



CYNULLIAD CENEDLAETHOL CYMRU

NATIONAL ASSEMBLY FOR WALES

OFFERYNNAU STATUDOL

STATUTORY INSTRUMENTS

2002 Rhif 3188 (Cy.304)

2002 No. 3188 (W.304)

**DIOGELU'R AMGYLCHEDD,
CYMRU**

**ENVIRONMENTAL
PROTECTION, WALES**

Rheoliadau Organeddau A
Addaswyd Yn Enetig (Eu Gollwng
Yn Fwriadol) (Cymru) 2002

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

NODYN ESBONIADOL

EXPLANATORY NOTE

(Nid yw'r nodyn hwn yn rhan o'r Rheoliadau)

(This note is not part of the Regulations)

Mae'r Rheoliadau hyn, sy'n gymwys i Gymru yn unig, yn rhoi ar waith Gyfarwyddeb 2001/18/EC Senedd a Chyngor Ewrop ("y Gyfarwyddeb Gollyngiadau Bwriadol") ar ollwng yn fwriadol i'r amgylchedd organeddau a addaswyd yn enetig ac ar ddiddymu Cyfarwyddeb y Cyngor 90/220/EEC. Maent yn dirymu Rheoliadau Organeddau a Addaswyd yn Enetig (Eu Gollwng yn Fwriadol) 1992 (O.S. 1992/3280) ac yn gwneud diwygiadau i Ran VI o Ddeddf Diogelu'r Amgylchedd 1990 ("Deddf 1990"). Mae naw rhan i'r Rheoliadau ac mae iddynt bum Atodlen.

Mae cynnwys y Gyfarwyddeb a'i rhagflaenydd yn ymwneud â rheoli gweithgareddau gollwng organeddau a addaswyd yn enetig yn fwriadol i'r amgylchedd a'u marchnata drwy osod gofyniad i sicrhau caniatâd ar gyfer y gweithgareddau hynny ac i gydymffurfio â'r amodau a bennwyd ar gyfer y caniatâd. Mae'r newidiadau a gyflwynwyd gan y Gyfarwyddeb yn cryfhau'r gyfundrefn reoli bresennol, yn enwedig mewn perthynas â monitro ar ôl marchnata.

Cafodd Cyfarwyddeb 1990/220/EEC ei gweithredu'n rhannol gan ddarpariaethau Rhan VI o'r Ddeddf (darpariaethau a oedd yn bodoli eisoes) ac yn rhannol gan Reoliadau Organeddau a Addaswyd yn Enetig (Eu Gollwng yn Fwriadol) 1992.

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

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

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

Mae'r Rheoliadau hyn yn cymhwyso yng Nghymru y diwygiadau a wnaed i'r Ddeddf gan Reoliadau Organeddau a Addaswyd yn Enetig (Eu Gollwng yn Fwriadol) 2002 ac y mae eu hangen i weithredu'r Gyfarwyddeb. Maent yn dirymu Rheoliadau 1992 hefyd.

Adran 111(1) o'r Ddeddf yw sail statudol y gofyniad i sicrhau caniatâd ar gyfer gollwng neu farchnata organeddau a addaswyd yn enetig. Mae'r achosion a'r amgylchiadau pan fydd yn ofynnol cael caniatâd yn cael eu rhangodi yn y Rheoliadau hyn. Mae gofyniad cyffredinol i sicrhau caniatâd ar gyfer gollwng neu farchnata organeddau a addaswyd yn enetig yn cael ei osod gan reoliad 9 (ar gyfer gollwng) a rheoliad 15 (ar gyfer marchnata). Mae'r gofyniad hwn yn ddarostyngedig i'r esemptiadau y darperir ar eu cyfer yn rheoliad 10 (ar gyfer gollwng) a rheoliad 16 (ar gyfer marchnata).

Mae'r diffiniadau sy'n cael eu defnyddio yn y darpariaethau sy'n ymwneud â'r gyfundrefn reoli wedi'u cynnwys yn adrannau 106, 107 a 127(1) o'r Ddeddf. Mae Rheoliadau 4 a 5 yn diwygio nifer o'r diffiniadau hyn i adlewyrchu'r Gyfarwyddeb. Mae Rheoliad 4 hefyd yn diwygio'r pŵer yn adran 106 i Gynulliad Cenedlaethol Cymru ragnodi technegau sy'n peri bod organeddau yn dod yn organeddau "sydd wedi'u haddasu'n enetig". Er hynny, pan ddaw'r Rheoliadau hyn i rym, dehonglir cyfeiriadau yn y Ddeddf at "organeddau sydd wedi'u haddasu'n enetig" drwy gyfeirio at y technegau addasu a ddisgrifir yn rheoliad 6.

Mae Rhannau II a III o'r Rheoliadau yn gosod gofynion ar gyfer ceisiadau am ganiatâd i ollwng a marchnata, yn eu tro, organeddau sydd wedi'u haddasu'n enetig (gan gynnwys darpariaethau trosiannol).

Mae Rhan IV yn pennu'r weithdrefn ar gyfer ymdrin â cheisiadau o'r amser y maent yn dod i law i amser eu penderfynu (ac, yn achos caniatadau i ollwng, eu hamrywio neu eu dirymu wedi hynny). Yn achos caniatadau i ollwng mae hyn yn cynnwys darpariaethau ar gyfer ymgynghori â'r cyhoedd ac ar gyfer caniatadau i farchnata (ac adnewyddu'r caniatadau hynny) mae'n cynnwys cytuno arnynt ar lefel y Gymuned Ewropeaidd.

Mae Rhan V yn cynnwys gofynion cyffredinol ar gyfer caniatadau i farchnata ac yn diwygio adran 112 o'r Ddeddf (sy'n gosod amodau ar gyfer caniatadau). Mae'n darparu hefyd ar gyfer yr hyn a ddylai ddigwydd pan ddaw gwybodaeth newydd ar gael sy'n effeithio ar yr asesiad risg ar gyfer marchnata organedd a addaswyd yn enetig.

Mae Rhan VI yn ychwanegu at adran 110 o'r Ddeddf i'r graddau y mae'n caniatáu i gamau gael eu cymryd i wahardd marchnata organedd a addaswyd yn enetig y mae caniatâd wedi'i roi ar ei gyfer er mwyn cysoni hynny â chymryd "camau i amddiffyn" ("*safeguard action*") o dan y Gyfarwyddeb.

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

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

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

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

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

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

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

Mae Rhan VII yn rhagnodi categorïau ychwanegol o wybodaeth sydd i'w chyhoeddi, er gwaethaf y ffaith y gallant fod yn fasnachol gyfrinachol, at ddibenion adran 123(7) o'r Ddeddf.

Mae Rhan VIII yn cynnwys y gofyniad i wahanol gategorïau o wybodaeth gael eu cynnwys yn y gofrestr gyhoeddus sydd i'w chadw gan Gynulliad Cenedlaethol Cymru o dan adran 122 o'r Ddeddf.

Mae Rhan IX yn cynnwys gofyniad bod Cynulliad Cenedlaethol Cymru yn cymryd yr egwyddor ragofalus i ystyriaeth wrth gyflawni ei swyddogaethau o dan y Ddeddf a'r Rheoliadau hyn. Term sy'n deillio o Erthygl 174 o'r Cytuniad i Sefydlu'r Gymuned Ewropeaidd yw'r ymadrodd "*precautionary principle*" ("egwyddor ragofalus"). Mae rhaglith y Gyfarwyddeb yn datgan bod rhaid cymryd yr egwyddor i ystyriaeth wrth weithredu'r Gyfarwyddeb.

Mae Atodlen 1 yn nodi'r wybodaeth sydd i'w chynnwys mewn ceisiadau am ganiatâd i ollwng neu farchnata uwchblanhigion a addaswyd yn enetig.

Mae Atodlen 2 yn nodi'r wybodaeth sydd i'w chynnwys mewn ceisiadau am ganiatâd i ollwng neu farchnata organeddau a addaswyd yn enetig heblaw am uwchblanhigion a addaswyd yn enetig.

Mae Atodlen 3 yn nodi'r wybodaeth sydd i'w chynnwys mewn cais am ganiatâd i farchnata organeddau a addaswyd yn enetig.

Mae Atodlen 4 yn nodi'r wybodaeth sydd i'w chynnwys mewn adroddiad asesu.

Mae Atodlen 5 yn pennu'r Rheoliadau sy'n cael eu dirymu gan y rheoliadau hyn.

Mae arfarniad rheoliadol wedi'i baratoi ar gyfer y rheoliadau hyn ac mae ar gael ar wefan Cynulliad Cenedlaethol Cymru (www.cymru.gov.uk). Gellir cael copïau oddi wrth Lywodraeth Cynulliad Cymru, Y Gangen Iechyd Planhigion a Biotechnoleg, Adeiladau'r Goron, Parc Cathays, Caerdydd, CF10 3NQ.

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

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

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

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

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

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

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

Schedule 5 specifies the Regulations revoked by these regulations.

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

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Rheoliadau Organeddau A
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Yn Fwriadol) (Cymru) 2002

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

Wedi'u gwneud *18 Rhagfyr 2002*
Yn dod i rym *31 Rhagfyr 2002*

Made *18th December 2002*
Coming into force *31st December 2002*

TREFN Y RHEOLIADAU

ARRANGEMENT OF REGULATIONS

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FOR ANY OTHER PURPOSE THAN FOR
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1. Information to be included in applications for consent to release or market genetically modified higher plants
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3. Information to be included in an application for consent to market genetically modified organisms
4. Information to be included in an assessment report
5. Revocations

Mae Cynulliad Cenedlaethol Cymru, gan ei fod wedi'i ddynodi(a) at ddibenion adran 2(2) o Ddeddf y Cymunedau Ewropeaidd 1972(b) mewn perthynas â rheoli a rheoleiddio gollwng yn fwriadol organeddau sydd wedi'u haddasu'n enetig, drwy arfer y pwerau a roddwyd iddo gan yr adran 2(2) honno a chan adrannau 106(4) a (5), 107(8), 111(1), (4), (5), (7) ac (11), 122(1) a (4), 123(7), a 126(1) o Ddeddf Diogelu'r Amgylchedd 1990(c), ac ar ôl ymgynghori â'r Asiantaeth Safonau Bwyd yn unol ag adran 126(5) o'r Ddeddf honno a phob pŵer arall sy'n ei alluogi yn y cyswllt hwnnw, drwy hyn yn gwneud y Rheoliadau canlynol:-

RHAN I Cyffredinol

Enwi, cychwyn a chymhwyso

1.-(1) Enw'r Rheoliadau hyn yw Rheoliadau Organeddau a Addaswyd yn Enetig (Eu Gollwng yn Fwriadol) (Cymru) 2002 a deuant i rym ar 31 Rhagfyr 2002.

(2) Mae'r Rheoliadau hyn yn gymwys i Gymru.

Dehongli

2.-(1) Yn y Rheoliadau hyn -

ystyr "asesiad risg amgylcheddol" ("*environmental risk assessment*") yw'r asesiad risg amgylcheddol y mae'n ofynnol ei gynnwys mewn cais am ganiatâd i ollwng neu farchnata organeddau a addaswyd yn enetig o dan reoliad 12(1)(c) a rheoliad 17(2)(c) yn ôl eu trefn;

ystyr "awdurdod lleol" ("*local authority*") yw cyngor sir neu fwrdeistref sirol;

mae "cais am ganiatâd i ollwng" ("*application for consent to release*") yn cynnwys unrhyw hysbysiad a wneir o dan Benderfyniad Cyntaf y Weithdrefn wedi'i Symleiddio (planhigion cnwd);

(a) O.S. 2001/3495.

(b) 1972 p.68.

(c) 1990 p. 43. Trosglwyddwyd swyddogaethau'r Ysgrifennydd Gwladol o dan y darpariaethau hyn (ac eithrio adran 156) i Gynulliad Cenedlaethol Cymru o dan Erthygl 2 o ac Atodlen 1 i Orchymyn Cynulliad Cenedlaethol Cymru (Trosglwyddo Swyddogaethau) 1999 (O.S. 1999/672). Trosglwyddwyd swyddogaethau'r Gweinidog Amaethyddiaeth, Pysgodfeydd a Bwyd o dan y darpariaethau hyn i Gynulliad Cenedlaethol Cymru o dan Erthygl 2 o Orchymyn Cynulliad Cenedlaethol Cymru (Trosglwyddo Swyddogaethau) 2000 (O.S. 2000/253) ac Atodlen 1 iddo.

The National Assembly for Wales, being designated(a) for the purposes of section 2(2) of the European Communities Act 1972(b) in relation to the control and regulation of the deliberate release of genetically modified organisms, acting in exercise of the powers conferred on it by the said section 2(2) and by sections 106(4) and (5), 107(8), 111(1), (4), (5), (7) and (11), 122(1) and (4), 123(7), and 126(1) of the Environmental Protection Act 1990(c), having consulted the Food Standards Agency in accordance with section 126(5) of that Act and of all other powers enabling it in that behalf, makes the following Regulations:-

PART I General

Citation, commencement and application

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

(2) These Regulations apply in relation to Wales.

Interpretation

2.-(1) In these Regulations -

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

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

"antibiotic resistance markers" ("*marcwyr ymwrthedd gwrthfotig*") means genes employed in the modification of an organism to make that organism express resistance to a particular antibiotic or antibiotics;

(a) S.I. 2001/3495.

(b) 1972 c.68.

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

ystyr "y Comisiwn" ("*the Commission*") yw'r Comisiwn Ewropeaidd;

ystyr "Cyfarwyddeb 1990" ("*the 1990 Directive*") yw Cyfarwyddeb y Cyngor 90/220/EEC(a) ar ollwng yn fwriadol i'r amgylchedd organeddau a addaswyd yn enetig fel y'i diwygiwyd gan Gyfarwyddeb y Comisiwn 1994/15/EC(b) a Chyfarwyddeb y Comisiwn 1997/35/EC(c);

mae i "cyfathrebiad electronig" yr un ystyr ag "*electronic communication*" yn Neddf Cyfathrebiadau Electronig 2000(ch);

ystyr "cynllun monitro" ("*monitoring plan*") yw'r cynllun sy'n ofynnol gan reoliad 17(2)(e);

ystyr "cynnyrch wedi'i gymeradwyo" ("*approved product*") yw cynnyrch y caniatwyd iddo gael ei farchnata drwy ganiatâd a roddwyd gan Gynulliad Cenedlaethol Cymru o dan adran 111(1) o'r Ddeddf neu yn unol ag Erthygl 15(3), 17(6) neu 18(2) o'r Gyfarwyddeb Gollyngiadau Bwriadol neu Erthygl 13(2) a (4) o Gyfarwyddeb 1990;

ystyr "y Ddeddf" ("*the Act*") yw Deddf Diogelu'r Amgylchedd 1990;

ystyr "y gofrestr" ("*the register*") yw'r gofrestr gyhoeddus sy'n cael ei chadw gan Gynulliad Cenedlaethol Cymru o dan adran 122 o'r Ddeddf;

ystyr "y Gyfarwyddeb Defnydd Amgaeëdig" ("*the Contained Use Directive*") yw Cyfarwyddeb y Cyngor 90/219/EEC(d) ar ddefnydd amgaeëdig micro-organeddau a addaswyd yn enetig fel y'i diwygiwyd ddiwethaf gan Benderfyniad y Cyngor 2001/204/EC(dd);

ystyr "y Gyfarwyddeb Gollyngiadau Bwriadol" ("*the Deliberate Release Directive*") yw Cyfarwyddeb 2001/18/EC Senedd a Chyngor Ewrop ar ollwng yn fwriadol i'r amgylchedd organeddau a addaswyd yn enetig(e);

ystyr "marcwyr ymwrthedd gwrthfotig" ("*antibiotic resistance markers*") yw genynnau a ddefnyddir wrth addasu organedd fel bod yr organedd hwnnw yn mynegi ymwrthedd i wrthfotig neu wrthfotigau penodol;

ystyr "organeddau a addaswyd yn enetig"

"application for consent to release" ("*cais am ganiatâd i ollwng*") shall include any notification made under the First Simplified Procedure (crop plants) Decision;

"approved product" ("*cynnyrch wedi'i gymeradwyo*") means a product permitted to be marketed by a consent granted by the National Assembly for Wales under section 111(1) of the Act or in accordance with Article 15(3), 17(6) or 18(2) of the Deliberate Release Directive or Article 13(2) or (4) of the 1990 Directive;

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

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

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

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

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

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

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

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

(a) OJ Rhif L117, 8.5.90, t.15.

(b) OJ Rhif L103, 22.4.94, t.20.

(c) OJ Rhif L169, 27.6.97, t.72.

(ch) 2000 p.7.

(d) OJ Rhif L117, 8.5.90, t.1.

(dd) OJ Rhif L73, 15.03.2001, t.32-34.

(e) OJ Rhif L106, 17.4.2001, t.1.

(a) OJ No. L117, 8.5.1990, p.1.

(b) OJ No. L73, 15.03.2001, p.32-34

(c) OJ No. L106, 17.4.2001, p.1.

(d) OJ No. L117, 8.5.90, p.15.

(e) OJ No. L103, 22.4.94, p.20.

(f) OJ No. L169, 27.6.97, p.72.

(g) 2000 c.7.

(h) OJ No. L292, 12.11.1994, p.31.

("genetically modified organisms") yw organedd a addaswyd yn enetig neu gyfuniad o organeddau a addaswyd yn enetig;

ystyr "Penderfyniad Cyntaf y Weithdrefn wedi'i Symleiddio (planhigion cnwd)" ("The First Simplified Procedure (crop plants) Decision") yw Penderfyniad y Comisiwn 94/730/EC(a);

ystyr "y Pwyllgor Ymgynghorol ar Ollyngiadau i'r Amgylchedd" ("the Advisory Committee on Releases to the Environment") yw'r Pwyllgor a benodwyd gan Gynulliad Cenedlaethol Cymru o dan adran 124 o'r Ddeddf;

ystyr "Rheoliadau 1992" ("the 1992 Regulations") yw Rheoliadau Organeddau a Addaswyd yn Enetig (Eu Gollwng yn Fwriadol) 1992(b);

ystyr "uwchblanhigyn" ("higher plant") yw planhigyn sy'n perthyn i'r grŵp tacsonomig *Spermatophytæ* (*Gymnospermae* neu *Angiospermae*).

(2) Yn y Rheoliadau hyn -

- (a) mae unrhyw gyfeiriad at reoliad â rhif neu Atodlen â rhif yn gyfeiriad at y rheoliad neu'r Atodlen yn y Rheoliadau hyn sy'n dwyn y rhif hwnnw; a
- (b) mae cyfeiriad at baragraff â rhif yn gyfeiriad at y paragraff sy'n dwyn y rhif hwnnw yn y rheoliad neu'r Atodlen y mae'r cyfeiriad hwnnw yn digwydd ynddo.

Dynodi awdurdod cymwys

3. Cynulliad Cenedlaethol Cymru fydd yr awdurdod cymwys mewn perthynas â Chymru at ddibenion y Gyfarwyddeb Gollyngiadau Bwriadol.

Diben Rhan VI o'r Ddeddf ac ystyr "organeddau a addaswyd yn enetig" ayb

4.-(1) Mae diwygiadau adran 106 o'r Ddeddf (diben Rhan VI o'r Ddeddf ac ystyr "genetically modified organisms" ayb), a wnaed gan Reoliadau Organeddau a Addaswyd yn Enetig (Eu Gollwng yn Fwriadol) 2002 yn effeithiol mewn perthynas â Chymru fel a ganlyn:

(2) Mae'r diwygiad a wnaed gan reoliad 3(2) o'r Rheoliadau hynny sy'n rhoi'r canlynol yn lle is-adran (1) -

(a) OJ Rhif L292, 12.11.1994, t.31.

(b) O.S. 1992/3280. Trosglwyddwyd swyddogaethau'r Ysgrifennydd Gwladol o dan y rheoliadau hyn i Gynulliad Cenedlaethol Cymru o dan Erthygl 3 ac Atodlen 1 i Orchymyn Cynulliad Cenedlaethol Cymru (Trosglwyddo Swyddogaethau) 2000 (O.S. 2000/253).

"higher plant" ("uwchblanhigyn") means a plant belonging to the taxonomic group *Spermatophytæ* (*Gymnospermae* or *Angiospermae*);

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

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

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

"the 1992 Regulations" ("Rheoliadau 1992") means the Genetically Modified Organisms (Deliberate Release) Regulations 1992(a).

(2) In these Regulations -

- (a) any reference to a numbered regulation or to a numbered Schedule is a reference to the regulation or Schedule in these Regulations so numbered; and
- (b) a reference to a numbered paragraph is a reference to the paragraph so numbered in the regulation or Schedule in which that reference occurs.

Designation of competent authority

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

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

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

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

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

"(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."

yn effeithiol hefyd yng Nghymru.

(3) Mae diwygiad is-adran (4) a wnaed gan reoliad 3(3) o'r Rheoliadau hynny, sy'n rhoi'r canlynol yn lle paragraff (a) -

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

yn effeithiol hefyd mewn perthynas â Chymru.

(4) Mae'r diwygiad a wnaed gan reoliad 3(4) o'r Rheoliadau hynny (sy'n mewnosod is-adrannau (4A) i (4D)) yn cael ei addasu gan baragraff (5) ac, o'i addasu felly, mae'n effeithiol hefyd mewn perthynas â Chymru.

(5) Yn is-adran (4D), fel y'i mewnosodwyd gan y rheoliad hwnnw, ar ôl "Secretary of State" mewnosodwch- "or, in relation to Wales, the National Assembly for Wales".

(6) Mae testun is-adrannau (4A) i (4D), o'i fewnosod gan y rheoliad hwnnw a'i addasu gan baragraff (5), fel a ganlyn -

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

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

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

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

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

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

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

(7) Mae'r diwygiad a wnaed gan reoliad 3(5) o'r Rheoliadau hynny (sy'n hepgor is-adrannau (5) a (6)) yn effeithiol hefyd mewn perthynas â Chymru.

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

also has effect in relation to Wales.

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

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

also has effect in relation to Wales.

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

(5) In subsection (4D), as inserted by that regulation, after "the Secretary of State" insert "or, in relation to Wales, the National Assembly for Wales".

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

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

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

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

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

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

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

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

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

Ystyr "damage to the environment" ayb

5.-(1) Mae diwygiadau adran 107 o'r Ddeddf (ystyr "damage to the environment" ayb) a wnaed gan reoliad 4 o Reoliadau Organeddau a Addaswyd yn Enetig (Eu Gollwng yn Fwriadol) 2002, fel y'u disgrifir ym mharagraff (2), yn effeithiol hefyd mewn perthynas â Chymru.

(2) Mae'r diwygiadau y cyfeirir atynt ym mharagraff (1) -

(a) yn rhoi yn lle is-adran (2) (ystyr "environment") -

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

(b) yn is-adran (3) (ystyr "damage to the environment") yn hepgor "to the living organisms supported by the environment",

(c) yn rhoi yn lle is-adran (6) (ystyr "harm") -

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

(ch) yn rhoi yn lle is-adran (9) (ystyr organedd sydd o dan "control" person) -

"(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.",

(d) yn rhoi yn lle is-adran (11) (ystyr organedd sy'n cael ei farchnata ("marketed")) -

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

Technegau addasu genedig

6.-(1) Tan y daw'r rheoliadau cyntaf o dan adran 106(4B)(a)(a) o'r Ddeddf i rym, rhaid cymryd bod genynnau neu ddeunydd genedig arall, at ddibenion is-adran (4) o'r adran honno, wedi'u haddasu'n artiffisial os ydynt wedi'u newid drwy ddefnyddio unrhyw un o'r technegau canlynol:

(a) technegau asid niwclëig wedi'u hailgyfuno sy'n cynnwys ffurfio cyfuniad newydd o ddeunydd genedig drwy fewnosod molecylau asid niwclëig a gynhyrchir drwy ba ddull bynnag y tu allan i organedd, i mewn i unrhyw firws, plasmid bacterol neu system fector arall a'u hymgorffori mewn organedd lletyol lle nad

(a) Diwygiwyd adran 106(4) gan reoliad 3(3) ac mewnosodwyd adran 106(4A) i 106(4D) gan reoliad 3(4) o Reoliadau Organeddau a Addaswyd yn Enetig (Eu Gollwng yn Fwriadol) 2002, a rhoddir effaith iddynt yng Nghymru yn ddarostyngedig i addasiadau pellach gan reoliad 4 o'r Rheoliadau hyn.

Meaning of "damage to the environment" etc.

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

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

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

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

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

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

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

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

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

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

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

Techniques of genetic modification

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

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

ydynt yn digwydd yn naturiol ond mae modd iddynt barhau i epilio;

- (b) technegau sy'n cynnwys cyflwyno'n uniongyrchol i mewn i organedd ddeunydd etifeddadwy a baratowyd y tu allan i'r organedd gan gynnwys microbigiad, macrobigiad a microamgáu;
- (c) ymasiad celloedd (gan gynnwys ymasiad protoplast) neu dechnegau croesiad pan gaiff celloedd byw gyda chyfuniadau newydd o ddeunydd genetig etifeddadwy eu ffurfio drwy ymasu dwy gell neu fwy drwy ddulliau nad ydynt yn digwydd yn naturiol.

(5) Tan y daw'r rheoliadau cyntaf o dan adran 106(4B)(b) o'r Ddeddf i rym, rhaid peidio ag ystyried bod genynnau neu ddeunydd genetig arall, at ddibenion is-adran (4) o'r adran honno, yn rhai sydd wedi'u haddasu'n artiffisial ond am eu bod wedi'u newid drwy ddefnyddio unrhyw un o'r technegau canlynol:

- (a) ffrwythloni in vitro,
- (b) prosesau naturiol megis cydgysylltiad, trosglwyddiad a thrawsnewid; ac
- (c) anwythiad polyploidedd,

ar yr amod nad yw technegau o'r fath yn golygu defnyddio molecylau asid niwclëig wedi'u hailgyfuno nac organeddau a addaswyd yn enetig ac a wnaed drwy dechnegau neu ddulliau ac eithrio -

- (i) mwtagenesis;
- (ii) ymasiad celloedd (gan gynnwys ymasiad protoplast) celloedd planhigion neu organeddau sy'n gallu cyfnewid deunydd genetig trwy ddulliau bridio traddodiadol.

(6) Tan y daw'r rheoliadau cyntaf o dan adran 106(4C) o'r Ddeddf i rym, rhaid cymryd nad yw organedd, at ddibenion Rhan VI o'r Ddeddf, yn organedd a addaswyd yn enetig os yw'n gynnwys a gafwyd drwy'r technegau neu'r dulliau a restrir ym mharagraffau (2)(i) neu (ii) ar yr amod nad oedd y technegau neu'r dulliau hynny yn golygu defnyddio molecylau asid niwclëig wedi'u hailgyfuno nac organeddau a addaswyd yn enetig ac eithrio'r rhai a wnaed drwy dechnegau neu ddulliau a restrir yn y paragraff hwnnw.

Asesiad risg amgylcheddol

7.-(1) Rhaid i asesiad risg amgylcheddol sydd wedi'i gynnwys mewn cais am ganiatâd i ollwng neu farchnata organeddau wedi'u haddasu'n enetig -

- (a) canfod a gwerthuso'r niwed posibl i'r amgylchedd, boed yn uniongyrchol neu'n anuniongyrchol, boed yn ddi-oed neu'n ohiriedig, a allai ddeillio o ganlyniad i ollwng neu farchnata organeddau a addaswyd yn enetig;

they do not naturally occur but in which they are capable of continued propagation;

- (b) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation;
- (c) cell fusion (including protoplast fusion) or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

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

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

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

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

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

Environmental risk assessment

7.-(1) An environmental risk assessment contained in an application for consent to release or market genetically modified organisms shall -

- (a) identify and evaluate the potential damage to the environment, whether direct or indirect, immediate or delayed, which may arise from the release or marketing of genetically modified organisms;

- (b) cael ei gyflawni yn unol ag Atodlen II o'r Gyfarwyddeb Gollyngiadau Bwriadol a chynnwys y casgliadau sy'n ofynnol yn Adran D o'r Atodlen honno; ac
- (c) cynnwys unrhyw gyfeiriadau llyfryddol a dangos y dulliau a ddefnyddiwyd lle bo hynny'n berthnasol.

(2) Pan fo'r genynnau a addaswyd yn enetig yn cynnwys marcwyr ymwrthedd gwrthfotig, rhaid i'r asesiad risg amgylcheddol gynnwys archwiliad o'r risgau penodol o niwed i'r amgylchedd a allai ddeillio o ollwng neu farchnata'r organeddau hynny a addaswyd yn enetig .

Cyfathrebu â cheisydd am ganiatâd

8.-(1) Pryd bynnag y bydd yn ofynnol i geisydd am ganiatâd neu am adnewyddu caniatâd y mae'r Rheoliadau hyn yn gymwys iddo neu ei bod hi'n ofynnol i ddeiliad caniatâd o'r fath o dan y Rheoliadau hyn gyflwyno unrhyw ddogfen yn ysgrifenedig, boed hynny cyn neu ar ôl i ganiatâd gael ei roi, mae'n ofynnol iddo gyflwyno'r ddogfen honno ar ffurf papur ac ar ffurf electronig a ddefnyddir yn gyffredin.

(2) Pryd bynnag y bydd yn ofynnol o dan y Rheoliadau hyn i unrhyw gyfathrebiad oddi wrth Gynulliad Cenedlaethol Cymru at y ceisydd am ganiatâd neu am adnewyddu caniatâd fod yn ysgrifenedig, bydd "ysgrifenedig" yn cynnwys cyfathrebiad electronig.

(3) Rhaid i unrhyw ddogfennau y mae'n ofynnol o dan y Rheoliadau hyn iddynt fod yn ysgrifenedig ac nad ydynt yn dod o dan ddarpariaethau paragraff (1) neu (2) uchod fod ar ffurf papur.

RHAN II

GOLLWNG ORGANEDDAU YN FWRIADOL AT UNRHYW DDIBEN AC EITHRIO EU GOSOD AR Y FARCHNAD

Y gofyniad am ganiatâd i ollwng

9. Yr achosion a'r amgylchiadau a ragnodwyd at ddibenion adran 111(1)(a) o'r Ddeddf mewn perthynas â gollwng unrhyw organeddau a addaswyd yn enetig yw'r holl achosion ac amgylchiadau lle bwriedir gollwng organeddau a addaswyd yn enetig.

Gweithgareddau esempt

10. Yr achosion a'r amgylchiadau a ragnodwyd at ddibenion adran 111(7) o'r Ddeddf lle mae personau yn esempt rhag gofynion adran 111(1)(a) o'r Ddeddf, i'r graddau y mae'r gofynion hynny yn gymwys i ollwng organeddau a addaswyd yn enetig, yw'r holl achosion ac amgylchiadau lle mae gollwng yn unol â chaniatâd a roddwyd gan Gynulliad Cenedlaethol Cymru o dan adran 111(1)(a) o'r Ddeddf i farchnata organeddau a

- (b) be carried out in accordance with Annex II of the Deliberate Release Directive and contain the conclusions required in section D of that Annex; and
- (c) include any bibliographic reference and indications of the methods used where applicable.

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

Communication with applicant for consent

8.-(1) Wherever an applicant for a consent or renewal of a consent to which these Regulations apply or a holder of such consent is required under these Regulations to submit any document in writing, whether before or after consent is granted, he or she is required to submit that document in both a paper and in a commonly used electronic form.

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

(3) Any documents required by these Regulations to be in writing which do not fall within the provisions of paragraph (1) or (2) above must be in paper form.

PART II

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

Requirement for consent to release

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

Exempt activities

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

addaswyd yn enetig neu lle mae cynnyrch a gymeradwywyd yn cael ei ollwng yn unol â'r amodau a'r cyfyngiadau y mae defnyddio'r cynnyrch yn ddarostyngedig iddynt.

Ceisiadau am ganiatâd i ollwng - darpariaethau cyffredinol

11.-(1) Rhaid i gais am ganiatâd i ollwng organeddau a addaswyd yn enetig gael ei wneud yn ysgrifenedig i Gynulliad Cenedlaethol Cymru.

(2) Caniateir hysbysu gollyngiadau arfaethedig o'r un organedd a addaswyd yn enetig neu gyfuniad o organeddau a addaswyd yn enetig ar yr un safle neu ar safleoedd gwahanol at yr un diben ac o fewn cyfnod penodedig mewn un cais.

(3) Pan fynegir bod cais am ganiatâd i ollwng organeddau a addaswyd yn enetig yn dibynnu ar Benderfyniad Cyntaf y Weithdrefn wedi'i Symleiddio (planhigion cnwd), os bydd unrhyw anghysondeb yn y gofynion ynglŷn â'r wybodaeth sydd i'w darparu o dan y Penderfyniad hwnnw a'r gofynion ynglŷn â'r wybodaeth sydd i'w darparu o dan y Rheoliadau hyn, darpariaethau'r Penderfyniad hwnnw fydd yn trechu.

Gwybodaeth i'w chynnwys mewn cais am ganiatâd i ollwng

12.-(1) Rhaid i gais am ganiatâd i ollwng organeddau a addaswyd yn enetig gynnwys -

- (a) yr wybodaeth a ragnodir yn -
 - (i) Atodlen 1 pan fo'r cais am ganiatâd i ollwng unrhyw uwchblanhigyn a addaswyd yn enetig, neu
 - (ii) Atodlen 2 mewn unrhyw achos arall,

i'r graddau y bo gwybodaeth o'r fath yn briodol i natur a graddfa'r gollyngiad neu'r cais,

- (b) gwybodaeth am ddata neu ganlyniadau o unrhyw ollyngiad blaenorol o'r organeddau, neu o'r un cyfuniad o organeddau, a gynhaliwyd gan y ceisydd, a gwybodaeth o unrhyw gais blaenorol ar gyfer gollwng yr organeddau, neu'r un cyfuniad o organeddau, y mae'r ceisydd wedi'i wneud i Gynulliad Cenedlaethol Cymru yn unol â'r Ddeddf neu i unrhyw awdurdod cymwys arall yn unol ag Erthygl 6 o'r Gyfarwyddeb Gollyngiadau Bwriadol,
- (c) asesiad risg amgylcheddol, a baratowyd yn unol â rheoliad 7,
- (ch) crynodeb ar y ffurf a sefydlwyd gan y Comisiwn o dan Erthygl 11(1) o'r Gyfarwyddeb Gollyngiadau Bwriadol, o'r wybodaeth a gynhwyswyd yn y cais.

(3) Caiff y cais gynnwys -

under section 111(1)(a) of the Act or in which an approved product is released in accordance with the conditions and limitations to which the use of the product is subject.

Applications for consent to release - general provisions

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

(2) Proposed releases of the same genetically modified organism or of a combination of genetically modified organisms on the same site or on different sites for the same purpose and within a defined period may be notified in a single application.

(3) Where an application for a consent to release genetically modified organisms is expressed to rely on the First Simplified Procedure (crop plants) Decision, in the event of any inconsistency in the requirements as to information to be provided under that Decision and the requirements as to information to be provided under these Regulations, the provisions of that Decision shall prevail.

Information to be contained in application for consent to release

12.-(1) An application for a consent to release genetically modified organisms must contain -

- (a) the information prescribed in -
 - (i) Schedule 1 where the application is for consent to release any genetically modified higher plant, or
 - (ii) Schedule 2 in any other case,

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

- (b) information on data or results from any previous release of the organisms, or of the same combination of organisms, which has been carried out by the applicant, and information from any previous application for the release of the organisms, or of the same combination of organisms, which the applicant has made to the National Assembly for Wales pursuant to the Act or to another competent authority in accordance with Article 6 of the Deliberate Release Directive,
- (c) an environmental risk assessment prepared in accordance with regulation 7,
- (d) a summary, in the format established by the Commission under Article 11(1) of the Deliberate Release Directive, of the information contained in the application.

(2) The application may contain -

- (a) data neu ganlyniadau o gais am ganiatâd i ollwng organeddau a addaswyd yn enetig a wnaed yn flaenorol gan rywun arall, ar yr amod bod copi o gytundeb ysgrifenedig y person hwnnw yn cael ei gynnwys yn y cais, a
- (b) mynegiad o'r wybodaeth sy'n cael ei chyflwyno yn y cais, y gallai ei datgelu niweidio safle cystadleuol y ceisydd ac y dylid felly ei thrin yn gyfrinachol, ac
- (c) unrhyw wybodaeth arall sy'n berthnasol ym marn y ceisydd.

(3) Rhaid i gyfiawnhad y gellir ei ddilysu gyd-fynd ag unrhyw fynegiad yn unol â pharagraff (2)(b).

Hysbysebu cais am ganiatâd i ollwng

13.-(1) Yn ddarostyngedig i baragraffau (2) a (3), rhaid i berson sy'n gwneud cais am ganiatâd i ollwng organeddau a addaswyd yn enetig, o fewn deg diwrnod fan bellaf ar ôl iddo anfon y cais hwnnw i Gynulliad Cenedlaethol Cymru, beri i hysbysiad yn cynnwys yr wybodaeth ganlynol gael ei gyhoeddi mewn cyhoeddiadau sydd i'w pennu gan Gynulliad Cenedlaethol Cymru -

- (a) enw a chyfeiriad y ceisydd,
- (b) disgrifiad cyffredinol o'r organeddau sydd i'w gollwng,
- (c) lleoliad a diben y gollyngiad,
- (ch) dyddiad neu ddyddiadau arfaethedig y gollyngiad,
- (d) datganiad y caiff gwybodaeth am y cais ei gosod ar y gofrestr gan Gynulliad Cenedlaethol Cymru o fewn deuddeg diwrnod i'r cais ddod i law,
- (dd) drwy ba fodd y gellir archwilio'r gofrestr,
- (e) datganiad y bydd Cynulliad Cenedlaethol Cymru yn ystyried unrhyw sylwadau a gyflwynwyd iddo mewn perthynas â risgiau o beri niwed i'r amgylchedd a allai ddeillio o ollwng yr organeddau a addaswyd yn enetig o fewn cyfnod y bydd yn ei bennu yn unol â'r Rheoliadau hyn,

a rhaid iddo anfon copi o'r cyhoeddiad sy'n cynnwys yr hysbyseb yn ddi-oed i Gynulliad Cenedlaethol Cymru.

(2) Nid oes rhaid i hysbysiad o dan baragraff (1) uchod gynnwys yr wybodaeth y cyfeiriwyd ati yn is-baragraffau (c) ac (ch) o'r paragraff hwnnw i'r graddau nad yw'r Penderfyniad Cyntaf y Weithdrefn wedi'i Symleiddio (planhigion cnwd) yn ei gwneud yn ofynnol i'r wybodaeth honno gael ei chyflwyno gyda'r cais ac nad yw'r wybodaeth honno yn cael ei chyflwyno gyda'r cais.

(3) Rhaid i geisydd am ganiatâd ddarganfod oddi wrth Gynulliad Cenedlaethol Cymru lefel y manylion

- (a) data or results from an application for consent to release genetically modified organisms previously made by some other person, provided that a copy of that person's agreement in writing is contained in the application,
- (b) an indication of the information submitted in the application, the disclosure of which might harm the competitive position of the applicant and which should therefore be treated as confidential, and
- (c) any other information which the applicant considers is relevant.

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

Advertisement of application for consent to release

13.-(1) Subject to paragraphs (2) and (3), a person who makes an application for a consent to release genetically modified organisms shall, not more than ten days after he or she sends that application to the National Assembly for Wales, cause to be published in publications to be specified by the National Assembly for Wales a notice containing the following information -

- (a) the name and address of the applicant,
- (b) the general description of the organisms to be released,
- (c) the location and purpose of the release,
- (d) the intended date or dates of the release,
- (e) a statement that information about the application will be placed on the register by the National Assembly for Wales within twelve days of the receipt of the application,
- (f) the means by which that register can be inspected,
- (g) a statement that the National Assembly for Wales will consider any representations made to it relating to risks of damage to the environment posed by the release of the genetically modified organisms within a period which it shall specify in accordance with these Regulations,

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

(2) A notice published under paragraph (1) above need not contain the information referred to in sub-paragraphs (c) and (d) of that paragraph insofar as the First Simplified Procedure (crop plants) Decision does not require that information to be submitted with the application and that information is not submitted with the application.

(3) An applicant for consent shall ascertain from the National Assembly for Wales the level of detail on the

ar gyfer y man gollwng a gaiff eu gosod ar y gofrestr a chynnwys yr un lefel o fanylion yn yr hysbysiad sydd i'w gyhoeddi o dan baragraff (1) uchod.

(4) Rhaid i berson sy'n gwneud cais am ganiatâd i ollwng organeddau a addaswyd yn enetig, o fewn deg diwrnod wedi iddo anfon y cais hwnnw i Gynulliad Cenedlaethol Cymru, hysbysu'r personau canlynol yn ysgrifenedig ei fod wedi gwneud y cais a rhaid iddo gynnwys yn yr hysbysiad hwnnw yr wybodaeth a ragnodwyd ym mharagraff (1)(a) i (e), ac eithrio i'r graddau y mae paragraff (2) yn caniatáu i'r fath wybodaeth gael ei heithrio o'r hysbysiad y cyfeirir ato ym mharagraff (1) -

- (a) yr awdurdod lleol ac unrhyw gynghorau cymuned ar gyfer ardal neu ardaloedd pob gollyngiad arfaethedig,
- (b) perchenog neu berchnogion y safle neu safleoedd pob gollyngiad arfaethedig, os yw'n berson heblaw am y ceisydd,
- (c) pob aelod o'r pwyllgor diogelwch addasu genetig a sefydlwyd gan y ceisydd o dan reoliad 16 o Reoliadau Addasu Genetig (Defnydd Amgaeedig) 2000(a),
- (ch) Cymdeithas Awdurdodau Parc Cenedlaethol,
- (d) Cyngor Cefn Gwlad Cymru(b),
- (dd) Asiantaeth yr Amgylchedd;

a rhaid iddo anfon copïau o'r hysbysiau yn ddi-oed i Gynulliad Cenedlaethol Cymru.

Darpariaethau trosiannol ar gyfer gollwng

14. Pan fydd Cynulliad Cenedlaethol Cymru wedi cael cais am ganiatâd i ollwng organeddau a addaswyd yn enetig cyn 31 Rhagfyr 2002 yn unol â Rheoliadau 1992 ac nad yw wedi penderfynu'r cais eto -

- (a) bydd y cais yn ddarostyngedig i ddarpariaethau'r Rheoliadau hyn;
- (b) rhaid i'r ceisydd gyflwyno i Gynulliad Cenedlaethol Cymru, yn ychwanegol at yr wybodaeth sydd wedi'i darparu eisoes mewn cysylltiad â'r cais, unrhyw wybodaeth bellach sy'n angenrheidiol er mwyn cydymffurfio â gofynion y Rheoliadau hyn erbyn 17 Ionawr 2003;
- (c) rhaid trin y cais fel un sydd wedi'i anfon i Gynulliad Cenedlaethol Cymru at ddibenion rheoliadau 13(1) a (4) ac sydd wedi dod i law Cynulliad Cenedlaethol Cymru at ddibenion rheoliad 21 pan fydd yr wybodaeth sy'n ofynnol o dan baragraff (b) wedi'i chyflwyno; ac
- (ch) os nad yw'r wybodaeth sy'n ofynnol o dan

(a) O.S. 2000/2831.

(b) *Gweler* adran 128 Deddf yr Amgylchedd 1990 (p.43).

location of the release which will be placed on the register and shall include the same level of detail in the notice to be published under paragraph (1) above.

(4) A person who makes an application for a consent to release genetically modified organisms shall, not more than ten days after he or she sends that application to the National Assembly for Wales, give to the following persons notice in writing that he or she has made the application and shall include in such notice the information prescribed in paragraph (1)(a) to (g), save in so far as paragraph (2) permits such information to be excluded from the notice referred to in paragraph (1) -

- (a) the local authority and any community councils for the area or areas of each proposed release,
- (b) the owner or owners of the site or sites of each proposed release, if a person other than the applicant,
- (c) each member of the genetic modification safety committee established by the applicant under regulation 16 of the Genetically Modified (Contained Use) Regulations 2000(a),
- (d) the Association of National Park Authorities,
- (e) the Countryside Council for Wales(b),
- (f) the Environment Agency;

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

Transitional provisions for release

14. Where the National Assembly for Wales has received an application for consent to release genetically modified organisms before 31st December 2002 pursuant to the 1992 Regulations and has not yet determined the application -

- (a) the application shall be subject to the provisions of these Regulations;
- (b) the applicant shall submit to the National Assembly for Wales such further information, additional to that already provided in connection with the application, as is necessary in order to comply with the requirements of these Regulations by 17th January 2003;
- (c) the application shall be treated as having been sent to the National Assembly for Wales for the purposes of regulations 13(1) and (4) and as having been received by the National Assembly for Wales for the purpose of regulation 21 on submission of the information required by paragraph (b); and
- (d) if the information required by paragraph (b)

(a) S.I. 2000/2831.

(b) *See* section 128 Environmental Act 1990 (c.43).

baragraff (b) wedi'i chyflwyno erbyn 17 Ionawr 2003, caiff Cynulliad Cenedlaethol Cymru wrthod bwrw ymlaen â'r cais.

has not been submitted by 17th January 2003, the National Assembly for Wales may refuse to proceed with the application.

Rhan III

GOSOD ORGANEDDAU AR Y FARCHNAD FEL CYNHYRCHION NEU MEWN CYNHYRCHION

Y gofyniad am ganiatâd i farchnata

15. Yr achosion a'r amgylchiadau a ragnodwyd at ddibenion adran 111(1)(a) o'r Ddeddf mewn perthynas â marchnata organeddau a addaswyd yn enetig yw'r holl achosion ac amgylchiadau mewn perthynas â marchnata organeddau a addaswyd yn enetig.

Gweithgareddau esempt

16.-(1) Yr achosion a'r amgylchiadau a ragnodwyd at ddibenion adrannau 108(7) a 111(7) o'r Ddeddf lle mae personau yn esempt rhag gofynion adran 108(1)(a) o'r Ddeddf (i gynnal asesiad risg) ac adran 111(1)(a) o'r Ddeddf (i sicrhau caniatâd), yn ôl eu trefn, i'r graddau y maent yn ymwneud â marchnata organeddau a addaswyd yn enetig yw'r holl achosion ac amgylchiadau -

- (a) lle mae cynnyrch a gymeradwywyd yn cael ei farchnata at ddefnydd y mae wedi'i gymeradwyo ar ei gyfer;
- (b) lle mae micro-organeddau a addaswyd yn enetig wedi'u rhoi ar gael ar gyfer gweithgareddau a reoleiddir o dan y Gyfarwyddeb Defnydd Amgaeedig;
- (c) lle mae organeddau a addaswyd yn enetig ac eithrio micro-organeddau sy'n dod o dan baragraff (b) wedi'u rhoi ar gael i'w defnyddio'n unig ar gyfer gweithgareddau lle mae mesurau amgáu llym priodol yn seiliedig ar yr un egwyddorion o amgáu â'r rhai a bennir yn y Gyfarwyddeb Defnydd Amgaeedig er mwyn cyfyngu ar y cysylltiad rhyngddynt â'r boblogaeth yn gyffredinol a'r amgylchedd a sicrhau lefel uchel o ddiogelwch iddynt;
- (ch) lle mae organeddau a addaswyd yn enetig wedi'u rhoi ar gael i'w defnyddio'n unig ar gyfer gollyngiadau bwriadol sy'n cydymffurfio â'r gofynion a nodwyd yn Rhan II;
- (d) lle mae organeddau a addaswyd yn enetig ac a awdurdodwyd o dan Reoliad y Cyngor (EEC) Rhif 2309/93(a), fel y'i diwygiwyd gan Reoliad y Comisiwn EC Rhif 649/98(b), yn cael ei farchnata; neu

(a) OJ Rhif L214, 24.8.1993, t.1.

(b) OJ Rhif L88, 24.3.1998, t.7.

Part III

PLACING ON THE MARKET OF ORGANISMS AS OR IN PRODUCTS

Requirement for consent to market

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

Exempt activities

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

- (a) an approved product is marketed for a use for which it has approval;
- (b) genetically modified micro-organisms are made available for activities regulated under the Contained Use Directive;
- (c) genetically modified organisms other than micro-organisms falling within paragraph (b) are made available to be used exclusively for activities where appropriate stringent containment measures based on the same principles of containment as laid down in the Contained Use Directive are used to limit their contact with and to provide a high level of safety for the general population and the environment;
- (d) genetically modified organisms are made available to be used exclusively for deliberate releases complying with the requirements laid down in Part II;
- (e) a genetically modified organism authorised under Council Regulation (EEC) No. 2309/93(a), as amended by Commission Regulation EC No. 649/98(b), is marketed; or

(a) OJ No. L214, 24.8.1993, p.1.

(b) OJ No. L88, 24.3.1998, p.7.

(dd) lle mae bwyd newydd neu gynhwysyn bwyd newydd o fewn cwmpas Rheoliad EC Rhif 258/97 Senedd a Chyngor Ewrop^(a) yn cael ei farchnata yn unol â'r Rheoliad hwnnw.

Cais am ganiatâd i farchnata

17.-(1) Rhaid gwneud cais am ganiatâd o dan adran 111(1) o'r Ddeddf yn ysgrifenedig i Gynulliad Cenedlaethol Cymru.

(2) Rhaid i gais am ganiatâd i farchnata organeddau a addaswyd yn enetig nad yw'n gais am adnewyddu caniatâd gynnwys yr wybodaeth ganlynol -

- (a) yr wybodaeth a ragnodir yn -
 - (i) Atodlen 1 pan fo'r cais yn gais am ganiatâd i farchnata unrhyw uwchblanhigyn a addaswyd yn enetig, neu
 - (ii) Atodlen 2 mewn unrhyw achos arall,

i'r graddau y bo gwybodaeth o'r fath yn briodol i natur a graddfa'r gollyngiad a allai ddeillio o'r marchnata;

- (b) gwybodaeth am ddata neu ganlyniadau o unrhyw ollngiad blaenorol o'r organeddau, neu o'r un cyfuniad o organeddau a gyflawnwyd gan y ceisydd naill ai y tu mewn neu'r tu allan i'r Gymuned Ewropeaidd, a gwybodaeth o unrhyw gais blaenorol am ganiatâd i ollwng yr organeddau, neu'r un cyfuniad o organeddau y mae'r ceisydd wedi'i wneud i Gynulliad Cenedlaethol Cymru yn unol â'r Ddeddf a'r Rheoliadau hyn neu i awdurdod cymwys arall yn unol ag adran 6 o'r Gyfarwyddeb Gollyngiadau Bwriadol;
- (c) asesiad risg amgylcheddol a baratowyd yn unol â rheoliad 7;
- (ch) yn ddarostyngedig i baragraff (3), yr wybodaeth a ragnodir yn Atodlen 3;
- (d) yr amodau arfaethedig ar gyfer marchnata'r cynnyrch, gan gynnwys amodau penodol ar gyfer ei ddefnyddio a'i drin;
- (dd) cyfnod arfaethedig ar gyfer y caniatâd na fydd yn hwy na deng mlynedd;
- (e) cynllun monitro wedi'i baratoi yn unol ag Atodlen VII o'r Gyfarwyddeb Gollyngiadau Bwriadol y mae'n rhaid iddo gynnwys cynnig ar gyfer cyfnod amser y cynllun a all fod yn wahanol i'r cyfnod arfaethedig ar gyfer y caniatâd;
- (f) cynnig ar gyfer labelu sy'n cydymffurfio â'r gofynion a bennwyd yn Atodlen 3;
- (ff) cynnig ar gyfer y pagediad;
- (g) crynodeb o'r cais ar y ffurf a sefydlwyd gan y Comisiwn o dan Erthygl 13(2)(h) o'r Gyfarwyddeb Gollyngiadau Bwriadol;

(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^(a) is marketed in accordance with that Regulation.

Application for consent to market

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

(2) An application for a consent to market genetically modified organisms which is not an application for renewal of consent must contain the following information -

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

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

- (b) information on data or results from any previous release of the organisms, or of the same combination of organisms which has been carried out by the applicant either inside or outside the European Community, and information from any previous application for consent to release the organisms, or the same combination of organisms, which the applicant has made to the National Assembly for Wales in accordance with the Act and these Regulations or to another competent authority in accordance with Article 6 of the Deliberate Release Directive;
- (c) an environmental risk assessment prepared in accordance with regulation 7;
- (d) subject to paragraph (3), the information prescribed in Schedule 3;
- (e) the proposed conditions for the marketing of the product, including specific conditions of use and handling;
- (f) a proposed period for the consent which shall not exceed ten years;
- (g) a monitoring plan prepared in accordance with Annex VII of the Deliberate Release Directive which shall include a proposal for the time period of the plan which may differ from the proposed period for the consent;
- (h) a proposal for labelling which shall comply with the requirements laid down in Schedule 3;
- (i) a proposal for packaging;
- (j) a summary of the application in the format established by the Commission under Article 13(2)(h) of the Deliberate Release Directive.

(a) OJ Rhif L43, 14.2.1997, t.1.

(a) OJ No. L43, 14.2.1997, p.1.

(3) Caiff y cais gynnwys hefyd -

- (a) data neu ganlyniadau o gais am ganiatâd i ollwng organeddau a addaswyd yn enetig a wnaed yn flaenorol gan rywun arall, ar yr amod bod copi ysgrifenedig o gytundeb y person hwnnw yn cael ei gynnwys yn y cais,
- (b) mynegiad o'r wybodaeth sy'n cael ei chyflwyno yn y cais, y gallai ei datgelu niweidio safle cystadleuol y ceisydd ac y dylid felly ei thrin yn gyfrinachol, ac
- (c) unrhyw wybodaeth arall sy'n berthnasol ym marn y ceisydd.

(4) Rhaid i'r wybodaeth a ddarperir yn unol ag is-baragraffau (2)(a) ac (ch) gymryd i ystyriaeth amrywiaeth y safleoedd sy'n defnyddio organeddau a addaswyd yn enetig a rhaid iddi gynnwys gwybodaeth am unrhyw ganlyniadau sy'n deillio o ymchwil a gollyngiadau datblygiadol ar effaith y gollyngiadau ar iechyd dynol a'r amgylchedd;

(5) Rhaid i gyfiawnhad y gellir ei ddilysu gyd-fynd ag unrhyw fynegiad yn unol â pharagraff (3)(b).

(6) Pan fydd y ceisydd yn gallu dangos yn ei gais er bodlonrwydd Cynulliad Cenedlaethol Cymru, ar sail canlyniadau unrhyw ollyngiad gan ddilyn ac yn unol â chaniatâd a roddwyd o dan adran 111(1) o'r Ddeddf o dan Ran B o naill ai'r Gyfarwyddeb Gollyngiadau Bwriadol neu Gyfarwyddeb 1990, neu am resymau gwyddonol rhesymegol sylweddol eraill, nad yw marchnata a defnyddio'r cynnyrch yn peri risg o niweidio'r amgylchedd, gall gynnig peidio â chyflenwi rhan neu'r cyfan o'r wybodaeth ragnodedig yn Rhan II o Atodlen 3.

Darpariaeth drosiannol ar gyfer marchnata

18. Pan fo Cynulliad Cenedlaethol Cymru wedi cael cais am ganiatâd i farchnata organeddau a addaswyd yn enetig cyn 31 Rhagfyr 2002 yn unol â Rheoliadau 1992 ac nad yw eto wedi penderfynu ar y cais hwnnw, neu, mewn achos pan fydd yn ofynnol i'r Comisiwn wneud penderfyniad yn unol ag Erthygl 13(3) o Gyfarwyddeb 1990, nad yw'r penderfyniad hwnnw wedi cael ei gymryd eto -

- (a) bydd y cais yn ddarostyngedig i ddarpariaethau'r Rheoliadau hyn;
- (b) rhaid i'r ceisydd gyflwyno i Gynulliad Cenedlaethol Cymru, yn ychwanegol at yr wybodaeth a ddarparwyd eisoes mewn cysylltiad â'r cais, unrhyw wybodaeth bellach sy'n angenrheidiol er mwyn cydymffurfio â gofynion y Rheoliadau hyn erbyn 17 Ionawr 2003;
- (c) rhaid trin y cais fel un sydd wedi dod i law Cynulliad Cenedlaethol Cymru at ddibenion rheoliad 24 pan fo'r wybodaeth sy'n ofynnol o dan baragraff (b) uchod wedi'i chyflwyno;

(3) The application may in addition contain -

- (a) data or results from an application for consent to release genetically modified organisms previously made by some other person, provided that a copy of that person's agreement in writing is contained in the application,
- (b) an indication of the information submitted in the application, the disclosure of which might harm the competitive position of the applicant and which should therefore be treated as confidential, and
- (c) any other information which the applicant considers relevant.

(4) The information provided in accordance with sub-paragraphs (2)(a) and (d) shall take into account the diversity of sites of use of the genetically modified organism and shall include information on any results obtained from research and developmental releases concerning the impact of the release on human health and the environment.

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

(6) Where the applicant can demonstrate in his or her application to the satisfaction of the National Assembly for Wales that, on the basis of the results of any release in pursuance of and in accordance with a consent granted under section 111(1) of the Act under Part B of either the Deliberate Release Directive or the 1990 Directive, or on other substantive, reasoned scientific grounds, that the marketing and use of the product does not pose a risk of damage to the environment, he or she may propose not to supply part or all of the information prescribed in Part II of Schedule 3.

Transitional provision for marketing

18. Where the National Assembly for Wales has received an application for consent to market genetically modified organisms before 31st December 2002 pursuant to the 1992 Regulations and has not yet determined that application, or, in a case where the Commission is required to take a decision in accordance with Article 13(3) of the 1990 Directive, that decision has not yet been taken -

- (a) the application shall be subject to the provisions of these Regulations;
- (b) the applicant shall submit to the National Assembly for Wales such further information, additional to that already provided in connection with the application, as is necessary in order to comply with the requirements of these Regulation by 17th January 2003;
- (c) the application shall be treated as having been received by the National Assembly for Wales for the purposes of regulation 24 on submission of the information required by paragraph (b) above;

- (ch) os, erbyn 31 Rhagfyr 2002, y mae Cynulliad Cenedlaethol Cymru wedi anfon i'r Comisiwn yr wybodaeth sy'n ofynnol gan reoliad 16(2) o Reoliadau 1992, rhaid iddo ychwanegu ato ac, os bydd hynny'n angenrheidiol yn ei farn ef, ei ddiwygio pan fydd yr wybodaeth bellach sy'n ofynnol gan baragraff (b) uchod wedi dod i law yng ngoleuni ei rwymedigaethau o dan y Rheoliadau hyn; a
- (d) os nad yw'r wybodaeth sy'n ofynnol gan baragraff (b) uchod wedi'i chyflwyno erbyn 17 Ionawr 2003, caiff Cynulliad Cenedlaethol Cymru wrthod bwrw ymlaen â'r cais.

Ceisiadau am adnewyddu caniatâd i farchnata

19.-(1) Pan fo Cynulliad Cenedlaethol Cymru wedi rhoi caniatâd i farchnata organeddau a addaswyd yn enetig, o dan adran 111(1) o'r Ddeddf, rhaid i unrhyw gais am adnewyddu'r caniatâd hwnnw gael ei wneud yn ysgrifenedig i Gynulliad Cenedlaethol Cymru -

- (a) cyn 17 Hydref 2006 pan roddwyd y caniatâd cyn 17 Hydref 2002, a
- (b) cyn pen naw mis cyn i'r caniatâd ddirwyn i ben ym mhob achos arall.

(2) Rhaid i'r cais gynnwys -

- (a) copi o'r caniatâd i farchnata'r organeddau a addaswyd yn enetig,
- (b) pan fo hynny'n gymwys, adroddiad ar ganlyniadau'r monitro a gynhaliwyd yn unol â gofynion rheoliad 29(dd),
- (c) unrhyw wybodaeth newydd arall sydd wedi dod ar gael mewn perthynas â'r risgiau y bydd y cynnyrch yn peri niwed i'r amgylchedd,
- (ch) fel y bo'n briodol, cynnig ar gyfer diwygio amodau'r caniatâd gwreiddiol neu ychwanegu atynt, gan gynnwys yr amodau sy'n ymwneud â monitro yn y dyfodol a therfynau amser y caniatâd newydd.

(3) Rhaid i unrhyw ganiatâd i farchnata organeddau a addaswyd yn enetig a gafodd ei roi gan Gynulliad Cenedlaethol Cymru o dan adran 111(1) o'r Ddeddf cyn 17 Hydref 2002 nad oes cais i'w adnewyddu o dan baragraff (1) uchod wedi dod i law cyn 17 Hydref 2006 gael ei drin fel pe bai wedi dirwyn i ben ar y dyddiad hwnnw.

RHAN IV

DYLETSWYDDAU AR ÔL GWNEUD CEISIADAU

Dyletswydd y ceisydd ar ôl gwneud cais am ganiatâd i ollwng neu i farchnata

20.-(1) Mae'r diwygiad i adran 111 o'r Ddeddf

- (d) if, by 31st December 2002, the National Assembly for Wales has forwarded to the Commission the information required by regulation 16(2) of the 1992 Regulations, it shall supplement it and, if it considers it to be necessary, revise it on receipt of the further information required by paragraph (b) above in the light of its obligations under these Regulations; and
- (e) if the information required by paragraph (b) above has not been submitted by 17th January 2003, the National Assembly for Wales may refuse to proceed with the application.

Applications for renewal of consent to market

19.-(1) Where the National Assembly for Wales has granted a consent to market genetically modified organisms, under section 111(1) of the Act, any application to renew that consent shall be made in writing to the National Assembly for Wales -

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

(2) The application shall contain -

- (a) a copy of the consent to market the genetically modified organisms,
- (b) where applicable, a report on the results of the monitoring carried out in accordance with the requirements of regulation 29(f),
- (c) any other new information which has become available with regard to the risks of the product causing damage to the environment,
- (d) as appropriate, a proposal for amending or adding to the conditions of the original consent, including the conditions concerning future monitoring and the time limitation of the new consent.

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

PART IV

DUTIES AFTER THE MAKING OF APPLICATIONS

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

20. -(1) The amendment of section 111 of the Act (consents required by certain persons) made by

(caniatadau y mae eu hangen gan bersonau penodol) a wnaed gan reoliad 19(1) o Reoliadau Organeddau a Addaswyd yn Enetig (Eu Gollwng yn Fwriadol) 2002, sy'n mewnosod y canlynol fel ail frawddeg yn is-adran (b)-

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

yn effeithiol mewn perthynas â Chymru.

(2) Rhaid i geisydd am ganiatâd i ollwng neu i farchnata organeddau a addaswyd yn enetig sy'n hysbysu Cynulliad Cenedlaethol Cymru o unrhyw wybodaeth yn unol ag adran 111(6A) o'r Ddeddf (y gofyniad i'r ceisydd roi hysbysiad o wybodaeth newydd am risgiau o niwed i'r amgylchedd) gyflwyno yn ysgrifenedig i Gynulliad Cenedlaethol Cymru fersiwn ddiwygiedig o'r cais gwreiddiol am ganiatâd sydd wedi'i ddiwygio i gymryd yr wybodaeth newydd i ystyriaeth.

Dyletswyddau Cynulliad Cenedlaethol Cymru wrth gael ceisiadau am ganiatâd i ollwng

21. Ar ôl cael cais am ganiatâd i ollwng organeddau a addaswyd yn enetig, rhaid i Gynulliad Cenedlaethol Cymru -

- (a) hysbysu'r ceisydd yn ysgrifenedig o'r dyddiad y daeth y cais i law;
- (b) gwahodd unrhyw berson drwy gyfrwng cais sy'n cael ei osod ar y gofrestr, i gyflwyno sylwadau iddo mewn perthynas â'r gollyngiad cyn diwedd cyfnod sydd i'w bennu, sef cyfnod y mae'n rhaid iddo beidio â bod yn llai na chwe deg diwrnod o'r dyddiad y daeth y cais i'w law;
- (c) sicrhau bod crynodeb o'r cais hwnnw ar y ffurf a sefydlwyd gan y Comisiwn o dan Erthygl 11(1) o'r Gyfarwyddeb Gollyngiadau Bwriadol yn cael ei anfon ymlaen i'r Comisiwn o fewn 30 diwrnod;
- (ch) archwilio'r cais i weld a yw'n cydymffurfio â gofynion y Ddeddf a'r rheoliadau hyn;
- (d) gwerthuso'r risgiau y bydd yr amgylchedd yn cael ei niweidio gan y gollyngiad arfaethedig gan barchu'r asesiad risg amgylcheddol;
- (dd) cymryd i ystyriaeth unrhyw sylwadau sy'n ymwneud â risgiau o beri niwed i'r amgylchedd drwy ollwng cyn diwedd y cyfnod a bennwyd yn unol â pharagraff (b) ac unrhyw sylwadau a wnaed gan awdurdod neu awdurdodau cymwys Aelod-wladwriaethau eraill wedi i'r Comisiwn ddsbarthu iddynt y crynodeb y cyfeirir ato ym mharagraff (c).

regulation 19(1) of the Genetically Modified Organisms (Deliberate Release) Regulations 2002, which inserts as a second sentence in subsection (6) the following -

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

also has effect in relation to Wales.

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

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

21. Following receipt of an application for consent to release genetically modified organisms the National Assembly for Wales shall -

- (a) inform the applicant in writing of the date of receipt of the application;
- (b) invite any person by means of a request placed on the register, to make representations to it relating to the release before the end of a period to be specified which shall not be less than sixty days from the date the application was received by it;
- (c) ensure that within 30 days a summary of that application in the format established by the Commission under Article 11(1) of the Deliberate Release Directive is forwarded to the Commission;
- (d) examine the application for its conformity with the requirements of the Act and of these regulations;
- (e) evaluate the risks of damage being caused to the environment by the proposed release having regard to the environmental risk assessment; and
- (f) take into account any representations relating to risks of damage being caused to the environment by the release made to it before the end of the period specified in accordance with paragraph (b) and any comments made by a competent authority or authorities of other Member States following the circulation to them by the Commission of the summary referred to in paragraph (c).

Penderfyniadau gan Gynulliad Cenedlaethol Cymru ar geisiadau am ganiatâd i ollwng

22.-(1) Ni chaiff Cynulliad Cenedlaethol Cymru roi caniatâd i ollwng organeddau a addaswyd yn enetig o dan adran 111(1) o'r Ddeddf fel y mae'n ymwneud ag amddiffyn iechyd dynol heb gytundeb yr Weithrediaeth Iechyd a Diogelwch(a).

(2) Ni chaiff Cynulliad Cenedlaethol Cymru roi na gwrthod caniatâd i ollwng organeddau a addaswyd yn enetig cyn diwedd cyfnod o chwe deg diwrnod gan ddechrau ar y dyddiad y daeth y cais am ganiatâd i law.

(3) Rhaid i Gynulliad Cenedlaethol Cymru gyfathrebu ei benderfyniad ar gais am ganiatâd i ollwng organeddau a addaswyd yn enetig i'r ceisydd a sicrhau bod ei benderfyniad yn cael ei gyfathrebu i'r Comisiwn cyn diwedd y cyfnod o 90 diwrnod gan ddechrau â'r diwrnod pan ddaeth y cais i law a chydag unrhyw gais a fydd yn cael ei wrthod rhaid iddo gynnwys y rhesymau dros y penderfyniad.

(4) Ni fydd y cyfnod a ragnodwyd ym mharagraff (3) yn cynnwys -

- (a) unrhyw gyfnod sy'n dechrau â'r diwrnod y mae Cynulliad Cenedlaethol Cymru yn hysbysu'n ysgrifenedig o dan adran 111(6) o'r Ddeddf bod angen gwybodaeth bellach mewn perthynas â'r cais ac sy'n gorffen ar y diwrnod pan fydd yr wybodaeth honno yn dod i law Cynulliad Cenedlaethol Cymru, neu
- (b) cyfnod amser pan fydd Cynulliad Cenedlaethol Cymru yn ystyried sylwadau a gyflwynwyd gan unrhyw bersonau yn unol â rheoliad 21(b), ar yr amod na fydd yr ystyriaeth hon yn ymestyn y cyfnod o 90 diwrnod y cyfeirir ato ym mharagraff (3) gan fwy na 30 diwrnod.

(5) Rhaid i ganiatâd i ollwng organeddau a addaswyd yn enetig ei gwneud hi'n ofynnol i'r ceisydd anfon unrhyw wybodaeth a allai fod yn berthnasol i asesu'r risg o beri niwed i'r amgylchedd, gyda chyfeiriad penodol, pan fo hynny'n briodol, at unrhyw gynnyrch y bwriedir ei farchnata yn y dyfodol, i Gynulliad Cenedlaethol Cymru ar ôl cwblhau'r gollyngiad ac wedi hynny, bob hyn a hyn yn ôl yr hyn y mae Cynulliad Cenedlaethol Cymru yn barnu ei fod yn briodol ar sail canlyniadau'r asesiad risg amgylcheddol.

(6) Rhaid i Gynulliad Cenedlaethol Cymru anfon i'r Comisiwn yr wybodaeth a gyflwynwyd iddo yn unol â pharagraff (5).

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

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

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

(3) The National Assembly for Wales shall communicate its decision on an application for a consent to release genetically modified organisms to the applicant and shall ensure that its decision is communicated to the Commission before the end of a period of 90 days beginning with the day on which the application was received and shall include in any refusal of consent the reasons for the decision.

(4) The period prescribed in paragraph (3) shall not include -

- (a) any period beginning with the day on which the National Assembly for Wales gives notice in writing under section 111(6) of the Act that further information in respect of the application is required and ending on the day on which that information is received by the National Assembly for Wales, or
- (b) a period of time during which the National Assembly for Wales is considering representations submitted by any persons in accordance with regulation 21(b), provided that this consideration shall not prolong the 90 day period referred to in paragraph (3) by more than 30 days.

(5) A consent to release genetically modified organisms shall require the applicant to send any information which might be relevant to assessing the risk of damage being caused to the environment, with, where appropriate, particular reference to any product which it is intended to market in the future, to the National Assembly for Wales after completion of the release and thereafter, at such intervals as the National Assembly for Wales shall consider appropriate on the basis of the results of the environmental risk assessment.

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

(a) *Gweler* adran 10 o Ddeddf Iechyd a Diogelwch yn y Gwaith 1974 (p.37).

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

Amrywio neu ddiddymu caniatâd i ollwng organeddau a addaswyd yn enetig

23. Dim ond pan fydd gwybodaeth newydd ar gael iddo a allai yn ei farn ef effeithio ar yr asesiad o'r risg o beri niwed i'r amgylchedd y caiff Cynulliad Cenedlaethol Cymru amrywio neu ddirymu caniatâd i ollwng organeddau a addaswyd yn enetig o dan adran 111(10) o'r Ddeddf heb gytundeb deiliad y caniatâd.

Dyletswyddau Cynulliad Cenedlaethol Cymru mewn perthynas â cheisiadau am ganiatâd i farchnata organeddau a addaswyd yn enetig

24.-(1) Ar ôl cael cais am ganiatâd i farchnata organeddau a addaswyd yn enetig rhaid i Gynulliad Cenedlaethol Cymru -

- (a) hysbysu'r ceisydd yn ysgrifenedig o'r dyddiad y daeth y cais i law;
- (b) sicrhau bod crynodeb o'r cais hwnnw ar y ffurf a sefydlwyd gan y Comisiwn o dan Erthygl 13(2)(h) o'r Gyfarwyddeb Gollyngiadau Bwriadol yn cael ei anfon yn ddi-oed i'r Comisiwn ac awdurdodau cymwys yr Aelod-wladwriaethau;
- (c) archwilio'r cais i weld a yw'n cydymffurfio â gofynion y Ddeddf a'r Rheoliadau hyn ac, os yw hynny'n angenrheidiol, gofyn i'r ceisydd gyflenwi gwybodaeth ychwanegol;
- (ch) cyn diwedd y cyfnod o 90 diwrnod, gan ddechrau â'r diwrnod y daeth y cais i'w law, naill ai-
 - (i) anfon at y ceisydd adroddiad asesu a baratowyd yn unol ag Atodlen 4 sy'n nodi y dylai'r organeddau a addaswyd yn enetig gael eu marchnata ac o dan ba amodau, neu
 - (ii) wrthod y cais, gan ddatgan y rhesymau dros ei benderfyniad, a hynny wedi'i ategu gan adroddiad asesu a baratowyd yn unol ag Atodlen 4 sy'n nodi na ddylid marchnata'r organeddau a addaswyd yn enetig;
- (d) sicrhau bod copi o'r cais yn cael ei anfon i'r Comisiwn pan gaiff ei fodloni ei fod yn cydymffurfio â'r gofynion a ragnodwyd yn rheoliad 15 a hynny heb fod yn hwyrach na phan y bydd yn anfon ei adroddiad asesu yn unol â pharagraff (ch).

(2) Rhaid i Gynulliad Cenedlaethol Cymru sicrhau bod -

- (i) ei adroddiad asesu,
- (ii) unrhyw wybodaeth bellach y mae wedi'i chael oddi wrth y ceisydd yn unol â chyflwyno hysbysiad o dan adran 111(6) o'r Ddeddf,

Variation or revocation of a consent to release genetically modified organisms

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

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

24.-(1) Following receipt of an application for consent to market genetically modified organisms the National Assembly for Wales shall -

- (a) inform the applicant in writing of the date of receipt of the application;
- (b) ensure that a summary of that application in the format established by the Commission under Article 13(2)(h) of the Deliberate Release Directive is forwarded immediately to the Commission and to the competent authorities of the Member States;
- (c) examine the application for its conformity with the requirements of the Act and of these Regulations and, if necessary, request the applicant to supply additional information;
- (d) before the end of a period of 90 days beginning with the day on which it received the application either -
 - (i) send to the applicant an assessment report prepared in accordance with Schedule 4 which indicates that the genetically modified organisms should be permitted to be marketed and under which conditions, or
 - (ii) refuse the application, stating reasons for its decision, supported by an assessment report prepared in accordance with Schedule 4 which indicates that the genetically modified organisms should not be marketed;
- (e) ensure that a copy of the application is forwarded to the Commission when satisfied it conforms to the requirements prescribed in regulation 15 and no later than when it sends its assessment report in accordance with paragraph (d).

(2) The National Assembly for Wales shall ensure that -

- (i) its assessment report,
- (ii) any further information it has received from the applicant pursuant to the service of a notice under section 111(6) of the Act,

- (iii) unrhyw wybodaeth ychwanegol y mae wedi seilio'i adroddiad asesu arni,

yn cael eu hanfon ymlaen i'r Comisiwn o dan yr amgylchiadau a ddisgrifiwyd yn rheoliad 24(1)(ch)(i), cyn pen diwedd cyfnod o naw deg diwrnod gan ddechrau â'r diwrnod pan ddaeth y cais i law, ac, o dan yr amgylchiadau a ddisgrifiwyd yn rheoliad 24(1)(ch)(ii), heb fod yn gynt na phymtheg diwrnod o'r dyddiad pan anfonodd yr adroddiad asesu at y ceisydd a heb fod yn hwyrach na chant a phum diwrnod o'r dyddiad y daeth y cais i law.

(3) Ni chaiff y cyfnodau o naw deg diwrnod a ragnodwyd ym mharagraffau (1) a (2) gynnwys unrhyw gyfnod sy'n dechrau â'r diwrnod y mae Cynulliad Cenedlaethol Cymru yn rhoi rhybudd ysgrifenedig o dan adran 111(6) o'r Ddeddf fod angen gwybodaeth bellach mewn perthynas â'r cais a chan ddiweddu ar y diwrnod y daeth yr wybodaeth i law Cynulliad Cenedlaethol Cymru.

(4) Pan fydd Cynulliad Cenedlaethol Cymru yn bwriadu cyflwyno i'r Comisiwn adroddiad asesu sy'n nodi y dylid caniatáu i'r organeddau a addaswyd yn enetig y mae'r cais yn ymwneud â hwy gael eu marchnata, rhaid i Gynulliad Cenedlaethol Cymru ymgynghori'n gyntaf â'r Weithrediaeth Iechyd a Diogelwch a rhaid iddo beidio ag anfon barn ffafriol ymlaen ar y cais fel y mae'n ymwneud â diogelu iechyd dynol os yw'r Weithrediaeth Iechyd a Diogelwch wedi hysbysu Cynulliad Cenedlaethol Cymru nad yw'n cyflawni gofynion y Ddeddf a'r Rheoliadau hyn.

Penderfyniadau gan Gynulliad Cenedlaethol Cymru ar geisiadau am ganiatâd i farchnata organeddau a addaswyd yn enetig

25.-(1) Ni chaiff Cynulliad Cenedlaethol Cymru gytuno ar gais am ganiatâd i farchnata organeddau a addaswyd yn enetig ond os yw wedi paratoi adroddiad asesu sy'n dangos y dylid caniatáu i'r organeddau a addaswyd yn enetig gael eu marchnata a naill ai -

- (a) nad oes unrhyw wrthwynebiad wedi'i godi gan awdurdod cymwys Aelod-wladwriaeth neu gan y Comisiwn yn ystod y cyfnod o 60 diwrnod gan ddechrau â'r dyddiad pan ddosbarthodd y Comisiwn yr adroddiad asesu, neu
- (b) bod gwrthwynebiad wedi'i godi neu wrthwynebiadau wedi'u codi gan naill ai awdurdod cymwys Aelod-wladwriaeth neu gan y Comisiwn ond bod pob un o'r materion a oedd heb ei benderfynu wedi cael ei ddatrys yn unol ag Erthygl 15(1) o'r Gyfarwyddeb Gollyngiadau Bwriadol o fewn cyfnod o 105 diwrnod gan ddechrau â'r diwrnod pan ddosbarthodd y Comisiwn yr adroddiad asesu, neu

- (iii) any additional information on which it has based its assessment report,

are forwarded to the Commission in the circumstances described in regulation 24(1)(d)(i), before the end of a period of ninety days beginning with the day on which it received the application and, in the circumstances described in regulation 24(1)(d)(ii), no sooner than fifteen days from the date it sent the assessment report to the applicant and no later than one hundred and five days from the date it received the application.

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

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

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

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

- (a) no objection has been raised by a competent authority of a Member State or by the Commission during a 60 day period beginning on the day the Commission circulated the assessment report, or
- (b) an objection or objections have been raised by either a competent authority of a Member State or by the Commission but all outstanding issues have been resolved in accordance with Article 15(1) of the Deliberate Release Directive within a 105 day period beginning on the day the Commission circulated the assessment report, or

(c) os oes gwrthwynebiad wedi'i godi gan awdurdod cymwys Aelod-wladwriaeth neu'r Comisiwn a bod y Comisiwn wedi mabwysiadu penderfyniad yn unol ag Erthygl 18(1) o'r Gyfarwyddeb Gollyngiadau Bwriadol o blaid rhoi caniatâd.

(2) Rhaid i Gynulliad Cenedlaethol Cymru hysbysu awdurdod neu awdurdodau cymwys pob Aelod-wladwriaeth a'r Comisiwn o'i benderfyniad i roi caniatâd i farchnata organeddau a addaswyd yn enetig o fewn tri deg diwrnod o roi ei ganiatâd.

(3) At y diben o gyfrifo'r cyfnod o bedwar deg pum diwrnod terfynol y cant a phum diwrnod yn is-baragraff (1)(b) uchod, rhaid peidio â chymryd i ystyriaeth unrhyw gyfnod pan ddisgwylir gwybodaeth bellach gan y ceisydd.

(4) Yn ddarostyngedig i baragraffau (5) a (6), caiff caniatâd i farchnata organeddau a addaswyd yn enetig ei roi am uchafswm cyfnod o ddeng mlynedd gan ddechrau â'r diwrnod pan roddwyd y caniatâd.

(5) At y diben o roi caniatâd i farchnata organedd a addaswyd yn enetig neu epil o'r organedd hwnnw a addaswyd yn enetig a'r epil hwnnw wedi'i gynnwys mewn amrywiad planhigyn lle mae'r amrywiad planhigyn wedi'i fwriadu ar gyfer marchnata ei hadau yn unig o dan ddarpariaethau perthnasol y Gymuned bydd cyfnod y caniatâd cyntaf yn dod i ben fan bellaf ddeng mlynedd ar ôl y dyddiad y cynhwyswyd am y tro cyntaf yr amrywiad planhigyn cyntaf sy'n cynnwys yr organedd a addaswyd yn enetig ar gatalog cenedlaethol swyddogol o'r amrywiadau planhigion yn unol â Chyfarwyddebau 2002/53/EC(a) a 2002/55/EC(b) fel y'u diwygiwyd.

(6) At y diben o roi caniatâd i farchnata organedd a addaswyd yn enetig sydd wedi'i gynnwys mewn deunydd fforest atgynhyrchiol, bydd cyfnod y caniatâd cyntaf yn dod i ben fan bellaf ddeng mlynedd ar ôl dyddiad y cynhwyswyd am y tro cyntaf y deunydd sylfaenol sy'n cynnwys yr organedd a addaswyd yn enetig ar gofrestr genedlaethol swyddogol o deunydd sylfaenol yn unol â Chyfarwyddeb y Cyngor 1999/105/EC(c).

Dyletswyddau Cynulliad Cenedlaethol Cymru wrth gael ceisiadau am adnewyddu caniatâd i farchnata organeddau a addaswyd yn enetig

26.-(1) Wrth gael cais am adnewyddu caniatâd i farchnata organeddau a addaswyd yn enetig rhaid i Gynulliad Cenedlaethol Cymru -

(a) hysbysu'r ceisydd yn ysgrifenedig o'r dyddiad y daeth y cais i law;

(a) O.J. Rhif L193, 20.7.2002, t1.

(b) O.J. Rhif L193, 20.7.2002, t33.

(c) Cyfarwyddeb y Cyngor 1999/105/EC ar farchnata deunydd atgenhedlu fforest OJ Rhif L11 15.1.2000 t. 17.

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

(2) The National Assembly for Wales shall inform the competent authority or authorities of each Member State and the Commission of its decision to grant consent to market genetically modified organisms within thirty days of its grant.

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

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

(5) For the purpose of granting consent to market a genetically modified organism or a progeny of that genetically modified organism contained in a plant variety where the plant variety is intended only for the marketing of its seeds under the relevant Community provisions the period of the first consent shall end at the latest ten years after the date of the first inclusion of the first plant variety containing the genetically modified organism on an official national catalogue of plant varieties in accordance with Directives 2002/53/EC(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).

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

26.-(1) Following receipt of an application for renewal of consent to market genetically modified organisms the National Assembly for Wales shall -

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

(a) OJ No. L193, 20.7.2002, p.1.

(b) OJ No. L193, 20.7.2002 p.33.

(c) Council Directive 1999/105/EC on the marketing of forest reproductive material OJ No. L11, 15.1.2000, p. 17.

- (b) archwilio'r cais i weld a yw'n cydymffurfio â gofynion y Ddeddf a'r Rheoliadau hyn ac, os yw hynny'n angenrheidiol, gofyn i'r ceisydd gyflenwi gwybodaeth ychwanegol;
- (c) naill ai -
 - (i) anfon at y ceisydd adroddiad asesu a baratowyd yn unol ag Atodlen 4 ac sy'n nodi y dylid parhau i farchnata'r organeddau a addaswyd yn enetig ac o dan ba amodau, neu
 - (ii) gwrthod y cais, gan ddatgan y rhesymau dros ei benderfyniad, a hynny wedi'i ategu gan adroddiad asesu sy'n nodi na ddylid parhau i farchnata'r organedd a addaswyd yn enetig;
- (ch) sicrhau bod copi o'r cais a'i adroddiad asesu yn cael ei anfon i'r Comisiwn.

(2) Pan fydd Cynulliad Cenedlaethol Cymru yn bwriadu cyflwyno i'r Comisiwn adroddiad asesu sy'n nodi y dylid caniatáu i'r organeddau a addaswyd yn enetig y mae'r cais yn ymwneud â hwy gael eu marchnata, rhaid i Gynulliad Cenedlaethol Cymru ymgynghori'n gyntaf â'r Weithrediaeth Iechyd a Diogelwch a rhaid iddo beidio ag anfon barn ffafriol ymlaen ar y cais fel y mae'n ymwneud â diogelu iechyd dynol os yw'r Weithrediaeth Iechyd a Diogelwch wedi hysbysu Cynulliad Cenedlaethol Cymru nad yw'n cyflawni gofynion y Ddeddf a'r Rheoliadau hyn.

Penderfyniadau gan Gynulliad Cenedlaethol Cymru ar geisiadau i adnewyddu caniatâd i farchnata organeddau a addaswyd yn enetig

27.-(1) Ni chaiff Cynulliad Cenedlaethol Cymru gytuno ar gais am adnewyddu caniatâd i farchnata organeddau a addaswyd yn enetig ond os yw wedi paratoi adroddiad asesu sy'n nodi y dylid parhau i farchnata'r organeddau a addaswyd yn enetig a naill ai

- (a) nad oes unrhyw wrthwynebiad wedi'i godi gan awdurdod cymwys unrhyw Aelod-wladwriaeth neu gan y Comisiwn yn ystod cyfnod o 60 diwrnod gan ddechrau â'r dyddiad pan ddisbarthodd y Comisiwn yr adroddiad asesu, neu
- (b) bod gwrthwynebiad wedi'i godi neu wrthwynebiadau wedi'u codi gan naill ai awdurdod cymwys unrhyw Aelod-wladwriaeth neu gan y Comisiwn ond bod pob un o'r materion a oedd heb eu penderfynu wedi'u datrys yn unol ag Erthygl 17(8) o'r Gyfarwyddeb Gollyngiadau Bwriadol o fewn cyfnod o 75 diwrnod gan ddechrau ar y diwrnod y dosbarthodd y Comisiwn ei adroddiad asesu, neu
- (c) bod gwrthwynebiad wedi'i godi gan awdurdod cymwys unrhyw Aelod-wladwriaeth neu'r

- (b) examine the application for its conformity with the requirements of the Act and of these Regulations and, if necessary, request the applicant to supply additional information;
- (c) either -
 - (i) send to the applicant an assessment report prepared in accordance with Schedule 4 which indicates that the genetically modified organisms should continue to be marketed and under which conditions, or
 - (ii) refuse the application, stating reasons for its decision, supported by an assessment report which indicates that the genetically modified organisms should not continue to be marketed;
- (d) ensure that a copy of the application and its assessment report is forwarded to the Commission.

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

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

27.-(1) The National Assembly for Wales may only grant an application to renew a consent to market genetically modified organisms when it has prepared an assessment report which indicates that the genetically modified organisms should continue to be marketed and either -

- (a) no objection has been raised by a competent authority of any Member State or by the Commission during a 60 day period beginning on the day the Commission has circulated the assessment report, or
- (b) an objection or objections have been raised by either a competent authority of any Member State or by the Commission but all outstanding issues have been resolved in accordance with Article 17(8) of the Deliberate Release Directive within a 75 day period beginning on the day the Commission circulated the assessment report, or
- (c) an objection has been raised by a competent authority of any Member State or the

Comisiwn a bod y Comisiwn wedi mabwysiadu penderfyniad yn unol ag Erthygl 18(1) o'r Gyfarwyddeb Gollyngiadau Bwriadol o blaid rhoi caniatâd.

(2) Rhaid i Gynulliad Cenedlaethol Cymru sicrhau bod yr awdurdod neu awdurdodau cymwys pob Aelod-wladwriaeth a'r Comisiwn yn cael eu hysbysu o'i benderfyniad i adnewyddu'r caniatâd i farchnata organeddau a addaswyd yn enetig o fewn tri deg diwrnod o'i adnewyddu.

(3) Caiff caniatâd a adnewyddwyd i farchnata organeddau a addaswyd yn enetig gael ei roi am uchafswm o 10 mlynedd oni bai bod Cynulliad Cenedlaethol Cymru o'r farn bod modd cyfiawnhau cyfnod byrrach neu gyfnod hwy, ac os felly rhaid iddo roi ei resymau yn ysgrifenedig.

(4) Caiff y ceisydd barhau i farchnata'r organeddau a addaswyd yn enetig o dan yr amodau a bennwyd yn y caniatâd gwreiddiol hyd nes y bydd y cais wedi'i benderfynu'n derfynol.

Organeddau a addaswyd yn enetig sy'n cynnwys marcwyr ymwrthedd gwrthfotig

28.-(1) Rhaid i Gynulliad Cenedlaethol Cymru beidio â rhoi caniatâd ar gyfer cais am ollwng neu farchnata organeddau a addaswyd yn enetig sy'n cynnwys marcwyr ymwrthedd gwrthfotig a allai gael effaith andwyol ar iechyd dynol a'r amgylchedd ar ôl -

- (i) 31 Rhagfyr 2004 yn achos marchnata, a
- (ii) 31 Rhagfyr 2008 yn achos gollyngiadau.

(2) Os cyn 31 Rhagfyr 2004 yn achos marchnata a 31 Rhagfyr 2008 yn achos gollyngiadau, y mae cais yn cael ei wneud am ganiatâd i ollwng neu farchnata organeddau a addaswyd yn enetig sy'n cynnwys marcwyr ymwrthedd gwrthfotig, rhaid i Gynulliad Cenedlaethol Cymru werthuso'r wybodaeth yn yr asesiad amgylcheddol sy'n mynd gyda'r cais, gan ystyried yn benodol y marcwyr ymwrthedd gwrthfotig hynny a ddefnyddir ar gyfer triniaethau meddygol neu filfeddygol, gyda'r nod o ganfod a diddymu'n raddol y weithred o ollwng neu farchnata'r organeddau a addaswyd yn enetig ac y cyfeiriwyd atynt ym mharagraff (1) o fewn y terfynau amser a bennwyd yn y paragraff hwnnw.

Commission and the Commission has adopted a decision in accordance with Article 18(1) of the Deliberate Release Directive in favour of granting consent.

(2) The National Assembly for Wales shall ensure that the competent authority or authorities of each Member State and the Commission are informed of its decision to renew consent to market genetically modified organisms within thirty days of its renewal.

(3) The renewed consent to market genetically modified organisms may be given for a maximum of 10 years unless the National Assembly for Wales considers that a shorter or longer period is justified, in which case it shall give its reasons in writing.

(4) The applicant may continue to market the genetically modified organisms under the conditions specified in the original consent until a final decision has been taken on the application.

Genetically modified organisms containing antibiotic resistance markers

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

- (i) 31st December 2004 in the case of marketing, and
- (ii) 31st December 2008 in the case of release.

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

RHAN V

DARPARIAETHAU CYFFREDINOL AR GYFER CANIATADAU

Darpariaethau cyffredinol caniatadau i farchnata organeddau a addaswyd yn enetig

29. Rhaid i ganiatâd i farchnata organeddau a addaswyd yn enetig a roddwyd gan Gynulliad Cenedlaethol Cymru o dan adran 111(1) o'r Ddeddf bennu -

- (a) cwmpas y caniatâd, gan gynnwys pa rai yw'r organeddau a addaswyd yn enetig sydd i'w marchnata, a'u marc adnabod unigryw;
- (b) y cyfnod pan fydd y caniatâd yn ddilys;
- (c) yr amodau ar gyfer marchnata'r cynnyrch, gan gynnwys unrhyw amodau penodol ar gyfer defnyddio, trafod a pheycynnu'r organeddau a addaswyd yn enetig, a'r amodau ar gyfer diogelu ecosystemau penodol neu amgylcheddau neu ardaloedd daearyddol fel y bo'n gymwys;
- (ch) bod rhaid i'r ceisydd sicrhau bod samplau rheoli ar gael i Gynulliad Cenedlaethol Cymru os gwneir cais amdanynt;
- (d) gofynion labelu, yn unol â pharagraff 8 o Atodlen 3, a rhaid iddynt gynnwys gofyniad i hysbysu Cynulliad Cenedlaethol Cymru o unrhyw enw masnachol newydd y cynnyrch ar ôl i ganiatâd gael ei roi;
- (dd) gofynion monitro y mae yn rhaid iddynt fod yn unol â'r cynllun monitro, a rhaid iddynt gynnwys cyfnod amser y cynllun monitro, rhwymedigaeth bod rhaid i'r ceisydd gyflwyno'r adroddiadau monitro i'r Comisiwn ac awdurdodau cymwys yr Aelod-wladwriaethau a, phan fo hynny'n briodol, unrhyw rwymedigaethau sydd ar unrhyw berson sy'n gwerthu'r cynnyrch neu unrhyw ddefnyddiwr i ddarparu gwybodaeth am lefel briodol ar leoliad yr organeddau a addaswyd yn enetig.

Amodau cyffredinol mewn caniatadau i ollwng neu farchnata organeddau a addaswyd yn enetig

30.-(1) Mae'r diwygiadau i adran 112 o'r Ddeddf (caniatadau: cyfyngiadau ac amodau) a wnaed gan Reoliadau Organeddau a Addaswyd yn Enetig (Eu Gollwng yn Fwriadol) 2002 yn effeithiol mewn perthynas â Chymru fel a ganlyn.

(2) Mae'r diwygiad i is-adran (1) a wnaed gan reoliad 29(2) o'r rheoliadau hynny, sy'n mewnosod ar ddiwedd yr is-adran honno y geiriau "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", yn effeithiol hefyd mewn perthynas â Chymru.

PART V

GENERAL PROVISIONS FOR CONSENTS

General provisions of consents to market genetically modified organisms

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

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

General conditions in consents to release or market genetically modified organisms

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

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

(3) Mae'r diwygiadau i is-adran (5) a wnaed gan reoliad 29(3)(a) a (b) o'r Rheoliadau hynny, fel y'u disgrifir ym mharagraff (4), yn effeithiol hefyd mewn perthynas â Chymru.

(4) Mae'r diwygiadau y cyfeirir atynt ym mharagraff (3) fel a ganlyn-

(a) yn is-adran (5)(b) -

- (i) ar ôl "Secretary of State" mewnosodwch "forthwith",
- (ii) hepgorwch is-baragraff (ii), a
- (iii) ar ôl yr is-baragraff hwnnw mewnosodwch -
"(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;", a

(b) rhowch yn lle is-adran (5)(c)

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

(5) Mae'r diwygiad i is-adran (5) a wnaed gan reoliad 29(3)(c) o'r Rheoliadau hynny, sy'n mewnosod paragraffau (d) ac (e), yn cael ei addasu gan baragraff (6) ac, o'i addasu felly, yn effeithiol hefyd mewn perthynas â Chymru.

(6) Ym mharagraffau (d) ac (e), fel y'u mewnosodwyd gan y rheoliad hwnnw, ar ôl "the Secretary of State", yn y ddau le y mae'n digwydd, mewnosodwch "or, in relation to Wales, the National Assembly for Wales".

(7) Mae testun paragraffau (d) ac (e) o is-adran (5), fel y'i mewnosodwyd gan y rheoliad hwnnw ac fel y'i addaswyd gan baragraff (6), fel a ganlyn -

"(d)notify the Secretary of State or, in relation to Wales, the National Assembly for Wales, of the measures (if any) taken as a result of new information becoming available or an unforeseen event occurring as described in paragraph (b) (iii) above; and

(e) in a case where new information becomes available or an unforeseen event so occurs, revise the information contained in his application for a consent accordingly and supply the revised information to the Secretary of State or, in relation to Wales, the National Assembly for Wales."

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

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

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

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

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

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

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

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

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

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

"(d)notify the Secretary of State or, in relation to Wales, the National Assembly for Wales of the measures (if any) taken as a result of new information becoming available or an unforeseen event occurring as described in paragraph (b) (iii) above; and

(e) in a case where new information becomes available or an unforeseen event so occurs, revise the information contained in his application for a consent accordingly and supply the revised information to the Secretary of State or, in relation to Wales, the National Assembly for Wales."

Prawf o gydymffurfio ag amodau'r caniatâd

31. Mae'r diwygiad i adran 119(1) o'r Ddeddf ("Onus of proof as regards techniques and evidence") a wnaed gan reoliad 30 o Reoliadau Organeddau a Addaswyd yn Enetig (Eu Gollwng yn Fwriadol) 2002, ac sydd ar ôl y geiriau "the accused to prove" yn mewnosod y materion a ddisgrifir yn is-adran (1A) isod:

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

- (a) in the case of an offence under section 118(1)(c) above consisting in a failure to comply with the general condition implied by section 112(5)(c) above -
 - (i) that no measures, other than the measures taken by him, were necessary to prevent damage being caused to the environment from the release or, as the case may be, marketing of the organisms, or
 - (ii) in a case where he took no measures, that no measures were necessary; and
- (b) in any other case,"

yn effeithiol hefyd mewn perthynas â Chymru.

Gwybodaeth newydd am y risgiau o beri niwed i'r amgylchedd

32.-(1) Rhaid i Gynulliad Cenedlaethol Cymru anfon ar unwaith i'r Comisiwn ac i awdurdod neu awdurdodau cymwys pob Aelod-wladwriaeth unrhyw wybodaeth newydd sy'n dod ar gael iddo ac a allai yn ei farn ef effeithio ar yr asesiad o'r risg o beri niwed i'r amgylchedd drwy ollwng neu farchnata organeddau a addaswyd yn enetig.

(2) Pan fo cais am ganiatâd neu adnewyddu caniatâd i farchnata organeddau a addaswyd yn enetig wedi'i gyflwyno i Gynulliad Cenedlaethol Cymru a bod yr wybodaeth y cyfeirir ati ym mharagraff (1) yn dod ar gael iddo, cyn bod y cais wedi'i benderfynu, caiff geisio dod i gytundeb gyda'r Comisiwn a'r Aelod-wladwriaethau eraill yn unol ag Erthygl 15(1) neu 17(7) o'r Gyfarwyddeb Gollyngiadau Bwriadol fel y bo'n gymwys.

(3) Pan fo cais am ganiatâd neu gais i adnewyddu caniatâd i farchnata organeddau a addaswyd yn enetig wedi'i gyflwyno i Gynulliad Cenedlaethol Cymru a bod yr wybodaeth y cyfeiriwyd ati yn rheoliad (1) wedi dod ar gael iddo wedi i'r caniatâd gael ei roi neu ei adnewyddu, rhaid iddo sicrhau bod adroddiad asesu wedi'i baratoi yn unol ag Atodlen 4, yn nodi a ddylid amrywio amodau'r caniatâd, ac, os felly, sut, neu a ddylid dirymu'r caniatâd, yn cael ei anfon ymlaen i'r Comisiwn o fewn 60 diwrnod o'r dyddiad y daeth yr wybodaeth newydd i law.

(4) Pan fo Cynulliad Cenedlaethol Cymru wedi nodi y dylid amrywio'r caniatâd a naill ai-

Proof of compliance with consent conditions

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

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

- (a) in the case of an offence under section 118(1)(c) above consisting in a failure to comply with the general condition implied by section 112(5)(c) above -
 - (i) that no measures, other than the measures taken by him, were necessary to prevent damage being caused to the environment from the release or, as the case may be, marketing of the organisms, or
 - (ii) in a case where he took no measures, that no measures were necessary; and
- (b) in any other case,"

also has effect in relation to Wales.

New information on risks of damage to the environment

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

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

(3) Where an application for consent or renewal of a consent to market genetically modified organisms has been made to the National Assembly for Wales and the information referred to in paragraph (1) becomes available to it after the consent has been granted or renewed, it shall ensure that an assessment report prepared in accordance with Schedule 4, indicating whether the conditions of the consent should be varied, and, if so, how, or whether the consent should be revoked, is forwarded to the Commission within 60 days of the date of receipt of the new information.

(4) Where the National Assembly for Wales has indicated that the consent should be varied and either-

- (a) bod dim gwrthwynebiad wedi'i godi gan awdurdod cymwys unrhyw Aelod-wladwriaeth neu gan y Comisiwn yn ystod cyfnod o 60 diwrnod gan ddechrau ar y diwrnod y dosbarthodd y Comisiwn yr adroddiad asesu, neu
- (b) bod gwrthwynebiad neu wrthwynebiadau wedi'u codi gan awdurdod cymwys unrhyw Aelod-wladwriaeth neu gan y Comisiwn ond bod pob mater a oedd heb ei benderfynu wedi cael ei ddatrys yn unol ag Erthygl 20(3) o'r Gyfarwyddeb Gollyniadau Bwriadol,

rhaid iddo amrywio neu ddirymu'r caniatâd fel y'i cynigiwyd a hysbysu'r ceisydd, awdurdod neu awdurdodau cymwys pob Aelod-wladwriaeth a'r Comisiwn ei fod wedi gwneud hynny o fewn 30 diwrnod i hynny.

(5) Rhaid i Gynulliad Cenedlaethol Cymru beidio ag amrywio na dirymu caniatâd i farchnata organeddau a addaswyd yn enetig o dan adran 111(10) o'r Ddeddf ac eithrio -

- (i) os yw'r wybodaeth y cyfeirir ati ym mharagraff (1) wedi dod ar gael iddo, ac os cydymffurfiwyd â'r weithdrefn y cyfeirir ati ym mharagraffau (3) a (4), neu
- (ii) yn unol â phenderfyniad a fabwysiadwyd gan y Comisiwn yn unol ag Erthyglau 18(1) neu 23(2) o'r Gyfarwyddeb Gollyniadau Bwriadol.

RHAN VI AMDDIFFYNIAD

Amddiffyniad

33.-(1) Dim ond os yw Cynulliad Cenedlaethol Cymru o'r farn y byddai gweithred a awdurdodwyd drwy ganiatâd a roddwyd ganddo o dan adran 111 o'r Ddeddf neu drwy ganiatâd a roddwyd ar gyfer cynnyrch a gymeradwywyd yn golygu risg o beri niwed i'r amgylchedd wedi'i seilio ar resymau manwl o ganlyniad i'r naill neu'r llall o'r canlynol, sef -

- (a) gwybodaeth newydd neu ychwanegol a roddwyd ar gael ers dyddiad rhoi'r caniatâd sy'n effeithio ar yr asesiad risg amgylcheddol mewn perthynas â'r cynnyrch hwnnw; neu
- (b) ailasesiad o'r wybodaeth bresennol mewn perthynas â'r cynnyrch hwnnw ar sail gwybodaeth wyddonol newydd neu ychwanegol, y caiff gyflwyno hysbysiad gwahardd o dan adran 110 o'r Ddeddf i wahardd gweithred o'r fath.

(2) Os, o dan yr amgylchiadau a ddisgrifiwyd ym

- (a) no objection has been raised by a competent authority of any Member State or by the Commission during a 60 day period beginning on the day the Commission circulated the assessment report, or
- (b) an objection or objections have been raised by a competent authority of any Member State or by the Commission but all outstanding issues have been resolved in accordance with Article 20(3) of the Deliberate Release Directive,

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

(5) The National Assembly for Wales shall only vary or revoke a consent to market genetically modified organisms under section 111(10) of the Act -

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

PART VI SAFEGUARD

Safeguard

33.-(1) The National Assembly for Wales may serve a prohibition notice under section 110 of the Act to prohibit an act which is authorised by a consent granted by it under section 111 of the Act or by a consent granted in respect of an approved product only if its opinion that doing such an act would involve a risk of causing damage to the environment is based on detailed grounds as the result of either -

- (a) new or additional information made available since the date of the consent which affects the environmental risk assessment in respect of that product; or
- (b) a reassessment of existing information in respect of that product on the basis of new or additional scientific information.

(2) Where, in the circumstances described in

mharagraff (1) uchod, y mae Cynulliad Cenedlaethol Cymru o'r farn bod y risg o beri niwed i'r amgylchedd yn ddifrifol rhaid iddo gyflwyno hysbysiad gwahardd sy'n yn ei gwneud hi'n ofynnol i gymryd unrhyw fesurau y mae'n barnu eu bod yn briodol ac unwaith y bydd unrhyw waith sy'n ofynnol o dan yr hysbysiad wedi'i gyflawni rhaid iddo gofnodi manylion y gwaith hwnnw ar y gofrestr.

(3) Mewn achosion y mae paragraff (1) a (2) uchod yn gymwys iddynt, rhaid i Gynulliad Cenedlaethol Cymru hysbysu'r Comisiwn ac Aelod-wladwriaethau eraill yn ddi-oed am ei weithgareddau gan roi iddynt ar yr un pryd -

- (a) ei resymau dros gymryd camau o'r fath,
- (b) canlyniadau ei adolygiad o'r asesiad risg amgylcheddol,
- (c) ei farn ynghylch a ddylid amrywio amodau'r caniatâd, ac, os felly, sut y dylid dirymu'r caniatâd, neu a ddylid gwneud hynny, ac
- (ch) pan fo hynny'n briodol, yr wybodaeth newydd neu ychwanegol yr oedd ei benderfyniad i weithredu wedi'i seilio arni.

(4) Bydd hysbysiad gwahardd a gyflwynir o dan adran 110 o'r Ddeddf yn unol â'r rheoliad hwn yn ddarostyngedig i unrhyw benderfyniad a fabwsiedir gan y Comisiwn yn unol ag Erthygl 23(2) o'r Gyfarwyddeb Gollyngiadau Bwriadol.

(5) Pan ddaw hysbysiad o benderfyniad gan y Comisiwn, y mae paragraff (4) yn cyfeirio ato, i law, rhaid i Gynulliad Cenedlaethol Cymru anfon copi ohono at ddeiliad y caniatâd y mae'r penderfyniad yn ymwneud ag ef, rhaid iddo dynnu'n ôl yr un pryd unrhyw hysbysiad gwahardd sy'n anghyson â'r penderfyniad hwnnw.

(6) Rhaid trin cyfeiriadau yn y rheoliad hwn at arfer swyddogaeth o dan adran 110 o'r Ddeddf gan Gynulliad Cenedlaethol Cymru, mewn unrhyw achos y mae adran 126(3) o'r Ddeddf yn gymwys iddo, fel cyfeiriadau at y ffaith bod Cynulliad Cenedlaethol Cymru a'r Asiantaeth Safonau Bwyd(a) yn gweithredu ar y cyd.

RHAN VII CYFRINACHEDD

Cyfrinachedd

34.-(1) At ddibenion adran 123(7) o'r Ddeddf, mae'r disgrifiadau canlynol o wybodaeth hefyd yn wybodaeth y mae'n ofynnol ei chynnwys er budd y cyhoedd yn y gofrestr hyd yn oed os yw'r wybodaeth honno yn fasnachol gyfrinachol -

- (a) lleoliad gollwng yr organeddau a addaswyd yn

(a) *Gweler* adran 1 o Ddeddf Safonau Bwyd 1999 (p.28).

paragraph (1) above, the National Assembly for Wales considers that the risk of damage being caused to the environment is severe it shall serve a prohibition notice requiring such measures to be taken as it may consider appropriate and once any work required by the notice has been carried out it shall enter details of it on the register.

(3) In cases to which paragraph (1) and (2) above apply, the National Assembly for Wales shall immediately inform the Commission and the other Member States of its actions and shall at the same time provide them with -

- (a) its reasons for taking such actions,
- (b) the results of its review of the environmental risk assessment,
- (c) its opinion as to whether the conditions of the consent should be varied, and, if so, how, or whether the consent should be revoked, and
- (d) where appropriate, the new or additional information on which its decision to take action was based.

(4) A prohibition notice served under section 110 of the Act in accordance with this regulation shall be subject to any decision adopted by the Commission in accordance with Article 23(2) of the Deliberate Release Directive.

(5) Upon receipt of notification of a decision by the Commission to which paragraph (4) refers the National Assembly for Wales shall send a copy of it to the holder of the consent to which the decision relates and shall at the same time withdraw any prohibition notice which is inconsistent with that decision.

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

PART VII CONFIDENTIALITY

Confidentiality

34.-(1) For the purposes of section 123(7) of the Act, the following descriptions of information are also information which the public interest requires to be included in the register notwithstanding that it may be commercially confidential -

- (a) the location of the release of the genetically

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

enetig y mae'r wybodaeth yn ymwneud â hwy,

- (b) y defnydd y bwriedir ei wneud o'r organedd a addaswyd yn enetig y mae'r wybodaeth yn ymwneud ag ef,
- (c) yr asesiad risg amgylcheddol,
- (ch) y dulliau a'r cynlluniau ar gyfer monitro ac ar gyfer ymateb i argyfwng mewn perthynas â'r organedd a addaswyd yn enetig y mae'r wybodaeth yn ymwneud ag ef,
- (d) enw a chyfeiriad deiliad caniatâd y mae hysbysiad gwahardd neu wybodaeth arall yn ymwneud ag ef.

(2) Mae diwygiadau adran 123(7) o'r Ddeddf (peidio â chynnwys gwybodaeth benodol yn y gofrestr: manylion sy'n cael eu cynnwys hyd yn oed os ydynt yn fasnachol gyfrinachol) a wnaed gan reoliad 33(2) o Reoliadau Organeddau a Addaswyd yn Enetig (Eu Gollwng yn Fwriadol) 2002, sydd -

- (a) ar ôl "section 122(1)(a)", yn mewnosod "(c)",
- (b) ym mharagraff (b) yn lle "the description" yn rhoi "the general description", ac
- (c) yn hepgor paragraffau (c) ac (e),

yn effeithiol hefyd mewn perthynas â Chymru.

modified organism to which the information relates,

- (b) the intended use of the genetically modified organism to which the information relates,
- (c) the environmental risk assessment,
- (d) the methods and plans for monitoring and for responding to an emergency in relation to the genetically modified organism to which the information relates,
- (e) the name and address of the holder of a consent to which a prohibition notice or other information relates.

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

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

also have effect in relation to Wales.

RHAN VIII

Y GOFRESTR GWYBODAETH

Gwybodaeth sydd i'w chynnwys ar y gofrestr

35.-(1) Rhaid i'r gofrestr gynnwys y manylion a nodir ym mharagraffau (2) i (10).

(2) Mewn perthynas â hysbysiad gwahardd a gyflwynwyd gan Gynulliad Cenedlaethol Cymru o dan adran 110 o'r Ddeddf -

- (a) enw a chyfeiriad y person y mae'r hysbysiad yn cael ei gyflwyno iddo,
- (b) disgrifiad o'r organeddau a addaswyd yn enetig y mae'r hysbysiad yn cael ei gyflwyno mewn perthynas â hwy,
- (c) y man lle bwriedir gollwng yr organeddau a addaswyd yn enetig,
- (ch) at ba ddiben y bwriedir gollwng neu farchnata'r organeddau a addaswyd yn enetig,
- (d) y rheswm dros gyflwyno'r hysbysiad,
- (dd) unrhyw ddyddiad a bennwyd yn yr hysbysiad fel y dyddiad y daw'r gwaharddiad i rym.

(3) Yn ddarostyngedig i baragraff (4), mewn perthynas â chais am ganiatâd o dan adran 111(1) o'r Ddeddf -

PART VIII

REGISTER OF INFORMATION

Information to be included on the register

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

(2) In relation to a prohibition notice served by the National Assembly for Wales under section 110 of the Act -

- (a) the name and address of the person on whom the notice is served,
- (b) the description of the genetically modified organisms in relation to which the notice is served,
- (c) the location at which the genetically modified organisms are proposed to be released,
- (d) the purpose for which the genetically modified organisms are proposed to be released or marketed,
- (e) the reason for the service of the notice,
- (f) any date specified in the notice as the date on which the prohibition is to take effect.

(3) Subject to paragraph (4), in relation to an application for a consent under section 111(1) of the Act -

- (a) enw a chyfeiriad y ceisydd,
- (b) disgrifiad cyffredinol o'r organedd a addaswyd yn enetig y mae'r cais yn cael ei wneud mewn perthynas ag ef,
- (c) y man lle bwriedir gollwng yr organeddau, i'r graddau y mae'r wybodaeth hon wedi'i hysbysu i Gynulliad Cenedlaethol Cymru,
- (ch) at ba ddiben arfaethedig y bwriedir gollwng yr organeddau a addaswyd yn enetig (gan gynnwys unrhyw ddefnydd y bwriedir ar eu cyfer yn y dyfodol) neu, mewn perthynas â chaniatâd i farchnata, at ba ddiben y byddant yn cael eu marchnata,
- (d) dyddiad arfaethedig eu gollwng,
- (dd) yr asesiad risg amgylcheddol,
- (e) y dulliau a'r cynlluniau ar gyfer monitro'r organeddau a addaswyd yn enetig ac ar gyfer ymateb i argyfwng, ac
- (f) crynodeb o unrhyw gyngor y mae Cynulliad Cenedlaethol Cymru wedi'i gael oddi wrth y Pwyllgor Ymgynghorol ar Ollyngiadau i'r Amgylchedd ynghylch a ddylid caniatáu neu wrthod cais i ollwng organeddau a addaswyd yn enetig, a naill ai -
 - (i) yr amodau neu'r cyfyngiadau y mae'r Pwyllgor hwnnw wedi cynghori y dylid rhoi'r caniatâd yn unol â hwy, neu
 - (ii) crynodeb o'r rhesymau pam y mae'r Pwyllgor hwnnw wedi cynghori na ddylid rhoi'r caniatâd.

(4) Os yw Cynulliad Cenedlaethol Cymru yn ymwybodol neu os daw'n ymwybodol fod gwybodaeth ynglŷn ag organeddau a addaswyd yn enetig neu ynglŷn â diben eu gollwng neu eu marchnata wedi'i gyhoeddi a bod honno'n fanylach na'r hyn a fyddai'n bodloni gofynion paragraff (3) uchod, rhaid iddo nodi cymaint o'r wybodaeth fanylach honno ar y gofrestr ag y bydd yn ystyried yn briodol.

(5) Mewn perthynas â chaniatadau a roddir o dan adran 111(1) o'r Ddeddf -

- (a) copi o'r caniatâd, a chyfeiriad at y cais y cafodd ei roi mewn perthynas ag ef,
- (b) unrhyw wybodaeth a gyflenwyd i Gynulliad Cenedlaethol Cymru yn unol ag amodau a bennwyd ar gyfer y caniatâd,
- (c) y ffaith bod y caniatâd wedi cael ei amrywio neu ei ddiddymu, cynnwys yr hysbysiad y cafodd y caniatâd ei amrywio neu ei ddirymu ganddo, a chopi o'r caniatâd wedi'i amrywio,
- (ch) crynodeb o unrhyw gyngor y mae Cynulliad Cenedlaethol Cymru wedi'i gael oddi wrth y Pwyllgor Ymgynghorol ar Ollyngiadau i'r Amgylchedd ynghylch a ddylid amrywio neu ddirymu caniatâd i ollwng organeddau a addaswyd yn enetig.

- (a) the name and address of the applicant,
- (b) a general description of the genetically modified organisms in relation to which the application is being made,
- (c) the location at which the genetically modified organisms are proposed to be released, to the extent that this information is notified to the National Assembly for Wales,
- (d) the purpose for which the genetically modified organisms are proposed to be released (including any future use to which they are intended to be put) or, in relation to a consent to market, the purpose for which they will be marketed,
- (e) the intended dates of the release,
- (f) the environment risk assessment,
- (g) the methods and plans for monitoring the genetically modified organisms and for responding to an emergency, and
- (h) a summary of any advice the National Assembly for Wales has received from the Advisory Committee on Releases to the Environment as to whether an application for release of genetically modified organisms should be granted or rejected, and either -
 - (i) the conditions or limitations in accordance with which that committee has advised that the consent should be granted, or
 - (ii) a summary of the reasons why that committee has advised that the consent should not be granted.

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

(5) In relation to consents granted under section 111(1) of the Act -

- (a) a copy of the consent, and a reference to the application in respect of which it was granted,
- (b) any information supplied to the National Assembly for Wales in accordance with conditions imposed on the consent,
- (c) the fact that the consent has been varied or revoked, the contents of the notice by which the consent was varied or revoked, and a copy of the varied consent,
- (d) a summary of any advice the National Assembly for Wales has received from the Advisory Committee on Releases to the Environment as to whether a consent to release genetically modified organisms should be varied or revoked.

(6) Yr wybodaeth ganlynol ynghylch y risg y byddai niwed yn cael ei beri i'r amgylchedd gan organeddau a addaswyd yn enetig -

- (a) unrhyw wybodaeth a ddarperir i Gynulliad Cenedlaethol Cymru yn unol ag adran 111(6A) neu 112(5)(b)(i) o'r Ddeddf,
- (b) unrhyw wybodaeth ynglŷn â digwyddiad anrhagweledig sy'n digwydd mewn cysylltiad â gollyngiad organedd a addaswyd yn enetig a allai effeithio ar y risgiau sy'n bodoli o beri niwed i'r amgylchedd a'r wybodaeth honno wedi'i hysbysu i Gynulliad Cenedlaethol Cymru yn unol ag adran 112(5)(b)(iii) o'r Ddeddf.

(7) Copi o unrhyw ganiatâd i farchnata organeddau a addaswyd yn enetig a roddwyd gan awdurdod cymwys Aelod-wladwriaeth arall.

(8) Lleoliad unrhyw organeddau a addaswyd yn enetig a dyfwyd yng Nghymru yn unol â chaniatâd i farchnata i'r graddau y mae'r wybodaeth honno yn cael ei chymhwyso i Gynulliad Cenedlaethol Cymru yn unol â'r gofynion monitro a bennwyd ar gyfer y caniatâd.

(9) Unrhyw benderfyniad a fabwysiadwyd gan y Comisiwn yn unol ag Erthygl 18 o'r Gyfarwyddeb Gollyngiadau Bwriadol.

(10) Mewn perthynas â cholffarnau am unrhyw dramgwydd o dan adran 118 o'r Ddeddf -

- (a) enw a chyfeiriad y person a gafwyd yn euog,
- (b) disgrifiad o unrhyw organeddau a addaswyd yn enetig y cafwyd y gollfarn mewn perthynas â hwy,
- (c) y dramgwydd a gyflawnwyd,
- (ch) y gosb a bennwyd ac unrhyw orchymyn a wnaed gan y llys o dan adran 120 o'r Ddeddf.

Cadw'r gofrestr

36.-(1) Rhaid i'r wybodaeth a ragnodir yn rheoliad 35(2) gael ei gosod ar y gofrestr o fewn deuddeg diwrnod o gyflwyno'r hysbysiad gwahardd.

(2) Rhaid i'r wybodaeth a ragnodir ym mharagraffau (a) i (e) o reoliad 35(3) gael ei gosod ar y gofrestr o fewn deuddeg diwrnod o'r adeg y mae'r cais am ganiatâd i ollwng neu farchnata wedi dod i law Cynulliad Cenedlaethol Cymru .

(3) Rhaid i'r wybodaeth a ragnodir yn rheoliad 35(3)(f) gael ei gosod ar y gofrestr o fewn deuddeg diwrnod o adeg rhoi neu wrthod y caniatâd.

(4) Rhaid i'r wybodaeth a ragnodir yn rheoliad 35(5)(a) gael ei gosod ar y gofrestr o fewn deuddeg diwrnod o roi neu wrthod y caniatâd.

(5) Rhaid i'r wybodaeth a ragnodir yn rheoliad 35(5)(b) ac (ch) gael ei gosod ar y gofrestr o fewn

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

- (a) any information provided to the National Assembly for Wales in accordance with section 111(6A) or 112(5)(b)(i) of the Act,
- (b) any information relating to an unforeseen event occurring in connection with a release of a genetically modified organism which might affect the risks there are of damage being caused to the environment notified to the National Assembly for Wales in accordance with section 112(5)(b)(iii) of the Act.

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

(8) The location of any genetically modified organisms grown in Wales pursuant to a consent to market insofar as that information is applied to the National Assembly for Wales in accordance with the monitoring requirements imposed on the consent.

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

(10) In relation to convictions for any offence under section 118 of the Act -

- (a) the name and address of the person convicted,
- (b) the description of any genetically modified organisms in relation to which the conviction was obtained,
- (c) the offence which was committed,
- (d) the penalty imposed and any order made by the court under section 120 of the Act.

Keeping the register

36.-(1) The information prescribed in regulation 35(2) shall be placed on the register within twelve days of the prohibition notice being served.

(2) The information prescribed in paragraphs (a) to (g) of regulation 35(3) shall be placed on the register within twelve days of the receipt by the National Assembly for Wales of the application for consent to release or market.

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

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

(5) The information prescribed in regulation 35(5)(b) and (d) shall be placed on the register within twelve

deuddeg diwrnod ar ôl iddi ddod i law Cynulliad Cenedlaethol Cymru.

(6) Rhaid i'r wybodaeth a ragnodir yn rheoliad 35(5)(c) gael ei gosod ar y gofrestr o fewn pedwar diwrnod ar ddeg o adeg dirymu neu amrywio'r caniatâd.

(7) Rhaid i'r wybodaeth a ragnodir yn rheoliad 35(6) a 35(10) gael ei gosod ar y gofrestr o fewn pedwar diwrnod ar ddeg o'r adeg y daeth i law Cynulliad Cenedlaethol Cymru.

(8) Rhaid i'r wybodaeth a ragnodir yn rheoliad 35(7) gael ei gosod ar y gofrestr o fewn pedwar diwrnod ar ddeg o'r adeg y daeth i law Cynulliad Cenedlaethol Cymru.

(9) Rhaid i'r wybodaeth a ragnodir yn rheoliad 35(8) gael ei gosod ar y gofrestr o fewn pedwar diwrnod ar ddeg o'r adeg y daeth i law Cynulliad Cenedlaethol Cymru.

(10) Rhaid i'r wybodaeth a ragnodir yn rheoliad 35(9) gael ei gosod ar y gofrestr o fewn pedwar diwrnod ar ddeg o'r adeg y cafodd Cynulliad Cenedlaethol Cymru ei hysbysu o'r penderfyniad.

Cyhoeddi sylwadau

37.-(1) Rhaid i Gynulliad Cenedlaethol Cymru, o fewn cyfnod o 28 diwrnod ar ôl rhoi caniatâd neu wrthod cais am ollwng organeddau a addaswyd yn enetig, drefnu bod manylion o ble a phryd y gellir archwilio copiâu papur o'r sylwadau a gafwyd ar gael i'r cyhoedd drwy ba ddull bynnag y bydd yn barnu ei fod yn briodol.

(2) Ni fydd paragraff (1) yn ei gwneud hi'n ofynnol i drefnu bod copiâu o'r sylwadau ar gael i'r cyhoedd pan fônt yn cynnwys gwybodaeth gyfrinachol a bod y person sy'n cyflwyno'r sylwadau wedi gofyn i Gynulliad Cenedlaethol Cymru drin yr wybodaeth honno yn gyfrinachol.

RHAN IX AMRYWIOL

Yr egwyddor ragofalus

38. Wrth gyflawni ei swyddogaethau o dan Ran VI o'r Ddeddf a'r Rheoliadau hyn, mae Cynulliad Cenedlaethol Cymru i gymryd i ystyriaeth yr egwyddor ragofalus.

Dirymiadau

39. Mae'r rheoliadau a nodir yn Atodlen 5 yn cael eu dirymu mewn perthynas â Chymru i'r graddau a bennir yn yr Atodlen honno.

days of its receipt by the National Assembly for Wales.

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

(7) The information prescribed in regulation 35(6) and 35(10) shall be placed on the register within fourteen days of its receipt by the National Assembly for Wales.

(8) The information prescribed in regulation 35(7) shall be placed on the register within fourteen days of its receipt by the National Assembly for Wales.

(9) The information prescribed in regulation 35(8) shall be placed on the register within fourteen days of its receipt by the National Assembly for Wales.

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

Publication of representations

37.-(1) The National Assembly for Wales shall, within a period of 28 days after granting consent to or rejecting an application for the release of genetically modified organisms, make available to the public by whatever means it shall consider appropriate details of where and when paper copies of representations received may be inspected.

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

PART IX MISCELLANEOUS

Precautionary principle

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

Revocations

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

Cymhwyso Rhan VI o'r Ddeddf i'r môr tiriogaethol

40.-(1) Mae diwygiad adran 127(2) o'r Ddeddf (diffiniadau ayb: cymhwyso i'r môr tiriogaethol) a wnaed gan reoliad 38(a) o Reoliadau Organeddau a Addaswyd yn Enetig (Eu Gollwng yn Fwriadol) 2002 yn effeithiol hefyd mewn perthynas â Chymru.

(2) Yn adran 127(2), o'i diwygio felly, ar ôl "as it applies in England" mewnosodwch "and applies to the territorial sea adjacent to Wales as it applies in Wales".

Cymhwyso Rhan VI o'r Ddeddf i Gymru

41.-O ganlyniad i'r ddarpariaeth a wnaed gan reoliadau 4, 5, 20(1), 30, 31, 34(2) a 40, mae effaith adran 163A o'r Ddeddf yn peidio.

Llofnodwyd ar ran Cynulliad Cenedlaethol Cymru o dan adran 66(1) o Ddeddf Llywodraeth Cymru 1998(a)

18 Rhagfyr 2002

Llywydd y Cynulliad Cenedlaethol

Application of Part VI of the Act to the territorial sea

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

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

Application of Part VI of the Act to Wales

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

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

18th December 2002

The Presiding Officer of the National Assembly

D. Elis-Thomas

(a) 1998 p.38.

(a) 1998 c.38.

ATODLEN 1

Rheoliadau 12 ac 17

YR WYBODAETH SYDD I'W CHYNNWYS MEWN CAIS AM GANIATÂD I OLLWNG NEU FARCHNATA UWCHBLANHIGION A ADDASWYD YN ENETIG

RHAN I

GWYBODAETH GYFFREDINOL

1. Enw a chyfeiriad y ceisydd, ac enw, cymwysterau a phrofiad y gwyddonydd a phob person arall a fydd yn gyfrifol am gynllunio ac am ollwng yr organeddau, ac am oruchwyllo a monitro'r gollyngiad, ac am ei ddiogelwch.
2. Teitl y prosiect.

RHAN II

GWYBODAETH SY'N YMWNEUD Â'R PLANHIGION RHINIOL NEU'R PLANHIGYN DERBYN

3. Enw llawn y planhigyn -
 - (a) enw teuluol,
 - (b) genws,
 - (c) rhywogaeth,
 - (ch) isrywogaeth,
 - (d) llinell cyltifar/fridio,
 - (dd) enw cyffredin.
4. Gwybodaeth ynghylch -
 - (a) atgenhedliad y planhigyn:
 - (i) dull neu ddulliau atgenhedlu,
 - (ii) unrhyw ffactorau penodol sy'n effeithio ar atgenhedlu,
 - (iii) amser cenhedliad; a
 - (b) cydweddoldeb rhywiol y planhigyn â rhywogaethau a gafodd eu trin neu rywogaethau planhigion gwyllt eraill gan gynnwys dosbarthiad y rhywogaeth gydweddol yn Ewrop.
5. Gwybodaeth ynghylch gallu'r planhigyn i oresi:
 - (a) ei allu i ffurfio strwythurau i oresi neu ar gyfer cysgadrwydd,
 - (b) unrhyw ffactorau penodol sy'n effeithio ar ei allu i oresi.
6. Gwybodaeth ynghylch gwasgariad y planhigyn:

SCHEDULE 1

Regulations 12 and 17

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

PART I

GENERAL INFORMATION

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

PART II

INFORMATION RELATING TO THE PARENTAL OR RECIPIENT PLANT

3. The full name of the plant -
 - (a) family name,
 - (b) genus,
 - (c) species,
 - (d) subspecies,
 - (e) cultivar/breeding line,
 - (f) common name.
4. Information concerning -
 - (a) the reproduction of the plant:
 - (i) the mode or modes of reproduction,
 - (ii) any specific factors affecting reproduction,
 - (iii) generation time; and
 - (b) the sexual compatibility of the plant with other cultivated or wild plant species including the distribution in Europe of the compatible species.
5. Information concerning the survivability of the plant:
 - (a) its ability to form structures for survival or dormancy,
 - (b) any specific factors affecting survivability.
6. Information concerning the dissemination of the plant:

- (a) dull a hyd a lled (megis brasamcan o sut y mae paill a/neu hadau hyfyw yn dirywio dros bellter pan fo hynny'n gymwys) y gwasgariad; a
 - (b) unrhyw ffactorau penodol sy'n effeithio ar wasgariad.
7. Dosbarthiad daearyddol y planhigyn.
 8. Pan fo'r cais yn ymwneud â rhywogaeth planhigyn nad yw'n cael ei dyfu yn arferol yn y Deyrnas Unedig, disgrifiad o gynffyn naturiol y planhigyn, gan gynnwys gwybodaeth am ysglyfaethwyr naturiol, parasitiaid, cystadleuwyr a symbontiaid.
 9. Unrhyw ryngweithiadau posibl eraill, sy'n berthnasol i'r organedd a addaswyd yn enetig, rhwng y planhigyn ag organeddau yn yr ecosystem lle caiff ei dyfu'n arferol, gan gynnwys gwybodaeth am effeithiau gwenwynig ar bobl, anifeiliaid ac organeddau eraill.

RHAN III

GWYBODAETH SY'N YMWNEUD Â'R ADDASIAD GENETIG

10. Disgrifiad o'r dulliau a ddefnyddiwyd ar gyfer yr addasiad genetig.
11. Natur a ffynhonnell y fector a ddefnyddiwyd.
12. Maint, swyddogaeth arfaethedig ac enw'r organedd neu'r organeddau rhoi pob rhan cyfansoddol o'r rhanbarth lle bwriedir eu cynnwys.

RHAN IV

GWYBODAETH SY'N YMWNEUD Â'R PLANHIGYN A ADDASWYD YN ENETIG

13. Disgrifiad o nodwedd neu nodweddion y planhigyn a addaswyd yn enetig sydd wedi'u cyflwyno neu wedi'u haddasu.
14. Yr wybodaeth ganlynol am y dilyniannau a fewnroddwyd neu a ddilewyd:
 - (a) maint a strwythur y mewnosodiad a'r dulliau a ddefnyddiwyd ar gyfer ei nodweddiad, gan gynnwys gwybodaeth am unrhyw rannau o'r fector a gyflwynwyd i'r planhigyn a addaswyd yn enetig neu unrhyw gariwr neu DNA estron sy'n dal i fod yn y planhigyn a addaswyd yn enetig,
 - (b) maint a swyddogaeth y rhanbarth neu'r rhanbarthau a ddilewyd,
 - (c) rhif copi y mewnosodiad, a

- (a) the means and extent (such as an estimation of how viable pollen and/or seeds declines with distance where applicable) of dissemination; and
- (b) any specific factors affecting dissemination.

7. The geographical distribution of the plant.
8. Where the application relates to a plant species which is not normally grown in the United Kingdom, a description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.
9. Any other potential interactions, relevant to the genetically modified organism, of the plant with organisms in the ecosystem where it is usually grown, or elsewhere, including information on toxic effects on humans, animals and other organisms.

PART III

INFORMATION RELATING TO THE GENETIC MODIFICATION

10. A description of the methods used for the genetic modification.
11. The nature and source of the vector used.
12. The size, intended function and name of the donor organism or organisms of each constituent fragment of the region intended for insertion.

PART IV

INFORMATION RELATING TO THE GENETICALLY MODIFIED PLANT

13. A description of the trait or traits and characteristics of the genetically modified plant which have been introduced or modified.
14. The following information on the sequences actually inserted or deleted:
 - (a) the size and structure of the insert and methods used for its characterisation, including information on any parts of the vector introduced into the genetically modified plant or any carrier or foreign DNA remaining in the genetically modified plant,
 - (b) the size and function of the deleted region or regions,
 - (c) the copy number of the insert, and

- (ch) lleoliad neu leoliadau y mewnosodiad neu'r mewnosodiadau yng nghelloedd y planhigyn (p'un a ydyw wedi'i integreiddio yn y cromosom, y cloroplastau, y mitochondria, neu ar ffurf anintegredig) a'r dulliau ar gyfer ei benderfynu.
- 15.** Yr wybodaeth ganlynol am fynegi'r mewnosodiad -
- (a) gwybodaeth am fynegiant datblygiadol y mewnosodiad yn ystod cylch bywyd y planhigyn a'r dulliau a ddefnyddiwyd ar gyfer ei nodweddiad,
- (b) y rhannau o'r planhigyn lle mae'r mewnosodiad wedi'i fynegi, megis gwreiddiau, coesau neu baill.
- 16.** Gwybodaeth ynghylch sut y mae'r planhigyn a addaswyd yn enetig yn wahanol mewn perthynas â'r planhigyn rhieiniol neu'r planhigyn derbyn o safbwynt y canlynol -
- (a) modd neu foddau a/neu gyfradd yr atgenhedlu,
- (b) gwasgariad,
- (c) y gallu i oroesi.
- 17.** Sefydlogrwydd genetig y mewnosodiad a sefydlogrwydd ffenotypig y planhigyn a addaswyd yn enetig .
- 18.** Unrhyw newid i allu'r planhigyn a addaswyd yn enetig i drosglwyddo deunydd genetig i organeddau eraill.
- 19.** Gwybodaeth am unrhyw effeithiau gwenwynig, alergenig neu effeithiau niweidiol eraill ar iechyd dynol sy'n deillio o'r addasiad genetig.
- 20.** Gwybodaeth am ddioglewch y planhigyn a addaswyd yn enetig i iechyd anifeiliaid, yn arbennig unrhyw effeithiau gwenwynig, alergenig neu niweidiol eraill sy'n deillio o'r addasiad genetig, pan fwriedir defnyddio'r planhigyn a addaswyd yn enetig mewn bwydydd anifeiliaid.
- 21.** Mecanwaith y rhyngweithio rhwng y planhigyn a addaswyd yn enetig ac organeddau targed, os yw hynny'n berthnasol.
- 22.** Newidiadau posibl yn rhyngweithiadau'r planhigyn a addaswyd yn enetig ag organeddau heb fod yn organeddau targed sy'n deillio o'r addasiad genetig.
- 23.** Y rhyngweithiadau posibl â'r amgylchedd anfiotig.
- 24.** Disgrifiad o dechnegau canfod ac adnabod ar gyfer y planhigyn a addaswyd yn enetig.
- 25.** Gwybodaeth ynghylch unrhyw ollyngiadau blaenorol o'r planhigyn a addaswyd yn enetig, os yw hynny'n gymwys.
- (d) the location or locations of the insert or inserts in the plant cells (whether it is integrated in the chromosome, chloroplasts, mitochondria, or maintained in a non-integrated form) and the methods for its determination.
- 15.** The following information on the expression of the insert -
- (a) information on the developmental expression of the insert during the lifecycle of the plant and methods used for its characterisation,
- (b) the parts of the plant where the insert is expressed, such as roots, stem or pollen.
- 16.** Information on how the genetically modified plant differs from the parental or recipient plant in the following respects -
- (a) mode or modes and/or the rate of reproduction,
- (b) dissemination,
- (c) survivability.
- 17.** The genetic stability of the insert and phenotypic stability of the genetically modified plant.
- 18.** Any change to the ability of the genetically modified plant to transfer genetic material to other organisms.
- 19.** Information on any toxic, allergenic or other harmful effects on human health arising from the genetic modification.
- 20.** Information on the safety of the genetically modified plant to animal health, particularly regarding any toxic, allergenic or other harmful effects arising from the genetic modification, where the genetically modified plant is intended to be used in animal feedstuffs.
- 21.** The mechanism of interaction between the genetically modified plant and target organisms, if applicable.
- 22.** The potential changes in the interactions of the genetically modified plant with non-target organisms resulting from the genetic modification.
- 23.** The potential interactions with the abiotic environment.
- 24.** A description of detection and identification techniques for the genetically modified plant.
- 25.** Information about previous releases of the genetically modified plant, if applicable.

RHAN V
GWYBODAETH YNGHYLCH SAFLE'R
GOLLYNGIAD

(Ceisiadau am ganiatâd i ollwng yn unig)

26. Lleoliad a maint safle'r gollyngiad neu safleoedd y gollyngiadau.
27. Disgrifiad o ecosystem safle'r gollyngiad, gan gynnwys hinsawdd, fflora a ffawna.
28. Manylion unrhyw rywogaethau perthnasau gwyllt neu rywogaethau planhigion trin sy'n gydweddol yn rhywiol ac yn bresennol yn safleoedd y gollyngiadau.
29. Agosrwydd safleoedd y gollyngiadau at fiotopau a gydnabyddir yn swyddogol neu ardaloedd gwarchoddedig y gall gollyngiadau effeithio arnynt.

RHAN VI
GWYBODAETH SY'N YMWNEUD Â'R
GOLLYNGIAD

(Ceisiadau am ganiatâd i ollwng yn unig)

30. Diben gollwng y planhigyn a addaswyd yn enetig, gan gynnwys ei ddefnydd cychwynnol ac unrhyw fwriad i'w ddefnyddio fel neu mewn cynnyrch yn y dyfodol.
31. Y dyddiad neu'r dyddiadau a ragwelir ar gyfer y gollwng a hyd y gollwng.
32. Y dull a gaiff ei ddefnyddio ar gyfer gollwng y planhigion a addaswyd yn enetig.
33. Y dull ar gyfer paratoi a rheoli safle'r gollyngiad, cyn, yn ystod ac yn dilyn y gollyngiad, gan gynnwys arferion amaethu a dulliau cynaeafu.
34. Bras amcan o nifer y planhigion a addaswyd yn enetig (neu blanhigion fesul m²) sydd i'w gollwng.

RHAN VII
GWYBODAETH AM REOLI, MONITRO,
CYNLLUNIAU ÔL-OLLWNG A THRIN
GWASTRAFF

(Ceisiadau am ganiatâd i ollwng yn unig)

35. Disgrifiad o -
 - (a) unrhyw ragofalon i gadw'r planhigyn a addaswyd yn enetig bellter i ffwrdd o rywogaethau planhigion sy'n gydnaws o ran rhyw, perthnasau gwyllt a chnydau.
 - (b) unrhyw fesurau i leihau neu atal gwasgariad unrhyw organ atgenhedlu y planhigyn a addaswyd yn enetig (megis paill, hadau, cloronen).

PART V
INFORMATION RELATING TO THE SITE
OF RELEASE

(Applications for consent to release only)

26. The location and size of the release site or sites.
27. A description of the release site ecosystem, including climate, flora and fauna.
28. Details of any sexually compatible wild relatives or cultivated plant species present at the release sites.
29. The proximity of the release sites to officially recognised biotopes or protected areas which may be affected.

PART VI
INFORMATION RELATING TO THE
RELEASE

(Applications for consent to release only)

30. The purpose of the release of the genetically modified plant, including its initial use and any intention to use it as or in a product in the future.
31. The foreseen date or dates and duration of the release.
32. The method by which the genetically modified plants will be released.
33. The method for preparing and managing the release site, prior to, during and after the release, including cultivation practices and harvesting methods.
34. The approximate number of genetically modified plants (or plants per m²) to be released.

PART VII
INFORMATION ON CONTROL,
MONITORING, POST-RELEASE AND
WASTE TREATMENT
PLANS

(Applications for consent to release only)

35. A description of any precautions to -
 - (a) maintain the genetically modified plant at a distance from sexually compatible plant species, both wild relatives and crops.
 - (b) any measures to minimise or prevent dispersal of any reproductive organ of the genetically modified plant (such as pollen, seeds, tuber).

36. Disgrifiad o'r dulliau ar gyfer trin y safle neu'r safleoedd ar ôl y gollyngiad.
37. Disgrifiad o ddulliau trin y deunydd planhigion a addaswyd yn enetig gan gynnwys gwastraff ar ôl y gollyngiad.
38. Disgrifiad o gynlluniau a thechnegau monitro.
39. Disgrifiad o unrhyw gynlluniau argyfwng.
40. Dulliau a gweithdrefnau i ddiogelu'r safle.

**RHAN VIII
GWYBODAETH AM FETHODOLEG**

41. Disgrifiad o'r dulliau a ddefnyddiwyd neu gyfeiriad at y dulliau safonol neu'r dulliau wedi'u cydnabod yn rhyngwladol a ddefnyddiwyd i grynhoi'r wybodaeth sy'n ofynnol o dan yr Atodlen hon, ac enw'r corff neu'r cyrff sy'n gyfrifol am gynnal yr astudiaethau.

ATODLEN 2

Rheoliadau 12 a 17

**YR WYBODAETH SYDD I'W CHYNNWYS
MEWN CEISIADAU AM GANIATÂD I
OLLWNG NEU FARCHNATA
ORGANEDDAU A ADDASWYD YN
ENETIG AC EITHRIO
UWCHBLANHIGION A ADDASWYD YN
ENETIG
RHAN I
GWYBODAETH GYFFREDINOL**

1. Enw a chyfeiriad y ceisydd, ac enw, cymwysterau a phrofiad y gwyddonydd a phob person arall a fydd yn gyfrifol am gynllunio a gollwng yr organeddau a addaswyd yn enetig, ac am oruchwylio a monitro'r gollyngiadau ac am eu diogelwch.
2. Teitl y prosiect.

**RHAN II
GWYBODAETH SY'N YMWNEUD Â'R
ORGANEDDAU A ADDASWYD YN
ENETIG**

Nodweddion yr organeddau rhoi, yr organeddau rhienioli a'r organeddau derbyn

3. Enw gwyddonol a thacsonomi.
4. Amrywogaeth, cyltifar neu enw arall arferol.
5. Marcwyr ffenotypig a genetig.

36. A description of the methods for post-release treatment of the site or sites.
37. A description of the post-release treatment methods for the genetically modified plant material including wastes.
38. A description of monitoring plans and techniques.
39. A description of any emergency plans.
40. Methods and procedures to protect the site.

**PART VIII
INFORMATION ON METHODOLOGY**

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

SCHEDULE 2

Regulations 12 and 17

**INFORMATION TO BE INCLUDED IN
APPLICATIONS FOR CONSENT TO
RELEASE OR MARKET
GENETICALLY MODIFIED
ORGANISMS OTHER THAN
GENETICALLY MODIFIED HIGHER
PLANTS
PART I
GENERAL INFORMATION**

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

**PART II
INFORMATION RELATING TO THE
GENETICALLY MODIFIED
ORGANISMS**

Characteristics of donor, parental and recipient organisms

3. Scientific name and taxonomy.
4. Usual strain, cultivar or other name.
5. Phenotypic and genetic markers.

6. Graddau'r berthynas rhwng yr organeddau rhoi a derbyn neu rhwng organeddau rhieniol.
 7. Disgrifiad o dechnegau adnabod a chanfod.
 8. Sensitifrwydd, dibynadwyedd (mewn termau meintiol) a phenodoldeb y technegau canfod ac adnabod.
 9. Disgrifiad dosbarthiad daearyddol a chynefin naturiol yr organeddau gan gynnwys gwybodaeth am ysglyfaethwyr naturiol, ysglyfaeth, parasitiaid a chystadleuwyr, symbiontiaid a lletywyr.
 10. Yr organeddau y gwyddys y mae trosglwyddo deunydd genetig yn digwydd drwyddynt o dan amodau naturiol.
 11. Gwiriad o sefydlogrwydd genetig yr organeddau a ffactorau sy'n effeithio ar sefydlogrwydd hwnnw.
 12. Y nodweddion patholegol, ecolegol a ffisiolegol canlynol -
 - (a) dosbarthu peryglon yn unol â rheolau presennol y Gymuned sy'n ymwneud â diogelu iechyd dynol a'r amgylchedd;
 - (b) hyd cenhedliad mewn ecosystemau naturiol, y cylch atgenhedlu rhywiol ac anrhywiol;
 - (c) gwybodaeth am oroesi, gan gynnwys amrywiad tymhorol, a'r gallu i ffurfio strwythurau goroesi, gan gynnwys hadau, sborau a sclerotia;
 - (ch) pathogenigrwydd, gan gynnwys heintusrwydd, gwenwyndra, mileindra, alergenigrwydd, cariwr (fector) pathogen, fectorau posibl, ystod lletywyr gan gynnwys organeddau nad ydynt yn darged a'r posibilrwydd y caiff ffirysau cudd eu hysgogi (profirysau) a'r gallu i gytfrefu organeddau eraill;
 - (d) ymwrthedd gwrthgyrff, a defnydd posibl y gwrthgyrff hyn mewn pobl ac organeddau domestig ar gyfer atal clefydau a therapi;
 - (dd) rhan mewn prosesau amgylcheddol, gan gynnwys cynrychu sylfaenol, trosiant maetholion, dadelfeniad deunydd organig a resbiradaeth.
 13. Dilyniant, amledd cynnull a sbesiffgedd fectorau cynhenid, a phresenoldeb genynnau yn y fectorau hynny, sef genynnau sy'n cyflwyno ymwrthedd i bwysau amgylcheddol.
 14. Hanes addasiadau genetig blaenorol.
6. The degree of relatedness between donor and recipient or between parental organisms.
 7. The description of identification and detection techniques.
 8. The sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques.
 9. The description of the geographic distribution and of the natural habitat of the organisms including information on natural predators, prey, parasites and competitors, symbionts and hosts.
 10. The organisms with which transfer of genetic material is known to occur under natural conditions.
 11. Verification of the genetic stability of the organisms and factors affecting that stability.
 12. The following pathological, ecological and physiological traits -
 - (a) the classification of hazard according to existing Community rules concerning the protection of human health and the environment;
 - (b) the generation time in natural ecosystems, sexual and asexual reproductive cycle;
 - (c) information on survivability, including seasonability and the ability to form survival structures, including seeds, spores and sclerotia;
 - (d) pathogenicity, including infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organisms and possible activation of latent viruses (proviruses) and ability to colonise other organisms;
 - (e) antibiotic resistance, and potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy;
 - (f) involvement in environmental processes, including primary production, nutrient turnover, decomposition of organic matter and respiration.
 13. The sequence, frequency of mobilisation and specificity of indigenous vectors, and the presence in those vectors of genes which confer resistance to environmental stresses.
 14. The history of previous genetic modifications.

Nodweddion y fector

15. Natur a ffynhonnell y fector.
16. Dilyniant transbwsionau, fectorau a segmentau genetig eraill nad ydynt yn codio a ddefnyddir i lunio'r organeddau a addaswyd yn enetig ac i wneud i'r fector a gyflwynwyd a'r

Characteristics of the vector

15. The nature and source of the vector.
16. The sequence of transposons, vectors and other non-coding genetic segments used to construct the genetically modified organisms and to

mewnosodiad weithredu yn yr organeddau hynny.

17. Amledd cynnull, galluoedd trosglwyddo genetig a/neu ddulliau o benderfynu'r fector a fewnosodwyd.
18. Y graddau y mae'r fector wedi'i gyfyngu i'r DNA sy'n ofynnol i gyflawni'r swyddogaeth arfaethedig.

Nodweddion yr organeddau a addaswyd yn enetig

19. Y dulliau a ddefnyddiwyd ar gyfer yr addasu.
20. Y dulliau a ddefnyddiwyd -
 - (a) i lunio mewnosodiadau a chyflwyno'r mewnosodiad neu'r mewnosodiadau i'r organedd sy'n eu derbyn;
 - (b) i ddileu dilyniant.
21. Disgrifiad unrhyw fewnosodiad a/neu wneuthuriad y fector.
22. Purdeb y mewnosodiad o unrhyw ddilyniant anhysbys a gwybodaeth am y graddau y mae'r dilyniant a fewnosodwyd wedi'i chyfyngu i'r DNA sy'n ofynnol i gyflawni'r swyddogaeth arfaethedig.
23. Y dulliau a'r meini prawf a ddefnyddiwyd ar gyfer dethol.
24. Dilyniant, hunaniaeth swyddogaethol a lleoliad y segmentau asid niwclëig dan sylw a newidiwyd, a fewnosodwyd neu a ddilewyd, ac yn benodol unrhyw ddilyniant niweidiol hysbys.

Nodweddion organeddau a addaswyd yn enetig

25. Disgrifiad o nodweddion genetig neu nodweddion ffenotypig ac yn benodol unrhyw nodweddion newydd a allai gael eu mynegi neu nad ydynt bellach yn cael eu mynegi.
26. Strwythur a swm unrhyw fector neu asid niwclëig rhoi sy'n parhau yng ngwneuthuriad terfynol yr organeddau a addaswyd.
27. Sefydlogrwydd yr organeddau o safbwynt nodweddion genetig.
28. Cyfradd a lefel mynegiant y deunydd genetig newydd yn yr organeddau, a dull a sensitifrwydd mesuriad y gyfradd a'r lefel honno.
29. Actifedd y cynnyrch genynnol.
30. Y disgrifiad o dechnegau adnabod a chanfod, gan gynnwys technegau ar gyfer adnabod a chanfod y dilyniant a'r fector a fewnosodwyd.
31. Sensitifrwydd, dibynadwyedd (yn nhermau meintiol), a sbesiffgedd y technegau canfod ac adnabod.

make the introduced vector and insert functions in those organisms.

17. The frequency of mobilisation, genetic transfer capabilities and/or methods of determination of the inserted vector.
18. The degree to which the vector is limited to the DNA required to perform the intended function.

Characteristics of the genetically modified organisms

19. The methods used for the modification.
20. The methods used -
 - (a) to construct inserts and to introduce it or them into the recipient organism;
 - (b) to delete a sequence.
21. The description of any insert and/or vector construction.
22. The purity of the insert from any unknown sequence and information on the degree to which the inserted sequence is limited to the DNA required to perform the intended function.
23. The methods and criteria used for selection.
24. The sequence, functional identity and location of the altered, inserted or deleted nucleic acid segments in question, and in particular any known harmful sequence.

Characteristics of the genetically modified organisms

25. The description of genetic trait or traits or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed.
26. The structure and amount of any vector or donor nucleic acid remaining in the final construction of the modified organisms.
27. The stability of the organisms in terms of genetic traits.
28. The rate and level of expression of the new genetic material in the organisms, and the method and sensitivity of measurement of that rate and level.
29. The activity of the gene product.
30. The description of identification and detection techniques, including techniques for the identification and detection of the inserted sequence and vector.
31. The sensitivity, reliability (in quantitative terms), and specificity of detection and identification techniques.

32. Hanes gollyngiadau neu ddefnyddiau blaenorol yr organeddau.
33. Mewn perthynas â iechyd dynol, iechyd anifeiliaid a iechyd planhigion -
- (a) effeithiau gwenwynig neu alergenig yr organeddau a/neu eu cynhyrchion metabolig,
 - (b) cymhariaeth rhwng yr organeddau â'r rhoddwr, y derbynnydd neu (os yw'n briodol) yr organeddau rhienirol mewn perthynas â phathogenigrwydd,
 - (c) gallu'r organeddau i gytreffu,
- (ch) os yw'r organeddau yn bathogenig i bobl sy'n imiwnogymwys-
- (i) yr afiechydon a achosir a mecanwaith y pathogenigrwydd gan gynnwys ymledoldeb a mileindra,
 - (ii) heintusrwydd,
 - (iii) dogn heintiol,
 - (iv) ystod lletywyr a'r posibilrwydd o newid,
 - (v) y posibilrwydd o oroesi y tu allan i'r lletywr dynol,
 - (vi) presenoldeb fectorau neu ddulliau lledaenu,
 - (vii) sefydlogrwydd biolegol,
 - (viii) patrymau ymwrthedd gwrthfotig,
 - (ix) alergedd, a
 - (x) argaeledd therapïau priodol; a
- (d) peryglon eraill y cynnyrch.

RHAN III

GWYBODAETH SY'N YMWNEUD Â'R AMODAU AR GYFER GOLLWNG

Y gollyngiad

34. Disgrifiad o'r gollyngiad bwriadol arfaethedig, gan gynnwys diben neu ddibenion y gollyngiad ac unrhyw fwriad i ddefnyddio'r organedd a addaswyd yn enetig fel neu mewn cynnyrch yn y dyfodol.
35. Dyddiadau arfaethedig y gollyngiad ac amserlen yr arbrawf gan gynnwys amledd a hyd y gollyngiadau.
36. Paratoi'r safle cyn y gollyngiad.
37. Maint y safle.
38. Y dulliau sydd i'w defnyddio ar gyfer y gollyngiad.
39. Swm yr organeddau sydd i'w gollwng.
40. Sut y caiff y safle ei aflonyddu, gan gynnwys math a dull yr amaethu, y cloddio, y dyfrhau neu'r gweithgareddau eraill.

32. The history of previous releases or uses of the organisms.
33. In relation to human health, animal health and plant health -
- (a) the toxic or allergenic effects of the organisms and/or their metabolic products,
 - (b) the comparison of the organisms to the donor, recipient or (where appropriate) parental organisms regarding pathogenicity,
 - (c) the capacity of the organisms for colonisation,
 - (d) if the organisms are pathogenic to humans who are immunocompetent-
- (i) diseases caused and mechanism of pathogenicity including invasiveness and virulence,
 - (ii) communicability,
 - (iii) infective dose,
 - (iv) host range and possibility of alteration,
 - (v) possibility of survival outside of human host,
 - (vi) presence of vectors or means of dissemination,
 - (vii) biological stability,
 - (viii) antibiotic resistance patterns,
 - (ix) allergenicity, and
 - (x) availability of appropriate therapies; and
- (e) the other product hazards.

PART III

INFORMATION RELATING TO THE CONDITIONS OF RELEASE

The release

34. The description of the proposed deliberate release, including the purpose or purposes of the release and any intention to use the genetically modified organism as or in a product in the future.
35. The intended dates of the release and time planning of the experiment including frequency and duration of releases.
36. The preparation of the site before the release.
37. The size of the site.
38. The methods to be used for the release.
39. The quantity of organisms to be released.
40. The disturbance of the site, including the type and method of cultivation, and mining, irrigation or other activities.

41. Y mesurau a gymerir i amddiffyn gweithwyr yn ystod y gollyngiad.
42. Sut y caiff y safle ei drin wedi'r gollyngiad.
43. Y technegau a ragwelir ar gyfer dileu neu sicrhau nad yw'r organeddau a addaswyd yn enetig yn actif ar ddiwedd yr arbrawf neu ddiben arall y gollyngiad.
44. Gwybodaeth am ollyngiadau blaenorol yr organeddau a addaswyd yn enetig a'u canlyniadau, ac yn arbennig, gollyngiadau ar raddfeydd gwahanol neu i ecosystemau gwahanol.

Yr amgylchedd (ar y safle ac yn yr amgylchedd ehangach)

45. Lleoliad daearyddol a chyfeirnod grid cenedlaethol y safle lle bwriedir gollwng, neu'r manau a ragwelir ar gyfer defnyddio'r cynnyrch.
46. Agosrwydd ffisegol neu fiolegol safle'r organeddau a addaswyd yn enetig at bobl a biota arwyddocaol eraill.
47. Agosrwydd at fiotopau arwyddocaol, ardaloedd gwarchoddedig neu gyflenwadau dŵr yfed.
48. Nodweddion hinsoddol y rhanbarth neu ranbarthau y mae'r gollyngiad yn debygol o effeithio arnynt.
49. Y nodweddion daearyddol, daearegol a phriddegol.
50. Y fflora a'r ffawna, gan gynnwys cynydu, da byw a rhywogaethau ymfudol.
51. Disgrifiad o'r ecosystemau targed a'r rhai nad ydynt yn darged ac y mae'r gollyngiad yn debygol o effeithio arnynt.
52. Cymhariaeth rhwng cynefin naturiol yr organeddau derbyn â safle neu safleoedd arfaethedig y gollyngiad.
53. Unrhyw ddatblygiadau neu newidiadau arfaethedig hysbys o ran defnydd tir yn y rhanbarth a allai ddylanwadu ar effaith amgylcheddol y gollyngiad.

41. The worker protection measures taken during the release.
42. The post-release treatment of the site.
43. The techniques foreseen for elimination or inactivation of the genetically modified organisms at the end of the experiment or other purpose of the release.
44. Information on, and the results of, previous releases of the genetically modified organisms, and in particular, releases on a different scale or into different ecosystems.

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

45. The geographical location and national grid reference of the site onto which the release will be made, or the foreseen areas of use of the product.
46. The physical or biological proximity of the site of the genetically modified organisms to humans and other significant biota.
47. The proximity to significant biotopes, protected areas or drinking water supplies.
48. The climatic characteristics of the region or regions likely to be affected.
49. The geographical, geological and pedological characteristics.
50. The flora and fauna, including crops, livestock and migratory species.
51. The description of the target and non-target ecosystems likely to be affected.
52. The comparison of the natural habitat of the recipient organisms with the proposed site or sites of release.
53. Any known planned developments or changes in land use in the region which could influence the environmental impact of the release.

RHAN IV
GWYBODAETH SY'N YMWNEUD Â'R
RHYNGWEITHIADAU RHWNG YR
ORGANEDDAU A ADDASWYD YN
ENETIG A'R AMGYLCHEDD

Nodweddion sy'n effeithio ar oroesiad, lluosiad a lledaeniad

54. Y nodweddion biolegol sy'n effeithio ar oroesiad, lluosiad a gwasgariad.
55. Yr amodau amgylcheddol y gwyddys amdanynt neu a ragwelir ac a allai effeithio ar oroesiad, lluosiad a lledaeniad gan gynnwys gwynt, dwr, pridd, tymheredd a pH.
56. Sensitifrwydd i gyfryngau penodol.

Rhyngweithiadau â'r amgylchedd

57. Cynefin rhagweledig yr organeddau a addaswyd yn enetig.
58. Yr astudiaethau ar ymddygiad a nodweddion yr organeddau a'u heffaith ecolegol a gynhaliwyd mewn amgylcheddau naturiol efelychiadol, megis microcosmau, ystafelloedd tyfu a thai gwydr.
59. Y gallu i drosglwyddo deunydd genetig ar ôl y gollyngiad -
 - (a) o'r organeddau a addaswyd yn enetig i organeddau mewn ecosystemau yr effeithir arnynt,
 - (b) o organeddau cynhenid i'r organeddau a addaswyd yn enetig.
60. Y tebygolrwydd y byddai detholiad ar ôl y gollyngiad yn arwain at fynegiad nodweddion annisgwyl ac/neu annymunol yn yr organeddau a addaswyd yn enetig.
61. Y mesurau a ddefnyddiwyd i sicrhau ac i wirio sefydlogrwydd genetig, disgrifiad o nodweddion genetig a allai atal deunydd genetig rhag cael ei wasgaru neu gadw hynny i'r lleiaf posibl, a dulliau i wirio sefydlogrwydd genetig.
62. Llwybrau gwasgariad biolegol, dulliau hysbys neu ddulliau posibl o ryngweithio â'r cyfrwng wasgaru, gan gynnwys anadliad, llyncu, cysylltiad arwyneb a thurio.
63. Disgrifiad o ecosystemau y gallai'r organeddau a addaswyd yn enetig gael eu wasgaru iddynt.
64. Y potensial ar gyfer cynnydd gormodol ym mhoblogaeth yr organeddau a addaswyd yn enetig sydd yn yr amgylchedd.
65. Mantais gystadleuol yr organeddau mewn perthynas â'r organedd neu organeddau derbyn neu rhieniol na chawsant eu haddasu.

PART IV
INFORMATION RELATING TO THE
INTERACTIONS BETWEEN THE
GENETICALLY MODIFIED
ORGANISMS AND THE
ENVIRONMENT

Characteristics affecting survival, multiplication and dissemination

54. The biological features which affect survival, multiplication and dispersal.
55. The known or predicted environmental conditions which may affect survival, multiplication and dissemination, including wind, water, soil, temperature and pH.
56. The sensitivity to specific agents.

Interactions with the environment

57. The predicted habitat of the genetically modified organisms.
58. The studies on the behaviour and characteristics of the organisms and their ecological impact carried out in simulated natural environments, such as microcosms, growth rooms and greenhouses.
59. The capability of post-release transfer of genetic material -
 - (a) from the genetically modified organisms into organisms in affected ecosystems,
 - (b) from indigenous organisms to the genetically modified organisms.
60. The likelihood of post-release selection leading to the expression of unexpected and/or undesirable traits in the genetically modified organisms.
61. The measures employed to ensure and to verify genetic stability, the description of genetic traits which may prevent or minimise dispersal of genetic material, and methods to verify genetic stability.
62. The routes of biological dispersal, known or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact and burrowing.
63. The description of ecosystems to which the genetically modified organisms could be disseminated.
64. The potential for excessive population increase of the genetically modified organisms in the environment.
65. The competitive advantage of the organisms in relation to the unmodified recipient or parental organism or organisms.

66. Adnabod a disgrifio'r organeddau targed os yw hynny'n berthnasol.
67. Y mecanwaith a'r canlyniad a ragwelir o'r ryngweithio rhwng yr organeddau a ollyngwyd a'r organeddau targed, os yw hynny'n berthnasol.
68. Adnabod a disgrifio'r organeddau nad ydynt yn darged ac y gallai gollwng yr organeddau a addaswyd yn enetig effeithio'n andwyol arnynt, a'r mecanweithiau a ragwelir ar gyfer unrhyw ryngweithiad andwyol a ganfuwyd.
69. Y tebygolrwydd o symudiadau mewn rhyngweithiadau biolegol neu yn yr ystod lletywyr ar ôl y gollwng.
70. Y rhyngweithiadau y gwyddys amdanynt neu a ragwelir ag organeddau nad ydynt yn darged yn yr amgylchedd, gan gynnwys cystadleuwyr, ysglyfaethau, lletywyr, symbiontiaid, ysglyfaethwyr, parasitiaid a phathogenau.
71. Y rhan y mae'r organeddau yn ei chwarae mewn prosesau biogeocemegol neu'r rhan y ragwelir y byddant yn ei chwarae.
72. Unrhyw ryngweithiadau posibl eraill rhwng yr organeddau â'r amgylchedd.

RHAN V

GWYBODAETH AM FONITRO, RHEOLI, TRIN GWASTRAFF A CHYNLLUNIAU YMATEB MEWN ARGYFWNG

Technegau monitro

73. Dulliau ar gyfer olrhain yr organeddau a monitro eu heffeithiau.
74. Sbesiffgedd (i adnabod yr organeddau a addaswyd yn enetig ac i'w gwahaniaethu o'r rhoddwr, y derbynnydd neu, os yw'n briodol, yr organeddau rhieniol), sensitifrwydd a dibynadwyedd y technegau monitro.
75. Technegau ar gyfer canfod trosglwyddiad y deunydd genetig a roddwyd i organeddau eraill.
76. Hyd ac amllder y monitro.

Rheoli'r gollyngiad

77. Y dulliau a'r gweithdrefnau i osgoi a/neu leihau ymlediad yr organeddau a addaswyd yn enetig y tu hwnt i safle'r gollwng neu'r ardal a ddynodwyd ar gyfer eu defnyddio.
78. Dulliau a gweithdrefnau i amddiffyn y safle rhag ymyrraeth gan unigolion heb awdurdod.
79. Dulliau a gweithdrefnau i atal organeddau eraill rhag cael mynediaid i'r safle.

66. The identification and description of the target organisms if applicable.
67. The anticipated mechanism and result of interaction between the released organisms and the target organisms, if applicable.
68. The identification and description of non-target organisms which may be adversely affected by the release of the genetically modified organisms, and the anticipated mechanisms of any identified adverse interaction.
69. The likelihood of post release shifts in biological interactions or in the host range.
70. The known or predicted interactions with non-target organisms in the environment, including competitors, preys, hosts, symbionts, predators, parasites and pathogens.
71. The known or predicted involvement of the organisms in biogeochemical processes.
72. Any other potential interactions of the organisms with the environment.

PART V

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

Monitoring techniques

73. Methods for tracing the organisms and for monitoring their effects.
74. Specificity (to identify the genetically modified organisms, and to distinguish them from the donor, recipient or, where appropriate, the parental organisms), sensitivity and reliability of the monitoring techniques.
75. Techniques for detecting transfer of the donated genetic material to other organisms.
76. Duration and frequency of the monitoring.

Control of the release

77. Methods and procedures to avoid and/or minimise the spread of the genetically modified organisms beyond the site of release or the designated area for use.
78. Methods and procedures to protect the site from intrusion by unauthorised individuals.
79. Methods and procedures to prevent other organisms from entering the site.

Trin gwastraff

80. Y math o wastraff a gynhyrchir.
81. Faint o wastraff a ddisgwylir.
82. Disgrifiad o'r driniaeth a ragwelir.

Cynlluniau ymateb mewn argyfwng

83. Y dulliau a'r gweithdrefnau ar gyfer rheoli'r organeddau a addaswyd yn enetig os ydynt yn ymledu'n annisgwyl.
84. Dulliau, megis difodi'r organeddau a addaswyd yn enetig, ar gyfer dadhalogi'r ardaloedd yr effeithiwyd arnynt.
85. Dulliau ar gyfer gwaredu neu lanweithio planhigion, anifeiliaid, priddoedd, ac unrhyw beth arall a amlygwyd yn ystod neu ar ôl yr ymlediad.
86. Dulliau ar gyfer ynysu'r ardaloedd yr effeithiwyd arnynt gan yr ymlediad.
87. Cynlluniau ar gyfer diogelu iechyd dynol a'r amgylchedd rhag ofn y bydd effaith annymunol.

RHAN VI

GWYBODAETH AM FETHODOLEG

88. Disgrifiad o'r dulliau a ddefnyddiwyd neu gyfeiriad at y dulliau safonol neu'r dulliau sydd wedi'u cydnabod yn rhyngwladol a ddefnyddiwyd i grynhoi'r wybodaeth sy'n ofynnol o dan yr Atodlen hon, ac enw'r corff neu'r cyrff sy'n gyfrifol am gynnal yr astudiaethau.

ATODLEN 3

Rheoliad 17(2)(ch) ac(f) a (6)

**YR WYBODAETH SYDD I'W CHYNNWYS
MEWN CAIS AM GANIATÂD I
FARCHNATA ORGANEDDAU A
ADDASWYD YN ENETIG**

RHAN I

GWYBODAETH GYFFREDINOL

1. Enw masnachol arfaethedig y cynnyrch ac enwau'r organeddau a addaswyd yn enetig yn y cynnyrch, ac unrhyw ddull adnabod, enw neu god penodol a ddefnyddir gan y ceisydd i adnabod yr organedd a addaswyd yn enetig.
2. Enw a chyfeiriad Cymunedol y person sy'n gyfrifol am osod y cynnyrch ar y farchnad, boed y gwneuthurwr, y mewnforiwr neu'r dosbarthwr.

Waste treatment

80. Type of waste generated.
81. Expected amount of waste.
82. Description of treatment envisaged.

Emergency response plans

83. Methods and procedures for controlling the genetically modified organisms in case of unexpected spread.
84. Methods, such as eradication of the genetically modified organisms, for decontamination of the areas affected.
85. Methods for disposal or sanitation of plants, animals, soils, and any other thing exposed during or after the spread.
86. Methods for the isolation of the areas affected by the spread.
87. Plans for protecting human health and the environment in case of the occurrence of an undesirable effect.

PART VI

INFORMATION ON METHODOLOGY

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

SCHEDULE 3

Regulation 17(2)(d) and (h) and (6)

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

PART I

GENERAL INFORMATION

1. The proposed commercial name of the product and names of the genetically modified organisms in the product, and any specific identification, name or code used by the applicant to identify the genetically modified organism.
2. The name and address in the Community of the person who is responsible for the placing on the market, whether it be the manufacturer, importer or distributor.

3. Enw a chyfeiriad cyflenwr neu gyflenwyr y samplau rheoli.
4. Disgrifiad o sut y bwriedir defnyddio'r cynnyrch a'r organedd a addaswyd yn enetig, gan amlygu unrhyw wahaniaethau yn y defnydd neu'r dull o reoli'r organedd a addaswyd yn enetig o'i gymharu â chynnyrch tebyg na chafodd ei addasu yn enetig.
5. Disgrifiad o'r ardal ddaearyddol neu'r ardaloedd daearyddol a'r mathau o amgylchedd lle bwriedir defnyddio'r cynnyrch o fewn y Gymuned, gan gynnwys, lle bo modd, brasman o raddfa'r defnydd ym mhob ardal.
6. Disgrifiad o gategoriâu arfaethedig defnyddwyr y cynnyrch, megis diwydiant, amaethyddiaeth neu ddefnydd gan y cyhoedd fel cwsmeriaid.
7. Gwybodaeth am yr addasiad genetig at ddibenion gosod ar un neu ragor o gofrestrau addasiadau mewn organeddau, y gellir eu defnyddio ar gyfer canfod ac adnabod cynnyrch penodol i hwyluso rheoli ac archwilio ar ôl marchnata. Dylai'r wybodaeth hon gynnwys, os yw'n briodol, cyflwyno samplau o'r organedd a addaswyd yn enetig neu ei ddeunydd genetig i Gynulliad Cenedlaethol Cymru, a manylion dilyniannau niwcleotid neu fath arall o wybodaeth sy'n angenrheidiol i adnabod y cynnyrch a'i epil, er enghraifft y fethodoleg ar gyfer canfod ac adnabod y cynnyrch, gan gynnwys data arbrofol sy'n arddangos sbesiffgedd y fethodoleg. Dylid dynodi gwybodaeth nad oes modd ei gosod, am resymau cyfrinachedd, ar y rhan o'r gofrestr sydd yn agored i'r cyhoedd.
8. Y labelu arfaethedig, a ddylai gynnwys, mewn label neu ddogfen sy'n mynd gyda'r cynnyrch, fel crynodeb o leiaf, enw masnachol y cynnyrch, datganiad i'r perwyl - "This product contains genetically modified organisms", enw'r organedd a addaswyd yn enetig ac enw a chyfeiriad y person sydd wedi'i sefydlu yn y Gymuned sy'n gyfrifol am ei osod ar y farchnad, a sut i gael gafeael ar yr wybodaeth yn y rhan o'r gofrestr sy'n agored i'r cyhoedd.
3. The name and address of the supplier or suppliers of control samples.
4. A description of how the product and the genetically modified organism are intended to be used, highlighting any differences in use or management of the genetically modified organism compared to similar non-genetically modified products.
5. A description of the geographical area or areas and types of environment where the product is intended to be used within the Community, including, where possible, an estimate of the scale of use in each area.
6. A description of the intended categories of users of the product, such as industry, agriculture or consumer use by the public.
7. Information on the genetic modification for the purposes of placing on one or several registers modifications in organisms, which can be used for the detection and identification of particular products to facilitate post marketing control and inspection. This information should include where appropriate the lodging of samples of the genetically modified organism or its genetic material with the National Assembly for Wales, and details of nucleotide sequences or other type of information which is necessary to identify the product and its progeny, for example the methodology for detecting and identifying the product, including experimental data demonstrating the specificity of the methodology. Information that cannot be placed, for confidentiality reasons, in the publicly accessible part of the register should be identified.
8. The proposed labelling, which must include, in a label or an accompanying document, at least in summarised form, a commercial name of the product, a statement that "This product contains genetically modified organisms", the name of the genetically modified organism and the name and address of the person established in the Community who is responsible for the placing on the market, and how to access the information in the publicly accessible part of the register.

RHAN II

GWYBODAETH BERTHNASOL YCHWANEGOL

9. Y mesurau sydd i'w cymryd pe bai organeddau yn y cynnyrch yn dianc neu pe bai'r cynnyrch yn cael ei gamddefnyddio.
10. Cyfarwyddiadau neu argymhellion penodol ar

PART II

ADDITIONAL RELEVANT INFORMATION

9. The measures to be taken in the event of the escape of the organisms in the product or misuse of the product.
10. Specific instructions or recommendations for

gyfer storio a thrafod y cynnyrch.

11. Cyfarwyddiadau penodol ar gyfer monitro a hysbysu'r ceisydd ac, os yw hynny'n angenrheidiol, Cynulliad Cenedlaethol Cymru, sy'n gyson â Rhan C o Atodlen VII o'r Gyfarwyddeb Gollyngiadau Bwriadol.
12. Y cyfyngiadau arfaethedig yn y defnydd a gymeradwywyd ar gyfer yr organedd a addaswyd yn enetig, megis lle gellir defnyddio'r cynnyrch ac at ba ddibenion.
13. Y pacediad arfaethedig.
14. Amcangyfrif o'r cynnyrch yn y Gymuned a/neu fewnforion iddi.
15. Unrhyw labelu ychwanegol arafethedig, a allai gynnwys, o leiaf fel crynodeb, yr wybodaeth y cyfeiriwyd ati ym mharagraffau 4 a 5 o Ran I o'r Atodlen hon, neu baragraffau 9 i 12 o'r Rhan hon.

ATODLEN 4

Rheoliadau 24, 26 a 32

YR WYBODAETH SYDD I'W CHYNNWYS MEWN ADRODDIAD ASESU

1. Nodi nodweddion yr organedd derbyn sy'n berthnasol i'r asesiad o'r organeddau a addaswyd yn enetig perthnasol.
2. Disgrifiad o'r ffordd y mae'r addasiad genetig yn effeithio ar nodweddion yr organeddau.
3. Nodi unrhyw risgiau hysbys o newid i'r amgylchedd a allai ddeillio o ollwng i'r amgylchedd yr organedd derbyn nas addaswyd.
4. Asesiad ynghylch a yw'r addasiad genetig wedi'i nodweddu'n ddigonol at ddibenion gwerthuso unrhyw risgiau i iechyd dynol a'r amgylchedd.
5. Dynodi unrhyw risgiau newydd i iechyd dynol a'r amgylchedd allai ddeillio o ollwng yr organeddau perthnasol a addaswyd yn enetig o'i gymharu â gollwng yr organedd cyfatebol nas addaswyd yn enetig, yn seiliedig ar yr asesiad risg amgylcheddol.
6. Diwedd glo sy'n mynd i'r afael â defnydd arfaethedig o'r cynnyrch, rheoli risg a'r cynllun monitro arfaethedig, ac sy'n datgan a ddylid marchnata'r organeddau perthnasol a addaswyd yn enetig ac o dan ba amodau, neu na ddylid eu marchnata, gan gynnwys rhesymau pam y daethpwyd i'r casgliad hwnnw, ac a fwriedir gofyn am farn awdurdodau cymwys yr Aelod-wladwriaethau eraill a'r Comisiwn ar agweddau penodedig yr asesiad risg amgylcheddol a beth yw'r agweddau hynny.

storage and handling of the product.

11. Specific instructions for carrying out monitoring and reporting to the applicant and, if required, the National Assembly for Wales, which are consistent with Part C of Annex VII of the Deliberate Release Directive.
12. The proposed restrictions in the approved use of the genetically modified organism, such as where the product may be used and for what purposes.
13. The proposed packaging.
14. The estimated product in and/or imports to the Community.
15. Any proposed additional labelling, which may include, at least in summarised form, the information referred to in paragraphs 4 and 5 of Part I of this Schedule, or paragraphs 9 to 12 of this Part.

SCHEDULE 4

Regulations 24, 26 and 32

INFORMATION TO BE INCLUDED IN AN ASSESSMENT REPORT

1. An identification of the characteristics of the recipient organism which are relevant to the assessment of the relevant genetically modified organisms.
2. A description of the way in which the characteristics of the organisms have been affected by genetic modification.
3. An identification of any known risks of change to the environment resulting from the release into the environment of the recipient non-modified organism.
4. An assessment of whether the genetic modification has been characterised sufficiently for the purpose of evaluating any risks to human health and the environment.
5. An identification of any new risks to human health and the environment that may arise from the release of the relevant genetically modified organisms as compared to the release of the corresponding non-modified organism, based on the environmental risk assessment.
6. A conclusion which addresses the proposed use of the product, risk management and the proposed monitoring plan, and states whether the relevant genetically modified organisms should be marketed and under which conditions, or should not be marketed, including reasons for that conclusion, and whether the views of the competent authorities of the other Member States and the Commission are being sought on specified aspects of the environmental risk assessment and what those aspects are.

DIRYMIADAU

<i>Y Rheoliadau a Ddirymwyd</i>	<i>Cyfeiriadau</i>	<i>Graddau'r dirymu</i>
Rheoliadau Organeddau a Addaswyd yn Enetig (Eu Gollwng yn Fwriadol) 1992	O.S. 1992/3280 fel y'i diwygiwyd gan Rheoliadau Organeddau a Addaswyd yn Enetig (Eu Gollwng yn Fwriadol) 1993 (O.S. 1993/152), Rheoliadau Organeddau a Addaswyd yn Enetig (Eu Gollwng yn Fwriadol) 1995 (O.S. 1995/304), Rheoliadau Organeddau a Addaswyd yn Enetig (Eu Gollwng yn Fwriadol ac Asesu'r Risg -Diwygio) 1997 (O.S. 1997/1900), a Rheoliadau Organeddau a Addaswyd yn Enetig (Defnydd Amgaeëdig) (O.S. 2000/2831).	Y Rheoliadau cyfan
Rheoliadau Organeddau a Addaswyd yn Enetig (Eu Gollwng yn Fwriadol) 1993	O.S. 1993/152	Y Rheoliadau cyfan
Rheoliadau Organeddau a Addaswyd yn Enetig (Eu Gollwng yn Fwriadol) 1995	O.S. 1995/304	Y Rheoliadau cyfan
Rheoliadau Organeddau a Addaswyd yn Enetig (Eu Gollwng yn Fwriadol ac Asesu'r Risg -Diwygio) 1997	O.S. 1997/1900	Rheoliad 2
Rheoliadau Organeddau a Addaswyd yn Enetig (Defnydd Amgaeëdig) 2000	O.S. 2000/2831	Rheoliad 31(2)

SCHEDULE 5

Regulation 39

REVOCATIONS

<i>Regulations revoked</i>	<i>References</i>	<i>Extent</i>
The Genetically Modified Organisms (Deliberate Release) Regulations 1992	S.I. 1992/3280 as amended by the Genetically Modified Organisms (Deliberate Release) Regulations 1993 (S.I. 1993/152), the Genetically Modified Organisms (Deliberate Release) Regulations 1995 (S.I. 1995/304), the Genetically Modified Organisms (Deliberate Release and Risk Assessment-Amendment) Regulations 1997 (S.I. 1997/1900), and the Genetically Modified Organisms (Contained Use) Regulations 2000 (S.I. 2000/2831).	The whole Regulations
The Genetically Modified Organisms (Deliberate Release) Regulations 1993	S.I. 1993/152	The whole Regulations
The Genetically Modified Organisms (Deliberate Release) Regulations 1995	S.I. 1995/304	The whole Regulations
The Genetically Modified Organisms (Deliberate Release and Risk Assessment-Amendment) Regulations 1997	S.I. 1997/1900	Regulation 2
The Genetically Modified Organisms (Contained Use) Regulations 2000	S.I. 2000/2831	Regulation 31(2)