WELSH STATUTORY INSTRUMENTS

2002 No. 3188

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

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 **[**F1and in accordance with the limitations and conditions to which the use of that product is subject**]**;

(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[M1], as amended by Commission Regulation EC No. 649/98 [M2]**[**F2or Regulation (EC) No. 726/2004 of the European Parliament and the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency**]**, is marketed; or

F3(f) . . . . . .

[F4(g) genetically modified food or feed authorised under the Food and Feed Regulation is marketed.**]**

Textual Amendments

F1 Words in reg. 16(a) inserted (15.7.2005) by The Genetically Modified Organisms (Deliberate Release) (Wales) (Amendment) Regulations 2005 (S.I. 2005/1913), regs. 1, **2(3)(a)**

F2 Words in reg. 16(e) inserted (20.11.2005) by The Medicines (Marketing Authorisations Etc.) Amendment Regulations 2005 (S.I. 2005/2759), reg. 1(b), **Sch. para. 12**

F3 Reg. 16(f) omitted (20.3.2019) by virtue of The Genetically Modified Organisms (Deliberate Release and Transboundary Movement) (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019 (S.I. 2019/379), regs. 1(2), **2(2)**

F4 Reg. 16(g) inserted (15.7.2005) by The Genetically Modified Organisms (Deliberate Release) (Wales) (Amendment) Regulations 2005 (S.I. 2005/1913), regs. 1, **2(3)(c)**

Marginal Citations

M1 OJ No. L214, 24.8.1993, p.1.

M2 OJ No. L88, 24.3.1998, p.7.

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) **[**F5subject to paragraph (2A),**]** the information prescribed in—

(i) **[**F6Schedule 1A**]** where the application is for consent to market any genetically modified higher plant, or

(ii) Schedule 2 in any other case;

F7...

(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 **[**F8European Union**]**, 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.

[F9(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.**]**

[F10(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.**]**

(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.

Textual Amendments

F5 Words in reg. 17(2)(a) inserted (30.10.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (Wales) Regulations 2019 (S.I. 2019/1316), regs. 1(2), **5(a)(i)**

F6 Words in reg. 17(2)(a)(i) substituted (30.10.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (Wales) Regulations 2019 (S.I. 2019/1316), regs. 1(2), **5(a)(ii)**

F7 Words in reg. 17(2)(a) omitted (30.10.2019) by virtue of The Genetically Modified Organisms (Deliberate Release) (Amendment) (Wales) Regulations 2019 (S.I. 2019/1316), regs. 1(2), **5(a)(iii)**

F8 Words in Act substituted (22.4.2011) by The Treaty of Lisbon (Changes in Terminology) Order 2011 (S.I. 2011/1043), **arts. 2**, 8, 9 (with arts. 8(2)(3), 9(3))

F9 Reg. 17(2)(k) inserted (30.10.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (Wales) Regulations 2019 (S.I. 2019/1316), regs. 1(2), **5(b)**

F10 Reg. 17(2A) inserted (30.10.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (Wales) Regulations 2019 (S.I. 2019/1316), regs. 1(2), **5(c)**

Transitional provision for marketing

F11 18. . . . . . .

Textual Amendments

F11 Reg. 18 omitted (20.3.2019) by virtue of The Genetically Modified Organisms (Deliberate Release and Transboundary Movement) (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019 (S.I. 2019/379), regs. 1(2), **2(3)**

Transitional measures for adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation

F12 18A. . . . . . .

Textual Amendments

F12 Reg. 18A omitted (20.3.2019) by virtue of The Genetically Modified Organisms (Deliberate Release and Transboundary Movement) (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019 (S.I. 2019/379), regs. 1(2), **2(3)**

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.

Status:
Point in time view as at 30/10/2019.

Changes to legislation:
There are currently no known outstanding effects for the The Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002, Part III.