OFFICE OF LICENSING & GUIDANCE

INSPECTORS REPORT ON A LICENCE APPLICATION

To:	DIRECTORS
From:	DR TOM MCLOUGHLIN **- LICENSING UNIT**
Date:	13 TH APRIL 2006
RE:	Notification for a license for a deliberate release into the environment of genetically modified (GM) potatoes with improved resistance to late potato blight (*Phytophthora infestans)* for purposes other than placing on the market-Field trials. Ref: B/IE/06/01 under Article 14 of the Genetically Modified Organisms (Deliberate Release) Regulations – S.I. No. 500 of 2003 which transposes Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms (GMOs) into Irish law.

Notification Details	
Notifier	**BASF Plant Science GmbH, Ludwigshafen, Germany**
Notification Ref. No.	**B/IE/06/01**
GMO Register No	**208**
Date Received by the Agency under Article 14 of the Genetically Modified Organisms (Deliberate Release) Regulations – S.I. No. 500 of 2003.	**13th January 2006**
Timeframe for EPA's Decision	**The Agency has 90 days to give consent with/without conditions or refuse consent**
Date by which decision is required:	**13th May 2006**
Site Inspection to proposed trial site:	**21st February 2006**

1. **Background to GMO Technology**

GMOs are defined as bacteria, viruses, fungi, plant and animal cells, plants and animals, capable of replication or of transferring genetic material in which the genetic material has been altered in a way that does not occur naturally by mating or natural recombination. GMO technology is often called 'modern biotechnology' or 'gene technology', 'recombinant DNA technology' or 'genetic engineering'. It allows selected individual genes to be transferred from one organism into another, also between non-related species.

For the last 33 years, it has become possible to introduce changes to the DNA of living organisms in a controlled manner in the laboratory, using recombinant DNA (rDNA) technology.

In brief, DNA encoding a specific property is isolated from one organism, purified, and introduced to the same, or a second, organism. If the proper signals have been provided, the newly introduced DNA will be translated and the new property is conferred on the host. This new organism is referred to as a Genetically Modified Organism (GMO).

Between October 1991and December 2005, > 2000 SNIFs (summary notification information format) relating to GMOs have been circulated in the EU under part B for purposes other than placing on the market (field trials) under Directives 90/220/EEC and 2001/18/EC repealing Directive90/220/EEC. About 99% of these releases have been with genetically modified plants. According to information supplied by the EU Commission, most of the SNIFs received consent although consent has been refused for a small number of notifications.

Thirteen (13) field trials were carried out with genetically modified herbicide tolerant sugar beet in Ireland between 1997 and 2000, regulated under the GMO Regulations, 1994, S.I. No 345 of 1994. The EPA granted consent in September 2002, to Schering Healthcare Ltd. to conduct a clinical trial (deliberate release into the environment) in patients suffering from angina pectoris (chest discomfort or pain, usually caused by narrowing of the blood vessels to the heart) using a Genetically Modified Micro-organism (GMM).

To date, twenty three (23) GMO products have been approved for placing on the market in the EU under Part C of Directives 90/220/EEC and 2001/18/EC.
They are: 3 animal vaccines, herbicide tolerant tobacco; hybrid oilseed rape and rape resistant to glufosinate ammonium (4 dossiers); glyphosate tolerant soybeans; male sterile chicory tolerant to glufosinate ammonium; insect resistant & herbicide tolerant maize (9 dossiers); test kit to detect antibiotic remnants in milk & GM carnations (3 dossiers).

In 1996, the first GM seeds were planted for commercial use in the US. In 2005, 8.5 million farmers from 21 countries grew GM crops on approx. 90 million

hectares worldwide. The most commonly grown GM crops were GM soybean, GM maize, GM cotton and rapeseed.

GM crops were also grown in five EU Member States although on a much smaller scale than in N. America. Spain, France, Portugal, Czech Republic, and Germany grew greater than 50,000 hectares of Bt maize. The bulk of the cultivation within the EU occurred in Spain. A conference on Co-Existence of GMO, conventional and organic crops-Freedom of Choice, which was held in Vienna on 4-6th April 2006. This conference was organised by the Austrian presidency and the EU Commission. Over 600 delegates were in attendance representing different groups, regulators, scientists, NGO, farmer etc. Divergent views were expressed at this meeting, some for the technology and others opposed to its use in European agriculture. It appears that Austria are going down the non-GM route with a preference for organics whereas the Netherlands are promoting co-existence to include GM crops, in particular, GM potatoes with altered starch production for use in the print industry. The Dutch Agricultural Minister indicated at the meeting that the NL government are also targeting funding into research for the possible use of GM blight tolerant potatoes for use in Dutch agriculture.

This notification that was received from BASF in January 2006, is the first GM crop notification received by the Agency for a deliberate release into the environment since 1998.

2. **Regulation of GM crop field trial at EU level**

Part B releases or field trials are regulated under Directive 2001/18/EC (repealing Council Directive 90/220/EEC), which came into force in EU Member States on 17th October 2002.

Part B field Releases

Experimental releases or **Part B** releases (commonly referred to as field trials) of GMOs into the environment are mainly carried out for the purposes of study, research, demonstration and development of novel varieties. The behaviour of the GMO in an open environment and its interactions with other organisms and the environment are studied. The experimental releases are subject to the provisions of Part B of Directive 2001/18/EC.

If the results of the experimental release are positive, the company may decide to place the GMO on the market, i.e. make it available to third parties either free of charge or for a fee. The GMO may be placed on the market for purposes of cultivation, importation, or transformation into different products. The placing on the market of a GMO cannot proceed without the prior approval under the provisions of **Part C** of Directive 2001/18/EC.

Directive 2001/18/EC

The following recitals should be noted in relation to field trials or Part B releases:

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.

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).

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.

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

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.

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.

3. **Irish GMO Regulations**

Implementing regulations were enacted in Ireland on 1st November 2003 giving rise to the GMO (Deliberate Release) Regulations 2003, S.I. No. 500 of 2003 which transposes Directive 2001/18/EC into Irish law under sections 6 and 111 (as amended by section 17) of the POE Acts 1992-2003. In particular, Part II of these regulations pertain to deliberate release of GMOs into the environment for purposes other than for placing on the market or Part B releases or field trials.

Under Part II of these regulations the Agency must have regard for the following:

- 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.
- if requested by a competent authority of a Member State of the EU for the purposes of the Directive, forward a copy of the notification to the said authority,

- 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)
- the risks posed by the proposed deliberate release (whether direct or indirect, immediate or delayed) for human health (including animal health) (e.g. inadvertent feeding of the GM plants, allergenic or toxic effects, arising from the cultivation of the proposed field trial)
- 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.
- the Agency shall give particular attention to the risks to human health or the environment posed by the proposed deliberate release of a genetically modified organism which contains 1 or more genes expressing resistance to antibiotics which are used in human or veterinary medicine and shall aim to phase out the use of such genes where such use may have an adverse effects on human health or the environment.
- record its conclusions in writing of its assessment of the notification.
- The Agency shall 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.

It should be noted that the Agency shall not grant consent under Part II of the GMO regulations after 31 December 2008, where the genetically modified organism contains 1 or more genes expressing resistance to antibiotics which are used in human or veterinary medicine and the Agency considers that the deliberate release of the said organism may have an adverse effects on human health or the environment.

4. **Irish Legal Case pertaining to a Part B notification (field trial)**

The Agency granted consent with specific conditions to Monsanto in May 1997 for the release of GM herbicide tolerant sugarbeet at Teagasc, Oakpark in Co Carlow. A judicial review sought on behalf of C. Watson of Genetic Concern and granted by the High Court (HC) challenged the EPA's procedure in granting the license to Monsanto. This hearing concluded in October 1998 with the High Court ruling against C. Watson on all the twelve issues of contention. The three main issues argued in this HC case were as follows:

- **<u>Level of risk:</u>**
  What is the correct standard by reference to which the EPA must decide whether or not to grant consent, i.e., the standard that pertains to the risks to the environment and human health from the deliberate release of the GM sugar beet. The Agency concluded that the risk was *"extremely low"*
- **<u>The twenty-one day point:</u>**

The Applicant contended that the Regulations should be construed so as to permit third party objectors to make further comment after the twenty-one days stipulated by the Regulations in relation to supplemental material furnished by the notifier in response to a Notice requesting further information issued by the EPA.

- **Wrongful delegation**
  The EPA required the notifer to submit a management protocol "in advance for agreement". The Applicant said that the EPA had no power to postpone any part of the overall consent and, secondly, that it had no power to delegate this part of the decision to the Scientific Officer of the Environmental Management and Planning Division of the EPA (Dr. McLoughlin) who is the person who actually agreed the protocol and gave the notifier the final go-ahead for the trial.

Subsidiary Issues :

Apart from the above main issues, there were a number of subsidiary issues which are summarised as follows:

1. Issues in relation to the newspaper advertisement to the effect that it was out of time, that it should have been in a national newspaper rather than a local one, and that the EPA had no power to require (as they did) re-publication of the first advertisement to correct an error.

2. There was no map or proper identification of the location of the trial.

3. The interest of the notifier in the site of the trial was not stated.

4. There is an assertion that planning permission is required for carrying out the trial with the inference that the lack thereof somehow invalidates the EPA's consent.

5. The Applicant claimed that she was not notified within a reasonable time of the consent - again with a similar inference.

6. It is alleged that the EPA failed to make independent decisions in respect of the two separate notifications received on the 16th December, 1997 and both consented to on the 1st May, 1998.

7. The EPA had no jurisdiction to grant a trial consent covering four years when the application was for a trial period of three years.

8. The proposal by the notifier to conduct the trial in May was in breach of the application which specified that it would be done in Spring.

9. The notification did not comply with all the requirements of the Regulations.

6. Government Policy re GMO crop field trials in Ireland

The Government has overall responsibility for policy matters in this area. The Minister for the Environment, Heritage and Local Government (DEHLG) has overall responsibility for policy matters in relation to Directive 98/81/EC amending Directive 90/219/EEC on the Contained use of GMOs, Directive 2001/18/EC of the European Parliament and of the Council on the Deliberate Release into the environment of GMOs and repealing Council Directive 90/220/EEC and Regulation 1946/2003 on transboundary movement of living modified organisms (LMOs or better known as GMOs). Government policy in relation to GM crop field trials emanates from the following:

- **Public consultation**
  A consultation paper entitled "Genetically Modified Organisms and the Environment" was issued by the Minister in August 1998, for the purpose of initiating a review of national environmental policy on the deliberate release of GMOs to the environment. The main objectives of the consultation process were to stimulate an informed public debate on the environmental implications of releasing GMOs, to review national policy and practice, and to develop a clear environmental policy position.
  The consultation formally concluded in October 1999 when the Minister issued a policy statement on "GMOs & the Environment". The policy position established in the statement recognises the need for balance in terms of environmental protection and socio-economic considerations and places primary emphasis on precaution well grounded on scientific risk assessment and management.

- **InterDepartmental Group on Modern Biotechnology**
  Although the above public consultation which the Minister for the Environment, Heritage and Local Government (DEHLG) initiated related specifically to the environmental aspects of releasing GMOs, the responses raised many wider issues including food production, quality and safety, and consumer protection and choice. In response to these wider issues, the Government decided in March 1999 to establish an InterDepartmental Group on Modern Biotechnology, chaired by the Department of Enterprise, Trade and Employment, to report on a co-ordinated overall Government position on genetic modification. The Group's report was issued in October 2000 and a number of recommendations were made. The following pertain in particular to **GM crop field trials**:

- *this country should take a positive but precautionary approach to GM issues at EU level and in international forums which acknowledges the potential benefits of modern biotechnology, while maintaining a fundamental commitment to human safety and environmental sustainability;*
- *trials of GM crops should continue subject to compliance with EU legislation and with the conditions laid down by the Environmental Protection Agency.*

In conclusion, the Government policy which was pronounced over 5 years ago is one of positive but of a precautionary stance.

Other relevant GMO documents in this area

- **Irish Council for Science, Technology & Innovation (ICSTI)**

In their report on biotechnology which was published in 2000, in relation to crop production they stated:
ICSTI considers that GM crops use less agricultural chemicals thereby reducing environmental damage, and offer the potential for plant based oral vaccines. Concerns related to GM crop production include the potential for superweeds, the development of insects resistant to insecticide and an over reliance on pesticides. There are also issues of seed ownership and the option of organic farming. In Ireland important areas of research include improving nutritive value, output and increased varieties of grassland, and pest and disease resistance in cereals.
In relation to biotechnology in crop production they concluded:
If GM technology is considered to be hazardous in introducing new gene combinations in the development of new crop plants, then it is likely that the same or perhaps even greater hazards arise from the use of conventional plant breeding.

- **Report of the Working Group on the Coexistence of GM crops with conventional and organic farming**

This report was published in September 2005, by an Inter Agency WG under the DAF. The report is currently undergoing a public consultation process. The Working Group concluded that the recommendations contained in the report, if fully implemented, would ensure the coexistence of the GM and non-GM crops discussed in the Report and minimise the risk of economic loss and the need for stakeholders to seek redress for any such loss through legal means.

- ***Irish Council for Bioethics***

A working group (WG) on GMOs was established to investigate ethical issues surrounding Genetically Modified Organisms (GMOs) in the medical, industrial and agricultural arenas, with particular reference to the Irish setting. The WG produced a report in November 2005 entitled 'Report Genetically Modified Crops and Food: Threat or Opportunity for Ireland? Opinion. In relation to GM crops they 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 be noted that the WG 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.

It should also be noted that 82% of the respondents agreed that GM crops pose a threat to the environment and that 78% did not support the cultivation of GM crops in Ireland.

7. **Notification for a Deliberate Release into the Environment**

Time frame for Agency's decision:
The Agency received the notification on 13/01/2006 and must respond in writing to the notifier within 90 days after receipt of the notification by indicating either:
(a) that it consents to the deliberate release, with or without conditions; or
(b) that consent is refused and give reasons for its refusal.

The Agency had until 12th April 2006, to make a decision, however, the clock was stopped on five (5) occasions as the EPA sought further clarification on questions raised by both itself and its reviewers. The EPA received the final portion of the requested information on 22nd March 2006 which extended the deadline to 13th May 2006.

The company requested that the following items be kept confidential:

- that the name of the owner of the farmland (and the person responsible person for conducting the trial),
- that the name of the applicant's representative should be considered as being confidential and therefore should not be placed on the public register, nor be disclosed to any third parties.

The Board of the EPA considered this request and decided that the following information be deemed confidential.

1. The name of the owner of the farm where the proposed Deliberate Release (DR) might take place, pending consent by the Agency.
2. The name of the person responsible for carrying out the proposed Deliberate Release, pending consent by the Agency.

However, the Agency decided that the following information will **not** be kept confidential:

The name of the notifier's representative as the Agency needs a name pertaining to this notification for correspondence purposes.

8. **Considerations for the Board of the Agency**

a.Description of the GMOs

Three cultivar/breeding lines namely P698, P835 and P880 were transformed using the *Agrobacterium tumefaciens* transformation system with binary vectors,

VCPMA16 and VCPMA19. A total of 380 transformed lines were selected following transformation.

According to the notifier the GM potato lines contain the following sequences:

- inserted resistance genes Rpi-blb1 and Rpi-blb2. These genes are derived from *Solanum bulbocastanum* (a wild potato species from Mexico with high levels of resistance against late blight) and they confer improved resistance to *Phytophthora infestans* - the potato blight fungus; and ,
- introduced ahas gene which originates from *Arabidopsis thaliana* (commonly known as thale cress or mouse-ear cress, a small flowering plant related to cabbage and mustard) and confers tolerance to Imidazolinone herbicides. This is a selectable marker gene to identify transgenic cells in tissue culture and no field tolerance is expected in the potato plants.

Out of the 380 different GM potato events approximately 320 individual events will be selected for planting in the first year of the release (2006). Per event approx. 40 plants will be planted in 2006, pending consent from the Agency. In the following years the number of individual GM events for planting will be reduced to approximately 50 in 2007 and to 5 in 2008, whereas the number of plants per event will increase.

b. Purpose of the Genetic Modification:

The specific purpose of this trial is to evaluate the genetically modified potato lines for improved resistance to *Phytophthora infestans* - the potato blight fungus.

In addition this trial proposes to

- compile data on agronomical performance and environmental effects, collect plant material for further analyses, and
- generate seed tubers.

c. Location of the proposed Deliberate Releases:

Deliberate release is proposed in one location, i.e., Arodstown, Summerhill, Co Meath. The deliberate release, if approved, will be for a five year period.
The genetically modified potato lines are planned to be released from April to October in the years 2006 to 2010 with planting taking place during April/May and harvesting in October of each year.

d. Information on control, monitoring, post-release and waste treatment plans as proposed by the company:

- A description of precautions to be taken:

There are no sexually compatible wild relatives to potato in Ireland. The only sexually compatible species will be commercially cultivated potatoes. The notifer is proposing that an isolation distance of 20 m between the GM potato lines and commercial potato cultivation will be observed throughout the testing period.

During transport and handling the potatoes will be clearly labelled, separated from conventional potatoes and packaged in closed containment. Any equipment or

machinery used for planting and harvesting will be cleaned on site. Any excess potato material (tubers after planting, after harvest) will be inactivated (e.g. via heat or via chopping).

Clarification was sought on the method of inactivation as the Agency had a concern re the chopping of potato tubers as it could lead to further propagation. Berries can also be formed to produce seed and they can germinate under Irish climatic conditions.

I am satisfied that the response received from the notifier on this aspect was satisfactory.

- Post-release treatment of the sites:

According to the information supplied in the notification, the release site will be managed according to conventional agricultural practice. The first year following the release the volunteer monitoring programme starts and the field plot will either remain fallow or will be cultivated with a species that facilitates weed management of the area that year. For the duration of the volunteer monitoring programme no potatoes will be planted on the field plot, however other crops (except for the first year) can be planted as long as they allow volunteer monitoring. Emerging volunteers will be destroyed by herbicide treatment (systemic herbicide e.g. glyphosate) prior to flower setting. The monitoring for volunteers will continue until no volunteers emerge. The cultivation of the release site in the years after the monitoring programme has concluded (sic) will be according to local crop rotation practice for potatoes.

The Agency sought clarification with respect to monitoring for volunteers and the notifier responded and stated:

It should be understood that in the case that volunteer plants appear the year after the trial has been carried out, those plants will be destroyed and the monitoring period will be prolonged by another year. In that way the monitoring will continue until no volunteers appear in the respective year.

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

The Agency sought clarification on their proposal to treat GM plant material including waste. The notifier stated:

Harvested tubers will be transported from the release site to certified contained facilities outside of Ireland. All potatoes grown within the release trial will be handled as GM potato lines irrespective of being GM potato lines or comparator lines. Therefore no distinction with regard to handling and destruction is made between GM and non-GM potato lines. Any excess tubers (remainders from planting) and also the complete harvest will be transported from the release site, either processed for analytical purposes or steamed/autoclaved at respective contained facilities approved for the purpose of handling GM material outside of

Ireland. The inactivated tubers will be placed for decomposition at approved contained facilities.

- Monitoring plans and techniques:

During the release: The site (where the GM plants are growing) will be visited and monitored (by the responsible scientist-BASF trial manager) at least once per month (from April to October)

Post release:

According to information supplied in the notification there will be no potato cultivation on the release plot for the duration of the volunteer monitoring programme. Only those crop plants will be cultivated that will permit observation of occurrence of volunteers. The responsible scientist or trained personnel will observe the area post-release at defined intervals (at least once a month). Should volunteers be detected they will be controlled according to good agricultural practice, recorded and destroyed by removal or treatment with a herbicide (systemic herbicide e.g. glyphosate).

I have included a consent condition, which specifies that the trial site will have to be visited by the notifier on a weekly basis.

e. Environmental and Health aspects considerations by the notifier:

- Likelihood of the genetically modified higher plant (GMHP) becoming more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats.
  The overall impact is considered negligible.

- Any selective advantage or disadvantage conferred to the GMHP
  No selective advantage foreseen.

- Potential for gene transfer to the same or other sexually compatible plant species under conditions of planting the GMHP and any selective advantage or disadvantage conferred to those plant species.
  Conclusion of the notifier
  There is no risk of introduction of the GM traits into conventional potato material as potato is propagated vegetatively.

- Potential immediate and/or delayed environmental impact resulting from direct and indirect interactions between the GMHP and target organisms, such as predators, parasitoids and pathogens (if applicable).
  Conclusion of the notifier
  The overall impact of resistant potatoes on target organisms is considered comparable to the impact of fungicide applications on non-genetically modified potatoes conducted according to conventional agricultural practice.

- Possible immediate and/or delayed environmental impact resulting from direct and indirect interactions of the GMHP with non-target organisms, (also taking into account organisms which interact with target organisms),

including impact on population levels of competitors, herbivores, symbionts (where applicable), parasites and pathogens.

Conclusion of the notifier

The overall impact on non-target organisms is considered negligible.

- Possible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the GMHP and persons working with, coming into direct contact with, or in the vicinity of the GMHP release(s).

  Conclusion of the notifier

  The potato plants are not for human consumption and measures taken with regard to planting, harvest, storage and transportation will minimize any contact to humans. Therefore the overall impact on human health is negligible.

- Possible immediate and/or delayed effects on animal health and consequences for the food/feed chain resulting from consumption of the GMO and any products derived from it if it is intended to be used as animal feed.

  Conclusion of the notifier

  The GM potatoes are not for animal feeding. Measures taken under current release practice will protect the trial against damage by wild animals (e.g. fences) and also ensure that seed stock and plant material are harvested, stored, transported or disposed of (e.g. cleaning of machinery, packaging) in such a way to minimise contact with animals. Therefore the overall impact on animal health is negligible**.**

- Possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of the GMO release(s).

  Conclusion of the notifier

  Due to a reduced need for fungicide treatments an increase in the populations of soil organisms might be expected. The overall impact on biogeochemical processes is negligible.

- Possible immediate and/or delayed, direct and indirect environmental impacts of the specific cultivation, management and harvesting techniques used for the GMHP where these are different from those used for non-GMHPs

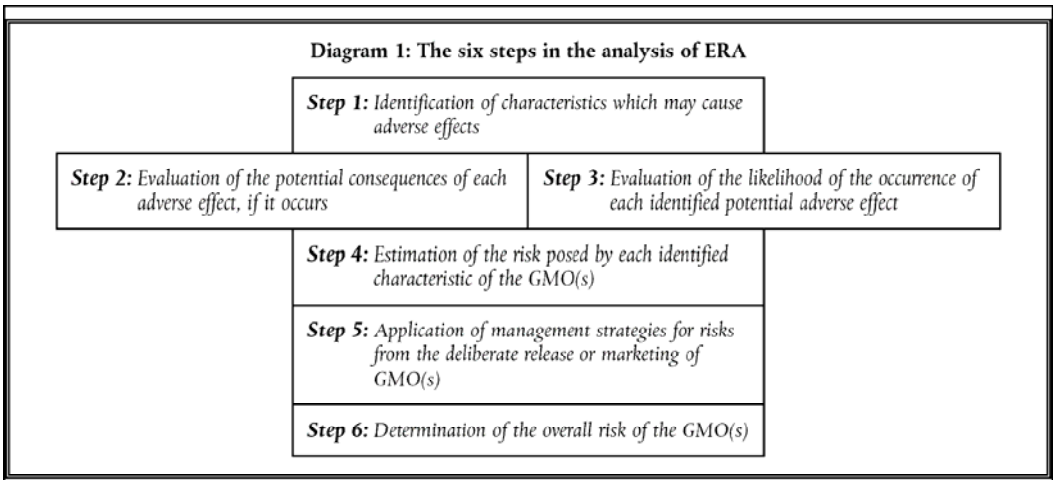
  Conclusion of the notifier

  The overall impact on the environment is negligible and comparable to the effect of the cultivation of non-genetically modified potatoes with a potentially positive impact on soil microflora.

f. Risk assessment:

Environmental risk assessment (ERA) is defined in Article 2(8) of Directive 2001/18/EC 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’.

In drawing conclusions for the ERA the following points should be addressed as main steps in the ERA.



It should be noted that a 'hazard' (harmful characteristics) is defined under Directive 2001/18/EC on the deliberate release into the environment as the potential of an organism to cause harm to or adverse effects on human health and/or the environment. A 'risk' is the combination of the magnitude of the consequences of a hazard, if it occurs, and the likelihood that the consequences occur.

The notifer submitted the following ERA as part of the notification.

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 characteristi c 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.	Negligible. The introduced traits do not confer competitive abilities in natural or agricultural habitats. Conventional practice and volunteer management are applied.	Very unlikely. Neither R-genes nor ahas gene confer characteristics to the GM potato that add competitive abilities in unmanaged ecosystems or allow to compete against plants of similar type for space. None of the characteristics transferred to the	Negligible. Surviving, reproductive potato plants are rarely seen outside the field.	Conventional agricultural practice and volunteer management (monitoring for volunteers and removal/destruction of volunteers in the field, isolation distance, crop rotation)	Overall impact is negligible.

		potato plants is anticipated to affect pollen production/fertility, seed dispersal or frost tolerance.			
Selective advantage – improved resistance to P. infestans	Moderate. The intended effect of the genetic modification is to improve the resistance to P. infestans, therefore a selective advantage is conferred in comparison to untreated non-resistant conventional potatoes.	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-resistant conventional potatoes in the agricultural environment.	Advantage applicable only in the agricultural environment and only in those cases where no other plant protection measures against P. infestans are applied. Potato plants are rarely seen outside the field. Resistance to P. infestans is not the key determinant for potential invasiveness of potatoes.	Conventional agricultural practice and volunteer management (monitoring for volunteers and removal/destruction of volunteers)	Overall impact is negligible.
Selective advantage – tolerance to Imidazolinones	Negligible. No selective advantage since Imidazolinone herbicides are not approved for use on crops in Ireland.	Not likely. The ahas gene confers tolerance to plant cells against imidazolinones, however only in tissue culture. No tolerance to a commercial spray regime of imidazolinones is achieved in the greenhouse for genetically modified potato plants carrying the ahas gene.	No selective advantage since Imidazolinone herbicides are not approved for use on crops in Ireland and since no tolerance to a commercial spray regime is conferred to the potato plants.	No risk management measures are required.	Overall impact is negligible.
Selective advantage or disadvantage conferred to sexually compatible plant species	Negligible. Potato is a vegetatively propagated crop and none of the traits confer a selective adavantage in the agricultural environment	Very unlikely. Neither of the traits confers a selective advantage in the agricultural environment under conventional agricultural practice. There are no sexually compatible wild relatives present in	In the unlikely case that pollen is transferred to non-genetically modified potatoes, the consequences are negligible since potato is a vegetatively	Conventional agricultural practice and volunteer management. Isolation distance to other potato crops.	Overall impact is negligible.

	under conventional agricultural practice.	Ireland. Pollen transfer to other cultivated potatoes is possible, but less likely due to short distance of pollen flow.	propagated crop.		
Potential environmental impact due to interactions between the GM plant and target organism (P. infestans)	Low. The intended effect of the transferred resistance genes is to reduce the infection by P. infestans, thereby reducing the population of P. infestans.	Very likely. The intended effect of the genetic modification is to confer tolerance against the target organism P. infestans.	The intended effect is a reduced population of P. infestans in the potato field, however this is acceptable and desired also under conventional agricultural practice, like via fungicide-treatment of potato fields.	None.	Overall impact is negligible.
Potential environmental impact due to interactions between the GM plant and non-target organisms	Negligible. Any effect is anticipated to be comparable to that of non-genetically modified potatoes under conventional agricultural practice.	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-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.	Monitoring plan including observations on disease and pest susceptibility.	Overall impact is negligible.
Potential effect on human or animal health due to introduced R-genes	Negligible. NBS-LRR genes not known to confer toxic or allergenic properties.	Very unlikely. NBS-LRR 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.	Overall impact is negligible.

Potential effect on human or animal health due to introduced ahas gene	Negligible. AHAS protein not known to confer toxic or allergenic properties.	Very unlikely. AHAS protein 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.	Overall impact is 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 plants to the soil.	Very unlikely. Soil fertility is not expected to be affected differently due to the cultivation of the genetically modified potato plants as compared to conventional potatoes. 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 the populations of soil organisms might be expected.	None.	Overall impact is negligible.
Possible environmental impact due to changes in cultivation practice	Low. 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.	Overall impact is negligible. Potentially positive impact on soil microflora.

The Agency also requested further information on the ERA part of the notification in particular in relation to the following aspects:

The notifier was asked

- to comment on whether the introduction of the GM blight resistant potatoes might alter the pathogenicity of the potato blight fungus under Irish soil conditions thus facilitating the dissemination of infectious diseases and/or creating new reservoirs or vectors.
- to support certain statements and explain how they concluded in their determination of the risk of the GMOs (in the ERA) that the overall impacts are negligible, if they cannot support these statements with relevant data/studies
- to provide information on aspects related to toxicity and allergenicity

Please refer to the response of the notifier to the Agency's questions re the risk assessment and other issues raised-see attached-Appendix 1.

9. **Information about previous releases of these GMOs**

In 2005, notifications were sent to Germany, Netherlands and Sweden by the applicant. The NL indicated that they had forgotten to put certain information on their web page at the start of the public consultation process and as a result of this, the consultation process was delayed. It should be noted that GM potato lines carrying the Rpi-blb2 gene were released in the field in Sweden in 2005 (consent B/SE/05/450). During these trials no unforeseen effects as compared to conventional potato varieties have been observed according to the notifier. Also, no adverse impacts on the environment or human health have been recorded from other potato lines with ahas gene in previous field trials in Sweden since 2002, according to the notifier.

It should also be pointed out that potatoes produced by plant breeding techniques containing R genes from *Solanum bulbocastanum* have been tested in field trials in several countries, US, the Netherlands and Germany and the hybrids showed high levels of resistance under field conditions. No adverse effects have been reported with regard to these trials.

10. **Implications for Ireland**

Production and distribution (Ref DAF co-existence report)

Potato (*Solanum tuberosum*) is cultivated for its tubers and is an annual, herbaceous plant that grows rapidly under the mild moist Irish climatic conditions. If the cultivar is fertile and the flowers are pollinated, berries will form that can contain up to several hundred true potato seed (TPS). TPS is primarily used in breeding programmes.

These berries can germinate under Irish soil conditions (Dr. D. Griffin. Potato Breeder, Teagasc Oakpark-person. comm).

Commercial potatoes are all propagated vegetatively from "seed tubers" - references to "seed potatoes" generally refer to seed tubers, and not to true potato seed. In 2004, there were 732 commercial potato growers in the country, producing a harvest of over 300,000 tonnes of potatoes annually. Commercial potato production utilises approximately 12,600 ha of land, with the organic sector producing upwards of 114 ha. Greater than 58% of the national potato production takes place in Meath, Dublin and Louth.

It should be noted that 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. Late blight (caused by Phytophthora infestans) is one of the more destructive potato diseases and imposes upon the sector an annual cost of over €10 million.

Mechanisms of gene dispersal and survival

- **Pollen dispersal and hybridisation with wild relatives**

The potato plant is primarily self-pollinating. As a consequence, the potential impact of pollen dispersing from a GM potato is limited. Estimates for cross-pollination range from 0-20% , with pollen primarily dispersed by wind. Reference 'published literature'(PL)

Field trials with a GM potato crop have recorded maximum pollen dispersal distances of between 5-10m (PL). 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 (PL). Therefore, if tubers taken from a crop that had been exposed to GM pollen were used as seed for the next crop, there would be no transmission of the GM material (PL). Insect pollination can occur but it is not considered a significant mechanism for pollen transfer in potato (PL).

Two related weed species ('woody nightshade' Solanum dulcamara and 'deadly nightshade' Solanum nigrum) of potato can be found in Ireland. However, research has concluded that cultivated potato cannot cross naturally with either of these weeds (PL). As such, potato is considered to be a naturally contained species within Europe (PL) and there is negligible risk of a GM trait escaping from a GM potato crop into a related weed species.

- ***Seed dispersal and volunteer plants***

A continuous problem associated with potato cultivation is the significant number of tubers that remain in/on the ground post-harvest. These volunteer tubers or 'groundkeepers', emerge in the next season, thereby causing a weed problem for the following crop(s). If not adequately managed, they in turn will produce tubers and if not controlled, the problem will persist for several years. The issue can be compounded further if the crop is sorted and graded in the field immediately after harvesting, which adds to the number of tubers over-wintering in the soil seed bank. Estimates in Denmark put the number of residual tubers at anywhere between several hundred to several thousand per hectare (PL). Though this level of variation can be attributed to local farming conditions and cannot be directly applied to Irish potato systems, it underlines the importance of appropriate post-harvest control.

Adequate groundkeeper control in the following non-potato crops can be achieved through the application of an appropriate herbicide. Post-harvest cultivation can be delayed, thereby exposing tubers to winter frosts and bird feeding leading to a significant reduction in tuber viability. While it is possible for tubers to be lost during transportation, they have negligible capacity to establish outside the controlled environment of the field. Therefore, feral potato plants present negligible risk of acting as a viable pollen source or recipient (PL).

According to the DAF, many years' Irish experience in potato breeding programmes would indicate that it is extremely unlikely that volunteers arising from true potato seed would cause a problem. There is no record of new potato

varieties being found in Irish land, as would be the case if plants originating from cross-pollinated true seed persisted. In almost ninety years of official inspections under the Seed Potato Certification Scheme, no new or unidentifiable variety has been found as a volunteer.

Admixture of GM and non-GM potato crops can occur during mechanical operations involving planting, harvesting, on-farm transport, on-farm storage, transport off-farm and at merchants premises.

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

The notifier (BASF) published a notice in the Irish Independent on 26/01/2006 informing the public of submission of a notification for the deliberate release of GM potatoes into he 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.

In accordance with article 16 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. The latest date for receipt of representations was 22nd February 2006. It was also required that the representation be accompanied by a fee of €10. One hundred and twenty one (121) representations were received in total of which 96 were valid and 25 were invalid on the grounds of non-payment of fee or received after the 22nd February 2006 deadline.
Of the Ninety-six (96) valid representations received ninty five (95) were opposed to the field trial and one (1) was in favour**.**
The concerns were identified grouped under main headings and counted.

The following concerns were raised:

A. Economic concerns

Contamination of Ireland's green image as a whole. Damaging to Ireland's GM free status, which is one of its main assets. This will have financial benefits as public demand for GM-free food grows and in tourism sector. 43*

The release of GM plants into the Irish Environment will devastate the livelihoods of non-GM conventional growers and organic and biodynamic growers. No benefit to farmers, risk to sustainable farming. EPA or other body cannot guarantee that there will not be contamination. 31

Corporations interested in economic profit. 'The technology is aggressive it will not live and let live' These products should be banned outright making their importation illegal. In 10 – 20 years time, those places that have allowed the growing of these crops and those who are downwind will be paying the consequences of another technological folly born of corporate greed. 24

* This denotes the estimated number of representations that raised this issue.

No market in Ireland for GM produce unless through inadequate labelling whereby people could be duped into purchasing it unawares. Since GM products must be clearly labelled there is quite clearly no market here. 11

Costs farmer more to grow GM crops, leaves him/her open to problems such as hostility, loss of confidence, markets. 8

Farmers don't want to grow GM crops or have it grown beside them rather they want to continue growing and eating natural food 7

Companies supplying these seeds and associated chemicals are the only beneficiaries. 7

No market in Europe for GM produce. 6

Force farmers contaminated produce to carry a GM label. 4

Where organic crops have become contaminated with GM crops farmers must begin a 3 – 5 year process to regain the right to certify their fields as organic. 4

Irish farming/family farming on decline. If we stay GM free viable niche, develop our marketing strategy, develop world recognition that Irish food is safe food, there will always be a market for our food, and people will be willing to pay higher prices. 4

Control of all areas of the food chain will be in the hands of non-Irish multinational corporations. 2

Proposed site is adjacent to Irelands most productive vegetable (including potatoes) growing region. This experiment could have catastrophic effects for agricultural production in the region and beyond. 1
Enough food in Ireland. 1

There are some crops where the yield is marginally greater for GM varieties but in many species the yield is proven to be lower. 1

Response:
A lot of the issues raised here (green image, GM free status, economic profit for companies, no market for GM crops, farming in decline etc) are policy matters pertaining to GM crops and I believe that they are a matter for the Government who decides on policy in these areas and thus fall outside the Agency's remit.

It should be noted that freedom of choice is the widely accepted cornerstone of the EU's policy re GM crops and that consumers are ensured the right to choose between products with or without GMOs through the EU labelling regime. This was re-iterated by the Commissioner for Agriculture and Rural Development at **the conference on co-existence of GM crops conventional and organic which was held in Vienna in early April 2006. 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. I do not agree with the argument that the release of these GM plants into the Irish Environment in this field trial will devastate the livelihoods of non-GM conventional growers and organic and biodynamic growers Environmental concerns/threat to organic farmers.

B. Deliberate release concerns

GMOs cannot be recalled. Once GM crops begin to interact with non-GM crops or cause an undesirable effect on people or crops it is too late to withdraw them. Containment is not possible 26

Isolation distance of 20m not adequate. No guarantee that cross contamination will not take place. Cross contamination and other effects will be greater the lesser the distance the trial is from other non-trial crops. 25

Irish Seed Savers Association (ISSA) collects grows and distributes a diversity of potato crops adapted to various local soil and climate conditions some of which are naturally resistant to potato blight. 21

Possible contamination of genotype of conventional/ organic potato crops. 20

Implementation of Precautionary Principle – if we are unsure of the consequences of growing GM food then they should not be planted - which Ireland ratified as part of Rio Declaration and remains a Policy Guiding Principle within the EU Commission's Draft Declaration on Sustainable Development. 18

Proposal that Ireland become a GM-free zone to act as control in relation to GM crop growing trials abroad. Also to protect the green and quality image of our food industry. Ireland is in an ideal position (environmental pragmatic and reasons of economic merit) to be GM free. In the years ahead there will be a substantial global market for GM free food. Would complement market trend toward organic farming. 18

Threat to organic farming. Threat to biological diversity and environmental health increase. Organic Farming promotes biological diversity and environmental health, encourages sustainable agriculture and growing and preservation of our heritage seeds and plants all of which will be under threat if GM crops are introduced.14

GM Potatoes should not be introduced into Ireland. The effects on our environment, biological indicators and the risk of cross-pollination and escapee plants cannot be under estimated. 6

Patent breach. Devastation economic effects on farmers who fell prey of Companies such as Monsanto (Monsanto Vs Schmeiser) 6

Transgene expression on farmland ecosystem. 4

Agribusiness has proved itself to be non sustainable by needing greater and greater inputs of fertiliser, weed killer, pesticides energy etc to the detriment of the environment. 3

Introduction of genes via highly mobile vectors (in this case 2 vector genes from *A.tumefaciens*) are known to easily migrate from host to host and to speed up the rate of mutations in the targeted pathogens (i.e. *P.infestans*). An increase in pathogenicity of *P.infestans* could be a disaster in Ireland. 2

Too many incidents of GE contamination (about 50 in 25 countries in 5 continents) 2

Patented genes - what safeguards are in place to prevent their escape? What protocols are in place to detect them? What penalties will BASF face if these genes escape for the field trial site? 2

Impossible to grow GM free crops. 2

Introduction of a marker gene that conveys tolerance to "Imazamox" herbicides. This is driven by vector genes for *A.tumefaciens* which are pathogenic bacteria. l

Ireland is dependent on oil and functioning transport system for its food imports. Potato is Ireland's staple crop, cultivated easily and generally produced locally, could constitute Ireland's safety net in event of global disruption to food transports. Therefore important that Ireland maintain a diversity of potato crops naturally adapted to Irish environment. l

Loss of seed varieties many of which will have adapted to local conditions over the years. l

GM food offers no benefit over non-GM food. l

GM crops are fertiliser dependent. l

These potatoes have a world patent, which enables patent owner to claim ownership of crops contaminated with patented genes and also to file patent infringement lawsuits and force farmers found growing the potatoes (whether by contamination or not) to pay annual royalties. This is unethical. GM Companies are not taking responsibility for the spread of their unwanted seeds 27

An irreversible legacy will be left to future generations 2

Man tampering with nature l

Monsanto's cotton plant devastated India's cotton economy after promising higher crop yields with fewer applications of chemicals when in fact there was an increase in the use of pesticide and lower yields forcing many farmers into bankruptcy and many suicides. 1

Nature cross breeds naturally and has done for centuries without the need for man's intervention. Nature only cross breeds within its own species. Genetic modification goes beyond these boundaries playing with the basic genetic building blocks and crossing different species genus and life forms with each other. l

Refusal to cover disaster risks by insurance companies, and this is after the manufacturer's alleged comprehensive tests and trials aimed at reassuring us that all is well. 6

Polluter pays principle should be fully implemented.2

Who is liable? Austria has introduced regulations, which would make the company carrying out genetic engineering liable for compensation of any damage, which may arise as a result of the trials. Ireland appears to have no such protection. l

Response:

In 2005, some 8.5 million farmers from 21 countries grew GM crops on approx. 90 million hectares worldwide of which approx. 50,000 ha were grown in Europe mainly GM Bt maize in Spain. At a Biosafety meeting held in Amsterdam in 2006, in which the Agency was represented, Spanish scientists reported that post-release monitoring of Bt maize has so far not shown any negative environmental aspect in independent studies that were carried out under Spanish soil conditions over the last 6 years.

However, it should be noted the results of the UK Farm Scale Evaluation (FSE) trials which were carried out over a number of years indicated that the planting of both GM herbicide tolerant oilseed rape and sugar beet and in particular, the management of these crops (herbicides that were used), could have an effect on biodiversity as fewer weeds would be available for organisms at higher trophic levels (e.g. farmland birds) compared to conventionally managed OSR & beet. This effect was not seen for GM herbicide tolerant maize that was tested in the FSE studies. It should also be noted that another UK funded study called the Bright project concluded that the GM varieties did not deplete the soil of weed seeds which was in direct contrast to the above study in particular for GM oilseed rape.

I am in agreement that the 20 m isolation distance is not adequate and this has been raised by both the Agency's expert reviewers and the members of the public, to this end a 40 m isolation is proposed in the Consent Conditions. It is understood that there is no potato production ongoing in the vicinity of the proposed field trials.

I believe that the risk to organic potato production is negligible from this field trial as the potato is primarly self-pollinating (80% selfing), consequently, the potential impact of pollen dispersing from a GM potato is limited. Also according to the published literature, field trials with GM potatoes recorded a maximum pollen dispersal distance of between 5-10 m. Insect pollination can occur but it is not considered a significant mechanism for pollen transfer in potato.

Research carried out by Teagasc showed the dispersal of potato pollen could be an issue in certain regions of Ireland where potato is cultivated for both tuber and true potato seed (TPS) production. My understanding is that the risk of gene flow from potatoes is low compared to other crops like oilseed seed rape (the publication was comparing different crops). As noted previously, this trial is not close to commercial potato production therefore the risk of gene flow is very low.

Also, the appearance of potato volunteers emerging from overwintered groundkeepers is a serious problem for potato growers and hence a feasible mechanism for seed mediated gene flow. The measures in Condition 5 will ensure that groundkeepers and TPS if they arise will be managed in a post release monitoring plan.

It is noted that the Irish Seed Savers Association (ISSA) collects and distributes 'wild' cultivars of potato some that are blight tolerant. In my view farmers can choose these potato lines if they so wish thus ensuring freedom of choice.

The precautionary principle has been taken into account and is enshrined in the conditions of this consent.

Whether Ireland should be a GM free zone is a policy matter for the government and outside the remit of the Agency.

Percy Schmeiser case:
Mr Schmeiser is a farmer who farms 1000 acre of oilseed rape (OSR) or canola in Saskatoon, Saskatchewan. In 2001, Mr Schmeiser was sued by Monsanto for allegedly growing Monsanto's patented, GM Roundup Ready OSR without paying for the seed.

The defendant claimed that he had no idea how his field had become contaminated with Monsanto's seeds, suggesting that perhaps they were the result of wind-blown seed or pollen from another GM planted field (despite the fact that the nearest GE canola field was five miles away) or had bounced off trucks driving past his fields (despite being planted in neat rows). The court ruled against Mr Schmeiser and he was found guilty when the court ruled that 95-99% of the crop that was planted in 1998 was GM.
Mr Schmeiser appealed the ruling to the Canadian Federal Court of Appeal and lost that case in 2002. Finally the Canadian Supreme Court agreed with lower court rulings against this farmer.

It should be noted that anti-GM groups will argue that agribusiness came after a defenseless small farmer, Mr Schmeiser, whose fields had been inadvertently contaminated with GE crops. Clearly this has not been the case according to the Canadian Supreme court ruling.

With regard to patents, plant breeders and including those who work in public institutes throughout the world hold patents for potatoes and indeed other crops that are used commercially in Ireland and elsewhere, receive royalties on these patents. So patenting is nothing new in this regard and I would not regard this as unethical.

C. Biodiversity concerns

Negative impact on biodiversity. 29

No environmental or human health impact studies or feeding studies carried out. Those in favour of GM food claim it is safe to eat. Yet there have been no scientifically efficacious trials into GM food performed on humans to justify this position.27

Harmful to human health and environment 22

Research has highlighted the negative effects of GM foods on human and animal health. Puzstai research utilising GM potato showed changes in the gut of rats fed with GM potatoes which infer that GM food has negative health effects on those that consume it and is therefore not safe to eat Animal testing has given rise to serious concern. 15

Public opinion is opposed to GM food (75% Europeans do not want to eat GM foods). 15

According to Joe Cummins the transfer of genes between potato *S.tuberosum* and its wild relative *S.bulbocastanum* may lead to novel proteins with powerful or fatal immune responses, potential inflammation as well as allergenicity effects. If the GM potato proves to be immunologically active the impact on both human and animals may be severe. 10

Research from other experiments around the world has not been positive - we have seen contamination of other wild plant species with genetic material which has resulted in " superweeds" the extinction of certain butterflies and insects which could not tolerate the change in genetic make up on the plants that are part of their diet. Spread/development of superweeds through heavy spraying and cross-pollination of GM crops and weeds. 9

That GMOs reduce use of herbicides and pesticides is unfounded. Increased use of chemicals on crops. 8

GM foods and crops pose unacceptable health and environmental risks including overwhelming evidence of deaths attributable to GM products among laboratory and farm animals and in the human population. 7

Proposition that NBS-LRR family of plant pest resistance genes and their products provide safe transgenes for human consumption and for environmental release because they are found in food crops (and for that reason require no further testing) is foolhardy. 5

Very little is known about the way in which introduced genes will be expressed when the modified plants are exposed to environmental stress under field conditions, may lead to unexpected toxicity in GM crops 5

Damage to the ecology of the soil. 5

80%+ Irish people object to GM crops being grown in Ireland. Counties Clare Monaghan and Fermanagh have declared themselves to be GMO Free zones. GM Free Ireland represents 32,000 farmers consumers and organisations all opposed to the planting and consumption of GMOs. In 2005 – 1000 GMO-free zones were created. 5

Consideration of human and environmental safety, RA and monitoring all seem to be based on wishful thinking rather than sound scientific studies and factual information. 4

Concern over use of antibiotics in GM production causing less resistance to diseases and affecting our immune system 4

Co-existence of GM crops with conventional or organic crops or with wild plants untenable. 4

Health surveillance systems in Ireland not adequate to detect adverse health effects should they arise from this planting – no baseline data. 3

Only 14% of Europeans believe GM foods to be safe or acceptable. 3

GM food appears to be genetically unstable. Potential risks from the consumption of untested food that has been mutated with gene sequences that are unstable often forming unpredicted combinations of DNA are substantial. 3

Likely to lead to commercial and private cultivation of this GM potato strain in Ireland which would lead to increased herbicide use on potatoes. This would lead to increased human and environmental exposure to pesticides since potatoes staple crop and ubiquitous in Ireland. 2

Chemical resistance can be transferred to non-target species with unknown consequences. 2

Risk of developing unknown pathogens 2

Concerns regarding the risks of GM food have not been allayed. 2

All surrounding landowners and farmers should be notified of the loss of land due to the separation distance that affects their land. 1

Organic sector fastest growing food sector at over 26% per year. GM is not a growing sector fell from 15% growth in 2001 to 11% in 2003. EPA and DAF should be promoting the benefits of organic farming.1

Impossible to conduct field trials on GM crop species without adversely impacting on the surrounding environment. Specifically1 volunteer GM plant per m^2 in a field would produce contamination rates of between 0.6% and 1.5% depending on variety

- the discovery of weedy population of wild turnip co-existing and hybridising with GM OSR in UK. One plant sampled had 81 GM seeds out of 167 (48.5%)
- 0.5% contamination rates in crops at distances up to 200m, 3.2% contamination rates at 105m in some OSR varieties. 1

Organic sector fastest growing food sector at over 26% per year. GM is not a growing sector fell from 15% growth in 2001 to 11% in 2003. EPA and DAF should be promoting the benefits of organic farming.1

Response:
A risk assessment has been carried out in accordance with the requirements of the GMO Regulations and I am satisfied that the notification meets the requirements of the GMO regulations. The consent conditions details certain risk management measures with which the notifier will have to comply in order to minimise any risks to human health and the environment, in particular, condition 5 which specifies management measures to ensure that the GM potatoes are not mixed with conventional potatoes that are cultivated in Ireland.
The notifer proposes to measure altered qualitative properties (e.g. tuber composition, nutrients, anti-nutrients, feeding studies during the second phase of the trials.). Condition 5 stipulates that the animal feeding studies be carried out after the 1st year harvest.
Such feeding studies will be carried out by the notifer during the course of these field trials will be required to meet the requirements of Part C, i.e., the placing on the market for possible commercial cultivation for food and feed purposes. This was an issue that the GMO AC wished to have addressed in any consent granted.

There are no reports of adverse effects to human health or the environment from the numerous field trials carried out in other countries using GM potatoes and potatoes bred traditionally to contain the R genes and ahas gene.

In relation to this notification, Dr. Pusztai who made a representation to the Agency concludes,

"In view of all the accumulating data showing that GM potatoes of all kinds investigated to date have shown unacceptable compositional, metabolic, immunological effects and potentially toxic behaviour, it is imperative for the

Irish EPA to reject this request by BASF for field trial of their GM potatoes until and unless they are first subjected to independent environmental and health risk assessments using a scientific protocol openly agreed and approved by independent scientists and representatives of the public and consumer groups."

In 1998, Dr. Pusztai voiced his concern in a British TV programme that testing procedures used to establish the safety of foodstuffs containing genetically modified (GM) material may not be adequate. He fed GM potatoes to rats and claimed that the GM potatoes damaged the rat's immune system and retarded their growth. All his scientific data was reviewed by an audit committee who concluded that Pusztia's data did not support his conclusions. However, he later published his finding in the medical journal the Lancet which proved to be controversial among the vast majority of the scientific community.

Dr Pusztai's, representation to the Agency on the BASF notification was discussed at the GMO AC meeting. It was felt that while his research might not be viewed by all as credible he has undertaken considerable research with different strains of GM potatoes, one of which contained a lectin gene which coded for a known toxin.

The Advisory Committee did not agree with Dr Putzai's conclusion that the notification should be rejected by the Agency.

I note that public opinion is opposed to eating GM food, however, this is again a policy issue and is outside the Agency's remit.

The regulation of GM food is outside the Agency's remit and the contents of this field trial will not go into the food chain.

I am not in agreement with Prof Cummin's assertion that the transfer of genes between potato *S.tuberosum* and its wild relative *S.bulbocastanum* may lead to novel proteins with powerful or fatal immune responses, potential inflammation as well as allergenicity effects. Information on this aspect will be provided by the notifier for a Part C application and will be assessed by EFSA and Member State Competent authorities to review the safety for human health under the food and feed legislation.

Regarding the emergence of 'superweeds' from this field trial, it is my opinion that this is a vanishingly low risk due to the biology of the potato (80% selfing) and the measures that have to be put in place under condition 5 to minimise even further this low risk.

It would be argued that this GM potato could lead to a reduction in the use of chemicals to control the blight fungus which could be potentially beneficial to both human health and the environment.

Monitoring with a view to measuring indicators of biodiversity and what effect , if any, will the introduction of these GM potato lines will have on soil biodiversity will have to be carried out by the licensee as per condition 9.

D. Public perception / Active opposition

The project is unnecessary - no-one wants to eat GM potatoes. 7

Need for increased public debate about this issue - most people not aware of the catastrophic consequences for Irish food production and human health. 6

Agri-biotech industry is ridden with secrecy. 4

BASF should conduct field trials in Germany. 4

Throughout the world farmers environmental groups and consumers have expressed their opposition to GM crops. 3

No guarantee that genetic modification of potatoes will be a permanent solution to the problem of late blight. 3

It is not the earth's ability to produce food which creates poverty but rather our inability to distribute equally the earth's resources. Supply of GM crops to Third world countries will increase poverty and starvation. The experience of Indian Farmers during the "Green revolution" in the 1960s when super strains of rice were introduced was that many were pushed off the land and poverty and starvation increased. 3

Rumoured that site of this release is on Teagasc land. Teagasc is a state Agency which should be fully open in respect of its dealings to the public. 2

Violates FF election promise on GMOs (never to allow GMO crops in Ireland, 1997). 2

GM crops appear to be genetically unstable . 2

Studies which have revealed evidence of adverse effects have been suppressed and ignored by Biotech industry and by governments. 2

Biological pollution will always increase, be passed on and multiplied from generation to generation. 2

Opposition in the form of sabotage of field trials is growing, case in point the French "Faucheurs volontaires" (deliberate reapers) is particularly active on this front. On December 9th the Orleans criminal court and the Versailles court on January 13th discharged protestors for deliberately reaped Monsanto's transgenic corn crops in 2004. The court recognised the 'necessity' of their action. 1

Seed production and other chemical components will become concentrated in the hands of an ever smaller number of multinational companies. 1

Underhand element at play in an effort to get sympathy of the Irish, canola would not be tolerated. 1

The release site is adjacent to Hill of Tara, inappropriate for such an experiment, no consultation with local interest groups including farmers in selecting site. 1

EPA AC could contain bias in favour of trial. Too few members could represent other than government agencies or industry. Some members may have possible

conflict of interest. Would feel more reassured if there more representatives of the environmental ecological and health interests. 1

Flavr-Savr and Endless Summer, 2 GM tomatoes have been withdrawn for commercial reasons (health reasons???) l

In conventional farming a high level of fungicide use will be necessary to control the various fungal disease listed in notification most of which at present are controlled by the broad spectrum fungicides used to control *P.infestans*. l

Number of leading farming groups and farming publications publicly opposed to this field experiment on basis of risk it poses to Irish Agriculture and Irish Food Industry.1

The future of growing GM potatoes is not sustainable. 1

In US there is evidence that pollen from GE corn is so rapidly contaminating all other corn that there may soon be no naturally bred corn left. 1

Not so long ago it was assumed that pesticides and insecticides like DDT and Dieldrin were perfectly safe. 1

Concerns for local area around trial. Similar trials in UK have been the site of demonstrations and confrontation between activists and the police. Might a trial in Ireland attract similar opposition. 1

Agency's primary concern should be to protect against habitat contamination and the potentially damaging effect this could have on people and wildlife. 1

Alleged benefits unproven. 1

EPA's responsibility to look at growing body of damning evidence and do what is best for human citizen and natural environment rather than biotech industry and economic interests. 1

Response:

I believe that it is prudent to carry out field trials under Irish soil conditions and that environmental studies be carried out on such trials as it is probable that this particular GMO might be placed on the market in the future for possible cultivation for food and feed purposes. Therefore, such experimental field trials will be useful to ascertain if anything untoward is seen before embarking on commercial production under Irish soil conditions in the future.

In 1998, the Minister for the Environment, Heritage and Local Government (DEHLG) undertook a public consultation process regarding the release of GM crops into the environment which was regarded as been very successful by many of the stakeholders. On foot of this consultation, a policy paper was subsequently produced by the Minister on this topic. This consultation was followed by the Inter Departmental Group on Modern Biotechnology which reported in October 2000, on wider GMO issues, for example, GMOs used in medicine, food etc. The following pertain in particular to GM crop field trials:

- ***this country should take a positive but precautionary approach to GM issues at EU level and in international forums which acknowledges the potential benefits of modern biotechnology, while maintaining a fundamental commitment to human safety and environmental sustainability;***
- ***trials of GM crops should continue subject to compliance with EU legislation and with the conditions laid down by the Environmental Protection Agency.***

The company are conducting field trials in Germany , Sweden and the Netherlands with the same GM potatoes.

I would concur that these GM potatoes may not always remain tolerant 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.

This trial will not take place on Teagasc land.

The Agency must evaluate the risks posed by the proposed release for human health and the environment. I believe that the Agency have fulfilled this task and I am of the opinion that the risks posed by this field trial are low, in particular when the a risk management strategy is used as outlined in the consent condition No 5.

No member of the GMO AC advised the Agency of having a conflict of interest regarding this notification. At the first meeting of the current (4th) GMO AC all GMO AC members were requested to sign declarations of interest regarding any potential conflict of interests. This was reiterated during the AC meeting of March 24th 2006, when this notification was discussed and no member of the committee declared a vested interest in either BASF or this proposed trial.

E. Regulation

No permission should be given for release of GM products whether for a field trial or commercial cultivation in Ireland prior to publication of DAFs Guidelines on the co-existence of GM crops with non-GM crops. 10

GMO seeds crops and livestock are illegal in Switzerland (Switzerland has introduced a 5 year moratorium) and prohibited or restricted by 175 regional governments and by over 4,500 local authorities and smaller areas across 22 EU countries because of health environmental and economic risks. 4

According to Council Decision 2002/813/EC the SNIF format should reflect the need to enable the fullest possible exchange of relevant information presented in a standardised and easily comprehensible manner. SNIFs B/NL/05/03 and B/SE/05/8615 did not inform that the same release was planned for Ireland. 3

GM Food is unsafe to eat until it has been proved otherwise. Due to rulings of the USA's EPA and FDA American Based biotechnology is untested for human consumption. They have declared GMOs as significantly equivalent to normal food so they fall into generally regarded as safe category, (when it came to

patenting they were regarded as ‘substantially different’) This means that bio-companies are under no obligation to prove that their products are safe for human or animal consumption. Every independent consumption test done on GM foods has raised causes for concern. 3

WTO has no legal or moral right to impose regulations regarding food products we import. EU Commission consists of members not elected by European citizens and should not be allowed to make decisions that affect EU citizens. Too many members of EFSA are not independent and have direct interests with biotech corporations and therefore cannot make independent unbiased decisions. Too many loopholes in EU regulation with result EU law is untransparent, undemocratic and enables corporations to flood market with GM produce against wishes of citizens. 2

No faith in regulating bodies such as EFSA or EU Commission - they have serious vested interests in biotech corporations.1

Recommendations set out in draft report on co-existence with regard to separation distances, written agreements with neighbours, locations of proposed releases – from contents of notification alone neighbouring farmer would not know location of proposed release. Where neighbouring farm is organic, separation distances would have to be increased. 1

Ireland is committed under Cartagena Protocol on Biosafety to the conservation and sustainable use of biological diversity. Ireland also committed to ‘Halt the Loss of Biodiversity’ by 2010 under the convention on Biological Diversity to which Ireland is a signatory. Biodiversity is defined as incorporating genetic diversity. 1

Risks posed by this GM potato field trial have not been adequately assessed as per Principle 15 of the Rio Declaration on Environment and Development (which requires the evaluation and management of risks relating to GMOs); the Cartagena Protocol on Biosafety and as per the legislative requirements as set out in 33(4) of the GMO Regulations. In this instance the ERA provided is insufficient to satisfy the Agency or any of the stakeholders involved that the release will not result in adverse effects on human health or the environment. The participation of civil society in decision making of this nature is enshrined in the Aarhaus Convention which is European Law. 1

The EU Directive while permitting a Member State to allow GMOs to be grown in the member states didn’t require member states to allow it in every case. Open to Ireland and EPA to refuse every time and declare republic GM free site. 5 Member States have refused to lift their national bans at all on GMOs Austria, France Germany Greece and Luxembourg. 1

Response:

The DAF ‘draft’ co-existence measures when adopted pertain to economic issues and are pertinent only for the cultivation of GM crops along side conventional and organic producers. It should also be pointed out here that co-existence measures pertain to possible economic loss due to potential admixture of GM material with organic or conventional and is not a biosafety issue. This field trial is not for commercial production. The risks from this

field trial are vanishingly low to both conventional and organic potato producers. The Agency is unaware of any conventional and organic potato producers in the vicinity of the field trials and consequently the chances of admixture are low.

The situation in Switzerland is noted. As mentioned previously the decision as to whether Ireland should be GM-free is a policy decision and is clearly a matter for the Irish Government to take a decision on.

The information supplied in the Dutch and Swedish SNIFs was in accordance with the legislation and correct at that time given that these SNIFs were dated Nov 2005 and the notifier had not submitted a notification to the Irish Competent Authority at that time.

The regulation of GM food is outside the Agency's remit as previously outlined under section C above.

The EU have introduced strict rules on both labelling and traceability thus giving consumers freedom of choice as to whether or not they wish to purchase GM products or products derived from GMOs.

I believe that the risks from this proposed field release are low. It should be noted that the GMO Regulations allow for public participation in the decision making process regarding GM crop releases into the environment by inviting members of the public to make representations to the Agency in writing. Under the GMO Regulations the Agency must consider all valid representations made within the statutory timeframe in determining the notification.

F. Research

Need for more independent research and risk assessments. Any independent testing is scarce due to lack of funding. 15

No peer reviewed publications of clinical studies on the human health effects of genetically engineered food. 3

Requirement for a mandatory monitoring system to investigate the ecological impacts on invertebrates, birds, mammals that rely on agricultural crop systems or grasslands. 3

Requirement for proper testing (not only allergenicity but also for inflammation) of plants in glasshouse conditions before releasing into the environment 2

Science of genetic engineering in its infancy and until long term exhaustive independent tests have been conducted there should be no releases of GM organisms into the environment. 2

Lack of transparency in research and also the lack of research on the particular effects on the environment and humans 2

There should be serious effort and studies made to assess the negative impacts before the study goes ahead and the results are irreversible. The risks are known and evident and it is the responsibility of the EPA to pursue this project. 2

A wider and more detailed independent scientific assessment of the full extent of potential interactions with wildlife and thus the possibilities for contamination into neighbouring lands must be carried out by the relevant authorities in this case the EPA. It must include a factual and scientific assessment of the possibilities of uprooting and transport of any GM tubers by mammals outside of the site and the full range of pollinators and their travelling distances in this particular landscape. 1

UK Farm scale trials indicate GM crops are harmful to the environment and damage biodiversity 1

No greenhouse trials under challenging conditions which is when mutation most frequently occurs. 1

Nature is totally interactive so determining the total safety of and being certain of the long term behaviour of the GM potato before release into the environment is essential. 1

An Article in New Scientist hypothesised that "junk DNA" is in fact the operating system of evolution and if this theory were ever proven our entire understanding of genetics would have to be re-written. I am not saying that this is the case but the fact that such basics currently remain unexplored and unknown, is not the point, that an irreversible technology should not be unleashed onto the environment particularly if it can affect food production? 1

A full cost benefit analysis of introducing GM crops to Ireland should be conducted before approving this and future deliberate release of GMOs. 1

No investigation carried out to determine animals at site. 1

No impact assessment on the impact of GMOs on the livelihood of family farming. 1

Need for areas of scientific interest such as nature designated sites under the Habitats and Birds Directive to be designated as GM free zones 1

Response:

I am of the opinion that it is essential that independent studies on potential environmental effects (both short and long term) be carried out under Irish soil and climatic conditions on genetically modified crops prior to the commercial growing of such GM crops in Ireland under Part C product application under Directive 2001/18/EC. This independent research is necessary in order to reassure the public, since they are likely to continue to

be sceptical of assurances given by bodies perceived to have an association with the proponents of GM technology. Notwithstanding any independent research undertaken at EU level, the specific climatic, geological and geographical position of Ireland underpins the need for such research to be carried out. For this reason it is my opinion that an independent monitoring programme be commissioned for such field trials which should be funded by the State (this is what is happening in other EU Member States (Spain, France, Germany, UK and others). The results of these studies should be made public and be published in peer reviewed journals.

G. Containment

Electric fencing provides no protection against activities of rats or crows, the two most common species carrying out the transport of potato tubers under Irish growing conditions. Potatoes can regenerate form very small pieces of potato, because of their food value rodents have been found to move/store potatoes at distances of over 100m from their point of origin. Further dissemination of seeds or pollen by wildlife, pollinating insects. 8

Nature cannot be controlled and BASF cannot definitively say that there will be no outcrossing. Outcrossing will occur. If licence is granted and the experiment deemed 'successful' the inevitable result would be larger areas of land being planted. So GM crop cultivation will lead to the widespread contamination of large areas of non-GM crops and land. 5

Tubers may be left in the ground and sprout anew the following season. 3

These GM potatoes/ seed will find their way into the animal food chain of our wildlife. 2

Measures to prevent unintended release as a result of vandalism are inadequate. 2

Transfer via pollen to other species or wild relatives at or near site described as 'very unlikely' - too weak to warrant consent. 1

Conclusion of too many of the impact assessments by BASF is that " overall impact is negligible" when dealing with human or environmental health negligible is not sufficient, only non-existent should be accepted. 1

Genes modified by 'splicing' in pieces of DNA from other organisms, the possibility of unforeseen combination or mutation must be borne in mind. In particular DNA of bacterial origin may carry a risk of recombining with other germs. 1

Contamination of non-GM crops by GM pollen would not be possible to detect until after non-GM potatoes had been harvested and put on the market as the contamination would not show up until the harvested seed had been grown as a new plant. 1

Possibility of horizontal gene flow is unknown, would imply that we should not be taking unnecessary risks. 1

Concern at the use of Cauliflower Mosaic virus as a promoter region in GE crops. It is conceivable that future genetic mutations would allow this promoter region to become attached to other genes changing the nature of whatever plant was so affected. 1

Widespread rejection by food brands, retailers and consumers. 7

No benefit to consumer. 4

Violation consumers right to choose safe GM free food. 3

Consumers have little control over what is put in food chain via restaurants and catering industry. Labelling has a limited role to play as there can be hidden GM ingredients below the threshold of mandatory labelling. 2

GM Potato will not reseed, will give a continuous monopoly to the supplier of potatoes and leaves the consumer in a very vulnerable position. 2

All food sources should be traceable to its source of production; if food is not labelled there is no traceability and therefore no responsibility on the multi-national , if there is an adverse medical effect on the consumer. 1

According to Irish Independent survey on 13th February 2006, a majority of Irish consumers would not buy GM products even if they offered specific health benefits l

Risk Assessments of the impact of this particular BASF experiment on non-target organisms seem to be based on an assumption of safety and do not provide for an adequate monitoring scheme. 5

Low level of monitoring proposed for the site. 1

On site monitoring will destroy volunteers on that site, but if pollen or seed is carried any considerable distance volunteers could be mixed with other conventional crops and not identified/ monitored .1

No length given for volunteer monitoring programme. 1

Section entitled Information on 'Control Monitoring Post Release and Waste Treatment Plans' fails to outline day-to-day measures that will be taken to ensure that cross-contamination of Irish Potatoes will not occur. 1

Post release treatment of the test site does not seem adequately monitored nor will it achieve a clean post harvest site. Requirement for post release monitoring to be carried out by an independent body 5

Response:
I am in agreement that an electric fence to control ingress by animals as stated in the notification is not adequate. The notifier will be required to erect a strong fence to ensure that neither large nor small animals gain access to the experimental site.

The risk management measures as outlined in the consent condition No 5 will minimise risks to human health and the environment from this field trial release with GM potatoes.

It should be noted that the post planting monitoring programme as outlined in the notification and in particular in the notifier's responses to the Agency's requests for additional information will be independently audited by the Agency.

H. Harvest

Conventional harvest methods will be used, therefore high level of tubers will be left in ground. These will not appear as volunteers until following spring but can be accessed by birds/rodents throughout winter. Unless commercial potato crop in vicinity has been harvested beforehand there is a risk that transgenic tubers can be moved by birds/rodents to commercial crop and mixed there. How is ground to be examined in sufficient detail to identify these tubers? 2

Seed spillages and failure to clean combine harvesters are likely to be a significant source of GM contamination.1

Will contaminate an area around the plantation for 26 kilometers. 1

Monitoring security and hygiene measures following harvest . 1

Closed containment used for transport, suggestion that it should be sealed.1

Response:

A condition of the consent requires a post-release monitoring strategy to ensure eradication of groundkeepers and True Potato seed (TPS). Refer to condition No 5.

Measures will also be used to ensure containment and storage of the tubers prior to planting and after harvest. Refer to condition No 5.

I. Notification

The handling, release controls and disposal of *P.infestans* innocula and infected plants was alluded to but not described in detail, unsatisfactory. 4

The risk assessment with respect to potential harmful impacts on non-target organisms and the environment and with respect to survivability and dissemination is flawed because it is based on vague or unknown facts and untested assumptions. This is acknowledged in the notification. (D10, F1, D7.) Potential negative impacts are downplayed and data are intended to be collected when they become more or less accidentally apparent during 4 weekly visits alongside the main purpose of the release. 3

Control of GM seeds and tuber escape from the site was not adequately described. 3

Silently suggested that these GM potatoes are safe because the inherited resistance genes come from a plant of the same family. That this does not mean harmless is evident from fact that recently harmful effects were detected in a (CSIRO project) GM pea that received a gene from a near relative, the bean. It was the case that these effects could only be determined because it was known that *to make the peas insect resistant the introduced bean protein had to go through a pathway in cells where it would undergo several processing steps including glycosylation.* Not told if GM potatoes were tested for such or similar potential effects in a similar way. Processes might be possible that are not as well understood as glycosylation. 2

Location of the site has been kept confidential which is unacceptable. Public cannot confirm details such as precise location and size of site, nature of the release site ecosystem including microclimate and flora. It does not enable public make informed comment on the proposed release of GMOs in the area, or conduct independent monitoring of the effects of this GMO release on lands in the vicinity of the site 2

RA poor. Not a sufficient assessment of the potential risks to this environment. Would have liked to have seen what effects were observed as compared with conventional varieties in the field trials in other countries (sect 13) 2

Concern about high number of lines to be released – suggests very little in the way of green house trials has been carried out since in conventional breeding a great deal of selection would be carried out before field trials. Suggests haste and commercial pressure are driving forces 2

Applicant did not consider the potential impact of possibility of GMO variety becoming mixed up with seed potatoes (i.e. tubers for planting) .2

Information provided by notifier with respect to temperatures affecting survivability is vague / wrong (doesn't mention if temperatures mentioned are below or above ground. Well known that under Irish conditions where no heavy or long frost periods potato tubers survive well underground.) 1

The information provided on preparing, managing site, prior to during and post release including cultivation practices and harvesting and precautions taken is vague. 1

Potatoes originated in the region where *S.bulbocastanum* is native and where there is a great variety of potato lines. *S.tuberosum* and *S.bulbocastanum* never crossed naturally or if so have not survived, leads to hypothesis that reasons for this could be that there is no potential benefit or that there would be negative effects to such plants themselves which should be scientifically researched and evaluated. 1

Somatic hybrids of *S. bulbocastanum* have to date shown a certain level of instability. While it is not a natural parent of *P.infestans* strains, it is possible that some of this instability may be carried in the transplanted genetic material. 1

No scientific explanation or proof that genetic modification has resulted in resistance to late blight or if the GM potatoes would be resistant to all strains , no scientific explanation as to why this should be the case and whether this was proven by previous testing . In this respect it would be necessary to know all the strains existing in Ireland. no such information provided. 1

Could GM potatoes cause the development of new strains of *P.infestans* with potential resistance to GM potatoes' new mechanism and to other treatments. Some strains affect both potatoes and tomatoes. Also not informed of strain which would be used for potential inoculation 1

Notifier did not submit report from previous trials which would be relevant.1

Part C incomprehensible to ordinary citizen, does not serve to fully inform i.e a full introduction and full comprehensible description of the process specific to the GMO has to be included in the notification. 1

Keeping name of farmer confidential infringes upon EU law which requires that neighbouring farmers be informed of the deliberate release. If address is concealed owing to perceived danger of sabotage this is matter for the Gardai rather than commercial confidentiality. 1

Trial managers name has been kept confidential which is unacceptable, cannot be established by public that he/she is appropriately qualified. 1

The statement that "no potatoes will be cultivated in close vicinity to the trial" cannot be verified given that location of release site is confidential. l

Notification in January for planting in April/May does not allow sufficient time for requisite appeals process to be carried through. 1

Lack of detail provided on post harvest storage and post harvest transport both of which are deemed to be secure. 1

Concern that Imidazolinone tolerance may be intended to force a change in regulations to permit this herbicide in Ireland perhaps using WTO as was recently done in case of EU reluctance to permit GMOs. 1

Adapting the technology involving Imidazolinon and tolerant varieties is unnecessary in the climatic and agricultural conditions of Ireland. Imidazolin-

tolerant varieties /hybrids of maize sunflower and soybean require post-emergent treatment with the herbicide. Normally, a systemic, non-selective product would be used as a pre-emergent, like Roundup. It may have a function in cultures that are not particularly effective in suppressing weeds but in the case of potato, especially in Ireland, there is no real need for a post emergent treatment. 1

Mechanism of localised cell death is combined with a systemic response which induces expression of defence related genes in remote parts of plants - no detail on those defence related genes. 1

Pre-harvest chemical defoliation. This will leave plant material lying on soil surface for digestion by soil organisms. Notification suggests that this material provides no hazard for soil life and there is no risk of take up of transgenic material which is expressed throughout the plant. Citations given very old and ignore more recent evidence to the contrary. Altho' take up is low, it is not non-existent. 1

Overall measures to be taken to avoid contamination appear to be entirely dependent on the goodwill of BASF. 1

Lack of detail regarding the specific genes being transferred into the potato, their intended purpose and the perceived merit in providing resistance to banned herbicides. 1

Request that further information requested from notifier by EPA be made available to public for comment. 1

The technology has the potential to bring major benefits to potato farmers combined with significant reduction in pesticide applications. 1

Crops produced through plant biotechnology have been grown commercially for a decade with no adverse effects to human health or to the environment. 1

Comments relating to the procedure for advertisement of the notification for consent to a deliberate release.

Only public notification required was to publish in one national newspaper, on one day. To say that if people are interested they will discover it is not fair comment. While it was on EPA website and published in Irish Independent this is still insufficient provision of information for the public especially bearing in mind obligations contained in such provisions as those of the Aarhaus Convention and the general right of the public to access of information.

I am asking the EPA CEO and others with responsibility for this decision to explain why it was decided to give Irish people just 28 days to decide on a crucial and fundamental issue. Is it any wonder there is cynicism as to whether it would really make any difference what submissions are made to the EPA or how many people voice objections?

Response:

Further information received from BASF revealed that *P. infestans* inoculation would not be carried out rather natural inoculum from the soil will be relied upon.

I am satisfied that the risks to human health and the environment are low and that measures outlined in the consent conditions will ensure that this is achieved.

The *ahas* gene is a herbicide tolerant marker gene and is present for purposes of plant material during selection in tissue culture. It does not confer herbicide tolerance to plants that were grown in the greenhouse. In any case the herbicide has not been approved for use in Ireland and thus cannot be used in Irish Agriculture.

I am satisfied that the field trial manger is a competent person and has the appropriate experience to manage these field trials.

I suggest that a lot of the concerns raised here have been answered by the notifier in response to requests for further information from the Agency. All of this information has been put on the Agency's web page to ensure openness and transparency.

The newspaper advertisement is in compliance with the GMO regulations. In accordance with the legislation the public had 28 days to make representations. Again this aspect is outside the EPA control as it is prescribed in national legislation. The Agency role as the Competent Authority is to implement the regulations.

12. Consultations by the Agency-Views of Reviewers

The notification was circulated to and reviewed by the Government Departments, Organisations and Advisory Committee listed in Table No. 1. A copy of the reports received from these reviewers are attached as Appendix 2. Please note that the Minute of the most recent meeting of Advisory Committee on GMOs has been circulated to the committee and will be finalised at the next meeting.

Table No. 1-Consultations by the Agency

Government Department or other institution	Recommendation
Dept. of Agric. Food	The Department of Agriculture and Food is the Certifying Authority in respect of the European Communities Seed Potato Regulations. As such the Department is responsible in ensuring that seed which is certified has a varietal purity varying between 99.9% for the lowest grade (Class H) to 100% for the highest grade (Pre basic) seed potatoes produced in Ireland. In this context and also given the concerns among consumers and in the potato industry generally in relation to this proposed trial the Department would be concerned about the possibility of adventitious cross contamination of contiguous certified seed and ware potato crops. If approval for the proposed trial is to be granted it would be essential that all necessary steps are taken to prevent gene transfer and carry-over from the GM potato trial to neighbouring non-GM potato crops. All risk areas and issues would need to be specifically addressed in the conditions attaching to any authorisation granted to BASF for the conduct of the GM potato trial. Comprehensive field trial and crop handling protocols and control arrangements covering all risk areas and issues would need to be agreed and fully implemented.

	They mentioned the following aspects be considered by the Agency: ➢ Sources of Admixture-ensure the GM tubers are not mixed with non-GM commercial potatoes ➢ Crop separation ➢ Ground-keepers (volunteer potatoes) ➢ Transport of tubers of-site post harvest ➢ Cleaning of machinery and equipment ➢ Storage ➢ Crop rotation post-trialling period ➢ Monitoring ➢ That contiguous neighbouring farmers should be informed in writing of the location of the trial site
Dept. of the Environment & Local Government	Indicated that there are certain constraints on the Department in responding to your letter given the Agency's role as Irish competent authority for the purposes of Directive 2001/18/EC, as confirmed by the Genetically Modified Organisms (Deliberate Release) Regulations 2003, and the nature of the relationship between the Agency and this Department under the Environmental Protection Agency Acts 1992 and 2003. They stated that the distance between the nearest Special Area of Conservation (the River Boyne SAC) and the site of the proposed release is approximately 7 km.
Teagasc	They raised a number of issues including the following: ➢ That a 40 m border be used ➢ Post-release monitoring plan be implemented ➢ Specific rotation measures ➢ Intrusion of birds could be a concern ➢ The fact that no animal feeding studies have been submitted that an Identity Preservation System to verify the absence of admixture with non-GM potato that may be harvested from adjacent fields be provided by the notifer In conclusion they stated: the risk posed to human and/or animal health is negligible based on the assumption that there will be no admixture events with conventional potato systems. However, it is strongly recommended that additional information (e.g. details of adjacent conventional potato systems, identity preservation system) be provided by the Notifier to underpin this eventuality. Based on the information provided (and the biology of potato) it is anticipated that the GM potato lines will pose no greater risk to the environment that experienced through the cultivation of conventional potato.
GMO Sub Committee under the FSAI	➢ There were no concerns raised with respect to the spectinomycin resistance gene, and the evidence demonstrates that it is not present in the plant lines proposed for trialling. ➢ There were no significant concerns raised with regard to risks to human health from the proposed field trial. If these potato lines are to be used in food or feed production in the future however, there are a number of technical issues that may need to be clarified and possibly further information requested. The GM potatoes contain added genetic material from plants or bacteria that are already present in the environment and though this does not guarantee absolute safety, the sub-Committee has not identified any specific human health implications. Based on the information provided by the company about the proposed field trial conditions, the genetic modification of the potato lines, the volunteer management programme and the general nature of the potato and its reproductive traits, the proposed field trial should not pose a significant risk to human health.
Advisory Committee on GMOs	**Written submissions were received from eight (8) of the AC and the following comments were made** ➢ The assessment of risk has not been adequately assessed. Not even animal studies have been carried out. However, it would seem unlikely that genetic transfer would occur but unless this is adequately assess these will only be assumptions. This AC member concluded by stating: To use the analogy of a new drug going to market is would appear that this proposal is like the scale up or the production on a drug that has not yet been proven to work or proven to be safe. There seems to be a large omission of experiments that would be deemed to be essential to adequately assess the products safety. ➢ Another member made the following comments: The negative risks to the environment would appear very low. The 20m separation distance should be sufficient as pollen wind dispersal distances of between 5-10 meters have only been recorded. This distance is in keeping with the draft Coexistence Measures. Crossing into weeds is not an issue with Potatoes. A number of issues were raised by this member including human health safety aspects of the GM product. *There is very little to suggest that the notifier will following through on environmental or health impact assessments except to say that "necessary data will be collected". As the detail on observations, data gathering and the nature and extent of records that will be kept are very limited. It would help if the extent of these other aims were more fully elucidated.* The following points were made by a member on behalf of the five NGO's who nominated the member to the

AC. I propose that approval should **not** be given for the proposed release of GM potatoes into the environment.

- There is no need for GM potatoes for blight resistance in Ireland. There are many strains of potatoes in Chile that are naturally blight resistant and could be used, instead of reducing the number and variation of potato strains used commercially by making them GM. Much of the cost of growing potatoes is in seed costs. This will be even greater if GM seeds are patented by their creators.
- The successful growth of these GM potatoes will benefit the chemical/biotechnological industry. There is no evidence that they will benefit consumers at all. No human health trials have been carried out on these potatoes, which presumably are being tested for use as a food crop. Surely this should be tested first before releasing them for field trials?
- Approval of this release opens the door to other GM trials in Ireland, which may have an even greater impact on our environment. There has been no decision taken about our GM status as an island. Our GM free status is treasured by Bord Bia, by Tourism Ireland and by the Irish Cattle and Sheep Farmers Association. A decision to change this status should not come about by giving approval to field trials for GM potatoes in a secret location in Co Meath.

- A committee member suggested that prior to field trialling it would appear prudent to conduct toxicity, anti-nutritional or allergenicity tests on animal and ultimately human subjects and requested that further information be obtained from the notifer including studies on animal and human toxicity, anti-nutritional and allergenicty.

Another member concluded:

- I do not envisage any risk to the environment or the health of humans or animals as a result of the proposed field trial with GM potatoes resistant to late blight.
- However, there are some weaknesses in the data given. For example, is the potato donor of the R-genes (*S. bulbocastanum*) a table potato consumed in some country or is it a wild potato species not consumed by any humans or animals
- A simple bioinformatic database search would have been useful to determine any possible toxicity or allergenicity features of the R-genes instead of just referring to their presence in many plants with no evidence of detrimental effects.

This member made a number of points against the notification, herewith find a few of these pertinent points:

- I was pleased to see that the EPA asked all the technical question about the BASF notification that I had wanted to ask myself, and added several points for good measure.
  However, their answers do not seem to me to be entirely satisfactory.
- There seems to be an attitude that because the trial is small scale it does not matter that impacts on human or animal health have not yet been studied. A great deal of work that one would have expected to be carried out at the contained growing stage appears to have been left for the field trials. Further, it seems that BASF are more interested in the impact of the environment on their potatoes than in the impact of their potatoes on the environment, if the information supplied on the studies they intend to do is an accurate representation of their position.
- Protein sequence comparisons for allergenicity look very close to levels at which allergenicity was found in the notorious Australian pea/bean situation
- Overall I find myself unconvinced that proper study design has gone into this. I rather get the feeling that someone has looked for a country where there are lots of blight spores floating about and decided to test there potatoes here because there is a really good chance of infection without actually examining either the growing conditions in Ireland or the possible impact that a mistake in such a trial could have on the Irish economy - I know the latter point is outside the EPA remit but it is nonetheless important to the potato farmers of Ireland. Equally I recognise how valuable blight resistance could be not only in terms of lowering crop spraying and therefore cost but also in terms of benefits to the health of the person doing the crop spraying, those harvesting the crop and those eating the potatoes.
- Another issue of importance which does not come under the EPA remit is that the requirement that a notification be published in a newspaper circulating in the area where the release is to take place means that it is easy for stakeholders to miss the announcement - as they did in this case in which it appears that almost all subsequent activity, not only from GM free Ireland et al. but from the IFA and others stems from the information sent to me by the EPA. I have been unable to trace any organisation or individual who has made a submission on this topic who was not notified by one or another member of the GMOAC. Had the notification been placed in the Meath Chronicle, as the local newspaper, rather than in the Independent, I suspect that the campaign would have been louder and more energetic. There really needs to be a change in the SI to make it easier for stakeholders to find out what is happening. Although I hope that many of these organisations will now realise that they need to monitor the EPA website.

A member suggested further information be requested on the management and post market monitoring of the trial while another Committee member had no comments to make.

Meeting of the GMO AC:

The notification was discussed at length at the 31st Meeting of the Advisory Committee on Genetically Modified Organisms which was held on 23rd March 2006 at EPA Headquarters and the following conclusion was reached:

All members present were satisfied that the proposed trial be granted with stringent conditions to ensure that admixture with conventional potatoes would not occur. One member had reservations regarding the need for an animal feeding trial prior to granting consent but added the caveat that if the contents of the trial would be for human consumption then

	such a trial would be required.
EU Commission	**No observations were made by any Member State.**
Department of Health and Children	They send the following response: This Department has consulted the Food Safety Authority of Ireland in regard to this proposed GM potato field trial. On foot of the advice received, we are confining our comments to the health risks to humans and specifically in respect of toxicity and allergenicity. The FSAI has informed this Department that genes transferred to the GM potato lines are from plants or bacteria already present in the environment, and the plants and associated tubers are not destined for human consumption so there is little risk of exposure to the public once the conditions of the field trial and subsequent volunteer management are adhered to. However, recent Australian research has demonstrated that a harmless protein found in beans became allergenic when transferred to peas. In this respect, the field trial application is considered deficient in allergenicity information in that the non-allergenic status of the LRR genes is presumed only on the basis of similarity to closely related genes. It is recognised, however, that even if there was an allergenic threat, the risk to humans is minimal since potatoes largely self pollinate and any pollination is predominantly by bees with wind playing little part if any part. The FSAI did not consider that there was a significant risk to the public from the proposed field trial but that further allergenic and toxicological data may be required on some of the transgenes should public consumption be considered. This Department's policy is to take a positive but precautionary approach in respect of advances in biotechnology. Consequently this Department raises no objection to the field trials. We do however request that the concerns raised by the FSAI be taken into account should an application be made to grow this crop for public consumption.
HSA	The Health and Safety Authority stated that they do not have sufficient expertise in the area of genetically modified organisms in order to carry out a detailed review of the risk assessment submitted in support of the notification. With regard to worker health and safety which is the primary role of the Health and Safety Authority they made a number of observations in particular: ➢ In the absence of any knowledge of the toxic or allergenic effects of these genes on human health stringent measures should be taken to minimize contact to humans.
State Laboratory	The Agency have discussed the method for the detection of the GM potatoes in detail with the State Lab (SL) who in turn are advising the Agency on this aspect. The notifier recently provided such a detection method in response to a request for further information from the Agency and it has been passed onto the SL for their review. This aspect is covered under Condition No 7.

13. **Conclusions of the Office of Licensing and Guidance under article 18 (1) (h) of the GMO (Deliberate Release) Regulations 2003, S.I. No. 500 of 2003**

1. After examining the information supplied in the notification and the further information that was received from the notifier, requested by the Agency, under article 19 (1) of the above regulations, I conclude that this notification is in compliance with article 18 (1)(C) of the aforementioned regulations.

2. The Agency expert reviewers agree that the risk to the environment and to human health from the release of these GM potato plants is low provided that certain risk management measures are implemented as outlined in the notification and in particular, information that is in the responses received from the notifier to questions raised by the Agency. I am in agreement with the expert advice in this regard and am confident that the measures as outlined in the consent conditions will ensure that the risk to human health and the environment is low from

the deliberate release of these GM potatoes at the experimental release site.

3. In my opinion it would be useful if Ireland gained experience from part B releases under Irish conditions, as it is likely that this product might be placed on the market under Part C of Directive 2001/18/EC in the future regardless of whether a field trial has been carried out in Ireland. By carrying out a small scale release it would give some information on how this GM crop would perform under Irish soil conditions.

4. In my opinion, it would be unreasonable to request the company to fund independent type studies that might be carried out by the Agency on this field trial. I am of the opinion that this aspect is not covered under the 'spirit' of the GMO regulations or Directive 2001/18/EC. I am not aware that other EU Member State's Competent Authorities request funding for such studies.

However, I have included a programme of post release monitoring to be drawn up by the licensee (to be funded by the licensee) in addition to their monitoring plan that is outlined in the notification and the further information that was submitted to the Agency. This programme of environmental monitoring has to be agreed with the Agency as per condition 9.

5. One issue that was raised by a number of the GMO AC members in their written responses and also made by a number of the public who made representations was the lack of animal feeding studies for this proposed deliberate release.

This issue was raised as recent research carried out by Australia scientists, showed that a native protein produced in the common bean plant was found to have allergenic properties when transferred to pea plants in animal (mouse) studies. This investigation demonstrated that transgenetic expression of non-native proteins in plants may lead to the synthesis of structural variants with altered immunogenecity.

The authors suggested that alteration in the post-translational modification of the protein in the pea plant could have lead to discrete changes in the molecular architecture of the expressed protein and this might explain subsequent cellular function and antigenicity.

The GMO AC noted the importance of this research findings but the majority agreed that animal feeding studies are not a requirement for Part B releases but clearly a Part C-requirement for the placing on the market of products containing or consisting of GMOs. They also advised that the feeding studies can be carried out in parallel with the field trials. I am in agreement with this advice.

I understand that other EU member State Competent Authorities (Germany, Netherlands, Sweden and the UK) do not require that animal studies for Part B releases (person.comm.)

It should also be noted that similar trials with some of the inserted genes have been field trialed in Sweden and in several other countries with both GM potatoes and non-GM potatoes (R genes inserted using traditional breeding techniques) and no reported adverse effects have been reported to human health or the environment from any of these field trials.

Nevertheless the notifier has informed the Agency that they plan under Phase (B) of the five (5) year trial to study among other things: **altered qualitative properties** (e.g. tuber composition, nutrients, anti-nutrients, **feeding studies**). This study is planned to take place in year 3-5 year of the trials. However, to allay any fears regarding this concern, I suggest that this study be carried out using tubers from the first year's harvest at the Co. Meath site. The animal feeding studies must be completed and the results must be sent to the Agency after completion. This aspect is covered under Condition No 5 (xiv). It should be noted that if anything untoward is found during the animal feeding studies this aspect will be dealt with under consent condition No. 3.

Finally, I am also of the opinion that it is desirable that independent studies (to be funded by the State) regarding potential risks be carried out under Irish soil and climatic conditions regarding genetically modified crops prior to the commercial growing of GM crops in Ireland under Part C product application under Directive 2001/18/EC. This independent research is necessary, in my view, to reassure the public, since they are likely to continue to be sceptical of assurances given by bodies perceived to have an association with the proponents of GM technology. Notwithstanding any independent research undertaken at EU level, the specific climatic, geological and geographical position of Ireland underpins the need for such research to be carried out. This was one of the recommendations of the Chairing panel's report regarding the National Consultation Debate on GMO's (set up by the Minister for the DELHG) and the environment which was published in 1999.

I wish to point out that a number of EU Member States (MS) are funding biosafety studies pertaining to GM crops over the last ten (10) years. Consequently, these MS have gained experience regarding potential risks pertaining to the cultivation of GM crops. Spain are also carrying out studies to ascertain whether co-existence measures are appropriate to ensure that GM, conventional and organic crop production can co-exist.

It is my opinion that pertinent information would be gained from biosafety studies regarding GM crops if they were carried out under Irish climatic conditions to ascertain whether or not GM crops might pose a

positive/negative effect on biodiversity. This information would be of paramount importance in the decision making process to this MS if such GM products were to be placed on the market under part C dossiers in the future, in particular, the possible position that this MS might take towards such products when voting under the comitology procedure in accordance with Directive 2001/18/EC.

14. **Charges**

The company shall pay the EPA a contribution of €55,506.00 per year (2006-2010) and a total of €3,600.00 per year for the years 2011-2014 towards the cost of site inspections, monitoring and auditing these field trials as per Condition 10. Any costs incurred by the Agency for the detection of the GM potatoes taken from the trial site will be charged to the licensee.

15. **Recommendation**

1. I have considered all the documentation submitted in relation to this notification including all of the representations made by the public and having regard to the expert opinion that the Agency received on the notification. I recommend that the Agency grant a licence subject to the conditions set out in the attached 'draft' Consent Conditions and for the reasons as drafted in accordance with article 18 (5) GMO (Deliberate Release) Regulations 2003, S.I. No. 500 of 2003 and article 6 of Directive 2001/18/EC having regard to articles 18 (2) 18 (3) and 18 (4) of the forementioned regulations.

2. That any field trial protocols, monitoring studies etc that must be agreed in advance by the Agency be approved by Director of OLG. .

Signed

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Inspectors name

I recommend that a consent be given for these trials subject to the conditions set out below: