Ministry of the Environment Environmental Risks Department

Prague, June 16, 2005 Reference Number: 642/OER/GMO/05

Decision

The Ministry of the Environment of the Czech Republic as the administrative body competent according to § 5 of the Act No.78/2004 Coll., on the use of genetically modified organisms and genetic products (hereinafter the "Act"), on the basis of a request of the BASF company located in Šafránkova 3, 155 00 Praha 5, decides under § 5 par. 8 of the Act:

BASF spol. s r. o., is granted consent

for the deliberate release into the environment genetically modified potatoes with modified starch content

Requirements of the consent according to § 18 par. 6 of the Act:

Authorised person

Name: BASF spol. s r. o., located in Šafránkova 3, 155 00 Praha 5 Identification Number (IČO): 41195469

Specification of the genetically modified organisms

The request shall be submitted according to § 18 par. 3 of the Act for the combination of genetically modified organisms – potato (*Solanum tuberosum* subsp. *tuberosum*), i.e. for AM02-1003, AM02-1005, AM02-1008, AM02-1010, AM02-1012, AM02-1014, AM02-1017 clones and for EH92-527-1 reference clone.

Specification of the genetic modification

All mentioned clones contain the same modification causing the varying level of the starch content. When the fragment of granule bound starch synthase gene (*gbss*) is inserted (in antisense orientation relative to the fragment of the potato *gbss* promoter), the amylase content in the tuber starch decreases. Such insertion causes the increase in the content of amylopectine in potatoes. The *gbss* gene is the own potato gene (*Solanum tuberosum*).

AM02-1003, AM02-1005, AM02-1008, AM02-1010, AM02-1012, AM02-1014 and AM02-1017 clones contain the selective AHAS gene of *Arabidopsis thaliana*, which induces the resistance to imazamox herbicid that is used during the selection of transformed plant tissue. Reference clone EH92-527-1 contains the selective gene for neomycin phosphotranspherase II (*nptII*) of *Escherichia coli* for the resistance to antibiotics kanamycin and neomycin that are used during the selection of the transformed plant tissue.

Conditions for the use

Genetically modified organisms above mentioned shall be used only in the way described in the request submitted to the Ministry of the Environment (hereinafter "MoE") on March 2, 2005, and supplemented by the submission delivered to MoE on May 19, 2005. The company BASF spol. s r. o. shall take delivery of all the harvested tubers to the other analyses and to the final disposal outside the territory of the Czech Republic.

Purpose of the use

The purpose of the use is to obtain data on modified potato clones introduced in the environment, and to compare them with the reference parent-species, i.e. to create data sets on agronomical characteristics and interaction with the environment (e.g. experiments concerning the dormancy, the liability to diseases and the sensitivity to pests). The other purpose of the tests is an experimental propagation of genetically modified potatoes in order to obtain the planting material for the future.

Requirements for labelling

In addition to the labelling according to § 11 par. 1 of the Act the packaging of the genetically modified potatoes that are to be transported shall be labelled with the notice "Not determined for cultivation".

Place of the deliberate release into the environment

Research Institute of Crop Production, Experimental Station Humpolec, Na Závodí 173, 396 01 Humpolec, Vysočina region, cadastral territory V Horách, tract No. 8 (cadastral numbers 1420, 1403/3 a 1425).

Requirements for monitoring and reporting of monitoring results

Monitoring shall be carried out in the place of the experimental release into the environment for the period of two years after a year of the experimental release into the environment in the monthly intervals during the vegetation season. The grown potato plants shall be monitored. Monitoring results shall be submitted to MoE in written and electronically always by February 15 of the consequent calendar year.

Validity time: by December 31, 2009

Instructions

The appeal against this Decision is not admissible since the applicant as the sole participant in the proceedings has abandoned his right to appeal (§ 53 of the Act No. 71/1967 Coll., on administrative proceedings (Administrative Code).

Ing. Karel Bláha, CSc. Department Director

This decision shall be received by:

- <u>Participant in the proceedings for personal delivery:</u> BASF spol. s r. o., Šafránkova 3, 155 00 Praha 5 A.
- B.
- For information:
 1. Ministry of Health
 2. Ministry of Agriculture