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Our ref: 17/R29/01

23 May 2024

**ENVIRONMENTAL PROTECTION ACT 1990, SECTIONS 111 AND 112:**

**CONSENT TO RELEASE GENETICALLY MODIFIED ORGANISMS REFERENCE 17/R29/01**

1. On 27<sup>th</sup> April 2017, in accordance with Section 111 of the Environmental Protection Act 1990, the Secretary of State for Environment, Food and Rural Affairs granted consent to The Sainsbury Laboratory to perform the release of the genetically modified organisms described in **paragraph 3**, in accordance with the particulars set out in **paragraph 4**, and subject to the limitations and conditions set out in the **Schedule** attached.

2. I am writing to give notice, in accordance with Section 111(10) of the Environmental Protection Act 1990, that the afore-mentioned consent is varied so that the post-trial monitoring stage may finish in May 2024 and that the trial is therefore terminated. This termination is dependent on the consent holder carrying out on site relocation and deep burial of the soil from the release sites that are under this monitoring schedule.

3. Genetically Modified Organism to be released:

The genetically modified organisms (GMOs) are potatoes (*Solanum tuberosum* L.) transformed with one or a combination of the following genes

- Rpi-vnt1.1 from *Solanum venturi*
- Rpi-amr3i from *Solanum americanum*
- Rpi-amr1e from *Solanum americanum*
- Oc-1ΔD86 from *Oryza sativa*
- Sequence coding for a repellent peptide – synthetic
- Sense and anti-sense fragments of Ppo from *Solanum tuberosum*
- Sense and anti-sense fragments of Vlnv from *Solanum tuberosum*

- Sense and anti-sense fragments of Ast1 from Solanum tuberosum
- The CSR allele of ALS from Solanum lycopersicum
- NptII from Escherichia coli

4. Particulars of the consent to release:

a) Maximum size of the release: The trial site shall not exceed 1 000 square metres. No more than 1 500 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.

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 was only permitted to take place between 1 May and 30 November in 2017-2021.

5. 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, in so far as they relate to the protection of human health and safety, with the Health and Safety Executive.



**Rt Hon Sir Mark Spencer MP**

## **Schedule to the letter of Consent to release Genetically Modified Organisms Application Reference 17/29/01**

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

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

## **CONDITIONS OF CONSENT**

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

- (1) restrict human access to the trial site to named personnel who are familiar with the limitations and conditions of the consent, or those escorted by named personnel, and
- (2) 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 and obtain agreement for this variation prior to sowing 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 be in keeping with the limitations and conditions of this consent as may be varied by the Secretary of State from time to time in accordance with Section 111(10) of the Environmental Protection Act 1990 and Regulation 22 of the Genetically Modified Organisms (Deliberate Release) Regulations 2002; and
- (2) the release of the GMOs 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) in each year of the trial the plot or plots is/are as described in paragraph 3 of the letter of consent;
- (2) during the release period, potatoes (other than those cultivated as part of this consent) are not grown in an area of at least 20 metres width surrounding the perimeter of the plot on which the GMOs are planted and that if this area is cropped, it is not with cultivated potatoes;

**Condition 5.** at least one week before the GMOs are sown the consent holder must provide to the Secretary of State (email [gm-regulation@defra.gov.uk](mailto:gm-regulation@defra.gov.uk) copied to [gm-inspec@apha.gov.uk](mailto:gm-inspec@apha.gov.uk))

- (1) the six-figure grid reference(s) of the plot(s) within the trial site;
- (2) a plan showing the location of the trial site; and
- (3) details of the GM potato lines to be planted.

Any deviation from the plan referred to in sub-paragraph (2) must be notified to the Secretary of State in writing as soon as practicable and in any event before planting of the GMO takes place.

### **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 (Contained Use) Regulations 2014 (SI 2014/1663), as amended, apply or to an authorised waste disposal facility for disposal by deep burial or incineration.

## **General monitoring requirements**

**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 for 4 consecutive years.
- (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, within two months of harvesting or terminating the GMOs on a plot within the trial site, submit a report to the Secretary of State via the Genetic Modification Inspectorate ([gm-inspec@apha.gov.uk](mailto:gm-inspec@apha.gov.uk)) in the format outlined in the Annex to Commission Decision 2003/701/EC (O.J. L254, 08/10/2003, p.21). Such report or reports 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 GMO,
- (2) whether the release on that particular plot 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**, each year the consent holder must submit a report in the format specified in the Annex to Decision 2003/701/EC to the Secretary of State via the Genetic Modification Inspectorate ([gm-inspec@apha.gov.uk](mailto:gm-inspec@apha.gov.uk)) within two calendar months of the post-trial monitoring being concluded. This report 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 on individual plots for more than 4 years and the reasons for this decision;
- (3) any additional precautions considered necessary to minimise the dispersal of the GMO 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 the trial is 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 their 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 the consent holder proposes to take to restrict the dispersal of the GMO 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 they reasonably believe is 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 GMOs 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.