Department for Environment Food & Rural Affairs

From George Eustice MP
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Dear Sirs

ENVIRONMENTAL PROTECTION ACT 1990, SECTION 111: CONSENT TO RELEASE GENETICALLY MODIFIED ORGANISMS, REFERENCE: 18/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:
   Genetically modified (GM) plant lines containing genetic elements carried on binary vectors pSUN2 or pRS-3G. The GM lines contain one or more of the fourteen DNA constructs developed using these vectors. These constructs are:
   - Construct DHA2015.1 containing seven heterologous genes under the control of seed-specific promoters that direct the synthesis of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). It also contains a visual selectable marker gene, *DsRed*.

   - Construct DHA2015.2 containing six heterologous genes under the control of seed-specific promoters that direct the synthesis of EPA and DHA. It also contains a visual selectable marker gene, *DsRed*.

- Construct DHA2015.3, which is identical to construct DHA2015.2 except that the C20-elongase in DHA2015.2 (from *Ostreococcus tauri*) has been replaced by the C20-elongase from *Ostreococcus* RCC809 in construct DHA2015.3.

- Construct DHA2015.4, which is identical to construct DHA2015.3 except that a Δ4-desaturase from *Ostreococcus RCC809* has been replaced by a Δ4-desaturase from *Thalassiosira pseudonana*.

- Construct DHA2015.5, which is identical to construct DHA2015.1 except that it also contains a Δ15-desaturase from *Perilla fructans*.

- Construct EPA2015.4 containing four heterologous genes under the control of seed-specific promoters that direct the synthesis of EPA. It also contains the visual selectable marker gene, *DsRed.*

- Construct EPA2015.8, which is identical to construct EPA2015.4 except that (i) construct EPA2015.8 contains a Δ15-desaturase from *Perilla fructans* not present in construct EPA2015.4; (ii) a Δ6-desaturase from *Mantionella squamata* (MsD6) in construct EPA2015.4 has been replaced by a Δ6-desaturase from *Ostreococcus tauri* in construct EPA2015.8 and (iii) a Δ5-desaturase from *Emiliana huxleyi* (EhD5) in construct EPA2015.4 has been replaced by a Δ5-desaturase from *Thraustochytrium* (TcD5*)* in construct EPA2015.8.

- Construct EPA2016.1, which is identical to construct EPA2015.4 except that (i) the Δ5-desaturase from *Emiliana huxleyi* (EhD5) in construct EPA2015.4 has been replaced by a Δ5 -desaturase from *Thraustochytrium* (TcD5) in construct EPA2016.1; (ii) transcription termination sequences from the *Camelina sativa fad2* gene and the *Arabidopsis thaliana hsp18.2* gene have been included in construct EPA2016.1, whereas they are not present in construct EPA2015.4 (iii) and the *bar* selectable marker gene that confers tolerance to glufosinate-ammonium herbicides has also been included in construct EPA2016.1.

- Construct ASX-A2 containing three heterologous genes under the control of seed-specific promoters that direct the synthesis of astaxanthin. It also contains

the selectable marker gene, *bar*, which confers tolerance to glufosinate-ammonium herbicides.

- Construct THIO14 containing DNA encoding the *fatb2* thioesterase gene derived from *Cuphea palustris* under the control of a seed-specific promoter. It also contains a visual selectable marker gene, *DsRed*.

- Construct MaMa14-6 contains the *fatb2* thioesterase gene from *C. palustris* and two genes that direct the synthesis of wax esters. These are a fatty acyl-CoA reductase (*far*) gene from *Marinobacter aquaeolei* and a wax synthase (*ws*) gene from *Marinobacter hydrocarbonoclasticus.* All three genes are under the control of seed-specific promoters. This construct also contains a visual selectable marker gene, *DsRed*.

- Construct GDH and construct GDH-PP. Both constructs contain genes derived from *Escherichia coli* that encode the D, E and F subunits of the glycolate dehydrogenase complex. In construct GDH, a single polypeptide is produced. In construct GDH-PP, three polypeptides are generated. Both constructs also contain a visual selectable marker gene, *DsRed*.

- Construct MAP22 containing the *Arabidopsis thaliana* gene *At4g23060* under the control of the 35S promoter from Cauliflower mosiac virus. It also contains a visual selectable marker gene, *DsRed*.

3. Particulars of the consent to release:

(a) Location of the release ("trial sites"):

If the release take place, this must only be conducted at Rothamsted Research farms at: Harpenden: at map grid reference TL1213 and/ or Brooms Barn at map grid reference: TL7565.

(b) Maximum size of the release:

i) There are two trial sites. The locations of the trial sites are specified in **paragraph 3(a)**. The total area of GMO(s) planted under this consent at the trial sites over the full duration of the release period specified at **paragraph**

3(c), shall not exceed 18 000 square metres and such plants must be planted in accordance with the limitations and conditions of this consent.

ii) The total area of GMO(s) planted in each year of the release period shall not exceed 5 000 square metres.

(c) Dates of the release period:

The release may only take place between 1st May 2018 and October 31st 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.

GEORGE EUSTICE MP

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

Schedule to the Letter of Consent dated 17th May 2018 to release Genetically Modified Organisms

Reference 18/R8/01

LIMITATIONS AND CONDITIONS OF CONSENT

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

(a) "GMO(s)" 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 trial sites 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(s) until the termination of the trial;

(i) "trial sites" means the areas 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;

(j) "experimental plot" means any area of land within the trial sites 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 sites to personnel who have been informed of the limitations and conditions of the consent, and

(2) allow the GM Inspectorate access to the trial sites 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 at each trial site shall be surrounded by a pollen barrier of non-modified *Camelina sativa*, which is to be sown on the same day and with the same base variety as the GMO(s), at an average stand density of no less than 150 plants per square metre. The pollen barrier, if sown, must be at least 6 metres wide, and must begin no more than 0.5 metres from the GMO(s) in the experimental plots.

Or,

b) there is a separation distance of at least 50 metres between the outer limit of the experimental plots at each trial site and any wild Camelina species, and a separation distance of at least 50 metres from the outer limit of the experimental plots to 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 sites;

(2) a plan showing the location of the trial sites; 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 sites

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 sites;

(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 combines should be 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 or on its pollen barrier, before the combine leaves a trial site;

(6) Clean all machinery (including wheels and tyres) used on the trial sites thoroughly before leaving a trial site;

(7) Ensure that all personnel entering the trial sites take appropriate steps to eliminate transfer of GMO(s) via clothing, footwear and vehicles from the trial sites;

(8) Ensure that all material (including straw) dislodged during cleaning of machinery is removed from the trial sites immediately or stored securely on site and ensure that it is transferred as soon as practicable for contained use or disposal in accordance with **Condition 7**;

(9) Following harvest of an experimental plot within the trial sites, 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 a trial site, inspect the experimental plot and the surrounding trial site (excluding other experimental plots in use) for Camelina volunteers at least once a month from February until October for a minimum of two years. Monitoring may cease if a) no Camelina volunteers are identified in the second year of monitoring or, following this, b) after the first Camelina 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 camelina 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 sites until after termination of the trial.

Material removed from the trial sites

Condition 7. The consent holder must ensure that **all** harvested seed and material collected during cleaning of machinery and removed from the trial sites 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 sites 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 Camelina 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 31st 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 experimental plot(s) 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 Camelina volunteers, including details of the number of volunteers detected each month in the trial sites,

(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 sites.

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 sites.

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

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.

GEORGE EUSTICE MP