
WELSH STATUTORY INSTRUMENTS

2019 No. 1316 (W. 228)

ENVIRONMENTAL PROTECTION, WALES

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

<i>Made</i>	- - - -	<i>7 October 2019</i>
<i>Laid before the National Assembly for Wales</i>	- -	<i>8 October 2019</i>
<i>Coming into force</i>	- -	<i>30 October 2019</i>

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.

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⁽⁴⁾ are amended in accordance with regulations 3 to 8.

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- (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.
- (4) [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.

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(5)”.

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.”.

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) 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—

“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,
- (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. 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. 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,
 - (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) 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.** 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.

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) 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. 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,
 - (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.

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.”.

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⁽⁶⁾ omit regulation 3(18)(c).

7 October 2019

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⁽⁶⁾ S.I. 2019/379 (W. 94).

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.

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.