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Our ref: 23/R08/01

25th March 2024

ENVIRONMENTAL PROTECTION ACT 1990, SECTIONS 111 AND 112:

CONSENT TO RELEASE GENETICALLY MODIFIED ORGANISMS REFERENCE 23/R08/01

1. In accordance with section 111 of the Environmental Protection Act 1990, the Secretary of State for Environment, Food and Rural Affairs hereby grants consent to Rothamsted Research to perform 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 limitations and conditions set out in the **Schedule** attached.

2. Genetically Modified Organism to be released:

The genetically modified organisms (GMOs) are *Camelina sativa* plants, based on one or other of the cultivars Celine and Suneson, that have been engineered to accumulate non-native lipids (such as omega-3 LC-PUFAs, ketocarotenoids) in their seed oils, or variations in the accumulation of native fatty acids such as oleic and palmitic acid and short chain fatty acids. The transgenic constructs to be incorporated into lines planned for release are as detailed in the consent application (ref. 23/R08/01 form part A1).

3. Particulars of the consent to release:

Maximum size of the release: The area sown with the GM *Camelina sativa* must not exceed 650 square metres (at the Rothamsted trial site), and 4000 square metres (at the Broom's Barn trial site) in each year and may take the form of one or more plots within the trial site.

(a) Purpose of the release:

To investigate genetically modified *Camelina sativa* plants that have altered agronomic performance and seed oil yield.

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

The release can be conducted at Rothamsted Research GM field trial site, Harpenden, Hertfordshire (map grid reference TL12 13) and Rothamsted Research, Brooms Barn, Suffolk (map grid reference TL76 65).

(c) Dates of the release period:

The release may only take place between 1 April 2024 and 31 December 2028.

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.

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Schedule to the letter of Consent to release Genetically Modified Organisms Application Reference 23/R08/01

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 50 metre border;
(c) "volunteer" means plants growing from seed remaining in the soil after harvest;
(d) "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;
(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(c)** 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 locations set out in **paragraph 3(b)** 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 such a 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 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 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, *Camelina sativa* are not grown in an area of at least 50 metres width ("the 50-metre border") surrounding the perimeter of the GMOs that are planted as part of this consent and that if this area is cropped, it is not with cultivated *Camelina sativa* or a compatible species;

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 copied to 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 *Camelina sativa* 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(s) takes place.

Management of the site

Condition 6.

The consent holder must:

(1) ensure that suitable measures are in place to keep birds out of the plots during and after sowing and at the first signs of emergence of *Camelina sativa* seedlings;

(2) between 1st May and 30th September in each year of the trial control any wild and weedy relatives or sexually compatible crops before they flower both within the plot on which the GMOs are planted and in the surrounding 50 metre border referred to in condition 4(2) either by hand pulling or application of a glyphosate herbicide;

(3) As far as is practicable, harvest non-GM *Camelina sativa* (if grown) after harvesting GM *Camelina sativa* on each plot; clean the combine on the plot from which the material is harvested after each plot is harvested but before the next plot is harvested;

(4) clean all machinery (including wheels and tyres) used on the trial site thoroughly before leaving the trial site;

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

(6) ensure that all material (including straw) dislodged during cleaning is removed from the trial site immediately and ensure that it is transferred for contained use or stored securely whilst awaiting disposal in accordance with **Condition 7**;

(7) when GM and non-GM seed is harvested on a plot, remove this material from the trial site or store securely on-site; and in the autumn of the same year, lightly till that plot to a depth of approximately 5 cm. The area should be left fallow over the following winter and lightly tilled to a depth of approximately 5cm in the spring;

(8) when GM and non-GM camelina is harvested on a plot, following the harvest, inspect that plot and the 50-metre border for volunteers at least once per calendar week until the end of November of the relevant year and then once per calendar month from 1 March until 31 August in the following two years. Record the number of volunteers detected in each calendar month (summing weekly records by month in the growing year, and recording numbers approximately if necessary) before they are controlled in accordance with **condition 6(9)(b)** below;

(9) during the following year after harvest of the GM and non-GM seed from a plot within the trial site:

   a. leave the plot fallow;
   b. treat all volunteers on the plot and the 50 metres border, including volunteers from non-GMOs, with an application of glyphosate herbicide or by hand-pulling prior to inflorescence formation;

(10) refrain from cultivating Camelina crops intended to enter the food and/or feed chain

on the trial site until monitoring of the plots for volunteers has ended and written confirmation of termination of the trial has been obtained in accordance with **Condition 11**.

Material removed from the trial site

Condition 7. The consent holder must ensure that **all** harvested seeds and material collected during cleaning of machinery 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 entire trial site and the 50-metre border during the period of cultivation of GMOs at least once a week and if it is observed that the limitations and conditions of this consent have not been met, inform the GM Inspectorate and/or the Secretary of State immediately.
(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 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) 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/will be 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) 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 volunteers, including details of the number of volunteers detected each month in the trial site and the 50-metre 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 50-metre borders have been controlled in accordance with **Conditions 6(9)(b)** and **6(10)**, 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.