Ministry of the Environment
Environmental Risks Department

The Decision came into force on 28 April 2009.

Prague, April 22, 2009
According to Reference Number: 1784/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 Syngenta Czech, s.r.o., located in Nové Butovice, Bucharova 1423/6, 158 00 Praha 13, for granting consent for the deliberate release into the environment of genetically modified (GM) maize – Bt11 x MIR162 x MIR604 x GA21, Bt11 x MIR604 x GA21, Bt11 x GA21, MIR162 and MIR604 in the Czech Republic, pursuant to § 5 par. 8 of the Act:

Company Syngenta Czech, s.r.o.,

Nové Butovice,

Bucharova 1423/6,

158 00 Praha 13

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

for the deliberate release

of genetically modified maize Bt11 x MIR162 x MIR604 x GA21, Bt11 x MIR604 x GA21, Bt11 x GA21, MIR162 and MIR604

into the environment in the Czech Republic

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

Authorised person

Name: Syngenta Czech, s.r.o.

Address: Nové Butovice, Bucharova 1423/6, 158 00 Praha 13

Identification Number (IČO): 45146365

Specification of the genetically modified organism

According to § 18, par. 3 of the Act, the company Syngenta has submitted an application for granting the consent for performing small-scale field trials with genetically modified maize lines Bt11 x MIR162 x MIR604 x GA21, Bt11 x MIR604 x GA21, Bt11 x GA21, MIR162 and MIR604 for research purposes.

Following hybrids of genetically modified maize will be used:
the stacked maize hybrid Bt11 x MIR162 x MIR604 x GA21
the stacked maize hybrid Bt11 x MIR604 x GA21
the stacked maize hybrid Bt11 x GA21
the maize line MIR162
the maize line MIR604

The GM maize hybrids Bt11 x MIR162 x MIR604 x GA21, Bt11 x MIR604 x GA21, Bt11 x GA21, MIR162 and MIR604, which have been described in the application, were produced by crossing insect resistant Bt11, MIR162 and MIR604 maize and GA21 maize which is tolerant to herbicide products containing glyphosate. There was no further genetic modification to produce the stacks. Therefore the stacks have characteristics of the events Bt11, MIR162, MIR604 and GA21.

- Event Bt11 maize produces a truncated protein Cry1Ab, for control of certain lepidopteran pests (European corn borer *Ostrinia nubilalis*), and a phosphinotricin acetyltransferase (PAT) protein that confers tolerance to herbicide products containing glufosinate ammonium.
- Event MIR162 maize expresses a Vip3Aa protein (indicated as Vip3Aa20) for control of certain lepidopteran pests, and a phosphomannose isomerase (PMI) protein, which acts as a selectable marker enabling the transformed plant cells to utilise mannose as the only primary carbon source.
- Event MIR604 maize produces a modified Cry3A (mCry3A) protein for control of certain coleopteran pests and a phosphomannose isomerase (MIR604 PMI) protein, which acts as a selectable marker enabling transformed plant cells to utilise mannose as a primary carbon source.
- Event GA21 maize produces a modified maize 5-enolpyruvylshikimate-3-phosphate synthase enzyme (mEPSPS) that confers tolerance to herbicide products containing glyphosate.
- The maize Bt11 x MIR162 x MIR604 x GA21 provides protection against certain lepidopteran and coleopteran pests, and tolerance to herbicide products containing glufosinate ammonium or glyphosate.

- The maize Bt11 x MIR604 x GA21 provides protection against certain lepidopteran and coleopteran pests, and tolerance to herbicide products containing glufosinate ammonium or glyphosate.
- The maize Bt11 x GA21 provides protection against certain lepidopteran pests and tolerance to herbicide products containing glufosinate ammonium or glyphosate.

The maize hybrids Bt11 x MIR162 x MIR604 x GA21, Bt11 x GA21, MIR162 and MIR604 produce the transgenic proteins inherited from single GM maize events (event Bt11: Cry1Ab, PAT, event MIR162: Vip3Aa20, PMI, event MIR604: mCry3A, PMI, and event GA21: mEPSPS):
- a truncated Cry1Ab protein for control of certain lepidopteran pests such as the corn borers (*Ostrinia nubilalis* and *Sesamia nonagrioides*) that are common maize pests in Europe.
- a phosphinotricin acetyltransferase (PAT) protein that confers tolerance to herbicide products containing glufosinate ammonium.
- a modified Cry3A (mCry3A) protein for control of certain coleopteran pests, e.g. Western corn rootworm (*Diabrotica virgifera virgifera)* that is a maize pest recently accidentally introduced into Europe where it is now spreading quickly.
- a phosphomannose isomerase (PMI) protein which as a selectable marker enables the transformed plant cells to utilise mannose as the carbon source, while without this protein the maize cells stop its growth.
- a modified maize 5-enolpyruvylshikimate-3-phosphate synthase (mEPSPS) enzyme that confers tolerance to herbicide products containing glyphosate.

Specification of the genetic modification

The insertion of allochthonous hereditary material:
The maize Bt11 has been developed through the system based on transformation and regeneration of protoplasts. The *Not*I restriction fragment from the plasmid pZO1502 derived from the plasmid pUC18 was used for the transformation. The fragment *Not*I contains a truncated Bt gene, which was derived from the *Bacillus thuringiensis cry1Ab* gene, as well as *pat gene* from *Streptomyces viridochromogenes* coding phosphinotricin acetyltransferase. The fragment *Not*I does not contain a gene *amp E.coli* that is presented in pZO1502, and confers resistance of bacterial cells to ampicillin.

The maize MIR162 was produced by transformation of immature maize embryos derived from a proprietary *Zea mays* line via *Agrobacterium tumefaciens*-mediated transformation. The plasmid pNOV1300 was used for the transformation. The sequence intended for the insertion contains a gene *vip3Aa19*, which is a modified version of the native gene *vip3Aa1* from *Bacillus thuringiensis*, and also contains the *pmi* gene from *E. coli, which* encodes the selectable marker, phosphomannose isomerase. The backbone sequences from transformation plasmid are not intended for the insertion. After insertion into the plant, the *vip3Aa19* gene from pNOV1300 was designated *vip3Aa20,* the encoded protein was designated Vip3Aa20.

The maize MIR604 was produced by transformation of immature maize embryos derived from a proprietary *Zea mays* line via *Agrobacterium tumefaciens*-mediated transformation. The vector pZM26 was used for the transformation. The sequence intended for the insertion contains a modified gene *cry3A (mcry3A)* from *Bacillus thuringiensis*, and contains also a *pmi* gene from *E. coli, which* encodes the selectable marker, phosphomannose isomerase. The backbone sequences from transformation plasmid are not intended for the insertion.

Event GA21 was produced through microprojectile bombardment, using plasmid pDPG434, derived from pSK vector, which is commonly used in molecular biology and is derived from pUC19 plasmid.

Risk assessment results

The assessment of possible immediate or delayed effects on the environment related to the direct or indirect interactions between GM maize and target or non-target organisms was carried out in accordance with the Annex II of the EU Directive 2001/18/EC. For the risk assessment the available up to date scientific information was used. The risk assessment was carried out in accordance with the EFSA Guidance document for the risk assessment of genetically modified plants and derived food and feed (EFSA, 2006), and with the Guidance Document for the risk assessment of genetically modified plants containing stacked transformation events (EFSA, 2007).

The field trials with **Bt11** maize have been carried out in the EU since the year 1994 in Spain, France, Italy, Portugal and Romania. The notification for the placing on the market of Bt11 maize including the cultivation in the EU was submitted in May 1996 pursuant to the approved Directive 90/220/EEC as amended by the Directive 2001/18/EC, and it is still in the pipeline. The EFSA issued a positive opinion regarding this notification for the cultivation of Bt11 maize on April 20, 2005 (EFSA 2005), and confirmed its opinion in November 2008.

The field trials with **MIR604** maize have been carried out in the EU in Spain, France and Romania. The EFSA assesses the application on the authorisation of **maize MIR604** for food and feed uses, import and processing submitted within the framework of Regulation (EC) No 1829/2003.
The field trials with GM maize **MIR162** have not been previously carried out in the EU, but the company has conducted field trials in the USA. Both import and use of the maize MIR162 have not been yet realised in the EU.
The field trials with the maize **GA21** have been realised in certain European countries: Czech Republic, Denmark, Spain, France, Sweden and Romania.

Notification:
The maize GA21 is authorised for the import and placing on the market as food or feed in the EU pursuant to Regulation (EC) 1829/2003 by the Commission Decision 2008/280/EC. An application for granting consent to all uses of GA21 maize including the cultivation was submitted by Syngenta in accordance with articles 5 and 17 of the Regulation (EC) No. 1829/2003 on June 30, 2008.
The field trials with the maize **Bt11xMIR604xGA21** and **Bt11xGA21** have been running in Spain and Romania.
No negative effect on the environment or human health in consequence of these field trials was recorded.

The risk assessment of small-scale field trials with maize provided no significant evidence that GM maize Bt11 x MIR162 x MIR604 x GA21, Bt11 x MIR604 x GA21, Bt11 x GA21, MIR162 and MIR604 would cause in given conditions any adverse effects to the environment. This is substantiated with facts as follows:
- The maize is non-invasive species occurring in nature and having no wild relatives in Europe, with which it could cross-pollinate and create hybrids at the place of occurrence.

Therefore the cross-pollination of the maize Bt11 x MIR162 x MIR604 x GA21, Bt11 x MIR604 x GA21, Bt11 x GA21, MIR162 and MIR604 with wild species is impossible.
- The cross-pollination of the maize Bt11 x MIR162 x MIR604 x GA21, Bt11 x MIR604 x GA21, Bt11 x GA21, MIR162 and MIR604 with the conventional maize varieties is possible theoretically, but the location and the way of carrying out of field trials will ensure that this risk will be minimized.
- After the end of the field trials all remaining plant material should be destroyed so that no genetically modified maize will enter the food chain, and in the subsequent year all volunteers should be uprooted during monitoring process. The risks from the exposure of people and animals to the genetically modified maize Bt11 x MIR162 x MIR604 x GA21, Bt11 x MIR604 x GA21, Bt11 x GA21, MIR162 and MIR604 used in field trials are negligible.
- Many field trials have been conducted with the maize Bt11 x MIR162 x MIR604 x GA21, Bt11 x MIR604 x GA21, Bt11 x GA21, MIR162 and MIR604, and no adverse effects on human or animal health have been reported yet.
- The maize Bt11, MIR604 and GA21 as well as Bt11 x MIR604 x GA21 and Bt11 x GA21 are authorised to be placed on the market and used as food and feed in the USA and Canada. No adverse effects on human health have been ever reported.

The maize plants containing the genes above mentioned have no other plus or selective advantage in relation to “common, non-GM” maize plants than just resistance to a herbicide contaning an active ingredient glyphosate or ammonium glufosinate and protection against certain lepidopteran and coleopteran pests.

Due to measures that will be in place during the deliberate release into the environment for field trial purposes (using protective buffer zones, insulation distances from conventionally cultivated maize varieties, monitoring for presence of maize volunteers in subsequent year) the potential gene escape by cross-pollination or seed will be practically excluded. The interaction of GM maize with non-target species and consequent effects are supposed to be comparable with currently cultivated varieties. No human toxic or allergic reactions are expected. The measures taken (according to the field trial practice) will ensure a partial protection against damages of experimental plots caused by animals or people. Moreover, the safe handling with seeds and plant material shall be ensured (harvesting, storage, transportation and liquidation) in order to minimize the risk of contact with human or animals.

Since the supposed result of modification is an increased resistance to insect and tolerance to herbicides, there is no evidence or reason to assume that the reproduction and dissemination will be influenced. The results of previous field trials conducted with the maize Bt11, MIR604, MIR162 and GA21 have shown that the genetically modified lines do not differ from recipient plant in the manner and speed of reproduction either.

On the grounds of previous field trials with the maize Bt11, MIR604, MIR162 and GA21 it may be stated that there is no evidence that genetic modifications influenced the survivability.

No direct effects on human health of the GM maize is expected, which is supported by facts as follows:
- No GM plant material will be used as food or feed. Many field trials have been conducted with the maize Bt11, MIR604, GA21 and Bt11 x MIR162 x MIR604 x GA21, Bt11 x MIR604 x GA21 and Bt11 x GA21 to date, and no adverse effects on human have been observed.
- The recipient organism, maize, has a long history of safe use throughout the world.

- No gene sequences or donors thereof are known to be pathogenic for human, and no pathogenic sequences were introduced as well.
- None of the proteins Cry1Ab, PAT, Vip3Aa20, PMI, mCry3A, MIR604 PMI and mEPSPS show any aminoacid sequence homology with known mammalian peptide toxins.
- The proteins Cry1Ab, PAT, Vip3Aa20, PMI, mCry3A, MIR604 PMI and mEPSPS are not likely to be allergenic.
- The acte oral toxicity studies does not revealed an indication of acute toxicity of some of these proteins.
- The agronomy and compositional analysis of the plants of maize Bt11, MIR162, MIR604 or GA21 with their isogenic, non-GM counterparts or conventional maize lead to the conclusion that these GM plants are substantially equivalent to conventional maize.

In conclusion it may be stated that immediate or subsequent effects on human health, related to the potential direct and indirect interactions of genetically modified plants described in the application with persons working or coming into direct contact with it, and occurring in close vicinity of it, do not pose increased risk in comparison with non-GM maize.
The Bt11 maize was repeatedly assessed by the scientific panel of the European Food Safety Authority (EFSA) on 19 January 2005, 20 April 2005, 7 November 2006, and finally on 29 October 2008. The opinion was positive in all cases, which means that it is unlikely that this event will have adverse effects on human and animal health or the environment. The similar opinion was adopted by the EFSA on 13 September 2007 when assessing genetically modified maize GA21. Therefoe these two events used for hybridisation can be considered as proved in the context of the placing on the market as well.
The maize MIR604 expresses a modified protein Cry3A (mCry3A). The gene contains a specific promotor from maize, which provides root-preferential expression. It is analogous to MON 863 containing cry3Bb1, which the EFSA identified as hazardless on April 2004. The marker gene is phosphomannose isomerase. This marker gene is also present in a line MIR162 with the transgene vip3Aa1 from bacteria *Bacillus thuringiensis*. It is a protein (a product of the above mentioned gene) acting in the digestive tract only in the presence of specific receptors. Therefore its effect is limited to the insect, which eat the plant tissue, and has these receptors. For that reason its risk for non-target organisms is minimal.
At present the application for import and processing of the maize Bt11 x MIR604 x GA21, Bt11 x MIR604, Bt11 x GA21, MIR604 x GA21 and MIR604 as food and feed under the Regulation (EC) No 1829/2003 is assessed by EFSA. The genes and vectors used, which structure is given in the application, have not sequences that make a reason for doubt about the safety thereof. The origin of the inserted genes does not make doubt as well.

Conditions for the use

Genetically modified organisms above mentioned shall be used only in the way described in the request Ref. No. 1784/ENV/09 submitted to the Ministry of the Environment on January 12, 2009, and supplemented by the submissions of January 20, 2009 and March 16, 2009, provided that all given conditions have been met, particularly as follows:
- Every handling with the genetically modified material shall be under conditions minimising a possibility of transgene escape into the environment.
- The manipulation of the maize Bt11 x MIR162 x MIR604 x GA21, Bt11 x MIR604 x GA21, Bt11 x GA21, MIR162 and MIR604 shall be located at the place of cultivation.
- The principles of good agricultural practice shall be adhered to the plan for minimisation of possibility of weed resistance development to glyphosate.

- The personnel involved in the field trial with GM maize shall keep the rules of occupational health protection. All the rules for setting the field trial, its treatment during vegetation season and harvesting, including the postharvest treatment and transportation of genetically modified organism pursuant to the Act No. 78/2004 Coll. as later amended and pursuant to an implementing Decree, shall be kept.
- Every staff member shall clean his working clothes or protective means after finishing work.
- The accredited courier from abroad shall transport the seeds intended for sowing by car in prescribed packaging (double-ply paper sacks inserted into bigger textile sacks, and these ones inserted into metal boxes labelled with notice GMO) to all the co-operating workplaces (VÚRV Praha, ZVÚ Kroměříž, VÚP Troubsko and NUTRIVET Pohořelice).
- The responsible trained personnel staff in all workplaces shall than just before sowing ensure the transportation to the experimental plot. The seed properly checked shall be on the sowing date transported in the safe way under valid regulations to the plot. When unloading the seeds on the plot the packaging shall be again checked according to sowing plan.
- The seeds shall be taken out of the packaging directly at the experimental plot, and the small-plot sowing machine shall be used for sowing without residuals.
- After the end of sowing all the subjects (with participation of the representative of the company Syngenta if appropriate) shall carry out on-site control of the sowing machine, and potential remains of the seeds shall be mechanically removed, all the seed remains shall be mechanically crushed and applied into soil between rows (the calcium cyanamide will be applied, which will speed up biomass degradation) and ploughed under in order to prevent it from getting into food or feed chain.
- The used machinery can leave the experimental place only after carrying out control whether no seed remains occur.
- For buffer strips the similar hybrids as GM maize hybrids with regard to genetic background are supposed, which means the similar maturity and growth.
- Every co-operating workplace using the genetically modified maize shall keep record in the Field trial diary (in written and electronic form) with precise records on all plant materials, working operations, state of vegetation and other changes that could have the impact on the environment.
- The personnel must not give GM material to third parties with the exception of purposes following from the contractual relations.
- All the personnel have a duty to keep all measures taken according to operational rules of particular workplaces when using the GMO.
- Record shall be kept of transportation, delivery of seeds, sowing of the field trial, and destruction of seeds.
- Plots on which the field trial with genetically modified maize will be carried out shall be labelled at all corners with visible warning signs as follows: ATTENTION! GENETICALLY MODIFIED ORGANISM! NO ENTRY! NOT FOR FEED! CHEMICALLY TREATED! NEITHER FOR FOOD OR FEED!
- The tested lines of maize shall be used only for field trials and professional analysis. The grain produced shall be used for analyses or harvested, weighed and its viability destroyed by crushing.
- The harvesting of maize grain of tested maize lines shall be carried out by small-plot combine harvester and in case of the composite part of the field trial by hand sampling. The part of plants (see Methodology for composite field trial) shall be harvested manually directly on the field.
- The grain samples (the chopped above ground parts of plants if appropriate) shall be packed on the field into double-ply paper packaging, labelled with the notice GMO, unique identification code and an appropriate sticker. The samples shall be transported from the field

in a safe way to the workplace, dried and stored until transportation abroad for further analyses. For the transportation abroad the samples shall be furthermore placed into metal containers. The delivery of samples shall be realised on the ground of the delivery protocol. On the field the machinery shall be cleaned, and checked for the remains of GM maize.
- The samples shall be transferred by personnel trained for transport of GMO and possible accidents of co-operating subjects to the workplace for drying, where they are stored and subsequently delivered in properly labelled packaging to the authorised carrier (World Courier Prague) for the transport to Syngenta abroad.
- All special packaging and stickers for labelling of particular samples will be provided and sent by the company Syngenta to the individual workplaces.
- The delivery protocol containing the list of all samples shall be elaborated for every delivery of samples.
- The harvested grain shall be weighed, subsequently crushed, dispersed on field surface and ploughed under. Any remains of grain or other plant material shall be chopped (the calcium cyanamide will be applied, which will speed up biomass degradation) and ploughed under on the experimental plot in order to prevent it from entering the food or feed chain. All remaining plant parts and grain which is not used for analyses shall be destroyed directly on the field by crushing and chopping, and subsequently ploughed under on the spot so that nothing can enter the food or feed chain.
- In case of unexpected spillage of seeds outside the places dedicated to manipulation with GMO such place shall be marked with a band, and all seeds shall be gathered up and placed into lockable packaging labelled with notice: “Genetically modified organism”, “Not for cultivation”, and transported to the place of destruction (the experimental plot). The entry of trespassers shall be prevented.
- After the seeds are gathered up and placed into the labelled packaging the place should be located and mapped so that it could be subsequently monitored on possible maize seedling emergence. The spilled seeds (or other parts of transgenic plants) outside of the experimental area and dedicated manipulation area could be removed by ordinary means (vacuum cleaner, shovel, broom), and the seeds could be used under the plan or destroyed by combustion at a designated place.
- If any seeds would incidentally grow, they should be destroyed by suitable means (mechanically or by spraying with any non-selective herbicide different from glyphosate and glufosinate) according to local conditions. This shall go on record plus the local competent environmental body and the Ministry of the Environment should be informed about this event and measures taken.
- In case of fire the particular workplaces have elaborated the Fire Control Set of Rules, Fire Alarm Directive and Fire Alert Plan, which must be followed.
- 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.
- In transportation the empty sacks for gathering of seeds and the suitable equipment (broom, shovel) should be loaded just in case of an accident.
- In the subsequent vegetation season the other crop than maize shall be cultivated on the particular place and it shall be monitored for the presence of volunteers. All the volunteers shall be destroyed in early phase of development before entering of plants to the generative stage.
- If 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 for the consent to carry out such experiments.
- 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 the 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 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 where 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 SYNGENTA, 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. So far no such occurrence has been observed in the realised field trials.
- 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 within 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 under § 5 par. 10 of the Act

- Every year at least 30 days before the plot is planted with GMOs the applicant shall notify the Ministry of the environment of information on deliberate release into the environment, plots where it will be carried out and about amendments in the original request (point 7 and following, part B of the Annex No. 2 of 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, in addition to that buffer strips shall be used sown with 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 field trial will begin with sowing seeds (not earlier than in April) and will finish by harvesting when the maize grain reaches the physiological maturity (in November at the latest).

- At 3 locations (VÚRV Praha, ZVÚ Kroměříž, VÚP Troubsko), where agronomic and composite trials are planed, the area with this genetically modified maize shall not exceed 2,000 m^2 per location, with maximum number of GM plants of 18,000 per location.
- At the 4th location (NUTRIVET Pohořelice), where the efficacy type of field trials is planed, the area shall not exceed 1,000 m^2, with maximum number of GM plants 9,000.
- The total area of all locations for cultivation of GM maize shall be no bigger than 7,000 m^2, with maximum number of GM plants 63,000.
- Next year after the cultivation of GM maize the other crop than maize shall be cultivated on the whole area of the experimental plot. If GM volunteers occur it shall be eliminated in a subsequent crop by herbicides that do not contain either glyphosate or ammonium glufosinate.
- The applicant shall in compliance with § 19 letter h) 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 submitting 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

The field trials have been suggested to obtain information and plant material of modified and non-GM maize under standard agronomic conditions, and to carry out analyses of grain and silage. The aim of field trials is to gather as wide as possible set of data on agronomic characteristics in Czech and European conditions and production of maize grain for comparative analyses, and to obtain further information on its efficacy against target pests in Czech conditions. At the same time, the potential effects on the environment, particularly effects on non-target organisms. Therefore the small-scale field trials will be located at various places in the Czech Republic. The genetically modified maize will be cultivated under conditions of the good experimental practice.
1) the field trial at three locations (*VÚRV Praha – Ivanovice na Hané station, ZVÚ Kroměříž, VÚP Troubsko)* consists of two partial stages – composite and agronomic.
2) the field trial at the fourth location (NUTRIVET *Pohořelice*) will be conducted as the efficacy experiment concerning performance of stacked maize hybrid Bt11 x MIR604 x GA21 and Bt11 x GA21 with escalating dose of fungicide seed treatment CRUISER (350 g/l of Thiamethoxam) and insecticide FORCE (15 g/kg of Tefluthrine) in comparison with conventional non-GM maize related to target pests in Czech conditions.

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 unique identification code (according to OECD database, Biotrack), if any has been assigned to those transgenic events:
- the unique identification code for Bt11: **MON-89Ø34-3.**
- the unique identification code for GA21: **MON- ØØØ 21-9.**

Place of the deliberate release into the environment

The field trials will take place at 4 locations always during the time period from April to November.
The size of all the field trials with genetically modified (GM) plants will not exceed 7,000 m^2 altogether (it means three locations per 2,000 m^2 and one location with 1,000 m^2). It will be sown no more than 63000 plants of GM maize altogether (it means three locations per 18,000 plants and one location with 9,000 GM plants).
1/ VÚRV Praha – experimental station Ivanovice na Hané:
Cadastral territory and parcel number – Ivanovice na Hané, land block No. 3101/1(square 560-1150).
2/ ZVÚ Kroměříž
Cadastral territory and parcel number – Jarohněvice, plot No. 260 and 261, land block 2705/1R.
3/ VÚP Troubsko
Cadastral territory and parcel number – Popůvky, plot No. 709/1, land tract 2002/5.
4/ NUTRIVET Pohořelice
Cadastral territory and parcel number – Pohořelice nad Jihlavou, square No. 600-1180, land block 8401.

Requirements for monitoring and reporting of monitoring results

The monitoring plan is based on the results of the risk assessment related to the environment, and its objective is to early observe and identify the events, which can have expected or non-expected consequences of the deliberate release of genetically modified maize plants into the environment.
The common characteristics of the plants Bt11 x MIR162 x MIR604 x GA21, Bt11 x MIR604 x GA21, Bt11 x GA21, MIR162 and MIR604 related to agronomic behaviour will be monitored and recorded in accordance with given methodologies. The occurrence of pests and diseases will be, managed by standard procedures, kept at the lowest level.
The company SYNGENTA 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 the subsequent year and general surveillance of any adverse effects, related to the use of GM maize.
The monitoring will be carried out at the place of the experimental deliberate release into the environment in VÚRV (Ivanovice), ZVÚ Kroměříž (Jarohněvice), VÚP Troubsko (Popůvky) and NUTRIVET Pohořelice pursuant to the plans of particular workplaces.
The personnel of the company Syngenta, which are responsible for the project, and the trained personnel of co-operating worklplaces according to the internal Syngenta´s methodology, shall carry out all agro technical measures, treatment during vegetation, observations, assessment and harvesting. Every subject shall keep record in the field diary (available shall be also in electronic form), where all necessary data shall be recorded as well as entries into the vegetation.
The observation during the deliberate release into the environment
Minimally once a month the monitoring of every respective plot shall be carried out over the course for the whole of the deliberate release into the environment during a vegetation season.
The field diaries shall be filled in regularly during the whole period of the deliberate release into the environment. The behaviour of genetically modified maize shall be compared with the behaviour of a recipient (which will be cultivated at the same experimental plot simultaneously). The information concerning unexpected consequential events (potential

adverse effects on the environment and human health) shall be immediately notified to the Ministry of the Environment and relevant authorities, and suitable measures taken according to circumstances.
In case of the seed (grain) spillage on the agricultural land the place shall be after elimination of the seed spillage also monitored on possible maize seedling emergence. If any seeds incidentally grow, they should be removed and destroyed by suitable means.
In case the elimination of the seed spillage will have to be carried out in contained spaces, after finishing it another responsible person shall perform monitoring and eventual destruction of individual grains.
The observing after deliberate release into the environment
In the subsequent year after harvest no maize shall be cultivated on the experimental plot where the GM maize was released into the environment. Only such crops shall be cultivated which allow monitoring of volunteers. Monitoring of volunteers shall be carried out in two-month intervals in the year following the experimental deliberate release into the environment. The potential occurrence of volunteers shall be recorded and particular individuals destroyed.
As some GM materials (MIR162) are deliberately released into the environment in the Czech Republic as well as in the EU for the first time, the non-specific monitoring of the volunteers occurrence shall be realised not only on particular experimental plot including its margins but also in close vicinity of planting areas.
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. In the course of the field trials and also of the subsequent monitoring the occurrence of weed species, which should be otherwise destroyed by used herbicides, shall be monitored. The occurrence of such plants shall be recorded, and these plants after obtaining its seeds shall be tested for resistance in glasshouse conditions.
The overall duration of the monitoring will be until the year 2013.
After finishing of the monitoring the written report on the course and results shall be submitted to the Ministry of the Environment.

Validity

This Consent shall apply for a period from **2009** to **2012**.

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:
Syngenta Czech, s.r.o., Nové Butovice, Bucharova 1423/6, 158 00 Praha 13

B. For information:
1. Ministry of Health
2. Ministry of Agriculture