Dear Sir,

ENVIRONMENTAL PROTECTION ACT 1990, SECTION 111:
CONSENT TO RELEASE GENETICALLY MODIFIED ORGANISMS
REFERENCE: 04/R39/1

1. The Secretary of State for Environment, Food and Rural Affairs, in accordance with section 111 of the Environmental Protection Act 1990, hereby grants consent for the release of genetically modified organisms as more particularly set out in paragraph 2 and subject to the limitations and conditions set out in the Schedule.

2. Particulars of the consent to release-

(a) Consent to release granted to:

(b) Genetically Modified Organism to be released:
The genetically modified organism (GMO) is *Pseudomonas fluorescens* variant 23.10 (a soil bacterium). The host organism is *P. fluorescens* strain SBW25, which has been transformed with the phenazine-1-carboxylic acid (PCA) biosynthetic operon *phz ABCDEFG*, derived from *P. fluorescens* 2-79 (Thomashow and Weller, 1998) and with a gene encoding neomycin phosphotransferase (*nptI*) from the mini-Tn10Km of phage λ1105 (Way et al., 1984).

(c) Maximum number of genetically modified organisms to be released:
A maximum of $5 \times 10^{12}$ *Pseudomonas fluorescens* variant 23.10 may be released in accordance with the limitations and conditions of this consent.

(d) Purpose of the release:
The object of this release is to evaluate the environmental impact of *P. fluorescens* 23.10 on soil microorganisms. As *P. fluorescens* variant 23.10 associates with plant roots, non-GM wheat plants will be grown on the trial site.
(e) **Location of the release:**

(f) **Type and area of release:**
Introducing *Pseudomonas fluorescens* variant 23.10 into the soil in an area no greater than sixty-five square metres.

(g) **Date by which the release shall take place:**
30th June 2004.

3. Before granting this consent, the Secretary of State has-

(a) taken advice from the Advisory Committee on Releases to the Environment; and

(b) agreed the terms, limitations and conditions of this consent, insofar as they relate to the protection of human health and safety, with the Health and Safety Executive.

Yours faithfully

Dr L Smith
By authority of the Secretary of State for Environment, Food and Rural Affairs.
Schedule to the Letter of Consent dated 30th April 2004, to release Genetically Modified Organisms

Reference 04/R39/1

LIMITATIONS AND CONDITIONS OF CONSENT

Reference in this Schedule to:

(a) "GMO" means the genetically modified organism set out in paragraph 2(b) of the letter of consent;
(b) "GMO area" means that area of the trial site where the GMO is released in accordance with the consent and more particularly described in Condition 2;
(c) "border areas" means those areas of the trial site surrounding the GMO area referred to in Condition 2;
(d) "trial" means the release of the GMO and management of that release in accordance with the limitations and conditions of this consent;
(e) "trial period" means the period from the release of the GMO until the termination of the trial;
(f) "trial site" means the area of land to be used for the trial, as referred to in Condition 2 situated at the location set out in paragraph 2(e) of the letter of consent;

General requirements of this consent

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

(1) subject to the conditions below, comply with the relevant conditions contained or referred to in section 112 of the Environmental Protection Act 1990,
(2) restrict human access to the trial site to personnel who have been informed of the limitations and conditions of the consent and
(3) allow the GM Inspectorate access to the trial site on request.

Size and description of the trial site.

Condition 2. The consent holder shall ensure that:

(1) the total area of land used for the trial shall not exceed four hundred square metres.
(2) the trial site shall be surrounded by a gated perimeter fence suitable to prevent access by deer and rabbits.
(3) there shall be a border area at least two metres wide within the perimeter fence.
(4) within the border area described in (3) above, there shall be an area at least half a metre wide reserved for the planting of wheat plants.

(5) within the area described in (4) above, there shall be a further border area at least one metre wide.

(6) the GMO area shall be within the area described in (5) above.

Management of the site

Condition 3. The consent holder shall:

(1) ensure that any wheat plants in the GMO area and in the area referred to in condition 2(4) are sown within forty-eight hours of the first release of the GMO.

(2) ensure that no wheat plants are sown in the border areas during the trial.

(3) harvest wheat plants by hand and remove them from the trial site before 1st October 2004.

(4) remove any plants growing in the border areas mechanically or by hand at least once a week.

(5) after harvesting and removal of wheat plants, remove all plants growing on the trial site mechanically or by hand at least once a week.

Material removed from the trial site

Condition 4. The consent holder shall ensure that material removed from the trial site has either been:

(1) treated to destroy the GMO using methods that are compatible with the Genetically Modified (Contained Use) Regulations, 2000 or

(2) placed in sealed, labelled bags or containers for transfer to conditions under which the Genetically Modified (Contained Use) Regulations, 2000 apply.

Monitoring

Condition 5. The consent holder shall:

(1) during the trial period inspect at least every month to ensure that the limitations and conditions of the consent are being met.

(2) during the trial period, analyse soil samples taken from the GMO area, the border areas and the guard row area of the trial site for the amount of the GMO.

(3) within one week of 1st October 2004 and thereafter at least every month, sample soil outside of the trial site, which is within ten metres of the perimeter fence and monitor for levels of the GMO.

(4) ensure that soil samples taken from within the GMO area are not combined with those from other areas prior to analysis for GMO content.
(5) maintain raw data and reports of inspections and monitoring of GMO levels and provide this information to the Secretary of State on request as soon as possible.

Termination of the trial

**Condition 6.** The following limitations and conditions apply:

(1) if during the period 1\(^{st}\) October 2004 to 1\(^{st}\) October 2006, the amount of the GMO in each of the soil samples is below ten cfu per gram of soil for three consecutive months, the consent holder may apply to the Secretary of State to terminate the trial, otherwise the provisions of (2) apply.

(2) the consent holder shall submit a plan to the Secretary of State before 1\(^{st}\) November 2006 for her approval detailing what action he shall take to reduce the amount of the GMO to below ten cfu per gram of soil in areas where the GMO has been detected.

(3) within one month of receiving an application to terminate the trial under the provisions of (1) above, the Secretary of State shall notify the holder of the consent as to whether the trial can be terminated or whether further monitoring shall be carried out. If further monitoring is required by the Secretary of State, the notification shall provide details of the monitoring required.

(4) within one month of receiving the plan referred to in provision (3), the Secretary of State shall notify the holder of the consent whether the plan has been approved and outline the criteria for termination of the trial.

Reports

**Condition 9.** The holder of the consent shall submit a report to the Secretary of State before 1\(^{st}\) November 2004 (the first report) which includes:

(1) the amount of the GMO detected each month within the GMO area, the border areas and the wheat guard row area.

(2) the assessment of any risks or actual or potential adverse effects to human health or the environment from the GMO.

(3) whether the trial progressed as planned and if it did not, what occurred and any additional measures that were taken and will be taken and why.

**Condition 10.** Subject to condition 11, the consent holder shall submit reports to the Secretary of State on each anniversary of the date that the first report is submitted, which shall include the following information:

(1) details of monitoring for the amount of the GMO, including details of the sampling procedure and in particular how many samples were analysed and from where they were taken,

(2) the re-evaluation of monitoring requirements, including whether the consent holder proposes to terminate the trial and why,
(3) any additional precautions considered necessary to minimise the dispersal of the GMO outside of the trial site.

Condition 11. The reports referred to in condition 10 shall be submitted until the Secretary of State has agreed that the trial has been terminated.

Emergency action

Condition 12. Subject to condition 13, in the event of an emergency, the consent holder shall:

(1) take immediate and appropriate preventative and remedial action to limit dispersal of the GMO.

(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.

(3) submit a plan to the Secretary of State for her 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. None of the provisions in condition 12 shall prevent the Secretary of State taking such action as she reasonably believes is necessary to prevent, reduce or remedy any risk of harm to human health or of damage to the environment.