



Department
for Environment
Food & Rural Affairs

Nobel House
17 Smith Square
London SW1P 3JR

T: 03459 335577
helpline@defra.gsi.gov.uk
www.gov.uk/defra

From George Eustice MP
Minister of State for Farming, Food and Marine Environment

The Sainsbury Laboratory
John Innes Centre
Colney Lane
Norwich
NR4 7UH

Date: 26 April 2016

Environmental protection act 1990, section 111: consent to release genetically modified organisms reference: 16/R29/01

1. In accordance with section 111 of the Environmental Protection Act 1990, I hereby grant consent for the release of the genetically modified organisms described in **paragraph 2**, to the Sainsbury Laboratory, in accordance with the particulars set out in **paragraph 3** and subject to the limitations and conditions set out in the **Schedule**.

2. Genetically Modified Organism to be released:

The genetically modified organisms (GMOs) are potatoes (*Solanum tuberosum* L.,) transformed with one of the following genes along with their native promoter and transcription terminator elements:

- *Rpi-vnt1.1* from *Solanum venturii*
- *Rpi-amr3* from *Solanum americanum*
- *Rpi-amr1e* from *Solanum americanum*
- *Rpi-amr1k* from *Solanum americanum*
- *Rpi-Smira1* from *Solanum tuberosum* (variety: Sarpo Mira)
- *Rpi-Smira3* from *Solanum tuberosum* (variety: Sarpo Mira)

In addition, the GMOs will be transformed with one of the following selectable marker genes:

- *neomycin phosphotransferase (nptII)* of bacterial origin, along with the *nopaline synthase (nos)* promoter and either the *nos* or *octopine synthase (ocs)* transcription terminator sequences.
- *bialophos resistance (bar)* of bacterial origin, along with the *nopaline synthase (nos)* promoter and transcription terminator sequences.

3. Particulars of the consent to release:

(a) Maximum size of the release:

- i) The trial site shall not exceed 1 000 square metres.
- ii) No more than 1 000 GMOs shall be planted at the trial site during the release period specified at **paragraph 3(d)** and such plants must be planted in accordance with the limitations and conditions of this consent.

(b) Purpose of the release:

To test field performance of the novel potato plants against potato late blight (*Phytophthora infestans*).

(c) Location of the release (“trial site”):

The release must be conducted at the John Innes Centre, near Norwich at map grid reference TG 1707.

(d) Dates of the release period:

The release may only take place between 1 May and 30 November in 2016, 2017, 2018 and 2019.

4. Before granting this consent, I have: -

- (a) taken advice from the Advisory Committee on Releases to the Environment and Natural England and
- (b) agreed the terms, limitations and conditions of this consent with the Food Standards Agency and, insofar as they relate to the protection of human health and safety, with the Health and Safety Executive.

GEORGE EUSTICE MP

By authority of the Secretary of State for Environment, Food and Rural Affairs

Genetically modified organisms

Limitations and conditions of consent

Schedule to the Letter of Consent dated 26 April 2016 to release Genetically Modified Organisms: Reference 16/R29/01

Reference in the letter of consent and in this Schedule to:

- (a) “GMOs” mean the genetically modified organisms set out in **paragraph 2** of the letter of consent;
- (b) “groundkeeper” means potato tubers and plants growing from potato tubers remaining in the soil after harvest;
- (c) “holder of the consent” means the party named in **paragraph 1** of the letter of consent or such other or additional party who has been approved by the Secretary of State;
- (d) “letter of consent” means the letter granting consent to release the GMOs which is subject to these limitations and conditions and “consent” in this schedule shall be construed accordingly;
- (e) “release” means planting the GMOs within the boundaries of the trial site during the release period;
- (f) “release period” means the period specified in **paragraph 3(d)** of the letter of consent.
- (g) “termination of the trial” means the completion of the trial period as more particularly described in **Condition 11**;
- (h) “trial period” means the period from the first release of the GMOs until the termination of the trial;
- (i) “trial site” means areas of land to be used for the trial in each year of the trial, as more particularly described in **Condition 4** and situated at the location set out in **paragraph 3(c)** of the letter of consent;
- (j) “trial” means the release of the GMOs and management of that release in accordance with the limitations and conditions of this consent;
- (k) “true potato seed” means seed resulting from fertilised potato flowers
- (l) “volunteer” means potato plants growing from true potato seed.

General conditions of this consent

Condition 1. The holder of the consent must, during the trial period:

- (1) subject to the express conditions below, comply with the relevant implied conditions specified in section 112 of the Environmental Protection Act 1990,
- (2) restrict human access to the trial site to personnel who have been informed of the limitations and conditions of the consent, and
- (3) allow the GM Inspectorate access to the trial site on request.

Condition 2. The holder of the consent must apply to the Secretary of State in writing for any variation to the consent **prior to planting** of the GMOs in any year during the release period.

Condition 3. Where the holder of the consent enters into any agreement with a person or persons who will perform the whole or any part of the trial on the holder's behalf, then:

- (1) such an agreement must be in writing and it must incorporate the limitations and conditions of this consent as may be varied by the Secretary of State from time to time in accordance with article 111(10) of the Environmental Protection Act 1990 and regulation 31(6) of the Genetically Modified Organisms (Deliberate Release) Regulations 2002; and
- (2) the first release of the GMOs in any year of the trial must not take place until that agreement or variation of that agreement has received the written approval of the Secretary of State.

Size and description of the trial sites

Condition 4. The consent holder must ensure that:

- (1) the total area of land used for the trial site must not exceed 1 000 square metres.
- (2) an area of at least 20 metres width surrounding the trial site must not be planted with potatoes during the period between the planting and harvest of the GMOs.

Condition 5. The consent holder must provide to the Secretary of State

- (1) At least one week before the GMOs are planted in each year of the trial
 - (i) the six figure grid reference of the trial site and
 - (ii) a plan showing the location of the trial site;
- (2) At least three weeks before the GMOs are planted in each year of the trial

details of the GM potatoes to be planted. This shall include evidence that the vector backbones from the plasmids used to transform these GMOs are not present. These GMOs may not be planted until it is confirmed in writing that the Secretary of State is content with the evidence provided. The Secretary of State shall inform the consent holder of the decision within two weeks of receiving the evidence.

Management of the site

Condition 6.

The consent holder must:

- (1) harvest the trial, and remove potato tops from the field, as soon as practical after research results have been obtained in order to minimise the maturation and shedding of true potato seed;
- (2) remove, as far as is practically achievable, all tubers and, if seed set may have occurred, potato tops (above ground green parts) from the trial site before the 30th November in each year of the release period and transfer them for contained use or disposal in accordance with **Condition 7**;
- (3) harvest potato tubers according to good agricultural practice to avoid groundkeepers;
- (4) ensure that all equipment used for planting and harvesting of potatoes within the trial site is cleaned thoroughly before leaving the trial site;
- (5) in the two years following final harvest of the GMOs, leave the trial site fallow and refrain from ploughing the land. Shallow tillage should be used at least annually to stimulate germination of any true potato seed which has been shed;
- (6) treat all potato groundkeepers and volunteers during the period referred to in **Condition 6(5)** with an application of an appropriate herbicide and remove and transfer from the trial site prior to flowering and in accordance with **Condition 7**. In subsequent years all tubers must be removed from the site prior to flowering to control groundkeepers and volunteers.
- (7) during the post-harvest monitoring period referred to in **Condition 8(2)** but after the two years in which the trial site has been left fallow in accordance with **Condition 6(5)**, refrain from cultivating potatoes or any plant species in which volunteers are difficult to identify or control.

and these conditions apply to all plants planted at the trial site, **including non-GMOs**.

Material removed from the trial site

Condition 7. The consent holder must ensure that **all** potato plant material removed from the trial site under condition 6 is placed in sealed, labelled bags or containers for transfer to conditions under which the Genetically Modified Organisms (Contained Use) Regulations 2014 (SI 2014/1663), as amended, apply or to an authorised waste disposal facility for disposal by deep burial, autoclaving or incineration.

Monitoring

Condition 8. The consent holder must:

- (1) inspect the trial site during the period of cultivation of GMOs at least once per month to ensure that the limitations and conditions of this consent are being met.
- (2) following harvesting of potatoes on individual plots within the trial site, inspect these plots at least once per month from March to November until there has elapsed a period of 2 consecutive years when no GM potato groundkeepers or volunteers have been found.
- (3) maintain raw data and reports of inspections of potato groundkeepers and volunteers and provide this information to the Secretary of State on request as soon as possible, or at least within two weeks of receiving the request.

Reports

Condition 9. The holder of the consent must by either one month after the date of harvesting potatoes in the first year of the trial, or by 30 November 2016, whichever is the sooner, submit a report to the Secretary of State in the format outlined in the Annex to Commission Decision 2003/701/EC (O.J. L254, 08/10/2003, p.21), (the first report). The first report must also include the following information:

- (1) an assessment of any risks or actual or potential adverse effects to human health or the environment from the GMOs,
- (2) whether the trial progressed as planned and if it did not:
 - i) what occurred;
 - ii) any additional measures that were taken;
 - iii) any additional measures that will be taken; and
 - iv) why these measures were taken.

Condition 10. Subject to **Condition 11**, the consent holder must submit reports in the format specified in the Annex to Decision 2003/701/EC to the Secretary of State by December 31st in each of the years following submission of the first report in accordance with **Condition 9**. These reports must include the following information:

- (1) an assessment of the effectiveness of measures to control potato groundkeepers and volunteers, including details of the number of potato groundkeepers and volunteers detected each month in the trial site.
- (2) the re-evaluation of monitoring requirements, including whether or not the consent holder proposes to continue monitoring and the reasons for this decision,
- (3) any additional precautions considered necessary to minimise the dispersal of the GMOs outside of the trial site.

Condition 11. The consent holder must continue to submit the reports referred to in **Condition 10** until the Secretary of State has agreed in writing that there has elapsed a period of 2 consecutive years when no GM potato groundkeepers or volunteers have been found on the trial site, and that the trial is therefore terminated.

Emergency action

Condition 12. In the event of an emergency, the consent holder must:

- (1) take immediate and appropriate preventative and remedial action;
- (2) notify the Secretary of State of the emergency as soon as practicable and in any event within thirty-six hours of the matter constituting the emergency, detailing the nature of the emergency and any action that has been taken; and
- (3) submit a plan to the Secretary of State for approval as soon as practicable and in any event within forty-eight hours of the matter constituting the emergency, detailing any continued or further action that he proposes to take to restrict the dispersal of the GMOs from the trial site.

Condition 13. For the purposes of **Condition 12**, an emergency includes vandalism or any other unauthorised interference with the trial site.

Condition 14. None of the provisions of **Condition 12** shall prevent the Secretary of State from taking such action as is reasonably believed to be necessary to prevent, reduce or remedy any risk of harm to human health or of damage to the environment. Note: The Environmental Protection Act 1990 also requires the consent holder to comply with implied general conditions for consents to release GMO as set out in section 112(5) and section 112(7) of that Act. These implied conditions have effect subject to the conditions imposed above.

April 2016