Post-market Monitoring of GM Crops in the Czech Republic

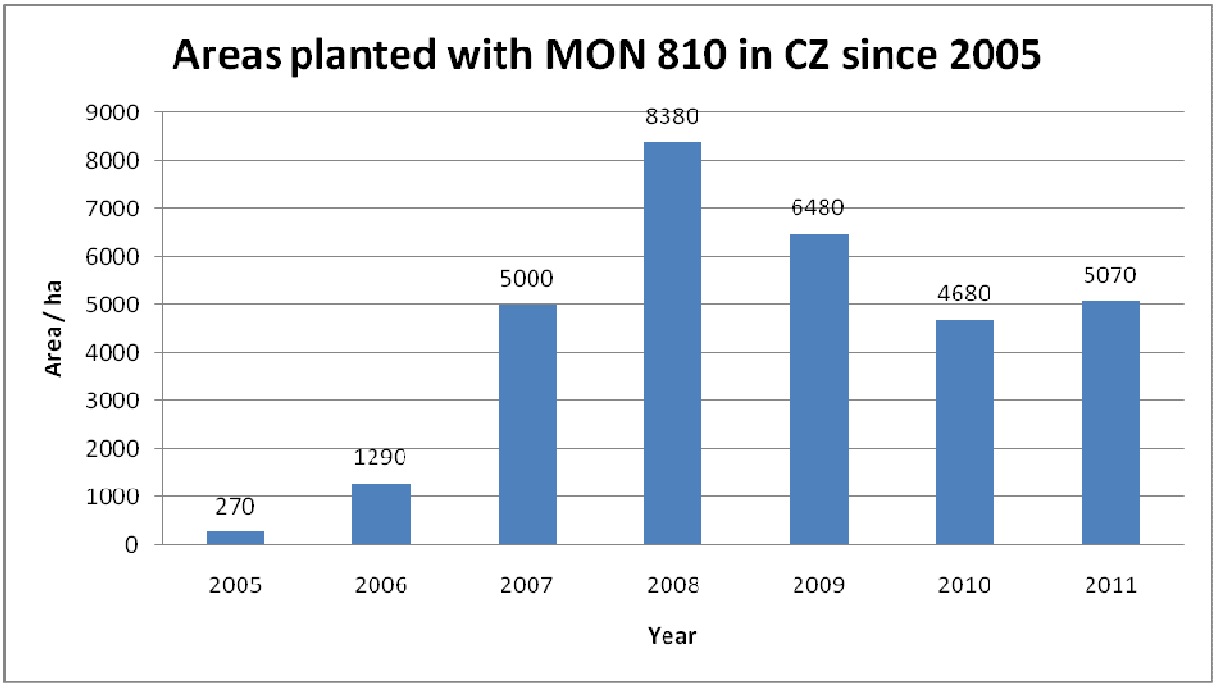
1. Background

1.1. Commercial cultivation

The Competent Authorities keep lists of growers and locations where GM crops are grown. Maps of the fields are available to the Authorities, Regional Agricultural Agencies and to farmers in the Land Parcel Identification System (LPIS).

Maize:
Following the registration of MON 810 varieties into the European seed catalogue this maize was commercially cultivated for the first time on 270 ha in 2005. Within the next three years the field area of GM maize increased to 8380 ha in 2008. In 2009, the area sown with the GM maize decreased for the first time by ca 22 % to 6480 ha. This trend continued in 2010, when MON 810 was cultivated on 4680 ha. A minor increase has been recorded this year as the cultivated area reached to 5 070 ha sown by 63 farmers and institutions (including variety testing conducted by the Central Institute for Supervising and Testing in Agriculture).

Note: Reasons for the decrease of GM maize cultivation since the peak year 2008 could be economical (more expensive seed) plus the experienced troubles with placing the production on the market (some food processors and big retailers require GM-free food/feed chain), together with administrative demands connected with GM production (separation, labelling, record keeping). In the regions where infestation of the corn borer does not present a significant problem, farmers have got back to non-modified varieties.



Potatoes:
GM potato Amflora (EH92-527-1) with increased accumulation of amylopectin starch in tubers was cultivated on 150 ha in the Czech Republic in the season 2010. The tubers have been processed to starch for industrial use tests. Due to problems with comingling with unauthorised GM potatoes in previous years and consequent lack of seed tubers for season 2011, BASF (the consent holder) decided to not cultivate Amflora this year in the Czech Republic. No cultivation is intended for 2012 for the same reason.

1.2. State Administration

The Competent Authority under Directive 2001/18/EC is the Ministry of the Environment of the Czech Republic.
The Ministry of the Agriculture of the Czech Republic is the Competent Authority under Regulation 1829/2003 on genetically modified food and feed. It also sets down the rules of coexistence.
Supervison Authorities:

- Central Institute for Supervising and Testing in Agriculture (CISTA) is in charge of variety registration, certification and inspections of seeds and feed;
- State Phytosanitary Administration (SPA) is responsible for phytosanitary care. Regarding GMO it monitors the biological efficiency of Bt-maize and supervises the compliance with coexistence rules;
- Czech Agriculture and Food Inspection Authority (CAFIA) is in charge of food supervision. Regarding GM food it supervises the correct labelling and detects unauthorised admixtures of GM material;
- Czech Environmental Inspectorate (CEI) is in charge of nature protection etc. Regarding GMOs it supervises their use in general, including transport, and inspects field trials with GM plants;
- Custom Authorities are in charge of import and export supervision.
- Certified laboratories, members of ENGL, are in charge of GMOs detection in samples collected by CAFIA and CEI inspectors.

2. Post-market Monitoring

The objective of post-market monitoring is to identify any direct or indirect, immediate and/or delayed adverse effects of GMOs, their products and their management, to human health or the environment, after the GM crop has been placed on the market. Case-specific monitoring should confirm that any assumptions regarding the occurrence and impact of potential adverse effects of the GMO or its use are correct. General surveillance should identify the occurrence of any adverse effects of the GMO or its use on human health or the environment which were not anticipated in the environmental risk assessment.

Due to limited financial and personal capacities, the Czech Authorities focus mostly on general surveillance of commercial GM crops, using the established surveillance networks and practices such as monitoring of agricultural plants, variety/seed registration, plant health and environmental observations.

2.1. Case-specific monitoring of MON810

The case-specific monitoring of MON810 is focused on interaction between GM plant and target organisms:

- development of resistance in pest populations,
- development of secondary pests.

According to Act. 326/2004 Coll. on phytosanitary care, the State Phytosanitary Administration observes the efficiency of GMOs used in plant protection. Annual reports summarise the results of monitoring Bt maize with resistance to European corn borer (*Ostrinia nubialis*) MON 810.

SPA uses its own methodology for the monitoring of efficiency of Bt maize by testing for potential resistance development in corn borers. The finding in Bt maize is evaluated as positive when the finding of cutworm of European corn borer was detected on infected plants and officially confirmed and when the Bt toxin inside the infected plant was confirmed by the consequent laboratory test.

Result: there has been no evidence of resistance development in ECB so far, nor any significant development of secondary pests on GM fields.

2.2. General surveillance of MON810

The general surveillance includes observation of:

- changes in fitness, survival and dissemination of GM plants,
- interaction between GM plant and non-target organisms, e.g. direct/indirect impact on non-target organisms, changes in susceptibility to non-target pests and diseases;
- impact on habitat diversity and biodiversity, including surrounding area,
- and others.

The State Phytosanitary Administration, Central Institute for Supervising and Testing in Agriculture and Czech Environmental Inspectorate observe potential effects of cultivation of GM maize as a part of their general activities (phytosanitary care, agricultural supervision, nature protection etc.). The Ministry of Environment is currently identifying environmental programmes that can be used for the general surveillance as well.

Result: no adverse effects of Bt maize cultivation have been identified so far.

2.3. General surveillance of Amflora potatoes in 2010

As 2010 was the first season of Amflora commercial cultivation, supervision by the Authorities was much stricter than controls of conventional potato fields.

The Central Institute for Supervising and Testing in Agriculture supervised the seed tubers, planting and cultivation:

- Seed tubers were checked, sampled and the ELISA test was carried out according to Council Directive 2002/56/EC of 13 June 2002 on the marketing of seed potatoes;
- After planting, compliance with co-existence rules was checked (isolation distance from conventional potato fields, notification of the fields to the Authorities);
- Visual inspection of the fields was performed when the plants reached average height of 20 cm;
- Photo documentation was taken during the inspections.

All results and findings were in compliance with the relevant legislation.

Neither the Authorities nor the Czech growers noticed any off-types nor other signs of unusual aberrations.

The harvest of Amflora fields proceeded under the supervision of CISTA and the transport and storage of Amflora tubers was supervised by the Czech Environmental Inspectorate. The field will be checked for volunteers in 2011.

2.4. Results

Neither negative impact on non-target organisms nor any other negative effects of commercial cultivation of the authorised GM crops have been reported.

2.5. Costs of monitoring

The costs of PMEM carried out by the Authorities are completely born by the government (state budget). It is very difficult to estimate the total costs as the general surveillance is performed partly within other tasks of the Authorities listed above. However, with the cuts in the state budget it is to be expected that the resources for supervision and control will be further reduced.

2.6. Controls carried out on applicants PMEM

The applicant / consent holder conducts its PMEM independently on the monitoring done by the Authorities. The Authorities check the consent holder´s report after its finalisation and submission to the European Commission. The consent holder´s data and conclusions on PMEM are compared with the Authorities´ results. Consultations with the consent holder may follow in case of discrepancies or if clarification is needed.

3. Other Relevant Activities

3. 1. Coexistence

General rules on coexistence of genetically modified crops with conventional and organic farming are set by the amendment to Act on Agriculture and are complemented by case-specific measures for each GM crop by an implementing Decree. So far detailed requirements for maize, potatoes and soybeans (although no GM soybeans have been authorised for cultivation) have been established. Coexistence rules in the Czech Republic are valid for every farmer who grows (or intends to grow) GM crops. The obligatory measures are as follows:

- To inform neighbouring farmers about the intention to cultivate GM crop before sowing (for all three crops at the latest by 1st March of appropriate calendar year).
- To inform the neighbouring farmers (at the latest by 15 days after the beginning of their cultivation), Ministry of Agriculture (30 days time period) and Ministry of the Environment (60 days time period) about the real cultivation of GM crop after sowing.
- To keep a minimum isolation distance of GM crop from the same crop which is not genetically modified. More stringent rules are in place if an organic farmer is in the neighbourhood. The requested crop-specific minimum isolation distances are tabled below:

	potatoes	maize	soybean
Minimum isolation distance between GM and non-GM (conventional) crop of the same species	3 m; 10 m – at the edge of the field where the machines rotate	70 m	10 m
Minimum isolation distance between GM and organic crop of the same species	20 m	200 m	20 m

In case of GM maize, it is possible to reduce or substitute the minimum isolation distance by creating buffer strips, which consist of conventional maize planted around GM maize (1 row of conventional maize buffer substitutes 2 m of the minimum isolation distance). Conventional maize from the buffer zone must be handled and labelled as GMO.

- To label the final product of GM crop after the harvest as "Genetically modified organism" or "Genetically modified maize/potatoes/soybean", incl. the unique identifier, and to provide this information to the buyer/user of the final product.
- To keep a record of the basic data, which describe the handling of GM crop from sowing till harvest, on the farm for a period of minimum five years.

Based on the experience with GM crops cultivation, the Czech co-existence rules have proved to be relevant for keeping different agricultural systems workable and their products separated and avoiding unwanted mixing of these systems. On the other hand, the coexistence rules slightly hinder farmers from wider use of GMO technology in agricultural practice.
The Ministry of Agriculture, in cooperation with its regional agricultural agencies and the State Phytosanitary Administration, supervises the compliance with the coexistence rules. Inspectors check the isolation distances and buffer strips *in situ* every year and if appropriate, send samples of plants to control laboratories. In case of non-compliance with the rules, farmers can be penalized with a fine of up to 250 thousand Czech crowns (round 10 thousand EUR).
During 2005 – 2010, both targeted controls of the fields with Bt maize and random controls of food and feed were carried out. Only few cases of non-compliance with the rules were identified (no buffer strips sown). No positive findings (above the 0,9 % threshold) in harvested maize products were detected.
Although the objective of the supervision as regards coexistence measures is not the same as that of post-market monitoring, some observations done during the coexistence inspections could serve for the general surveillance of GM crops cultivation.

3. 2. Survey on farmers experience with Bt maize

The Ministry of Agriculture performed a questionnaire survey in 2006 – 2008 among Bt maize growers to evaluate the first three years of cultivation (2005 – 2007) as regarded the practical experience gained with the new technology.
Especially the following information was ascertained:

- Advantages and disadvantages of Bt maize growing;
- Use of Bt maize, possible problems with sales;
- Crop yields achieved with Bt maize in comparison with conventional hybrids;
- Level of fungal infection in Bt maize in comparison with conventional hybrids;
- Regular methods of treating conventional maize against ECB on the farm;
- Possible local effects of Bt maize cultivation on the environment.

The feedback from the farmers was very good, 90 % of them responded to the questionnaire.
Main observations on Bt maize cultivation:

- Reliable tool in control of the European corn borer;

- Better quality of GM maize products (less fungi, consequently less mycotoxins);
- Higher yields (on average by 7,5 – 9,5 %);
- More administrative and organisational demands;
- Increased profitability of maize production but problems with sale;
- Results of the technology locally and year-to-year dependent;
- Coexistence with other maize production is possible;
- Agricultural market is capable of regulating use of the biotechnological products itself on the basis of consumers' demand – there is no need for state restrictions;
- Real possibility of choice for producers and consumers;
- Lower environmental burden thanks to no chemicals insecticides;
- No negative effects on the environment observed.

The survey was published by the Ministry of Agriculture both in Czech and in English in 2010 both in printing and on the web:
http://eagri.cz/public/web/en/mze/agriculture/publications/bt-maize-cultivation-05-09.html

3.3. Relevant research projects

Study of selected factors influencing adventitious presence of GMOs and biodiversity in the context of coexistence of genetically modified, conventional and organic crops

The aim of the project is to look into technical possibilities of spatial isolation of genetically modified crops in the selected areas of the Czech Republic. Acquired data can be used when the Good Agriculture Practice dealing with the release and monitoring of genetically modified crops is being put in practice. Outputs of the project help to fulfil the legislative precautions and recommendations of the EU. Obtained input information on biodiversity of couch-grass in the monitored areas contributes to optimisation of agricultural systems and will reduce risks to environment. The project is also oriented on monitoring changes in farming practices on set of farms once GM crops are commercialised.

Keywords: GMO; risks; agricultural systems; biodiversity; *Elytrigia repens*; monitoring

Participants: Crop Research Institute Prague; Agrotest fyto, Ltd., Kroměříž

The production of quality and safe cereal products using different control strategies of maize and store products

The aim of the project is to obtain new knowledge for the reduction of mycotoxins occurrence in feed and food products from maize by the innovation of control strategies during maize growing and storage and to evaluate their influence on health of livestock. Four different control strategies of maize will be tested to ascertain their influence on the reduction of injury of maize caused by European corn borer, on the occurrence of toxigenic mikromycets and the content of mycotoxins in corn and silage.

Keywords: plant protection, mycotoxins; micromycetes; maize; wheat; barley; European corn borer, silage; transgenic Bt-maize, insecticides; Trichogramma; cattle, health, nutrition value; rumen process; milky efficiency; milk composition

Participants: Crop Research Institute Prague; Research Institute for Fodder Crops, Ltd. Troubsko; Research Institute for Cattle Breeding, Ltd. Rapotín; Biology Centre

of the Academy of Sciences of the Czech Republic, v. v. i.; České Budějovice; Institute of Chemical Technology, Prague

The methods of development and validation for effective application and control of GMOs in the agriculture and food production in order to fulfill EU legislation and national standards

Evaluation and validation of PCR methods and DNA arrays for GMO identification, co-existence rules protection, DNA-chip validation of preparing control materials for reference use.

Keywords: GMO methods; food control; co-existence

Participant: Crop Research Institute Prague

Insecticidal effect of the genetically modified crops: importance of allelochemicals and oxidative radicals

The project concerns possible impact of the genetic modifications (GM) on the natural crop defence against insect herbivores. Plants produce allelochemicals curbing insect digestion. Their degradation in the gut generates damaging oxidative radicals and the insects deploy several antioxidant systems for their elimination. The role of tannins, lignin, and endogenous alkaloids in the generation of radicals was examined in the potatoes expressing *Galanthus nivalis* lectin and *Bacillus thuringiensis* toxin Cry3Aa, respectively, and in the maize expressing toxin Cry1Ab. The growth, development, and reproduction was followed in two lepidopterans and in the Colorado potato beetle fed on the control and the GM plants and on semi-artificial diets supplemented with tested allelochemicals. Insect performance was correlated with the titer of oxidative radicals in the gut, the mode and intensity of their elimination, and the activity of digestive proteases.

Keywords: GMO; allelochemicals; oxidative radicals; antioxidant mechanisms; proteases; insect digestion

Participant: Biology Centre of the Academy of Sciences of the Czech Republic, v. v. i.; České Budějovice

The evaluation and prevention of environmental benefits and risks related to deliberate release of genetically modified crops in the Czech Republic

The project deals with the evaluation of environmental and ecological benefits and risks related to the deliberate release of genetically modified crops under conditions of the Czech Republic. Research is focused on hybridisation ant its consequences in crop plant –wild relative plant complex, study of biotic and abiotic factors influencing transgene persistence in the environment, influence of technological practices using GM crops on non-target organisms, and changes of weed composition in agrophytocenoses.

Keywords: genetically modified crops, GMO; rape; maize; sugar beet; beet; environmental risks; hybridisation; transgene persistence; non-target organisms, arachnofauna; weeds; crop-wild-weed complex; glyphosate; glufosinate; co-existence

Participants: Czech University of Life Sciences, Prague; Masaryk University Brno

Systems for sustainable cultivation of agricultural crop plants and production of high-quality and safe foodstuffs, feedstuffs and raw materials

The subject matter of the research plan is to support scientific development in the areas of plant production, phytopathology, stored products pest control, protection and use of natural resources, protection of biodiversity, genetics and molecular biology, plant breeding and seed science, agroecology, agrochemistry, plant physiology and nutrition, plant product quality and foodstuff and feedstuff safety. The objective of the research plan is to acquire knowledge supporting sustainable development of agriculture in the conditions of the Czech Republic concerning the available natural resources and landscape ecology by implementing innovations in the systems of agricultural plant cultivation and by safeguarding the production of high-quality, safe foodstuffs, feedstuffs and raw materials for energy and industrial use. The research outputs will help to meet the new requests placed on agricultural production, they will contribute to increased economic efficiency of soil management.

Keywords: research plan, research, plant production, phytopathology, stored products pest control, protection, use of natural resources, protection of biodiversity, genetics and molecular biology, plant breeding, seed science, agroecology, agrochemistry

Participant: Crop Research Institute Prague

Introduction of insect-resistant and herbicide-tolerant transgenic maize varieties in the Czech Republic, with respect to the biotic elements of agroecosystems

Project concerns influence of growing technologies of two types of genetically modified maize (insect-resistant and herbicide tolerant) on the diversity of associated organisms within agroecosystems in comparison with conventional technologies. In case of insect resistance, the occurrence of corn root worm, its natural enemies and important arthropod groups have been studied. In case of herbicide-tolerant maize varieties, the influence of growing technology on weed community, associate herbivores, and their predators have been observed. Results can be used as original information for both regulatory bodies and agricultural practice concerning conservation of non-target biodiversity within agroecosystems.

Keywords: corn root worm, arthropods, genetic modification, glyphosate, herbicide tolerance, maize, weed communities, natural enemies, insect resistance

Participants: Czech University of Life Sciences Prague; Crop Research Institute Prague; Biology Centre of the Academy of Sciences of the Czech Republic v. v. i.; České Budějovice

The effect of Bt maize on the entomofauna

The major objective of this study was to investigate potential impact of MON810 transgenic maize on the environment. Its commercial genetically modified hybrid cultivar YieldGard® carries a gene for a bacterial toxin Cry1Ab, which is known to act lethally on some Lepidoptera. To assess possible environmental impact the Bt and non-Bt maize were grown for the three successive years (2003-2005), each on 5 plots of 0.5 ha that were distributed checker-wise in a 14 ha field. Enzyme-linked immunosorbent assay (ELISA) was used to quantify the amount of Cry1Ab in the plants. Bt maize expresses consistently around 1 ppm Cry1Ab in leaves and stem and undetectable amounts in flowers and ears. The toxin provided full protection against the caterpillars of *Ostrinia nubilalis* (ECB); only adults, eggs, and first instar larvae were found. The abundance of aphids, thrips, ladybirds and lacewings were

recorded in every season on ten plants per plot (i.e. 50 plants in total) in two-week intervals. Evaluation of insect distribution on individual plants with EstimateS software revealed that analysis of 20 plants yielded 95% reliability of the results and 100% reliability was achieved with 36 plants. The results were evaluated for each sample date and finally for the entire experimental period. Obtained data showed that the species composition and their population densities changed in dependence on the date of collection, year, and plot, but were not affected by Cry1Ab. Some variations in insect communities could be explained by the temperature and precipitation differences from year to year.

Conclusion: The study revealed no significant negative effect of Bt maize on the plant dwelling non-target insects and on the epigeic beetles and spiders.

Participant: Biology Centre of the Academy of Sciences of the Czech Republic v. v. i.; České Budějovice

Research of GM maize hybrids resistant to insect pests and tolerant to non-selective herbicides in the Czech Republic regarding biotic compounds of agroecosystem

Project deals with influence of growing technologies of two types of genetically modified maize (insect resistant and herbicide tolerant) on the diversity of associated organisms within agroecosystems in comparison with conventional technologies. In case of insect resistance, the occurrence of corn root worm, its natural enemies and important arthropod groups are studied. In case of herbicide-tolerant maize varieties, the influence of growing technology on weed community, associate herbivores, and their predators will be observed. Results can be used as original information for both regulatory bodies and agricultural practice concerning conservation of non-target biodiversity within agroecosystems.
Ongoing activities: Field trials with maize MON 88017 that is resistant to the beetle Diabrotica virgifera virgifera and at the same time tolerant to the herbicide glyphosate. The purpose is to compare environmental impact of this GM maize, its non-GM isoline (treated or non-treated with the insecticide DURSBAN 10G (chlorpyrifos) as a preventive measure against D. v. virgifera), and two reference cultivars. The investigations started in 2009 and will be terminated in 2011. Each year, the content of the Bt toxin Cry3Bb1 is measured in various parts of the plants during the vegetation and all insects occurring on the plants are counted and identified.

Conclusions: ELISA test revealed that the expression of Cry3Bb1 toxin in maize MON 88017 was maximal in the root and leaves in both study years. Statistical analyses did not disclose any effect of maize MON 88017 on the composition and abundance of the non-target arthropods dwelling on the plants.

Keywords: Corn root worm, arthropods, genetic modification, glyphosate, herbicide tolerance, maize, weed communities, natural enemies, insect resistance

Participant: Biology Centre of the Academy of Sciences of the Czech Republic v. v. i.; České Budějovice

4. Conclusions

Recommendations based on gained experience:

- Key parameters, criteria for monitoring and indicators should be harmonised;
- Monitoring should be performed in a systematic and focused way;
- Results of monitoring at all levels should provide feedback to environmental risk assessment;
- Competent Authority (Ministry of the Environment) should coordinate the monitoring activities (conducted by agricultural and environmental authorities, networks). Due to the limited budget, information sharing and coordination is crucial for meeting the objectives of post-market monitoring;
- It is necessary to evaluate the whole technology (e.g. in case of herbicide-tolerant crops the change of agricultural practices, changes in overall use of the herbicide) and to perform monitoring in a complex manner;
- Base-line data is mostly not available, therefore it is difficult to identify / distinguish the impact of the technology *per se*. Other factors than cultivation of GM crops itself can often have even more significant impact on biodiversity (e.g. weather conditions, crop variety, various agricultural practices).

14 June 2011

Zuzana Doubkova, Dr. Hana Jirakova, Ministry of the Environment

contacts: Zuzana.Doubkova@mzp.cz, Hana.Jirakova@mzp.cz