Department
for Environment
Food & Rural Affairs

Nobel House
17 Smith Square
London SW1P 3JR

T 08459 335577
helpline@defra.gsi.gov.uk
www.defra.gov.uk

Rothamsted Research
West Common
Harpenden
Hertfordshire
AL5 2JQ

8 June 2013

From Lord de Mauley
Parliamentary Under Secretary

ENVIRONMENTAL PROTECTION ACT 1990, SECTION 111: CONSENT TO RELEASE GENETICALLY MODIFIED ORGANISMS. REFERENCE: 11/R8/01

1. Pursuant to section 111 of the Environmental Protection Act 1990, I grant consent to Rothamsted Research 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 organism (GMO) is wheat *Triticum aestivum*, which has been transformed with one or both of the following synthetic genes: *(E)-β-farnesene synthase* and *farnesyl diphosphate synthase*. In addition both constructs contain the constitutive *Ubi* promoter and *nos T* terminator, the *bar* gene conferring herbicide tolerance and may contain further sequences of bacterial origin including the neomycin phosphotransferase (*nptI*) selectable marker gene.

3. Particulars of the consent to release:

(a) Maximum size of the release:

i) The trial site must not exceed 12,800 square metres

ii) The trial site shall comprise two plots, each not exceeding 6,400 square metres, located at least 20 metres apart.

iii) Sowing density at the trial site must not exceed 500 seeds per square metre

(b) Purpose of the release:

To test field performance of the novel wheat plants resistance to aphids.

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

The release must be conducted at the Rothamsted Research farm, Harpenden at map grid reference TL 1213.

(d) Dates of the release period:

The release may only take place between 1 March 2012 and 31 December 2013.

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 sincerely

Rupert de Mauley

Schedule to the Letter of Consent to release Genetically Modified Organisms
Reference 11/R8/01

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(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 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) "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 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 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) in each year of the trial only one of the two plots can be used at one time for the planting of the GMOs. The plots are described in paragraph 3(a)(ii) of the letter of consent;

(2) a wheat pollen barrier of at least 2 metres width surrounding the GMOs is sown on the same day as the GMOs with the variety *Cadenza* within the perimeter of the plot;

(3) during the release period, cereals 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 cropped with a non cereal crop.

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) details of the GM wheat to be planted

at least one week before the GMOs are sown. 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 trial site during and after sowing and at the first signs of emergence of wheat ears

(2) control *Elytrigia repens* (common couch grass) before flowering within the plot on which the GMOs are planted and surrounding area of at least 20m width referred to in condition 4(3) ("the 20m border") either by hand pulling or application of a glyphosate herbicide between 1st May and 30th September in each year of the trial.

(3) harvest non-GM wheat grain after harvesting GM wheat grain 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 other machinery (including wheels and tyres) used on the trial site thoroughly and over plastic sheeting on 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 disposal in accordance with **Condition 7**;

(7) when GM and non-GM grain is harvested on a plot, immediately remove this material from the trial site and lightly till that plot to a depth of approximately 5cm;

(8) when GM and non-GM grain is harvested on a plot, following the harvest, inspect that plot and the 20m border 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 of the

following year and control them in accordance with condition 6(9)(b) below.

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

a. leave the plot fallow;

b. treat all volunteers on the plot and the 20m border, including volunteers from non GMOs, with an application of glyphosate herbicide prior to inflorescence formation;

(10) refrain from cultivating cereal crops intended to enter the food and/or feed chain on the trial site until August 2014.

(11) GMOs that are sown in the autumn of 2013 shall be treated with broad-spectrum herbicide(s) before the end of December 2013. Thereafter:

a. the plot on which these plants are grown shall be monitored at least once a month from January 2014 until June 2014. GM wheat plants exhibiting stem elongation shall be treated with broad spectrum herbicide(s) and/ or mowed before the plot is monitored again;

b. dead GM plant material shall be left on the plot;

c. the plot shall be left fallow and uncultivated until June 2014;

d. cereal crops intended for the food and/or feed chain shall not be grown on the trial site before August 2014.

Material removed from the trial site

Condition 7. The consent holder must ensure that **all** harvested grain 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 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) monitor the behaviour of the target and non target insects on the plot on which the GMOs are planted once a week from the time of emergence until (a) harvest and removal of grain from the trial site, or (b) treatment with broad-spectrum herbicide(s) in the case

of the autumn-sown crop, and terminate the trial immediately if unexpected significant changes in behaviour are observed

(3) 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 within one month of harvesting or terminating the GMOs on a plot 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. 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 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 or observed adverse effects on insect behaviour as referred to in Condition 8(1)

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.