STATUTORY INSTRUMENTS.

S.I. No. 442 of 2010

GENETICALLY MODIFIED ORGANISMS (CONTAINED USE) (AMENDMENT) REGULATIONS 2010

(Prn. A10/1341)

S.I. No. 442 of 2010

GENETICALLY MODIFIED ORGANISMS (CONTAINED USE) (AMENDMENT) REGULATIONS 2010

I, JOHN GORMLEY, Minister for the Environment, Heritage and Local Government, in exercise of the powers conferred on me by sections 6 and 111 of the Environmental Protection Agency Act 1992 (No. 7 of 1992) and for the purpose of giving further effect to Council Directive 2009/41/EC of 6 May 2009, hereby make the following regulations:

Citation

1. These Regulations may be cited as the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2010.

2. These Regulations and the Genetically Modified Organisms (Contained Use) Regulations 2001 may be cited together as the Genetically Modified Organisms (Contained Use) Regulations 2001 to 2010 and should be construed together as one.

Interpretation

3. In these Regulations, 'Regulations of 2001' refers to the Genetically Modified Organisms (Contained Use) Regulations 2001.

Amendment to Article 21 of the Regulations of 2001

4. The Regulations of 2001 are amended by the substitution of the following for article 21(2):

> "For the purposes of calculating the period of 45 days referred to in article 19(2)(*a*) or the period of 90 days referred to in article 19(2)(*b*), any period of time during which the Agency is:
>
> (i) awaiting any further information which it may have requested from the notifier in accordance with article 25(1) or
>
> (ii) carrying out a public inquiry or consultation in accordance with article 23(1),
>
> shall not be taken into account."

Amendment to Article 27 of the Regulations of 2001

5. The Regulations of 2001 are amended by the substitution of the following for article 27(1):

> "(*a*) Where a user becomes aware of new information which could have significant consequences for the risks posed by the contained use for

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 17*th September*, 2010.

human health or the environment, the user shall discontinue the contained use and, as soon as practicable, inform the Agency.

(*b*) Where the Agency becomes aware of new information which could have significant consequences for the risks posed by the contained use, the Agency may require the user to modify the conditions of, or suspend or terminate, the contained use.

(*c*) Article 27(1)(b) shall apply irrespective of the source of the information concerned."

Amendment to Article 37 of the Regulations of 2001

6. The Regulations of 2001 are amended by the substitution of the following for article 37(1):

"(1) In the case of a proposed contained use, in respect of which an assessment has been given to the Agency in accordance with article 36(1), the Agency shall issue a decision either granting consent with or without conditions or refusing consent, within 45 days after submission of the assessment."

Amendment to Article 40 of the Regulations of 2001

7. The Regulations of 2001 are amended by the substitution of the following for article 40:

"(1) The Agency may, in the case of a notification under this Part, request the user to provide further information on the notification.

(2) Where the Agency is not satisfied that a contained use is being carried out in accordance with this Part, it may require the user to modify, suspend or terminate the said contained use.

(3) For the purposes of calculating the period of 45 days referred to in article 37(1), any period of time during which the Agency is awaiting further information which it may have requested from the user in accordance with article 40(1), shall not be taken into account."

Amendment to the Fifth Schedule of the Regulations of 2001

8. The Regulations of 2001 are amended by the substitution of the following for Part C of the Fifth Schedule:

PART C

"Information required for the notification referred to in article 19:

- the date of submission of the notification under article 16,
- the names of the persons responsible for supervision and safety and information on their training and qualifications,
- the recipient or parental micro-organism to be used,

- the host-vector system to be used (where applicable),
- the source and intended function of the genetic material involved in the modification,
- identity and characteristics of the genetically modified micro-organism,
- the culture volumes to be used,
- description of the containment and other protective measures to be applied, including information about waste management including the type and form of wastes to be generated, their treatment, final form and destination,
- the purpose of the contained use including the expected results,
- description of the parts of the premises,
- information about accident prevention and emergency response plans, if any,
- any specific hazards arising from the location of the premises,
- the preventive measures applied such as safety equipment, alarm systems and containment methods,
- procedures and plans for verifying the continuing effectiveness of the containment measures,
- a description of information provided to workers,
- the information necessary for the competent authority to evaluate any emergency response plans if required under article 30, and
- a copy of the assessment referred to in article 13."

L.S.

GIVEN under my Official Seal,
1 September 2010.

JOHN GORMLEY,
Minister for the Environment, Heritage and Local Government.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation)

The principal purpose of these Regulations is to amend the Genetically Modified Organisms (Contained Use) Regulations 2001 for the purpose of ensuring that Ireland complies in all respects with the provisions of Council Directive 2009/41/EC of 6 May 2009 on the contained use of genetically modified micro-organisms.

The Genetically Modified Organisms (Contained Use) Regulations 2001 give effect to Directive 2009/41/EC, which is a re-cast of EU Directive 98/81/EC. The Genetically Modified Organisms (Contained Use) Regulations 2001, which were amended by the Genetically Modified Organisms (Deliberate Release) Regulations 2003 (S.I. No. 500 of 2003), are further amended to give full effect to Directive 2009/41/EC.

In particular, these Regulations amend Article 21(2), Article 27(1), Article 37(1), Article 40, and the Fifth Schedule of the Regulations of 2001.

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
Le ceannach díreach ón
OIFIG DHÍOLTA FOILSEACHÁN RIALTAIS,
TEACH SUN ALLIANCE, SRÁID THEACH LAIGHEAN, BAILE ÁTHA CLIATH 2,
nó tríd an bpost ó
FOILSEACHÁIN RIALTAIS, AN RANNÓG POST-TRÁCHTA,
AONAD 20 PÁIRC MIONDÍOLA COIS LOCHA, CLÁR CHLAINNE MHUIRIS,
CONTAE MHAIGH EO,
(Teil: 01 - 6476834 nó 1890 213434; Fax: 094 - 9378964 nó 01 - 6476843)
nó trí aon díoltóir leabhar.

_____

DUBLIN
PUBLISHED BY THE STATIONERY OFFICE
To be purchased directly from the
GOVERNMENT PUBLICATIONS SALE OFFICE
SUN ALLIANCE HOUSE, MOLESWORTH STREET, DUBLIN 2,
or by mail order from
GOVERNMENT PUBLICATIONS, POSTAL TRADE SECTION,
UNIT 20 LAKESIDE RETAIL PARK, CLAREMORRIS, CO. MAYO,
(Tel: 01 - 6476834 or 1890 213434; Fax: 094 - 9378964 or 01 - 6476843)
or through any bookseller.

_____

ISBN 978-1-4064-7468-8

€2.54

9 781406 474688

Wt. (B27810). 315. 9/10. Cahill. Gr. 30-15.