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18 April 2016

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

Dear Sirs

ENVIRONMENTAL PROTECTION ACT 1990, SECTION 111: CONSENT TO RELEASE GENETICALLY MODIFIED ORGANISMS, REFERENCE: 16/R8/01

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 Rothamsted Research, 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 Organisms to be released:

Three single transformation events and one 'stacked' event (which combines two of these events) will be released (four GM plant 'lines' in total). Two of the constructs (B7.2 and DHA2015.1) each encode seven omega-3 LC-PUFA biosynthesis genes, six of which are identical on both constructs. In construct B7.2, the seventh gene (a $\Delta 4$ -desaturase) originates from *Thalassiosira pseudonana*, whereas in construct DHA2015.1, the $\Delta 4$ -desaturase originates from *Ostreococcus* RCC809. All the omega-3 LC-PUFA biosynthesis genes originate either from algal, moss or fungal gene sequences. Together, the seven genes confer the ability to produce one or both of the omega-3 long-chain polyunsaturated fatty acids eicosapentaenoic acid and docosahexaenoic acid in the seed oil of the plant.

The third construct ASX-A2, encodes three heterologous genes which direct the synthesis of the ketocarotenoid astaxanthin, each under the control of seed promoters. It also encodes the selectable marker gene BAR, which confers resistance to glufosinate-ammonium herbicides.



The fourth line includes a stack of constructs ASX-A2 and B7.2.

3. Particulars of the consent to release:

(a) Maximum size of the release:

- i) The trial site will not exceed the limits of the existing (approximately) three hectare double-fenced site on the Rothamsted experimental farm at the location specified in **paragraph 3(c)**. The inner-most chain-linked fence will be considered the boundary of the trial site.
- ii) The total area of GMO(s) planted under this consent at the trial site over the full duration of the release period specified at **paragraph 3(d)**, shall not exceed 1000 square metres and such plants must be planted in accordance with the limitations and conditions of this consent.
- iii) The total area of GMO(s) planted in each experimental plot shall not exceed 125 square metres.
- iv) The stand density of GM Camelina in each experimental plot shall not exceed 300 plants per square metre.

(b) Purpose of the release:

To test the agronomic and yield performance of the GMO(s).

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

The release must be conducted at Rothamsted Research farm, Harpenden at map grid reference TL1213.

(d) Dates of the release period:

The release may only take place between 24th April 2016 and October 31st 2017.

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 18 April 2016 to release Genetically Modified Organisms: reference 16/R8/01

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

- (a) “GMO” means the genetically modified organism(s) 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 GMOs that are subject to these limitations and conditions and “consent” in this schedule shall be construed accordingly;
- (e) “release” means planting the GMO(s) 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 GMO(s) 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 **paragraph 3(a)** 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;
- (j) “experimental plot” means any area of land within the trial site planted with the GMO(s), which includes areas of bare ground left between parts planted with the GMO(s);
- (k) “trial” means the release of the GMO(s) and management of that release in accordance with the limitations and conditions of this consent.

General conditions of this 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 planting** of the GMO(s) 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 section 111(10) of the Environmental Protection Act 1990 and regulation 22 of the Genetically Modified Organisms (Deliberate Release) Regulations 2002; and
- (2) the first release of the GMO(s) 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) Either:

- a) The experimental plots shall be surrounded by a pollen barrier of non-modified *C. sativa*, which is to be sown on the same day and with the same variety as the GMO(s), at an average stand density of 150 plants per square metre. The pollen barrier must be at least 6 metres wide, and must begin no more than 0.5 metres from the GMO(s) in the experimental plot.

Or,

- b) there is a separation distance of at least 50 metres between the outer limit of the experimental plots and any wild *Camelina* species, and a separation distance of at least 50 metres from the outer limit of the trial site (the innermost chain-linked fence surrounding the trial site) and any cultivated *Camelina* species.

In the case that (a) is compromised, (b) will be enforced.

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

- (1) the six figure grid reference of the experimental plots within the trial site;
- (2) a plan showing the location of the trial site; and
- (3) details of the GMO(s) to be planted

at least one week before GMO(s) are 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 away from the experimental plots during and after sowing and from the first signs of emergence of *C. sativa* flowers;
- (2) Control plants of any *Camelina* species found within the separation distance (if used) before flowering, by hand-pulling or herbicide application;
- (3) After sowing, any drilling equipment used should be thoroughly cleaned before leaving the trial site;
- (4) Prior to harvest the combine to be used should be prepared so as to minimise any loss of small seeds through augers, sieves, etc. The combine should be one designed to minimise admixture between plots and to facilitate cleaning down;
- (5) After harvest the plot combine should be thoroughly cleaned on the most recently harvested experimental plot before the combine leaves the trial site;
- (6) Clean all machinery (including wheels and tyres) used on the trial site thoroughly before leaving the trial site;
- (7) Ensure that all personnel entering the trial site take appropriate steps to eliminate transfer of GMO(s) via clothing, footwear and vehicles from the trial site;
- (8) Ensure that all material (including straw) dislodged during cleaning of machinery is removed from the trial site immediately and ensure that it is transferred for contained use or disposal in accordance with **Condition 7**;
- (9) Following harvest of an experimental plot within the trial site, leave the whole plot fallow until the following spring, then shallow cultivate the experimental plot to a depth of no more than 5 cm to stimulate germination of any volunteers in the seed bank;
- (10) Following harvest of an experimental plot within the trial site, inspect the experimental plot and the trial site (excluding other experimental plots that are

in use) for volunteers at least once a month from February until October for a minimum of two years. Monitoring may cease if a) no volunteers are identified in the second year of monitoring or b) after the first volunteer-free year. Volunteers should be allowed to emerge sufficiently for identification and numbers should be recorded (approximately if necessary), before volunteers are then destroyed by herbicide application or hand-pulling before flowering. Data on the numbers of volunteers should be provided to Defra as specified in **Condition 10** below;

- (11) Refrain from cultivating any crop intended to enter the food and/or feed chain on the trial site until after termination of the trial.

Material removed from the trial site

Condition 7. The consent holder must ensure that **all** harvested seed and material collected during cleaning of machinery and 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 or incineration.

General monitoring requirements

Condition 8. The consent holder must:

- (1) Inspect the entire trial site during the period of cultivation of GMO(s) 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 of volunteers and provide this information to the Secretary of State on request as soon as possible.

Reports

Condition 9. The holder of the consent must 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) by December 1st in the first year of the trial period. 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(s),
- (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**, the consent holder must submit a report in the format specified in the Annex to Decision 2003/701/EC to the Secretary of State on each anniversary of the date that the first report is submitted in accordance with **Condition 9**. 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,
- (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(s) 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 has been controlled in accordance with **Condition 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 her/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(s) 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 she/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 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.