

Ministry of the Environment

Environmental Risks Department

The Decision came into force on 29 April 2009

Prague, April 27, 2009

According to Reference Number: 3880/ENV/09

Reference Number: 31517/ENV/09

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“) and in § 10 of the Act No. 500/2004 Coll., the Administration Code, as later amended,

has decided

on the basis of a request of the company MONSANTO ČR, s.r.o., located in Londýnské nám. 856/2, 639 00 Brno, for granting consent for the deliberate release into the environment of genetically modified (GM) maize to perform field trials in the Czech Republic, pursuant to § 5 par. 8 of the Act:

Company MONSANTO ČR, s.r.o.,

Londýnské sq. 856/2

639 00 Brno

i s g r a n t e d c o n s e n t

for the deliberate release

**of genetically modified maize MON 89034 x NK603 and MON 89034 x
MON 88017**

into the environment in the Czech Republic.

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

Authorised person

Name: MONSANTO ČR, s.r.o.

Address: Londýnská nám. 856/2, 639 00 Brno

Identification Number (IČO): 636 77 628

Specification of the genetically modified organism

According to § 18, par. 3 of the Act, the application for the deliberate release into the environment has been submitted for GM maize hybrids MON 89034 x NK603 and MON 89034 x MON 88017. The maize hybrids MON 89034 x NK603 and MON 89034 x MON 88017 have not been as yet introduced into the environment in the Czech Republic.

The stacked maize hybrid MON 89034 x NK603

was produced by crossing of two genetically modified parental lines MON 89034 and NK603. Therefore the seed of F1 generation has inherited from MON 89034 the resistance to lepidopteran pests, in our conditions to the European corn borer (*Ostrinia nubilalis* Hübner), and from NK603 the tolerance to glyphosate that is the active ingredient in Roundup[®] herbicides.

The stacked maize hybrid MON 89034 x MON 88017

is the combination of two genetically modified parental lines MON 89034 and MON 88017 which inherited resistance to lepidopteran pests from MON 89034 and tolerance to glyphosate and from MON 88017 the resistance to certain coleopteran pests, in our conditions to the Western corn rootworm (*Diabrotica virgifera virgifera* LeConte).

Specification of the genetic modification

The stacked maize hybrid MON 89034 x NK603

The parental lines MON 89034 and NK603 were produced via *Agrobacterium tumefaciens*-mediated transformation and microprojectile bombardment method respectively.

Like **MON 89034** parental line, maize hybrid **MON 89034 x NK603** expresses insecticidal proteins Cry1A.105 and Cry2Ab2 which protect it against feed damage caused by the European corn borer (*Ostrinia nubilalis*) and the other lepidopteran pests. The protein Cry1A.105 is a modified *Bt* Cry1A protein, whilst the protein Cry2Ab2 is derived from *Bacillus thuringiensis* subsp. *kurstaki*. The combination of both insecticidal proteins in the same plant is an innovation of the current single protein use (e.g. the maize MON 810) and it provides an additional tool against insect's resistance development to *Bt* toxin.

For **MON 89034** maize transformation the plasmid vector PV-ZMIR245 constructed using standard molecular biology techniques was used. MON 89034 does not include the *nptII* gene. Like **NK603** parental line, maize hybrid **MON 89034 x NK603** expresses two proteins CP4 EPSPS (CP4 EPSPS and CP4 EPSPS L214P) that confer tolerance to glyphosate (the active ingredient of a broad spectrum Roundup[®] herbicide). The EPSPS is an enzyme involved in aromatic amino acid biosynthetic pathway of plants and microorganisms. In comparison to the original type of this enzyme in maize the affinity of CP4 EPSPS enzymes to glyphosate is reduced significantly and their catalytic activity remains even in the presence of glyphosate. So when the maize plants expressing CP4 EPSPS proteins are treated with glyphosate, they are not anyhow damaged due to functional CP4 EPSPS enzymes production of aromatic amino acids which cover its usage.

The maize event NK603 was produced by a particle acceleration transformation method using a restriction fragment of plasmid vector containing *epsps* gene (5-enolpyruvylshikimate-3-phosphate-synthase) from *Agrobacterium sp.* strain CP4. NK603 contains only the *cp4 epsps* plant gene expression cassettes and does not contain the *nptII* selectable marker gene or origin of replication.

The stacked maize hybrid MON 89034 x MON 88017

MON 89034 x MON 88017 was produced by crossing of two events using conventional breeding methods.

Like **MON 89034** parental line, maize hybrid **MON 89034 x MON 88017** expresses insecticidal proteins Cry1A.105 and Cry2Ab2 which protect it against feed damage caused by the European corn borer (*Ostrinia nubilalis*) and the other lepidopteran pests. Cry1A.105 is a modified *Bt* Cry1A protein, while Cry2Ab2 is a protein derived from *Bacillus thuringiensis* subsp. *kurstaki*. The combination of insecticidal proteins Cry1A.105 and Cry2Ab2 in the same plant is an innovation of current use of single protein (e.g. in the maize MON 810) and it provides an additional tool against insect's resistance development to *Bt* toxin. For **MON 89034** maize cells transformation the PV-ZMIR245 vector was used. MON 89034 does not include the *nptII* gene.

Like **MON 88017** parental line, maize hybrid **MON 89034 x MON 88017** expresses the CP4 EPSPS protein derived from the *Agrobacterium sp.* strain CP4 that confer tolerance of plants to glyphosate. Moreover, MON 89034 x MON 88017 expresses as like as MON 88017 the modified Cry3Bb1 protein derived from *Bacillus thuringiensis* subsp. *kumamotoensis*. The expression of this Cry3Bb1 protein provides the protection against certain coleopteran pests, in our conditions to the Western corn rootworm (*Diabrotica virgifera virgifera* LeConte).

For **MON 88017** maize transformation the plasmid vector PV-ZMIR39 constructed using standard molecular biology techniques was used. This is a part of binary *Agrobacterium tumefaciens* vector system. Backbone sequences of PV-ZMIR39 vector plasmid coding the resistance to spectinomycin and streptomycin has not been integrated into the MON 88017 maize genome.

Risk assessment results

The risk assessment has been carried out pursuant to the Act and Decree No. 209/2004 Coll., on detailed conditions for the use of genetically modified organisms and genetic products. When assessing the risks of the use of genetically modified maize it is compared to the use of non-genetically modified (conventional maize). The possible direct and indirect, immediate and subsequent adverse effects of this use, particularly the effects on human and animal health and the environment, are assessed.

MON 89034 x NK603 risk assessment

There is no evidence that the hereditary material inserted into the maize plants of **MON 89034 x NK603** or the used vector could have adverse effects on human and animal health or the environment. There is no evidence that any gene, which is important in term of the host genome function, was mutated due to the insertion of the construct into parental lines. Any significant change in molecular characteristics of these inherited DNA inserts in MON 89034 x NK603 is very unlikely, and that is for reasons as follows:

- There is no known mechanism through which both inserts located on different places of separate chromosomes could stimulate a mutual recombination (those do not express proteins involved in recombination mechanisms).

- The frequency of mitotic recombinations between the inherited DNA MON 89034 and NK603 in the MON 89034 x NK603 maize is negligible.

Therefore we can state that the risk of the possible occurrence of adverse effects related to the insert is negligible.

The field trials with MON 89034 x NK603 have been planned on a few locations and on a limited area (the total area is approximately 7,442 m²). With regard to this area, nature of the experiments and locations (operated by the research workplace), the risk of the possible occurrence of adverse effects related to the place and scope of the use of genetically modified organism can be considered as negligible.

The environment at the experimental area consist of the parcels used for farming. The technical barriers such as the combination of the insulation distances and buffer zones will be applied in order to reduce a pollen escape of genetically modified maize into the neighbouring environment. The limitation of seed escape is ensured by controlled procedures of the setting and harvesting of the field trials. All the transferred seed shall be transported in the closed and labelled packaging, and the records are kept. It can be stated that the risk of possible adverse effects on the environment at the place, where the genetically modified organism is used, is negligible.

Regarding to the phenotypic and agronomic characteristics (excepting the inserted properties) the MON 89034 x NK603 is similar to the conventional maize. Therefore it can be stated that ecological interactions of MON 89034 x NK603 either with non target organisms of the environment or inanimate nature, under the conditions given by the deliberate release into the environment, will not differ from the interactions of the conventional maize (non-genetically modified).

The properties of the MON 89034 x NK603 maize are consistent with the properties of the conventional maize (non-modified) with the exception of the resistance to target lepidopteran pests and tolerance to glyphosate.

It has been proven by the field trials focused on the assessment of phenotypic, agronomic, reproduction, and other features, that this genetically modified maize does not differ from the conventional maize. With regard to the fact that the genetic modification of parental lines MON 89034 and NK603 as well as the inheritance of those properties in the maize MON 89034 x NK603 have not incurred any biologically significant differences in the phenotype, which could change a state of health and vitality of this maize in comparison with the conventional maize, it is very unlikely that MON 89034 x NK603 would be more persistent in field conditions or more invasive in nature. The inserted properties of resistance to target lepidopteran pests and tolerance to glyphosate should not evoke any significant advantage or disadvantage influencing the survival of the maize in the environment.

The probability of unintended spread of MON 89034 x NK603 into the non-agricultural environment is negligible due to the limited abilities of the maize to become a weed. In comparison with the conventional maize either the persistence of this GM maize in field conditions or its ability of spreading into the neighbouring environment are not changed. In very unlikely case that the plants of MON 89034 x NK603 grow in „non-agricultural“ environment the consequences would be negligible.

No field trial material should enter the food or feed chain. Therefore the risk of any adverse effects of MON 89034 x NK603 related to the human or animal exposure to inserted proteins can be considered as negligible.

MON 89034 x NK603 poses only negligible risk of the adverse environmental impacts in consequence of its interaction with target organisms. When assessing the risk the potential environmental benefits of the cultivation of this GM maize were also taken into account as follows:

- 1) the maize protection against certain lepidopteran pests when preserving useful species;

- 2) the potential reduction of broad-spectrum chemical insecticides usage, and the consequent reduction in treating of vegetation (fuels);
- 3) the compliance with methods of integrated pest management (IPM) and sustainable agriculture;
- 4) the reduced risk of the resistance development to *Bt* proteins;
- 5) the potentially reduced content of mycotoxins, such as fumonisins of corn grain in consequence of the lower damage of maize plants caused by caterpillars, and subsequent lower fungal disease infection.

The GM-plant property, tolerance to glyphosate, facilitate the weed regulation in accordance with current state of vegetation having regard to soil protection.

In conclusion it may be stated that there have not been identified any properties of genetically modified maize, which could be harmful for the environment under given conditions.

The safety of food and feed derived from the maize **NK603**, and its substantial equivalence with the conventional maize have been already supported at the European Union level in the application of the company Monsanto in the framework of the EC Regulation No. 258/97 and by the notification C/ES/00/01 according to the Directive 2001/18/EC. On 25 November 2003 the European Food Safety Authority (EFSA) published a favourable opinion on the safety of NK603 which resulted into the consent to import, process and utilize in feed of this maize in the EU (the Commission Decision 2004/643/EC). On 26 October 2004 the consent for the use in food was granted (the Commission Decision 2005/448/EC). The application for the placing on the market including the cultivation of this maize was submitted under Regulation (EC) No. 1829/2003 in 2005 (EFSA-GMO-NL-2005-22). Field trials on genetically modified maize event NK 603 are carried out in several EU Member States.

MON 89034 x MON 88017 risk assessment

There is no evidence that the hereditary material inserted into the maize plants of MON 89034 x MON 88017 could have adverse effects on human and animal health or the environment.

There is no evidence that any gene, which is important in term of the host genome function, was mutated due to the insertion of the construct into parental lines. Therefore it can be stated that the risk of the possible occurrence of adverse effects related to the insertion of the construct is negligible.

The field trials with MON 89034 x MON 88017 have been planned on a few locations and on a limited area (the total area is approximately 7,442 m²). With regard to this area, nature of the experiments and locations (operated by the research workplace), the risk of the possible occurrence of adverse effects related to the place and scope of the use of genetically modified organism can be considered as negligible.

The risk of unintended spread of MON 89034 x MON 88017 into the environment is negligible due to the limited abilities of the maize to become a weed. The possibility of the transfer of the MON 89034 x MON 88017 hereditary material to the wild species is not real in the European conditions. The transfer to other maize materials is limited by climatic conditions, flowerage synchronisation, and the insolation distance required for field trials. With regard to phenotypic and agronomic characteristics the MON 89034 x MON 88017 is similar to the conventional maize excepting the inserted properties of resistance to lepidopteran and coleopteran target pests, and tolerance to glyphosate.

Therefore it can be stated that ecological interactions of MON 89034 x MON 88017 either with non target organisms of the environment or inanimate nature, under the conditions given for field trials, will not differ from the interactions of the conventional maize (non-genetically modified).

So the assessment of possible adverse effects caused by direct or indirect interactions of GM maize and target organisms concerns the inherited insecticidal proteins. These adverse effects

of MON 89034 x MON 88017 are very unlikely as both of parental lines have never shown such either immediate or delayed effects.

MON 89034 x MON 88017 in consequence of its interaction with target organisms poses only negligible risk of the adverse environmental impacts. In given conditions of the field trials the MON 89034 x MON 88017 poses only a minimum risk of potential immediate or delayed environmental impact in consequence of its interactions with non-target organisms, including effects on population levels of competitors, herbivores, symbionts, parasites and pathogens.

According to the Act no material from field trials should enter the food or feed chain. Nevertheless, the potential health effects have been assessed as well. Based on a specificity of binding sites of target organisms (catterpillars and beetles) the absence of toxicity for human and animals can be supposed. The mammals miss this mode of action. The results of studies have shown that MON 89034 x MON 88017 is substantially equivalent to the conventional maize in term of the grain composition and nutritive value, and therefore it is as safe as the conventional maize. The probability that some adverse effects on human or animal health will occur in consequence of the contact with GM maize MON 89034 x MON 88017 does not differ from the occurrence probability of such effects in case of the conventional maize.

The probability of the significant exposure of organisms in the soil ecosystem to this maize resulting in its composition changes is negligible under conditions of the field trials. In given conditions the risk of possible immediate or delayed effects on biogeochemical cycles resulting from potential direct or indirect interactions of GM maize MON 89034 x MON 88017 and target and non-target organisms in the vicinity of GMO release into the environment, can be considered as negligible.

Field trials on genetically modified maize **MON 89034 x NK603** are carried out in France, Spain and Germany, and planned in Romania, Poland and Slovakia. Outside of Europe this maize was tested in USA and Argentina.

Field trials on genetically modified maize **MON 89034 x MON 88017** are carried out in France, Spain, Germany, Romania and Slovakia. Outside of Europe this maize was tested in USA and Argentina.

Conclusions

In conclusion it may be stated that no properties of GM maize have been identified, which could, under given conditions of the field trials, be harmful to the environment. The cultivation, management or harvesting of the planned field trials with MON 89034 x NK603 and MON 89034 x MON 88017 will influence the environment in the same way as the cultivation of any other maize.

Conditions for the use

Genetically modified organisms above mentioned shall be used only in the way described in the application Ref. No. 3880/ENV/09 submitted to the Ministry of the Environment on January 21, 2009, and supplemented with the submission of March 16, 2009, when keeping all given conditions especially as follows:

- Every handling with the genetically modified material shall be under conditions minimising a possibility of transgene escape into the environment.
- **Since** the company MONSANTO ČR s.r.o., as a founder of the field trials, has a sufficient professional potential it will carry out the supervision over the field trials with the genetically

modified maize at the workplaces of the Crop Research Institute (VÚRV, v.v.i., Ivanovice na Hané) and the Agricultural Research Institute (ZVÚ Kroměříž).

- The principles of good agricultural practice shall adhere to the plan for minimisation of possibility of weed resistance development to glyphosate.

- The import of seed to the Czech Republic shall be realised by air or by the road. The company MONSANTO ČR, s.r.o. shall handle with the seed only for the transportation purposes which means that the company shall pick up the seed from the carrier and ensure the transport by car to the place of storage.

- The transportation of GM maize seed to the plot is ensured by particular workplaces as well as the transportation of possible samples of plant material during realisation of the experiments in the scope of the workplace. The seed shall be transported in closed and labelled packaging.

- The transportation of the seed of genetically modified maize shall be carried out in strong, properly closed and labelled packaging (e.g. gunnies or multi-ply paper-sacks). During transportation GM maize seeds shall be deposited in double packaging where at least one of that shall be solid (e.g. the seed sacks are placed into the lockable box or outer gunnies). The crates shall be equipped with the codes of the field trial, variant number of the field trial, and signed as follows "GMO, NEITHER FOR FOOD NOR FOR FEED".

- The transportation, transfer of seeds or plant material samples for analysis, the delivery of seeds, the sowing of the field trial and destruction of seeds shall be acknowledged in written form.

- The seeds remains shall be properly stored at the particular workplaces, where it can be reused in subsequent years in experiments, in compliance either with the methodological guidelines of the company Monsanto or conditions laid down in the particular Consent. Moreover, the remains of seeds may be returned to the Monsanto company (dispatched to the foreign workplace of the company Monsanto) or destroyed together with the harvested grain (biomass if appropriate) or ploughed under the ground together with the remains of grain samples and other plant material directly at the experimental plot, where the GM maize MON 89034 x NK603 and MON 89034 x MON 88017 hybrids were cultivated.

- GM maize will be introduced into the environment by mechanized sowing (small-plot sowing machine) or manually.

- The approximate number of genetically modified maize plants per m² will be from 8 to 10 at average.

- The field trials are intended for grain or silage harvest, if appropriate. The harvest will be carried out by small-plot combine harvester or manually. More information on harvest method will be submitted within applications of particular workplaces.

- Further use of GM maize materials after harvest (produced grain or silage if appropriate) is limited to the potential assessment of taken samples in the laboratory of a particular workplace (the samples can be analysed on the field as well), and also to possible transfer of samples for analyses abroad. It will be ensured by the company Monsanto. The storage of seed or grain samples at workplaces, or the destruction of harvested grain including grain or other plant samples can be considered as the further use. More information will be provided in the applications of the particular workplaces.

- The field trial with genetically modified maize shall be surrounded by 8 rows of conventional maize. For the buffer strip a hybrid with similar genetic background as GM maize hybrid is supposed to be used. In case that such material will not be available the hybrid of similar ripeness and growth should be used.

- The important measure to prevent the seed from propagation is the proper cleaning of mechanization (seeder, combine harvester) directly on the spot after sowing/harvesting termination.

- The harvested grain shall be weighed and left on the field for destruction. In case where the sampling is required by the methodology, these samples will be taken on the field, packed into double packaging, labelled according to labelling requirements for GM materials, and transferred to GM storage facility at the workplace. Here, they will be stored until transferred abroad. The delivery shall be acknowledged in written form.
- The plots where the field trial with genetically modified maize will be carried out shall be signed at all corners, by visible boards with notices as follows: ATTENTION! GENETICALLY MODIFIED ORGANISM! NO ENTRY! NOT FOR FEED! CHEMICALLY TREATED! NOT FOR FOOD!
- The remains of seeds, the harvested grain, silage or other parts of plants including samples and the conventional maize from buffer strips can be considered as waste from the use of genetically modified maize MON 89034 x NK603 and MON 89034 x MON 88017. After the field trial is finished (harvest) the experimental area shall be ploughed under the ground. The nitrogen fertiliser with a quick-release N source shall be applied on the organic matter dispersed on the soil surface before being ploughed under the ground in order to speed up biodegradation of the organic matter in the soil.
- Records shall be kept on waste handling including destruction of the genetically modified maize material.
- In the subsequent year after the GM maize cultivation the other crop than maize shall be cultivated on the whole area of the experimental plot. If any volunteers occur in subsequent crop it shall be destroyed in compliance with current agricultural practice.
- As herbicides will be used for verification of phytotoxicity (or the effectiveness of given model of treatment), which means a different application from registered use of the product, before that an application shall be submitted under § 44 of the Act 326/2004 Coll. On phytosanitary care as later amended to the State Phytosanitary Administration, Section for Plant Protection Products, Zemědělská 1a, 313 00 Brno.
- In case of an accident the Ministry of the Environment and other administrative bodies mentioned in § 27 according their responsibilities should be pursuant to § 21 of the Act among subjects being notified.
- All staff that is getting into contact with GM maize shall be trained every year about rules for the use of genetically modified organisms by a professional consultant.
- The Decision of the Ministry of the Environment Ref. No. 80723/ENV/GMO/06 of 23 February 2007 has laid down the provision that an applicant must give an opinion on the weed resistance (development of the resistance) after the application of preparations based on glyphosate. The opinion on the weed resistance (development of resistance) to preparations based on glyphosate will be a part of the final report under § 19, letter d) of the Act. An occurrence of resistant weed at the experimental plots must be monitored before and in the course of an experiment so the later discovery of the presence of a resistant weed individual could or could not be interpreted as the consequence of the field trial. Regarding to the information published in special literature that many plants (including weeds) express the same type of resistance to glyphosate (lower affinity of the EPSPS enzyme to the herbicide), a greater attention should be paid to distribution of weedy species at the field trial location. The level of weeds resistance to the herbicide active ingredient, glyphosate, shall be monitored with the aim to propose an anti-resistance strategy to prevent or postpone the resistance development.
- The potential occurrence of development of herbicide-resistant weeds after repeated application of herbicides should be monitored. In case the low efficacy of glyphosate which will not be the typical one for given species of weed will be observed, this shall be communicated to the company Monsanto ČR, s.r.o., and further measures for the assessment

of this case should be taken. The State Phytosanitary Administration shall be informed about all the facts related to this finding.

- The applicant shall in accordance with § 19 letter c) of the Act submit to the Ministry data on the amount of maize and on handling with it in written and electronic form annually, always by February, 15 in the calendar year, and pursuant to § 19 letter d) of the Act submit to 60 days from termination of the use of genetically modified organisms a final report on the course and consequences of this activity, particularly with regard to risk for human health and the environment. The final report shall be submitted also in English pursuant to the Annex of the Commission Decision 2003/701/EC.

Other conditions on the use of GMOs stipulated under § 5 par. 10 of the Act

- Every year the starting sowing date is supposed to be on April 15, and the duration of field trial (harvesting) is supposed to be no later than November 30.

- Every year at least 30 days before sowing the applicant shall notify the Ministry of the Environment an updating list of tested hybrids and information on deliberate release into the environment and on amendments in the original application (point 7 and following, part B of the Annex No. 2 to the Decree No. 209/2004 Coll., on detailed conditions for the use of genetically modified organisms and genetic products).

- In every stage of the experiments the minimum isolation distance of 200m shall be kept between cultivated GM maize and commercially planted non-GM maize, together with buffer strips of conventional non-GM maize, which means at least 8 rows of conventional maize of higher growth than GM maize with 70 to 75 cm spacing between rows.

- Minimum isolation distance of 600 m shall be kept between cultivated GM maize and non-GM maize cultivated by organic farming.

- The applicant shall in compliance with § 19 letter f) of the Act, co-operate with the administrative bodies (Ministry of the Environment, CEI - Czech Environmental Inspection, CISTA - Central Institute for Supervising and Testing in Agriculture) pursuant to § 28 and § 31- 33 when inspecting plots, areas and facilities dedicated to the use of genetically modified organisms, or plots, areas and facilities where the use is or may be realised, including the written documents, and whenever during the use allow the free sampling of genetically modified organisms above mentioned or genetic material thereof for control purposes.

Purpose of the release

Planned field trials with genetically modified maize MON 89034 x NK603 and MON 89034 x MON 88017 are intended to obtain data for the assessment of its basic agronomic characteristics. Methods of herbicide weed regulation will be compared, and the efficacy of insect-resistant maize protection against the most important maize pest in the Czech Republic, European corn borer, will be assessed. Moreover, the field trials will enable the verification of the concept for potential application of so called stacked hybrids MON 89034 x NK603 and MON 89034 x MON 88017 under the Czech Republic conditions, and demonstration of stacked GM maize materials.

Since the Western corn rootworm is the pest which is spreading also in the Czech Republic, the above mentioned activities may bring the interesting results towards future potential application of the GM maize as one of possibilities of protection against this pest.

Possible benefits of the GM maize cultivation will be verified as follows:

- The effective method of selective regulation of target lepidopteran and coleopteran pests.
- The potential of lower consumption of chemical insecticides, including the reduction of people's exposure to the pesticides during its application.
- Suitability for the integrated pest management (IPM), in compliance with the sustainable agriculture, and the reduction in need for the entry of machinery into vegetation.
- The potential of the reduction in fumonisin mycotoxins contents in maize grain.
- The lower probability of resistance development of the lepidopteran pests to *Bt* proteins.
- The post emergent weed control with the broad-spectrum herbicide during the growth of a herbicide-tolerant crop according to an actual weed occurrence. The potential benefit is the soil protection.

Other requirements for labelling

For deliberate release of GMO the common requirements for labelling of genetically modified organism have been laid down in law.

All the packaged GM maize materials including transport packaging shall be labelled as follows: „NEITHER FOR CULTIVATION NOR FOR FOOD OR FEED“ together with a unique identification code (according to OECD database, Biotrack):

For MON 89034 x NK603 hybrid: **MON-89034-3 x MON-00603-6**

For MON 89034 x MON 88017 hybrid: **MON-89034-3 x MON-88017-3**

Place of the deliberate release into the environment

The company MONSANTO ČR, s.r.o. as an applicant supposes the deliberate release of maize hybrids MON 89034 x NK603 and MON 89034 x MON 88017 into the environment through the research workplaces of VÚRV, v.v.i., in Ivanovice na Hané, and ZVÚ Kroměříž, at the total area of approximately 7,442 m².

Requirements for monitoring and reporting of monitoring results

The company MONSANTO ČR s.r.o., will be the professional guarantee and co-ordinator which will perform both the supervision over the field trials including monitoring of the occurrence of volunteers in subsequent year and general surveillance of any harm effects related to the use of GM maize. The monitoring plan shall be based on the risk assessment results related to the environment, and its objective is an early observation and identification of adverse effects, which could be expected or unexpected consequence of the deliberate release of genetically modified maize plants into the environment.

If occurred, any adverse effects in connection with the deliberate release of GM maize into the environment shall be immediately reported to the Ministry of the Environment and relevant authorities. After the end of the field trials the final report on the use of the GM maize shall be submitted to the Ministry of the Environment pursuant to the Act as well. The level of weeds resistance to the herbicide active ingredient, glyphosate, shall be also monitored with the, aim to propose an anti-resistance strategy to prevent or postpone the weed resistance development. The occurrence of weed species, which could have been otherwise reliably destroyed by the herbicides applied, shall be monitored in the course of the field trials and subsequent monitoring of the experimental plots. The occurrence of such plants shall be recorded, and these plants after obtaining its seeds shall be tested for resistance in glasshouse conditions.

The monitoring of volunteers after the termination of the field trial shall be carried out on the actual experimental area including its margins and vicinity. On the experimental plot, where the GM maize was deliberately released into the environment, other crop than maize shall be planted during the subsequent year after harvest. Only such crops can be grown, which allow the monitoring of maize volunteers. The adventitious presence and detection of volunteers shall be recorded, and such plants removed according to well-established agricultural practice. During the course of the field trials all the non-standard situations shall be monitored within the scope of the planned agronomic assessment, and monthly during vegetation season in the subsequent year after the harvest of the field trial. The monitoring shall last until the year 2012.

After the end of the monitoring the Ministry of the Environment shall be notified in written on its course and results. This report shall be elaborated in compliance with the Act and the Commission Decision 2003/701/EC.

Validity

This Consent shall apply for a period from **2009** to **2011**.

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

Within 15 days from the date of the notification of this Decision there is an opportunity by the submission to the Ministry of the Environment, Vršovická 65, 100 10, Praha 10, make representations to 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 will decide.

Ing. Pavel Forint
Department Director

This decision shall be received by:

- A. Participant in the proceedings for personal delivery:
MONSANTO ČR s.r.o., Londýnské sq. 856/2, 639 00 Brno
- B. For information:
 - 1. Ministry of Health
 - 2. Ministry of Agriculture