This Report has been cleared by
Frank Clinton, Programme Manager,
for submission to the Board
Signed: Bea Claydon Dated: 27 June 12

OFFICE OF CLIMATE, LICENSING & RESOURCE USE

INSPECTOR'S REPORT

TO:	BOARD OF DIRECTORS
FROM:	Bernie Murray Environmental Licensing Programme
DATE:	27th June 2012
RE:	Notification from Teagasc, Oak Park, Co Carlow, under Part II of the GMO (Deliberate Release) Regulations (S.I. 500 of 2003) to conduct a field trial using genetically modified potatoes (GMO Register No: G0469-01).

Applicant:	Teagasc Oak Park Co Carlow
GMO Register Entry No:	G0469-01
SNIF No:	B/IE/12/01
Notification under Article 14(1) of S.I. No 500 of 2003:	The deliberate release of a genetically modified organism for purposes other than placing on the market (Part B Release – Field Trial).
Timeframe for EPA's Decision under Article 18(5) of S.I. No 500 of 2003:	A person shall not deliberately release a genetically modified organism (GMO) for purposes other than placing on the market unless consent in writing has been granted by the EPA. The EPA shall communicate its decision (either grant consent with or without conditions or refuse consent) in writing to the notifier within 90 days of receipt of the notification.
Date of receipt of notification under Article 14 of S.I. No 500 of 2003:	27th February 2012
Request for additional information under Article 19 of S.I. 500 of 2003:	15th March 2012 4th April 2012 23rd May 2012
Additional Information submitted under Article 19 of S.I. 500 of 2003:	11th April 2012 14th June 2012. A correction was received on the 27th June 2012.

Date by which decision is required:	24th August 2012
Representations to the EPA relating to this notification under Article 16 of S.I. 500 of 2003:	81

1. Introduction

1.1. What are GMOs?

In accordance with article 3 of the GMO (Deliberate Release) Regulations, S.I. No 500 of 2003, Genetically Modified Organisms (GMOs) are defined as organisms with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally through mating and/or natural recombination.

An organism is a biological entity (living animal or plant, bacteria, fungi or virus) capable of replication and of transferring genetic material.

For centuries, farmers have been altering the genetic make-up of crop plants and livestock in order to develop and select offspring with desired traits and/or qualities. Traditional plant and animal breeding techniques require that the individual species involved are the same or closely related. The development of genetic engineering techniques has meant it is possible to introduce genes from another organism, or otherwise alter its genetic makeup, with a view to producing new substances or performing new functions. The techniques required to alter the genetic profile of an organism have only been discovered in the past 40 years and are still being developed.

1.2. GM crop field trials

In excess of 2,530 SNIFs (Summary Notification Information Format) of some 188 different genetically modified plant species have been circulated in the EU for purposes other than placing on the market (field trials) under Directive 90/220/EEC and Directive 2001/18/EC (repealing Directive 90/220/EEC) between October 1991 and July 2012.

To date, no GM crops have been grown commercially in Ireland. Thirteen field trials have been carried out on herbicide tolerant GM sugar beet between 1997 and 2000.These trials were authorised under the GMO Regulations S.I. No. 345 of 1994.

A field trial on blight resistant potato was authorised under the GMO (Deliberate Release) Regulations, S.I. No 500 of 2003, in Co Meath during the period 2005 – 2010 (G0208-01, B/IE/06/01), however the applicant, BASF, did not proceed with the trial.

Worldwide, GM crop cultivation has increased year-on-year since 1996 with 160 million ha of GM crops being cultivated in 29 countries in 2011, by 16.7 million farmers. GM soybean was the principal GM crop grown in 2011, followed by GM maize, GM cotton and GM canola. Herbicide tolerance is the dominant trait (Source ISAAA[1]).

A number of GM products have been approved for placing on the market in the EU under Part C of Directives 90/220/EEC and 2001/18/EC. At present, only 2 GM plants are authorised for cultivation in the EU - neither of which are relevant to Irish agriculture or Industry - namely:

- MON810 maize (Monsanto) resistant to the European corn borer. Six EU countries (Spain, Portugal, Czech Republic, Poland, Slovakia and Romania) planted 114,490 ha of MON810 maize in 2011;
- Amflora potato (BASF) with increased Amylopectin content for the starch production industry (starch potato). In 2010, 235ha of Amflora potatoes were grown for seed potato multiplication in Germany and Sweden, and starch potato production in the Czech Republic.

EFSA, however, is currently considering an application from BASF for a GM potato, resistant to late blight disease (in addition to several other crop trait combinations), for authorisation under Regulation 1829/2003 for GM food and feed. This application is for the import, processing and cultivation of a Phytophthora (late blight) resistant potato within the EU and could have relevance for Irish agriculture.

At present GM potatoes with improved resistance to late blight are being trialed in Belgium (B/BE/10/V1 and B/BE/10/V2) and the UK (B/GB/10/R29/01) over a 2-3 year period. These trials commenced in March 2011 (BE) / May 2010 (UK) and will continue until October 2012.

In addition, The GM potato line which is the subject of this notification (A15-031) was planted in 2011 in 3 locations in the NL under Reference No B/NL/09/02.

1.3 Regulation of GM crop field trials in the EU

The deliberate release of GMOs into the environment for purposes other than placing on the market or Part B releases (so called because they are dealt with under Part B of Directive 2001/18/EC) or field trials, are regulated under Directive 2001/18/EC on the deliberate release into the environment of GMOs.

Part B releases are performed for the purposes of study, research, demonstration and biosafety /risk assessment purposes. The behaviour of the GMO in an open environment and its interactions with other organisms and the environment are studied.

[1] International Services for the Acquisition of Agri-biotech Applications

No GMO, as or in products, can be considered for placing on the market without first having been subjected to satisfactory field testing at the research and development stage in ecosystems which could be affected by their use (Recital 25 Directive 2001/18/EC).

The following recitals to Directive 2001/18/EC should be noted in relation to field trials or Part B releases.

(4) Living organisms, whether released into the environment in large or small amounts for experimental purposes....., may reproduce in the environment and cross national frontiers thereby affecting other Member States. The effects of such releases on the environment may be irreversible.

(5) The protection of human health and the environment requires that due attention be given to controlling risks from the deliberate release into the environment of genetically modified organisms (GMOs).

(8) The precautionary principle has been taken into account in the drafting of this Directive and must be taken into account when implementing it.

(23) The deliberate release of GMOs at the research stage is in most cases a necessary step in the development of new products derived from, or containing GMOs.

(24) The introduction of GMOs into the environment should be carried out according to the "step by step" principle. This means that the containment of GMOs is reduced and the scale of release increased gradually, step by step, but only if evaluation of the earlier steps in terms of protection of human health and the environment indicates that the next step can be taken.

(25) No GMOs, as or in products, intended for deliberate release are to be considered for placing on the market without first having been subjected to satisfactory field testing at the research and development stage in ecosystems which could be affected by their use.

1.4 Irish GMO Regulations

The GMO (Deliberate Release) Regulations, S.I. No 500 of 2003, transposing Directive 2001/18/EC into Irish law under sections 6 and 111 (as amended by section 17) of the Protection of the Environment Acts 1992 – 2011, came into force on 1st November 2003.

Part II of the aforementioned Regulations relate to the deliberate release of GMOs into the environment for purposes other than placing on the market. In

accordance with article 18 of the Regulations the Agency must have regard to the following, further to receipt of a notification:

- examine the notification for compliance with the Regulations;

- decide whether the environmental risk assessment carried out by the notifier is appropriate; consider any observations received from a competent authority of another Member State of the European Communities for the purposes of the Directive where such observations are received by the Agency within a period of 30 days of publication of the SNIF on WebSNIF by the Joint Research Commission (JRC); where requested, forward a copy of the notification to the competent authority of an EU Member State;

- evaluate the risks posed by the proposed deliberate release (whether direct or indirect, immediate or delayed) for the environment (e.g. the spread of the GMO in the environment, the transfer of genetic material to other organisms);

- pay particular attention to the risks posed to human health and the environment by the proposed deliberate release of a GMO containing one or more genes expressing resistance to antibiotics which are used in human or veterinary medicine. The Agency shall not grant consent where it considers that the deliberate release of the abovementioned GMO may have an adverse effect on human health and the environment;

- evaluate the potential adverse effects that the proposed deliberate release may pose, whether direct or indirect, for human health or the environment, or both, arising from the transfer of 1 or more genes from a genetically modified organism to another organism;

- record its conclusions of its assessment of the notification in writing;

- respond in writing to the notifier within 90 days of receipt of the notification by indicating that consent to the deliberate release is either -

  (a) granted, with or without, conditions, or
  (b) refused and the reasons for the refusal.

  A period of time during which the Agency is awaiting any further information on a notification from the notifier shall not be taken into account.

1.5 Irish Legal case pertaining to Part B notifications

In 1997, the EPA granted consent subject to conditions to Monsanto for the release of GM herbicide tolerant sugar beet at Teagasc, Oak Park, Co Carlow. Ms Clare Watson of Genetic Concern sought a High Court Judicial Review of the EPA's decision to grant a consent. This hearing concluded in October 1998 with the High Court ruling against Ms Watson on all twelve main areas of contention.

1.6 Government Policy re GMO Crop field trials in Ireland

The Minister for the Environment, Community and Local Government (DECLG) has overall responsibility for policy matters in relation to Directive 2009/41/EC on the Contained use of GMOs, Directive 2001/18/EC (repealing Council Directive 90/220/EEC) on the Deliberate Release into the environment of GMOs and Regulation 1946/2003 on transboundary movement of living modified organisms (LMOs or better known as GMOs).

Food Harvest 2020

The 2011 Programme for Government makes no explicit reference to policy in relation to GMOs in Ireland. Food Harvest 2020 - a draft strategy for the medium-term development of the agri-food, fisheries and forestry sector for the period to 2020 - identifies the importance of new technological innovations in developing agriculture and the agri-food sector.

"*With the aim of ensuring the competitiveness and viability of Irish production, DAFF should monitor and appraise policy, trade and commercial developments at EU and other relevant levels with respect to the use of existing and emerging technologies in areas such as biotechnology and genetically modified organisms (GMOs)*".

The 2011 Programme for Government is committed to Food Harvest 2020.

Strategy for Science, Technology and Innovation 2006 – 2013

The Strategy for Science, Technology and Innovation 2006 – 2013 under the Department of Jobs, Enterprise and Innovation sets out the Government's targets in relation to science, technology and innovation and the mechanisms for achieving them. It supports and promotes the development of new technologies such as Bio and Nano technology.

"Potential areas for application include animal and plant sciences, food innovation, forestry and wood chain and other non-food crops as well as risk evaluation of GMOs and their implications for agri-food"

Public Consultation on GMOs, Report of the Chairing Panel and the Report of the Inter-Departmental Group on Modern Biotechnology.

In August 1998, the then Minister for the Environment and Local Government issued a national consultation paper entitled "*GMOs and the Environment*" in order to stimulate public debate in advance of reviewing national environmental

policy in this area. The Minister then invited respondents to the consultation paper to participate in a two part debate in May/June 1999. This debate was managed by an independent chairing panel. The Chairing Panel's Report published in July 1999 concluded that "*the focus of national environmental policy on the deliberate release of GMOs should be positive in recognising the potential economic benefits of genetic engineering, but should also reflect a fundamental national commitment to safety and environmental sustainability based on scientific risk assessment and management*".

In addition, the Chairing Panel's Report recommended "*the identification, supervision and funding of a programme of independent generic research (i.e. not specific to any particular product) by the EPA, specifically on safety issues related to the deliberate release of GMOs into the environment*". ....."*Notwithstanding any independent research undertaken at EU level, the specific climatic, geological and geographical position of Ireland underpins the need for a national programme*". In the opinion of the Chairing Panel, the performance of national research was deemed necessary in order to reassure the public.

Many wider issues relating to GMOs were raised during the public consultation process, including, food production, quality and safety, consumer protection and choice. In response to these wider issues, the Minister established an Inter-Departmental Group on Modern Biotechnology to report on a co-ordinated overall Government position on genetic modification. The Report of the Inter-Departmental Group on Modern Biotechnology reiterated the Chairing Panel's recommendation on the need to perform national research "*that independent generic research (i.e. not limited to any particular product) be conducted in this country into all aspects of GMOs, including human health and safety, animal health and live crops, and the effects of GMOs on the Irish environment having regard to our distinctive climatic and geological conditions.*"

In October 1999, the Minister issued a policy statement confirming Government acceptance of the conclusions of the independent chairing panel. On foot of this report, the Agency formulated a programme of generic research but there was no available funding.

Irish Council for Bioethics

In November 2005, the Irish Council for Bioethics produced an opinion entitled *'Report Genetically Modified Crops and Food: Threat or Opportunity for Ireland ?'* The report examined the ethical consequences of the introduction of GM crops and food in Ireland would have for consumers and farmers. In relation to GM crops the report concluded:

'On balance, the Irish Council for Bioethics does not view the genetic modification of crops as morally objectionable in itself. GM crop and food technology holds a great deal of promise; however, it also introduces new risks for consumers, farmers, and the environment'.

It should also be noted that the Irish Council for Bioethics working group carried out a GM crop/food public consultation survey as part of the above report and a total of 560 submissions were received from the public. The survey concluded:
It is abundantly clear from the findings of the consultation that those responding are greatly opposed to the introduction of GM crops, and are largely of the view that GM foods currently on sale are not safe for human consumption. It is also apparent from the comments of the majority of respondents that there are many reasons underlying the opposition to GMOs, and that there is a high degree of concern about many aspects of GM crops and food.

82% of the respondents were of the view that GM crops pose a threat to the environment and 78% did not support the cultivation of GM crops in Ireland.

The reports produced by the Chairing Panel, the Inter-Departmental Group on Modern Biotechnology and the Irish Council for Bioethics were drafted in response to the only consultation debate on GMOs and the environment to have taken place in Ireland.

2. Considerations for the Board

2.1 Description of the GMO

GM Potato line A15-031 was generated by insertion of the Rpi-vnt1-1 or R gene, conferring improved resistance to *Phytophthora infestans* (Rpi) (causative organism of late blight disease in potato), into the genome of *Solanum tuberosum* cv[2]. Desiree (also referred to as cv. Desiree). This GM potato line is cisgenic in nature, that is to say that the late blight resistance gene, Rpi-vnt1-1, was originally removed from the wild potato species *Solanum venturii* along with its native promoter and terminator and was inserted into a phylogenetically related potato line (i.e. *S. tuberosum* cv. Desiree). The gene encodes gene products that occur naturally in the wild potato species, *S. venturii*. The genetic modification of the *S. tuberosum* cv. Desiree genome was mediated by *Agrobacterium tumefaciens* in a process termed *Agrobacterium tumefaciens* mediated transformation which uses the natural ability of the bacterium to deliver T-DNA into the potato cell.

The binary plasmid pBINAW2:Rpi-vnt1-1 is used to generate the A15-031 cisgenic potato line. The Rpi-vnt1.1 gene is inserted into the target potato cell's DNA with its promoter and terminator intact such that the gene remains under the control of the native promoter and terminator sequence. The antibiotic resistance marker gene NPTIII is also present in the plasmid for purposes of selecting transformed Agrobacterium. Table 1 of the application provides molecular data confirming that the vector backbone DNA, including the NPTIII and TetA genes were not

[2] cultivar

transferred into the potato genome during transformation. Teagasc provided gel/PCR data confirming the absence of the aforementioned genes.

The resistance gene, Rpi-vnt1-1, is a class of Rpi genes from tuber bearing Solanum species that belong to the nucleotide binding site – leucine rich repeat (NBS-LRR) class of disease resistance genes. This class of genes are present in many cultivated plants including non-GM potato varieties cultivated in Europe. During the infection of potato by *P. infestans*, the pathogen's genes produce effector proteins which are necessary for disease onset. These effector proteins are recognised by the proteins produced by the Solanum (potato) Rpi genes and a resistance response is initiated by the host against the pathogen. This results in localised cell death in the infected cells which effectively forms a barrier or blocks *P.infestans* from colonising the plant.

The cisgenic GM potato line A15-013 was selected from a larger population of A15 lines grown under field conditions in the Netherlands. According to the notifier the inserts are genetically stable based on the expression of the resistance trait in successive generations.

2.2 Purpose of the release

This field trial, if approved by the Agency, will be performed as part of a pan-European research consortium through the EU's Seventh Framework Programme (FP7) for Research and Technological Development. The project entitled 'AMIGA' (Assessing and Monitoring the Impacts of Genetically modified plants on Agro-ecosystems) has 22 partners across 15 EU Member States.

The purpose of the field trial is to:

- Quantify the impact of GM potato cultivation on bacterial, fungal, nematode and earthworm diversity in the soil, compared to a conventional potato system;
- Identify integrated pest management (IPM) strategies and components which could be positively or negatively affected by the adoption of GM late blight resistant potato;
- Employ the project's resources as a tool for education and demonstration in order to proactively engage and discuss the issues that most concern stakeholders and the public at large in regards to the cultivation of GM crops in Ireland.

2.3 Location of the proposed Deliberate Releases

It is proposed that the deliberate release of GM potato line A15-013 will take place at Teagasc Crops Research Centre, Oak Park, Co Carlow.

While Teagasc propose a minimum separation distance of 40m, the actual separation distance between the proposed GM potato trial site and Teagasc's non-GM national potato breeding programme is 750m.

The proposed GM potato trial site has been in continuous perennial ryegrass for in excess of 10 years and has been used for grazing.

2.4 Timeframe for the proposed deliberate release

It is proposed in the notification that planting will take place during the 2012, 2013, 2014 and 2015 growing seasons. Each year where planting is undertaken, the crops would be planted from March - June and would be harvested in October. Planting will be delayed in 2012 owing to setbacks with regard to the importation of the plantlets for sowing (condition 2.2 permits planting from 1st July during 2012).

While Teagasc do not plan to plant in 2016, it could become necessary in the event that a year is lost due to destruction of the trial or unfavourable climatic conditions. Condition 2.2 provides for this eventuality by permitting planting in 2016.

Three years of planting would meet the level of repetition typically required for statistical validity of field data.

2.5 Quantities to be released during the proposed trial

It was originally proposed in the notification that in 2012 approximately 100 plantlets would be sown on a single plot no greater than 0.404 hectare (ha) in size. However, the GM plant material arrived late in Oak Park. Consequently, the combined number of GM and non-GM potato plants that will be sown during the 2012 season will now be minimal and will occupy an area no greater than $10m^2$.

According to the notification two sites will be sown in 2013, 2014 and 2015 and each site will not exceed 1 ha in total. The number of tubers planted during the period 2013 – 2015 will depend on the number of tubers harvested during the previous year's sowing but the proposed 2 x 1ha area may well be reduced. GM tubers will be sown as per conventional crop densities of approximately 30 plants per m^2.

2.6 Field Trial Design

The experimental design has yet to be finalised as it is wholly dependent on the amount of plantlets/tubers available in any given year. Condition 5.0 requires Teagasc to submit the experimental plan for each site 1 week prior to planting. The following experimental design details have been made available to the EPA:

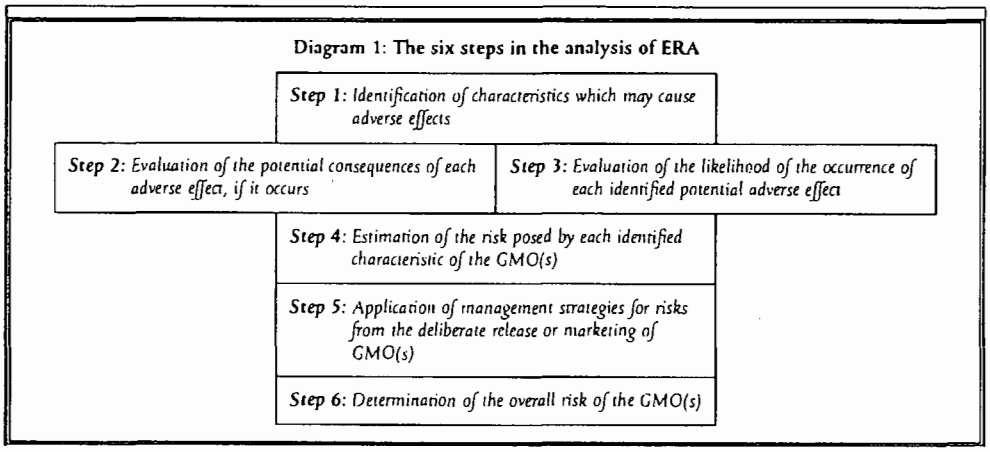
- Two potato genotypes will be tested in order to ensure statistical validity; A15-013 and the comparator non-GM *S. tuberosum* cv. Desiree;
- Non-GM comparator lines will be grown in parallel to the GM lines within each site;
- At a minimum there will be 3 treatments; no spray, full spray and reduced spray against blight disease;
- For each interaction, there will be a minimum of 3 replicated blocks.

Each site will be defined and measured by GPS to facilitate site identification and monitoring in subsequent years.

2.7 Environmental Risk Assessment

Environmental Risk Assessment (ERA) is defined in Article 2(8) of Directive 2001/18/EC on the deliberate release into the environment of GMOs as '*the evaluation of risks to human health and the environment, whether direct or indirect, immediate or delayed, which the deliberate release or the placing on the market of GMOs may pose*'.

Commission Decision 2002/623/EC establishing guidance notes supplementing Annex II (Principles for the ERA) to Directive 2001/18/EC states that 'in drawing conclusions for the ERA,... the following points should be addressed as the main steps in the ERA.



Commission Decision 2002/623/EC defines:

- 'hazard' (harmful characteristics) as 'the potential of an organism to cause harm to or adverse effects on human health and/or the environment'; and,
- 'risk' as the combination of the magnitude of the consequences of a hazard, if it occurs, and the likelihood that the consequences occur.

The Risk Assessment as received from the notifier, in the above format, is provided here below.

Table : Risk assessment of A15-031 in accordance with respective legislation governing deliberate release into the environment					
Step 1 ***Potential adverse effect (hazard) which may be caused by the characteristics of the GM plant***	***Step 2*** ***Evaluation of the potential consequences of each adverse effect if it occurs***	***Step 3*** ***Evaluation of the likelihood of the occurrence of each identified potential adverse effect***	***Step 4*** ***Estimation of the risk posed by each identified characteristic of the GMO***	***Step 5*** ***Application of management strategies for risks from the deliberate release***	***Step 6*** ***Determination of the overall risk of the GMO***
Increased invasiveness in natural habitats or persistence in agricultural habitats.	The potential consequences are negligible because the Rpi-vntl.1 gene is specifically targeted against *P. infestans*. In addition, potatoes are not an invasive crop species. Within the managed system physical and chemical methods are used to control volunteers.	Highly unlikely. The Rpi-vntl.1 gene neither confers characteristics to the GM potato that add competitive abilities in unmanaged ecosystems or allow the cisgenic line to compete against plants of similar type for space. None of the characteristics transferred to the potato plants is anticipated to affect pollen production/fertility, seed dispersal or frost tolerance.	Negligible	Groundkeepers and volunteers arising from true potato seed will be controlled by a robust management protocol which is based on experience of gene flow trials previously conducted by Teagasc at Oak Park.	Negligible.
Selective advantage – improved resistance to *P. infestans*	The consequence of the Rpi-vntl.1 cisgene is to increase resistance to *P. infestans*, therefore a selective advantage is conferred in the cisgenic line in	Likely. The intended effect of the genetic modification is to improve the resistance to *P. infestans*. Thus under *P. infestans* pressure resistant potatoes are intended to have a selective advantage in comparison to untreated non-	This will only be advantageous in the confines of a managed cropping system. Potato plants are rarely seen outside the field and there is no evidence to show that resistance to *P.*	Robust management protocol for volunteer management and monitoring for potential escapes through surveys of surrounding area.	Negligible.

	comparison to untreated non-resistant conventional potatoes.	resistant conventional potatoes in the agricultural environment.	*infestans* is the key determinant for potential invasiveness of potatoes.		
Selective advantage or disadvantage conferred to sexually compatible plant species	Negligible. Potato is clonally propagated so there is no potential of the cisgene introgressing into conventional potato systems. .	Very unlikely. There are no sexually compatible wild relatives present in Ireland. Pollen-mediated gene flow to cultivated potatoes is possible, but is mitigated by the imposition of a minimal isolation zone of 40m around the GM plots.	In the unlikely case that pollen is transferred to non-genetically modified potatoes, the consequences are negligible since potato is a vegetatively propagated crop.	Isolation distance to other potato crops.	Negligible.
Potential environmental impact due to interactions between the GM plant and target organism (*P. infestans*)	Minimal. The intended effect of the transferred resistance genes is to reduce infection by *P. infestans*, thereby this will reduce the sporulation potential of *P. infestans*.	Very likely if climatic conditions are suitable for *P. infestans* outbreaks during the growing season.	The risk of the intended effect is minimal to the environment and will only impact on *P. infestans* within the GM plots. The outcome desired with the introduction of the Rpi-vnt1.1 cisgene is what is typically achieved with standard *P. infestans* control measures in conventional potato systems.	None.	Negligible.
Potential environmental impact due to interactions between the GM plant and non-	The potential environmental impact with NTOs is negligible as the Rpi-vnt1.1 is targeted to *P. infestans*. Any other	Very unlikely due to specificity and mode of action of R-genes.	Any effect on non-target organism due to the introduced trait of *P. infestans* tolerance is anticipated to be comparable to that of non-	Monitoring plan including observations on disease and pest susceptibility.	Negligible.

target organisms	impact will be equivalent to that typically recorded with the cultivation of conventional potatoes.		genetically modified potatoes under conventional agricultural practice. Due to a reduced need for fungal treatments an increase in the populations of non-target organisms might be expected.		
Potential effect on human or animal health due to introduced R-genes	Negligible. Rpi genes are not known to confer toxic or allergenic properties.	Very unlikely. Rpi genes not known to confer toxic or allergenic properties.	Material from field trial not intended for human/animal consumption.	Measures with regard to planting, harvest, storage and transportation minimize the contact to humans and animals.	Negligible.
Potential effects on biogeochemical processes (changes in soil decomposition of organic material)	Negligible. None of the newly expressed proteins is expected to be exuded from the cisgenic plants to the soil.	Unlikely. Soil fertility is not expected to be affected differently due to the cultivation of the genetically modified potato plants as compared to conventional potatotes. None of the newly expressed proteins is expected to be exuded from the plants to the soil.	Negligible. Any effect is expected to be comparable to that of non-genetically modified potatoes under conventional agricultural practice. Due to a reduced need for fungal treatments an increase in soil microflora is hypothesised and will be the focus of research.	None.	Negligible.
Possible environmental impact due to changes in cultivation practice	Minimal. Potential positive effects on the population of soil organisms, due to a reduction in fungal treatments.	Likely. Application of conventional agricultural practice, except for a reduction in fungal treatments against *P. infestans*.	Potential positive effects on the population of soil organisms.	None.	Negligible

2.8 Molecular Characterisation

According to the notifier, the Rpi-vnt1.1 gene that has been inserted into *S. tuberosum* cv. Desiree (producing cisgenic line A15-031) is highly specific. It is solely related to conferring broad spectrum resistance against multiple genotypes of *P. infestans*. Therefore, in the presence of *P. infestans*, cisgenic line A15-013 will have a competitive advantage over non-GM comparators, which will display susceptibility to the disease. Furthermore, any selective advantage will be confined to within the managed environment of a cropping system, since potatoes are not invasive in ecosystems that are not managed. In the absence of *P. infestans,* the only difference between the GM and the non-GM line A15-013 is the presence of the Rpi gene in the former. According to the notifier, the two potato plant lines are otherwise equivalent.

2.9 Dissemination

2.9.1 Dissemination via True Potato Seed (TPS) and pollen

2.9.1.1 Crop-to-crop pollen mediated gene flow

The recipient potato strain *S. tuberosum* cv. Desiree is male fertile[3] and it produces a lot of flowers. Pollen mediated gene transfer (by self-pollination or cross-pollination), leads to the production of berries containing up to several hundred true potato seed (TPS). Commercial potatoes are all propagated vegetatively from "seed tubers" - references to "seed potatoes" generally refer to seed tubers and not to true potato seed.

Pollen from a GM potato crop is unlikely to affect the receiving crop (conventional/organic), as fertilisation of the flower and subsequent seed production has no influence on tuber production. Therefore, if tubers taken from a crop exposed to GM pollen were used as seed for the next crop, there would be no transmission of the GM event.

Sexual reproduction via true potato seed is possible under field conditions depending on the cultivar in question. However, the Department of Agriculture, Food and the Marine (DAFM) have stated that no new or unidentifiable potato variety has been recorded in Ireland in almost 90 years of official inspections under the Seed Potato Certification Scheme.

In 2005 and 2010, Teagasc (the notifier) carried out studies quantifying the potential for pollen mediated gene flow from donor plot *S. tuberosum* cv. Desiree to receptor plot cv. British Queens under Irish conditions. Cv. British Queens does not produce fertile pollen, therefore, the presence of a berry on British Queens plants indicates the occurrence of successful pollen-mediated gene flow.

[3] Only male fertile potato cultivars are capable of pollen dispersal

The results of the 2005 study indicated that pollen mediated gene flow in potato extended up to 21m from the pollen donor population and yielded 140 berries of which 4 berries contained seed. Only 23 (36%) seed germinated under greenhouse conditions. This experiment was repeated in 2010, during which pollen mediated gene flow extended to 11m from the pollen donor population, 34 berries were formed from which 1,765 seed were recovered and 1,219 of those seed germinated under controlled glasshouse conditions.

These results highlight the relatively low levels of pollen dispersal by cv. Desiree and the average pollen drift is 11m with a maximum drift of 21m. Also, the number of viable true potato seed produced as a result of pollination highlights the potential for volunteers derived from true potato seed to survive in the field and emerge through a rotation over time.

Gene-flow studies carried out by Teagasc (the notifier) in 2007 examined the management and flowering characteristics of *S. tuberosum* cv. Desiree. While the cultivar will produce berries with viable true potato seed under Irish field conditions, the plants arising from the seed were found to be agronomically weak, not capable of competing against weeds and grasses and were very vulnerable to herbicide applications and crop competition. Control of volunteers arising from true potato seed is achieved by ploughing, harrowing or employing a broad spectrum herbicide (e.g. glyphosate).

2.9.1.2 Pollen mediated gene flow to wild relatives

The potato has no sexually compatible wild relatives in Ireland. Two related weed species of potato (*Solanum dulcamara* 'bittersweet nightshade' and *Solanum nigrum* 'black nightshade') can be found in Ireland. Hand-mediated crosses performed by Teagasc between *S. tuberosum* cv. Desiree and *S. nigrum* populations found on the Oak Park estate, did not lead to the formation of viable progeny. Rather this result confirmed that *S. tuberosum* is genetically incompatible with Irish ecotypes of *S. nigrum* found in Oak Park.

2.9.1.3 Pollen dispersion

a. Pollen dispersion by wind

The potato is predominantly self-pollinating. Cross pollination is estimated to occur at a level of 0 – 20% with pollen being primarily dispersed by wind.

b. Pollen dispersion by insects

Insect pollination can occur but it is not considered a significant mechanism for pollen transfer in potato. It has been observed

during pollen dispersal studies carried out at Oak Park in previous years that bumblebees act as the primary insect pollinator of potato. The bumblebee moves only short distances between flowers so the majority of pollen is deposited in the immediate surroundings of the pollen source[4]. The potato produces no nectar so honeybees are not usually attracted to the flowers especially as other sources of pollen and nectar will be available during the Summer months.

c. *Pollen dispersion by pollen beetle*

A 1994 Swedish study[4] reported potato pollen dispersal up to 1000m from the donor potato population. This was thought to be attributable to the pollen beetle.

2.9.1.4. Tuber dispersion

Tuber dispersal is primarily operator related and will occur pre-sowing and post-harvest. Poor storage of seed tubers and harvested tubers during transport can lead to tuber loss within the confines of the field and along the routes from the field to the contained facility where tubers will be stored.

Tuber loss during harvest operations can lead to tubers lying on the soil surface. Tubers are frost sensitive and will be destroyed if they remain on the soil surface during periods of -3°C or lower. The inclusion of the Rpi gene in the potato genome is not expected to enhance its capability to tolerate frost.

Tuber survivability increases when tubers become buried during post-harvest tillage operations leading to the emergence of volunteers in the subsequent rotational crop. This was confirmed by Teagasc research carried out in 2010 and 2011, during which, commercial fields where non-GM potatoes were cultivated during the 2009 growing season, were surveyed for the emergence of potato volunteers. The application of herbicides during the cereal crops rotation significantly reduced the number of recorded volunteers observed in the rotation.

2.9.1.5. Animal mediated dispersion

Animal mediated dispersion can cause a limited amount of tuber loss from the field. Wild animals, mammals and birds occasionally feed on potatoes that are exposed after sowing or that remain in the field post-harvest.

[4] Skogsmyr I (1994), Gene dispersal from transgenic potatoes to conspecifics: A field trial. Theor. Appl. Genet. 88: 770-774.

In order to prevent animal entry into the site, the site will be cordoned off to a height of approximately 4 feet with a small mesh chicken wire fence, the top of which will be electric. The fence will be buried to a depth of 6 inches.

Glycoalkaloids, which are toxic to animals and birds, are found in harmful amounts mainly in the above ground parts of the potato plant i.e. stem, leaves and fruits. In the tubers of cultivated potato varieties, the glycoalkaloid content is usually low, less than 100mg per kilogram fresh weight. The incorporation of the R gene into the potato genome will not render the potato tuber increasingly toxic or allergenic since to date no member of the NB-LRR protein class has been identified as possessing toxic and/or allergenic properties. According to the notifier animal and/or bird predation is not applicable, owing to the glycoalkaloid content of berries. Condition 3.5.1 requires the removal of all GM tubers from the soil surface to prevent possible dispersal to areas outside the trial site.

2.10. Feeding Studies

Teagasc has clarified that the harvested GM tubers will not be made available to commercial livestock as a feed substitute.

2.11. Toxicity and Allergenicity

With regard to allergenicity and toxigenicity, the Agency consulted with the Food Safety Authority of Ireland (FSAI) and asked them to look at the impact of any inadvertent consumption by humans or animals. The FSAI consulted with its own external experts and responded that no safety concerns arising from inadvertent consumption were identified.

2.12. Information on control, monitoring post-release and waste treatment plans as proposed by the notifier

2.12.1. A description of the precautions to be taken

The notifier has proposed that a minimum separation distance of 40m will be observed between the perimeter of the GM potato trial site and conventional potato crops throughout the testing period (condition 3.2). This is twice the separation distance between GM and non-GM potatoes, recommended by the Irish working group on the co-existence of GM crops with conventional and organic farming, in their 2005 report.

In order to prevent dispersal of the GM tubers / plantlets as well as to prevent admixture between the GM tubers and non-GM potato tubers, the GM tubers/plantlets will be stored in the contained facility at Oak Park pre-sowing and post-harvest. They will be transported to the cultivation site in closed labelled containers and GM material that is not sown will be bagged before removal off-site for appropriate storage or destruction. All containers will be checked to ensure that they are leak

free and there is no risk of accidental loss of GM material during transfer to and from the field site.

In order to minimise predation by animals, the trial area will be fenced off as previously described and any tubers exposed above the soil surface will be covered during site visits by project personnel. If it is not possible to cover exposed tubers they will be bagged and removed off site for destruction. Condition 3.3 of the consent conditions, as drafted, requires site visits by project personnel to be scheduled at least two times per week.

Accurate records will be kept of the number of tuber/plantlet populations stored before planting, the number planted, the number destroyed/remaining in storage and the number harvested (condition 5.5).

All machinery used on the site will be inspected and cleaned thoroughly before and after use on the site (condition 3.7).

2.12.2. GM potato planting

During the period 2012 – 2015 the tubers harvested each year will be saved and sown the following year. The number of GM tubers available for planting will depend on the number of tubers harvested in the previous year. GM material that is not sown will be bagged before removal from the cultivation site. In the event that more tubers are harvested than are required for sowing, the surplus tubers will be destroyed.

2.12.3. GM potato harvest

GM potato harvesting will be completed by hand or with the use of conventional potato harvesters. The harvested tubers will be removed from the field in closed labelled containers (condition 3.4) and stored within the laboratory/glasshouse contained use facility in Oak Park (GMO Register No: G0102-01) (condition 3.6). The plots will undergo two additional harvests to minimise tuber loss and will then be surveyed and mini-tubers / tuber pieces collected in sealed bags for destruction. Above ground green tissues of the GM plants will be destroyed prior to harvesting with a chemical application and will then remain on the release site for decomposition.

2.12.4 Post-harvest

Berries formed on the potato plants will not be physically removed from the plants during the course of the trial, rather they will be left to drop off and they will be retained / contained within the trial site (condition

3.2). Volunteers emerging from dropped berries during subsequent rotation will be treated with a broad spectrum herbicide.

The notifier has proposed that post-harvest, each GM potato trial site be cultivated with perennial ryegrass which is a strong competitor for nutrients over potato volunteers[5]. At the 3 - 4 leaf stage volunteers will be destroyed by selective herbicides (e.g. glyphosate) (condition 3.5). The site will then be tilled and cultivated with ryegrass.

2.12.5 Post-release treatment methods for the GM plant material including wastes

GM material that is not sown will be collected in labelled bags and placed in sealed containers before removal off-site for appropriate storage (condition 3.6) or destruction (condition 3.8). Destruction will be achieved by validated steam sterilisation.

2.12.6 Monitoring

Pending approval of this application followed by GM potato plantlets in 2012, the monitoring programme will commence in Spring 2013 and will continue through to the Autumn of 2020, four years after completion of the trials in 2016.

Each Spring, each site will be sown with perennial ryegrass. Project personnel - conditioned to walk the site monthly (condition 3.3) - will monitor the site for the emergence of volunteers. Quantitative data will be recorded by measuring the number of volunteers sitting in a $1m^2$ quadrat, with up to 100 quadrats recorded per site visit.

2.13. Releases in other EU Member States

The GM potato line A15-031 was planted in 2011 in 3 locations in the Netherlands (NL) under Reference No B/NL/09/02. Consultation with the NL authorities revealed that nothing unusual was observed in phenotypic characteristics or interactions in the environment.

GM potatoes with improved resistance to late blight are currently being trialled in Belgium (B/BE/10/V1 and B/BE/10/V2) and the UK (B/GB/10/R29/01) over a 2-3 year period. These trials commenced in March 2011 (BE) / May 2010 (UK) and will continue until October 2012.

3.0 Waste Management

Condition 3.8 of the consent conditions, as drafted, requires that GM material be destroyed by autoclaving. Autoclaving will take place in a 330L autoclave in the Teagasc Crops Research Centre at Oak Park. Autoclave sterilisations will be performed at 121°C for 40 mins at a pressure of 2 – 3 psi. A biological indicator

[5] A volunteer plant is a crop growing from seed or vegetative material from a previous crop.

will be included with each load to confirm inactivation. The sterilised tubers will then be disposed of as standard waste.

4.0 Implications for Ireland

The potato remains the most important field grown horticultural crop in Ireland supporting an industry worth an estimated €74m. There were approximately 11,000 hectares of potatoes planted in Ireland in 2010 producing in the region of 462,000 tonnes of potatoes valued at approximately €150m[6].

Potatoes are susceptible to several bacterial, fungal and viral diseases both during the growing season and post-harvest. As a result, significant quantities and frequent applications of crop protection products are applied. According to Teagasc[7], *Phytophthora infestans* (late blight) is a major problem in Ireland causing annual losses in yield and quality estimated at €15 million per year. Currently, under Irish climatic conditions, in order to ensure adequate protection of the potato crop, this pathogen requires as many as 15 fungicide applications during the planting season.

5.0 Representations made under Article 16(1) of the GMO (Deliberate Release) Regulations, S.I. No 500 of 2003

The notifier (Teagasc) published a notice in the Irish Independent newspaper on 29/02/2012 informing the public of the submission of a notification for the deliberate release of GM potatoes into the environment, to the EPA and inviting any person or body to make representations on the notification in accordance with the requirements of article 16(1) of the GMO (Deliberate Release) Regulations, S.I. No 500 of 2003.

Representations were required to be made in writing to the EPA at Agency Headquarters within a period of 28 days beginning on the date of publication of the notice (by 27th March 2012). In accordance with Article 16(4)(b) of the Regulations, the Agency is required to consider the representations in determining the notification.

Eighty-one (81) representations were received, all of them opposed to the proposed field trial. Some of the representations had multiple signatures. The Agency has read all of the representations received and has grouped the concerns raised into broad categories, as outlined below.

In addition, two online petitions entitled "Stop GM potato trials in Ireland" and "a 5 year moratorium on growing GM crops and food in Ireland" gathered 2,869 and 1,863 signatures respectively, at the time of submission of this report to the Board of the Agency on 28/06/2012.

---

[6] An Bord Bia

[7] Flannery, M. et al, *An Economic Cost-Benefit Analysis of GM Crop Cultivation, An Irish Case Study*, AgBioForum, 2004, Vol 7, No 4, p149-157.

The number after each representation denotes the approximate number of representations that raised this issue.

5.1. ECONOMIC CONCERNS.

1. GM crops will damage Ireland's reputation of high quality food (unique selling point) and compromise our clean image/GM free status. The intentional release of GM plants into the Irish environment will seriously diminish this unique selling point. The Irish potato market is worth €80 - 85 million annually to farmers. Greater than half of Ireland's agri food production is exported with over 70% of that being sold within the EU. **48**
2. If GMO releases into the environment are permitted, the marketing of GM alongside non-GM Irish potatoes will accelerate the demise of Irish potato consumption. It requires significant promotional campaigns to get consumers to buy and cook potatoes. Selling a GM potato ....would be a 'death-knell' for potato consumption. **1**
3. The programme for Government and Food Harvest 2020 is committed to developing and building Food Brand Ireland as a brand with green credentials. Harvest 2020 recognises there will be an increased demand for food and this will translate into consumers seeking better quality food and food that is GM free. Agricultural producers can capitalise on the higher price paid for their produce. **1**
4. 2007/2009 Programme for Government was opposed to GM production "To optimise Ireland's competitive advantage as a GM free country". Abandoning this policy would seriously damage our food exporting prospects. Change in this policy took place without public participation. **3**

Agency Response (to 1 – 4 inclusive)

A lot of the issues raised here (green image, GM free status, economic profit for companies, no market for GM crops, farming/potato consumption in decline, etc) are policy matters relating to GM crops. Such policy issues are a matter for the Government who decides on policy in these areas and thus falls outside the Agency's remit.

That said, the principal concern raised during the public consultation related to the damage that GM crops would do to Ireland's clean image/GM free status. Ireland cannot be described as GM free. As already stated, 13 GM crop field trials were performed in Ireland between 1997 and 2000. In addition, in excess of 1 million tonnes of GM feed is imported into Ireland each year to support our livestock industry. Therefore, our reputation as a producer of high quality produce already exists in the context of GM and the performance of a small scale, biologically contained, GM field trial ($10m^2$) should not compromise this.

While the 2011 Programme for Government makes no specific reference to GMOs, it endorses 'Food Harvest 2020' which in turn supports continuing research and the keeping abreast of policy, trade and commercial development with respect to existing and emerging technologies such as biotechnology and GMOs.

5. Market dominance by a few multinationals. Negative impact on national farming systems through patenting of GM seeds (prevents farmers from saving their own seeds). There is increased reliance on their associated products such as herbicides. Percy Schmeiser case. **17**
6. GM production is not sustainable.

Agency Response (to 5 and 6)

The concerns raised in this representation are part of the wider GM debate and do not directly impact on the notification under review, which is in respect of a small scale field trial.

It is not for the Agency to say whether or not GM production is sustainable. The 2000 report of the Inter-Departmental Group on Modern Biotechnology supported a positive but precautionary approach to the deliberate release of products containing or consisting of GMOs. The report went onto say that this positive but precautionary approach should also "*reflect a fundamental national commitment to safety and environmental sustainability, based on scientific risk assessment and management. Environmental sustainability in this context should be interpreted as including the avoidance of:*

- ***any impact which would undermine the overall viability of conventional or organic farming;"***

7. Costs arising through contamination incidents, 300 reported contamination incidents worldwide up to Jan 2011 which have caused trade disruptions, have cost farmers food processors and supermarkets billions of dollars with many liability cases still pending. Contamination incidents in EU equally common with 280 contamination incidents of GM authorised seeds between 2001 and 2006. Some of these contaminations originated at the trial stage. **5**

Agency Response

With regard to contamination incidents, a non-authorised GM potato was identified in Amflora[8] cultivated fields in Sweden, in 2010. This contamination or unauthorised release was attributed to admixture of the authorised and un-authorised GM potato varieties prior to planting despite the implementation of an Identity Preservation

[8] Amflora is the name given to a GM starch potato approved for cultivation by the European Commission in 2010.

System[9]. This illustrates the fact that failures can occur and robust trial management procedures are essential.

The national potato breeding programme run by Teagasc is situated 750m from the site of the proposed GM potato field trial. The risk areas have been identified and the measures outlined under condition 3 (field trial procedures, crop management and handling protocols, trial-site management measures, post-release monitoring strategies and reporting) will be implemented in order to counteract those risks and prevent gene transfer and carry-over from the GM potato trial to any neighbouring non-GM potato crops.

8. Any economic benefit of GM cultivation is outweighed by the economic costs of segregation of non-GM and GM in seeds, fields, harvesters, mills and in food production. **1**

Agency Response

Effective labelling requires segregation or an Identity Preservation System. Such systems are necessary in order to prevent admixture and the likelihood is that their implementation (of an Identity Preservation System in particular) would incur significant costs. The extent to which any financial benefit would be eroded is not for the Agency to say.

9. GM production could mean the loss of organic farming and loss of choice for consumers. **4**

10. Organic farmers would lose their organic licence if GM contamination was detected on their non-GM farms. **1**

Agency Response (to 9 and 10)

Many organic/non-organic farmers and their representative groups are of the view that their businesses could be negatively impacted and where relevant, organic standards compromised with the introduction of GM crops.

The distance between the location of the proposed GM potato field trial and the nearest conventional potato plants (which happens to be the national potato breeding programme) is 750m. The nearest organic potato producer is at a distance greater than 750m. The potato has a high degree of biological containment. Potatoes can be described as a low risk crop for gene flow from crop to crop and from crop to wild relatives. Cross-pollination between production crops is not considered an issue since the harvested tuber is not affected by incoming pollen[10]. Volunteers however can be persistent and

[9] Identity preservation is a process or system of maintaining the segregation and documenting the identity of a product

[10] Eastham K, Sweet J, (2002) Genetically Modified Organisms (GMOs): The significance of gene flow through pollen transfer, European Environment Agency, Copenhagen.

chemical and mechanical measures have been conditioned to control their development for a period of 4 years following completion of the trial. Spatial management systems have been conditioned to prevent admixture. Any material left over from the trial will be destroyed. Finally the scale of this release is very small – 10m^2.

5.2. BIODIVERSITY CONCERNS

1. GM crops pose a risk to biodiversity not least through cross-contamination with wild and native plant populations. Expression of HT genes in weeds, conventional/organic potato crop.**25**

Agency Response

Any modification to farming practice would impact on landscape biodiversity. The introduction of GM varieties will be no different.

That said the potato plant is largely self-pollinating and the potato is not an invasive crop species therefore any impact is expected to be low. The risk of gene flow from potatoes is low compared to other crops like oilseed seed rape. The results of trials carried out by Teagasc suggest that the average drift of pollen is 11m with a maximum drift of 21m. This very small scale trial will be located 750m from any other potato plants. As already indicated, pollen mediated gene flow will have no impact on the formation or the genetic constitution of tubers of the receiving crop (conventional/organic). Cross-pollination can give rise to true potato seed which can survive in the soil bank for up to 10 years. However, volunteers are unlikely to pose a problem since a new potato variety (originating from cross-pollinated true potato seed) has never been identified on Irish land[11]. Therefore there is no record of plants originating from true potato seed persisting in the environment. Nonetheless, volunteers can be effectively dealt with by both physical and chemical methods.

2. Impact on birds, insects and soil biota. Development of resistance in insect populations exposed to GM crops. Recent research indicates that GM plants can have a dangerous effect on secondary species feeding on aphids. **8**

Agency Response

Wild animals, mammals and birds occasionally feed on potatoes that are exposed after sowing or that remain in the field post-harvest. To minimise animal ingress, 4ft high animal proof electric fencing, sunk to a level of 6 inches will enclose the site. In addition, during the growing season, project personnel will visit the site at least twice weekly (condition 3.3) and cover any exposed tubers with soil or

[11] Department of Agriculture, Food and the Marine.

where this is not possible the tubers will be removed for destruction (condition 3.8).

The above mentioned research reported increased larval mortality in the 2 spot ladybird in experimental feeding studies. The study relates to Bt Maize and is not directly relevant to the proposed experimental work under review.

3. Risks posed by GM plants to bees. **1**

Agency Response

Honeybees rarely forage in potato crops while bumblebees act as the primary insect pollinator of potato. It is unlikely that the GM potato line A15-031 will pose a risk to bee populations since the GM trait in question (resistance to late blight disease) does not target insects.

4. Research on GM crops on farmland biodiversity in the UK on more than 200 plots demonstrated: 68% lower abundance of bees and butterflies in GM fields than in conventional fields; reduced biodiversity in field margins; reduced range of pollinators and other beneficial invertebrates. **1**

Agency Response

The above statement is taken from an Institute of Science in Society (ISIS) online report on the GM crop Farm Scale Evaluations (FSEs) carried out in the U.K. 1999 – 2002. The objective of this 4 year research programme carried out by independent researchers was to study the effect, if any, that the management practices associated with GM herbicide tolerant crops might have on farmland wildlife compared with weed control used with non-GM crops. The crops tested were spring oilseed rape, beet and maize and the genetic modification trait was resistance to specific herbicides.

Some insect groups such as bees and butterflies were recorded more frequently in and around the conventional crops because there were more weeds to provide food and cover. There were also more weed seeds in conventional beet and spring oilseed rape crops than in their GM counterparts. However, there were some species (springtails and their predators) that were found in greater numbers in all the GM fields compared with their conventional equivalents.

In contrast, there were more weeds in and around the GM herbicide maize crops, more butterflies and bees at certain times of the year and more weed seeds.

The FSE report concluded that it was not the GM nature of the crops that was responsible for these differences, rather, it was the herbicide management applied to them.

5. GM crop production leads to large areas of mono-cropping. This invariably leads to diminishing soil quality, increased use of herbicides, pesticides and fertilisers. This in turn will lead to increased costs for farmer, reduced yield and lower quality of produce. **8**

Agency Response

Large area mono-cropping tends to be a feature of GM and non-GM crop production in the Americas rather than in Europe. European agricultural landscape tends to be highly fragmented with small average field sizes which does not lend itself to large area mono-cropping.

6. Development of superweeds. **4**

Agency Response

The genetic trait in this instance is disease resistance and the development of superweeds as a consequence of this trait is not foreseen.

7. There is a build-up and persistence of herbicide residue in soil, crops and the environment. **2**

Agency Response

In this instance, the build-up and persistence of herbicide residue is expected to be no greater than with conventional potato systems, since stewardship of the site will be in accordance with standard conventional practices for the cultivation of commercial potato.

8. GM crops increase the need for pesticide control. GM crops have been responsible for increased herbicide use in the US over the first 13 years of commercial use. This increased herbicide use negates decreased insecticide use attributed to corn and cotton **3**

Agency Response

This statement is taken from a 2009 report entitled "Impacts of GE crops on pesticide[12] use in the US: the first 13 years by Charles Benbrook, the Organic Centre 2009." In brief, this report concludes that herbicide tolerant (HT) crops have increased pesticide use by 382.6 million pounds, while Bt transgenic varieties have reduced insecticide use by 64.2 million pounds in 13 years. Thus, total pesticide use has risen some 318 million pounds over the 13 year period.

Increased pesticide use, largely due to increased pesticide use in HT crops, especially HT soybean, is not surprising. Heavy reliance on HT crops and a single herbicide for weed management might lead to changes in weed communities and resistance. This triggers the need to apply additional herbicides and/or increase application rates to

[12] The term pesticide encompasses herbicides applied to control weeds, insecticides used to manage insects and fungicides sprayed to manage plant diseases.

achieve the same level of weed control. This phenomenon is not solely a GM crop issue since it existed ever before the advent of GM crops.

5.3. HEALTH CONCERNS

1. Insufficient studies and / or a need for studies to establish that there is no toxic, allergenic or harmful effects on animal / human health and / or the environment. **7**
2. *S. tuberosum venturii* is not an edible potato, what are its toxicity levels and is this trait being carried through to the next generation? Or the Rpi gene could be toxic to mammals evidence to the contrary has not been provided. **2**

Agency response (to 1 and 2)

GM potatoes arising from this trial will not be made available to commercial livestock as a feed substitute.

While the notifier has offered to carry out feeding studies to run concomitantly with the field trials, feeding studies do not fall within the remit of the Agency and therefore the Agency has not conditioned for the performance of a feeding study.

The Agency consulted the FSAI with regard to the impact of inadvertent consumption of the GM potato by humans or animals. The FSAI responded that no safety concerns arising from inadvertent consumption were identified.

The risks posed by this proposed deliberate release to human health and the environment were considered to be low by all the Agency expert reviewers including the majority of the GMO Advisory Committee.

5.4. PUBLIC PERCEPTION / PUBLIC CONSULTATION

1. The majority of people of Ireland and Europe do not want GM crops / foods. **16**

Agency Response

The 2010 Eurobarometer[13] survey showed that 23% of those surveyed agreed and 61% disagreed with the statement "GM food should be encouraged". The percentage opposed to GM food had increased from 57% in the previous survey in 2005. However, when asked about the applications of GM, the majority of those interviewed said they would buy GM food if it was healthier (56%) or contained less pesticide residues (61%) while only 36% of the respondents

[13] Eurobarometer is a series of surveys regularly performed on behalf of the European Commission. It produces reports of public opinion of certain issues relating to the European Union across the member states.

said they would buy GM food if it was cheaper, while 56% said they would not buy GM in this case. It was also reported that 61% of Irish people surveyed (55% of Europeans) would accept a cisgenic variety while 36% of Irish people (33% of Europeans) would accept a transgenic variety.

In February 2007, Teagasc surveyed potato growers for their attitudes regarding the possible cultivation of GM potatoes in Ireland[14]. Of the 12% of the commercial potato growers surveyed, 60% stated that they would be in favour of growing blight resistant GM potatoes on condition that there was a market and that the growing of the crop did not pose a risk to the environment or to human health. Significantly, the survey highlighted a requirement by growers for more information on several aspects of GM cropping so that they can make an informed decision if or when GM potato seed becomes available.

In the event that BASF's application for a GM potato resistant to late blight disease is approved for cultivation in the EU , Irish farmers will have the option to grow it. Therefore, it could happen that in future years Irish farmers will look to Teagasc for advice and information on the cultivation of GM potatoes in Ireland. The research that is being proposed now will form a basis for that advice and will in the interim help to inform public opinion.

2. Blight tolerant conventional potatoes have already been developed. There is no need for GM potatoes/crops. 14

Agency response

Blight resistant conventional potato varieties (non-GM) have already been developed and farmers/growers have the freedom of choice to choose to grow these potato lines.

3. If one GM crop is introduced, it is probable that more GM crops will be introduced in the future which have a higher rate of cross pollination and contamination thereby threatening our entire seed crop varieties. **4**

Agency Response

The belief expressed here seems to be that the approval of GM crop trials would establish a precedent and open the door to the trialing/ cultivation of other GM food crops. In accordance with the legislation each application received in respect of a proposed GM crop trial must be assessed on a case-by case basis.

[14] Are farmers willing to grow GM potato? Martin O'Brien and Ewen Mullins, 2007.

4. Need for greater public awareness/consultation and discourse around proposal. **5**

5. There is insufficient knowledge about the effects of GM crops on soil and other plants, soil microbes, insects, other animals and humans. **3**

6. There should be a 5 - 10 year moratorium on all GM foods being trialed and grown in Ireland. GM trials should not proceed until such time as the impact of GM plants is fully known and understood. **10**

Agency Response (to 4, 5 and 6)

In 1999, the report of the Chairing Panel[15] recommended "*the identification, supervision and funding of a programme of independent generic research (i.e. not specific to any particular product) by the EPA, specifically on safety issues related to the deliberate release of GMOs into the environment*". This was reiterated in 2000 when the Inter-Departmental Group on Modern Biotechnology[16] chaired by the then Department of Enterprise Trade and Employment recommended '*that independent generic research (i.e. not limited to any particular product) be conducted in this country into all aspects of GMOs, including human health and safety, animal health and live crops, and the effects of GMOs on the Irish environment having regard to our distinctive climatic and geological conditions.*'

This small scale field trial proposes to assess the potential impact GM potatoes resistant to late potato blight disease could have on our ecosystems as well as monitoring how the blight fungus and the ecosystem react to GM strains over a number of years. It is only with the performance of such research that the GM debate – particularly in the context of the impact of GMOs on the Irish environment - can be informed.

7. This is not a good time to be embarking on such trials since Monsanto and BASF have closed down research facilities in the EU. An increasing number of countries are imposing restrictions or bans on GM crops. **7**

Agency Response

In January 2012, BASF announced that it was relocating its European Headquarters to the US (it will retain offices in Belgium and Germany) owing to the European public's hostility to GM crops. Despite this, EFSA is continuing to review 3 applications received from BASF in 2010 and 2011 in respect of GM starch potato and blight resistant potato varieties. The scope of these applications is for food and feed uses, processing and cultivation. There has been no

[15] National Consultation Debate on GMOs and the Environment, Report of the Chairing Panel, July 1999.

[16] Report of the Inter-Departmental Group on Modern Biotechnology, Department of Enterprise, Trade and Employment, October 2000

indication from Monsanto that it will close its European research facilities.

8. There is a tendency for companies to manipulate test results to get the desired results. Fundamental flaws in how biotech companies test. Application seems to predict the outcome of the trial. **3**

Agency Response

The Environmental Risk Assessment (ERA) has been completed in accordance with the legislative requirements.

9. Ireland could be the one EU MS to act as the control (not use GM) and explore the cultivation of biodiversity and other alternative techniques to stave off blight. **1**

Agency Response

The promotion of Ireland as a GM free region is a Government policy related issue.

5.5. INTELLUCTUAL PROPERTY / CONFLICT OF INTEREST

1. The blight resistance gene involves a patent that is owned by a group of scientists including R. Visser and E. van der Vossen who are cited as two of the authors of reference no 19, referenced in the application. Conflict of interest statements have not been made by the two patent holders, yet they stand to benefit from acceptance of the GM potato. Would an unintentional release of seeds, pollen and tubers constitute an infringement of intellectual property rights which would put Irish potato growers at risk of litigation in the future? **7**

2. Reference No 19 (Societal costs of late blight in potato and prospects of durable resistance through cisgenic modification. Potato Research 51: 47 – 57) deemed unacceptable as the authors include A.J. Haverkort project manager of the DuRPh cisgenic potato project and R. Visser and E. van der Vossen who hold patents on aspects of cisgenic potatoes. Are GM potato patent holders involved in AMIGA? Many aspects of other blight related networks and consortia are partially or fully funded by Biotech companies Syngenta, Du Pont, Certis, BASF, Bayer, AVEBE, Dacom, Dow, Germicopa.

Agency Response (to 1 and 2)

Without patents, institutions and individuals would be deterred from making investments in research and development (R&D), since unprotected intellectual property can be exploited quite easily. Patents also provide an incentive to continue to invest in R&D.

Whether or not the abovementioned patent holders are involved in AMIGA is not a consideration for the EPA. Rather it is a consideration for the co-ordinators of AMIGA.

3. There is a perception that this is pre-market research. The Teagasc trials are not genuinely objective or impartial. Obligations of Teagasc as a public research performing project partner in an FP7 project are not known. How will any intellectual property developed during the project be treated? **8**

Agency Response

This is pre-market research, in that the notifier proposes to investigate how the GM potato will perform under Irish soil and climatic conditions. The treatment of any intellectual property developed during the course of this project is a consideration for the co-ordinators of AMIGA.

4. If Teagasc are the organisation promoting this trial, it would be a conflict of interest for them to lead an investigation of public opinion on the topic, (in reference to proposed open day, outreach programme etc). **1**

Agency Response

To date, Teagasc has carried out the majority of independent research in this area. Teagasc is therefore best placed to disseminate information on the results of that research, be that through an open day or through the Teagasc website. It is then up to the members of the public to judge the validity and implications of that research for themselves.

5.6. REGULATION

1. The Aarhus convention on Access to Information Public Participation in Decision making and Access to Justice in Environmental matters obliges the Irish Government via the Treaty of Rome to ensure that the Irish people have a legal right to information and participation in decisions affecting the health of their environment. There is no public participation in GM crop / food or feed policies in Ireland. **11**

Agency Response

The Aarhus Convention was ratified by Ireland on 12 June 2012. Despite recent ratification, according to DECLG (with whom the Agency consulted on this topic), all Environmental legislation was heretofore in compliance with the requirements of the Convention. In addition, in accordance with the GMO (Deliberate Release) Regulations, S.I. No. 500 of 2003, organisations which in the opinion of the Agency are concerned with environmental protection are served with 2 representatives on the GMO Advisory Committee. A broad range of NGOs were consulted with regard to these nominations.

Furthermore, in accordance with Article 15 of the Regulations, the notifier published a notice of the proposed field trial, in the Irish Independent newspaper on 29 February 2012, informing members of the public of the proposed trial and that representations could be

submitted to the EPA within 28 days of publication of the notice. The EPA published full details of the proposed trial on its webpage.

2. Application requires assessment under the SEA Directive 2001/42/EC on the basis of "the requirement of Regulations SI 500/2003 for numerous plans associated with the planned release of GMOs". **2**

Agency Response

The Strategic Environment Assessment (SEA) Directive, 2001/42/EC, relates to planning issues. The Deliberate Release Regulations refer to monitoring and emergency response plans which bear no relation to the SEA Directive.

3. IE has responsibilities under the International Convention on Biodiversity not to support policies or practices which would damage or impact our biodiversity. **1**
4. Application contravenes the Cartagena Protocol in that it ignores the known biosafety issues regarding GM crops (spelled out in the Protocol). **1**

Agency Response (to 3 and 4)

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity is an international agreement which aims to ensure the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health. The GMO (Transboundary Movement) Regulations 2003 give effect to the Regulation 1946/2003 on transboundary movements of GMOs and the Cartagena Protocol and it constitutes a system for notifying and exchanging information on the transboundary movements of GMOs to third countries, outside the EU, therefore it has no bearing in this instance.

5. C.2 (1) of 2nd Schedule of S.I. No 500 of 2003 includes the statement "It is important not to discount any potential adverse effect on the basis that it is unlikely to occur". Teagasc has numerous examples that seem to discount adverse effects (e.g. page 29, H6). **1**

Agency Response

Section C.2.1 (entitled 'Identification of characteristics which may cause adverse effects') of the Second Schedule of the GMO (Deliberate Release) Regulations, S.I. No 500 of 2003, relating to 'Principles for the Environmental Risk Assessment' (ERA) states as follows *'It is important not to discount any potential adverse effect on the basis that it is unlikely to occur'*. This statement is made in the context of hazard identification, where the notifier is required to identify the property or situation that could lead to harm or cause adverse effects. This is the first step in the 6 step analysis of ERA. Subsequent steps evaluate the consequences of each adverse effect,

the magnitude of the consequence if the hazard were to occur, and the probability of the hazard occurring.

Commission Decision 2002/623/EC provides further guidance on ERA, section 4.2.3 of which refers to "the likelihood of occurrence". It goes on to say "*For each adverse effect identified, the relative likelihood of the consequence can probably not be assessed quantitatively, but it can be expressed in terms of 'high', 'moderate', 'low' or 'negligible'.*" Similarly, section 4.2.4 ('Estimation of the risk posed....') states that '*quantitative evaluation is unlikely to be possible*' and that the magnitude of the consequences and the likelihood of the adverse effect can be expressed in terms of 'high', 'moderate', 'low' or 'negligible'.

Therefore it is permissible to use of such terms as 'highly unlikely', 'likely', 'very unlikely', or 'negligible' in the ERA. Furthermore, the use of such terms in the notification has been supported with proposed management strategies.

Finally, ERA is an iterative process. If new information on the GM plant and its effects on human health or the environment becomes available, the ERA can be re-addressed under articles 21 / 22 of the Regulations. This is provided for in the Consent Conditions under condition 1.4.

6. The right of a region to remain free of GM crop contamination is enshrined in European legislation. **2**
7. Support for subsidiarity proposal[17] . **1**

Agency Response (to 6 and 7)

The right of a region to remain GM-free and the subsidiarity proposal are Government policy related issues.

8. Such decisions (i.e. the performance of GM field trials) should have the endorsement of Dail Eireann. **1**

Agency Response

The Agency is responsible for implementing the GMO legislation.
Article 6(5) under Part B of Directive 2001/18/EC on the deliberate release into the environment of GMOs, stipulates that the Competent Authority shall inform the notifier whether his notification is in compliance with the Directive and accordingly, whether the release may proceed or whether the notification is rejected.

This Directive has been transposed into Irish Law as the GMO (Deliberate Release) Regulations S.I. No 500 of 2003. Article 4 of the Regulations assigns the function of Competent Authority to the EPA.

[17] Commission proposal to give Member States the freedom to allow, restrict or ban the cultivation of Genetically Modified Organisms (GMOs) on part or all of their territory

9. A basic requirement of Directive 2001/18/EC that the ERA is conducted in a "scientifically sound and transparent manner" is not fulfilled and therefore the risks cannot be assessed properly **1**

Agency Response

A number of the public representations received, claimed that the notifier discounted potential adverse effects on the basis that they were unlikely to occur and used such words as 'negligible' and 'no propensity'. This claim has already been dealt with in the context of the legislation under representation 5 of 'Regulation', (section 5.6).

It is also a general fact that there is no such thing as zero risk, there is always some degree of uncertainty. The notifier has identified the risks and the corresponding management strategies that need to be implemented in order to control those risks and cover the uncertainties. The measures employed must be proportionate to the level of risk and the level of uncertainty[18].

These and other risk management strategies have been conditioned by the Agency.

10. Precautionary Principle - GM crops should not be trialed in Ireland unless it can be proven beyond all possible doubt that there will be no harm to our biodiversity, ecosystems or food chain. **8**

Agency Response

The precautionary principle does not state that '... unless it can be proven beyond all possible doubt' rather it states that 'Member States ... must ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release .... of GMOs'. The precautionary principle has been taken into account and is enshrined in the conditions of this consent.

11. The role of the EPA is both specific (as in this instance) and big picture - how does this application fit into the Irish Environment big picture? It is not the remit of the EPA to licence the release of GM constructs into the Irish environment for demonstration or education purposes. **2**

Agency Response

It is the role of the EPA to evaluate the risks posed by the proposed deliberate and to issue consent only if it is satisfied that the proposed release will not result in adverse effects on human health or the environment. Pending consent, Teagasc plan to conduct an outreach programme with their stakeholders and the wider public. The Agency has no involvement in this programme.

---

[18] Commission Decision 2002/623/EC establishing guidance notes supplementing Annex II to Directive 2001/18/EC on the deliberate release into the environment of GMOs

12. Provision of Habitats Directive Articles 6(3) and 12 in particular need to be considered. Impact of this release on Natura 2000 sites and on protected species. EPA must determine with scientific certainty the likely significant effects and the effects on site integrity. There is insufficient information in the application to do this. **2**

Agency Response

Article 6(3) of the Habitats Directive 92/43/EC states "*Any plan or project not directly connected with or necessary to the management of the site but likely to have a significant effect thereon, either individually or in combination with other plans or projects, shall be subject to appropriate assessment of its implications for the site in view of the site's conservation objectives.*"

The proposed location of the GM potato field trial is approximately 1.47km from the River Barrow and River Nore Special Area of Conservation across farmland, the Waterford-Dublin railway line and a section of Oak Park forest. Applying the provisions of the GMO (Deliberate Release) Regulations, S.I. No 500 of 2003[19] ensures that an approved GM trial does not have an adverse effect on the environment. It therefore follows that a GM field trial is not seen as "likely to have a significant effect" on a site covered by the Habitats Directive.

13. GM crops once released, cannot be recalled. Who will be responsible for liability in the event of contamination of an organic or conventional unit from the test site? (18)

Agency Response

The Environmental Liability Regulations S.I. No 547 of 2008 defines environmental damage under three categories of which land damage is probably be most applicable to the scenario outlined in the representation above. 'Land damage' is defined as "*any contamination that creates a significant risk of human health being adversely affected as a result of the direct or indirect introduction in or under the land of substances, preparations, organisms or micro-organisms*". Where 'land damage' is deemed to have occurred, the operator is liable under the aforementioned Regulations. However the overall risk to human health and the environment is low from this proposed field trial.

[19] Part II.E of the Third Schedule of the Regulations seeks the following information: a description of the release site ecosystem, including climate, flora and fauna; details of sexually compatible wild relatives or cultivated plant species present; and, the proximity to officially recognized biotopes or protected areas which may be affected.

5.7. GENETIC MODIFICATION

1. GM transformation process is imprecise, can cause widespread mutations in plant DNA which in turn can disrupt the functioning and regulation of 100's of genes leading to unpredictable and potentially harmful effects. Insufficient knowledge about the genetic stability of GM crops. Most genes code for many proteins. **18**

2. Application provides no definition of the term 'cisgenic'. The implication is that cisgenic is less risky than transgenic. GE technology is common to both cisgenesis and transgenesis. **4**

3. The term cisgenic is defined as "the GM of a recipient plant with a gene from a crossable - sexually compatible - plant" but S. *tuberosum* and cv Desiree are not sexually compatible (protoplast fusions could not be obtained) therefore we are dealing with a transgenic as opposed to a cisgenic cross. It is the genetic engineering technique which gives rise to unpredictable effects and those effects are the source of the risk. **6**

Agency Response (to 1, 2 and 3)

In February 2012, further to a request from the European Commission, EFSA published a scientific opinion[20] on plants developed through cisgenesis in terms of the risks they might pose.

EFSA indicated that in general, integration patterns obtained by *Agrobacterium*-mediated transformation are regarded as more precise and less complex when compared to the integration patterns of DNA delivered to the plant cell by means of direct gene transfer methods (i.e. without the help of a vector).

The same types of changes are expected in cisgenic plants as in conventional breeding. Undesirable changes in the genome can occur in conventional breeding as well as during the production of cisgenic / transgenic plants, however undesirable phenotypes can be discarded by the breeder or may be eliminated by backcrossing where possible.

It is true that transgenesis and cisgenesis both use the same techniques of genetic modification. Consequently, irrespective of whether transgenesis or cisgenesis is involved, this experimentation falls within the scope of Directive 2001/18/EC on the deliberate release into the environment of GMOs.

This Scientific Opinion was discussed by the GMO Advisory Committee on 19th April 2012. The final draft minutes from that meeting are provided in Appendix 1.

---

[20] EFSA, 2012, Scientific opinion addressing the safety assessment of plants developed through cisgenesis and intragenesis.

5.8. THE STUDY

5.8.1. GENERAL

1. Blight is constantly evolving (*P.infestans* constantly mutates and will mutate during the course of this trial) and susceptibility to it can occur with all potato varieties over time, including GM varieties. **15**

Agency Response

It is probably true to say that the GM potato variety will in time become susceptible to the blight fungus as this fungus has the propensity to mutate and produce new 'physiologic races' of the fungus which become tolerant to fungicides. While 'Sarpo Mira' - the blight resistant conventional potato variety currently on the market - is blight resistant, it is not blight free; susceptibility to late blight disease has been known to occur. 'Sarpo Mira' is mainly used by home gardeners. It is not a major variety planted by Irish farmers.

2. 28 days to respond to a 35 page technical document is insufficient and allows no time for consultation. **9**

Agency Response

A 28 day period for public consultation is specified in the GMO (Deliberate Release) Regulations S.I. No 500 of 2003. An increased period for public consultation is a matter for the DECLG who have responsibility for policy matters relating to GMOs.

3. Teagasc are only considering intensive industrial agriculture and are not taking other forms of Irish agriculture into account. There is a lack of expertise and knowledge in Teagasc about organic agriculture and natural farming systems. Call upon Teagasc to conduct research into organic production or improve existing varieties. **8**
4. Why is the Irish taxpayer being asked to fund research without proper public consultation. **4**

Agency Response (to 3 and 4)

The nature of the research carried out by Teagasc and how this research is funded are issues which can only be addressed by Teagasc. However, the Report of the Inter-Departmental Group on Modern Biotechnology published in 2000 stated that Teagasc has a central role to play in devising and undertaking research into GM crops and foods which takes adequate account of Irish needs and conditions. The report went on to recommend that Teagasc should have the capacity to undertake its own programme of efficacy trials of GM crops.

5. Teagasc has been conducting GM research in greenhouses and controlled environments, some information on the findings from these trials should be made publically available. **1**

Agency Response

Teagasc, Oak Park, has been engaged in studies involving the contained use of GM plants since 2001. The publication of findings from these studies is again, a matter for Teagasc.

6. This trial is part of a wider EU trial with 22 institutions involved. Some experiments have been carried out over 2 years, information on the results to date should be made available. **3**

Agency Response

The GM potato line A15-031 was planted in 2011 in 3 locations in the NL under Reference No B/NL/09/02. Consultation with the NL authorities revealed that nothing unusual was observed in phenotypic characteristics or interactions in the environment.

7. What measures will be taken if the results from the study show that the production of GM potatoes impacts negatively both environmentally and economically? **1**

Agency Response

Article 21 of the GMO (Deliberate Release) Regulations, S.I. No 500 of 2003, reproduced in the Consent Conditions under condition 4.0) requires the notifier to take immediate protective measures and duly inform the Agency where 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 Agency in turn under Article 22 of the Regulations has the power to modify the consent conditions or suspend or terminate the release, following an evaluation of the new information / unintended change concerned (condition 1.4). In the event that the Agency suspends the trial, the trial cannot resume unless the Agency sanctions its resumption in writing to the notifier (condition 4.0).

The notifier is required to submit end of year reports to the Agency (condition 5.6) as well as a final report (condition 5.7) on completion of the deliberate release. The format for the final report is established under Commission Decision 2003/701/EC and it will provide results from the release and a post release evaluation of the risks to human health and the environment. The Agency in turn is required to forward the final report to the European Commission for publication on the GMO WebSNIF webpage. Teagasc in their notification have committed to "*making all datasets publicly available once the project's*

***deliverables have passed the scientific standard to international peer-review'*. The Agency will similarly make all reports in its receipt publicly available.**

The Agency has no remit for the economic aspects of this proposed trial.

8. High levels of fungicides and biocides have been applied to grounds at Oak Park over the years therefore soil conditions at Oak Park do not replicate those of potato growers in Ireland. The results of cropping from the tests and the examination of the effect GM propagation has on the soil will not be relevant to conditions relating to potato growers in Ireland.**1**

Agency Response:

The proposed site for the performance of the GM potato field trials has been in grassland for more than 10 years. Stewardship of the site will be in accordance with standard conventional practices for the cultivation of commercial potato.

9. Request that the trial be carried out in containment prior to environmental release and that the following data be collected:

- biochemical studies to support equivalence in protein and enzyme structure carried out to minimise issues with wildlife and insect populations
- Impact on the pollinators involved in the dissemination of potato pollen should also be fully studied prior to an introduction of a GM variety of potato into open field trials 1
- Investigation of the impact of the Rpi gene on pest species, insect biodiversity and soil micro-organisms should be investigated in a greenhouse rather than in the open field to establish a baseline of interaction prior to any field trials 1

Agency Response

Directive 2001/18/EC constitutes a framework for the deliberate release of GMOs into the environment. The Directive states as follows:

- ***"The deliberate release of GMOs at the research stage is in most cases a necessary step in the development of new products derived from, or containing GMOs."* (Recital 23);**
- ***"The introduction of GMOs into the environment should be carried out according to the 'step by step' principle. This means that the containment of GMOs is reduced and the scale of release increased gradually, step by step, but only if***

evaluation of the earlier steps in terms of protection of human health and the environment that next step can be taken." **(Recital 24);**

- ***No GMOs, as or in products, intended for deliberate release are to be considered for placing on the market without first having been subjected to satisfactory field testing at the research and development stage in ecosystems which could be affected by their use."*** **(Recital 25).**

While there is no requirement for the performance of studies under containment in advance of field studies, in most instances it is likely that studies in containment have preceded trials.

Applications made under Part B of Directive 2001/18/EC (i.e. field trials) do not necessarily need to be in preparation for commercial releases - trials for pure research, development demonstration and biosafety /risk assessment purposes may also be undertaken.

10. Pollen mediated gene flow study - variation between the 2 studies (2005 and 2010 study) is so great in terms of distance of seed produced from the donor plot as well as the number of berries produced and the quantity of viable seed produced would call results into question and imply that further studies in this area are required before any definitive statement can be made as to the level of pollen dispersal in potato species under Irish conditions. **1**

Agency Response

The 2005 and 2010 studies (both of which have been described under section 2.9.1 dealing with 'Dissemination via TPS and pollen') looked at pollen dispersion in cv Desiree. During the 2010 study the average pollen drift for cv Desiree was found to be 10m. During the 2005 study, which was designed to maximise pollen transfer in a 'worst case scenario', the maximum pollen drift was 21m. Mindful of this result, the notifier proposed a 40m minimum separation distance between the proposed GM potato trial site and neighbouring conventional potato crops. In reality, the nearest sexually compatible potato crop will be located 750m from the proposed GM potato trial site.

11. Purpose of the release is given as ".... a tool for education and demonstration in order to proactively engage and discuss the issues that most concern stakeholders and the public at large in regards to the cultivation of GM crops in Ireland" so Teagasc propose to engage

with the public after the GM potatoes have been planted. Public engagement must happen before the trial is considered. **10**

Agency Response

With regard to public consultation, the Agency only has remit to consider representations received from members of the public in its decision making process, in accordance with the procedures set out under articles 15 and 16 of the GMO (Deliberate Release) Regulations, S.I. No 500 of 2003.

The public engagement that the notifier, Teagasc, is proposing is outside of the Agency's remit.

5.8.2. RISK ASSESSMENT (RA)

1. No detail/evidence is given as to the point of insertion of the 2 gene copies and the genes disrupted or deleted in the GM cv Desiree variety. No DNA sequencing of molecular analysis provided. **2**

2. Random insertion events are common occurrences under such transformation processes. **1**

3. Potential for transfer of Rpi genes or other unintended products of the GE process to soil bacteria and other microorganisms. Risk of HGT from GM potatoes via *A. tumefaciens* **3**

4. Something is expelled to make room for the newly inserted gene which may have implications for plant and cause it to interact with surrounding environment. **2**

Agency Response (to 1, 2, 3 and 4)

As already indicated undesirable changes in the genome can occur in conventional breeding as well as during the production of cisgenic / transgenic plants, however undesirable phenotypes can be discarded by the breeder or may be eliminated by backcrossing where possible.

5. No evidence of the following produced:
   - phenotypical stability;

Agency Response

During the course of the NL trials, no changes were observed in phenotype or growth characteristics (such as behaviour, fitness, reproduction, survivability or dissemination) of the GM potato plant compared to the non-GM comparator.

- increased resistance to *P.infestans* consistently expressed in successive generations;

Agency Response

In the event that the Rpi-vnt1.1 gene was genetically unstable it would not confer the desired phenotype. As a result, significant degrees of *P. infestans* infection and disease would be expected, equivalent to what is recorded on the non-GM comparator Desiree. In such a scenario the GM potato line A15-031 would be of no use to the proposed study and would not be included in the notification. Furthermore, the GM potato tubers harvested each year will be sown the following year thereby indicating that the Rpi-vnt1.1 gene is passed from one generation to the next.

- substantial equivalence of GM and non-GM comparators;

Agency Response

The GM potato line A15-031 has only been modified with the Rpi-vnt1.1 gene, which remains under the control of the native promoter and terminator sequence. As such, the expression of the insert is dependent on whether particular tissues of the plant are exposed to the pathogenic organism *P. infestans*. Cultivation in the Netherlands indicates the phenotypic equivalence of A15-031 and the comparator Desiree in respect of which the notifier has provided photographic images.

- that the NPTIII gene has been removed entirely (100%) (Specify process used to remove it). **3**

Agency Response

The molecular characterisation report submitted by Teagasc on 14 June 2012 was reviewed by an independent expert (see section 7.1.2) who confirmed the absence of the antibiotic resistance genes *tetA* and *nptIII* from GM potato line A15-031.

6. The RA contains a number of assumptions regarding persistence and invasiveness

- "the R gene ....will only confer a competitive advantage in the presence of *P.infestans* inoculum"

Agency Response

The GM potato line A15-031 is genetically equivalent to its comparator Desiree, with the exception of the presence of the Rpi-vnt1.1 gene from the wild potato species *Solanum venturii*. The Rpi-vnt1.1 gene is disease specific and only confers durable resistance to *P. infestans*. Therefore in comparison to the non-cisgenic comparator (which does not contain Rpi-vnt1.1) A15-031 is equipped with a selective ability to resist *P. infestans* disease.

- H2 Page 28 similarly contains a statement for which no reference is provided i.e. "Coupled with the fact that *P.infestans* resistance is

not a key determinant for inducting potential invasiveness, it can be concluded...

Agency Response

The primary criterion for an invasive plant species is an ability to out-compete neighbouring plants outside the confines of a managed environment (e.g rhododendron). Potato is incapable of establishing feral populations outside of the managed field environment (e.g. hedgerows), due to its inability to compete with weed species. As *P. infestans* does not infect common weed species it can be concluded that *P. infestans* resistance would not infer a fitness advantage that would permit GM potato line A15-031 to become invasive.

- Specificity of Rpi gene - may be the situation in the lab but unlikely in environment.**1**

Agency Response

GM potato field trials performed in the NL (using the same Rpi gene) have demonstrated blight resistance.

7. Request for confirmation that no other plasmid backbone material has been inserted. **1**

Agency Response

The Agency has requested the notifier to provide molecular data to confirm the results provided in Table 1 of the notification which indicates that GM potato line A15-031 nuclear genome does not contain plasmid backbone material nor the NPTIII/Tet A genes. The molecular characterisation report submitted by Teagasc on 14 June 2012 was reviewed by an independent expert (see section 7.1.2) who confirmed the absence of the antibiotic resistance genes *tetA* and *nptIII* from GM potato line A15-031. Teagasc provided no information on the presence/absence of left or right borders in their report of June 14. However they stated that their presence/absence would not confer any environmental risk since their role is solely to co-ordinate the Agrobacterium mediated transformation process. The Agency's independent expert confirmed in his report (Appendix 2) that this is correct.

8. No indication is given as to how non-GM potato crop grown in parallel will be treated. **3**

Agency Response

Non-GM comparator plants will be removed from the trial site and stored within the EPA licensed facility contained use facility in Oak Park thereby ensuring complete separation from any non-GM commercial potato lots. All plots on the site will undergo repeat harvesting to minimise tuber loss post-harvest

and the site will be surveyed by project personnel who will collect mini tubers and tuber pieces (irrespective of being GM or comparator) in sealed bags for disposal by steam sterilisation. It is intended that the non-GM comparator tubers collected from the 2012 harvest will be used to supplement the number of tubers required for the following 2013 season and the same will occur from 2013-2014 and 2014-2015. No non-GM comparator tuber material will be supplied to animals for feed purposes during the course of the study.

9. The RA is not in compliance with the requirements of Directive 2001/18/EC as it appears to discount virtually all potential adverse effects with words like 'negligible' and 'no propensity'. **3**

Agency Response

The issues raised here have already been addressed in the Agency's response to representation 5 and representation 9 under Regulation (section 5.6).

10. Unclear how the effects on soil ecology and biodiversity are being measured **2**

Agency Response

The duty of the Agency - further to receipt of a notification for the release of a GMO into the environment for the purposes of performing a field trial - is specified under article 18 of the GMO (Deliberate Release) Regulations, S.I. No 500 of 2003. It is also outlined in detail under the section of this report dealing with the Irish GMO Regulations (section 1.4). The Regulations make no legislative provision for the Agency to seek information in relation to or to review methodologies. The NL Competent Authority with whom we consulted on this point is also of the same opinion.

11. Teagasc have not established how they intend to control and avoid extrapolation into the environment. **3**

Agency Response

The notifier has proposed a number of measures to prevent dissemination into the environment and these have been outlined in detail under "*Information on control monitoring post-release and waste treatment plans as proposed by the notifier*" in section 2.12 of this report.

12. Allergenicity concerns **1**

Agency Response

Allergenicity has already been addressed in the Agency's response to representation 1 and 2 under Health Concerns (section 5.3).

13. The 'agri-environment' is not defined therefore it is unclear what is being assessed. **1**

Agency Response

Within the confines of the proposed notification, the term 'agri-environment' refers to the farmland-related biodiversity and associated ecological networks within the confines of a managed agricultural land system.

5.8.3. CONTAINMENT

1. Control of seed spread. Seed may be spread by rodents or other animals such as foxes, badger etc (may drag berries across boundaries). Fencing will not keep small animals out. Possibility for transfer of seed through people working on the site is not addressed. (4)
2. Application states that potato berries are not eaten by rodents due to high glyco-alkaloid - rodents often eat berries. 'Berries can survive for up to 10 years in the soil'. (Therefore monitoring should take place for at least 10 years to ensure there is no germination of transgenic seed). (7)
3. Cv Desiree is an unsuitable variety for open field trials owing to prolific berrying capacity and potential for pollen flow. (2)
4. Spread by pollen beetle - 40m exclusion zone is inadequate when one study shows the dispersal of transgenes was up to 1000m. Also 40m exclusion zone bound to fail given capacity for high / gale force winds to disseminate pollen.(5)

Agency Response (to 1 - 4 inclusive)

The potato is predominantly self-pollinating. Crop-to-crop, pollen mediated gene transfer is estimated to occur at a level of 0 – 20% with wind dispersal being the main mode of dispersion. Bumblebees (dealt with in the Agency's response to representations 5 – 7) and other insects such as the pollen beetle are possible vectors for dispersion.

The majority of field studies have detected pollen at a maximum distance of 20 m from the source. The one exception was a study performed in Sweden in 1994 which demonstrated pollen dispersion up to distances of 1000m and for which the pollen beetle was thought to be attributable. Subsequent experiments performed by other researchers contradicted this finding.

Research performed by Teagasc in 2007 acknowledged the potential for cross-pollination by the pollen beetle but indicated that it would account for haphazard pollination events that would be dependent on the travel circumference of the beetle. Teagasc studies also found the maximum pollen drift to be 21m.

Pollination gives rise to the formation of seeds which in turn may be dispersed by animals/birds foraging on the site or people working on the site, (to minimise animal ingress, a 4 feet high, small mesh electric fence, sunk to a depth of 6 inches, will surround the trial site).

Irrespective of whether gene flow is achieved through pollination or seed dispersal, the seed must germinate (not all seed will be viable), develop into a volunteer potato plant and be harvested along with a non-GM potato crop. Volunteers arising from seed are agronomically weak; they do not compete with weeds and grasses and are vulnerable to herbicide application and crop competition. Volunteers from tubers on the other hand can be persistent but can be controlled by chemical and mechanical measures. In crop production systems, volunteer tubers and plants are usually removed with the production practices that are normally used for potatoes and the crops that succeed potatoes in the rotation[21]. In the case of this trial, volunteer plants emerging post-trial will be treated with herbicide. According to the DAFM, no new or unidentifiable potato variety has been recorded in almost 90 years of official inspections under the Seed Potato Certification Scheme.

The removal of flowers as a means to prevent cross-pollination was discussed by the GMO Advisory Committee (GMO AC). Two AC members expressed the following views:

- **removing flowers from the GM plants may satisfy public concern;**
- **flowers should only be removed where this action would result in a significantly reduced risk.**

As outlined above the risk arising from cross pollination is considered very low, therefore the removal of flowers has not been conditioned for.

With regard to monitoring, the trial site be monitored for the emergence of volunteers for at least four years post-harvest.

[21] Eastham K, Sweet J (2002) Genetically modified organisms (GMOs): The significance of gene flow through pollen transfer, European Environment Agency, Copenhagen, pp. 1–75

Monitoring over a longer period may be required by the Agency where volunteer plants persist (condition 3.3).

The potato is a naturally contained species. It does not colonise unmanaged ecosystems.

5. Many of the risk management strategies proposed are not standard farm practice. **3**
6. Pollen spread by bees. Bees and other insects can travel up to 5km in any direction. An organic beehive must be placed 4 km from any source of contamination to allow for natural pollen collection distances covered by bees. Bumble bee mediated pollen flow may extend over 9 km. **6**
7. Risk of GM pollen in honey, testing/extraction etc would put increased financial burden on beekeeper. The honey would require a label stating it was GM - unlikely that honey with such a label would be saleable. Beekeepers with colonies within 3 miles could end up with GM pollen in their honey. **6**

Agency Response (to 5 – 7 inclusive)

The GM potato trial sites will be active research experiments, therefore, there will be mitigating measures in order to minimise/prevent the dissemination of material from the site. The experimental status of this proposed trial also dictates that the risk management strategies are not standard farm practice.

A number of beehives are situated in Oak Park (as part of the National Apiculture Research Programme) some 700m from the proposed location of the GM potato field trial. The notifier has no knowledge of other beehives in the surrounding district. Since potato does not produce nectar, honeybees are not usually attracted to the flowers especially as other sources of pollen and nectar will be available during the summer months. Bumblebees tend to fly short distances between pollination Furthermore bumble bees tend to 'buzz' pollinate potato flowers by vibrating their wing muscles to cause a release of pollen often leading to the self-pollination of the flower[22].

In 2011, the European Court of Justice (ECJ) ruled that honey containing GM pollen will be subject to EU authorisation regardless of the level of contamination. Most honey contains pollen apparently, though there is likely to be honey without any detectable pollen. Despite the ECJ ruling and some interpretations of the honey legislation, pollen is not essential

[22] Treu, R.,and J. Emberlin. (2000). Pollen dispersal in the crops Maize (Zea mays), oilseed rape (Brassica napus spp oleifera). Potatoes (Solanum tuberosum), sugar beet (Beta vulgaris spp vulgaris) and wheat (Triticum aestivum). A report for the Soil Association from the National Pollen Research Unit.

for the production of honey and is present merely as a botanical contaminant. For this reason, the presence of pollen from a GM plant (authorised or not) does not cause that honey to require any specific authorisation or labelling under GM legislation (Regulation EC 1829/2003 on GM Food and Feed). This may change in the future in light of the ECJ ruling and any resolution undertaken by the Commission and Member States, but for now this is how EU food law enforcement bodies interpret the situation. In any case a method to extract pollen from and detect pollen in honey is still under development by the Joint Research Commission.

8. No provision to perform additional pollen flow studies. **1**

Agency Response

The performance of additional pollen flow studies is a matter for the notifier, Teagasc.

9. That tubers will not survive in the ground at low temperatures typically between -3°C to -10°C is questionable. **1**

Agency Response

Tubers are frost sensitive and will be destroyed if they remain on the soil surface during periods of -3°C or lower. Tuber survivability increases when tubers become buried during post-harvest tillage operations and this will lead to the emergence of volunteers in the subsequent rotational crop. This is a feasible mechanism for seed mediated gene flow.

Volunteers will be controlled by collecting as many potatoes as possible at harvest. Perennial ryegrass which will be sown on the site the following Spring is a strong competitor for nutrients over potato volunteers. Emerging volunteer plants will be destroyed through the application of herbicide. The site will be further monitored for at least 4 years post-harvest for the emergence of volunteers from true potato seed and/or dormant tubers.

10. What is the proximity of Teagasc's proposed trial to its own non-GM plantings and to the farmland of three of Ireland's declared GM free counties? **7**

11. There are GM- free zones in Ireland and buffer zones cannot be relied upon even when they are several km. **3**

12. Organic and GM potatoes cannot co-exist side by side without contamination occurring. **1**

Agency Response (to 10 – 12)

The notifier is unable to specify the location of the nearest commercial potato field (organic/conventional) in the surrounding district. The actual separation distance between the site of the proposed GM potato field trial and the National Potato Breeding Programme within Oak Park is 750m.

A number of Irish counties are self-declared GM free zones i.e. free from the cultivation of GM plants. Co Carlow where Oak Park is situated is not such a GM free zone. The legal status of such zones is unclear.

13. No independent body is taking charge of destruction of residual material. **1**

Agency response

The destruction of residual GM material will be handled in house as outlined in detail under the section of this report dealing with Waste Management (section 3.0).

14. Security - Teagasc facility is not very secure as demonstrated by the recent theft of 3 beehives on two separate visits therefore theft/removal of a potato is highly probable. **5**

Agency Response

The notifier Teagasc has provided for the threat of vandalism in their emergency response plan.

6.0. Site inspection of proposed deliberate release site

On the 3rd April 2012, the Agency visited Teagasc, Oak Park and saw the proposed location for the GM potato field trial pending approval. The proposed trial site has been in grassland for in excess of 10 years. The Agency also visited the lab / greenhouse where the GM tubers / plantlets will be stored / cultivated respectively.

The Agency was satisfied with the proposed arrangements.

7.0. Review of the notification by the EPA

The Agency's review of the notification involved both an internal and external review.

7.1. External Review

7.1.1. View of the GMO Advisory Committee

The Agency held a meeting of the GMO Advisory Committee on the 19th April 2012.

Written submissions were received from 2 GMO AC members who were unable to attend the meeting:

- The first written submission sought clarification on a number of aspects of the trial. These in turn were addressed to the applicant under a request for further information or have been conditioned for under the consent conditions;

- The second written submission indicated that the making available of information to the public by Teagasc 'may assuage or even negate' some of the concerns raised.

The final draft minute[23] of this meeting is provided in appendix 1.

Two NGO representatives of the AC were strongly opposed to the performance of this proposed trial, on balance, the majority of the AC supported it.

In the aftermath of the GMO AC meeting, the Agency received correspondence from three GMO AC members.

1. In the first instance, the Agency requested one Committee member to reiterate in writing the point made by him during the GMO AC meeting. He duly obliged stating the application lacked sufficient detail in key areas. Most notably, it lacked information on the risk assessment as well as the methodology that will be used to quantify the impact of the GMO on bacteria / fungi. Details of the 'compartments', controls and fungicide treatment regimes were omitted as was the capacity for the GMO, GMO/pathogen, GMO/pathogen/fungicide combinations to have direct or indirect effects on the microbiota. The existing ERA includes statements indicating that no adverse effects are expected but no experimental evidence is provided to underpin such statements. A step-by-step science based evidence must be provided to guide the risk assessment process.

Agency Response

The role of the Agency is clearly established under Article 18 of the GMO (Deliberate Release) Regulations, S.I. No. 500 of 2003. It is to evaluate the risks posed by the proposed release and to issue consent only if it is satisfied that the proposed release will not result in adverse effects on human health or the environment.

The provision of methodologies relating to further studies identified in the notification is not a requirement under the Regulations or under Directive 2001/18 /EC from which the Regulations are transposed. This interpretation was confirmed

[23] This final draft minute will be approved at the next meeting of the GMO Advisory Committee.

by the Dutch Competent Authority with whom the Agency consulted on this point.

Commission Decision 2002/623/EC (ERA guidance) states that "*the ERA should include the results of adequate research into the potential risks involved in the deliberate release ..., along with any clearly documented comparable experience.*" However, this guidance also acknowledges that ERA can be based on limited scientific information, "*The ERA may not always result in definitive answers to all questions considered because of lack of data.*" It is however recommended that the overall uncertainty for each identified risk is described, possibly including documentation relating to: assumptions and extrapolations made at various levels in the ERA; different scientific assessments and viewpoints; uncertainties; the known limits of mitigation measures; and, conclusions that can be derived from the data.

This issue has also been addressed in the Agency's response to representation 9 under 'Regulation' (section 5.6).

2. A second GMO AC member submitted correspondence pinpointing the following critical points which were originally identified during the public consultation and that she wished to have considered during the decision making process. I will respond to these 'critical points' here.

- Teagasc fails to comply with S.I. 500 of 2003 by its multiple discounting of potential adverse effects on the basis that they were unlikely to occur.

Agency response:

This has already been addressed in the Agency's response to representation 5 and representation 9 under Regulation (section 5.6).

- There is still a significant amount of molecular data outstanding from those itemised in some PR's, and about which I'm not aware that Teagasc have been requested to supply the information.

Agency response

The Agency requested the notifier to provide molecular / PCR data to support the 'summary of PCR tests for A15 cisgenic lines' outlined in Table 1 of the application. The Agency has requested this data in order to verify the absence of the nptIII and tetA genes, vector backbone material and left and right border sequence from the A15-031 cisgenic line, as stated in the application. The provision of this data will meet the legislative

requirements outlined under Part II.D.2 of the Third Schedule of the GMO (Deliberate Release) Regulations, S.I. No 500 of 2003, which requires details of "*size and structure of the insert and methods used for its characterisation, including information on any parts of the vector introduced in the GM higher plant or any carrier or foreign DNA remaining in the GM higher plant*". This data will be reviewed and its content verified by Dr Tommy Gallagher, UCD, an independent Plant Molecular Biologist.

- Regarding the dearth of molecular data, it is simply not acceptable, as was suggested by one GMO AC member, that molecular data needed to secure a patent is sufficient to assure him regarding the gap in molecular data provided by Teagasc, and so should be sufficient for all GMO AC members and the EPA.

Agency Response

In accordance with Article 18(1)(c) of the GMO (Deliberate Release) Regulations, S.I. No 500 of 2003, the Agency must ensure that the notification received in respect of the deliberate release into the environment of a GMO for purposes other than placing on the market is in compliance with the aforementioned Regulations. In this regard see the Agency's response to the previous representation.

- Rpi-vnt1.1 is repeatedly described by Teagasc as giving rise to a single trait, ie, blight resistance. Teagasc must provide detailed evidence for this conclusion.

Agency Response

The genetic sequence that has been inserted into A15-031 is the Rpi-vnt1.1 cisgene, which includes the native promoter and terminator. Rpi-vnt1.1 confers resistance to *P. infestans* only[24].

- At least 3 public representations described the Teagasc research as poorly designed. It's design shortcomings must be taken into account in EPA's decision making, considering that the research involves plant material, capable of self-replication, and known to be risky.

Agency Response

The field trial design has not yet been finalised by the notifier as it is dependent on the amount of plantlets/tubers available in any given year. The notifier has provided some detail with regard to experimental design as outlined under the section of

[24] Vleeshouwers et al Understanding and exploiting late blight resistance in the age of effectors. The Annual review of Phytopathology (2011) 49:507-31
Zhu et al (2011) Functional stacking of three resistance genes against *Phytophthora infestans* in potato (DOI 10.1007/s11248-011-9510-1)

this report dealing with 'Field Trial Design' (section 2.6). Under condition 3.1 of the consent, the notifier is conditioned to provide '*detailed written Standard Operating Procedures on trial management, operations and maintenance of the trial site for each growing season*' which in turn must take account of the trial site plan. Details of the trial site plan for each site must be forwarded to the Agency for agreement at least one week in advance of planting. The trial site plan must take account of the location of the GM tubers / plantlets as well as the location of the non-GM comparators within the trial site plan.

- Teagasc must provide a definition of 'agri-environment' as used in the title of its licence application, and for cisgenic, as used in the same application.

Agency Response

A definition of the term agri-environment is provided in the Agency's response to representation 13 under 'Risk Assessment' (section 5.8.2).

Cisgenesis is the modification of a recipient organism with a gene (cisgene) from a crossable - sexually compatible – organism (same species or closely related species). The gene includes its introns (if present) and its flanking native promoter and terminator in the normal sense orientation.

- Teagasc must provide details of all patents attached to *S. tuberosum* cv Desiree-Rpi-vnt1.1.

Agency Response

The involvement of patent holders in the 'AMIGA' project is a matter for the co-ordinators of AMIGA. It does not fall within the Agency's remit.

- It is not acceptable, in terms of natural justice, citizens' right to environmental information, or under the Aarhus Convention as it operates via the EU's ratification of the convention, that a GM crop trial should proceed that has as one of its aims to inform the public about GM crop issues AFTER the trial has been licensed.

Agency Response

The issue raised here has already been addressed in the Agency's response to representation 11 under 'The Study – General' (section 5.8.1).

3. A third GMO AC member submitted their own unpublished article on the impact of genetically engineered crops on biodiversity citing many issues of concern and indicating that the level of knowledge we currently have is not sufficient to support the authorisation of

such GM crops and to simultaneously be certain that microorganisms in the soil and other living organisms will not be harmed. Rather, further research is needed before this step can be taken.

Agency Response:

Any claim that GM crops will potentially give rise to positive or negative effects on the Irish environment can only be confirmed and substantiated by carrying out controlled assessments in the field under Irish environmental conditions. The notifier, Teagasc, is proposing to measure the environmental impact of GM potato cultivation on bacterial, fungal, nematode and earthworm diversity in the soil as well as the impacts on crop management strategies in a small scale field trial. Management strategies will be implemented in order to minimise / prevent the dissemination of GM material from the site.

4. In a separate e-mail the same GMO AC member requested evidence that alternative splicing does not occur.

Agency Response:

The phenomenon of alternative splicing refers to the ability of a cell to produce multiple proteins from a single RNA transcript, which is translated from a specific DNA sequence, containing exons (coding regions) interspersed with introns (non-coding regions). The introns play a key role in deciding the prevalence of alternative splicing. The Rpi-vnt1.1 gene belongs to the NBS-LRR type of resistance genes and containing a single exon does not contain any introns. Indeed, to date no alternative splicing has been detected among intronless CC-NBS-LRR[25] resistance genes in the model research plant, Arabidopsis[26].

Separately, it is important to note that alternative splicing is a natural phenomenon in eukaryotic organisms and provides increased protein diversity and functionality. Indeed, recent literature[25] discusses the subject of alternative splicing in potato and the suggested role that alternative splicing may play a crucial role in preserving the stability of the hyper-resistance resistance response. Therefore, while the absence of introns in Rpi-vnt1.1 negates the potential for alternative splicing to occur; if it were to occur the consequence of such an event is likely to extend the durability of the cisgene's activity against *P. infestans*. This is due to the fact that resistance against *P. infestans* is only possible due to the precise recognition of

[25] CC-NBS-LRR - Coiled-coil nucleotide binding site leucine rich repeat

[26] Lozano et al. (2012) Genome wide identification and mapping of NBS-encoding resistance genes I *Solanum tuberosum* group Phureja PLoS ONE 7(4) e34775

specific *P. infestans* effector proteins by the resistant proteins of the GM potato. So if alternative splicing occurred it would lead to the production by the GM plant of variant resistant proteins against *P. infestans*, hence extending the durability and efficacy of A15-031's blight resistance phenotype.

7.1.2 Independent Expert

The Agency consulted with Dr Tommy Gallagher, a Plant Molecular Biologist and Head of the School of Biology and Environmental Science at University College Dublin. Dr Gallagher reviewed the molecular characterisation report submitted by Teagasc in respect of GM potato line A15-031 on 14 June 2012.

He confirmed the presence of the Rpi-vnt1.1 gene in GM potato line A15-031 and the absence of antibiotic resistance genes *tetA* and *nptIII* in the same GM potato line. This confirms the identity of the notified GM potato line. Dr Gallagher also confirmed the absence of the Rpi-vnt1.1 gene from the non-GM potato line Desiree (which will be used as non-GM comparator during the course of this study) and King Edward.

While Dr Gallagher queried the determination of insert copy number, the reality is that without a sufficiently high insert copy number the Rpi-vnt1.1 gene will not be expressed in the field and the plants will be susceptible to blight.

Dr Gallagher's report is provided in Appendix 2.

7.1.3 Consultation with other regulatory bodies and government departments

The Agency also consulted the following regarding the proposed deliberate release:

a. Department of Agriculture, Food and the Marine (DAFM);
b. Food Safety Authority of Ireland (FSAI);
c. Department of the Environment, Community and Local Government (DECLG);
d. National Biodiversity Data Centre;
e. National Parks and Wildlife Service (NPWS).

a. Department of Agriculture, Food and the Marine

DAFM responded to the Agency in writing on 16th April 2012. In its response DAFM stated that its main concern is the possibility of adventitious cross contamination of contiguous certified seed and ware (eating) potato crops. DAFM is the certifying Authority in respect of the European Communities Seed Potato Regulations and is responsible for ensuring that seed potatoes produced in Ireland are of the highest purity standards.

To this end, DAFM stated that in the event that the proposed trial is authorised by the Agency, it is essential that all necessary precautions are taken to prevent gene transfer and carryover from the GM potato trial to any neighbouring non-GM potato crops. "*It is imperative that all the risk areas are identified and covered in a comprehensive manner and the necessary field trial procedures, crop handling protocols and control arrangements are specifically addressed in the conditions attaching to any authorisation granted to Teagasc for conducting the GM potato trial.*"

b. Food Safety Authority of Ireland (FSAI)

The Agency requested the FSAI to consider the impact of inadvertent consumption by humans or animals. The FSAI consulted with its own external experts and responded that no safety concerns arising from inadvertent consumption were identified. Furthermore, an article on the Teagasc GM potato Field Trial in the March/April 2012 edition of FSAI News states "*the FSAI is satisfied that the natural vulnerability of potatoes, along with the safeguards proposed by Teagasc, during and after the period of this field study, provides sufficient reassurance that the risk of inadvertent consumption of the tubers is negligible*".

c. Department of the Environment, Community and Local Government (DECLG)

The DECLG representative on the GMO AC provided comments within the submitted comments under the aegis of the GMO AC.

d. National Biodiversity Data Centre

The National Biodiversity Data Centre carried out a review of Ireland's biodiversity in 2010 and two key monitoring programmes were identified as gaps in Ireland's biodiversity knowledge, namely, the Soil Biodiversity Monitoring Programme and Vascular Plant Monitoring. While the Data Centre indicated that it had no direct information on the impact (if any) this development would have on Ireland's biodiversity, it did state that any case that could be made for the development of a monitoring programme (such as those identified above) would be very welcome.

e. National Parks and Wildlife Service (NPWS)

No response was received from the NPWS within the timeframe.

7.1.5. Consultation with the European Commission and other EU Member States

In accordance with Article 18(1)(b) of the Regulations, the Agency is required to forward the Summary Information Notification Format (SNIF) to the Commission within 30 days of receipt of the notification. The SNIF was submitted to GMO-WebSNIF online on 1st March 2012 and it was

published to the GMO-WebSNIF webpage[27] on 13th March 2012. The Agency did not receive any comments or observations from other EU Member States.

On 11th April 2012, the Agency informed the Department of the Environment, Northern Ireland, of the receipt of the notification and that it would in due course inform them of the Agency's decision in relation to the proposed trial.

It was stated in the notification that GM potato line A15-031 has been grown in NL under field conditions and is continuing to be trialled there under Notification B/NL/10/06. The Agency consulted with the NL Competent Authority who reported that GM potato line A15-031 was grown in the NL in 2011 and that no negative effects as compared to conventional potato varieties were found during the first year, that is to say that nothing unusual was observed in the phenotypic characteristics or in terms of interactions with in the environment.

Identical field trials are also proposed to take place in Finland (FI). Again the Agency consulted with the Finnish Competent Authority who confirmed that no such application has been received to date.

7.2 Internal review

The EPA has reviewed the notification any additional information received from the notifier.

8.0. Conclusions of the Office of Climate, Licensing and Resource Use under Article 18(1)(h) of the GMO (Deliberate Release) Regulations 2003, S.I. No 500 of 2003

1. The proposed mitigation measures to prevent cross pollination are appropriate as potato is largely self-pollinating.

2. After examining the information supplied in the notification under Article 14 of the GMO (Deliberate Release) Regulations, S.I. No 500 of 2003 and the further information provided by the notifier in response to a request from the Agency under article 19(1), ELP conclude that this notification is in compliance with the aforementioned Regulations.

3. The scale of this trial will be small. The trial site area will not exceed $10m^2$ in 2012 and while the area in subsequent years will not exceed 2 ha, the area to be planted is very much dependent on the number of tubers harvested during the previous growing season. While a minimum separation distance

[27] The SNIF is made publicly available on http://gmoinfo.jrc.ec.europa.eu.

of 40m is required, the nearest non-GM potato crop will be located 750m from the GM potato field trial site.

4. The potato plant demonstrates a high degree of biological containment. It is largely self-pollinating and it does not reseed easily. Potatoes do not survive well outside a controlled agronomic environment.

5. The majority of Agency expert reviewers agree that the risk to the environment and to human health from the release of these GM potato plants at the experimental release site is low, provided that certain risk management measures are implemented as outlined in the notification and in the consent conditions.

6. GM potatoes with improved resistance to late blight disease have also been trialed in the Netherlands, Belgium and the UK and no adverse effects have been reported with regard to human health or the environment.

7. An application for the cultivation of a GM potato, resistant to late blight disease, is currently under review at EU level. Therefore, it is not inconceivable that a GM potato will be placed on the market under Part C of Directive 2001/18/EC in future years. In the event of this happening it would be beneficial to Irish agriculture to have some prior knowledge of how this crop / trait combination would potentially perform under Irish soil and climatic conditions.

8. The 1999 Chairing Panel report and the Inter-Departmental Group on Modern Biotechnology in 2000 both recommended the performance of '*independent generic research*'. This AMIGA programme is publicly funded EU research and its objective is to look at the impact of growing GM potatoes in Ireland and monitoring how the blight fungus and the ecosystem reacts to the GM potato variety in the field, over several growing seasons. The results of this research, will be made known to the Irish public and will serve to inform public opinion.

9.0 Charges

The notifier, Teagasc, shall pay the EPA €6426.3 in total over a period of three years (2012 – 2014) towards the cost of site inspections, monitoring and auditing these field trials as per Condition 8. This will be broken down as follows. €2462.1 will be paid to the Agency in 2012 (inclusive of the cost of an independent expert) and €1982.1 will be paid in 2013 and again in 2014.

10.0 Fee payable to the EPA

The appropriate fee of €3,000 as outlined in the Part IV of the GMO (Deliberate Release) Regulations (S.I. 500 of 2003) has been paid in respect of a notification for a proposed deliberate release for purposes other than placing on the market.

11.0 Recommendation

I have considered all the documentation submitted in relation to this notification including all of the representations made by members of the public.

I am satisfied on the basis of the review carried out and in particular, on the basis of the comments received from the GMO Advisory Committee and the GMO sub-Committee that the risks posed to the environment and human health by the deliberate release of this GM potato line A15-031 are negligible.

In accordance with article 18(5) of the GMO (Deliberate Release) Regulations 2003, S.I. No. 500 of 2003, I recommend that the Agency grant consent to Teagasc, to perform a field trial under Part B of the GMO (Deliberate Release) Regulations at Oak Park, Co Carlow subject to the conditions set out in the attached draft Consent Conditions

Signed: _____ Date: 27/06/2012.

Bernie Murray
Inspector
Office of Climate Licensing & Resource Use

Appendix 1

The 37th Meeting of the Advisory Committee on Genetically Modified Organisms was held on 19th April 2012 at Stillorgan Park Hotel, Stillorgan Road, Dublin 18.

Members present:
Mr Frank Clinton (chair), Mr Raymond O'Rourke, Dr Pat O'Mahony, Professor Fergal O'Gara, Dr Elizabeth Cullen, Ms Stella Coffey, Dr Darren Arkins, Mr Nicolas dePaor, Dr Barry O'Reilly, Professor Greg Atkins, Brid O'Higgins.

Apologies:
Mr Dara Lynott, Dr John O'Neill, Dr James McIntosh, Dr Patrick O'Reilly.
Dr John O'Neill and Dr James McIntosh had both provided written submissions to the Agency prior to the meeting

In attendance:
Dr Tom McLoughlin, Ms Suzanne Wylde and Ms Bernie Murray.

The chair explained that Dara Lynott (chair of the GMO AC) and John O'Neill (deputy chair) were both unable to attend. Mr Frank Clinton was deputised by the Board of the Agency to chair the meeting in their absence.

There followed a tour de table for introductions.

Item 1 **Approval of Agenda**
A GMO Advisory Committee (GMO AC) member queried the terms of reference for the meeting and how decisions would be arrived at by the Committee.

The Agency informed the Committee that it was the role of the GMO AC to advise the Agency on any aspect of its functions in relation to GMOs which the Agency considers appropriate. A vote per se has never been taken, but rather the comments of the Committee are minuted and their views are taken into consideration in relevant inspector's reports to the Board of the Agency. The judge in the Monsanto High Court case in 1996 put a lot of emphasis on the advice of the GMO AC.

The draft Agenda was agreed.

Item 2 **Approval of the draft minutes of the 36th GMO AC meeting held on the 27th July 2011 and matters arising**
A Committee member queried ensuing developments relating to the malaria vaccine. The Agency updated the GMO AC on the status of the clinical trial. The trial is currently underway at Beaumont Hospital and the Agency carried out a site inspection of the trial site on 30th March 2012.

The draft minutes were agreed and signed by the chair.

Item 3

Presentation by Dr Ewen Mullins
"Assessing and monitoring the impact on the agri-environment of GM potatoes with resistance to late blight disease"
The Chair outlined the existing status of the notification received by the Agency from Teagasc, Oak Park, for intent to make a deliberate release into the environment of genetically modified (GM) potatoes that are resistant to late potato blight (*Phytopthora infestans*) under Article 14 of the GMO (Deliberate Release) Regulations (S.I. No 500 of 2003).

Dr Ewen Mullins serves on the GMO AC and offered to resign his position on foot of his notification to the Agency. While the Agency did not accept his resignation, he was attending this meeting and giving a presentation to the Committee in the capacity of applicant. The chair informed the Committee that Dr Mullins would remain for the second presentation to be given by Ms Coffey and Dr Cullen and for the Question and Answer session following that presentation.

Dr Mullins joined the meeting at this stage to make his presentation. The presentation covered the following:

- Background of Teagasc GM crop research;
- Context of the current notification to the Agency;
- Details of *P. infestans* in Ireland;
- Comparison of GM breeding / conventional breeding;
- AMIGA project consortium;
- Use of wild potato genes to control blight disease;
- *Agrobacterium* mediated transformation;
- Purpose of the proposed deliberate release;
- Location, plot size and logistics of the trial site;
- Site monitoring;
- Pollen mediated gene flow in potatoes.

There followed a question and answer session.

Q. What was the outcome of the consultation on the co-existence strategy?
A. Dr Mullins replied that the European Commission (EC) required each Member State (MS) to produce its own guidelines. In Ireland, such guidelines were produced in respect of each crop and while Teagasc focuses on the potato and oilseed rape (OSR), the consultation concluded that further research was needed. Potato gene flow, compared to OSR, is relatively contained. Some gene flow studies have been completed at Oak Park with cv. Desiree which is the same species as that used in the proposed trial.

Q. Are Teagasc investigating non-GM methods of improving potato strain 'Sarpo Mira' for blight resistance?
A. Teagasc has worked with the Wales based lab involved in the development of 'Sarpo Mira' over last 2 years. This blight resistant potato strain has not been incorporated into the Oak Park potato breeding programme, reasons being that its processing potential is not as good as other potato varieties and also for some people it does not

have a good taste. Marker assisted selection is used widely in the Oak Park potato breeding programme.

Q. Elaborate on the General Surveillance (GS) monitoring that will be performed during the proposed trial.
A. The problem with EU legislation is that the requirements for GS are not clear. GS monitoring is looking for some difference between the control and treatment plants, e.g ladybird dominance on control plants and their absence on treatment plants. During the proposed trial, GS monitoring will be carried out 2/3 days per week.

Q. Further information requested about pollen flow studies involving bees carried out at Oak Park.
A. During the course of gene flow studies involving var. Desiree and British Queens potato varieties at Oak Park, honey bees were not sighted on either potato variety. British Queens do not produce nectar so one would not expect to see honey bees in their vicinity. On the other hand quite a lot of bumble bees were sighted on var. Desiree. Teagasc would be prepared to remove flowers from the potato plants in which case there would be no issue with bees or pollen.

The Committee member who posed the question made reference to the occurrence of potato pollen on bees as cited in a French paper[28] and in the Irish Beekeepers representation to the Agency.

Q. Request to comment on the EC's refusal to provide Committee member with access to AMIGA's project proposal in order to fully assess Teagasc's involvement. Their refusal gave the impression that AMIGA was convened to promote and support acceptance of the cisgenic potato.
A.While Teagasc has no difficulty in releasing the aspects of the proposal that it is involved in, it is not up to Teagasc alone. All of the institutions involved must agree to its release. Its early and untimely release could result in another institution performing and publishing the work. Dr Mullins assured the Committee that Teagasc were transparent and had no hidden agenda with regard to cisgenic potatoes and that the relevant documentation would be released by the EC in due course.

One Committee member (Consumer affairs representative) commented that if the Agency were to grant consent to this trial, Ireland would essentially be moving into the pro-GM camp in a political sense, whereas in the past, Ireland has been abstaining in the GM voting comitology procedure at EU level.

Q. Does the proposal to hold open days/summer schools move the focus of the trial away from the science?
A. The nature of this notification means that public interest and attention cannot be avoided and should not be ignored. Teagasc is an open research agency for agriculture science. There is a need to have

[28] "An analysis of the pollen washed out of the hairs of the bees showed that there was potato pollen in all bee samples and in one sample, potato pollen was the leading species." Hazards of pesticides to bees. Avignon (France) September 07 – 09 1999 by L.P. Belzunces, C. Pelissier and G.B. Lewis

openness and transparency in order to ensure the research is discussed.

Q. Request for further information on the trials that have taken place to date in the Netherlands (NL). Are there results available?
A. The Agency stated that they will request further information on these trials from the NL competent authority.

Q. Request for further information on the amount of fungicide used per year in Ireland on potatoes.
A. Dr Mullins responded that while the data is available, he did not have it to hand. On average, farmers spray 15 times during the growing season.

Q. Will the same plots be used three years in a row for growing potatoes?
A. The plots will be moved around the designated trial site. This is to ensure that other diseases do not disrupt the trial.

Q. Request for further information on the control of volunteers and groundkeepers
A. Following harvest the plots will be planted with ryegrass which will compete better with volunteers and groundkeepers. Emerging volunteers / groundkeepers will be treated with a selective herbicide. The sites will be rotated and will be monitored / treated repeatedly for 4 years post-harvest.

Item 4 **Presentation by Dr Liz Cullen and Ms Stella Coffey**
"The hazards of Genetic Engineering"

Dr Cullen and Ms Coffey gave a joint presentation. The presentation was entitled "*Some thoughts, facts, concepts, fallacies, perspectives and evidence relevant to Teagasc licence application B/IE/12/01 to EPA*" and covered the following:

- Soil, soil biodiversity;
- Uncertainties surrounding GM crops and biodiversity;
- Issues around genetic engineering;
- The Precautionary Principle;
- Antibiotic resistance;
- Polychlorinated carbon compounds;
- Risk assessments & issues with risk;
- Risk assessment of Intel Pentium chip;
- Brief critique of the GM regulatory system;
- The problem.

No questions were asked during the question and answer session which followed.

At this stage, Dr Mullins absented himself from the meeting.

Item 5 **Notification from Teagasc, Oak Park, for intent to make a deliberate release into the environment of genetically modified (GM) potatoes that are resistant to late potato blight (*Phytopthora***

***infestans*) under Article 14 of the GMO (Deliberate Release) Regulations – S.I. No 500 of 2003 – Ref: B/IE/12/01 (G0469-01).**
The Agency introduced this item.

The chair obtained the views of each member of the Committee with regard to the following questions:

(a) Is there sufficient information (including the molecular data) in the notification to make a scientific recommendation?
(b) Is this GM potato likely to cause an adverse effect on the environment (whether direct or indirect, immediate or delayed) e.g. the spread of the GMO in the environment, the transfer of genetic material to other organisms?
(c) Is this GM potato likely to cause an adverse effect on human and animal health e.g. through inadvertent feeding of the GM plants, allergenic or toxic effects arising from the cultivation of the proposed field trial?
(d) Should the EPA give consent/or refuse consent?
(e) In the event that the EPA gives consent, what conditions, if any, should be imposed?

The following views were expressed by the 9 Committee members present:

1. A committee member stated that the application provides no comparison of the proposed benefits of the engineered crop and the risks posed by the application of significant quantities of herbicide to the conventional potato crop. Surely it is a positive development to be moving away from the application of plant protection products to control the late blight fungus.
   The Committee member went on to say that sufficient information was provided in relation to the molecular biology of the GM plant. All aspects were sufficiently explained and in his view there was nothing likely to cause adverse effects to human or animal health or the environment. The EPA should issue consent.
   The Agency responded by saying that there is no provision in the Directive to consider the benefits of GM crops. Another Committee member disagreed saying that large area mono-culture is an inherent aspect of GM crop production and is problematic in that a blight attack can cause heavy destruction. In South America the focus is on small scale local growing where the farmer will grow several potato varieties which will not be wiped out entirely.
   The same Committee member identified that two members of the AMIGA consortium were patent holders of the Rpi gene and since they stood to gain financially, this amounted to a conflict of interest.

2. The following items required under the legislation have not been provided by Teagasc in their application:
   - Emergency response plan;
   - History of previous releases particularly in relation to the trials carried out in the NL.

   Also, the Board of the Agency should consider the impact this proposed trial would have on the work of Bord Bia and their food programme. The Agency responded by saying that the current Government policy was 'Food Harvest 2020', which states that the Department of Agriculture, Food and the Marine (DAFM)

should "monitor and appraise policy, trade and commercial developments at EU and other relevant levels with respect to the use of existing and emerging technologies in areas such as biotechnology and genetically modified organisms (GMOs)". One Committee member disagreed and did not believe that Food Harvest 2020 could be construed as government policy since it was not developed in accordance with standard policy development practice in operation in other government departments. The Committee member described it as a product of a limited think-tank type group which was then adopted as policy by the DAFM.

3. Potential for *P. infestans* to evolve and for the GM potato variety to becomes susceptible. The Agency responded that this scenario presents a challenge. GM technology is not in itself a panacea.

4. The national potato breeding programme is run by Teagasc at Oak Park. The DAFM is the Competent Authority for the EU Seed Regulations and as such is responsible for ensuring that seed potatoes are produced to the highest purity standard. The 2005 report on the co-existence of GM and non-GM crops in Ireland made specific recommendations for the co-existence of GM and non-GM potato. Among the recommendations included a 20m exclusion zone, effective monitoring and control of potato groundkeepers / volunteers and the thorough cleaning of machinery and equipment to prevent transfer through physical means. However, this proposed field trial differs from co-existence in that the GM plant is unauthorised and is purely for experimental purposes only. Therefore, the DAFM are anxious to ensure that any leakage / transfer of the GM trait to conventional seed and ware potatoes is prevented. The question arises as to whether the co-existence recommendations are adequate for this purpose. According to the Report of the Working Group on Coexistence, volunteers arising from true potato seed are unlikely to pose a problem since a new potato variety (originating from cross-pollinated true potato seed) has never been identified on Irish land. The containment measures proposed in the application in some instances exceed the co-existence recommendations (e.g. a 40m exclusion zone)

   The Agency posed the question to this Committee member if it would be appropriate to remove flowers from the potato plants to ensure any cross pollination with conventional potatoes does not occur. The Committee member noted that in almost 90 years of official inspections under the Seed Potato Certification Scheme, no new or unidentifiable potato variety had been recorded over that time. However, removing flowers from the GM plants may satisfy public concern.

5. Another Committee member supported this type of project. However, it was noted that there is insufficient detail on key elements of the application most notably the methodology to assess the impact of GM potato cultivation on bacterial, fungal, nematode and earthworm diversity. The approach taken with regard to microbial biodiversity is an ambitious one and he

suggested that greenhouse studies would need to be carried out simultaneously. The Agency supported by another Committee member indicated that the provision of such data was not a requirement under the relevant legislation. After some discussion it was agreed that this Committee member would submit their query/concern in writing.

6. The proposed trial should go ahead. The 'clean green food' image of Ireland and the use of GM crops are not necessarily contradictory. Furthermore, while Ireland has a strong reputation for providing safe food and for rapidly and successfully handling any problems that may arise, the 'clean green food' marketing image may be somewhat overplayed in light of real world experiences with BSE, and the pig meat dioxin crisis. GM does not seem to be a high priority issue for Irish consumers. The Food Safety Authority of Ireland receives in excess of 12,000 communications per year with very little interest expressed in GM food or other GM related issues. This Committee member also noted that flowers should only be removed where this action would result in a tangible risk reduction for consumers or the environment.

7. A member stated that 'given that there is no proposal to 'place on the market', a positive but precautionary approach should be adopted'.

8. In accordance with the legislation, a step by step approach must be adopted. Greenhouse trials must precede field trials particularly with regard to soil biodiversity studies. There is no baseline data on soil biodiversity. The molecular data is inadequate / absent. Evidence of removal of NPTIII gene is required. The application is not clear / detailed enough and includes a number of assumptions which are not supported by references.

   The term 'cisgenesis' is not defined. Evidence of Teagasc's claim that the potato line is a cisgenic line is required. The use of the term 'cisgenic' is disputed in that the insert (by definition) originates from "a crossable sexually compatible plant" but the donor and recipient potato plant strains are not sexually compatible, therefore, these plants are transgenic. The implication is the term 'cisgenic' is less risky than transgenic, however, GE technology is common to both cisgenesis and transgenesis. Cisgenesis is an example of 'regulatory capture'.

   Evidence exists that GM plants pose a risk and give rise to unpredictable effects. It constitutes a risky technology and the Agency should refuse consent.

   Another Committee member intervened to say that the patent for the Rpi gene could not have been successful without the provision of molecular data and that probably there is more than one patent application involved.

   It was noted that a complaint has been made to the EU ombudsman in respect of the Chairperson of the EFSA GMO

Panel. The complaint relates to his alleged links with the International Life Science Institute (ILSI) funded by the food and agrochemical industry, some affiliates of which produce GM plants and the impact of such links on EFSA's independence as assessor of the risks of new GM plants. One committee member stated that he wished to be dissociated from this comment.

9. No baseline data on soil biodiversity has been provided. The application needs to be substantiated with more evidence.

The Agency informed the AC that 2 of the 3 absent members had submitted written comments. The majority of the AC advised that the Agency should grant consent.

Item 6 **Public consultation on the notification**

The Agency circulated a document summarising the comments and concerns raised during the public consultation.

The Agency provided a summary of the document. Eighty-one (81) representations were received, all opposed to the proposed trial. The Agency read all submissions received and grouped the concerns raised under the following broad categories:

- Economic concerns;
- Biodiversity concerns
- Health concerns:
- Public perception;
- Intellectual property / conflict of interest;
- Regulation;
- Genetic Modification;
- The Study;
    - General;
    - Risk assessment;
    - Containment.

In accordance with Article 16(4)(b) of the GMO (Deliberate Release) Regulations, S.I. No 500 of 2003, the Agency must consider the representations in determining the notification.

One Committee member noted that Teagasc's response to the Agency's request for molecular data was not satisfactory (Agency request for additional information). The Agency stated that Teagasc have indicated that they will provide this information.

Item 7 **EFSA's Scientific Opinion addressing the safety assessment of plants developed through cisgenesis and intragenesis**

This item was introduced by the Agency. Cisgenesis was one of 8 techniques discussed by the New Techniques Working Group (NTWG) set up by the EC. The draft report of the WG was issued in January 2012 following which the EC requested EFSA to issue an opinion on the risks posed by plants developed through cisgenesis and intragenesis and the applicability of the existing guidance documents.

According to the NTWG report cisgenesis is similar to self-cloning which already falls outside the scope of the contained use legislation. So it is conceivable that cisgenesis could fall outside the scope of the deliberate release legislation. This decision would have to be taken at EU level.

One committee member stated that if recombinant techniques were used then the resulting organism was transgenic. Furthermore there was a judicial move to have this opinion queried based on conflict of interest claims relating to the EFSA GMO Panel.

Item 8 **Any other business**

The Agency provided the Committee with an update from the meeting that was organised by the EU Commission in March 2012, in relation to environmental monitoring of GM crops. Details of the meeting were uploaded to the DG SANCO website. The Agency agreed to circulate the appropriate link to the Committee.

Chairperson: _____

Appendix 2

Report of independent expert Dr Tommy Gallagher

Evaluation of study to address the question: "Please provide molecular data (gel data) supporting the data given in Table 1 and Figure 4 on pages 16 and 17 of the application, respectively".

In the original report "**Assessing and monitoring the impact on the agrienvironment of genetically modified potatoes with resistance to *Phytophthora infestans*, causative organism of late blight disease (2012 – 2016)**" table 1 summarises a number of different molecular characterisation studies. These are all based on PCR in one form or another:

qPCR was used to determine insert copy number

- endpoint PCR was used to verify the presence/absence of specific regions of the T-DNA *viz.*T-DNA left and right border sequences, Rpi-vnt1 (the gene of interest), *nptII* & *tetA* (two vector backbone sequences), EF1α (a potato positive control sequence)
- qRT-PCR was used to measure the expression of the Rpi-vnt1 transcript.

Pages 15, 16 and 17 of the original report refer to:

- **(a) size and structure of the insert and methods used for its characterisation, including information on any parts of the vector introduced in the genetically modified higher plant or any carrier or foreign DNA remaining in the genetically modified higher plant**
- **(b) in case of deletion, size and function of the deleted region(s)**
- **(c) copy number of the insert**
- **(d) location(s) of the insert(s) in the plant cells (integrated in the chromosome, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its determination.**

Figure 4 is a sketch (not to scale) of the position and orientation of primers used to verify the left border (LB) right border (RB) relative to the insert present in pBINAW2:Rpi-vnt1.1 and expected to be transferred into cisgenic plants. The location of the primers relative to the T-DNA of the vector is indicated.

Table 2 List of primer sequences

Primer	name sequence (5'---> 3')	Target gene	Annealing Temp (°C)	length of PCR product (bp)	Location
	ATTGGAAACGGATATGCTCCA	*Ef1*-alfa	57	101	
	TCCTTACCTGAACGCCTGTCA				
	CCTTCCTCATCCTCACATTTAG	*Rpi-vnt1*	60	302	
	CTCATCTAATAGATCCTCCAC				
	CTGCTAGGTAGCCCGATACG	TetA	61	296	
	CCGAGAACATTGGTTCCTGT				
	GAAAGCTGCCTGTTCCAAAG	NptIII	61	162	

	GAAAGAGCCTGATGCACTCC				
MN591	cccgccaatatatcctgtca	pBINAW2	61	435	RB
MN592	gaagcttcgtgcaacctctc	*Rpi-vnt1*	60		
MN593	acaccgttcgtcccaattta	*Rpi-vnt1*	60	513	
MN594	tggcaggatatattgtggtgt	pBINAW2	58		LB
MN657	TATCCTGTCAggtacgaattc	RB	54	425	
MN659	tggtgtaaacTCTAGAGGATC	LB	51	498	

Table 2 (reproduced above) lists the sequences of the primers used the amplify a specific potato (Ef1-alpha) or a variety of sequences within the T-DNA border. The first eight primers are correct with the exception of the predicted size for the *Ef1*-alfa primers. The last six primers target sequences within the T-DNA. NM592 and NM593 target the *Rpi-vnt1* sequence. The remaining primers target the T-DNA border sequences and are used in conjunction with either NM592 or NM593. NM591 targets the RB sequence and NM594 targets the LB sequence. These primers are generic to a range of T-DNA sequences based on the binary vector pBI121 from which pBINAW2:Rpi-vnt1.1is derived. NM657 and NM659 partially overlap the RB and LB primers respectively (the section in uppercase) the remainder of these two primers targets specific sequences immediately inside the RB and LB sequences. These primers in combination with NM592 and NM593 are construct specific . Thus there are two primer combinations that can be used to amplify the LB and RB sequences into the T-DNA; a generic pair e.g. NM591/NM592 or a construct specific pair e.g. NM657/NM592.

The present study provides gel data and analysis in relation to point **(a).** The study uses end point PCR to determine if the transgenic potato line A15-031 contains any elements from the transforming T-DNA plasmid pBINAW2:Rpi-vnt1.1; in particular elements of the *nptIII* and *tetA* genes. The method chosen is end point PCR employing primers specific for sections of each of these genes. The data generated from this type of PCR is the presence or absence of a DNA fragment of the predicted size on a gel. There are only two possible results; positive – a band of the predicted size is present or negative – the predicted band is absent. One of the difficulties of a study such as this is that the hypothesis being tested is that the vector backbone is absent from line A15-031. Evidence for this is failure of the target sequence to amplify in a PCR reaction. It is important to ensure that failure to detect amplification is not due to technical failure. Inclusion of a positive control, in this instance amplification of a fragment of and endogenous gene (*EF1α*) tests for this possibility.

The report presents four gel images. **Gel A** is the positive control where the *EF1α* gene is amplified from A15-031 and A15-044 -two cisgenic lines and from three of non-cisgenic lines Desiree, Balfour and an unreported line that I presume is King Edward. In all cases the predicted 110 base pair fragment is detected. The no template control (water) gives no amplification. This confirms that the different DNA templates are suitable for PCR. It should be noted that in this report the predicted size for the *EF1α* sequence is 110 base pairs not the 200 bp indicated in the original report. I fact I determine that the predicted size to be 101 bp, however, this 9 bp difference in size would not be resolved on the gel system used.

Gel B is an analysis for *tetA*, a tetracycline resistance gene present on the backbone of plasmid pBINAW2:Rpi-vnt1.1. The predicted PCR product is 296 pb which is the correct size for a fragment amplified with the indicated primers. The two cisgenic lines and two non-cisgenic lines Desiree and Balfour are analysed. Line A15-044 is positive and line A15-031 is negative for this gene. This is consistent with the results reported in Table 1 of the original report. Faint higher molecular weight products are present in A14-031 and the two non-cisgenic controls. These faint bands probably represent off-template amplification products. The generation of faint additional fragments is a common feature of PCR, particularly when the target site is absent in the template. As they are faint bands and of the incorrect size they do not indicate the presence of vector backbone in A15-031.

Gel C is an analysis for *nptIII*, a kanamycin resistance gene. The predicted size of 162 bp is correct. Line A15-044 is positive with all the other sampled being negative. This is consistent with the results presented in Table 1 of the original report. There are faint higher molecular weight bands in A15-031 and Balfour. As these are the incorrect size and faint they do not represent the presence of the *nptIII* gene in the samples.

Gel D is an analysis for *Rpi-vnt1.* The predicted size is ~300 bp, in fact the actual size of the target sequence is 302 bp. The two cisgenic lines and three non-cisgenic lines are analysed. Both A15-031 and A15-044 have bands of the predicted size, the non-cisgenic controls Desiree and King Edward are negative, there is a faint suggestion of a band at the predicted size in Balfour. On this gel there is evidence of low molecular weight bands in all lanes, including the water control. This is most probably indicative of the generation of primer dimers during the PCR reaction. Primer dimers are a common feature of PCR with some primer combinations. One of the main drawbacks of primer dimer formation, separate from the presence of low molecular bands, is that it reduces the available primer abundance and can result reduced efficiency of the reaction. The authors indicate their intention of designing primers to generate larger PCR products which should result in clearer demonstration of the presence of the cisgene in the transformed lines.

Overall this analysis clearly demonstrates that line A15-031 does not contain either of the antibiotic resistance markers present in the backbone of in pBINAW2:Rpi-vnt1.1. Having both positive (A15-044) and negative controls (Desiree, Balfour and King Edward) makes the interpretation simple and clear. The gel data are presented in an unprocessed fashion which makes judgement easier. PCR is the most sensitive technique that can be used to determine the presence (or absence) a particular sequence in a specific DNA template. The methods used here are appropriate to the determination being made.

(b) in case of deletion, size and function of the deleted region(s)
No specific data are presented on this point.

(c) copy number of the insert and expression analysis
The original report indicates that copy number of the insert was determined by qPCR. This is an appropriate technique for such an analysis. The authors indicate that due to sample limitation they are unable to conduct qPCR. I am unclear about this. Were the

previous qPCR results to determine insert number in question? If so then additional qPCR analysis is required. End point PCR cannot be used to determine copy number.

The original report indicated that cisgene expression was determined by qPCR. The authors indicate that material to repeat this analysis is not available currently. In this they are correct. DNA is relatively stable and may be stored for long periods and subsequently used as a template in PCR. RNA is much less stable, making quantitative RT-PCR dependant on the availability of good quality RNA. In addition end point PCR is an inappropriate means of determining gene expression, at best it can be used to indicate large variation in gene expression, qRT-PCR is the method of choice for expression analysis.

(d) location(s) of the insert(s) in the plant cells (integrated in the chromosome, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its determination

There is no information on flanking sequences presented. The authors comment that the absence of border sequences does not confer any environmental risk, in which they are correct. They cite a report that indicates the presence on multiple T-DNA like elements within the potato genome. The absence of border sequences has been previously observed in with this vector where border-free transformants have been reported (http://ip.com/patfam/xx/38180587).

This Report has been cleared by
Frank Clinton, Programme Manager,
for submission to the Board
Signed: Bea Claydon Dated: 2 July 2012

Environmental Protection Agency
An Ghníomhaireacht um Chaomhnú Comhshaoil

OFFICE OF CLIMATE, LICENSING & RESOURCE USE

ADDENDUM TO INSPECTOR'S REPORT

TO:	BOARD OF DIRECTORS
FROM:	Bernie Murray Environmental Licensing Programme
DATE:	2nd July 2012
RE:	Notification from Teagasc, Oak Park, Co Carlow, under Part II of the GMO (Deliberate Release) Regulations (S.I. 500 of 2003) to conduct a field trial using genetically modified potatoes (GMO Register No: G0469-01).

Applicant:	Teagasc Oak Park Co Carlow
GMO Register Entry No:	G0469-01
SNIF No:	B/IE/12/01
Notification under Article 14(1) of S.I. No 500 of 2003:	The deliberate release of a genetically modified organism for purposes other than placing on the market (Part B Release – Field Trial).
Timeframe for EPA's Decision under Article 18(5) of S.I. No 500 of 2003:	A person shall not deliberately release a genetically modified organism (GMO) for purposes other than placing on the market unless consent in writing has been granted by the EPA. The EPA shall communicate its decision (either grant consent with or without conditions or refuse consent) in writing to the notifier within 90 days of receipt of the notification.
Date of receipt of notification under Article 14 of S.I. No 500 of 2003:	27th February 2012
Request for additional information under Article 19 of S.I. 500 of 2003:	15th March 2012 4th April 2012 23rd May 2012
Additional Information submitted under Article 19 of S.I. 500 of 2003:	11th April 2012 14th June 2012. A correction was received on the 27th June 2012.

Date by which decision is required:	24th August 2012
Representations to the EPA relating to this notification under Article 16 of S.I. 500 of 2003:	83

Representations made under Article 16(1) of the GMO (Deliberate Release) Regulations S.I. No 500 of 2003

The Agency received 2 further representations relating to the proposed field trial on 2nd July 2012 bringing the overall number of representations received to 83. These representations were dated 26th March 2012, were addressed to Dr Gerry Boyle, Director General of Teagasc, and were submitted by hand along with the prescribed payment to the EPA's Richview office before the deadline of 5pm on 27th March 2012. They were subsequently misplaced and were not discovered and brought to my attention until 29th June 2012.

With regard to content, both representations are identical and the concerns raised have been considered in the inspectors report.

Signed: _____ Date: 02/07/2012.

Bernie Murray
Inspector
Office of Climate Licensing & Resource Use

Suzanne Barror
31 Chelsea Gardens
Clontarf
Dublin 3

Dr Gerry Boyle
Director
Teagasc
Teagasc HQ
Oakpark
Carlow

Environmental Protection Agency
- 2 JUL 2012
Environmental Licencing

26 March 2012

Dear Dr Boyle

I'm writing this letter to you in the context of Teagasc's recent application to the EPA for a licence to grow GM potatoes in trials at Oak Park. I feel as a concerned citizen that I do not have enough information on what the ultimate effects of this testing will be.

It is universally accepted that transgenic organisms (this definition is inclusive of cisgenic organisms) can have unpredictable effects. This is the risk which underpins my concern regarding the recent Teagasc licence application. Unfortunately, the GM regulatory system in place has not accommodated a full public discussion of the issues relevant to GM technology and its introduction to Ireland.

To put a solution forward, as Teagasc has done, when it appears the problem has not yet been properly defined, is highly questionable. Particularly so, when that solution involving releasing a plant (by its very nature capable of reproducing itself and therefore 'uncontrollable' in nature) into a field, appears not to take the national interest into account. As such, such a solution is simply indefensible.

There are aspects other than farmers' current use of 'up to 20' fungicide sprays per crop to be considered regarding potato cultivation in Ireland.

My request is this: For Teagasc to explicitly state ALL the reasons it is doing the research at Oak Park described in its EPA licence application on GM potatoes.

I hope that when the information requested is in the public domain, there can then be a full public discussion about the issue and all of its implications.

Meanwhile, perhaps Teagasc would consider withdrawing its licence application so that the public discussion can take place without the immediate threat of a GM potato planting at Oak Park.

Yours sincerely

Suzanne Barror

By hand

Dr. Gerry Boyle,
Director,
Teagasc
Teagasc H.Q.
Oakpark,
Carlow.

Miriam Berry,
Apt 1, 23 Temple Lane South,
Temple Bar,
D. 2

Dr Gerry Boyle
Director,
Teagasc,
Teagasc HQ,
Oakpark,
Carlow

Environmental Protection Agency
- 2 JUL 2012
Environmental Licencing

26th March 2012

Dear Dr Boyle,

I'm writing this letter to you in the context of Teagasc's recent application to the EPA for a licence to grow GM in trials at Oak Park. It's universally accepted that transgenic organisms can have unpredictable effects. This is the risk which underpins my concern regarding the recent

Teagasc licence application. Unfortunately, the GM regulatory system in place has not accommodated a full public discussion of the issues relevant to GM technology and its introduction to Ireland.

To put a solution forward, as Teagasc has done, when it appears the problem has not yet been properly defined, is highly questionable. Particularly, when that solution involving releasing a plant (by its very nature capable of reproducing itself and therefore 'uncontrollable' in nature) into a field, appears not to take the national interest into account. As such, such a solution is simply indefensible.

There are aspects other than farmers' current use of 'up to 20' fungicide

Sprays per crop to be considered regarding potato cultivation in Ireland.

My request is this:

For Teagasc to explicitly state ALL the reasons it is doing the research at Oak Park described in its GPA licence application on GM potatoes.

I hope that when the information requested is in the public domain, there can then be a full public discussion about the issue and all of its implications.

Meanwhile, perhaps Teagasc would consider withdrawing its licence application so that the public discussion can take place without the immediate threat of a GM potato planting at Oak Park.

Yours sincerely, Alicia Bero

BY HAND

Dr Gerry Boyle,
Director,
Teagasc.
Teagasc Hq.
Oak Park,
Carlow.

This Report has been cleared by
Frank Clinton, Programme Manager,
for submission to the Board
Signed: Bea Claydon Dated: 9 July 12

Environmental Protection Agency
An Ghníomhaireacht um Chaomhnú Comhshaoil

OFFICE OF CLIMATE,LICENSING & RESOURCE USE

SECOND ADDENDUM TO INSPECTOR'S REPORT

TO:	BOARD OF DIRECTORS
FROM:	Bernie Murray Environmental Licensing Programme
DATE:	9 July 2012
RE:	Notification from Teagasc, Oak Park, Co Carlow, under Part II of the GMO (Deliberate Release) Regulations (S.I. 500 of 2003) to conduct a field trial using genetically modified potatoes (GMO Register No: G0469-01).

Applicant:	Teagasc Oak Park Co Carlow
GMO Register Entry No:	G0469-01
SNIF No:	B/IE/12/01
Notification under Article 14(1) of S.I. No 500 of 2003:	The deliberate release of a genetically modified organism for purposes other than placing on the market (Part B Release – Field Trial).
Timeframe for EPA's Decision under Article 18(5) of S.I. No 500 of 2003:	A person shall not deliberately release a genetically modified organism (GMO) for purposes other than placing on the market unless consent in writing has been granted by the EPA. The EPA shall communicate its decision (either grant consent with or without conditions or refuse consent) in writing to the notifier within 90 days of receipt of the notification.
Date of receipt of notification under Article 14 of S.I. No 500 of 2003:	27th February 2012
Request for additional information under Article 19 of S.I. 500 of 2003:	15th March 2012 4th April 2012 23rd May 2012
Additional Information submitted under Article 19 of S.I. 500 of 2003:	11th April 2012 14th June 2012. A correction was received on the 27th June 2012.

Date by which decision is required:	24th August 2012
Representations to the EPA relating to this notification under Article 16 of S.I. 500 of 2003:	81

Further submission received from GMO AC Advisory Committee member regarding Teagasc application to EPA under Part II of the GMO (Deliberate Release) Regulations (S.I. 500 of 2003) to conduct a field trial using genetically modified potatoes (GMO Register No: G0469-01).

On the 28th June, a GMO Advisory Committee (GMO AC) member made a further submission to the Agency in relation to the proposed GM potato field trial application from Teagasc. This submission raises 16 points, of which, I have addressed those most relevant to this notification under review, here below.

This submission demands that the Teagasc licence application not be decided as yet, that it be re-advertised to the general public and be given more time.

1. The GMO AC member has sought and has been denied access to the AMIGA project proposal. In her view she is being denied access in order to protect commercial interests and intellectual property rights of AMIGA participants. Conflict of interest matters with any of the parties and/or other agents involved in the application and the European Food Safety Authority (EFSA) are also raised.

Agency Response:

Intellectual property and conflict of interest has already been dealt with under Section 5.5, pages 31 and 32, of the inspector's report.

In addition to that, EFSA has no remit for the assessment of notifications relating to GMO field trials, under Part B of Directive 2001/18/EC on the deliberate release into the environment of GMOs. In accordance with Article 6(5) of the Directive the Competent Authority (i.e. the EPA) shall inform the notifier whether the proposed release may proceed or whether the notification is rejected.

2. The EPA must apply proper assessment and 2 explicit process points have not been properly addressed.
   2.1. Step-by-step principle for introducing GMOs into the environment. 'This means that the containment of GMOs is reduced and the scale of release increased gradually, step-by-step, but only if evaluation of the earlier steps in terms of protection of human health and the environment indicates that the next step may be taken'.
   2.2. Case-by-case basis

Agency Response

2.1 While there is no legislative requirement for the performance of studies under containment in advance of field studies, the 'step-by-step' approach refers to the performance of successive lab / greenhouse / field studies. Teagasc have performed greenhouse

studies with blight tolerant potatoes since 2009. Furthermore the GM potato line which is the subject of this notification has undergone field trials in the Netherlands since 2011 and no adverse effects have been identified.

This proposed field trial is small scale ($10m^2$ in 2012 and <2ha per year during the period 2013 – 2016) and a range of risk management strategies are conditioned in order to reduce risks to a negligible level.

2.2 The GM plant, the GM trait concerned, the receiving environment and the potential areas of risk have all been thoroughly considered and addressed during the assessment of this notification. I am satisfied that this proposed release will not result in adverse effects on human health and the environment, provided the risk management measures outlined in the consent conditions are implemented.

3. GM crops and risk: GM crops cannot be recalled from uncontained locations and consequently their deliberate release is irreversible. Such release furthermore poses risks to human health and the environment.

Agency Response

Further to Agency's response under 2.2 above, the potato is largely self-pollinating, while cross pollination does occur, it has no impact on the formation or the genetic constitution of tubers of the receiving crop (conventional/organic). Potato cannot cross-pollinate with wild relatives to produce viable offspring. It does not reseed easily and it does not persist outside a controlled agronomic environment. The scale of the proposed field is small and a range of control measures have been conditioned.

4. Substantial equivalence: where a GM crop and its non GM counterpart are deemed to be equivalent it is assumed that the GM variety is as safe as the non-GM variety.

Agency Response

In the context of the notification under review, the issue of substantial equivalence has been dealt with under section 5.8.2, representation 5 (page 43) of the inspector's report.

5. The credibility of GM regulatory science is fundamentally flawed with particular reference to a perceived flaw in 'a recent application for licence to cultivate MON89034'.

Agency Response

MON89034 relates to a GM maize and the 'application for licence' referred to was under Part C of Directive 2001/18/EC (placing on the market) neither of which have any bearing on the notification on hand, for the performance of a GM potato field trial under Part B of the aforementioned Directive. Much reference was again

made to EFSA which, as already stated, has no remit for the assessment of notifications under Part B of Directive 2001/18/EC.

Signed: Bea Claydon Date: 9 July 2012

pp **Bernie Murray**
Inspector
Office of Climate Licensing & Resource Use