

Individual 1 Exercise

Background: Agricultural engineer.

Case Study: Amflora potato

Materials provided for the exercise: Doc 1-Roadmap pages 1-16, Doc2-Annex III Cartagena Protocol, Doc 3-Amflora SNIF provided by applicant. BCH information database link.

Comments:

Meaningful data: No raw data provided, all information has been provided in conclusions

Scientific quality: See above

Uncertainty: See above

Context and scope: Potato cultivation

Ecology, general potential receiving environment, use and duration provided by applicant.

Comparator: Isogenic potato variety Prevalent

Step1: Identification of any novel genotypic and phenotypic characteristics associated with the LMO that may have adverse effects...

What adverse effects, why and how:

The characterization of the LMO has been provided in the applicant document in summary (seems to be that there are annexes that have been not provided). From the document 3, the characterization is clear enough.

Even though, there is a list of potential adverse effects on the guidance (Doc 1) actually it is quite difficult to establish all the potential adverse effects, unless there is some expertise on Risk Assessment. On the other hand, providing a full detailed list of all possible adverse effects to be considered under all conditions and for all types of LMOs, it is a extremely complicated task.

The step 1 of the Guidance is a key step on the Risk assessment and if it is not well defined it could lead to a RA bad formulation and conclusions and it is not easy to determine the adverse effects unless several experts work together study the application.

In the exercise, the following adverse effects have been identified: Horizontal and vertical gene flow, stability, non target organisms and activities (pollinators, rizosphere, Microorganism, insects, etc), competitiveness, plant adaptation, feeding with by-products, animal toxicology, resistances, allerginity, cross pollination with compatible species etc

Step2

This step is well defined in the Guidance Doc 1 and the likelihood is easy to be established if the proper information is provided. In case of this information is not provided, it is needed to ask applicant for the information and it is necessary to know which tools and analysis need to be run in order to get the information desired and expertise again is necessary.

Step 3:

This step is well defined in the Guidance Doc 1 and the evaluation of the magnitude of the consequences is easy to be established if the proper information is provided. In case of this information is not provided, it is needed to ask applicant for the information and it is necessary to know which tools and analysis need to be run in order to get the information desired and expertise again is necessary. (example allergenicity studies are not discussed in Doc 3)

Step 4

No comments.

Step 5

To determine the best management strategies once identified and assess the risks requires good knowledge of the legal framework, expertise on the LMO ecology, etc. Also, a proper monitoring and surveillance plan is necessary as well as a reporting of the use of the LMO and the incidences found etc in order to improve the risk management and reassess the risks.

In the documentation provided, no management measures have been indicated although a surveillance plan is set up.

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