Department for Environment Food & Rural Affairs

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John Innes Centre
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9 April 2019

Dear Sirs

ENVIRONMENTAL PROTECTION ACT 1990, SECTION 111: CONSENT TO RELEASE GENETICALLY MODIFIED ORGANISMS. REFERENCE: 19/R52/01

1. Pursuant to section 111 of the Environmental Protection Act 1990, I grant consent to the John Innes Centre for the release of the genetically modified organisms described in **paragraph 2**, in accordance with the particulars set out in **paragraph 3** and subject to the conditions set out in the **Schedule** attached**.**

2. Genetically Modified Organism to be released:
The genetically modified organisms (GMOs) are *Brassica oleracea* plants (subspecies *alboglabra* and *italica*) that have been genome-edited to contain small insertions or deletions in the *Myb28 gene*.

3. Particulars of the consent to release:

Maximum size of the release: The trial site must not exceed 1 000 square metres

(a) Purpose of the release:

The purpose of this trial is to better understand the effect of the *Myb28* gene under field conditions.

(b) Location of the release ("trial site"):

The release must be conducted at the John Innes Centre at map grid reference TG 179 075)

(c) Dates of the release period:

The release may only take place between 1 April 2019 and 31 December 2022.

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.

Yours faithfully

ROBERT GOODWILL MP

Schedule to the Letter of Consent to release Genetically Modified Organisms Reference 19/R52/01

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) "volunteer" means plants growing from seed 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 GMO which is subject to these limitations and conditions and "consent" in this schedule shall be construed accordingly;

(e) "release" means planting the GMO within the boundaries of the trial site during the release period;

(f) "release period" means the period specified in **paragraph 3(c)** 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 GMO until the termination of the trial;

(i) "trial site" means the area of land to be used for the trial as more particularly described in **Condition 4** below and situated at the location set out in **paragraph 3(b)** 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;

CONDITIONS OF CONSENT

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

(1) restrict human access to the trial site to personnel who have been informed of the limitations and conditions of the consent, 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 **prior to sowing or transplanting** 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 22 of the Genetically Modified Organisms (Deliberate Release) Regulations 2002; and

(2) the 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) *Brassica napus* is sown or transplanted around plots containing GMOs;

(2) during the release period, *Brassica* plants, other than those referred to in **Condition 4(1)**, are not grown in an area of at least 20 metres width of the plots on which the GMOs are planted.

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

(1) the six figure grid reference of the plots within the trial site;

(2) a plan showing the location of the trial site; and

(3) at least three weeks before the GMOs are planted in each year of the trial, details of the GM *Brassica oleracea* plants to be planted.

This must 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.

at least one week before the GMOs are sown or transplanted. 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) ensure that suitable measures are in place to keep pigeons and other large birds out of the plots immediately after GM seed is sown and until the majority of GM plants have germinated.

(2) control plants within the genera *Brassica, Eruca, Erucastrum, Hirschfeldia, Moricandia, Raphanus* and *Sinapis* before flowering both within plots in which the GMOs are planted and in the surrounding area of at least 20m width referred to in **Condition 4(2)** ("the 20m border") either by hand pulling or application of a herbicide between 1st May and 30th September in each year of the trial.

(3) clean all machinery (including wheels and tyres) used on the trial site thoroughly and over plastic sheeting on the trial site before leaving the trial site. Ensure that this material is transferred for contained use or disposal in accordance with **Condition 7**;

(4) ensure that all personnel entering the trial site take appropriate steps to eliminate transfer of GMOs via clothing and vehicles from the trial site.

(5) when the GM and non-GM *Brassica oleracea* material is harvested, immediately remove it from the trial site and store it securely until it is transferred for contained use or disposal in accordance with **Condition 7**. In the autumn of the same year, lightly till that plot(s) to a depth of approximately 5cm. The area(s) should be left fallow over the following winter and lightly tilled to a depth of approximately 5cm in the spring.

(6) after harvesting the GM and non-GM *Brassica oleracea* plants in each year of the trial, inspect the plots on which they were grown for volunteers at least once a week until the end of November of the relevant year and then once a month from 1 March until 31 August in the following two years. Record the number of *Brassica*

oleracea volunteers detected in each month (approximately if necessary) before they are controlled in accordance with **Condition 6(9)(b)** below.

(7) when the *Brassica napus* material described in **Condition 4(i)** is harvested, immediately remove it from the trial site and store it securely until it is transferred for contained use or disposal in accordance with **Condition 7**. In the autumn of the same year, lightly till the soil it was grown in to a depth of approximately 5cm. The area(s) should be left fallow over the following winter and lightly tilled to a depth of approximately 5cm in the spring.

(8) after harvesting the *Brassica napus* plants in each year of the trial, inspect the plots and the area(s) in which the *B. napus* plants were grown for volunteers at least once a week until the end of November of the relevant year and then once a month from 1 March until 31 August in the following two years. Record the number of *Brassica napus* volunteers detected in each month (approximately if necessary) before they are controlled in accordance with **Condition 6(9)(b)** below.

(9) during the two years following harvest of the *Brassica oleracea* and *Brassica napus* plants within the trial site:

a. leave the plots fallow;

b. treat all volunteers on the plot and the 20m border, including volunteers from non GMOs, with herbicide or by hand-pulling prior to inflorescence formation;

(10) refrain from cultivating any crops intended to enter the food and/or feed chain on the trial site until monitoring of the plots for volunteers has ended.

Material removed from the trial site

Condition 7. The consent holder must ensure that **all** GM and non-GM *Brassica.oleracea* and *Brassica napus* material is 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 2000 (SI 2000/2831), 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 entire trial site and the 20m border during the period of cultivation of GMOs at least once a week to ensure that the limitations and conditions of this consent are being met.

(2) maintain raw data and reports of inspections and provide this information to the Secretary of State on request as soon as possible.

Reports

Condition 9. The holder of the consent must, within two months of harvesting or terminating the GMOs within the trial site, 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). 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. After submission of the first report, in accordance with Condition 9, the consent holder must submit a report in each of the following years for the duration of the release period, subject to **Condition 11**. These must be submitted to the Secretary of State by December 31st in each year and in the format specified in the Annex to Decision 2003/701/EC. Each report must include the following information:

(1) an assessment of the effectiveness of measures to control volunteers, including details of the number of volunteers detected each month in the trial site and the 20m borders

(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 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 site and where appropriate, the 20m borders have been controlled in accordance with Conditions 6(9)(b) and 6(11)(b), 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 his 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 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 he reasonably believes 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.