



OFFERYNNAU STATUDOL
CYMRU

WELSH STATUTORY
INSTRUMENTS

2019 Rhif 1316 (Cy. 228)

2019 No. 1316 (W. 228)

**DIOGELU'R AMGYLCHEDD,
CYMRU**

**ENVIRONMENTAL
PROTECTION, WALES**

**Rheoliadau Organeddau a
Addaswyd yn Enetig (Eu Gollwng
yn Fwriadol) (Diwygio) (Cymru)
2019**

**The Genetically Modified
Organisms (Deliberate Release)
(Amendment) (Wales) Regulations
2019**

NODYN ESBONIADOL

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

Mae rheoliadau 3 i 8 o'r Rheoliadau hyn yn diwygio Rheoliadau Organeddau a Addaswyd yn Enetig (Eu Gollwng yn Fwriadol) (Cymru) 2002 (O.S. 2002/3188 (Cy. 304)) ("Rheoliadau 2002"). Mae Rheoliadau 2002 yn gweithredu Cyfarwyddeb 2001/18/EC ynghylch gollwng organeddau a addaswyd yn enetig yn fwriadol ("Cyfarwyddeb 2001"). Mae angen y diwygiadau hyn er mwyn gweithredu Cyfarwyddeb y Comisiwn (EU) 2018/350 sy'n diwygio Cyfarwyddeb 2001/18/EC Senedd Ewrop a'r Cyngor o ran asesu risg amgylcheddol organeddau a addaswyd yn enetig (O.J. Rhif L 67, 9.3.2018, t. 30) ("Cyfarwyddeb 2018").

Mae rheoliad 3 yn diwygio'r diffiniad o Gyfarwyddeb 2001 i adlewyrchu'r diwygiadau a wnaed iddi gan Gyfarwyddeb 2018.

Mae'r diwygiadau a wneir gan reoliadau 4 i 7 yn ymwneud â'r wybodaeth sydd i'w chynnwys mewn ceisiadau am ganiatâd i ollwng uwchblanhigion a addaswyd yn enetig mewn perthynas â threialon (diwygiadau i reoliad 12 o Reoliadau 2002 ac Atodlen 1 iddynt gan reoliadau 4 a 6 yn y drefn honno). Maent hefyd yn gwneud darpariaeth mewn perthynas â'r wybodaeth sydd i'w chynnwys mewn ceisiadau am ganiatâd i ollwng uwchblanhigion a addaswyd yn enetig at ddibenion masnachol (diwygiadau i reoliad 17 o Reoliadau 2002 a mewnosod Atodlen 1A iddynt gan reoliadau 5 a 7 yn y drefn honno). Mae'r newidiadau hyn yn angenrheidiol oherwydd bod Atodiadau III a IIIB i Gyfarwyddeb 2001 wedi eu hamnewid gan Gyfarwyddeb 2018.

EXPLANATORY NOTE

(This note is not part of the Regulations)

Regulations 3 to 8 of these Regulations amend the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002 (S.I. 2002/3188 (W. 304)) ("the 2002 Regulations"). The 2002 Regulations implement Directive 2001/18/EC relating to the deliberate release of genetically modified organisms ("the 2001 Directive"). These amendments are necessary to implement Commission Directive (EU) 2018/350 amending Directive 2001/18/EC of the European Parliament and of the Council as regards the environmental risk assessment of genetically modified organisms (O.J. No L 67, 9.3.2018, p. 30) ("the 2018 Directive").

Regulation 3 amends the definition of the 2001 Directive to reflect the amendments made to it by the 2018 Directive.

The amendments made by regulations 4 to 7 relate to the information to be contained in applications for consent to release genetically modified higher plants in relation to trials (amendments to regulation 12 of, and Schedule 1 to, the 2002 Regulations by regulations 4 and 6 respectively). They also make provision in relation to the information to be included in applications for consent to release genetically modified higher plants for commercial purposes (amendments to regulation 17 of, and the insertion of Schedule 1A to, the 2002 Regulations by regulations 5 and 7 respectively). These changes are necessary owing to the substitution, by the 2018 Directive, of Annexes III and IIIB to the 2001 Directive.

Mae rheoliad 8 yn gwneud mân newidiadau i Atodlen 3 i Reoliadau 2002.

Mae rheoliad 9 yn diwygio Rheoliadau Organeddau a Addaswyd yn Enetig (Eu Gollwng yn Fwriadol a'u Symud ar draws Ffin) (Diwygiadau Amrywiol) (Cymru) (Ymadael â'r UE) 2019 (O.S. 2019/379 (Cy. 94)) sy'n dod i rym ar y diwrnod ymadael ac a fydd yn diwygio Atodlen 3 i Reoliadau 2002. Diben y diwygiad yw hepgor darpariaeth yn O.S. 2019/379 y bydd rheoliad 8 o'r Rheoliadau hyn yn ei gwneud yn ddiangen.

Ystyriwyd Cod Ymarfer Gweinidogion Cymru ar gynnal Asesiadau Effaith Rheoleiddiol mewn perthynas â'r Rheoliadau hyn. O ganlyniad, ystyriwyd nad oedd yn angenrheidiol cynnal Asesiad Effaith Rheoleiddiol o'r costau a'r manteision sy'n debygol o ddeillio o gydymffurfio â'r Rheoliadau hyn.

Regulation 8 makes minor changes to Schedule 3 to the 2002 Regulations.

Regulation 9 amends the Genetically Modified Organisms (Deliberate Release and Transboundary Movement) (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019 (S.I. 2019/379 (W. 94)) which come into force on exit day and will amend Schedule 3 to the 2002 Regulations. The purpose of the amendment is to omit a provision in S.I. 2019/379 which regulation 8 of these regulations will render redundant.

The Welsh Ministers' Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, it was not considered necessary to carry out a Regulatory Impact Assessment as to the likely costs and benefits of complying with these Regulations.

2019 Rhif 1316 (Cy. 228)

**DIOGELU'R AMGYLCHEDD,
CYMRU**

**Rheoliadau Organeddau a
Addaswyd yn Enetig (Eu Gollwng
yn Fwriadol) (Diwygio) (Cymru)
2019**

Gwnaed 7 Hydref 2019

*Gosodwyd gerbron Cynulliad Cenedlaethol
Cymru* 8 Hydref 2019

Yn dod i rym 30 Hydref 2019

2019 No. 1316 (W. 228)

**ENVIRONMENTAL
PROTECTION, WALES**

**The Genetically Modified
Organisms (Deliberate Release)
(Amendment) (Wales) Regulations
2019**

Made 7 October 2019

Laid before the National Assembly for Wales
8 October 2019

Coming into force 30 October 2019

Mae Gweinidogion Cymru wedi eu dynodi(1) at ddibenion adran 2(2) o Ddeddf y Cymunedau Ewropeaidd 1972(2) mewn perthynas â mesurau sy'n ymwneud â rheoli a rheoleiddio gollwng organeddau a addaswyd yn enetig yn fwriadol, eu gosod ar y farchnad a'u symud ar draws ffin.

Mae Gweinidogion Cymru yn gwneud y Rheoliadau a ganlyn drwy arfer y pwerau a roddir gan adran 2(2) o Ddeddf y Cymunedau Ewropeaidd 1972 ac adran 111(4) ac (11) o Ddeddf Diogelu'r Amgylchedd 1990(3), ar ôl ymgynghori â'r Asiantaeth Safonau Bwyd yn unol ag adran 126(5) o'r Ddeddf honno.

The Welsh Ministers are designated(1) for the purposes of section 2(2) of the European Communities Act 1972(2) in relation to measures relating to the control and regulation of the deliberate release, placing on the market and transboundary movements of genetically modified organisms.

The Welsh Ministers make the following Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972 and section 111(4) and (11) of the Environmental Protection Act 1990(3), having consulted the Food Standards Agency in accordance with section 126(5) of that Act.

(1) O.S. 2003/2901. Yn rhinwedd paragraffau 28(1) a 30 o Atodlen 11 i Ddeddf Llywodraeth Cymru 2006 (p. 32), mae O.S. 2003/2901 yn cael effaith fel pe bai wedi ei wneud o dan adran 59(1) o'r Ddeddf honno.

(2) 1972 p. 68; diwygiwyd adran 2(2) gan adran 27(1)(a) o Ddeddf Diwygio Deddfwriaethol a Rheoleiddiol 2006 (p. 51), a chan adran 3 o Ddeddf yr Undeb Ewropeaidd (Diwygio) 2008 (p. 7) a Rhan 1 o'r Atodlen iddi.

(3) 1990 p. 43. Mae is-adran (11) yn diffinio "prescribed". Amnewidiwyd adran 126 gan baragraff 18 o Atodlen 3 i Ddeddf Safonau Bwyd 1999 (p. 28). Trosglwyddwyd swyddogaethau'r Ysgrifennydd Gwladol o dan y darpariaethau hyn i Gynulliad Cenedlaethol Cymru o dan erthygl 2 o Orchymyn Cynulliad Cenedlaethol Cymru (Trosglwyddo Swyddogaethau) 1999 (O.S. 1999/672) ac Atodlen 1 iddo. Yn rhinwedd paragraff 30 o Atodlen 11 i Ddeddf Llywodraeth Cymru 2006 trosglwyddwyd y swyddogaethau hyn wedi hynny i Weinidogion Cymru.

(1) S.I. 2003/2901. By virtue of paragraphs 28(1) and 30 of Schedule 11 to the Government of Wales Act 2006 (c. 32), S.I. 2003/2901 has effect as if made under section 59(1) of that Act.

(2) 1972 c. 68; section 2(2) was amended by section 27(1)(a) of the Legislative and Regulatory Reform Act 2006 (c. 51), and section 3 of, and Part 1 of the Schedule to, the European Union (Amendment) Act 2008 (c. 7).

(3) 1990 c. 43. Subsection (11) defines "prescribed". Section 126 was substituted by paragraph 18 of Schedule 3 to the Food Standards Act 1999 (c.28). The functions of the Secretary of State 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 Function) Order 1999 (S.I. 1999/672). By virtue of paragraph 30 of Schedule 11 to the Government of Wales Act 2006 these functions were then further transferred to the Welsh Ministers.

Enwi, cychwyn a chymhwyso

1.—(1) Enw'r Rheoliadau hyn yw Rheoliadau Organeddau a Addaswyd yn Enetig (Eu Gollwng yn Fwriadol) (Diwygio) (Cymru) 2019.

(2) Daw'r Rheoliadau hyn i rym ar 30 Hydref 2019.

Diwygio Rheoliadau Organeddau a Addaswyd yn Enetig (Eu Gollwng yn Fwriadol) (Cymru) 2002

2. Mae Rheoliadau Organeddau a Addaswyd yn Enetig (Eu Gollwng yn Fwriadol) (Cymru) 2002(1) wedi eu diwygio yn unol â rheoliadau 3 i 8.

Diwygio rheoliad 2

3. Yn rheoliad 2 (dehongli), yn y diffiniad o “y Gyfarwydddeb Gollyngiadau Bwriadol” yn lle'r testun o “2015/412 Senedd Ewrop” hyd at “yn eu tiriogaeth” rhodder “2018/350 sy'n diwygio Cyfarwydddeb 2001/18/EC Senedd Ewrop a'r Cyngor o ran asesu risg amgylcheddol organeddau a addaswyd yn enetig(2)”.

Diwygio rheoliad 12

4. Yn rheoliad 12 (gwybodaeth i'w chynnwys mewn cais am ganiatâd i ollwng)—

(a) ym mharagraff (1)(a)—

(i) o flaen “yr wybodaeth” mewnosoder “yn ddarostyngedig i baragraff (1A),”,

(ii) hepgorer y geiriau o “i'r graddau” hyd at y diwedd,

(b) ar ôl paragraff (1)(ch) mewnosoder—

“(d) crynodebau o'r astudiaethau y cyfeirir atynt yn y cais a'u canlyniadau, gan gynnwys esboniad o'u perthnasedd i'r asesiad risg amgylcheddol, fel y bo'n briodol.”,

(c) ar ôl paragraff (1) mewnosoder—

“(1A) Dim ond os oes ei hangen er mwyn cwblhau asesiad risg amgylcheddol yng nghydestun cais penodol y mae'n ofynnol darparu'r wybodaeth a bennir ym mharagraff (1)(a), a gall lefel y manylder y mae rhaid ei ddarparu amrywio yn ôl natur a graddfa'r gollyngiad bwriadol arfaethedig.”.

Title, commencement and application

1.—(1) The title of these Regulations is the Genetically Modified Organisms (Deliberate Release) (Amendment) (Wales) Regulations 2019.

(2) These Regulations come into force on 30 October 2019.

Amendment of the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002

2. The Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002(1) are amended in accordance with regulations 3 to 8.

Amendment of regulation 2

3. In regulation 2 (interpretation), in the definition of “the Deliberate Release Directive” for the text from “2015/412 of the European” to “in their territory” substitute “2018/350 amending Directive 2001/18/EC of the European Parliament and of the Council as regards the environmental risk assessment of genetically modified organisms(2)”.

Amendment of regulation 12

4. In regulation 12 (information to be contained in application for consent to release)—

(a) in paragraph (1)(a)—

(i) before “the information” insert “subject to paragraph (1A),”,

(ii) omit from “to the extent” to the end,

(b) after paragraph (1)(d) insert—

“(e) summaries and results of studies referred to in the application, including an explanation of their relevance to the environmental risk assessment, as appropriate.”,

(c) after paragraph (1) insert—

“(1A) The information specified in paragraph (1)(a) is only required to be provided if it is necessary for the completion of an environmental risk assessment in the context of a specific application, and the level of detail to be provided may vary according to the nature and the scale of the proposed deliberate release.”.

(1) O.S. 2002/3188 (Cy. 304), fel y'i diwygiwyd gan O.S. 2019/463 (Cy. 111). Mae O.S. 2002/3188 hefyd wedi ei ddiwygio gan O.S. 2019/379 ac mae'n cael effaith o'r diwrnod ymadael; mae diwygiadau eraill ond nid yw'r un ohonynt yn berthnasol.

(2) O.J. Rhif L 67, 9.3.2018, t. 30.

(1) S.I. 2002/3188 (W. 304), as amended by S.I. 2019/463 (W. 111). S.I. 2002/3188 is also amended by S.I. 2019/379 with effect from exit day; there are other amendments but none is relevant.

(2) O.J. No L 67, 9.3.2018, p. 30.

Diwygio rheoliad 17

5. Yn rheoliad 17 (cais am ganiatâd i farchnata)—

- (a) ym mharagraff (2)(a)—
 - (i) o flaen “yr wybodaeth” mewnosoder “yn ddarostyngedig i baragraff (2A),”
 - (ii) ym mharagraff (i), yn lle “Atodlen 1” rhodder “Atodlen 1A”,
 - (iii) hepgorer y geiriau o “i’r graddau” hyd at y diwedd,
- (b) ym mharagraff (2), ar ôl is-baragraff (g) mewnosoder—

“(ng) mewn cysylltiad â phob is-set o wybodaeth sy’n ofynnol yn y paragraff hwn—

- (i) crynodebau o’r astudiaethau y cyfeirir atynt yn y cais a’u canlyniadau, gan gynnwys esboniad o’u perthnasedd i’r asesiad risg amgylcheddol, fel y bo’n briodol,
 - (ii) manylion yr astudiaethau y cyfeirir atynt yn y cais, gan gynnwys y deunyddiau a’r dulliau a ddefnyddiwyd neu gyfeiriad at ddulliau safonedig neu ddulliau a gydnabyddir yn rhyngwladol ac enw’r corff neu’r cyrff sy’n gyfrifol am gynnal yr astudiaethau hynny.”
- (c) ar ôl paragraff (2) mewnosoder—

“(2A) Dim ond os oes ei hangen er mwyn cwblhau asesiad risg amgylcheddol yng nghydestun cais penodol y mae’n ofynnol darparu’r wybodaeth a bennir ym mharagraff (2)(a), a gall lefel y manylder y mae rhaid ei ddarparu amrywio yn ôl natur a graddfa’r gollyngiad arfaethedig o ganlyniad i farchnata uwchblanhigyn a addaswyd yn enetig.”

Diwygio Atodlen 1

6.—(1) Mae Atodlen 1 (yr wybodaeth sydd i’w chynnwys mewn cais am ganiatâd i ollwng neu farchnata uwchblanhigion a addaswyd yn enetig) wedi ei diwygio fel a ganlyn.

(2) Yn y teitl, yn lle’r geiriau ar ôl “ganiatâd i ollwng” rhodder “uwchblanhigion a addaswyd yn enetig at ddibenion nad ydynt yn ymwneud â marchnata”.

(3) Yn lle’r nodyn ar gwr y dudalen rhodder “Rheoliad 12”.

Amendment of regulation 17

5. In regulation 17 (application for consent to market)—

- (a) in paragraph (2)(a)—
 - (i) before “the information” insert “subject to paragraph (2A),”
 - (ii) in paragraph (i), for “Schedule 1” substitute “Schedule 1A”,
 - (iii) omit from “to the extent” to the end,
- (b) in paragraph (2), after sub-paragraph (j) insert—

“(k) in respect of each subset of information required in this paragraph—

- (i) summaries and results of studies referred to in the application, including an explanation of their relevance to the environmental risk assessment, as appropriate,
- (ii) details of studies referred to in the application, including materials and methods used or reference to standardised or internationally recognised methods and the name of the body or bodies responsible for carrying out those studies.”

(c) after paragraph (2) insert—

“(2A) The information specified in paragraph (2)(a) is only required to be provided if it is necessary for the completion of an environmental risk assessment in the context of a specific application, and the level of detail to be provided may vary according to the nature and the scale of the proposed release resulting from the marketing of a genetically modified higher plant.”

Amendment of Schedule 1

6.—(1) Schedule 1 (information to be included in applications for consent to release or market genetically modified higher plants) is amended as follows.

(2) In the title, for the words following “consent to release” substitute “genetically modified higher plants for non-marketing purposes”.

(3) For the shoulder note substitute “Regulation 12”.

(4) Ym mharagraff 7, ar y diwedd mewnosoder “yn Ewrop”.

(5) Ym mharagraff 8, yn lle “yn y Deyrnas Unedig” rhodder “yn Ewrop”.

(6) Yn lle paragraff 15 rhodder “Gwybodaeth am rannau o’r planhigyn lle mae’r mewnosodiad wedi’i fynegi”.

(7) Ar ôl paragraff 15 mewnosoder—

“15A. Sefydlogrwydd genetig y mewnosodiad a sefydlogrwydd ffenotypig y planhigyn a addaswyd yn enetig.

15B. Casgliadau am nodweddiad moleciwlaidd y planhigyn a addaswyd yn enetig.”.

(8) Hepgorer paragraffau 16 a 17.

(9) Yn lle paragraffau 18 i 23 rhodder—

(4) In paragraph 7, at the end insert “in Europe”.

(5) In paragraph 8, for “in the United Kingdom” substitute “in Europe”.

(6) For paragraph 15 substitute “Information on parts of the plant where the insert is expressed”.

(7) After paragraph 15 insert—

“15A. The genetic stability of the insert and phenotypic stability of the genetically modified plant.

15B. Conclusions on the molecular characterisation of the genetically modified plant.”.

(8) Omit paragraphs 16 and 17.

(9) For paragraphs 18 to 23 substitute—

“RHAN 4A

Gwybodaeth am feysydd penodol sy’n peri risg

18. Gwybodaeth am—

- (a) unrhyw newid i barhausrwydd neu ymledoldeb y planhigyn a addaswyd yn enetig a’i allu i drosglwyddo deunydd genetig i berthnasau sy’n gydweddol yn rhywiol a’r effeithiau amgylcheddol andwyol sy’n deillio o hynny,
- (b) unrhyw newid i allu’r planhigyn a addaswyd yn enetig i drosglwyddo deunydd genetig i ficro-organeddau a’r effeithiau amgylcheddol andwyol sy’n deillio o hynny,
- (c) mecanwaith y rhyngweithio rhwng y planhigyn a addaswyd yn enetig a’r organeddau targed, os yw hynny’n gymwys, a’r effeithiau amgylcheddol andwyol sy’n deillio o hynny,
- (ch) newidiadau posibl i ryngweithiadau’r planhigyn a addaswyd yn enetig ag organeddau heb fod yn organeddau targed o ganlyniad i’r addasiad genetig a’r effeithiau amgylcheddol andwyol sy’n deillio o hynny,
- (d) newidiadau posibl i arferion amaethyddol a dulliau rheoli’r planhigyn a addaswyd yn enetig o ganlyniad i’r addasiad genetig, os yw hynny’n gymwys, a’r effeithiau amgylcheddol andwyol sy’n deillio o hynny,

“PART 4A

Information on specific areas of risk

18. Information on—

- (a) any change to the persistence or invasiveness of the genetically modified plant and its ability to transfer genetic material to sexually compatible relatives and the adverse environmental effects arising,
- (b) any change in the ability of the genetically modified plant to transfer genetic material to micro-organisms and the adverse environmental effects arising,
- (c) the mechanism of interaction between the genetically modified plant and target organisms, if applicable, and the adverse environmental effects arising,
- (d) potential changes in the interactions of the genetically modified plant with non-target organisms resulting from the genetic modification and the adverse environmental effects arising,
- (e) potential changes in agricultural practices and management of the genetically modified plant resulting from the genetic modification, if applicable, and the adverse environmental effects arising,

(dd) y rhyngweithiadau posibl â'r amgylchedd anfiotig a'r effeithiau amgylcheddol andwyol sy'n deillio o hynny,

(e) unrhyw effeithiau gwenwynig, effeithiau alergenig neu effeithiau niweidiol eraill ar iechyd dynol sy'n deillio o'r addasiad genetig,

(f) casgliadau am y meysydd penodol sy'n peri risg."

(10) O dan y pennawd i Ran 5 hepgorer "(Ceisiadau am ganiatâd i ollwng yn unig)".

(11) O dan y pennawd i Ran 6 hepgorer "(Ceisiadau am ganiatâd i ollwng yn unig)".

(12) O dan y pennawd i Ran 7 hepgorer "(Ceisiadau am ganiatâd i ollwng yn unig)".

(13) Yn lle paragraff 35 rhodder—

"35.—(1) Disgrifiad o unrhyw ragofalon i sicrhau y cedwir y planhigyn a addaswyd yn enetig, o ran ei leoliad, ac, yn ôl y digwydd, o ran amser, ar wahân i rywogaethau planhigion sy'n gydweiddol yn rhywiol.

(2) Yn is-baragraff (1) ystyr "rywogaethau planhigion" yw—

(a) perthnasau gwyllt a chwynnog,

(b) cnydau."

Mewnosod Atodlen 1A

7. Ar ôl Atodlen 1 mewnosoder—

ATODLEN 1A Rheoliad 17

Yr wybodaeth sydd i'w chynnwys mewn ceisiadau am ganiatâd i farchnata uwchblanhigion a addaswyd yn enetig

RHAN 1

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, ac am oruchwylio a monitro'r gollyngiadau ac am eu diogelwch.

(f) potential interactions with the abiotic environment and the adverse environmental effects arising,

(g) any toxic, allergenic or other harmful effects on human health arising from the genetic modification,

(h) conclusions on the specific areas of risk."

(10) Under the heading to Part 5 omit "(Applications for consent to release only)".

(11) Under the heading to Part 6 omit "(Applications for consent to release only)".

(12) Under the heading to Part 7 omit "(Applications for consent to release only)".

(13) For paragraph 35 substitute—

"35.—(1) A description of any precautions to maintain spatial and, as the case may be, temporal separation of the genetically modified plant from sexually compatible plant species.

(2) In sub-paragraph (1) "plant species" means—

(a) wild and weedy relatives, or

(b) crops."

Insertion of Schedule 1A

7. After Schedule 1 insert—

SCHEDULE 1A Regulation 17

Information to be included in applications for consent to market genetically modified higher plants

PART 1

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. Dynodiad a manyleb y planhigyn a addaswyd yn enetig, a chwmpas y cais, ac yn benodol a yw'r cais mewn cysylltiad ag amaethu, at ryw ddiben arall (y mae rhaid ei bennu), neu'r ddau.

RHAN 2

Gwybodaeth sy'n ymwneud â'r planhigyn rhieniol neu'r planhigyn derbyn

3. Enw llawn y planhigyn—

- (a) enw teuluol,
- (b) genws,
- (c) rhywogaeth,
- (ch) isrywogaeth,
- (d) llinell cyltifar neu linell fridio,
- (e) enw cyffredin.

4. Gwybodaeth ynghylch—

- (a) atgennedliad y planhigyn—
 - (i) dull neu ddulliau atgennedlu,
 - (ii) unrhyw ffactorau penodol sy'n effeithio ar atgennedlu,
 - (iii) amser cennedliad, a
- (b) cydweddoldeb rhywiol y planhigyn â rhywogaethau eraill a gafodd eu trin neu rywogaethau planhigion gwyllt eraill, gan gynnwys dosbarthiad y rhywogaeth gydweddol yn Ewrop.

5. Gwybodaeth ynghylch gallu'r planhigyn i oroesi—

- (a) ei allu i ffurfio strwythurau i oroesi neu ar gyfer cysgadrwydd,
- (b) unrhyw ffactorau penodol sy'n effeithio ar ei allu i oroesi.

6. Gwybodaeth ynghylch gwasgariad y planhigyn—

- (a) dull a hyd a lled (megis brasamcan o sut y mae pail hyfyw 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 yn Ewrop.

2. The designation and specification of the genetically modified plant, and the scope of the application, in particular whether the application is in respect of cultivation, for some other use (which must be specified), or both.

PART 2

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 or breeding line,
- (f) common name.

4. Information concerning—

- (a) the reproduction of the plant—
 - (i) the mode or modes of reproduction,
 - (ii) any specific factors affecting reproduction,
 - (iii) generation time, and
- (b) the sexual compatibility of the plant with other cultivated or wild plant species, including the distribution in Europe of the compatible species.

5. Information concerning the survivability of the plant—

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

6. Information concerning the dissemination of the plant—

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

7. The geographical distribution of the plant in Europe.

8. Pan fo'r cais yn ymwneud â rhywogaeth planhigyn nad yw'n cael ei dyfu yn arferol yn Ewrop, disgrifiad o gynefin naturiol y planhigyn, gan gynnwys gwybodaeth am ysglyfaethwyr naturiol, parasitiaid, cystadleuwyr a symbiontiaid.

9. Unrhyw ryngweithiadau posibl eraill, sy'n berthnasol i'r organedd a addaswyd yn enetig, rhwng y planhigyn ac organeddau yn yr ecosystem lle caiff ei dyfu'n arferol, neu yn rhywle arall, gan gynnwys gwybodaeth am effeithiau gwenwynig ar bobl, anifeiliaid ac organeddau eraill.

RHAN 3

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 rhoi neu'r organeddau rhoi ar gyfer pob darn cyfansoddol o'r rhanbarth y bwriedir ei fewnosod.

RHAN 4

Gwybodaeth sy'n ymwneud â'r planhigyn a addaswyd yn enetig

13. Disgrifiad o nodwedd neu nodweddion y planhigyn a addaswyd yn enetig a gyflwynwyd neu a addaswyd.

14.—(1) Yr wybodaeth ganlynol am y dilyniannau a fewnosodwyd neu a ddilëwyd—

- (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 DNA cludo 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 ddilëwyd, pan fo hynny'n briodol,
- (c) rhif copi y mewnosodiad,

8. Where the application relates to a plant species which is not normally grown in Europe, 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 3

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 4

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.—(1) The following information on the sequences 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, where appropriate,
- (c) the copy number of the insert,

- (ch) lleoliad isgellog unrhyw fewnosodiad yng nghelloedd y planhigyn (p'un a yw wedi ei integreiddio yn y cnewyllyn, y cloroplastau, y mitochondria, neu ar ffurf anintegredig) a'r dulliau ar gyfer ei benderfynu,
 - (d) trefn a dilyniant y deunydd genetig ym mhob safle mewnosod ar ffurf electronig safonedig,
 - (dd) dilyniant y DNA genomaidd o bob tu i bob safle mewnosod ar ffurf electronig safonedig,
 - (e) dadansoddiad biowybodeg i nodi ymyriadau genynnau hysbys,
 - (f) gwybodaeth am Fframiau Darllen Agored o fewn y mewnosodiad a Fframiau Darllen Agored sy'n cael eu creu yng nghysylltle'r mewnosodiad a'r DNA genomaidd,
 - (ff) dadansoddiad biowybodeg i nodi unrhyw debygrwydd rhwng unrhyw Fframiau Darllen Agored sy'n cael eu creu gan yr addasiad genetig a genynnau hysbys a allai gael effeithiau andwyol,
 - (g) y dilyniant asidau amino, ac os oes angen, strwythurau eraill proteinau a gynhyrchir o ganlyniad i'r addasiad genetig,
 - (ng) dadansoddiad biowybodeg i nodi homologaethau dilyniannol, ac os oes angen, unrhyw debygrwydd strwythurol rhwng proteinau a gynhyrchir o ganlyniad i'r addasiad genetig a phroteinau a pheptidau hysbys ac iddynt effeithiau andwyol posibl,
 - (h) yn achos addasiadau genetig ac eithrio mewnosod neu ddileu, gwybodaeth am swyddogaeth y deunydd genetig a dargedir gan yr addasiad genetig cyn ac ar ôl ei addasu, yn ogystal â newidiadau uniongyrchol i fynegiant y genynnau o ganlyniad i'r addasiad.
- (d) the subcellular location of any insert in the plant cells (integrated in the nucleus, chloroplasts, mitochondria, or maintained in a non-integrated form) and methods for its determination,
 - (e) the organisation and sequence of the genetic material at each insertion site in a standardised electronic format,
 - (f) the sequence of genomic DNA flanking each insertion site in a standardised electronic format,
 - (g) bioinformatic analysis to identify interruptions of known genes,
 - (h) information on Open Reading Frames ("ORFs") within the insert and ORFs created at the junction of the insert and genomic DNA,
 - (i) bioinformatic analysis to identify similarities between any ORFs generated by the genetic modification and known genes that may have adverse effects,
 - (j) the amino acid sequence and if necessary, other structures of proteins produced as a results of the genetic modification,
 - (k) bioinformatic analysis to identify sequence homologies, and if necessary, structural similarities, between proteins produced as a result of the genetic modification and known proteins and peptides with potential adverse effects,
 - (l) in the case of genetic modifications other than insertion or deletion, information on the function of the genetic material targeted by the genetic modification before and after modification, as well as direct changes in the expression of genes as result of the modification.

(2) Yn y paragraff hwn, ystyr Ffrâm Ddarllen Agored yw dilyniant niwcleotid sy'n cynnwys llinyn o godonau heb ymyrraeth codon gorffen yn yr un ffrâm ddarllen.

(2) In this paragraph, an ORF is a nucleotide sequence that contains a string of codons uninterrupted by the presence of a stop codon in the same reading frame.

15. Yr wybodaeth ganlynol am fynegi'r mewnosodiad—

- (a) gwybodaeth am fynegiant datblygiadol y DNA a fewnosodwyd neu'r DNA a addaswyd 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 ei fynegi, megis gwreiddiau, coesau neu baill,
- (c) mynegiant anfwriadol posibl Ffrâm Ddarllen Agored newydd (mae i "Ffrâm Ddarllen Agored" yr ystyr a roddir ym mharagraff 14(2)), sydd wedi deillio o fewnosod neu ddileu deunydd genetig mewn gennyn hysbys (fel a nodir o dan baragraff 14(dd)) ac sy'n codi pryder o ran diogelwch,
- (ch) data am fynegiant proteinau o blanhigion a addaswyd yn enetig sydd wedi eu tyfu o dan amodau maes.

16. Sefydlogrwydd genetig y mewnosodiad a sefydlogrwydd ffenotypig y planhigyn a addaswyd yn enetig.

17. Casgliadau am nodweddiad moleciwlaidd y planhigyn a addaswyd yn enetig.

18. Yr wybodaeth ganlynol am y dadansoddiad cymharol o nodweddion agronomig a ffenotypig a chyfansoddiad—

- (a) dewis cyfatebydd confensiynol ac unrhyw gymaryddion ychwanegol a ddefnyddiwyd mewn dadansoddiadau cymharol,
- (b) dewis lleoliad y safle maes ar gyfer cynhyrchu deunydd planhigion ar gyfer dadansoddiadau cymharol,
- (c) dyluniad yr arbrawf gan gynnwys dadansoddiad ystadegol,
- (ch) dewis deunydd planhigion i'w ddadansoddi, pan fo hynny'n berthnasol,
- (d) dadansoddiad cymharol o nodweddion agronomig a ffenotypig,
- (dd) dadansoddiad cymharol o gyfansoddiad, os yw'n berthnasol,
- (e) casgliadau'r dadansoddiad cymharol.

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

- (a) information on the developmental expression of the inserted or modified DNA 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,
- (c) the potential unintended expression of a new ORF (which has the meaning given in paragraph 14(2)), which has resulted from the insertion or deletion of genetic material into a known gene (as identified under paragraph 14(f)) and which raises a safety concern,
- (d) protein expression data from genetically modified plants grown under field conditions.

16. The genetic stability of the insert and phenotypic stability of the genetically modified plant.

17. Conclusions on the molecular characterisation of the genetically modified plant.

18. The following information on the comparative analysis of agronomic and phenotypic characteristics and of composition—

- (a) choice of a conventional counterpart and any additional comparators used in comparative analyses,
- (b) choice of field site location for producing plant material for comparative analyses,
- (c) experimental design including statistical analysis,
- (d) selection of plant material for analysis, where relevant,
- (e) comparative analysis of agronomic and phenotypic characteristics,
- (f) comparative analysis of composition, if relevant,
- (g) conclusions of comparative analysis.

RHAN 5

Gwybodaeth am feysydd penodol sy'n peri risg

19. Ar gyfer pob un o'r meysydd sy'n peri risg a restrir yn adran D.2 o Atodiad 2 i'r Gyfarwyddeb Gollwng yn Fwriadol rhaid i'r ceisydd ddisgrifio pob llwybr a allai arwain at niwed mewn cysylltiad â gollwng planhigyn a addaswyd yn enetig, gan ystyried y peryglon a dod i gysylltiad â'r planhigyn.

20. Rhaid i'r ceisydd ddarparu—

- (a) yr wybodaeth a ddisgrifir ym mharagraffau 21 i 27, a
- (b) y gwerthusiad cyffredinol o risg a'r casgliadau a ddisgrifir ym mharagraff 28,

ac eithrio pan fo'r ceisydd o'r farn nad yw hynny'n berthnasol oherwydd y modd y bwriedir defnyddio'r planhigyn a addaswyd yn enetig.

21. Gwybodaeth ynghylch parhausrwydd ac ymledoldeb gan gynnwys trosglwyddo genynnau o blanhigyn i blanhigyn gan gynnwys—

- (a) asesiad o'r potensial i'r planhigyn a addaswyd yn enetig ddod yn fwy parhaus neu'n fwy ymledol a'r effeithiau amgylcheddol andwyol sy'n deillio o hynny,
- (b) asesiad o'r potensial i'r planhigyn a addaswyd yn enetig drosglwyddo trawsennau i berthnasau sy'n gydweiddol yn rhywiol a'r effeithiau amgylcheddol andwyol sy'n deillio o hynny,
- (c) casgliadau am effaith amgylcheddol andwyol parhausrwydd ac ymledoldeb y planhigyn a addaswyd yn enetig gan gynnwys effaith amgylcheddol andwyol trosglwyddo genynnau o blanhigyn i blanhigyn.

22. Gwybodaeth ynghylch trosglwyddo genynnau o blanhigyn i ficro-organedd gan gynnwys—

- (a) asesiad o'r potensial ar gyfer trosglwyddo DNA sydd newydd ei fewnosod o'r planhigyn a addaswyd yn enetig i ficro-organeddu a'r effeithiau amgylcheddol andwyol sy'n deillio o hynny,

PART 5

Information on specific areas of risk

19. For each of the areas of risk listed in section D.2 of Annex 2 to the Deliberate Release Directive the applicant must describe each pathway through which harm could occur in respect of the release of a genetically modified plant, taking hazard and exposure into account.

20. The applicant must provide—

- (a) the information described in paragraphs 21 to 27, and
- (b) the overall risk evaluation and conclusions described in paragraph 28,

except where the applicant considers it is not relevant in view of the intended use of the genetically modified plant.

21. Information relating to the persistence and invasiveness including plant to plant gene transfer including—

- (a) an assessment of the potential for the genetically modified plant to become more persistent or invasive and the adverse environmental effects arising,
- (b) an assessment of the potential for the genetically modified plant to transmit transgenes to sexually compatible relatives and the adverse environmental effects arising,
- (c) conclusions on the adverse environmental effect of persistence and invasiveness of the genetically modified plant including the adverse environmental effect of plant to plant gene transfer.

22. Information relating to plant to micro-organism gene transfer including—

- (a) an assessment of the potential for transfer of newly inserted DNA from the genetically modified plant to micro-organisms and the adverse effects arising,

- (b) casgliadau am effaith andwyol trosglwyddo DNA sydd newydd ei fewnosod o'r planhigyn a addaswyd yn enetig i ficro-organeddau ar iechyd dynol ac ar iechyd anifeiliaid ac ar yr amgylchedd.

23. Gwybodaeth ynghylch rhyngweithiadau'r planhigyn a addaswyd yn enetig, os yw'n berthnasol, ag organeddau targed gan gynnwys—

- (a) asesiad o'r potensial ar gyfer newidiadau yn y rhyngweithiadau uniongyrchol ac anuniongyrchol rhwng y planhigyn a addaswyd yn enetig ac organeddau targed a'r effeithiau amgylcheddol andwyol sy'n deillio o hynny,
- (b) asesiad o'r potensial ar gyfer esblygiad ymwrthedd yr organedd targed i'r protein a fynegwyd yn seiliedig ar hanes esblygiad ymwrthedd i blaladdwyr confensiynol neu blanhigion trawsenynnol sy'n mynegi nodweddion tebyg, ac unrhyw effeithiau andwyol sy'n deillio o hynny,
- (c) casgliadau am effeithiau amgylcheddol andwyol rhyngweithiadau'r planhigyn a addaswyd yn enetig ag organeddau targed.

24.—(1) Gwybodaeth ynghylch rhyngweithiadau'r planhigyn a addaswyd yn enetig ag organeddau heb fod yn organeddau targed gan gynnwys—

- (a) asesiad o'r potensial ar gyfer rhyngweithiadau uniongyrchol ac anuniongyrchol rhwng y planhigyn a addaswyd yn enetig ac organeddau heb fod yn organeddau targed, gan gynnwys rhywogaethau gwarchoddedig, a'r effaith amgylcheddol andwyol sy'n deillio o hynny,
- (b) casgliadau am effeithiau amgylcheddol andwyol rhyngweithiadau'r planhigyn a addaswyd yn enetig ag organeddau heb fod yn organeddau targed.

(2) Rhaid i'r asesiad a ddisgrifir yn is-baragraff (1) ystyried yr effaith andwyol bosibl ar wasanaethau ecosystemau perthnasol ac ar y rhywogaethau sy'n darparu'r gwasanaethau hynny.

- (b) conclusions on the adverse effect of the transfer of newly inserted DNA from the genetically modified plant to micro-organisms on human and animal health and the environment.

23. Information relating to the interactions of the genetically modified plant, if relevant, with target organisms including—

- (a) an assessment of the potential for changes in the direct and indirect interactions between the genetically modified plant and target organisms and the adverse environmental effects arising,
- (b) an assessment of the potential for evolution of resistance of the target organism to the expressed protein based on the history of evolution of resistance to conventional pesticides or transgenic plants expressing similar traits, and any adverse environmental effects arising,
- (c) conclusions on adverse environmental effects of interactions of the genetically modified plant with target organisms.

24.—(1) Information on the interactions of the genetically modified plant with non-target organisms including—

- (a) an assessment of the potential for direct and indirect interactions of the genetically modified plant with non-target organisms, including protected species, and the adverse effect arising,
- (b) conclusions on adverse environmental effects of interactions of the genetically modified plant with non-target organisms.

(2) The assessment described in sub-paragraph (1) must take into account the potential adverse effect on relevant ecosystem services and on the species providing those services.

25. Gwybodaeth ynghylch effeithiau'r technegau amaethu, rheoli a chynaeafu penodol gan gynnwys—

- (a) mewn cysylltiad â phlanhigion a addaswyd yn enetig ar gyfer amaethu, asesiad o'r newidiadau yn y technegau amaethu, rheoli a chynaeafu penodol a ddefnyddir ar gyfer y planhigyn a addaswyd yn enetig a'r effeithiau amgylcheddol andwyol sy'n deillio o hynny,
- (b) casgliadau am effeithiau amgylcheddol andwyol y technegau amaethu, rheoli a chynaeafu penodol.

26. Gwybodaeth am brosesau biogeocemegol gan gynnwys—

- (a) asesiad o'r newidiadau posibl yn y prosesau biogeocemegol yn yr ardal lle mae'r planhigyn a addaswyd yn enetig i'w dyfu ac yn yr amgylchedd ehangach, a'r effeithiau andwyol sy'n deillio o hynny,
- (b) casgliadau am effeithiau andwyol ar brosesau biogeocemegol.

27. Gwybodaeth ynghylch yr effeithiau ar iechyd dynol ac ar iechyd anifeiliaid gan gynnwys—

- (a) asesiad o ryngweithiadau uniongyrchol ac anuniongyrchol posibl rhwng y planhigyn a addaswyd yn enetig a phersonau sy'n gweithio gyda'r planhigyn a addaswyd yn enetig neu sy'n dod i gysylltiad ag ef, gan gynnwys drwy baill neu lwch o blanhigyn a addaswyd yn enetig sydd wedi ei brosesu, ac asesiad o effeithiau andwyol y rhyngweithiadau hynny ar iechyd dynol,
- (b) ar gyfer planhigyn a addaswyd yn enetig na fwriedir iddo gael ei fwyta gan bobl, ond pan allai'r organedd derbyn neu'r organedd rhienioli gael ei ystyried i'w fwyta gan bobl, asesiad o debygolrwydd cymeriant damweiniol a'r effeithiau andwyol posibl ar iechyd dynol o ganlyniad i gymeriant damweiniol,
- (c) asesiad o'r effeithiau andwyol posibl ar iechyd anifeiliaid pe bai anifeiliaid yn bwyta'n ddamweiniol y planhigyn a addaswyd yn enetig neu ddeunydd o'r planhigyn hwnnw,

25. Information on the impacts of the specific cultivation, management and harvesting techniques including—

- (a) in respect of genetically modified plants for cultivation, an assessment of the changes in the specific cultivation, management and harvesting techniques used for the genetically modified plant and the adverse environmental effects arising,
- (b) conclusions on adverse environmental effects of the specific cultivation, management and harvesting techniques.

26. Information on biogeochemical processes including—

- (a) an assessment of the potential changes in the biogeochemical processes within the area in which the genetically modified plant is to be grown and in the wider environment, and the adverse effects arising,
- (b) conclusions on adverse effects on biogeochemical processes.

27. Information on the effects on human and animal health including—

- (a) an assessment of potential direct and indirect interactions between the genetically modified plant and persons working with or coming into contact with the genetically modified plant, including through pollen or dust from a processed genetically modified plant, and assessment of the adverse effects of those interactions on human health,
- (b) for a genetically modified plant not destined for human consumption, but where the recipient or parental organisms may be considered for human consumption, assessment of the likelihood of and possible adverse effects on human health due to accidental intake,
- (c) an assessment of the potential adverse effects on animal health due to accidental consumption of the genetically modified plant or of material from that plant by animals,

(ch) casgliadau am yr effeithiau ar iechyd dynol ac ar iechyd anifeiliaid.

28.—(1) Rhaid i'r gwerthusiad cyffredinol o risg a'r casgliadau gynnwys crynodeb o bob un o'r casgliadau a bennir ym mharagraffau 21 i 27.

(2) Rhaid i'r crynodeb y cyfeirir ato yn is-baragraff (1) ystyried y nodweddiad risg yn unol â chamau 1 i 4 o'r fethodoleg a ddisgrifir yn Adran C.3 o Atodiad 2 i'r Gyfarwyddeb Gollwng yn Fwriadol a'r strategaethau rheoli risg a gynigir yn unol â phwynt 5 o Adran C.3 o Atodiad 2 i'r Gyfarwyddeb honno.

(d) conclusions on the effects on human and animal health.

28.—(1) The overall risk evaluation and conclusions must include a summary of each of the conclusions specified in paragraphs 21 to 27.

(2) The summary referred to in sub-paragraph (1) must take into account the risk characterisation in accordance with steps 1 to 4 of the methodology described in Section C.3 of Annex 2 and the risk management strategies proposed in accordance with point 5 of Section C.3 of Annex 2 to the Deliberate Release Directive.

RHAN 6

Gwybodaeth ynghylch canfod ac adnabod y planhigyn a addaswyd yn enetig a gollyngiadau blaenorol ohono

30. Disgrifiad o dechnegau canfod ac adnabod ar gyfer y planhigyn a addaswyd yn enetig.

31. Gwybodaeth ynghylch gollyngiadau blaenorol o'r planhigyn a addaswyd yn enetig, os yw hynny'n gymwys.”.

Diwygio Atodlen 3

8. Yn Atodlen 3 (yr wybodaeth sydd i'w chynnwys mewn cais am ganiatâd i farchnata organeddau a addaswyd yn enetig), yn lle paragraff 7 rhodder—

“7.—(1) Gwybodaeth am—

- (a) dulliau ar gyfer canfod ac adnabod y digwyddiad trawsnewid, a phan fo hynny'n briodol, ei feintioli,
- (b) samplau o'r organeddau a addaswyd yn enetig a'u samplau rheoli,
- (c) y man lle gellir cyrchu'r deunydd cyfeirio.

(2) Rhaid nodi'r wybodaeth o dan is-baragraff (1) na ellir ei gosod ar y gofrestr am resymau cyfrinachedd.”.

PART 6

Information about the detection, identification and previous releases of the genetically modified plant

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

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

Amendment of Schedule 3

8. In Schedule 3 (information to be included in an application for consent to market genetically modified organisms), for paragraph 7 substitute—

“7.—(1) Information on—

- (a) methods for the detection, identification and, where appropriate, quantification of the transformation event,
- (b) samples of the genetically modified organisms and their control samples,
- (c) the place where the reference material can be accessed.

(2) Information under sub-paragraph (1) that cannot be placed on the register for confidentiality reasons, must be identified.”.

Diwygio Rheoliadau Organeddau a Addaswyd yn Enetig (Eu Gollwng yn Fwriadol a'u Symud ar Draws Ffin) (Diwygiadau Amrywiol) (Cymru) (Ymadael â'r UE) 2019

9. Yn Rheoliadau Organeddau a Addaswyd yn Enetig (Eu Gollwng yn Fwriadol a'u Symud ar draws Ffin) (Diwygiadau Amrywiol) (Cymru) (Ymadael â'r UE) 2019(1) hepgorer rheoliad 3(18)(c).

Amendment of the Genetically Modified Organisms (Deliberate Release and Transboundary Movement) (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019

9. In the Genetically Modified Organisms (Deliberate Release and Transboundary Movement) (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019(1) omit regulation 3(18)(c).

Lesley Griffiths

Gweinidog yr Amgylchedd, Ynni a Materion Gwledig,
un o Weinidogion Cymru
7 Hydref 2019

Minister for Environment, Energy and Rural Affairs,
one of the Welsh Ministers
7 October 2019

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