

INFORMATION TO THE SWISS AUTHORITIES ON THE POTENTIAL ENVIRONMENTAL IMPACT OF GENETICALLY MODIFIED PLANTS IN ACCORDANCE WITH ANNEXES IIB AND III OF DIRECTIVE 90/220/EEC

This application, submitted by Pioneer Hi-Bred International Inc. and Mycogen Seeds c/o Dow AgroSciences LLC, is for the approval in Switzerland to import products of genetically modified *B.t.* Cry1F maize line 1507 and progeny derived from conventional breeding between 1507 maize with any traditionally-bred non-GM maize, referred to as 1507 maize, for the purposes of food and animal feed. There is no intention to cultivate 1507 maize in Switzerland.

The 1507 maize has been genetically modified (GM) to express CRY1F protein for resistance to certain lepidopteran insect pests, such as the European corn borer (ECB), and to express phosphinothricin-N-acetyltransferase (PAT) protein for tolerance to glufosinate-ammonium herbicide.

However, no cultivation of 1507 maize hybrids is intended in Switzerland. Therefore, any potential environmental impact from the import of 1507 maize products for the purposes of food and animal feed will be limited to the unintentional release of 1507 maize such as accidental spillage of 1507 maize grain during transport.

This document contains the evaluation of the potential environmental impact from such limited release of 1507 maize, as required by the Swiss Federal Office of Public Health and the Swiss Federal Office of Agriculture in accordance with Annexes IIB and III of Directive 90/220/EEC. The evaluation is supported by further information in the attached annex:

Annex 1: The EU notification (23 November 2000) submitted to the Netherlands to import genetically modified 1507 maize in accordance with Directive 90/220/EEC (Ref: C/NL/00/10).

EVALUATION OF POTENTIAL ENVIRONMENTAL IMPACT FROM THE IMPORT OF 1507 MAIZE INTO SWITZERLAND

This application is to import grain products derived from 1507 maize for the purposes of food and animal feed. There is no intention to cultivate 1507 maize hybrids in Switzerland and therefore any environmental impact will be limited to the unintentional release of 1507 grain.

An evaluation of the potential environmental impact from the import of 1507 maize into Switzerland is presented below.

1. Likelihood of 1507 maize becoming more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats

There is negligible likelihood of 1507 maize becoming more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats.

Maize is not generally persistent in agricultural habitats and will not survive in Europe from one growing season to the next because of poor dormancy and sensitivity to low temperatures. In addition, maize does not exhibit weedy tendencies and is non-invasive in natural habitats (Canadian Food Inspection Agency, 1994).

The 1507 maize has been genetically modified to express CRY1F protein for resistance to certain lepidopteran insect pests, such as the European corn borer (ECB), and to express phosphinothricin-N-acetyltransferase (PAT) protein for tolerance to glufosinate-ammonium herbicide. The genetic modification in 1507 maize does not increase the likelihood of maize becoming more persistent in agricultural habitats or more invasive in natural habitats.

2. Any selective advantage or disadvantage conferred to 1507 maize

As intended by the genetic modification, expression of CRY1F and PAT proteins in 1507 maize confers specific selective advantages in agricultural habitats: resistance to certain lepidopteran insect pests, such as the European corn borer, and tolerance to glufosinate-ammonium herbicide. However, this application to the Swiss Federal Office of Public Health and the Swiss Federal Office of Agriculture is for import into Switzerland of 1507 maize products for the purposes of food and animal feed, respectively, and there is no intention to cultivate 1507 maize hybrids in Switzerland. Therefore, any unintentional release of 1507 maize into the natural environment will be limited and, in such case, the selective advantages conferred to 1507 maize would be negligible as insect pest pressure is not an important factor for selection of maize in the natural environment and broad-spectrum herbicides, such as glufosinate-ammonium, are not commonly used outside agricultural habitats.

3. Any selective advantage or disadvantage conferred to other sexually compatible plant species, which may result from genetic transfer from the genetically modified plant

Maize has no sexually compatible wild relatives in Europe and transfer of genetic material through hybridization is therefore limited to other maize grown in culture. However, there is no intention to cultivate 1507 maize in Switzerland and therefore genetic transfer is highly unlikely.

4. Potential environmental impact of the interaction between the genetically modified plant and target organisms

This application to the Swiss Federal Office of Public Health and the Swiss Federal Office of Agriculture is for import into Switzerland of 1507 maize products for the purposes of food and animal feed, respectively, and there is no intention to cultivate 1507 maize hybrids in Switzerland. Therefore, there will be no potential environmental impact of the interaction between 1507 maize and target organisms.

5. Possible environmental impact resulting from potential interactions with non-target organisms, including any potential biogeochemical effects

This application to the Swiss Federal Office of Public Health and the Swiss Federal Office of Agriculture is for import into Switzerland of 1507 maize products for the purposes of food and animal feed, respectively, and there is no intention to cultivate 1507 maize hybrids in Switzerland. Therefore, there will be no potential environmental impact resulting from potential interactions between 1507 maize and non-target organisms, including any potential biochemical effects.

6. Possible effects on human health

The potential effects on human health have been considered in detail in Point **D.d.** of the applications to the Swiss Federal Office of Public Health and the Swiss Federal Office of Agriculture is for import into Switzerland of 1507 maize products for the purposes of food and animal feed, respectively. In summary, the genetic modification in 1507 maize does not introduce any pathogenic, toxic or allergenic substances harmful to human health.

In addition, and as shown by the compositional analyses presented in Point **D.e.** of the applications, the levels of existing potential anti-nutrients in 1507 maize are comparable to those of traditionally-bred (non-GM) maize.

7. Possible effects on animal health and the feed/food chain

The potential effects on animal health have been considered in detail in Point **D.d.** of the applications to the Swiss Federal Office of Public Health and the Swiss Federal Office of Agriculture is for import into Switzerland of 1507 maize products for the

purposes of food and animal feed, respectively. In summary, the genetic modification in 1507 maize does not introduce any pathogenic, toxic or allergenic substances harmful to animal health and therefore no adverse effects on animal health and the feed/food chain will arise from the use of 1507 maize for the purpose of animal feed.

In addition, and as shown by the compositional analyses presented in Point **D.e.** of the applications, the levels of existing potential anti-nutrients in 1507 maize are comparable to those of traditionally-bred (non-GM) maize.

8. Possible environmental impact of changes in agricultural practices

The agricultural practices in Switzerland will not be affected as there is no intention to cultivate 1507 maize hybrids in Switzerland.

CONCLUSIONS

There is no intention to cultivate 1507 maize in Switzerland and therefore any potential environmental impact from the import of 1507 maize can only arise from unintentional release, for example accidental spillage of 1507 maize grain during transport. Assessment of the characteristics of 1507 maize and its potential environmental impact, with particular emphasis to Switzerland, has confirmed the following:

1. The characteristics of the introduced traits present in 1507 maize (CRY1F and PAT protein expression) have no effect on the persistence, spread or invasiveness potential of maize.
2. Outside the managed agricultural habitats, there are no selective advantages in 1507 maize conferred by the introduction of the insect resistance (CRY1F protein) and glufosinate-ammonium tolerance (PAT protein) traits.
3. There is no potential for transfer of the introduced traits to other plant species in Europe.
4. There will be no interaction with target or non-target organisms as no cultivation of 1507 maize will take place in Switzerland.
5. Consumption of foods and animal feed products derived from 1507 maize is as safe as consumption of products derived from any other traditionally-bred (non-GM) maize.
6. The agricultural practices will not be affected, as there is no intention to cultivate 1507 maize in Switzerland.

In summary, 1507 maize is as safe to the environment and to human and animal health as any other traditionally-bred (non-GM) maize. Based on the evidence presented above and as contained in the applications to the Swiss Federal Office of Public Health and the Swiss Federal Office of Agriculture for approval to import

products containing genetically modified organisms for the purposes of food and animal feed, respectively, we conclude that the potential environmental impact of import of 1507 maize into Switzerland for the purposes of food and animal feed is negligible.