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BASF Plant Science

Application for the release into the environment of potato lines with improved resistance to *Phytophthora infestans*, 2011 and 2012

Public Dossier

A General information

Name and address of the notifier

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This field trial application is connected to the potato field trial application of the University Gent which is being submitted at the same time. These two applications refer to the same intended field trial including lines described in both applications.

The genetically modified potato lines are planned to be released from April to October in the years 2011 and 2012 with planting taking place earliest in April and latest in June and harvesting in September/October of each year.

B Purpose of the project

The aim of this project is to develop potatoes with improved resistance to *Phytophthora infestans*, the causal agent of potato late blight.

C Research framework and description of the GMO

Introduction to Potato Late Blight Disease

The origin of potatoes lies in two areas in South America, the high Andes from eastern Venezuela to northern Argentina and the lowlands of south-central Chile. The potato was first introduced in Europe in 1567 and spread from there worldwide. Nowadays potatoes are cultivated across Europe and are considered one of the most important crop plants globally.

The oomycete *Phytophthora infestans*, causing late blight in different crops, remains the most important pathogen in the majority of the potato producing regions of the world. It has a potential to devastate crops within few weeks if meteorological conditions are conducive for onset and spread of an epidemic. The western world became aware of *Phytophthora infestans* with the devastating late blight epidemics in the north-eastern United States and Europe in the 1840s. The Irish Potato Famine is a well-known result of these early epidemics.

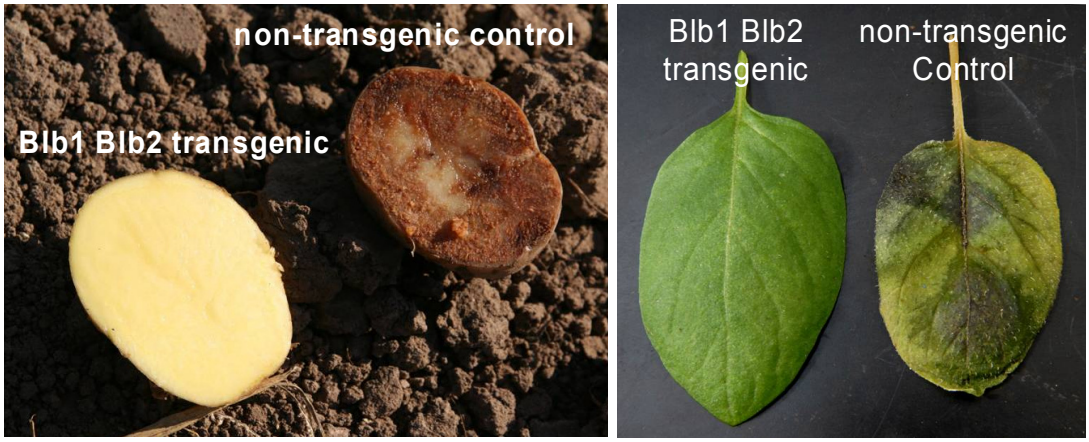

Figure 1: Genetically modified potato tuber and leaves inoculated with *Phytophthora infestans* in comparison to the parental conventional potato

Phytophthora infestans is one of ~70 Phytophthora species that are arguably the most devastating pathogens of dicotyledonous plants. Despite a fungus-like filamentous growth habit, they belong to the oomycetes and are closer related to brown algae than to fungi.

Disease management in developed countries is currently based on the very frequent application of fungicides. Frequent seasonal spraying with fungicides imposes high input costs to the farmer and imposes a pressure on the pathogen for developing resistance to the active ingredients of the crop protectants applied which could lead to high losses in the potato harvest.

Resistance Breeding

During the 20th century, breeding of new potato cultivars with high levels of resistance to *Phytophthora infestans* has been considered an alternative for the use of fungicides. Breeders have introgressed from the wild potato species *Solanum demissum* the dominant resistance genes R1, R2, R3, R4 and R10 into *Solanum tuberosum*. But within a few years several races of the pathogen were able to overcome the resistance mediated by these genes. These resistance genes mediate a resistance only against some isolates of *Phytophthora infestans*. The goal of potato breeding now is to identify additional resistance genes conferring broad-spectrum resistance to potato late blight and to introgress them in modern potato varieties.

A number of functional resistance genes from diverse wild potato species have recently been cloned. Unfortunately, classic transfer of resistance from most wild Solanum species to cultivated potato is frequently prevented due to differences in ploidy and endosperm balance number.

Diploid *Solanum bulbocastanum* from Mexico and Guatemala is one of the tuber bearing species that is known for its high level of resistance to late blight. From this species two resistance genes, designated Rpi-blb1 and Rpi-blb2, were isolated and transferred to *Solanum tuberosum*. These resistance genes confer high levels of resistance to a very wide range of *Phytophthora infestans* isolates with complex race structures carrying multiple virulence factors.

Starting in 2006 these genetically modified potato lines have already been successfully tested in the field in the Netherlands, Sweden, UK, Czech Republic and Germany and were exposed to the local *Phytophthora infestans* strains with remarkable results (see Fig. 1 and 2).

Blb1 - Blb2 transgenic plants **Non-transgenic controls**

Figure 2: Genetically modified potato lines inoculated with *Phytophthora infestans* in comparison to the parental conventional potato.

Genes introduced into the genetically modified potato lines to be released

Two resistance genes, Rpi-blb1 and Rpi-blb2 from the wild potato *Solanum bulbocastanum* for improving resistance to *Phytophthora infestans* were transferred to conventional potato varieties via plant transformation.

A gene conferring resistance to imidazolinone herbicides was transferred to the plant lines to enable a selection of the genetically modified plant tissue after transformation. No tolerance to imidazolinone herbicides is intended under field growing conditions.

D Surplus value of the deliberate release

The planned field trial will be conducted to screen these genetically modified potato lines for improved resistance to *Phytophthora infestans* under realistic Belgian climatic and soil conditions with local *Phytophthora infestans* strains. Additionally, the release will provide an opportunity to investigate potential interactions with the environment via recording and comparing the occurrence of other diseases and insects.

E Potential impact on human and animal health as well as the environment

The genetically modified potatoes differ from conventional potato varieties in their resistance to *Phytophthora infestans* conferred by the introduced resistance genes. Potato already contains a large number of resistance genes conferring tolerance against other plant diseases where the majority of those genes belong to the NBS-LRR class. None of these genes are known to exert any toxic or allergenic effects to human health. The introduced genes are expressed by their endogenous promoters at extremely low levels leading to very low amounts of protein in the plants.

The resistance genes introduced into the genetically modified potatoes are of the NBS-

LRR class and thereby are very specific, limited to species or even race, in their recognition of target organisms. Due to the specificity of the response reaction no effects on other organisms than *Phytophthora infestans* are expected other than those that also apply to the interaction with non-genetically modified potatoes under conventional agricultural practice. Due to a reduced need for fungal treatments an increase in the populations of those non-target organisms that respond to the antifungal treatments might be expected. The overall impact on non-target organisms is considered negligible and no other changes in interactions are anticipated.

The introduced selection marker gene is expressed as the enzyme AHAS, which is an enzyme found in all plant species and not known to confer any toxic or allergenic properties. The safety of plants with AHAS-mediated tolerance to imidazolinone herbicides has been assessed by Health Canada and the Canadian Food Inspection Agency for imidazolinone tolerant maize, rice, canola, sunflower, lentils and wheat. Imidazolinone herbicide tolerant maize or CLEARFIELD maize has been cultivated in the US since 1992, CLEARFIELD canola since 1996 and CLEARFIELD wheat since 2001.

No changes in the reproduction characteristics or the dissemination into the environment compared to the control lines have been observed in the agronomic and phenotypic assessments in previous field trials. No changes in the survivability characteristics compared to the control lines have been observed in the agronomic and phenotypic assessments in previous field trials.

The genetically modified potatoes with increased resistance to *Phytophthora infestans* are unlikely to have any change in their interaction with the abiotic environment compared to non-genetically modified potatoes. None of the introduced genes are related to frost, drought tolerance or salt tolerance leading to a modified survival of the tubers in the soil.

The genetically modified potatoes for improved resistance to *Phytophthora infestans* are not expected to exert any toxic, allergenic or harmful effects on human and animal health or the environment.

Based on the information given in the technical dossier, in the risk assessment and based on the results from previous field trials the overall impact of the conduct of the envisaged field trial on the environment, animal or human health is considered negligible.

F Controlling and monitoring of the field trial

The release site will be managed according to conventional agricultural practice. During transport and handling the potatoes will be clearly labeled, separated from conventional potatoes and packaged in closed, double layer packaging. 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).

As a safety measure an isolation distance of at least 10 m between the GM potato lines and commercial potato cultivation will be observed throughout the testing period. However, at this specific trial location no other potato cultivation will take place within a distance 150 meter of the trial plot.

Harvesting will be performed manually. Any left-over tubers identified on the release area after harvest, will be collected and transported off site for inactivation. The genetically modified potato tubers originating from the trial will not be used for human food or animal feed.

During the course of the entire vegetation period (from about April to October) of the potato lines the area of release will be visited by BASF Plant Science compliance personnel and trained personnel to observe the release at defined intervals (at least

once a month). During the period with expected Phytophthora occurrence the trial will be inspected once a week.

The first year following the release the volunteer monitoring program starts and the field plot will either remain fallow or will be cultivated with maize.

During this volunteer monitoring program the release site will be monitored for potato plants emerging from potato tubers that might have survived during the winter (so called volunteers). Any emerging volunteer potato plants will be destroyed. Should volunteers emerge the first year of monitoring, the monitoring for volunteers will be extended by one year until there is a whole season without any finding of potato volunteers.