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

Consent for Notification No. B/IE/12/01

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

GMO Register Number:	G0469-01
Location of Deliberate Release:	Oak Park Co Carlow
Notifier:	Teagasc

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 implementing Directive 2001/18/EC on the deliberate release into the environment of GMOs], for the reasons hereinafter set out, grants this consent to:

Teagasc, Oak Park, Co Carlow

to carry out the deliberate release of GM potato line (potato strain *Solanum tuberosum* cv. Desiree transformed with the Rpi gene, Rpi-vnt1.1, from wild potato species *Solanum venturii* along with its native promoter and terminator, to produce the cisgenic line A15-031) into the environment for purposes other than for placing on the market at one location:

Oak Park, Co Carlow

subject to eight (8) conditions as set out in the conditions attached hereto.

Sealed by the Seal of the Agency on this the 25th day of July, 2012

PRESENT when the seal of the Agency was affixed hereto

Gerard O'Leary
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 from the deliberate release of the GM potato line (potato strain *Solanum tuberosum* cv. Desiree transformed with the Rpi gene, Rpi-vnt1.1, from wild potato species *Solanum venturii* along with its native promoter and terminator to produce the cisgenic line A15-031) into the environment.

Having regard to the location of the deliberate release field trial at Teagasc, Oak Park, Co. Carlow, and the proximity of the field trial to nearby receptors, the nature of the field trial as well as the processes to be undertaken in the operation and management of the field trial as described in the Notification, it is considered that the field trial, if managed, operated and controlled in accordance with the consent conditions will not result in the contravention of any relevant environmental quality standard or cause environmental pollution.

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

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 the 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 genetically modified organisms 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. The register entry provides details of the deliberate release of GMOs.

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 the above paragraph, 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 Agency Acts 1992 to 2011 and includes any biological entity capable of replication or of transferring genetic material.
Volunteer	A volunteer plant (or groundkeeper) is a crop growing from seed or vegetative material from a previous crop.

Conditions

Condition 1 Scope

1.1. 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 performance of field trials as specified in Condition 2.

1.2. Nothing in this consent shall be construed as negating the notifier's statutory obligations or requirements under any other enactments or regulations.

1.3. 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.

1.4. If the Agency becomes aware of new information that in its view could have significant consequences for the risks to human health or the environment, it may, following evaluation of the issues concerned:

1.4.1. terminate the deliberate release trial; or,

1.4.2. modify or suspend the conditions of this consent.

Reason:	**To clarify the scope of the consent**

Condition 2 Duration, location and area of the field trials

2.1. This consent is for experimental trials with genetically modified (GM) potatoes at one (1) location: Teagasc, Oak Park, Co Carlow.

2.2. The GM potato line may be planted in the years 2012, 2013, 2014, 2015 and 2016, with planting taking place each year from 1st March (1st July during 2012) and harvesting each year up to 31st October. Each experimental site must be monitored for a minimum of four (4) years post planting. The site planted in 2016 must be monitored until October 2020.

2.3. The field trial site, for purposes of planting shall not exceed an area of 2 hectares (4.942 acres) in size in any given year.

Reason:	**To clarify the duration, location and area of the field trials.**

Condition 3 Management of the Field Trial

3.1. Pre-planting

3.1.1. The notifier shall provide detailed written Standard Operating Procedures (SOPs) on trial management, operations and maintenance of the trial site for each growing season, to include information on the following:

3.1.1.1. Site map;
3.1.1.2. trial site plan;
3.1.1.3. methods of planting, harvesting and trial termination;
3.1.1.4. methods to minimise seed dispersal from the experimental site;
3.1.1.5. storage locations / methods (before planting and post-harvest);
3.1.1.6. monitoring plan for the duration of the trials;
3.1.1.7. monitoring methods for volunteers/groundkeepers and True Potato Seed (TPS),
3.1.1.8. transportation off-site;
3.1.1.9. site security; and,
3.1.1.10. emergency plans.

3.1.2. SOPs as outlined under 3.1.1 must be submitted to the EPA for approval at least one week in advance of commencement of the field trial. The SOPs must be made available to all personnel involved in the execution of the trial, prior to commencement of the trial.

3.1.3. SOPs as outlined under 3.1.1 must be made available on site for inspection by Agency personnel or nominated agent.

3.1.4. The trial site(s) must be defined and measured by GPS in respect of fixed points in the environment, such that it can be identified in subsequent years.

3.1.5. The trial site(s) must be secured adequately to prevent, minimise and reduce ingress by small and large animals and to prevent unauthorised access to the site.

3.2. Planting

3.2.1. A minimum separation distance of 40 metres must be implemented to separate the experimental trial from any commercial potato planting including organic production that might take place in or around the trial area.

3.2.2. All GM tubers / plantlets and non-GM comparator tubers / plantlets must be transported to the field trial site in separate, clearly labelled containers.

3.2.3. Any surplus GM tubers / GM plantlets and non-GM tubers / plantlets which are not sown must be collected in labelled bags, placed in labelled sealed containers and removed from the trial site for storage (condition 3.6) or destruction (condition3.8).

3.2.4. Any berries formed on any of the potato plants will be left to drop off the plants and they will be retained / contained within the trial site.

3.3. Monitoring

3.3.1. The trial crop / site where GM tubers and non-GM comparators are grown must be examined by the notifier at least twice weekly during the growing season.

3.3.2. Each trial site must be monitored monthly by the notifier for at least four years post-harvest for any sign of emergence of volunteers (groundkeepers) or True Potato Seed (TPS), and for longer periods if so required by the Agency should volunteers or TPS persist.

3.3.3. Any tubers exposed above the soil surface must be covered with soil or removed for destruction (condition 3.8) as soon as possible.

3.3.4. All vehicles used for the transport of all potatoes (GM and non-GM) must be checked to ensure that spillage does not occur during transport to and from storage facilities.

3.4. Harvest

3.4.1. GM tubers and/or non-GM comparator tubers must be harvested from the site in separate labelled bags and placed in separate labelled sealed containers and removed from the trial site for storage (condition 3.6) or destruction (condition 3.8).

3.4.2. Two repeat harvests of the trial site must be carried out immediately after the initial harvest in order to minimise the number of tubers remaining in the soil.

3.5. Post-Harvest

3.5.1. All GM tubers must be removed from the soil surface to prevent possible dispersal to areas outside the trial site. They must be collected in labelled bags and placed in labelled sealed containers and removed from the trial site for storage (condition 3.6) or destruction (condition 3.8)

3.5.2. Perennial Ryegrass must be planted in the trial site area for the subsequent rotation in the year after each potato trial. All potato volunteers (groundkeepers) emerging during this cultivation must be destroyed through the application of a commercially approved herbicide.

3.5.3. 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

3.5.4. GM tubers and/or non-GM comparator tubers harvested from the site or any surplus GM tubers and/or non-GM comparator tubers not sown shall not be used as animal feedstuff.

3.6. Storage

3.6.1. All GM tubers / plantlets and non-GM comparator tubers / plantlets must be stored both prior to planting and after harvest within the laboratory / glasshouse contained use facility in Oak Park.

3.6.2. The GM tubers / plantlets and the non-GM comparator tubers / plantlets must be stored in separate clearly labelled sealed containers.

3.7. Equipment

3.7.1. All farm machinery and equipment must be cleaned and thoroughly inspected prior to, and after, sowing, field operations and harvesting.

3.8. Waste Management

3.8.1. All GM material shall be inactivated by autoclaving.

3.8.2. Autoclaving will take place on site in Teagasc Crops Research Centre, Oak Park, and the autoclave shall be validated. A biological indicator shall be included with each load to confirm inactivation.

3.8.3. The sterilised tubers will be disposed of as standard waste

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 4 Duty of the notifier to inform the Agency of new information

4.1. If, after the Agency has granted consent, new information relevant to the deliberate release becomes available, or there is an unintended change to the deliberate release which could have consequences for the risks to human health or the environment, the notifier shall:

4.1.1. immediately take the necessary measures to protect human health and the environment;

4.1.2. inform the Agency as soon as the new information becomes available or the unintended change is known; and,

4.1.3. inform the Agency as soon as possible of such further measures the notifier has taken or proposes to take in relation to the matters concerned.

4.1.4 in the event that the Agency suspends the deliberate release further to an evaluation of the new information / unintended change, the deliberate release shall not resume until such time as the notifier obtains written consent from the Agency permitting its recommencement.

Reason:	**To provide and update information on the trial**

Condition 5 Reporting to the Agency

5.1. Reporting to the Agency shall be in accordance with Annex 1.

5.2. Details of the trial site fixed points measurement must be forwarded to the Agency at least one week prior to planting.

5.3. The site map, the SOPs as outlined under 3.1.1. and a copy of the trial site plan for each site shall be sent to the Agency in a format to be agreed at least one week prior to planting, indicating the location of the GM tubers / plantlets and the non-GM comparator tubers / plantlets in the experimental plots.

5.4. Prior to planting, the notifier shall provide the Agency with a validated procedure for the identification of the GM potato plants (leaf and tuber) based on conventional PCR in accordance with Condition 6.

5.5. 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.

5.6. Accurate detailed records shall be maintained by the notifier in respect of:

5.6.1. the number of GM tubers / plantlets stored before sowing;
5.6.2. the number of GM tubers / plantlets sown;
5.6.3. the number of GM tubers harvested and stored for the subsequent growing season;
5.6.4. the number of GM tubers destroyed and destruction details as per condition 3.8;

5.6.5. dates of inspections carried out in accordance with condition 3.3 and details of any findings including the number of volunteers (groundkeepers) that emerged and how they were dealt with.

These records shall be retained on site by the notifier and shall be made available to the Agency, or nominated agent, on request.

5.7. The notifier shall submit a report to the Agency every two months during the growing season from 2012 to 2016 inclusive. The first report shall be submitted to the Agency following planting and the last report shall be submitted following harvest. This report shall provide information on the performance of planting and harvest (condition 3.2 and 3.4 respectively) where relevant, the performance of monitoring activities (condition 3.3), the results of monitoring and the notifier's conclusions.

5.8. The notifier shall submit a report to the Agency on or before the 23rd December each year, up to 23rd December 2020. This report shall include information on the results of monitoring activities carried out in accordance with conditions 3.3 and 3.5 and shall provide details of the number of volunteers (groundkeepers) recorded under section 5.6.5 and how these volunteers were dealt with.

5.9. Further to completion of the deliberate release field trial, the notifier shall submit a report to the Agency, in the format set out under Commission Decision 2003/701/EC[1], on or before the 23rd December. This report shall include the following information:

5.9.1. the results of the deliberate release; and,

5.9.2. a post-release evaluation of the risks to human health and the environment.

5.10. The notifier shall notify the Agency of the completion of the experimental trials as established under condition 2, as soon as is practicable.

Reason:	**To provide for the collection and reporting of information on the trial and to make provision for the reporting to the Agency of any impacts of the completed trials and any associated risks.**

Condition 6 Detection method for the identification of the GM potatoes

6.1. The notifier shall develop / acquire a validated procedure for the identification of the GM potato plants (leaf and tuber) based on conventional Polymerase Chain Reaction (PCR). All stages of the

[1] Commission Decision of 29 September 2003 establishing pursuant to Directive 2001/18/EC of the European Parliament and of the Council a format for presenting the results of the deliberate release into the environment of genetically modified higher plants for purposes other than placing on the market *(notified under document number C(2003) 3405)* (2003/701/EC)

procedure including initial sample preparation and DNA extraction shall be included in this protocol of detection. The protocol shall also include a species specific endogenous control procedure for conventional PCR.

6.2. The procedure should be fully documented in SOP format so that a laboratory can easily replicate the exact procedure used as well as to ensure consistent application. Refer to ISO 17025[2] for the type of information that should be included in such a detection method.

6.3. The notifier must provide positive and negative control samples when requested to do so by the Agency.

Reason:	**To provide methodology and samples for detection purposes.**

Condition 7 Sampling the trial site.

7.1. The Agency, or its appointed agent, may collect potato plant tissue from the released potato lines within the trial site at any time.

7.2. Any costs incurred by the Agency for this testing shall be charged to the notifier.

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

Condition 8 Charges for carrying out site inspections, auditing & monitoring

8.1 The notifier, Teagasc, shall pay the EPA €9,233.41 in total over a period of three years (2012, 2013 & 2014). €3,398 shall be paid to the Agency in 2012 and €2,918 shall be paid in 2013 and again in 2014. The amount for 2012 shall be paid within one month of issue of this consent and by January 31st in subsequent years.

8.2 The notifier shall also be responsible for any further costs properly incurred by the Agency during the term of the field trial.

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

[2] ISO 17025 is the main standard for testing and calibration laboratories

Annex 1

SCHEDULE OF REPORTING

YEAR	DEADLINE	To be submitted to the EPA
2012	1 week prior to planting	A validated procedure for the identification of the GM potato plants (leaf and tuber) based on conventional PCR
2012 – 2015 inclusive 2016 (in the event that planting takes place during 2016)	1 week prior to planting (each year)	• The trial site fixed points measurement as per condition 3.1.4. • The site map, the SOPs as outlined under condition 3.1.1 and a copy of the trial site plan for the site showing the location of the GM tubers / plantlets and the non-GM comparator tubers / plantlets in the experimental plots • The proposed date for planting
	1 week prior to harvest (each year)	The proposed date for harvest
2012 – 2015 inclusive 2016 (in the event that planting takes place during 2016)	Bimonthly (every 2 months) report from planting to harvesting	Report on planting, harvesting and monitoring activities as per condition 5.7
2012 – 2016 inclusive	On or before 23rd December (each year)	Report on monitoring activities as per condition 5.8
2016	On or before 23rd December	Final report in the format set out under Commission Decision 2003/701/EC and Condition 5.9.
2017 – 2020 inclusive	On or before 23rd December (each year)	Report on monitoring activities as per condition 5.8