Environmental Protection Agency
An Ghníomhaireacht um Chaomhnú Comhshaoil

Headquarters,
PO Box 3000,
Johnstown Castle Estate,
County Wexford,
Ireland

Consent for Notification No. B/IE/06/01

Consent to a deliberate release of GM potato lines (with improved resistance to late potato blight) into the environment for purposes other than for placing on the market (field trials).

GMO Register Number:	208
Location of Deliberate Release:	Arodstown, Summerhill, County Meath.
Notifier:	BASF Plant Science GmbH

DECISION

The Environmental Protection Agency, in exercise of the powers conferred on it by the Genetically Modified Organisms (Deliberate Release) Regulations [S.I. No. 500 of 2003] for the reasons hereinafter set out, grants this consent to:

BASF Plant Science GmbH, Carl-Bosch-Str. 38 D-67056 Ludwigshafen, Germany

to carry out the deliberate release of GM potato lines (with improved resistance to late potato blight) into the environment for purposes other than for placing on the market at one location:

Arodstown, Summerhill, County Meath.

subject to ten (10) conditions as set out in the conditions attached hereto.

Sealed by the Seal of the Agency on this the 4th day of May, 2006

PRESENT when the seal of the Agency was affixed hereto

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Dr. Padraic Larkin
Director

REASONS FOR THE DECISION

The Environmental Protection Agency is satisfied, on the basis of the information provided, that subject to compliance with the conditions of this consent the notifier will ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment. Furthermore the Agency believes that the risk to human health and the environment from the deliberate release of these GMOs are low.

In reaching this decision the Agency has considered all the documentation submitted in relation to this notification including all of the representations made by the public and having regard to the expert opinion that the Agency received on the notification and the report of its inspector.

The consent is granted in accordance with Article 18 (5) (a) of the Genetically Modified Organisms (Deliberate Release) Regulations [S.I. No. 500 of 2003] subject to the attached consent conditions.

INTERPRETATION

Agency	The Environmental Protection Agency (EPA).
Competent Authority	The EPA is the Competent Authority for the purposes of the Genetically Modified Organisms (Deliberate Release) Regulations 2003- S.I. No. 500 of 2003.
Consent	Consent issued in accordance with Article 18 (5) of the Genetically Modified Organisms (Deliberate Release) Regulations 2003- S.I. No. 500 of 2003.
Directive	Means Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.
Deliberate Release	Means any intentional introduction into the environment of a genetically modified organism or a combination of genetically modified organisms for which no specific containment measures are used to limit their contact with, and to provide a high level of safety for, the general population and the environment, and cognate words and expressions shall be construed accordingly.
Environmental Risk Assessment	Means an evaluation, carried out in accordance with the Second Schedule, of risks to human health or the environment, whether direct or indirect, immediate or delayed, which the deliberate release or the placing on the market of a genetically modified organism may pose.
EPA	Environmental Protection Agency.
GMO	Genetically Modified Organism means an organism, other than a human being, in which the genetic material has been altered in a way that does not occur naturally by mating or natural recombination, or by a combination of both.

GMO Register	A register of GMO users in Ireland, which is available for inspection at Agency, headquarters by any person during office hours. Each register entry provides details of both deliberate release and contained use of GMOs in Ireland.
GMO Regulations	Genetically Modified Organisms (Deliberate Release) Regulations 2003- S.I. No. 500 of 2003.
Notification	Means the submission of required information to the Competent Authority.
Notifier	Means any legal or natural person submitting a notification or, where the context so requires, any legal or natural person responsible for a deliberate release or for a placing on the market, or for meeting any other requirement of these Regulations in relation to a deliberate release or a placing on the market.
Obligations	A person who carries out a deliberate release or placing on the market shall ensure that all appropriate measures are taken to avoid adverse effects on human health or the environment arising from the deliberate release or placing on the market. Without prejudice to any other provision of these Regulations, a person who proposes to submit a notification for consent in accordance with Part II to deliberately release a genetically modified organism or in accordance with Part III to place a genetically modified organism on the market shall, prior to submitting the said notification, carry out an environmental risk assessment in accordance with the Second Schedule. In making an assessment pursuant to paragraph (a), the person proposing to carry out the deliberate release or placing on the market shall give particular attention to the risks to human health or the environment posed by the deliberate release or the placing on the market of a genetically modified organism which contains one or more genes expressing resistance to antibiotics used in human or veterinary medicine.

Organism	Has the meaning given to it in section 111 of the Environmental Protection Act 1992 and includes any biological entity capable of replication or of transferring genetic material.

Consent Conditions for Notification No. B/IE/06/01

Condition 1 Scope

(i) This consent is for the purposes of compliance with the Genetically Modified Organisms (Deliberate Release) Regulations-S.I. No. 500 of 2003 only, in relation to the carrying out of field trials as specified in Condition 2.

(ii) Nothing in this consent shall be construed as negating the notifiers statutory obligations or requirements under any other enactments or regulations.

(iii) No modifications to the deliberate release, as described in the notification and supporting information submitted to the Agency, shall take place without the written approval of the Agency.

(iv) The Agency may, if it becomes aware of new information that, following evaluation of the matters concerned, in its view could have significant consequences for the risks to human health or the environment,

(a) terminate the deliberate release trial or

(b) modify or suspend the conditions of this consent.

Reason: To clarify the scope of the consent

Condition 2 Duration, Location and Area of the Trials

This consent is for experimental trials with genetically modified (GM) potatoes at one (1) location: Arodstown, Summerhill, Co Meath.

The GM potato lines can be planted in the years 2006 to 2010 with planting taking place during April/May and harvesting in October of each year. Each experimental site must be monitored for a minimum of four (4) years post planting and the site planted in 2010 must be monitored until the Autumn of 2014.

The trial area shall not exceed 1 ha (2.471 acres) in size for planting purposes in any given year.

Reason: To clarify the Duration, Location and Area of the trials.

Condition 3 Duty of the notifier to inform the Agency of new information

If, following the grant of this consent, new information relevant to the deliberate release becomes available that could have consequences for the risks to human health or the environment, the licensee shall:

- inform the Agency as soon as the new information becomes available;
- take necessary measures to protect human health and the environment; and
- inform the Agency as soon as possible of such further measures the licensee has taken or proposes to take in relation to the matters concerned.

Reason: To provide and update information on the trial

Condition 4 Post-release procedures

After completion of the deliberate releases, the notifier shall send to the Agency the results of the deliberate releases in a format as set out under Commission Decision C (2003) 3405 and in particular shall submit:

- a post-release evaluation of the risks to human health and the environment, and
- where appropriate, a statement on the results of the deliberate release in relation to any product, or type of product, in respect of which consent to placing on the market may be sought.

Reason: To make provision for the reporting to the Agency of any impacts of the completed trials and any associated risks.

Condition 5 Management of the Field Trial

(i) The notifier shall provide detailed written instructions and procedures on trial management, operations and maintenance for the trial site for each growing season, which must include information on the following:

a. site plan,
b. methods of planting, harvesting and trial termination,
c. relocation (within the designated field) in years 2-5,
d. methods to minimise seed dispersal from the experimental site,
e. storage (before planting and post harvest),
f. monitoring plan for the duration of the trials
g. monitoring for groundkeepers and True Potato Seed (TPS),
h. transportation off-site,
i. site security and
j. emergency plans.

Instructions and procedures as outlined above must be made available to and used by the staff involved in the execution of the trial. A copy of the instructions and procedures must be forwarded to the Agency for agreement at least one week in advance of planting.

(ii) The trial crop must be examined on a weekly basis during the growing season. Any tubers exposed above the soil surface must be removed or covered as soon as practicable.

(iii) Any berries formed on any of the potato plants must be removed, before destruction of the potato haulms by spraying, and stored in a safe manner until they are transported off-site as per condition 5 (v).

(iv) All tubers must be removed from the soil surface post-harvest to prevent possible dispersal to areas outside the trial area. A number of harvest cultivations of the trial site should be carried out immediately after the initial harvest to minimise the number of tubers remaining in the soil.

(v) All tubers (GM and non-GM) including any excess tubers from the plantings and berries from the experimental site must be collected in labelled bags and placed in labelled sealed containers before being transported outside of Ireland. The chopping of potato tubers on site is prohibited.

(vi) All GM potatoes must be stored both prior to planting and after harvest in a secure place separate from any non-GM commercial potatoes. An accurate detailed record must be maintained at the

storage location of all containers, used for the storage of harvested tubers from the experimental site.

(vii) The time and date of the transfer off site (outside of Ireland) of all potatoes (GM, non-GM and berries) from the experimental site must be documented and maintained by the notifier. The details of such records shall be submitted to the Agency within one week of the transfer off site.

(viii) All farm machinery and equipment must be thoroughly cleaned prior to, and after, sowing, field operations and harvesting. All vehicles used for the transport of all potatoes (GM, non-GM and including berries) must be checked to ensure that spillage does not occur during transport to storage facilities and during export outside of Ireland.

(ix) A spring cereal crop must be planted in the trial area in the year after each potato trial. All potato tubers arising during this cultivation must be destroyed through the application of a commercially approved herbicide.

(x) The trial site must be defined and measured in respect of fixed points in the environment, such that it can be identified in subsequent years. Details of this measurement must be recorded and a copy of the record provided to the Agency at least one week prior to planting.

(xi) Each trial site must be monitored for at least four years post harvest for any sign of emergence of groundkeepers or True Potato Seed (TPS), and for longer periods if so required by the Agency should groundkeepers or TPS persist. The post-release monitoring strategy, which includes both a case-specific and a general surveillance component as outlined in Section G of the notification and subsequent information submitted to the Agency on 22nd March 2006, must be implemented.

(xii) A separation distance of 40 metres must be used to separate the experimental trial from any commercial potato planting including organic production that might take place in or around the trial area. The potato trial area in year 2 and subsequent years shall have a 6 metre separation border, separating the new trial site from the previous trial site.

(xiii) The planting of commercial non-GM potato crops in the trial area is prohibited for a minimum of 4 years after the trial has concluded. The planting of a seed potato crop in the experimental site area is prohibited for a minimum of 6 years after the trial has concluded.

(xiv) Animal feeding studies based on EFSA guidance (Guidance document of the Scientific Panel on Genetically Modified

Organisms for the risk assessment of genetically modified plants and derived food and feed, the EFSA Journal (2004) 99, 1-94) and other appropriate International standards including the publication by Prescott *et. al*. 2005, J. Agric. Food Chem. 2005, 9023-9030, must be carried out prior to second year's planting using tubers from the first year's GM potato harvest at this site. The results of the animal feeding studies shall be forwarded within one month of completion to the Agency.

(xv) The GM and non-GM potatoes from this field trial shall not be used for food or feed other than in the context of the animal feeding trials referred to in (xiv) above.

(xvi) The trial sites must be secured adequately to prevent, minimise and reduce ingress by small and large animals and unauthorised access to the site. Details of the measures to be taken are to be agreed in writing by the Agency prior to planting.

Should it prove necessary, the notifier shall carry out the emergency plans outlined in Section G of the notification.

(xvii) The notifier shall provide details of measures, to be agreed in advance by the Agency, to protect tubers (during planting, growing and harvesting) from possible bird intrusion at the experimental site.

Reason: To make provision for management of the trial on a planned basis, having regard to the desirability of ongoing assessment, recording or reporting of matters affecting the environment and human health.

Condition 6 Reporting to the Agency

The Agency shall be informed in writing of the planting and harvesting dates for each planting season at least one week prior to planting and harvest.

- A copy of the experimental plan for each site shall also be sent (one week prior to planting) to the Agency indicating the location of the GM tubers in the experimental plots.

- A report on the monitoring activities outlined in the notification, trial results and the notifier's conclusions must be submitted to the Agency on a monthly basis during the growing season for 2006, 2007, 2008, 2009, 2010 up to and including 2014 (post release monitoring) and summarised in an annual report by 31st December

of each calendar year. For the 2nd, 3rd and 4th year monitoring programme on sites that were planted with GM potatoes, a report must be sent in the Spring, Summer and Autumn of each year.

Reason: To provide for the collection and reporting of adequate information on the trial.

Condition 7 Provide Detection method for identification of the GM potatoes

Prior to planting the notifier shall provide a validated protocol for the identification of the GM potato plants (leaf and tuber) based on conventional PCR. All stages of the procedure including initial sample preparation and DNA extraction in this protocol of detection shall be included. The protocol shall also include a species specific endogenous control procedure for conventional PCR. The protocol should be fully documented in standard operating procedure format to ensure consistent application so that a laboratory can easily replicate the exact procedure used. Refer to ISO 17025 for the type of information that should be included in such a detection method.

The notifier must provide positive and negative control samples if requested by the Agency.

Reason:To provide methodology and samples for detection purposes.

Condition 8 Sampling the trial site.

Leaf or tuber tissue may be collected from the trial site at any time post planting by the Agency, or its Agent, in order to verify that released potato lines carry the t-DNA described in the notification. Any costs incurred by the Agency for this testing will be charged to the notifier.

The Agency, or its Agent, shall be allowed to take other samples from the experimental site for the purpose of post release monitoring.

Reason:To ensure that the Agency can identify the GM potatoes.

Condition 9 Post-release Monitoring studies connected the GM potato trial site

Post release monitoring studies, outlined below, shall be carried out by an independent contractor (to be agreed by the Agency) on behalf of the notifier. All costs incurred in carrying out these studies will be borne by the notifier. This monitoring is in addition to the monitoring plan detailed in Section G of the notification and the further information submitted to the Agency on 24th February 2006. The studies shall include:

- Measurement of indicators of biodiversity (to include a baseline comparision) that might be affected by the deliberate release (direct or indirect, immediate or delayed) both above and below ground **(**e.g., the potential effects, both positive and negative, of the GM potatoes on beneficial soil microbes).

- Potential pollen flow to adjacent crops, e.g., planting both male sterile and fertile potato bait lines at different distances around the perimeter of the GM trial for each year of the trial. Berries that form on any bait plant shall be tested for the presence of viable true potato seed. Any resulting seedlings shall be analysed for the presence of the transgene.

- The potential for the GM tubers to persist both inside and outside the agricultural system over a period of 4 years.

Plans for these studies must be submitted to, and agreed in advance by, the Agency prior to planting. Results of these studies shall be sent to the Agency within one month of completion. The results of these studies will be made publicly available.

Reason: To confirm that assumptions regarding the occurrence and impact of potential adverse effects of the GMO or its use in the environmental risk assessment are correct.

Condition 10 Charges for carrying out site inspections, auditing & monitoring

The company shall pay the Agency a contribution of €55,506.00 per year (2006-2010) and a total of €3,600.00 per year for the years 2011-2014. The amount for 2006 shall be paid within one month of issue of this consent and by January 31st in subsequent years.

Reason:To provide for adequate financing for monitoring and financial provisions for measures to protect the environment