RESPONSE TO CONSULTATION:

APPLICATION FOR A PART B CONSENT FROM BASF PLANT SCIENCE TO RELEASE GENETICALLY MODIFIED POTATOES WITH IMPROVED RESISTANCE TO Phytophthora Infestans

APPLICATION REFERENCE: 06/R42/01

Dear all,

It is very interesting to note what conditions the Irish Environmental Protection Agency (EPA) felt necessary to impose in order to protect the environment and the Irish potato industry, and what ACRE have said (minutes from 28th September meeting).

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

ACRE: The applicant proposed to monitor volunteer potatoes at release sites until none had been found for two years. ACRE was content with this proposal and advised that BASF should provide details of groundkeeper and volunteer presence in annually submitted post-release monitoring reports.

EPA: Condition 5 Management of the Field Trial

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

a. site plan,

b. methods of planting, harvesting and trial termination,

c. relocation (within the designated field) in years 2-5,

d. methods to minimise seed dispersal from the experimental site,

e. storage (before planting and post harvest),

f. monitoring plan for the duration of the trials

g. monitoring for groundkeepers and True Potato Seed (TPS),

h. transportation off-site,

i. site security and

j. emergency plans.

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

ACRE: do not as yet seem to demand this level of information.

EPA:

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

ACRE: do not as yet seem to demand this level of oversight or safety.

EPA:

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

ACRE: do not as yet seem to demand this level of safety.

EPA:

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

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

ACRE:

ACRE concluded that once the GM potatoes had been harvested on each trial site, the ground should be left fallow to encourage the germination of true potato seed. This strategy also enables the identification and early treatment of potato groundkeepers and volunteers by hand pulling before viable tubers have set or by herbicide treatment with a systemic herbicide.

The committee also advised that the land should not be ploughed after the potato trial

harvest but that shallow tillage should be used on the release site for the next 2 years. The company proposes to chop or heat-treat the potato tubers following harvest and removal to an off-site location and ACRE was content with this proposal. The company also plans to leave parts of the potato plants other than tubers on the soil surface at each site to decompose. ACRE was content with this proposal if the fallow cropping and herbicide regime proposed by the committee is followed.

EPA:

(vi) All GM potatoes must be stored both prior to planting and after harvest in a secure place separate from any non-GM commercial potatoes. An accurate detailed record must be maintained at the storage location of all containers, used for the storage of harvested tubers from the experimental site.

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

ACRE: do not as yet seem to require this level of oversight and information.

EPA:

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

ACRE: do not as yet seem to require this level of safety.

EPA:

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

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

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

submitted to the Agency on 22nd March 2006, must be implemented.

ACRE:

The applicant proposed to monitor volunteer potatoes at release sites until none had been found for two years. ACRE was content with this proposal and advised that BASF should provide details of groundkeeper and volunteer presence in annually submitted post-release monitoring reports.

EPA:

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

ACRE:

BASF has proposed a separation distance of 20 metres and ACRE considers that this distance is sufficient to ensure that potatoes containing GM events have an extremely low probability of entering the food chain.

EPA:

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

ACRE: do not as yet seem to demand this level of safety.

EPA:

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

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

ACRE: do not as yet seem to demand this level of safety.

EPA:

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

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

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

ACRE: concluded that fencing of the trial site for this purpose should not be required.

EPA: Condition 6 Reporting to the Agency

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

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

A report on the monitoring activities outlined in the notification, trial results and the notifier's conclusions must be submitted to the Agency on a monthly basis during the growing season for 2006, 2007, 2008, 2009, 2010 up to and including 2014 (post release monitoring) and summarised in an annual report by 31st December - Page 8 of 10 - of each calendar year. For the 2nd, 3rd and 4th year monitoring programme on sites that were planted with GM potatoes, a report must be sent in the spring, summer and autumn of each year.

ACRE: as yet do not seem to require this level of information.

EPA: Condition 7 Provide Detection method for identification of the GM potatoes

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

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

ACRE: do not as yet seem to demand this level of information.

EPA: Condition 8 Sampling the trial site.

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

ACRE: do not as yet seem to demand these powers or any costs recovered from BASF.

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

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

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

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

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

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

ACRE: do not as yet seem to demand this level of monitoring, information or safety.

ACRE: do not as yet seem to demand associated costs to be recovered from BASF.

EPA: Condition10 Charges for carrying out site inspections, auditing & monitoring

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

ACRE: do not seem to require BASF to cover these costs.

Seems it is subjective after all!

Yours sincerely,

Anthony Jackson
on behalf of Munlochy GM Vigil

http://www.munlochygmvigil.org.uk

8th October 2006