is at Annex F. There are 2 basic types of conditions—(i) general conditions and (ii) specific conditions.

**Conditions on Part B consents**

15. Decisions on whether or not to issue Part B (non-commercial) consents and any conditions placed on them are taken at the Member State level, and Directive 2001/18 gives individual competent authorities a large amount of flexibility in how they apply such conditions. In essence the Secretary of State can attach any condition she sees fit to a Part B consent, provided it is designed to prevent adverse impacts on human health or the environment, and the reasoning behind them must have a sound science basis. This allows the Secretary of State to have a high level of control over Part B releases, which are small-scale and intensively managed.

**Conditions on Part C consents**

16. Decisions on whether or not to issue Part C (commercial) consents and any conditions placed on them are taken collectively by the European Commission and all Member States. Section 112 of the EPA sets out general conditions applicable to all consents. Regulation 28 also requires that each Part C consent specifies:

- the scope of the consent
- its period of validity
- conditions under which the GMO can be placed on the market, including:
  - specific conditions on use
  - handling and packaging of the GMOs as or in products
- conditions for the protection of particular ecosystems/environments and/or geographical areas
- that the consent holder must make control samples available to the competent authority on request
- labelling requirements
- monitoring requirements, including any monitoring obligations on users of the GMO.

17. Importantly, conditions on Part C consents can be made to apply to users of GMOs, not just the consent holder. For example, the labelling requirements attached to a GM crop consent can be made to apply to (i) the consent holder (ii) the farmer who buys the seed (iii) the merchant who buys the harvested crop, and so on down the supply chain. Placing conditions on users of GMOs may also provide us with an opportunity to act on suggestions arising from the public debate. To illustrate, if the debate demands that no GMO be grown near a national park - a Part C consent may require that a GMO may not be grown...
within say 2km of a national park provided this can be justified on the grounds of environmental protection. If a farmer ignored this condition, it would be the farmer (who would not necessarily be the consent holder) that Defra would prosecute.

Advisory Committee on Releases into the Environment (ACRE)

18. Section 124 of the EPA requires the Secretary of State to appoint a committee to advise on the exercise of powers under the EPA. This committee is the Advisory Committee on Releases into the Environment (ACRE), a group of independent scientific experts from a range of fields relevant to the release of GMOs into the environment. ACRE plays a crucial role in giving the Secretary of State expert advice, on a case-by-case basis, of the risks posed by GMOs to human health and the environment. The advice of ACRE in respect of applications to release GMOs must be made public12.

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12 See Regulation 32(3)(h)
Chapter 4 – Guidance on the 2002 Regulations

PART I
General

Regulation 1 Citation, extent and commencement

(1) These Regulations may be cited as the Genetically Modified Organisms (Deliberate Release) Regulations 2002, and shall come into force on 17 October 2002.

(2) Except for this regulation, regulation 38, insofar as it relates to the continental shelf, and regulation 2, insofar as it defines “the Act” for the purposes of regulation 38, these Regulations shall extend only to England and Wales.

(3) Except for this regulation, regulations 3, 4, 19(1), 29, 30, 33(2), 38 and 39 and regulation 2, insofar as it defines “the Act” for the purposes of the regulations referred to in this paragraph, these Regulations shall apply only to England.

Guide 1 These regulations (except for the provision relating to the continental shelf) apply in England only. The Scottish Executive, the National Assembly for Wales and the Department for the Environment, Northern Ireland will implement regulations with regard to their own territories.

Accordingly, a person wishing to release a Part B GMO in England should apply for authorisation to the Secretary of State for Environment, Food and Rural Affairs. A person wishing to release a Part B GMO elsewhere in the UK should apply to the relevant territorial competent authority. A person wishing to release a GMO in more than one territory of the UK should make a Part B application in each of the territories in which a release is proposed (e.g. in order to conduct a programme of research on a GMO in both England and Scotland, a consent would be required from both English and Scottish competent authorities).

A person wishing to apply for a Part C consent (i.e. to market a GMO product in the EU) should make an application to the UK CA or Member State in whose territory the GMO is first intended to be marketed.

Regulation 2 Interpretation

(1) In these Regulations –

"the Act" means the Environmental Protection Act 1990;

"the Advisory Committee on Releases to the Environment“ means the committee appointed by the Secretary of State under section
124 of the Act;

“antibiotic resistance markers” means genes employed in the modification of an organism to make that organism express resistance to a particular antibiotic or antibiotics;

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

“approved product” means a product permitted to be marketed by a consent granted under section 111(1) of the Act by a person other than the Secretary of State or otherwise 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” means the European Commission of the Communities;


“electronic communication” means the same as in the Electronic Communications Act 2000(h);

“environmental risk assessment” means the environmental risk assessment required by to be contained in an application for consent to release or market genetically modified organisms by Regulation 11(1)(c) and Regulation 16(2)(c) respectively;

“the First Simplified Procedure (crop plants) Decision” means Commission Decision 94/730/EC(i);

“genetically modified organisms” means a genetically modified organism or a combination of genetically modified organisms;

“higher plant” means a plant belonging to the taxonomic group Spermatophytae (Gymnospermae or Angiospermae);

“local authority” means a county council, a district council, a London borough council, the Common Council of the City of
London in its capacity as a local authority, and the Council of the Isles of Scilly;

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

“the register” means the public register kept by the Secretary of State under section 122 of the Act.

“the 1992 Regulations” means the Genetically Modified Organisms (Deliberate Release) Regulations 1992(j)

(a) OJ No L117, 8.5.1990, p.1.
(b) OJ No K297, 18.11.1994, p.29
(c) OJ No L330, 5.12.1998, p.13
(e) OJ No L117, 8.5.1990, p.15
(f) OJ No L103, 22.4.1994, p.20
(g) OJ No L169, 27.6.97, p.72
(h) 2000 c.7.
(i) OJ No L292, 12.11.1994, p.31.
(j) SI 1992/3280

Guide 2

Regulation 2 defines key terms used in the regulations. Detailed definitions of terms setting the purpose, scope etc of the regulatory framework are in the EPA as described in Chapter 3.

An “approved product” may be an article, preparation, plant diagnostic kit, etc. consisting of or including a GMO or combination of GMOs. It only becomes “approved” on the granting of a consent to market by the Secretary of State, by devolved administrations or by the authorities of another EC state in accordance with the Deliberate Release Directive “environmental risk assessment” is covered in detail by separate guidance produced by the Advisory Committee on Releases to the Environment (ACRE) (Guidance Note 12). Separate guidance is also being drafted by the Commission.

“the 1992 Regulations” have been replaced by the 2002 Regulations (but consents already granted remain valid, subject to the provisions for renewal).

A “genetically modified organism (GMO)”, and other terms regarding the scope of the legislation, is defined partly by the EPA (see Chapter 3) and partly by the regulations (see regulation 5).

“The local authority for the area of the proposed release” is included among the bodies to be notified of applications for consent to release GMOs. In practice this is likely to be the local Environmental Health Department.

Advice on the “first simplified procedure” (Commission Decision 94/730/EC) will be issued separately and will be available on the
Defra website.

“monitoring plan” – detailed guidance on post-market monitoring has been produced by the European Commission [add footnote to where to find it when available]. This will be supplemented in the UK by guidance produced by the Advisory Committee on Release to the Environment (ACRE)

Purpose of Part VI of the Act and meaning of “genetically modified organisms”, etc.

(1) In section 106 of the Act (purpose of Part VI of the Act and meaning of “genetically modified organisms” etc.) is amended as follows.

(2) For subsection (1) substitute –

“(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.”

(3) In subsection (4) (definition of organism which is genetically modified) for paragraph (a) (modification of prescribed artificial technique) substitute -

“(a) have been artificially modified, or”.

(4) After that subsection insert -

“(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.”.

(5) Subsections (5) and (6) are omitted.

Regulation 4

(1) Section 107 of the Act (meaning of “damage to the environment” etc) is amended as follows.

(2) For subsection (2) (meaning of “environment”) substitute -

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

(3) In subsection (3) (meaning of “damage to the environment”) omit “to the living organisms supported by the environment”.

(4) For subsection (6) (meaning of “harm”) substitute –

“(6) “Harm” means adverse effects as regards the health of humans or the environment.”.

(5) For subsection (9) (meaning of organism being under a person’s “control”) substitute –

“(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.”.

(6) For subsection (11) (meaning of organism being “marketed”) substitute–

“(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.”.

Guide 3 & 4

Regulations 3 and 4 make a number of amendments to the key definitions of the terms used by the Environmental Protection Act 1990 – e.g. genetically modified, damage to the environment, harm, environment and marketed, - to bring the 1990 Act into line with the requirements of Directive 2001/18/EC. Detailed explanation of these key terms is in Chapter 3.

Regulation 5

Techniques of genetic modification

(1) Until the coming into force of the first regulations under section 106(4B)(a)(a) 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,

(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;

(ii) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods; and

(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 paragraph (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.

(a) Section 106(4) is amended by regulation 3(3) and section 106(4A) to 106(4D)
is inserted by regulation 3(4).

Guide 5
Regulation 5 specifies, in terms of the techniques of genetic
modification used, whether organisms will be “genetically modified
organisms” for the purposes of the control regime.

Regulation 6
Environmental risk assessment

(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;

(c) include 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.

Guide 6
Regulation 6 deals with a fundamental aspect of the deliberate
release regulatory framework. All applications for Part B and Part
C consents must contain an environmental risk assessment in
line with Annex II of the Directive(i). This risk assessment is
crucial to the processing of applications to release GMOs under
the new regime, and underpins all decisions taken.

The scope of risk assessments has been clarified and extended
by Directive 2001/18/EC. They are now required to identify and
evaluate potential damage to the environment arising from the
proposed release of a GMO whether it be direct or indirect,
immediate or delayed. The extension of risk assessments to
cover indirect and long-term risks is one of the major new
precautionary steps introduced by Directive 2001/18/EC, and will
require wider effects of GMOs on biodiversity to be taken into
account.

Risk assessments have also been extended to take into account
particular risks posed by GMOs that contain antibiotic resistance marker genes. This is linked to Regulation 25, which deals with the phasing out of antibiotic resistance marker genes that may have adverse effects on human health and the environment.

Detailed guidance on environmental risk assessment has been produced by the Advisory Committee on Releases into the Environment (ACRE Guidance Note 12).

(i) EPA 111(4) allows the Secretary of State to prescribe information to be included in an application for consent. Regulation 10(1)(c) and 14(1)(c) require environmental risk assessments to be included in Part B and Part C applications respectively.

**Regulation 7**

Communication with applicant for consent

(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, he 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 Secretary of State 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.

**Guide 7**

Regulation 7 requires that whenever an applicant is required to submit a document under the regulatory framework, it must be submitted in both paper and electronic form. This is intended to make the processing of applications more efficient – for instance it will speed up the placing of information on the public register (and website).

**PART II**

**RELEASING ORGANISMS FOR ANY OTHER PURPOSE THAN MARKETING**

**Regulation 8**

*Requirement for consent to release*

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.

**Guide 8**

Part II of the 2002 Regulations contains some of the regulations specifically relevant to the making of Part B applications (i.e. release of GMOs for any other purpose than marketing) in England. Regulation 10 sets out some general provisions for
such applications.

Regulation 8 sets the scope of this part of the Regulations by making clear that it applies only to non-commercial releases of GMOs (i.e. “Part B” releases). Regulation 9(2) establishes that anyone wishing to make a Part B release in England must apply for authorisation to the Secretary of State in writing.

Regulation 9

Exempt activities

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 the release is in accordance with a consent to market genetically modified organisms 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.

Guide 9

Regulation 9 ensures there is no requirement to apply for a non-commercial consent, if the GMO in question has already been granted a commercial consent to be marketed in the EU under Part C of Directive 2001/18. This is, of course, dependent on the GMO being used in accordance with the conditions of its Part C consent.

Regulation 10

Applications for consent to release – general provisions

(1) An application for a consent to release genetically modified organisms must be made in writing to the Secretary of State.

(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.

Guide 10

In order to facilitate the efficient handling of applications and to reduce costs, Regulation 10(2) allows a single application for a Part B consent to cover number of proposed releases, either of different GMOs at the same site, or of the same GMOs at different sites, provided that the release or releases are made for the same
purpose and within a limited period. For instance, this would allow multi-site research to be carried out under a single Part B consent – e.g. if a company proposed to conduct a programme of research on a GMO on say 20 different sites across England over a period of two years, it could apply to the Secretary of State for a single Part B consent to authorise the work. The Secretary of State (in light of expert advice and public consultation) would either grant or refuse a Part B consent, and if such a consent was granted it could cover the whole programme of work.

The extent to which a single application may cover a release or releases “for the same purpose and within a defined period” would need to be considered case-by-case. The purpose of the release might be a one-off experiment lasting weeks or months (at the end of which the releaser would remain under a duty to protect the environment from any after effects). Alternatively, the applicant might envisage a programme of work lasting several years. Whether the latter could be covered in a single consent application would depend on a number of factors. As a minimum, the applicant would need to be able to show that the programme related only to one description of GMO and that sufficient risk assessment information could be given from the outset in relation to the whole programme.

If this could be shown in the case of plant breeding, for example, a single application covering early research, development and performance trials could be considered. Any consent granted could then apply, subject to appropriate conditions, to releases at all sites and for the period of the specified programme. Such conditions would be likely to include a requirement for periodic reports to the Secretary of State, which would form the basis of any necessary variations to the consent needed (following consultation with ACRE) before the next phase in the programme could begin.

This process differs from that provided for under Commission Decision 94/730/EC (the “first simplified procedure”)(i). Any multi-site application made under the standard Part B procedure would have to contain all the information normally required under Part B. For instance, the proposed sites and times of the releases would have to be notified in the original application - thus detailed aspects of the programme of work would have to be known at the time the application was made, perhaps well in advance of when the actual release takes place. The first simplified procedure provides for specific circumstances where multi-site research must be conducted but it is not possible to know detailed information on dates, times etc far in advance. Regulation 9(4) ensures there is no contradiction between the standard procedure and the first simplified procedure. Guidance on Part B applications under the first simplified procedure will be published separately and will be available on the Defra website.
Regulation 11

Information to be contained in application to consent to release

(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 and at the level of detail 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 Secretary of State pursuant to 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 6,

(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, and

(b) any other information which the applicant considers relevant.

Guide 11

Regulation 11 sets out the wide range of information that must be contained in a Part B application, including the information specified by either Schedule 1 or Schedule 2 of the 2002 Regulations(i). This includes a general description of the GMO, the location and intended date of the proposed release, and the environmental risk assessment. The Secretary of State is
required to place this information (subject to commercial confidentiality) on the public register within 12 days of receipt (ii).

The format for a Part B consent application is available on the Defra website at [www.defra.gov.uk/environment/gm/formats](http://www.defra.gov.uk/environment/gm/formats) or from the Chemical and GM Policy Division, Defra, Zone 3/H10, Ashdown House, 123 Victoria Street, London SW1E 6DE.

The core of each application is formed by the statements made on the items of information set out in Schedules 1 and 2. Detailed guidance on each of these items is provided later in this document. Together with the risk assessment required under Regulation 10(1)(c), the statements given in response to each of the points listed in the Schedule comprise the technical information necessary for the Secretary of State’s evaluation of the application.

In many cases some of the information requirements listed in Schedules 1 and 2 may not be appropriate to the specific release proposed. In making an application, only appropriate information need be given, provided it can be shown to be adequate in relation to the assessment of any risks associated with the release proposed. However, applicants should be aware that if regulators (and/or their expert advisers) are not satisfied that sufficient information has been given they will require that more information is supplied before they proceed with the application. In such cases the “clock stops” – i.e. any time spent waiting for further information does not count towards the period of time during which applications must be processed – and if information is not supplied in time the application may be rejected. Thus it is in the interests of applicants to ensure their applications meet the highest standard before they are submitted.

The bulk of relevant information may also be reduced by making reference to earlier applications made under the 1992 or 2002 Regulations, to applications made by others, or to published sources, etc. For instance:

- data and results from a previous release or programme of work that are relevant to a current application. This might include information on research conducted in a laboratory under contained use legislation.

- information from applications made to another EC country in accordance with the Deliberate Release Directive or from releases made in a country outside the EC may also be taken into account. The relevance of such information to a current application will, however, vary from case to case according to such factors as the geographical location, climatic conditions, etc. of the site of the earlier release or intended release.
• data or results from applications or releases made by other persons, providing these persons have agreed to the use of their information.

(i) Schedule 1 covers detailed information requirements for applications concerning GM higher plants (e.g. GM agricultural crops, GM horticultural plants etc). Schedule 2 covers detailed information for any GMO other than GM higher plants (e.g. GM animals, GM micro organisms etc).

(ii) See Regulations 32(3) and 33(3)

Regulation 12

Advertisement of applications for consent to release

(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 sends that application to the Secretary of State, cause to be published in a national newspaper to be specified by the Secretary of State 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 Secretary of State within twelve days of her receipt of the application,
(f) the means by which that register can be inspected,
(g) a statement that the Secretary of State will consider any representations made to her relating to risks of damage to the environment posed by the release of the genetically modified organisms within a period to be specified which she shall specify in accordance with these Regulations

and shall immediately send a copy of the newspaper containing the advertisement to the Secretary of State.

(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 Secretary of State 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 sends that application to the Secretary of State, give
to the following persons notice in writing that he 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 parish 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(a),
(d) the Association of National Park Authorities
(e) English Nature(b)
(f) the Environment Agency

and shall immediately send to the Secretary of State copies of the
notices.

(a) S.I. 2000/2831
(b) See section 128 of the Environmental Protection Act 1990 (c.43) and
section 73 of the Countryside and Rights of Way Act 2000 (c.37)

Guide 12

Regulation 12 requires the applicant to advertise the application in
a national newspaper [and local newspaper(s)] within 10 days of
sending it to the Secretary of State. The advertisement must
contain information on the GMO, and the location, dates and
purpose of the intended release. It should also mention that
details of the application will be placed on the public register, and
that the Secretary of State will invite representations (i.e. hold a
public consultation) on [safety] issues raised by the proposed
release(i). The required format for the advertisement is at Annex
C. Details of the specific national [and local] newspapers that
must be used to make the advertisement can be obtained by
contacting regulators(ii).

The applicant is also required to inform a number of organisations
of the application, including the local authority, the parish council,
the Environment Agency, English Nature and the Association of
National Park Authorities. Details for specific contacts are at
Annex E

(i) See Regulation 18
(ii) It is likely that the required national newspaper will be varied from time to
time to ensure that different types of readerships are informed that public
consultations on proposed Part B releases take place. [Local newspapers will
be chosen case-by-case to cover areas where specified proposed releases are
intended to take place].

Regulation 13

Transitional provisions for release

Where the Secretary of State has received an application for
consent to release genetically modified organisms before 17 October 2002 pursuant to the 1992 Regulations and has not yet determined the application –

(a) the application shall be subject to the provisions of these Regulations,

(b) the applicant shall submit to the Secretary of State such further information, additional to that already provided in connection with the application, as is necessary in order to comply with the requirements of these Regulations by 17 January 2003,

(c) the application shall be treated as having been sent to the Secretary of State for the purposes of regulations 12(1) and (4) and as having been received by the Secretary of State for the purpose of regulation 20 on submission of the information required by paragraph (b), and

(d) if the information required by paragraph (b) has not been submitted by 17 January 2003, the Secretary of State may refuse to proceed with the application.

Guide 13
Regulation 13 requires that Part B applications submitted under the previous regime upon which no decision has been taken when the new Regulations come into force will become subject to the new regulations. Such applications must be brought up to the new standards, whereupon they will start their journey through the new procedure. If updated applications have not been received by 17 January 2003, Defra may refuse to proceed. In such cases, the applicant could resubmit the application (in line with the new standards) at a later date.

PART III
Marketing Organisms

Regulation 14
Requirement for consent to market

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.

Guide 14
See Guide 15 below.

Regulation 15
Exempt activities

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(a), as amended by Commission Regulation EC No 649/98(b), 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(c) is marketed.

(c) OJ No L42, 14.2.1997, p.1.

Guide 15

The Directive requires that before any GMO can be marketed in the EU it must be granted a Part C consent under the Directive (i.e. a Part C consent issued in one of the 15 Member States)(i). This is implemented by regulation 14 which requires consent to be obtained from the Secretary of State whenever it is intended to market a GMO.

Regulation 15(a) excludes from this requirement in cases where a GMO already has consent for the intended use (i.e. it has been granted by another UK territorial authority or another Member State). The remaining exclusions are contained in regulation 15(b) to (f). These exclusions mainly represent cases in which marketing of such GMOs is covered by other legislation that provides a level of protection to human health and the environment equal to that provided by Directive 2001/18/EC. For
instance, a Part C consent would not be needed for:

- products containing GM microorganisms (GMMs) that are placed on the market for use under Directive 90/219/EEC on the Contained Use of GMOs (the “Contained Use Directive”), i.e. if they are marketed on the condition that they are only to be used in containment and must not be “released” into the environment. The Contained Use legislation administered by the Health and Safety Executive fully applies in these cases. (see paragraph 9 of Chapter 2)

- medicinal products containing [living] GMOs for human and veterinary use that are authorised for commercial marketing under Council Regulation 2309/93 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use. In such cases, applications should be made to the European Medicines Evaluation Agency (EMEA), the regulatory body established under Regulation 2309/93.

- GM novel foods marketed under Council Regulation 258/97 concerning novel foods and novel food ingredients. Applications for novel foods and ingredients in the UK should be made to the Food Standards Agency.

**Regulation 16**

**Applications for consent to market**

(1) An application for consent to market genetically modified organisms under section 111(1) of the Act must be made in writing to the Secretary of State.

(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 Secretary of State 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 6,

(d) 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, and

(b) 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) Where the applicant can demonstrate in his application to the satisfaction of the Secretary of State, that, on the basis of the results of any release in pursuance of and in accordance with a consent under section 111(1) of the Act or under Part B of either
the Deliberate Release Directive or the 1990 Directive, or on other substantive, reasoned scientific grounds, the marketing and use of the product do not pose a risk of damage to the environment, he may omit from the application part or all of the information prescribed in Part II of Schedule 3.

Guide 16

Regulation 16 establishes that (in England) a person wishing to market a GMO must apply to the Secretary of State for authorisation to do so in the case that:

(a) the product has not already been “authorised” – i.e. that it does not already have a Part C consent issued either by the Secretary of State, a devolved administration, or by another EU Member State (or alternative marketing authorisation under novel foods, medicinal products or contained use legislation). For instance, this may cover a GMO that has undergone research under a Part B consent and is now applying for Part C marketing authorisation. It may also apply to GMOs that are already being grown commercially outside the EU for which Part C authorisation is sought so they can be placed on the EU single market.

(b) the product has been authorised under Part C for a certain type of use, but the consent holder wishes to use it for a different (as yet unauthorised) purpose. For example, if a GM crop was authorised for import only (i.e. not for cultivation in the EU), and at a later date the consent holder wished to extend the consent to cover cultivation in the EU, a new Part C consent would have to be applied for.

Regulation 16 applies only to persons wishing to market a GMO for the first time in England. Under the broader legislative umbrella of the Directive, a person could also apply for a Part C consent to a devolved administration in the UK, or to another EU Member State.

Anyone intending to conduct clinical trials using live GMOs (but not non-viable products obtained from GMOs) may need to comply with the GMO (Contained Use) Regulations 2000, or they may require a consent to release under the Deliberate release regulations. Each case will be judged on its own merits depending on the circumstances.

Regulation 16 also sets out information that anyone applying to the Secretary of State for a Part C consent must supply in their application (under the Directive, anyone applying to a devolved administration or another Member state will have to supply similar information). This includes a wide range of information, including information required by Schedules 1 or 2, and an environmental risk assessment(i). Part C applicants are also required to supply a post-market monitoring plan(ii) setting out how the proposed release will be monitored for unanticipated effects on the...
environment, and a **proposal for labelling** of the GMO. These are both new requirements introduced by Directive 2001/18/EC. As with Part B applications, the Secretary of State is required to place a copy of any Part C application submitted to her (subject to confidentiality) on the public register within 12 days of receipt.

Applications for consent to market GMO products will usually be made after pre-product trials, involving experimental release of the GMOs concerned, have been carried out. Data or results from such trials must be given in the application for consent. If trials were conducted in the UK in accordance with a consent to release GMOs granted under Section 111 of the 1990 Act a copy of the relevant application must be attached to the marketing consent application.

If the trials were conducted elsewhere in the European Community, the reference number of the notification made to the competent authority concerned should be given together with a copy of the application in English and the results of the release(s) equivalent to the report explained in [ ]. Data and results from any previous releases made outside the European Community should also be given. However, such information may not always be directly transferable to the UK and the Community if, for example, there are differences in climatic conditions.

The European Commission has produced a summary format or the exchange of information on applications for consent to market GMOs. This is similar to the format required under Regulation [ ] in respect of applications for consent to release GMOs and is required to be submitted as part of consent applications.

It is likely that the applicant will find that a number of information requirements under Schedule 1 will not be applicable to an application to market a GMO product. A very brief explanation of why that is the case should be given. If particular information cannot be provided, for example as result of technical difficulties, these should be summarised.

Applicants may on the basis of the results of the trials they have conducted, or on other substantive reasoned scientific grounds, consider that the product for which a marketing consent is sought poses no risk of damage to the environment. In this case, they may propose not to provide information on any or all of the matters set out in Part II of Schedule 3, such as labelling or packaging. The reasons for such proposals will need to be substantiated by the assessment of the risks to human health and the environment.

(i) Separate guidance on environmental risk assessments produced by the Advisory Committee on Releases to the Environment can be found at [ ]

(2) Separate guidance on post-market monitoring has been produced by the European Commission [details] and by the Advisory Committee on release to the Environment
Regulation 17

Transitional provision for marketing

Where the Secretary of State has received an application for consent to market genetically modified organisms before 17 October 2002 pursuant to the 1992 Regulations and has not yet determined that application, or, in a case where the Commission is required to take a decision in accordance with Article 13(3) of the 1990 Directive, that decision has not yet been taken -

(a) the application shall be subject to the provisions of these Regulations,

(b) the applicant shall submit to the Secretary of State such further information, additional to that already provided in connection with the application, as is necessary in order to comply with the requirements of these Regulations by 17 January 2003,

(c) the application shall be treated as having been received by the Secretary of State for the purposes of regulation 23 on submission of the information required by paragraph (b),

(d) if, by 17 October 2002, the Secretary of State has forwarded to the Commission the information required by regulation 16(2) of the 1992 Regulations, she shall supplement it and, if she considers it to be necessary, revise it on receipt of the further information required by paragraph (b) above in the light of her obligations under these Regulations, and

(e) if the information required by paragraph (b) above has not been submitted by 17 January 2003, the Secretary of State may refuse to proceed with the application.

Guide 17

Regulation 17 sets out how pending (i.e. undecided) Part C applications made to the Secretary of State under the old Directive 90/220 regime will be dealt with when the new regulatory framework comes into force. In such cases, the application will become subject to the new regulations, and the applicant will be required to bring the application into line with the more stringent standards of the new regime. If the Secretary of State has not received an updated application by 17 January 2003, she may refuse to proceed with it.

Regulation 18

Applications for renewal of consent to market

(1) Where the Secretary of State 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 Secretary of State -

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

(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 28(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 existing consent, including the conditions concerning future monitoring, and a proposal for the time limitation of the consent.

(3) Any consent to market genetically modified organisms granted by the Secretary of State under section 111(1) of the Act before 17 October 2002 for which no application for renewal under paragraph (1) above has been received before 17 October 2006 shall be treated as having expired on that date.

Guide 18

Regulation 18, implements another new aspect introduced by Directive 2001/18/EC – the placing of time limits on all Part C consents, after which they have to be renewed. Any current holder of a Part C consent issued by the Secretary of State under the old Directive 90/220 regime must apply for a renewal of the consent before 17 October 2006(i). If no application for renewal is received, the consent will be treated as having expired. Similarly, any Part C consent issued by another Member State under the 90/220 regime will be subject to the same renewal deadline under the national legislation of the Member State that issued the consent.

In the case of any Part C consent that may be issued by the Secretary of State in accordance with the new Directive 2001/18 regime, the consent holder must apply to have the consent renewed no later than 9 months before the expiry of the consent. Applications for renewal of consent must contain certain information, including results of post-market monitoring where relevant.

(i) Four Part C consents have been issued by the UK since 1990 (2 for GM oil seed rape, and one each for GM varieties of maize and soya).
PART IV
DUTIES AFTER THE MAKING OF APPLICATIONS

Regulation 19 Duty of the applicant after applying for consent to release or to market

(1) In section 111 of the Act (consents required by certain persons) in subsection (6) (power of Secretary of State or the National Assembly for Wales to require further information) insert as a second sentence –

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

(2) An applicant for a consent to release or to market genetically modified organisms who notifies the Secretary of State 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 Secretary of State a revised version of the original application for consent amended to take account of the new information.

Guide 19 Regulation 19 amends EPA 111(6) to bring it into line with the Directive, and applies to both Part B and Part C applications for consents. The Secretary of State may require further information from the applicant while considering an application, and in such cases she must specify the reason for requiring the information.

Regulation 19 also covers duties of applicants if they become aware, before a decision has been taken on whether or not to grant a consent, of new information with regard to risks posed by the GMO. In such cases the applicant must inform Defra of the new information, and revise the application.

Regulation 20 Duties of the Secretary of State in relation to applications for consent to release

Following receipt of an application for consent to release genetically modified organisms the Secretary of State shall –

(a) inform the applicant in writing of the date of receipt of the application,

(b) invite any persons by means of a request placed on the register, to make representations to her relating to any risks of damage being caused to the environment by the release before the end of a period to be specified which shall not be less than 60 days from the date the application was received by her;

(c) within 30 days of the date the application was received by her forward to the Commission a summary of that application in the format established by the Commission under Article 11(1) of
the Deliberate Release Directive,

(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 her 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) above.

**Guide 20**

Regulation 20 contains a number of requirements on the Secretary of State when she receives a Part B application. For instance, as soon as an application is received it must be examined to make sure it is in order (e.g. that it contains all the required risk assessment and other information). The Secretary of State is also required to acknowledge receipt of the application. In practice, any application will also be forwarded to the Advisory Committee on Releases to the Environment (ACRE), which will be asked for their independent expert advice on the application. Other interested Government departments will also have the opportunity to comment and give advice.

Regulation 20(b) introduces the new system of mandatory public consultation on applications for Part B consents. On receipt of a Part B application the Secretary of State must invite the public and others to make representations to her on any risks of damage being caused to the environment by the proposed release.

The period of each consultation has been set at a mandatory minimum of 48 days (the 48 day period comes from the fact that details of Part B applications must be placed on the public register within 12 days of receipt (Regulations 11, 34(3) and 35(2)) and that the period of consultation must not end less than 60 days from the date the application was received (Regulation 20(b).) The Secretary of State also has the option to extend this period if appropriate (e.g. if, say, the Secretary of State spends a significant amount of time waiting for additional information to be supplied by the applicant. Such time does not count toward period in which application must be processed.).

Regulation 20(f) requires relevant representations to be taken into account in making decisions on applications. This includes representations made by competent authorities from other Member States, and any of the bodies to which the applicant must
notify of the application under Regulation 12.

See also regulation 36

Following receipt of an application, a summary of it must also be sent to the European Commission by the Secretary of State. The Commission then forwards the summary to the other Member States, which have 30 days to ask questions about or make observations on the application.

Decisions by the Secretary of State on applications for consent to release

(1) The Secretary of State shall not grant 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(a).

(2) The Secretary of State shall not grant or refuse consent to release genetically modified organisms before the end of a period of 60 days beginning on the day on which the application for consent was received.

(3) The Secretary of State shall communicate her decision on an application for a consent to release genetically modified organisms to the applicant and 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 Secretary of State 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 Secretary of State, or

(b) any period of time during which the Secretary of State is considering representations submitted by any persons in accordance with regulation 20(b), provided that this consideration shall not prolong the ninety 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 Secretary of State as soon as reasonably practicable and after completion of the release and thereafter, at such intervals as the
Secretary of State shall consider appropriate on the basis of the results of the environmental risk assessment.

(6) The Secretary of State shall send to the Commission the information submitted to her in accordance with paragraph (5).

(a) See section 10 of the Health and Safety at Work etc. Act 1974 (c.37)

Guide 21

Regulation 21 sets the timescale within which a Part B application must be administered by Defra. Defra must communicate a decision to the applicant within 90 days subject to two qualifications:

(i) the 90-day period will not include any time Defra spends waiting for further information from the applicant, and

(ii) Defra may extend the 90-day period by up to 30-days for the purpose of consulting the public.

Regulation 21 also requires that Defra may not make a decision on an application in less than 60 days from the date the application was received – this supports the minimum consultation period set by Regulation 20.

This means that the minimum time in which an applicant could expect a decision on whether their Part B application has been approved or rejected would be 60 days from receipt. The maximum time will depend on the case. If a Part B application proceeds smoothly a decision may be reached within 90 days, but if more time is needed for public consultation this time could be extended up to 120 days. It might be expected that most decisions are made in this 60-120 days period. Of course, if a problem is encountered (e.g. if the application is not in order, or if more information is requested by regulators) the “clock stops” while the new information is provided. The timescale in which the applicant must supply the extra information would usually be set by the Secretary of State following discussion with the applicant. Depending on the case this may vary from a few days to several months (or even more if significant new scientific information is required).

Although the Secretary of State is the competent authority for the release and marketing of GMOs in England, the 2002 Regulations require that the Health and Safety Executive are consulted on any decision to grant or refuse a consent. This reflects their responsibility for, and expertise in, health and safety issues. The regulations require that the Secretary of State may not grant a consent without the approval of HSE.

Regulation 22

Variation or revocation of a consent to release

(1) The Secretary of State 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 her which she considers would affect the assessment of the risk of damage being caused to the environment by the release.

(2) The Secretary of State shall not revoke or vary a consent to release genetically modified organisms under section 111(10) of the Act as it relates to the protection of human health without the agreement of the Health and Safety Executive.

Guide 22

Section 111(10) of the EPA empowers the Secretary of State to vary the conditions of, or revoke, any Part B consent. Regulation 22 brings this into line with the Directive by specifying that such action can only be taken (without the agreement of the consent holder) if new information has come to light which would affect the risk of damage to the environment.

Since health and safety factors may be relevant, no revocation or variation may be made without HSEs consent, so far as human health and safety are concerned.

Regulation 23

Duties of the Secretary of State in relation to applications for consent to market

(1) Following receipt of an application for consent to market genetically modified organisms the Secretary of State shall –

(a) inform the applicant in writing of the date of receipt of the application,

(b) forward to the Commission and to the competent authorities of the other member States a summary of that application in the format established by the Commission under Article 13(2)(h) of the Deliberate Release Directive,

(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 she 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 her decision, supported by an assessment report prepared in accordance with Schedule 4 which indicates that the genetically modified
organisms should not be marketed, and

(e) once she is satisfied it conforms to the requirements prescribed in regulation 16, and no later than when she sends her assessment report in accordance with paragraph (d), forward a copy of the application to the Commission.

(2) The Secretary of State shall forward to the Commission

(a) her assessment report

(b) any further information she has received from the applicant pursuant to the service of a notice under section 111(6) of the Act,

(c) any additional information on which she has based her assessment report,

in the circumstances described in regulation 23(d)(i), before the end of a period of 90 days beginning with the day on which she received the application and, in the circumstances described in regulation 23(d)(ii), no sooner than 15 days from the date she sent the assessment report to the applicant and no later than 105 days from the date she 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 Secretary of State 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 Secretary of State.

(4) Where the Secretary of State 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, she shall first consult the Health and Safety Executive and shall not forward her favourable opinion on the application as it relates to the protection of human health where the Health and Safety Executive has informed her that it does not fulfil the requirements of the Act and of these Regulations.

Guide 23

Regulation 23 sets out what the Secretary of State is required to do if she receives a Part C application (i.e. for consent to place a GMO on the EU single market).

The Secretary of State must acknowledge receipt of the Part C application in writing to the applicant. She must also check that the application is in order, and if necessary ask the applicant to supply further information (in such cases the “clock stops” – i.e. any period spent waiting for the extra information does not count
towards the 90 day period in which the assessment report must be prepared). ACRE will be asked for their advice on the proposal and other interested Government Departments (e.g. the Food Standards Agency and the Health and Safety Executive) will also have the opportunity to comment and give advice.

Upon receipt of a Part C application, the Secretary of State is also required to send a summary of the Part C application to the Commission and other Member States(i). A similar requirement is placed on the competent authorities of other Member States in the event that a Part C application is made to them(ii).

Defra is also required to prepare an assessment report (in accordance with Schedule 4) indicating whether it considers that consent should be granted or the application rejected. This leads to two potential situations:

- if the assessment report recommends that a Part C consent is granted, it must be forwarded to the Commission within 90 days of receipt of the application, along with a copy of the full application(iii). The assessment report (and supporting information) will also detail the conditions that should be attached to the proposed consent. The application (sometimes called a “dossier” when it is being considered at EU level) then proceeds to scrutiny and decision making at the EU level. The SoS must also forward the assessment report to the applicant. (The Secretary of State cannot produce an assessment report recommending that a Part C consent is granted without the agreement of the Health and Safety Executive).

- if the assessment report recommends that a Part C consent is refused, the Secretary of State must inform the applicant – with a copy of the assessment report and stating her reasons for the refusal. She must also forward the assessment report to the European Commission not less than 15 days after it has been sent to the applicant (See Regulation 23(2)), and not more than 105 days after initial receipt. If this happens the application is dead although the applicant would be free to resubmit the application, to another competent authority (e.g. in a devolved administration or another Member State).

(i) The summary should be in the format prescribed by the Commission. [Explain SNIF and say where it can be found].
(ii) Under Article 24.1 of Directive 2001/18, the Commission is required to make these summaries available to the EU public, which may make comments within 30 days. Copies of any public comments received must be copied by the Commission to all Member States (i.e. for them to take into account when deciding national positions for the collective decision making process on whether to grant or refuse Part C consents).
(iii) The Commission is required by Article 24.1 of the Directive to make the
assessments are available to the public, and to invite comments within 30 days (in addition to the 30 day period described in the paragraph above).

Decisions by the Secretary of State on applications for consent to market

(1) The Secretary of State may only grant an application for consent to market genetically modified organisms only where she has prepared an assessment report which indicates that the genetically modified organisms should be marketed and either -

(a) no objection has been raised by a 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 member State or by the Commission but outstanding issues have been resolved in accordance with Article 15(1) of the Deliberate Release Directive within a 105 day period beginning on the day the Commission circulated the assessment report, or

(c) an objection has been raised by a 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 Secretary of State shall inform the competent authority or authorities of each member State and the Commission of her decision to grant consent to market genetically modified organisms within 30 days of its grant.

(3) For the purpose of calculating the final 45 day period of the one hundred and five days in sub-paragraph (1)(b) no period during which further information is awaited from the applicant shall be taken into account.

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

(5) For the purpose of granting consent to market a genetically modified organism or any progeny of that genetically modified organism contained in a plant variety where that 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(a) and 2002/55/EC(b) 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(c).


Guide 24

Regulation 24 picks up from Regulation 23(d)(i) – i.e. cases where a Part C application has been made to the Secretary of State, and she has sent an assessment report to the Commission recommending that a Part C consent is granted. Regulation 24 sets out rules for how the Secretary of State must either grant or refuse a Part C consent in accordance with the collective decision taken by the European Commission and all 15 Member States(i)

In essence:

- if the collective decision is that a consent should be granted, the Secretary of State will grant the Part C consent, inform the applicant, and inform the Commission and other Member States within 30 days. The GMO can then be released into the EU marketplace in accordance with the conditions placed on the consent.

- If the collective decision is that a consent should be refused, no Part C consent may be issued.

Regulation 24 also requires that any Part C consent issued by Defra is limited to a duration of ten years or less. The only exceptions to this are GM seeds and GM forest reproductive material, in which cases the maximum 10 year duration of consent starts from the time they are entered on national lists. This is because these GMOs are covered by additional EU legislation, the requirements of which would have to be satisfied before the GMO could be placed on the market (even if the GMO in question had a Part C consent under Directive 2001/18). Subject to the approval of the Commission and other Member States, the Secretary of State may also grant a renewal of consent for longer than a 10 year duration if there is a particular reason for doing so.

(i) A summary of the EU decision making procedure can be found at [ ].

Regulation 25

**Duties of the Secretary of State on receiving applications for renewal of consent to market**

(1) On receipt of an application for renewal of consent to market genetically modified organisms the Secretary of State 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 her decision, supported by an assessment report which indicates that the genetically modified organisms should not continue to be marketed,

(d) forward to the Commission a copy of the application and her assessment report.

(2) Where the Secretary of State 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, she shall first consult the Health and Safety Executive and shall not forward her favourable opinion on the application as it relates to the protection of human health where the Health and Safety Executive has informed her that it does not fulfil the requirements of the Act and of these Regulations.

Guide 25
See Guide 26 below.

Regulation 26

Decisions by the Secretary of State on applications for renewal of consent to market genetically modified organisms

(1) The Secretary of State may only grant an application to renew a consent to market genetically modified organisms only where she has prepared an assessment report which indicates that the genetically modified organisms should continue to be marketed and –

(a) no objection has been raised by 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 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 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 Secretary of State shall inform the competent authority or authorities of each member State and the Commission of her decision to renew consent to market genetically modified organisms within 30 days of its renewal.

(3) The consent to market genetically modified organisms shall be given for a maximum of ten years unless the Secretary of State considers that a shorter or longer period is justified, in which case she shall give her 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.

Guide 25 & 26

Regulations 25 and 26 set out the requirements for dealing with applications to renew Part C consents originally granted by the SoS. Much of the process is similar to that described above for the processing of standard Part C applications. Defra is required to prepare an assessment report (in accordance with Schedule 4) recommending either that a renewal of consent is granted or that it is refused. If Defra prepares a favourable assessment, and EU-level consideration of the application supports the assessment report, the Secretary of State will issue a renewal of Part C consent. If the assessment report is negative, Defra must inform the applicant that the application for renewal has been rejected. While applications for renewal of consent are being considered, the consent holder may continue to market the GMO under the terms of the original consent until a decision has been taken.

Regulation 27

Genetically modified organisms containing antibiotic resistance markers

(1) The Secretary of State shall not grant a consent to an application for the release or marketing of genetically modified organisms containing antibiotic resistance markers which may have adverse effects on human health and the environment after –

(i) 31 December 2004 in the case of marketing, and

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

(2) Where prior to 31 December 2004 in the case of marketing and 31 December 2008 in the case of release, an application is made for consent to release or market genetically modified organisms containing antibiotic resistance markers, the Secretary of State shall evaluate the information in the environmental risk
assessments 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.

Guide 27

Regulation 27 implements a new precautionary element introduced by the new Directive - the phasing out of GMOs containing antibiotic resistance marker genes (ARMs) that may have an adverse effect on human health and the environment. It requires that consents may not be issued for GMOs containing such ARMs from the end of 2004 in the case of Part C and 2008 in the case of Part B. Prior to these dates, when considering applications to release GMOs that contain ARMs, Defra is required to take special account of the need to phase out ARMs by the required timescales. (Regulation 6 requires applications for the release of GMOs to take special account of the particular risks of damage to the environment which may be caused by GMOs containing antibiotic resistance marker genes.)

Of course, the requirements of Regulation 27 do not override the Secretary of State’s primary responsibility under the new regime to ensure that all appropriate measures are taken to avoid adverse effects of GMOs on human health and the environment. If, prior to the above phase-out dates, she considered that a GMO containing an ARM posed an unacceptable risk she would move to ensure either that the application was rejected, or that the consent was varied or revoked.

The emphasis that the Directive places on the need for a special level of scrutiny in assessing GMOs that contain ARMs is intended generally to discourage researchers and biotechnology companies from using ARMs if there is any chance that negative impacts on human health, animal health or the environment may arise from their use. In doing this the Directive is encouraging the use of alternative methods of establishing whether or not techniques of genetic modification have been successful.

PART V
General Provisions for Consents

Regulation 28
General provisions of consents to market

A consent to market genetically modified organisms granted by the Secretary of State 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 marketing 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 Secretary of State on request,

(e) the labelling requirements, in accordance with paragraph 8 of Schedule 3, which shall include a requirement to notify the Secretary of State of any new commercial name of the product after consent has been given, and

(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 which may include an obligation to provide information at an appropriate level on the location of the genetically modified organisms that are grown.

Guide 28

Regulation 28 sets specific requirements for what must be contained within any Part C consent issued by the Secretary of State. The Secretary of State is required to place any such consent on the public register within 12 days of granting the consent (see Regulations 34(5)(a) and 35(4)). All such consents must specify:

- the scope of the consent
- the identity of the GMO (inc. unique identifier)
- the period of validity
- conditions of marketing (inc. use, handling and packaging)
- conditions for protection of the environment(s)
- a requirement that control samples of the GMO must be given to Defra on request
- labelling requirements
- monitoring requirements, including obligations on sellers and users of the GMO (i.e. down the supply chain from the consent holder) to supply information.

A Part C consent may also contain other conditions. In setting these conditions the authority that issues the consent (in accordance with the EU level decision) has a large amount of flexibility [see section on conditions placed on consents in Chapter 3]
General conditions on consents to release or market

(1) In section 112 of the Act (Consents: limitations and conditions) is amended as follows.

(2) In subsection (1) (power of Secretary of State or National Assembly for Wales to impose limitations and conditions) at the end insert “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”.

(3) In subsection (5) (implied condition when releasing or marketing) –

(a) in paragraph (b) (obligation to notify Secretary of State or National Assembly for Wales of new information etc) –

(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;”,

(b) for paragraph (c) (duty as regards preventing damage to environment) substitute –

“(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;”, and

(c) after that paragraph insert –

“(d) notify the Secretary of State 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
Regulation 29 amends section 112 of the EPA to bring it into line with the Directive, and applies both to Part B and Part C. Under this provision consent holders are required to notify Defra of any new information that comes to light (e.g. through post-market monitoring or by other means) regarding risks posed by the GMO to human health or the environment. Consent holders are also required to inform Defra of any proposed alterations to releases, and take action to prevent damage to the environment. They must also submit a revised version of the original application for consent, taking account of the new information.

Guide 30

Regulation 30 amends section 119 of the EPA. Previously anyone accused of an offence under relevant sections of the EPA would be required, where relevant, to prove that they had attempted to remedy the offence using the best available technique not entailing excessive cost (BATNEEC). The new regime maintains the approach where the burden of proof is on the accused to prove that they have employed the best available technique to remedy the offence. However, the new regulations amend the EPA to remove the qualification that the best technique should not entail any excessive cost. This is in line with Directive 2001/18, which contains no BATNEEC provision.
Regulation 31

New information on risks of damage from marketing genetically modified organisms

(1) The Secretary of State shall immediately forward to the Commission and the competent authority or authorities of each member State any new information which becomes available to her which she considers could affect the assessment of the risk of damage being caused to the environment by 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 Secretary of State and the information referred to in paragraph (1) becomes available to her before the application has been determined, 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 for renewal of consent to market genetically modified organisms has been made to the Secretary of State and the information referred to in paragraph (1) becomes available to her after the consent has been granted or renewed, she shall within 60 days after receipt of the new information, forward to the Commission 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.

(4) The Secretary of State shall not forward an assessment report indicating that the consent to market genetically modified organisms as it relates to the protection of human health should be varied or revoked without the agreement of the Health and Safety Executive.

(5) Where the Secretary of State has indicated that the consent should be varied or revoked and either-

(a) no objection has been raised by 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 a member State or by the Commission but all outstanding issues have been resolved in accordance with Article 20(3) of the Deliberate Release Directive,

she 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 she has done so within 30 days thereof.
(6) The Secretary of State shall only vary or revoke a consent to market genetically modified organisms under section 111(10) of the Act –

(a) where the information referred to in paragraph (1) has become available to her, and the procedure referred to in paragraphs (3) and (5) has been complied with, or

(b) in accordance with a decision adopted by the Commission in under Article 18(1) or Article 23(2) of the Deliberate Release Directive.

Guide 31

Regulation 31 deals with responsibilities of the Secretary of State if new information on risks posed by a Part C GMO becomes available. In all such cases Defra must immediately forward the new information to the Commission and other Member States. In the case that the new information concerns a GMO that already has a Part C consent granted by her, an assessment report must be sent to the Commission indicating whether the consent should be varied or revoked.

PART VI
SAFEGUARD

Regulation 32

Safeguard

(1) The Secretary of State may serve a prohibition notice under section 110 of the Act to prohibit an act which is authorised by a consent granted by her under section 111(1) of the Act or by a consent granted in respect of an approved product only if her 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), the Secretary of State considers that the risk of damage being caused to the environment is severe she shall serve a prohibition notice requiring such measures to be taken as she may consider appropriate and once any work required by the notice has been carried out she shall enter details of it on the register.

(3) In cases to which paragraph (1) and (2) apply, the Secretary of State shall immediately inform the Commission and the other member States of her actions and shall at the same time provide them with –
(a) her reasons for taking such actions,

(b) the results of her review of the environmental risk assessment,

(c) her 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 her 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 Secretary of State 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 which is inconsistent with that decision.

(6) References in this regulation to the Secretary of State 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 Secretary of State and the Food Standards Agency(a) acting jointly.

(a) see section 1 of the Food Standards Act 1999 (c.28)

Guide 32

Article 23 of the Directive is a safeguard clause under which a member State may, and in some cases must, provisionally restrict or prohibit the use and/or sale of a GMO with Part C consent on its territory if there are detailed grounds to believe that the GMO constitutes a risk to human health or the environment. Any provisional safeguard action must be notified to the Commission and other Member States, whereupon a collective decision is taken at EU-level on whether or not the Part C consent should be revoked or varied.

The safeguard clause is implemented in the UK by section 111(10) of the EPA, which gives the Secretary of State powers to revoke or vary a consent, and EPA 110, which allows the Secretary of State to issue a prohibition notice to restrict or prohibit the use of a GMO. Regulations 31(7) and 32 bring the EPA into line with the Directive.

PART VII
Confidentiality

55
Regulation 33

Confidentiality

(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) In section 123 of the Act (exclusion from register of certain information) in subsection (7) (particulars included even if commercially confidential) –

(a) after “section 122(1)(a),“ insert “(c),”,
(b) in paragraph (b) for “the description” substitute “the general description”, and
(c) paragraphs (c) and (e) are omitted.

Guide 33

Section 123 of the EPA requires the Secretary of State to treat some information contained in applications in confidence – for instance information that may be of commercial interest to an applicant’s competitors. Section 123(7), as amended by regulation 33, implements Article 25.4 of the Directive, which sets out information that cannot be treated as confidential (i.e. in the public interest it must be made publicly available). This includes the location and intended uses of the GMO, the environmental risk assessment, the methods and plans for monitoring the GMO, and any emergency measures. This applies to both Part B and Part C applications being dealt with by the Secretary of State.

When compiling their proposed register entry, applicants are asked to make clear which information they regard as being commercially confidential for the purposes of the register and why. Such information should be on separate sheets.

Information not identified as being commercially confidential will be assumed to be non-confidential. Under Section 123(3) of the
1990 Act, the Secretary of States is required to decide whether any representations by the applicant that information in the application is commercially confidential should be upheld.

If the Secretary of State decides that information which an applicant declared as being commercially confidential should nevertheless be included on the register, she will inform the applicant. This will give the applicant the opportunity of either withdrawing the application before the 12 day period elapses) or proceeding with it. If the application is withdrawn no information will go on the register and the applicant’s original assessment of commercial confidentiality will be protected. If the applicant decides to proceed with the application, the information which the Secretary of State regards as not being commercially confidential or as requiring disclosure in the public interest will be placed on the register.

PART VIII
Register of Information

Regulation 34
Information to be included in the register

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

(2) In relation to a prohibition notice served by the Secretary of State 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 Secretary of State,

(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 environmental 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 Secretary of State 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 Secretary of State 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, she shall enter so much of that more detailed information on the register as she 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 Secretary of State 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 Secretary of State 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 Secretary of State 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 Secretary of State 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 England pursuant to a consent to market insofar as that information is supplied to the Secretary of State in accordance with 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.

Guide 34

See Guide 35

Regulation 35

Keeping the register

(1) The information prescribed in regulation 34(2) shall be placed on the register within 12 days of the prohibition notice being served.

(2) The information prescribed in paragraphs (a) to (g) of
regulation 34(3) shall be placed on the register within 12 days of the receipt by the Secretary of State of the application for consent to release or market.

(3) The information prescribed in regulation 34(3)(h) shall be placed on the register within 12 days of the consent being granted or refused.

(4) The information prescribed in regulation 34(5)(a) shall be placed on the register within 12 days of the consent being granted.

(5) The information prescribed in regulation 34(5)(b) and (d) shall be placed on the register within 12 days of its receipt by the Secretary of State.

(6) The information prescribed in regulation 34(5)(c) shall be placed on the register within 14 days of the consent being revoked or varied.

(7) The information prescribed in regulation 34(6) and 34(10) shall be placed on the register within 14 days of its receipt by the Secretary of State.

(8) The information prescribed in regulation 34(7) shall be placed on the register within 14 days of its receipt by the Secretary of State.

(9) The information prescribed in regulation 34(8) shall be placed on the register within 14 days of its receipt by the Secretary of State.

(10) The information prescribed in regulation 34(9) shall be placed on the register within 14 days of the decision having been notified to the Secretary of State.

Guide 34 and 35

Regulation 34 supplements section 122 of the EPA by setting out information that must be placed on the public register. This includes:

- details of any prohibition notice served by Defra
- details of any application received by Defra for a Part B or a Part C consent
- any Part B or Part C consent issued by Defra, and information required by the consent
- any new information sent to Defra regarding risks posed by a Part B or Part C GMO
- any information relating to an unforeseen event occurring in connection with a release of a Part B GMO
- a copy of any Part C consent issued by another Member State
- the location of any Part C GMOs grown in England
any decision taken by the Regulatory Committee or the Council in accordance with Article 18 of the Directive

details of convictions for any offences committed under the EPA.

Section 110 of the 1990 Act enables the Secretary of State to prohibit the release or marketing of GMOs, for example, because it is known that someone proposes to undertake an unauthorised release or has placed a GMO product on the market without the consent. Details of prohibition notices must be placed on the register within 14 days of their issue.

Regulation 34 concerns the information about release or marketing consent applications which must be placed on the register. As with other register entries, the responsibility for ensuring that the correct prescribed particulars are placed on the register rests with the Secretary of State. For administrative convenience, applicants for consent are asked to compile a proposed register entry on items 3(a)-(g) as part of their consent application (items (c) and (e) are not however, relevant to the marketing consent applications). The information is required to go on the register within 12 days of the receipt of an application by the Secretary of State (Regulation 35(2)). Item 3(h) is the record of ACRE’s advice on the application, which is placed on the register 12 days after receipt of the advice by the Secretary of State (Regulation 35(3)).

Regulation 35 sets out the timescales for placing information on the register of information.

The register for England is kept at:

Defra
Ashdown House
123 Victoria Street
London SW1E 6DE

**Publication of representations**

(1) The Secretary of State 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 she 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 Secretary of State to treat that information as confidential.
Regulation 36 adds transparency to the new system by requiring the Secretary of State to make paper copies of the representations received during consultation available for public inspection, unless she has specifically been asked to treat the responses in confidence and accepts that the information they contain is confidential.

PART IX
Miscellaneous

Regulation 37
Revocations

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

Regulation 38
Application of Part VI of the Act to territorial sea and continental shelf

In section 127(2) of the Act (definitions etc) in subsection (2) (application to territorial sea and continental shelf) –

(a) for “applies to the territorial sea adjacent to Great Britain,” substitute “applies to the territorial sea adjacent to England as it applies in England”, and

(b) for the words from “to any” to the end substitute “applies to any area for the time being designated under section 1(7) of the Continental Shelf Act 1964(a) as it applies in England”.

(a) 1964 c.29

Regulation 39
Application of Part VI of the Act: England and Wales

After section 163 of the Act insert –

“163A Application of Part VI: England and Wales

(1) The amendments made to the provisions of Part VI by the 2002 Regulations, other than the amendment of section 127(2) as it relates to the continental shelf, have effect in relation to England only, and accordingly, in the application of that Part in relation to Wales, the provisions listed in subsection (2) below continue to have effect without the amendments made by the 2002 Regulations.

(2) The provisions referred to in subsection (1) above are –

(a) section 106(1) and (4) to (6);

(b) section 107(2), (3), (6), (9) and (11);

(c) section 111(6);
(d) section 112(1) and (5);
(e) section 119(1);
(f) section 123(7);
(g) section 127(2) in so far as it relates to the territorial sea.

(3) In this section “the 2002 Regulations” means the Genetically Modified Organisms (Deliberate Release) Regulations 2002.”.
SCHEDULE 1
Regulations 11 and 16
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.**

   In most cases, the name and address of the “applicant” will be a corporate body – e.g. company, university, institute, etc. For consent applications to release, information should be given on the scientist responsible for the proposed release(s), and not necessarily information on every person. For all applications the name of a person to be the contact point in respect of that application should be provided.

2. **The title of the project.**

   The title should reflect the general theme and purpose of the consent application, e.g.: *consent application [for a x year programme of work] to release [to market] spring oilseed rape genetically modified for herbicide tolerance*. State if the application is made in accordance with the First Simplified Procedure Decisions.

Part II
Information relating to parental or recipient plant

Each of the following points require, at an appropriate level of relevant detail, summary data sets, relating, as appropriate, to the:

“Parental”: organism used in cell fusion experiments where the genome of the fusion product is a hybrid of the entire genomes of the two original cells (organisms), neither of which can therefore be considered to be the recipient donor.

“Recipient”: an organism which undergoes a genetic modification, for example, by the introduction of a foreign gene transferred from another, donor, organism.

In the case where the organism is
used in cell fusion experiments where the genome of the fusion product is a hybrid of the entire genomes of the two original cells (organisms), neither of which can therefore be considered to be the recipient donor, the organism may be considered to be the “parental” organism.

3. The full name of the plant

(a) family name,
(b) genus,
(c) species,
(d) subspecies,
(e) cultivar/breeding line,
(f) common name.

Give sufficient information on each point to describe the parental or recipient plant using references to taxonomic literature where appropriate.

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.

Describe how the plant reproduces and any environmental factors which might affect reproduction. Information should include the extent and frequency of seed production with respect to plant growth, whether the plant is predominantly self-fertilising or out-crossing and where appropriate, development of tubers, rhizomes or other vegetative propagules. Describe whether the plant is able to transfer or exchange genetic material with the same species or with different species growing under cultivation or naturally in the environment, resulting in any production of viable seed.

5. Information concerning the survivability of the plant:

(a) its ability to form structures for survival or dormancy,
(b) any specific factors affecting survivability.

Describe how the plant survives and any environmental factors which might affect its survival. The information should include factors such as longevity in the environment (soil), sensitivity to temperature, viability of seed and any period of dormancy.

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.

Describe how the plant disseminates genetic material, such as via pollen and seed, and any environmental factors which might affect this dissemination. The information should include means of pollen dispersal to other compatible plants,
dissemination. dispersal and spread of seed by biotic and abiotic factors.

7. The geographical distribution of the plant. Give details of the countries/climatic regions where the plant is or might be found. Identify and describe any region/habitat in the UK where the plant is or may be grown under cultivation or where it can be found growing naturally.

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. If the plant is not cultivated or does not naturally occur in the UK, describe the habitat where the plant normally grown, and its interaction with other organisms in its native habitat. A comparison of the plant’s natural habitat with that where it will be grown in the UK should also be made.

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. Describe any interactions of the plant with other organisms in the release environment that may be significant. This information should attempt to consider likely interactions, direct or indirect, with pollinators, symbionts, pathogens (e.g. viruses and bacteria) and pests (e.g. invertebrates, birds and mammals), and any toxic or antagonistic effects on these organisms as well as any toxic or allergenic effects on humans.

Part III
Information relating to the genetic modification

10. A description of the methods used for the genetic modification. Describe the methods used to produce the GM plant, where possible referring to standard techniques. For example, state whether a disabled Agrobacterium-mediated or other vector-mediated method, biolistics or microinjection techniques were used. Details should be given if the method is novel, unpublished or relevant to risk assessment.

11. The nature and source of the vector used. Give details of the type of vector used and the name of the organism from which it was derived.
12. The size, intended function and name of the donor organism or organisms of each constituent fragment of the region intended for insertion.

Give details of each DNA fragment of the construct used in the genetic modification and intended for insertion into the plant. This should include the size in base pairs of each fragment, its intended function, for example, “gene encoding neomycin transferase” or, at the very least, a description such as selectable marker or regulatory sequence (promoter or termination sequence). The name of the organism from which each DNA fragment was derived (donor) should be given together with any characteristics of the donor such as harmful (pathogenic/toxic) properties. A plasmid map indicating the orientation and proximity of contained sequences should also be provided.

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.

Describe all the traits and their phenotypic characteristics modified or introduced into the GM plant. The description should include the sequences inserted or deleted, the anticipated end effect and any intermediate effects, focussing on the difference between the recipient organism and the GMO.

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

Give information on the sequences which have been inserted, deleted or otherwise affected by the modification. This should include information on the size of the inserted/deleted sequence(s) and the(ir) structure, for example have sequence orientations been maintained as intended relative to each other. In particular it is important to consider whether any part of the vector or other extraneous DNA has been inserted or affected as a result of the modification process.

The copy number of any inserted sequence(s) should be determined and stated together with the method of that determination. Evidence of copy
(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.

number may be requested and should be provided when possible.

The genetic and intracellular location of the modified sequences should be determined and stated together with the method of that determination. Evidence of location may be requested and should be provided when possible.

Give information on the rate and level of expression of the gene(s) inserted, the amount of and the activity of the gene products. Information on the methods used for characterization and quantification of expression of the gene products will be helpful. Where applicable, a comparison should be made between gene expression and activity of the gene product in the recipient plant with that in the donor organism.

Consideration should be given to the potential of the genetic modification to affect reproduction, dissemination or survivability of the GM plant compared to that of the parental or recipient plant. This should include the nature of that effect or difference. If the modification is considered to be unlikely to affect some or all of these characteristics, reasons should be given.

Give information on the stability of the insert in the GM plant. This should be supported by data wherever possible, for example, molecular or expression data, or number of passages or generations. Stability of any phenotypic characteristics arising as a result of the modification should be given including any distinguishing phenotypic markers.

Give information on any changes which may have occurred as a result of the modification to the ability of the GM plant to transfer genetic material.
19. **Information on any toxic, allergenic or other harmful effects on human health arising from the genetic modification.**

Possible hazards to human health arising as a result of the modification should be considered. Factors to be taken into account include those due to the viable organism itself and also to any metabolic products or components contained within or produced by the GM plant.

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 feedingstuffs.**

Information should be provided to enable a detailed evaluation of the safety of the feed material, both for the animal to which it will be fed and also for the consumer of the food products derived from those animals. This should include both compositional and safety data and should address any effects of the novel gene products, possible unintended secondary effects and potential intakes and dietary impacts. Any effects on animal health and welfare also need to be addressed.

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

Describe the mechanism of interaction of the GM plant with target organisms. If the GM plant is modified for disease or pest resistance, for example resistance to insects, nematodes, fungi, bacteria, viruses, etc. this description should include the mode of that resistance.

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

Describe any interactions which may occur with non-target organisms, for example the interaction of insect resistant plants with pollinators or beneficial predatory arthropods, or the interaction of disease resistant plants with symbionts (such as mycorrhizas or rhizobia). Where non-target organisms may not be affected directly by or as a result of immediate
contact with the GM plant, assess whether organisms such as predators or parasitoids may be affected indirectly at a tertiary level, for example by consuming prey which, having fed on the pest resistant GM plant, might contain toxicologically significant levels of toxins.

**23. The potential interactions with the abiotic environment.**

Describe any potential interactions with environmental aspects such as tolerance to low temperatures, heavy metal accumulation, drought resistance, or salt tolerance.

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

Provide a detailed description of methods for detecting and identifying the GM plant. The information may include specific phenotypic characteristics but should be of sufficient calibre to distinguish the GM plant from the parental and related organisms. Ideally, information on molecular methods of detection should be provided.

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

Give information on any previous release(s) of the GM plant including a brief summary of the risk assessment and the outcome of the release with the results of any monitoring. If releases were in the UK, please give the reference number of the application. Any other information on the GM plant which might be of relevance to the proposed release should also be given, for example release of a different plant with the same inserted genes.

### 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.**

State the location of the proposed release sites together with its dimensions and the dimensions of the wider release area which will include any control and/or buffer zones. If a number of sites are to be used, supply this information for each site.
27. A description of the release site ecosystem, including climate, flora and fauna.

Describe the ecosystem of the release site, for example, arable agricultural, grassland, orchard, woodland, etc. and indicate any differences in the ecosystem to the natural or normal habitat of the recipient/parental organism and how this is likely to affect the GM plant. Where relevant to the risk assessment, information on climate should include average temperatures during the release period and other periods at the location of release. Give information on the flora and fauna at the release site and the surrounding area. For Programmes of Work, this information should be for all the proposed releases.

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

Give information on the presence and abundance of wild relatives or feral populations of compatible plant species including volunteers at the proposed release site(s), up to an area of 1km from the edge of the release site, taking into account relevance to pollen and seed dispersal.

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

Give information on any sites of special scientific interest or protected areas, which may be affected by the release. [As a guide internationally recognised biotopes or protected areas include those specified by Directive 79/409/EEC on the protection of birds, the RAMSAR Convention and the RAMSAR Directory of Wetlands, the World Heritage Convention and the Man and Biosphere Programme of the United Nations.]

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.

Provide a brief statement giving the purpose of the release outlining the aims and the objectives of the proposed release. If the application is for a programme of work then the statement should include the
overarching principle behind the programme as well as any further intentions.

31. The foreseen date or dates and duration of the release.
Give information on dates for planting, duration of the release and harvesting or termination. A window of time within which activities such as planting will be performed will be acceptable if exact dates are not known. The duration of the release in years should be given.

32. The method by which the genetically modified plants will be released.
Give information on the methods proposed for the release of GM plants, for example, whether they will be planted as seeds or germinated seedlings, by hand or machinery, etc. This information may be given as a summary of the protocol for the proposed release.

33. The method for preparing and managing the release site, prior to, during and after the release, including cultivation practices and harvesting methods.
Give information on the site preparation prior to the release, management of the site during the proposed release and harvesting methods and management of the site after harvest including information on the agricultural practices and any additional practices proposed to minimise risks, such as herbicide treatment after harvest and type of crop rotation.

34. The approximate number of genetically modified plants (or plants per m²) to be released.
Give an estimate of the maximum number of GM plants to be released.

Part VII
Information of 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
Give information on any measures to isolate the proposed release of GM plants from the nearest compatible plant species in cultivation or in the wild. Information on any measures to minimise or prevent pollen or seed dispersal, such as border rows, removal of flowers, harvesting prior to
(such as pollen, seeds, tuber).

flowering or seed dispersal, destruction of vegetative material or mechanisms to prevent seed dispersal at harvest should be given.

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

Describe the methods proposed for treatment of the release site following harvest. This should include information on methods proposed to prevent or minimise survival or persistence of the GM plant by either germination of lost seed or vegetative re-growth.

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

Describe the methods proposed for treatment of the GM plant material following harvest, e.g. storage, removal of residues. Give information on any further use of the harvested material from GM plants, and methods for destruction/disposal. This should include proposed plans for destruction of any plant material left in the ground after harvesting. Indicate if any material from the trial is intended for use in taste trials or for human food or animal feed.

NB: If it is intended that harvested seed be used in further releases, separate consent may be required. If it is intended that storage of harvested seed be undertaken a notification under the GMO (Contained Use) Regulations 2000 may be required.

38. A description of monitoring plans and techniques.

Describe the intended monitoring and its purpose. This should include information on the techniques proposed for the monitoring for the period during the release and the period after harvest, the area and frequency of monitoring and the duration of the period over which monitoring will be undertaken. The monitoring should be linked to any potential risks identified in the risk assessment.


Describe procedures that will be adopted to prevent or minimise
environmental damage if unexpected events occur. Give information on physical, chemical or any other methods to be used for the effective termination of the release, e.g. unexpected environmental or human health effects in the event of acts of vandalism.

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.

State what measures will be taken to protect the site, for example, fencing or netting to prevent access to wild animals or birds, pollen barriers, separation zones.

State what methods, references or other sources of information have been used in the compilation of this application, together with those responsible for that information.
SCHEDULE 2
Regulations 11 and 16
INFORMATION TO BE INCLUDED IN APPLICATIONS FOR CONSENT TO
RELEASE OR MARKET 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 organisms, and for the supervision, monitoring and safety of the release.**

   In most cases, the name and address of the “applicant” will be a corporate body – e.g. company, university, institute, etc. For consent applications to release, information should be given on the scientist responsible for the proposed release(s), and not necessarily information on every person. For all applications the name of the person responsible for the application should be given as the contact point.

2. **The title of the project**

   The title should reflect the general theme and purpose of the consent application, e.g.: consent application [for a x year programme of work] to release genetically modified x for the purpose of...

Part II
Information relating to the organisms

**Characteristics of donor, parental and recipient organisms**

3. **Scientific name and taxonomy.**

   Each of the following points (3-14) require, at an appropriate level of relevant detail, summary data sets, relating, as appropriate, to the:

   “Recipient”: an organism which undergoes a genetic modification, for example, by the introduction of a foreign gene(s) transferred from another organism or “donor” and/or deletion of genes.

   “Donor”: an organism from which the genetic material to be inserted is taken or derived.

   In the case where the organism is used in cell fusion experiments where the genome of the fusion product is a
hybrid of the entire genomes of the two original cells (organisms), neither of which can therefore be considered to be the recipient or donor, the organism(s) may be considered to be the “parental” organism.

Give all scientific names of the organism and a full taxonomy using references to taxonomic literature where appropriate.

4. **Usual strain, cultivar or other name.**

Give all other identifiers of the donor, parental or recipient organism, such as strain, cultivar or breed.

5. **Phenotypic and genetic markers.**

Give details of distinguishing phenotypic and/or genotypic characteristics of the organisms, which could be used for identification purposes. Markers (phenotypic and genotypic) which can be used to distinguish organisms from closely related organisms will be particularly important. Examples include use of Polymerase chain reaction and substantiating data.

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

Give information on the biological relatedness of the donor and recipient strains or between parental organisms referring to taxonomic data where appropriate.

7. **The description of identification and detection techniques.**

Provide a detailed description of methods for detecting and identifying the GMO. The information may include specific phenotypic characteristics but should be of sufficient calibre to distinguish the organisms from the related organisms. Ideally, information on molecular methods of detection should be provided.

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

State the sensitivity, reliability and specificity of all the detection and identification methods to be used in relation to this GMO and its release.

9. **The description of the geographic**

Give details of the countries/climatic
10. The organisms with which transfer of genetic material is known to occur under natural conditions.

Describe whether the organism is able to transfer or exchange genetic information with other organisms and vice versa, for example by conjugation, transduction, reproduction.

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

Provide evidence for the stability of the organisms and, in particular, provide information on any history of genetic instability such as high mutation rates. Comment on any external environmental factors (e.g. UV, $\text{O}_2$) which could affect the genetic stability of the organism.

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;

This refers to classification of organisms as hazardous to human, animal or plant health (these classifications reflect “pathological traits”). The relevant classifications are contained in the following community legislation:

- Directive 90/679/EEC on the protection of workers from risks related to exposure of biological agents at work;

- Directive 77/93/EEC (as amended by Directive 92/103/EEC) on the
(b) the generation time in natural ecosystems and the 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, ability to act as a 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;

protective measures against introduction into member states of organisms harmful to plant products, as amended [until now.]


This will be fairly simple to quantify for many multicellular organisms, but nearly impossible for some microorganisms. If no such information is available or easily obtainable for microorganisms, data on generation times from laboratory studies or microcosms should be given.

State how the organism usually reproduces and if by more than one mode, indicate the relative frequency and ecological importance of each mode. Any relevant factors affecting the mode and rate of reproduction should be indicated.

State known forms of the organism (including survival structures, for example spores and sclerotia), the order of their longevity in the environment and any relevant factors which might affect longevity and survival. Include any relevant information on their ecology and behaviour.

State whether the organism is known to be pathogenic to any other organism and provide information on its infectivity, virulence, host range and ability to colonise other organisms and also state whether the modification is likely to have changed any of these characteristics.

Indicate whether the organism is a vector of a pathogen or can activate latent viruses. The latter point will be
(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.

State whether the organisms carry antibiotic resistance genes and whether these could be expressed in the final GMO. If such genes are present, indicate whether the antibiotic concerned is used for therapeutic purposes for humans or animals.

This point is particularly relevant to microorganisms and should be addressed in relation to biogeochemical processes (see point 71)

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.

List known indigenous vectors of the recipient or parental organism and give the information as listed. For item (d), in addition to antibiotic resistance, indicate whether any of the sequences encode for resistance to other environmental stresses.

14. The history of previous genetic modifications.

Characteristics of the vector

15. The nature and source of the vector.

State whether the vector is a plasmid, bacteriophage, virus, cosmid, phagemid, transposable element etc. Give its usual designation and organism from which it was derived.

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

Provide a genetic map and/or restriction map of the vector, transposons and other sequences used in the construction of the GMO. Detailed information on base pair sequences will normally not be required. This is not the same as the information required at Point 24. State the organisms from which each constituent part of the vector is derived, including regulatory sequences.

17. The frequency of mobilisation, genetic transfer capabilities and/or methods of

Give a brief account of the genetic transfer capabilities (e.g. host range,
determination of the inserted vector. conditions for the transfer) and a best estimate of the frequency of mobilisation. Include a brief description of the methods used for determination

18. **The degree to which the vector is limited to the DNA required to perform the intended function.** Information provided in point 16 may be referenced here in order to increase clarity. State the amount of sequence within the vector which is beyond that minimum necessary to obtain the desired modification of the recipient organism. State the function(s) of that sequence and the reason for it remaining in the vector.

**Characteristics of the modified organisms**

**Information relating to the genetic modification**

Points 19-24 concentrate on the methods used to prepare and insert the genetic material during modification of the organism. The ‘insert’ denotes all the genetic material introduced into the GMO including all the sequences derived from the donor or parental organism(s), regulatory sequences and any vector sequences remaining in the genome of the recipient after modification.

19. **The methods used for the modification.** Précis the methods used referring where possible to standard techniques or published methods. Detail need only be given if the steps undertaken are novel.

20. **The methods used –**

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

   Describe the methods by which the intended insert(s) was constructed (for example if the intended insert is an expression cassette, explain how the cassette was generated) and give details of the method(s) used to introduce the insert(s) into the recipient organism, expanding on the information given in point 19 as necessary.

   (b) to delete a sequence.

   If the modification involves a deletion, details of this deletion and the method used to achieve it should be given.

21. **The description of the insert and/or vector construction.** Any relevant information not contained in points 15, 18, 22 and 24, should be
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.

State whether the sequence intended for insertion, the inserted sequence(s) or the sequence to be used during the deletion modification, is limited to sequences which carry out the required function. Indicate the size of the extraneous sequences, their position in the insert and, if known, their likely function.

23. The methods and criteria used for selection;

Provide information, including where relevant molecular data, on the actual sequences inserted/deleted or otherwise altered in the GMO. In particular attention should be drawn to any harmful sequences which may have been inserted or may have been affected by the modification.

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

Characteristics of the genetically modified organisms in their final form GMO

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.

This should focus on the changes caused in the GMO relative to the recipient/parental organism.

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

State what sequences have remained in the GMO after the modification procedure. In particular this should focus on those sequences remaining which it was not the intention to introduce or alter.

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

Give information on the genetic and phenotypic stability of the modification to the GMO. This should be supported by data wherever possible, for example, molecular or expression data, or number of passages or generations. Stability of any phenotypic characteristics arising as a result of the modification should include any distinguishing phenotypic markers.

28. The rate and level of expression of the

Give data on the rate and level of
new genetic material in the organisms, and the method and sensitivity of measurement of that rate and level.

expression of the gene(s) inserted, the amount of and the activity of the gene products. Information on the methods used for characterization and quantification of expression of the gene products will be helpful. Where applicable, a comparison should be made between gene expression and activity of the gene product in the recipient organism with that in the donor organism.

29. The activity of the gene product.

Give results of standard assay procedures, where possible. Otherwise compare expressions to that normally seen in the source organism.

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

Provide a detailed description of methods for detecting and identifying the GMO. The information may include specific phenotypic characteristics but should be of sufficient calibre to distinguish the GMO from the parental/recipient and related organisms. Information on molecular methods of detection of the GMO should be provided where possible, together with molecular data specific to the inserted/altered sequences and vector.

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

Supply this information, where possible, for all techniques described in response to point 30. If quantitative data are not available, respond with comparative qualitative data.

32. The history of previous releases or uses of the organisms.

State whether the GMO has ever been released before and, if so, for what purpose (reference to previously submitted information is permitted, however, this application must act as a stand-alone document). If the GMO has been used previously in contained use facilities reference should be made to this also.

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

Possible hazards to human, animal and plant health posed by the GMO should be considered.
Factors to be considered include those due to the viable GMO itself (pathogenic hazards) and also to any metabolic products or components contained within or produced by the GMO (toxic or allergenic hazards). Pathogenic effects are normally equated with causing disease by means of infection of the body (organs, cells, etc.) by live, virulent organisms.

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

State whether the GMO is intended to be, or is known to be, toxic or allergenic to humans, animals or plants, or whether it may produce or contain toxic or allergenic compounds; include data where possible. If the GMO is not considered to be, or to produce compounds which are, toxic or allergenic, some justification should be given.

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

State whether the modified organism is pathogenic for humans, animals or plants and, whether the pathogenic traits exhibited derive from the donor, the recipient or (where appropriate) the parental organisms. If known, state whether the GMO exhibits greater or lesser pathogenicity than the donor, etc. Details of any available data concerning alterations in pathogenicity should be supplied.

(c) the capacity for colonisation

State whether the GMO is known to colonise humans, animals or plants and (if known) the possible routes of entry of the GMO (including inhalation, ingestion, inoculation, venereal or direct contact) and sites of colonisation.

(d) if the organisms are pathogenic to humans who are immunocompetent-

If the organism is pathogenic for humans and in particular those who are immunocompromised (usually only applicable to microorganisms and parasites) state:

i. diseases caused and mechanism

For each disease caused, the
of pathogenicity including invasiveness and virulence, mechanisms of pathogenicity (where known). Particular attention should be paid to invasiveness and virulence of the organisms.

ii. communicability, If the organism is communicable (i.e. can be transmitted by any route to humans, including direct contact, transmission by airborne dissemination, insect or other vector, food or water, etc.), identify the means of transmission and give an estimate of the transmission which could occur in the community. See also point vi below.

iii. infective dose, Estimate the number of organisms required to produce an infection in immunocompetent humans (estimates to an order of magnitude would suffice);

iv. host range and possibility of alteration, state the host range of the organism. Indicate whether this may be altered, either as a result of the modification or due to environmental or other factors;

v. possibility of survival outside of human host, if the organism could survive outside the human host, indicate possible niches or reservoirs of infection, e.g. other mammalian species present in the area of the release, particular physical environments such as bodies of water, etc. and likely survival times;

vi. presence of vectors or means of dissemination, if vectors (or other means of dissemination) have been identified in (ii) above, state if these are likely to be present in the release area;

vii. biological stability, state whether any instability identified in relation to point 27 may have biological consequences in terms of altered pathogenicity;

viii. antibiotic resistance patterns, if the organism is resistant to antibiotics (whether in clinical use or not): list the antibiotics to which the organism has been shown to be resistant; indicate which resistances, if any, are a result of the genetic
modification; indicate whether the resistances are chromosomally or plasmid borne (if known); list also any antibiotics to which the organism has been shown to be sensitive;

ix. allergenicity,

If the organism is, or contains substances, allergenic to humans, give an indication of the normal/average level of allergenicity;

x. availability of appropriate therapies, and

If therapy is available, indicate the nature of the therapy (e.g. antibiotic treatment), its efficacy, and whether pre-exposure treatment (vaccination, immunisation, etc.) is available or advisable.

(e) other product hazards.

This will only be relevant in the case of applications where the GMO forms part of a product formulation (rather than being a product itself). For such applications, any possible hazards (i.e. pathogenic, toxic or allergenic) associated with the final product should be considered. These considerations should take into account the formulation, the intended use of the product, and any possible hazards which may arise during such use. Further details relating to data required in relation to GMOs which are to be marketed as a food can be obtained from the Scientific Secretary of the Advisory Committee on Novel Foods and Processes, Food Standard Agency (address at Annex H)

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.

Provide a brief statement outlining the aims and objectives of the release and any known intended products. If the application covers a programme of work, the objectives and broad outline of that programme should be given here.

35. The intended dates of the release and

Give information on dates for the
time planning of the experiment including frequency and duration of releases.

release and its termination. A window of time within which planned activities will be performed will be acceptable if exact dates are not known. If a programme of work is proposed, the duration in years should be given.

36. The preparation of the site before the release.

Give information on the site preparation prior to the release, management of the site during the proposed release, methods of termination of the release and management of the site after termination including information on standard practices and any additional practices proposed to minimise risks such as persistence of the GMO.

37. The size of the site.

38. The method or methods to be used for the release.

Give a summary of the protocol to be used in releasing the GMO.

39. The quantity of organisms to be released.

Give the approximate maximum number of organisms to be released.

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

Summarise any foreseeable sources of disturbance to the site.

41. The worker protection measures taken during the release.

The worker protection measures to be taken during the release should be assessed, based on the factors identified in point 33 such as pathogenicity, allergenicity and toxicity of the released organism or the product of which it forms part. The Control of Substances Hazardous to Health (COSHH) Regulation (SI 1999/437) require that, where appropriate, a suitable and sufficient assessment of risks is identified, and suitable control measures employed to control the risks of working with such agents. The protective measures that could be appropriate will depend upon the release but should follow the hierarchy of control measures detailed in the COSHH regulations, i.e. elimination, substitution, enclosure, exhaust.
42. The post-release treatment of the site. Describe the methods proposed for treatment of the release site following termination of the release. This should include information on methods proposed to prevent or minimise survival or persistence or dissemination of the GMO, for example by site sterilisation or administration of antibiotics.

43. The techniques foreseen for elimination or inactivation of the organisms at the end of the experiment or other purpose of the release. State how the GMO will be eliminated or inactivated. State known efficacy of techniques.

44. Information on, and the results of, previous releases of the organisms, and in particular, releases on a different scale or into different ecosystems. Give a brief précis of relevant information. Source material should be adequately referenced.

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

45. The geographical location and national grid reference of the site or sites onto which the release will be made, or the foreseen areas of use of the product. This point is to elicit information on the geographical location of the release(s) and detail on ecosystems into which the GMO is to be introduced [is not appropriate here?]. If the application is for consent to market a product “areas of use of the product” means countries, regions or types of ecosystem where the product is intended for use.

46. The physical or biological proximity of the site of the organisms to humans and other significant biota. Physical proximity should be indicated by stating distances of the release site from sites of human habitation or other significant biota. “Other significant biota” will usually mean any species under human control for the purpose of agricultural, industrial or recreational benefit as well as related or target wild species. Biological proximity should be estimated from the likelihood of successful spread/dispersal of the GMO, or
47. The proximity to significant biotopes, protected areas or drinking water supplies.

Microbial releases are likely to be of most concern here as microbes or their products could seep into water sources and eventually into groundwater.

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

Give a summary of the likely climatic characteristics of regions affected or likely to be affected by the release. Relevant information could include average temperature, rainfall, winds etc. If such data are quoted, give the normal degree of variability. This is likely to be particularly pertinent to organisms dispersed by wind or rain splash and to those adapted to a narrow range of climatic conditions.

49. The geographical, geological and pedological characteristics.

Use standard terms to describe sites: for example, chalk grassland, eutrophic peat bog or estuarine.

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

Provide a general description of the flora and fauna in the vicinity (i.e. within the potential dispersal area of the GMO) of the site. State whether the flora and fauna are typical of any particular habitat, for example, that typically found in grassland, heathland, forest, agricultural or wetland areas. If possible, include estimates of the abundance of each predominant species (e.g. hectarage, population size, etc.) State whether any of the species are rare or protected under UK law.

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

Target ecosystems are likely to be those in the immediate vicinity of the release which are targeted for any product containing the GMO. As a consequence of the release, non-target, ecosystems could be affected, “Run-off” of microbial applications into rivers or lakes could also affect non-target ecosystems.

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

Describe the site of release e.g. terrestrial, freshwater, estuarine, coastal, marine or other. State
whether this is the same as the natural habitat of the unmodified recipient/parental organism (see point 9). Indicate any differences in the habitat of the proposed release site that would affect growth, performance or survivability of the GMO when compared to the natural habitat, e.g. improved soil conditions, absence of competitors/natural predators, etc.

53. Any known planned developments or changes in land use in the region which could influence the environmental impact of the release. Particularly relevant are any planned changes that would increase the spread or persistence of the GMO. For example, the movements of large amounts of earth for landscaping purposes may transport soil borne GMOs or propagules of other GMOs resident in the soil (spores, rhizomes, seeds, eggs, etc.) into other areas away from the original site of release. Agricultural land may be sold for other uses, construction, recreational, etc. In this case, the holder of a consent may need to apply to the Secretary of State [i.e. subsequently] for a variation in his consent.

Part IV
Information relating to the interactions between the organisms and the environment

Characteristics affecting survival, multiplication and dissemination

54. The biological features which affect survival, multiplication and dispersal. Describe any features of the GMO that would enhance survivability such as the ability of microbes to form specialist structures, e.g. spores, sclerotia and cysts. State if the organism is able to reproduce itself rapidly, particularly by asexual means. Where applicable, include specific details on generation times, number of generations per year and clonal or vegetative growth.

55. The known or predicted environmental conditions which may affect survival, multiplication and dissemination, including wind, water, soil, temperature Identify the environmental conditions that would initiate the adoption of survival measures and the formation of survival structures. State how the
and pH.

reproductive process are affected by environmental constraints, such as temperature, photoperiod, rainfall, etc.

56. **The sensitivity to specific agents.**

Specific agents will include antibiotics, heavy metals, pesticides, etc.

**Interactions with the environment**

57. **The predicted habitat of the organisms.**

Describe the predicted habitat the GMO will be expected to occupy. State if this is likely to be different to that which would be occupied by the unmodified recipient/parental organism or unmodified organism of the same species.

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.**

Indicate if any of the studies performed in a simulated environment suggest that changes in the characteristics of the organism as a result of genetic modification are likely to have significant ecological impacts when compared to unmodified organisms of the same species.

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.**

State or indicate the probability of the exchange of genetic material with other organisms. In particular, provide information on:

- conjugation, transduction and transformation between microorganisms;
- transfer of genetic material by viral vectors;
- transfer of genetic material by insect vector;

State whether any processes, including those described above, are likely to result in the transfer of genetic material from indigenous organisms to the released GMO.

60. **The likelihood of post-release selection leading to the expression of**

State whether there is a possibility that the modification will in any way
unexpected and/or undesirable traits in the genetically modified organisms.

cause expression of genes that are responsible for undesirable trait(s). State whether the undesirable trait(s) would be expressed if post-release selection were to occur in favour of the modification.

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.

Give information on the genetic stability of the GMO. This should be supported by data wherever possible, for example, molecular or expression data, or number of passages or generations. Stability of any phenotypic characteristics arising as a result of the modification should be given including any distinguishing phenotypic markers.

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

State all known routes of biological dispersal of the GMO and whether any stage in the life-cycle of the modified organism is capable of movement and dispersal unassisted, such as in larvae and adults of some species of insects and fish. State any abiotic or biotic constraints that may limit dispersal, for example, microorganisms or their survival structures may be transported by birds or other animals including arthropods;

If possible, for each of the main routes of dispersal, provide some indications of the numbers of modified organisms that would be involved and the distance the organism is likely to be transferred. State if dispersal mechanisms are unknown.

63. The description of ecosystems to which the organisms could be disseminated.

State whether the organism is likely to be limited to a particular ecosystem. If not, describe in general terms the type of ecosystem(s) into which the organism is likely to be dispersed, e.g. marine, coastal, freshwater, heath, forest, agricultural, etc. Indicate if the ecosystem(s) contains target or any other organisms which maybe affected.

64. The potential for excessive population

If the modification is likely to result in
increase of the organisms in the environment.

65. The competitive advantage of the organisms in relation to the unmodified recipient or parental organism or organisms.

State whether the genetic modification is designed to improve the performance of the organism in the environment and increase survival. This will include modifications that promote growth, increase tolerance to harsh environmental conditions such as high temperatures or pH, broaden/alter host range, etc. Give an assessment of the probability that the modifications will also confer a significant competitive advantage over recipient or parental organisms.

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

If the target organism is a microbe, include details of the method of detection and the sensitivity of the technique. If identification of higher organisms is not straightforward, also provide details of any special procedures used. This might include molecular probing, use of specific keys, comparison with reference collections, etc.

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

For modified biological control agents, explain exactly how the target organism will be affected and the cause of mortality. If the modified organism is designed to improve the performance of another organism, for example root-nodulating bacteria intended for plant growth promotion, explain how the process will occur.

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

This may be of particular relevance to biological control agents. Identification should be carried out in a similar way to that described for target organisms (point 66).
<table>
<thead>
<tr>
<th>69.</th>
<th>The likelihood of post release shifts in biological interactions or in the host range</th>
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<td></td>
<td>Describe the original host range of the recipient/parental organism. State whether the biological host range is likely to have been broadened or narrowed by the genetic modification either intentionally or unintentionally. State whether the selection pressures following release will be likely to change the host range in any way.</td>
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<tr>
<th>70.</th>
<th>The known or predicted interactions with non-target organisms in the environment, including competitors, preys, hosts, symbionts, predators, parasites and pathogens.</th>
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</table>
|     | Describe how non-target organisms within an ecosystem to which the GMO has been released are likely to be directly affected. State what effect this is likely to have on population dynamics and species composition. 

State which non-target organisms are likely to be indirectly affected. Say whether the modification is likely to confer an advantage that will alter the competitive or natural balance between species within the community of introduction; for example: 

- a GMO released as a biological control agent may create a vacant niche for the potential invasion by an organism similar to that controlled that would otherwise have been previously suppressed by the target organism 

- the target organism may be involved in a complete food web, the removal of which would result in the loss of species at several levels. 

- modified root nodulating bacteria may promote extensive growth also resulting in a crop plant becoming invasive due to an increase in competitive ability. 

Consider any effect of a successful invasion into non-target habitats. 

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<th>71.</th>
<th>The known or predicted involvement in biogeochemical processes.</th>
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<tbody>
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<td></td>
<td>State whether the recipient or parental organisms play a key role in any of the major cycles. For example, carbon,</td>
</tr>
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</table>
nitrogen and sulphur. State whether the modification is likely to change the role the organism plays within a cycle and the overall predicted result. Examples include organisms that are modified to fix atmospheric gases such as nitrogen.

72. Any other potential interactions of the organisms with the environment.

Include any interaction considered to be of importance that has not been addressed.

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.

Where possible, a range of techniques should be considered, from the simplest and most inexpensive to the most sensitive. Concentrate on techniques which are appropriate to the task required.

In the case of microorganisms provide details of any molecular techniques that are envisaged for detection. Describe how differences between the parental/recipient and modified organisms will be determined if there are no obvious phenotypic differences. State whether molecular or other techniques will be adopted.

Consideration should also be given to the likely effects of the release, and how these effects might be followed.

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

Make a statement on the detection limits using molecular techniques (see also point 30) including use of the methods on environmental samples. State how efficient the sampling processes for monitoring animals such as fish or insects are.

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

Describe any molecular or other techniques envisaged to detect transferred genetic material in other organisms, indicating the expected limits of detection.
76. Duration and frequency of the monitoring.

The frequency and duration of monitoring may usefully be summarised in a table if the same GMO is to be released at several sites, or if a number of different GMOs are to be released.

**Control of the release**

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

Give information on any measures that will be undertaken to contain the GMO within the release site such as fencing, trenching, netting or reduction of potential escapes by physical or chemical means.

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.

Indicate the material nature of the waste, for example whether it is solid or liquid, whether it consists of live or treated GMOs or contains the GMO.

81. Expected amount of waste.

82. Description of treatment envisaged.

Provide information on the proposed fate of the waste. This should cover all types of the anticipated waste. Describe the efficiency of the methods proposed.

**Emergency response plans**

83. Methods and procedures for controlling the organisms in case of unexpected spread.

Provide details of any physical and chemical methods that are envisaged to isolate and render the GMO inactive. State the efficiency of these methods.

84. Methods, such as eradication of the organisms, for decontamination of the areas affected.

State whether decontamination of the site is likely to be immediate or will have to take place over an extended period. State the probability of success of restoring the site to its pre-release state, with an indication of the timescale.
85. Methods for disposal or sanitation of plants, animals, soils, and any other thing exposed during or after the spread.

State whether affected material can be disposed of in a manner described in point 82. If sanitation of exposed organisms is possible, state how long this will take. State whether quarantine is proposed for GM animals.

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

Outline all plans to isolate the affected area including the evacuation of any livestock and other fauna that might be adversely affected and to prevent any further entry.

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

Describe any other procedures that will be adopted to prevent environmental damage if unexpected events occur.

Part VI
Information on methodology

A description of the methods used or a reference to standardised or internationally recognised methods used to compile the information required by this Schedule, and the name of the body or bodies responsible for carrying out the studies.
SCHEDULE 3  
Regulation 16 (2)(d) and (h) and (5)  

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.  

Provide the intended commercial name and any other name by which the product is or may be known. Give the name and nature of each type of GMO contained in the product but include only the name of the recipient or parental organism(s) with an indication of the modified genetic function(s) provided by the donor organism(s).  

Give any unique identification of the GMO according to internationally agreed standards.  

For each type of GMO included in the product indicate the type of biological entity (viroid, RNA virus, DNA virus, bacterium, fungus, plant, animal, etc.).  

If the person responsible is neither a domestic manufacturer nor an importer, their function should be indicated.  

2. The name and address in the Community of the person who is responsible for the marketing, 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.  

4. Give details of the particular properties of the product concerning its use (e.g. its toxicity to a particular group of insects). The conditions of use, the frequency and method of application, dosage, measures to protect the user, organisms on which the product is used, and restrictions on use (e.g. not to be used in the summer months, in drought, in rainy seasons, etc.) might also be included.  

5. A description of the geographical area or 

A general description of the
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.

Indicate whether the product is a vaccine, pesticide, crop plant, ornamental plant, bioremediation agent, diagnostic reagent, food, food ingredient, etc.

Also indicate whether the product will be used in industry, skilled trades, contained use facilities, state agencies or by consumers, etc. If there are multiple intended uses, this should be stated.

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 Secretary of State, 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 marketing the product, 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.

Specify measures to be used where product use is not consistent with guidelines for use of the GMO, consent conditions or generic best practice.

This question should be answered by those proposing to market GMO products intended for use in the environment as well as GM products used commercially in laboratories which have deliberate release consent. Relevant points to consider would be procedures needed in cases of:
- microbial escapes (products such as diagnostic kits, some vaccines, biopesticides and bioremediation agents) etc.
- plants growing in areas not recommended which could result in environmental damage.
- animals escaping into areas where their use/presence is not recommended.

If the product was misused, state what action would need to be taken to protect both the environment and human health and safety.

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

The information given here should state what is appropriate so as to avoid unintended release or misuse of the product and should include
recommendations for best practice during handling and use of the product. This should be in accordance with any agreed guidelines.

Any requirements for actions to be taken by users of the product arising from the post-market monitoring plan should be defined here.

11. Specific instructions for carrying out monitoring and reporting to the applicant and, if required, the Secretary of State 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 production 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.
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 damage 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 of damage to the environment.

5. An identification of any new risks of damage to 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 not 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 specific aspects of the environmental risk assessment and what those aspects are.
### SCHEDULE 5
#### Regulation 37

## REVOCATIONS

<table>
<thead>
<tr>
<th>Regulations revoked</th>
<th>References</th>
<th>Extent</th>
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</thead>
<tbody>
<tr>
<td>The Genetically Modified Organisms (Deliberate Release) Regulations 1993</td>
<td>S.I. 1993/152</td>
<td>The whole Regulations</td>
</tr>
<tr>
<td>The Genetically Modified Organisms (Deliberate Release) Regulations 1995</td>
<td>S.I. 1995/304</td>
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</tr>
<tr>
<td>The Genetically Modified Organisms (Deliberate Release and Risk Assessment–Amendment) Regulations 1997</td>
<td>S.I. 1997/1900</td>
<td>Regulation 2</td>
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<tr>
<td>The Genetically Modified Organisms (Contained Use) Regulations 2000</td>
<td>S.I. 2000/2831</td>
<td>Regulation 31(2)</td>
</tr>
</tbody>
</table>
CHAPTER 5: EU ASPECTS

(1) RESOLUTION OF ISSUES WITHIN EC UNDER DIRECTIVE

Since the main purpose of Directive 2001/18 is to provide for single EC market approval of GM products, there are a number of places where the Directive provides a mechanism for resolving possible differences between different Member States and/or the Commission. The main instances are summarised below.

“Part C” applications

2. The Commission and Member States seek to resolve outstanding issues within 105 days of the circulation of assessment reports on consent applications, excluding any period during which further information is awaited from the applicant.

3. If any Member State or the Commission maintains an objection after the 105-day period, the Commission proposes a decision on the application for adoption by the Regulatory Committee under Article 30 of the Directive within 120 days.

4. If the Regulatory Committee cannot reach a decision by qualified majority voting (QMV) on whether the application should be accepted or rejected, the application goes to the Council of Ministers.

- The 120-day period excludes any time the Commission is awaiting further information from the applicant, or is consulting relevant EC Scientific Committee (which should not exceed 90 days), or is awaiting a decision of the Council of Ministers, if necessary

- If the Council of Ministers cannot reach a decision by QMV within 3 months on whether the application should be accepted or rejected, the decision proposed by the Commission stands.

Monitoring and handling of new information on “Part C” consents

- If new information about the risks of a GMO placed on the market becomes available from post-market monitoring, or from any other source, the competent authority of the Member State that issued the consent must assess that information and prepare an assessment report proposing whether to modify or terminate the consent.

- A similar process of consultation with other Member States and the Commission to that undertaken for Part C consent applications is launched. If there are no reasoned objections within 60 days of circulation of the new information, or if any outstanding issues are resolved within 75 days of the assessment report, the lead Member State takes the action proposed in its assessment report.

- Any objection that cannot be resolved is referred to the Regulatory Committee as above.
“Safeguard” procedure

- This is a similar procedure to handling new information arising from monitoring, but is intended for use in cases where any Member State considers that there is a risk to human health or the environment sufficient to warrant the temporary restriction or prohibition of the GM product concerned.

- Given the likely greater urgency in such cases, the Regulatory Committee is required to take a decision within 60 days of the action proposed by the lead Member State, excluding awaiting any further information from the consent holder, consultations with the EC Scientific Committee(s), or a decision from the Council of Ministers, if necessary.
EU guidance being drafted. Current guidance available in ACRE Guidance Note 12
ROLE OF THE HSE AND FSA /CONSULTATION

References are made throughout the Regulations (for example Regulations 19(7), 24(2), 29(4), 29(6)) requiring the Secretary of State to have the agreement of the Health and Safety Executive (HSE) before taking certain decisions on the applications to release GMOs. This reflects HSE’s responsibility for, and expertise, in health and safety issues, particularly in relation to the potential effect on the health and safety of the workers that handle the GMOs in question which is the primary responsibility of the HSE.

The Secretary of State is also required to consult the Food Standards Agency (FSA) in making decisions on applications to release GMOs in which the FSA has an interest, for example GMOs intended for use in foods and animal feedingstuffs. Specific references to this requirement are not made in the Regulations because they are covered by the Environmental Protection Act (See Section 126 as amended by the Food Standards Act 1999 Schedule 3 Part III sections 17 and 18).
1. For all release applications

Regulation 12 requires the applicant to publish an advertisement in a national newspaper, and specifies what this advertisement must contain. The suggested formats below should be read in conjunction with Regulation 12, and applicants should ensure that the letter and spirit of this regulation are adhered to.

[Name and address of body applying for consent] hereby give notice that they have applied to the Secretary of State for Environment, Food and Rural Affairs for a consent to release genetically modified organisms under Section 111 of the Environmental Protection Act 1990.

The organisms concerned are [ ] modified to express [ ].

The general purpose of the proposed release is to [ ].

The proposed release will take place at [location A], [location B] etc in [month X], [month X-Z] etc. respectively.

The Secretary of State will consider any representations made to her relating to risks of damage to the environment posed by the release of the genetically modified organisms within a period that she shall specify in accordance with the Genetically Modified Organisms (Deliberate Release) Regulations 2002.

The Secretary of State will place information on this proposed GMO release on a public register within 12 days of her receipt of the application. The public register can be inspected by means of contacting the address below. Information will also be placed on the Defra website at www.defra.gov.uk/environment/gm/indexhtm. The register will include details of how and when representations may be made in respect of the application. Enquiries on this public consultation should be directed to the address below.

GMO Controls and Regulation Unit
Defra
Zone 3/G9
Ashdown House
123 Victoria Street
London
SW1E 76DE
(email: gm@defra.gsi.gov.uk)

2. For all applications under the First simplified Procedure

[Name and address of body applying for consent] hereby give notice that they have applied to the Secretary of State for Environment, Food and Rural Affairs for a consent to release genetically modified organisms under Section 111 of
the Environmental Protection Act 1990. The application is for a programme of releases and is made under Commission Decision 94/730/EC establishing a simplified procedure for the release into the environment of genetically modified crop plants.

The organisms concerned are [    ] modified to express [      ].

The general purpose of the proposed release is to [                                   ].

The proposed release will take place at [location A], [location B] etc in [month X], [month X-Z] etc. respectively

(If applicable:)
The programme of releases covers additional releases for which the dates and sites are not yet known.

The Secretary of State will consider any representations made to her relating to risks of damage to the environment posed by the release of the genetically modified organisms within a period that she shall specify in accordance with the Genetically Modified Organisms (Deliberate Release) Regulations 2002.

The Secretary of State will place information on this proposed GMO release on a public register within 12 days of her receipt of the application. The public register can be inspected by means of contacting the address below. Information will also be placed on the Defra website at www.defra.gov.uk/environment/gm/index.htm. The register will include details of how and when representations may be made in respect of the application. Enquiries on this public consultation should be directed to the address below.

GMO Controls and Regulation Unit
Defra
Zone 3/G9
Ashdown House
123 Victoria Street
London
SW1E 76DE
(email: gm@defra.gsi.gov.uk)

3. For compliance with a condition attached to a consent granted under the First Simplified Procedure Decision

[Name and address of body holding consent] hereby give notice that they have been granted a consent [reference number] to release genetically modified organisms under section 111 of the Environmental Protection Act 1990 by the secretary of State. The consent is for a programme of releases and is made under Commission Decision 94/730/EC establishing a simplified procedure for the release into the environment of genetically modified crop plants.

The organisms concerned are [    ] modified to express [      ].
The general purpose of the proposed release is to [   ].

The proposed releases will take place at [location A], [location B], etc. in [month X], [months X-Z], etc. respectively.

(If applicable:)
The programme of releases covers further additional releases for which the dates and sites are not yet known.

The Secretary of State will consider any representations made to her relating to risks of damage to the environment posed by the release of the genetically modified organisms within a period that she shall specify in accordance with the Genetically Modified Organisms (Deliberate Release) Regulations 2002.

The Secretary of State will place information on this proposed GMO release on a public register within 12 days of her receipt of the application. The public register can be inspected by means of contacting the address below. Information will also be placed on the Defra website at www.defra.gov.uk/environment/gm/index.htm. The register will include details of how and when representations may be made in respect of the application. Enquiries on this public consultation should be directed to the address below.

GMO Controls and Regulation Unit
Defra
Zone 3/G9
Ashdown House
123 Victoria Street
London
SW1E 76DE
(email: gm@defra.gsi.gov.uk)
ANNEX D

Suggested format for notification to specified bodies for the purposes of regulation 11(4) of the 2002 regulations

The enclosed notice has been placed in [name of newspaper] today in relation to an application for consent to release genetically modified organisms under section 111 of the Environmental Protection Act 1990. In accordance with Regulation 11(4) of the Genetically Modified Organisms (Deliberate Release) [England] Regulations 2002, I am required to bring this application to your attention.

Enquiries about the notice should be directed to the above address. Further details and the consultation for this application may be found on the public register of information about deliberate releases of GMOs, which is held at the address given below or the Defra website at www.defra.gov.uk/environment/gm/index.htm.

Any comments on the application should be addressed to the GM Policy and Regulation Unit, Department for Environment, Food and Rural Affairs, Zone 3/G9, Ashdown House, 123 Victoria Street, London, SW1E 6DE (email: biotech@defra.gsi.gov.uk) or via the consultation website quoting the above reference number.

Address of Public Information Register:
Department for Environment, Food and Rural Affairs, Ashdown House, 123 Victoria Street, London, SW1E 6DE Tel: 020 7944 3409
ANNEX E

Addresses (where relevant) of bodies to be notified for purposes of regulation 11 of the 2002 Regulations

(a) the owner or owners of the site of the proposed release, if a person other than the applicant,

(b) the local authority and any parish councils for the area of the proposed site.

(c) each member of the genetic modification safety committee established by the applicant under regulation 16 of the Genetically Modified Organisms (Contained Use) Regulations 2000.

(d) The Association of National Park Authorities,

Association of National Park Authorities
126 Bute Street,
Cardiff, CF10 5LE

Tel: 029 2049 9966
Fax: 029 2049 9980

(e) English Nature

English Nature
Northminster House
Peterborough, PE1 1UA

Tel: 01733 455 000
Fax: 01733 568 834

(f) The Environment Agency

Environment Agency
Head Office
Rio House
Waterside Drive
Aztec West
Almondsbury
Bristol, BS32 4UD

Tel: 01454 624 400
Fax: 01454 624 409
Environmental Protection Act, Part VI: Provisions brought into force by commencement order

Provision Purpose

[To be updated and added]
ANNEX G

List of relevant publications

Legislation/Directives

The Environmental Protection Act 1990

The Environmental Protection Act 1990 (Commencement No. 7) Order 1991, SI 1991, No. 1042 (C.27)

The Environmental Protection Act 1990 (Modification of section 112) Regulations 1992, SI 1992, No. 353 (C.101),

The Genetically Modified (Contained Use) Regulations 2000, SI 2000, No.2831

The Genetically Modified (Contained Use) (Amendment) Regulations 2002, SI 2002, No.63

The Genetically Modified (Deliberate Release) (England) regulations 2002

The Environmental Information Regulations 1992, SI 1992, No 3240

The Health and Safety at Work, etc. Act 1974

The European Communities Act 1972

The Animals (Scientific Procedures) Act 1986,

The Control of Substances Hazardous to Health Regulation, SI 1999 No 437


Directive 90/313 on the freedom of access to Environmental Information, OJ No. L158, 23.6.90 [New Directive under discussion]


Regulation 258/97/EC concerning novel foods and novel food ingredients. OJ L43/1, 14.2.97

ACRE Guidance Notes

Guide No.4 - Guidance for Experimental Releases of Genetically Modified Plants
Guide No.5 – Guidance for Experimental Releases of Genetically Modified Microorganisms (excluding viruses and similar agents)

Guide No.6 – Guidance for Experimental Releases of Genetically Modified Baculoviruses

Guide No.8 – Guidance for Experimental Releases of Genetically Modified Fish


**Other Guidance**


**ANNEX H**

**Departmental Contacts**

Health and Safety Executive  
Biotechnology Policy Section 6NW  
Rose Court  
2 Southwark Bridge  
London  
SE1 9HS

Tel: 020 7717 6278  
Fax: 020 7717 6199

www.hse.gov.uk

Health and Safety Executive  
Biotechnology Section  
Magdalen House  
Stanley Precinct  
Bootle  
Merseyside  
L20 3QZ

Tel: 0151 951 4831  
Fax: 0151 922 7918

Veterinary Medicines directorate  
Woodham Lane  
New Haw  
Addlestone  
Surrey  
KT15 3LS

Tel: 01932 336911  
Fax: 01932 336618  
www.vmd.gov.uk

Medicines control Agency  
Department of Health  
Market Towers  
1, Nine Elms Lane  
London  
SW8 5NQ

Tel: 020 7273 0463  
Fax: 020 7273 0190  
www.mca.gov.uk

European Medicines Evaluation Agency  
7 Westferry Circus  
Canary Wharf  
London  
E14 4HB

Tel: 020 7418 8400  
Fax: 020 7418 8416  
www.emea.eu.int

Department of Health  
Pharmaceutical Industry Branch  
Richmond House  
79 Whitehall  
London  
SW1A 2NL

Tel: 020 7210 5358  
Fax: 020 7210 5843  
www.doh.gov.uk
**Glossary**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>ACRE</td>
<td>Advisory Committee for Releases to the Environment</td>
</tr>
<tr>
<td>ARM</td>
<td>Antibiotic Resistance Marker</td>
</tr>
<tr>
<td>CEC</td>
<td>Commission of the European Community</td>
</tr>
<tr>
<td>Contained Use Regulations</td>
<td>The Genetically Modified Organisms (Contained Use) Regulations 2000</td>
</tr>
<tr>
<td>COSHH</td>
<td>Control of substances hazardous to health Regulations 1999 [These regulations will be revoked by the 2002 Regulations which come into force on 21 November]</td>
</tr>
<tr>
<td>Deliberate Release Regulations</td>
<td>the Genetically Modified (Deliberate Release) (England) Regulations 2002</td>
</tr>
<tr>
<td>Defra</td>
<td>Department for Environment Food and Rural Affairs</td>
</tr>
<tr>
<td>DOE</td>
<td>Department of the Environment (now part of Defra)</td>
</tr>
<tr>
<td>EC</td>
<td>European Commission</td>
</tr>
<tr>
<td>EPA</td>
<td>the Environmental Protection Act 1990</td>
</tr>
<tr>
<td>EMEA</td>
<td>European Medicines Evaluation Agency</td>
</tr>
<tr>
<td>EU</td>
<td>European Union</td>
</tr>
<tr>
<td>FSA</td>
<td>Food Standards Agency</td>
</tr>
<tr>
<td>GMO</td>
<td>Genetically modified organism</td>
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<tr>
<td>GMM</td>
<td>Genetically modified micro-organism</td>
</tr>
<tr>
<td>HSE</td>
<td>Health and Safety Executive</td>
</tr>
<tr>
<td>Higher Plant</td>
<td>a plant belonging to the taxonomic group Spermatophytae (Gymnospermae or Angiospermae);</td>
</tr>
<tr>
<td>Local Authority</td>
<td>a county council, a district council, a London borough council, the Common Council of the City of London in its capacity as a local authority, and the Council of the Isles of Scilly</td>
</tr>
<tr>
<td>Part B</td>
<td>Consent to release a GMO for research purposes under Part B of the Directive</td>
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Part C  Consents to release a GMO for commercial purposes under Part C of the Directive
Public Register  means the public register kept by the Secretary of State under section 122 of the Act
SOS  Secretary of State
SNIF  Summary notification information format
The Act  The Environmental Protection Act 1990
The Commission  The European Commission