

**Ministry of the Environment
Environmental Risks Department**

Prague, May 5, 2006
Reference Number: 5091/ENV/GMO/06

D e c i s i o n

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, as amended by the Act No. 346/2005 Coll. (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.,
Šafránkova 3,
155 00 Praha 5**

is g r a n t e d c o n s e n t
for the deliberate release into the environment genetically modified potatoes
with increased content of amylopectin in tuber starch

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 genetically modified organism – potato (*Solanum tuberosum* subsp. *tuberosum*), with modified starch content in tubers towards higher amylopectin content, AM04-1002, 1003, 1006 to 1013, 1015 -1017, 1019 and 1020 clones. The origin of a transgenic variety: cultivator G.J. Kuper (The Netherlands) for P800.

Specification of the genetic modification

Genetically modified (GM) potato clones - AM04-1002, 1003, 1006 to 1013, 1015 -1017, 1019 and 1020 - showing a shift towards higher amylopectin content in tuber starch and thereby towards lower content of amylose, was obtained by means of transformation of P800 variety, when the fragment of granule bound starch synthase gene (*gbss*) was inserted (in antisense orientation relative to the fragment of the potato *gbss* promoter).

Parallely inserted selective acetohydroxyacid synthase gene (*ahas*) induces the resistance of transformed plants and plant tissue to imidazolinon herbicide (commercially Imazamox). Gene *ahas* originates from *Arabidopsis thaliana* genome.

Risk assessment results

Considering the measures to be taken for the deliberate release into the environment (the distance from cultivated plants and their wild relatives or the absence thereof) the potential transmission of a gene will be practically eliminated. Even if the improbable case occurs that pollen will be transmitted to non-modified potatoes (non-GM), it will have no consequences as potatoes are commonly reproduced by tubers, not seeds.

The interaction between GM potato line and non-target types and the resulting consequences may be comparable with common potato varieties. In field trials carried out last time no consequences of inserting characteristic feature of starch content modification or inducing the resistance to herbicides were seen (even at present they are not awaited).

No toxic or allergenic effects of either the increased amylopectin content in starch or the presence of *ahas* gene are awaited. Measures taken according to current praxis in field trials ensure prevention of deterioration of experimental sites by animals; the safe use of the planting and vegetable material (harvest, storage, transport, and disposal) will be also ensured in order to reduce at minimum a risk of contacts with people and animals. No other effects on biochemical processes in addition to those observed for ordinary potato varieties are expected. GM potato lines will be cultivated under conditions of current agricultural praxis. No difference concerning the persistence in agricultural localities or the aggressive release into the environment, when comparing with commercial potato varieties, is expected. Inserting the characteristic features for reduction of amylose content and inducing the resistance to Imazamox induce neither selective advantage nor disadvantage in potato clones.

Conditions for the use

- Genetically modified organism above mentioned shall be used only in the way described in the request submitted to the Ministry of the Environment (hereinafter "MoE") on January 24, 2006, and supplemented by the submission delivered to MoE on April 4, 2006. Whereas this request is related to the request of Ref. No. MŽP 5826/ENV/06 of the Research Institute of Crop Production, Drnovská 507, 161 06 Praha 6 - Ruzyně, the same conditions for the use have been stipulated for both applicants.

- The tested material will be grown at a field site in Humpolec. The same lines will be introduced by the company BASF, s.r.o. into the environment also in Germany, the Netherlands and Sweden.

- The applicant is obliged to forward in writing information about experimental locations intended in the following years for planting GM potatoes (it would be best in the form of the up-dated request – part C, point 4: "Workplaces and locations, where the deliberate release into the environment will be running", including an enclosed map with the distinguished experimental location), and that should be always before the beginning of planting.

- It is not allowed to plant either potato (requested for the purpose of monitoring) or legume (requested for the purpose of preventing the use of Imazamox herbicide) at the harvested location for following two years. Therefore, it is not considered that in any year during field trials the area larger than 1 ha would be planted. In accordance with the process of selection of tested materials the number of tested lines will be reduced along with increasing the amount of planted tubers of tested lines. The total number of tubers planted should not exceed 45000 in any year of the duration of field trials. The list of the lines planted including the number of tubers should be always updated before the beginning of the vegetation season in the letter forwarded to the Ministry of the Environment.
- Whereas the experiments will run in the city of Humpolec at a workplace of the Research Institute of Crop Production (hereinafter RICP), in which Ing. Zdena Martínková is the expert adviser, she is responsible for the running of the experiment pursuant to the requirements in the request and decision of Ref. No. MŽP 5091/ENV/GMO/06. Solely the staff of RICP should carry out all the activities connected with the planting in a field trial, treating and harvesting thereof, and the management of RICP is responsible for the control of the activities implementing the “Emergency Plan”.
- About 60 tubers (for every line) will be placed at given location plan, and the planting density will be according to current agricultural praxis. Simultaneously, the same number of tubers of reference varieties not genetically modified (non-GM) will be planted. In the next vegetation seasons the number of the lines tested will gradually decrease, while the number of every line’s tubers planted will gradually increase. The planting density of potato shall be in compliance with a common agricultural praxis, it means 4.5 plants per square meter. Maximum number of tubers of one line shall not exceed 2000.
- Isolation distance between the location of experimental release into the environment and the neighbour location, where conventional non-transgenic potatoes are cultivated, should be 10 m, and this land should be kept plant free.
- To prevent unauthorised persons entering the experimental locations is not possible. Nevertheless, all measures have been taken to minimise the entry of such persons. In every corner of the location shall be fasten a notice: “BEWARE GMO NO ENTRANCE POISON TREATED”. Since the crop concerned could not be eaten by human beings in place, and even it does not contain a gene sequence causing toxic hazard to humans, these measures can be considered as sufficient.
- Safeguarding a location against animals: genetically modified plants shall be planted out always at locations, where is not situated any forest in neighbourhood. Around the location an electric fence must to be built as the protection from animals. Wild boars were not observed in the vegetation season 2005 at the location where genetically modified potatoes were cultivated (see the permit No. 642/OER/05, location V Horách).
- no sexual compatible plants shall occur directly at the experimental area or in the neighbourhood of the location (the check before planting).
- the seed potatoes shall be transported to the place of experimental release into the environment in the Czech Republic, and the harvested potatoes shall be transported from the experimental site to the storing site and laboratories in EU (laboratories in Germany or Sweden) for analysis. The safe transport of tubers has been proved in long-term field trials in other EU Member States (see part A, point 6), and the transport shall be timely synchronized so that time of storing tubers in the city of Humpolec can be the shortest as possible. The transport shall be realised by a suitable car equipped with separated compartments for transgenic and non-transgenic potatoes. Tubers for planting double packed shall be transported by the trained person from the staff of BASF Plant Science GmbH to the field directly from a foreign country. The integrity of the tubers as well as the number of transgenic lines shall be controlled during the delivery according to the completion certificate. Loading

area shall be protected from the loss of packaging, and packaging shall be controlled according to the evidence during the unloading at the location. The cup-fed planting machine shall be used for planting. After the outplanting the blind ploughing up and harrowing shall come, and then the gathering with the hiller shall come. To spray potatoes the sprinkler Hardy NV shall be used. Herbicides Afalon+Command, Gallant Super and Redlone, further the fungicides Dithane, Casoar, Altima and the insecticide Calypso shall be used.

- A person from the staff of BASF Plant Science GmbH shall also carry out the transport of harvested tubers under the same conditions outside the territory of the Czech Republic. Tubers shall be saved in double-layer packaging labelled as “Genetically modified organism”, „Not intended to be cultivated“. Tubers delivered for planting shall be saved in the original packaging into the lockable steel and metal shed. The same shed shall be used for harvested tubers, which are stored separately on pallets labelled with a sign “GMO” and with names of particular lines (see point j).

- Planting and harvesting machine shall be cleaned at the site. The harvest shall be realised by the combine harvester with the side lateral lift. Tubers shall be transported for the storing and analysis in closed and labelled double-layer containers separated from conventional potatoes.

- GM potatoes sample analyses shall be carried out outside the territory of the Czech Republic, and all harvested tubers shall be annually transported outside the territory of the Czech Republic.

- Harvested potatoes shall be deposited in closed and labelled double-layer containers, and they shall be stored in separate lockable steel and metal shed until delivery.

- Remaining tubers shall be gathered, placed in double-layer packaging, and transported for disposal and liquidation (e.g. through the thermal treatment – combustion, autoclaving, steam treatment) to Germany at the address: Ingenieurbuero Hetterich, Bamberger Str. 50, D-97359 Schwarzach.

- If the greater number of tubers will be transported, the tubers must be weighed before packing in order to find out the losses in case of an accident if appropriate.

- Potato leaves shall be disinfected prior to harvesting.

- The introduced genetically modified lines have been cultivated only in field trials till now, and therefore the seed for the subsequent year must originate from the previous field trials.

- If the tubers are being unexpectedly spilled outside the areas determined for manipulation, such place should be marked by a tape to prevent unauthorised persons entering the location. After removing the tubers, while they are gathered into the closeable packaging labelled “Genetically modified organism”, “Not intended to be cultivated”, the site shall be located and the layout drawn in thereof, so that it can be possible in case of the loss of tubers to check, whether on this contaminated location any potato plants are not grown. Sanitation agents shall be stored in the store under the steel and metal shed.

- In case of a fire the objects affected can be considered to be relieved of genetically modified organisms. If it is possible to save a part of tubers, the tubers of transgenic plants should be carried out preferably in the direction of an officer in charge or a head of the station, provided that the fire is liquidated by their own, in order to prevent uncontrolled contamination of the GMOs object. The expert adviser shall decide of the further handling with these tubers. Otherwise the liquidation of a fire or accident is directed under fire protection regulations of a workplace and pursuant to the emergency plan.

- The staff of a workstation is obliged to meet the labour protection rules. It shall be met all regulations of the experiment’s setup, the treatment during vegetation and the harvest including the post harvesting treatment and transport of genetically modified organism pursuant to the Act No. 78/2004 Coll. and the related Decree. Since only the testing trials with already created genetically modified potato varieties are involved, the special protected agents are not necessary. To prevent from uncontrolled spread of tubers the thorough cleaning of all

agricultural machines used at the location (in particular the seeding and harvesting machines). No agricultural machine shall leave the location before the control of removing all tubers and post harvesting residues. Regarding to the size of genetically modified organisms there is no serious danger of the spread of tubers on clothing or shoes of workers, and therefore it is sufficient only visual checking of clothing and shoes.

- Green parts of plants and desiccated residues thereof, if appropriate, shall be disposed of at the location when putting into soil. The ploughing is considered as the effective protection from growing plants from released ripe seeds as well in some case. The trenches turned up shall be checked, whether any tubers not harvested occur. Such tubers should be manually gathered, and transported in a separate packaging for disposal outside of the territory of the Czech Republic (according to the requirement of the company BASF, see the request, point 6.6, part C). If the potato plants occur alongside the subsequent crop (spring barley) at the location, they should be plucked and liquidated by the herbicide spray (Reglone). When the work is finished, the agricultural technics should be looked over at the location, and all GMOs residues should be removed.

- It is not allowed to use GMOs by other way than is stipulated in the Book on the Operation of Field Trials that is deposited by the head of the station. Moreover, it is not allowed to transmit GMOs to other persons besides the trained persons and namely designated for the use of GMOs.

- The strict record on field trials with genetically modified potatoes shall be kept in the day book of all working operations, the state of vegetation and other changes, which may effect the environment.

Other conditions for the use

- Review on procedures obliged for the staff:

Planting potatoes and treatment of vegetation during the vegetation season (the fed-cup planting machine should be used for seeding, tubers are unloaded from packaging directly on a field, the trial is separated by the protective strap of 10 m in order to prevent the spread of pollen). The cleaning of all agricultural machines (in particular seeding and harvesting machines) from post harvest residues and tubers (tubers and post harvest residues should be removed mechanically on site; the strict control shall be carried out of the occurrence of tubers prior to the mechanization leaves the location). The desiccation of green parts of plants and putting the desiccated residues into soil. The harvest of tubers by the combine harvester (the strict cleaning of the combine harvester and the check of tubers presence). Packing of harvested tubers in double-layer packaging labelled „Genetically modified organism“, „Not intended to be cultivated, consumed and fed“.

- Throughout the whole vegetation period the all non-standard situations shall be observed and reported to the particular authorities.

- Since the whole area of planting GM potatoes in the subsequent years cannot be determined in the first experimental year, the applicant must submit this information to MoE as soon as it is known, but always in advance of the planting, and that is the list of clones including the expected amount, areas, identification of the location and the maps.

The duration of monitoring is set two years after the end of the experiment (monitoring of the occurrence of GM potatoes shall be carried out on cultivation areas as well as in the neighbourhood thereof, and also non-specific monitoring of the environment in order to reveal unexpected affects of GMOs, if appropriate. The grown potato plants shall be plucked and liquidated by the spray Reglone.

Purpose of the use

The purpose of the deliberate release of GM potatoes into the environment is to obtain data related to studies concerning the modified potato clones introduced in the environment, and to compare them with the reference parent-species. The purpose of the field trial is to create data sets on agronomical characteristics and also on composition, interaction with the environment (e.g. experiments concerning the dormancy, the liability to diseases and the sensitivity to pests), and to carry out an experimental propagation of genetically modified potatoes in order to obtain the planting material for the future.

The company BASF, s.r.o. shall introduce into the environment the same lines in Germany, the Netherlands and Sweden as well.

Requirements for labelling

According to § 11 par. 1 of the Act the bags with harvested potato tubers shall be labelled with the notice „Genetically modified organism“, „Not intended to be cultivated, consumed and fed“.

Place of the deliberate release into the environment

Research Institute of Crop Production, Experimental Station Humpolec, Na Závodí 173, 396 01 Humpolec, cadastral territory Na Klínku, tract No. 1 (cadastral numbers 1192/2, 1192/1 and 1189). The area of the location No. 1 determined for the cultivation of all permitted field trials in 2006 is 2.10 ha. The range of an experimental release into the environment is about 1 ha. The locations for the subsequent years shall be specified prior to planting.

Requirements for monitoring and reporting of monitoring results

Monitoring shall be carried out in the place of the experimental release into the environment and in the neighbourhood of the planting areas as well as non-specific monitoring of the environment revealing the unexpected affects of GMOs on the environment.

The following observing plan is a part of the request, and concerns the surveys during the deliberate release into the environment and situation after the experimental release of potato clones AM04-1002, AM04-1003, AM04-1006, AM04-1007, AM04-1008, AM04-1009, AM04-1011, AM04-1012, AM04-1013, AM04-1015, AM04-1016, AM04-1017, AM04-1019 and AM04-1020.

In course of the whole vegetation season (maybe from April to October) the head of the project and the trained staff shall visit the area of the experimental release into the environment (and that will be minimally every four week) in order to pursue the running of the experiment. The single Vegetation Book on potato vegetation shall be conducted. The common characteristics of the plants related to the agronomic behaviour of potato lines, any soil effects and climate effects (frost tolerance) shall be pursued and recorded according to the common agricultural praxis (UPOV). The occurrence of diseases and pests shall be by the use of proven methods reduced at minimum. In case of an extreme extent of pest and disease infestation the differences in the behaviour of GMOs shall be reported as far as they occur. The reports on field trials shall be supplemented during the whole period of the deliberate release into the environment. The behaviour of genetically modified potato lines shall be compared with the behaviour of recipient varieties (they are cultivated in parallel at the same experimental site). Information concerning unexpected serious events (possible negative effects on the environment and human health closely connected to the genetic modification of potatoes) shall be immediately forwarded to the pertinent authorities, and the appropriate measures according to circumstances shall be taken.

At the location, where the experiments with the deliberate release into the environment will be running, no potatoes shall be cultivated for two years following the experiments. There shall be cultivated only such crops those allow to pursue the occurrence of the single plants grown

up from seeds or tubers. The head of the project or the trained staff shall pursue the location after the end of the experiment in predetermined intervals. If the plants grown up from the seeds are detected, they should be treated in accordance with the common agricultural praxis. The monitoring should be carried out for the period of two years following the year of the experimental release into the environment.

After every vegetation season the field trial shall be assessed in the annual report submitted to the Ministry of the Environment at latest on February 15 in the subsequent year. The results shall be described summarily in the final report /§ 19, c), d) of the Act/.

Validity time of the consent:

The time period for the deliberate release of GM potatoes into the environment: 2006-2010

I n s t r u c t i o n s

Within 15 days from the date of the notice of this Decision there is an opportunity by the submission to the Ministry of the Environment, Vršovická 65, 100 10, Praha 10, to appeal against this Decision according to § 152, par. 1 of the Act No. 500/2004 Coll., on administrative proceedings (Administrative Code), whereupon the Minister for the Environment shall decide.

Ing. Karel Bláha, CSc.
Department Director

This decision shall be received by:

- A. Participant in the proceedings for personal delivery:
BASF spol. s r.o., Šafránková 3, 155 00 Praha 5
- B. For information:
 - 1. Ministry of Health
 - 2. Ministry of Agriculture
 - 3. Regional Authority of the Vysočina Region, Žižkova 57, 587 33 Jihlava
 - 4. Municipal Authority of Humpolec City, Horní náměstí 300, 396 22 Humpolec