



Environmental Protection Agency
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Dr. Ewen Mullins
Teagasc
Oak Park
Co Carlow

4 April 2012

Request for further information under Article 19 (1) of S. I. No. 500 of 2003 with regard to notification for consent to release GMOs into the environment for purposes other than placing on the market (GMO Register G0469-01, Reference B/IE/12/01) – 2nd request

Dear Dr Mullins

I refer to the above mentioned notification, and request the following information which is required to assist the Agency in their review of the application.

1. According to the notification, two sites will be sown in each of 2013, 2014 and 2015 yet the trial is not scheduled to end until 31/12/2016. What activities will take place on the sites between harvest 2015 and 31/12/2016?
2. Page 10/11 refers to 2005/2010 pollen mediated gene flow studies during which the presence of berries indicated the occurrence of successful pollen mediated gene flow. Data is also given regarding the % berries containing seed and the % seed capable of germination under controlled greenhouse conditions. What is the significance of this data, in particular, what might occur in the field situation as opposed to a controlled greenhouse?
3. In addition, in relation to the aforementioned 2005 study it is stated in the application that 2.8% berries contained seed. In the 2010 study, rather than providing a percentage it is stated that 1,765 seeds were collected from berries (of which 69% were capable of germination). What percentage of berries contained seed?
4. Please provide an explanation of figure 2 on Page 13. In particular what do the values on the Y axis represent?
5. Page 24/Section G. proposes methods for the destruction of the GM potato namely “..validated steam sterilisation or burial in a designated pit (~6 feet in depth) for larger volumes”.



- Where will the proposed steam sterilisation be performed?
 - Provide details of time, temperature and pressure applied and how the heat inactivated tubers will be disposed of.
 - Is burial to a depth of 6 feet a recognised standard methodology for the disposal of such tubers?
6. Page 25/Section G.3 states "*No tuber material will be supplied to animals for feed purposes during the course of the study*"; then on Page 26/Section G.4 it is stated that "*...a separate Teagasc project will conduct feeding studies on the GM potatoes....*" and then further on "*the results of the feeding studies will be forwarded to the EPA....*" Please clarify whether feeding trials will take place. In the event that such trials are being proposed, what will be the main aims/objectives and what quantity of tubers would be needed for such a study?
 7. Page 26/Section G.4 states that the volunteer monitoring and management programme "*will be repeated each year for 4 years after the initial GM plantings*". If initial plantings take place in 2012, monitoring will only take place up to and including 2016. Page 27/Section H1 states that the "*eradication of groundkeepers and volunteers post-harvest is carefully monitored for up to 4 years after the experimentation is completed*". Please clarify when the volunteer monitoring and management programme is proposed to commence and conclude. In addition, please provide further detail on the proposed monitoring,
 8. Please comment on the potential risk of the GM potato pollen contaminating locally produced honey to be sold commercially.
 9. What is the distance between the proposed location of the GM potato field trial and the location of :
 - Teagasc's non-GM potato breeding programme within Oak Park;
 - the nearest potato producer in the surrounding district;
 - Teagasc's bee hives within Oak Park;
 - the nearest honey producer in the surrounding district?
 10. Page 28/Section H.4 states "*As conventional fungicide programmes impact significantly on a range of non-target organisms, ...*" Please provide information/data to substantiate this statement.
 11. Please provide molecular data (gel data) supporting the data given in Table 1 and Figure 4 on pages 16 and 17 of the application, respectively.
 12. Please comment on the potential risk arising from intrusion of animals and birds into the proposed GM potato trial site. Provide details of animal-proof fencing to be employed.
 13. Please provide details of the cropping history of the proposed GM potato trial site. In addition, provide more detail on the proposed experimental design.

14. Please submit an amended notification taking account of Articles 14 (2)(c) and (d) of the GMO (Deliberate Release) Regulations, S.I. No 500 of 2003, as follows:

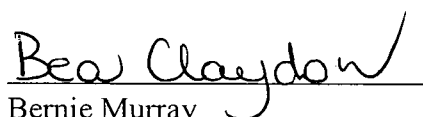
Section H of the notification is entitled 'Risk Assessment'. This section would be more appropriately entitled 'Conclusions' since the headings correspond with those set out under Section D2 of the Second Schedule of the GMO (Deliberate Release) Regulations S.I. No 500 of 2003.

Similarly the table on pages 31 – 33 inclusive would be more appropriately entitled 'Risk Assessment' (RA) since it corresponds with the RA methodology described in Commission Decision 2002/623/EC establishing guidance notes supplementing Annex II to Directive 2001/18/EC on the deliberate release into the environment of GMOs.

Section D.13 of the notification (Page 20) should also be amended to clarify the Netherlands notification under which GM potato line A15-013 is being trialled.

In accordance with Article 8(1) of the GMO (Deliberate Release) Regulations, S.I. No 500 of 2003, *"a period of time during which the Agency is awaiting any further information on a notification, which it may have requested from the notifier, shall not be taken into account"*, i.e., the clock is stopped until such time as all the requested information is received by the Agency.

Yours sincerely



Bernie Murray

Inspector

Office of Climate, Licensing and Resource Use.