



Summary of the Application for a Permit to Release GMPs for Experimental Purposes

A. General Information

Application number

B/CH/15/01 (B15001)

Date of publication of application in the Swiss Federal Gazette

24 November 2015

Title of the project

Investigation of Cisgenic Apples with Improved Fire Blight Resistance

Proposed period of release

2016-2021

Name of the institute

Institute for Plant Production Sciences IPS and Institute for Sustainability Sciences ISS, Agroscope

Is the same genetically modified plant (GMP) release planned elsewhere?

No

Has/Have the Applicant(s) already applied for a permit to release the same GMP? If so, what were the Application numbers?

No

B.1 Genetically Modified Plant (GMP)

1. Complete name of the recipient or (if applicable) parental plant(s)

Common name	Family name	Genus	Species	Subspecies	Cultivar/breeding line
Apple	<i>Rosaceae</i>	<i>Malus</i>	<i>Malus x domestica</i> Borkh	-	Gala Galaxy

2. Description of the traits and characteristics which have been introduced or modified, including marker genes and previous modifications

A resistance gene against *Erwinia amylovora* (*FB_MR5*), which originates from the wild apple *Malus x robusta* 5, was introduced into the apple variety 'Gala Galaxy'. *Erwinia amylovora* is the causal agent of fire blight.

The GM apple line does not carry marker genes.

B.2 Genetic Modification

3. Type of genetic modification

Insertion

4. In case of insertion of genetic material, give the source and intended function of each constituent fragment of the region to be inserted

The *FB_MR5* gene with the native promoter and terminator conferring resistance to fire blight. The gene originates from the wild apple *Malus x robusta* 5.

6. Brief description of the method used for the genetic modification

The target gene (*FB_MR5*) was cloned into a „disarmed“ T-DNA of *Agrobacterium tumefaciens*. The transfer of the T-DNA into the apple genotype ‘Gala Galaxy’ was mediated by agrobacteria using a binary vector system. The marker genes were removed upon activation of a recombinase from the transgenic intermediate product.

C. Experimental Release

1. Purpose of the release

Verification under orchard condition if morphologic, physiologic and genetic differences are present between the cisgenic line and its wild type (‘Gala Galaxy’). Any differences will be compared to the corresponding differences that may be present among the control genotypes. The latter are other, naturally arisen Gala mutants that are also planted in the orchard.

2. Geographical location of the release site

„Protected Site’ of Agroscope at Zurich, Reckenholz, Reckenholzstrasse 191, 8046 Zurich

3. Size of the site (m²)

The apple orchard will have an approximate size of 30m x 60m.

4. Relevant data regarding previous releases carried out with the same GMP, if any, specifically related to the potential environmental and human-health impacts from the release

This apple line was not released so far.

D. Environmental Impact and Risk Management

1. Summary of the potential environmental impact from the release of the GMPs

The risk assessment of the GM *FB_MR5* line showed that the risk of possible harmful effects on the environment is negligible:

- By the application of the proposed measures, the risk that the GM trees, or their seedlings, may establish in the natural environment is very low.

- By the application of the proposed measures, the risk of the GM plants outcrossing is very low. Even in the very improbable event that pollen were to be transferred to genetically unmodified apple trees, the apple fruits of the pollinated tree would not be GM, as the apple fruits develop from the receptacle of the non-GM tree, and therefore the DNA of the apple fruits are identical to those of the pollinated plant. New genetic combinations resulting from the pollinations are only found in seeds (embryo and endosperm).
- The *FB_MR5* gene is also used in classical apple breeding. The *FB_MR5* mediated resistance is a very specific interaction with *E. amylovora* and according to the experience with classically bred selections carrying *FB_MR5* that are planted in orchards, there are no indications that the expression of this gene in cisgenic lines may lead to significant effects on non-target organisms. The risk of such effects is gauged as very low.
- There are no indications of nutrient cycles being at risk. The risk is very low.
- By the application of the proposed measures, the risk that *E. amylovora* may develop a resistance against *FB_MR5* is very low.
- The influence on the environment from the planting and management of the trials of the GM plants is regarded as not differing from that of other apple trials.

2. Brief description of any measures taken for the management of risks

General measures:

- Perimeter fencing around the test field
- Training of all persons who enter the field for the handling of GM material
- Transport of all kind of GM plant material outside the experimental orchard is done in closed, double-walled and labelled containers/bags
- Cleaning of the machines and instruments if GM plant material attached to them may potentially establish outside of the experimental orchard.
- An emergency plan governs the measures in case of special events

Culture-specific measures:

- Total netting of the experimental orchard aiming at preventing that GM pollen be transported by insects on to apple trees and on to trees of species potentially sexually compatible with apple outside the experimental orchard (outcrossing). This measure also prevents that pollen is transported by bees in beehives and may end up in honey.
- Distance requirements (i.e. isolation distances) to other apple trees and trees of species potentially sexually compatible with apple, to prevent outcrossing by transport of pollen by wind.

Final Report

(Not yet available)

Decision of the Swiss Federal Office for the Environment (FOEN) on the granting of the permit

Authorised on 3 May 2016 subject to conditions. In addition to the general measures, the flow of pollen from the GM apple trees has to be completely prevented.

Version: 3 May 2016