MON810 Scientific Background Report

MON810 in a nutshell

MON810 is a variety of corn with a troubled history. In 1988 it was one of the first genetically modified plants to be allowed for cultivation in the European Community. In Europe, cultivation of MON810 takes mainly place in Spain. This corn variety, developed by Monsanto, produces its own insecticide, which is specifically directed against the European corn borer, a moth that can seriously damage the corn harvest. The most important advantage of MON810 is the increased harvest certainty: it is some kind of insurance for farmers. They pay a little more for the seed, but in exchange they have a higher certainty that the harvest will be successful. Moreover, farmers need to use fewer insecticides; this keeps costs down and further lowers the environmental impact of the crop.

Millions of tons of MON810 are harvested and consumed worldwide every year. Scientific research shows that MON810 does not have any harmful consequences on human health or on the environment. However, various EU member states have blocked its cultivation in their country. Why? Public opinion in various member states is still very opposed to the introduction of genetically modified crops. Politicians see blocking MON810 as a way of meeting the expectations of the public.

About this report

In this background report, VIB, a life sciences institute in Flanders, Belgium, gives an overview of the most recent scientific knowledge on MON810. VIB is a research institute with 1200 researchers, and has research groups at UGent, K.U.Leuven, Antwerp University, and the Vrije Universiteit Brussel. The Flemish government has given VIB the task of spreading information about biotechnology based on scientific data.

About the references

Next to each paragraph of this document you will find the references to the scientific publications from which the information was derived. Some of these publications can be downloaded in full, while others cannot be obtained free of charge. In this case, you can consult the author or search for the publication in your nearest university library.

What is MON810?

Corn with incorporated insecticide production

MON810 is a variety of corn that has been genetically modified in order to produce a natural insecticide (Bt toxin). This insecticide kills, among others, the larvae of the European corn borer (scientific name *Ostrinia nubilalis).* Scientists have developed Bt corn by transferring the genetic information of the *Bacillus thuringiensis* bacterium, responsible for the production of a toxin, to corn. Besides MON810 there are other Bt corn varieties, including MON863, Bt11, etc. These varieties produce toxins against other kinds of insects or produce toxin in a different location in the plant (roots, stem, and leaf).


The European stalk borer: larva and moth

The problem: the European stalk borer

The European corn borer (*Ostrinia nubilalis*) is an inconspicuous moth whose larvae eat its way upwards through the corn stems and cobs. It is an important corn pest worldwide, but it appears mainly in southern and eastern Europe and in large parts of the USA and Canada. In the years that the moth appears in large quantities, it can destroy up to 30% of the corn harvest (Bohn, 1999). Since the larvae of the moth live inside the stem, they are hard to reach with insecticides that are sprayed on the crop.

The consequences of the gnawing by the corn borer:

- Plants lose their strength and as a consequence easily fall over during wind gusts.
- Mould growth: the places where the corn has been eaten by the larvae are an ideal point of growth for moulds. These moulds produce mycotoxins. In affected plants, a much higher concentration of these toxic agents is found. They reduce the quality of the corn as forage, as the basis of human foodstuffs (Magg, 2002), but also as the basis for the production of bio-ethanol.

Originally the European stalk borer was a plague for millet cultivators. During the twentieth century the moth arrived in the United States, where it quickly became an important plague for the cultivators of corn. Consequently, despite its name, the European corn borer was originally an American problem with regard to the cultivation of corn.

For the time being, the European corn borer is not present in Belgium. There are, however, indications that the stalk borer is advancing northwards – and that it is already 100 km from the Belgian border. In the United States, Canada, France, Italy, Germany and many other countries, the corn borer constitutes an important plague for the cultivators of corn.

Bohn, M, Kreps, RC, Klein, D, Melchinger, AE, 1999 *Damage and grain yield losses caused by European stalk borer (Lepidoptera: Pyralidae) in early maturing European maize hybrids*, Journal of Economic Entomology

Magg, T, Melchinger, AE, Klein, D, Bohn, M, 2002, *Relationship between European stalk borer resistance and concentration of mycotoxins produced by Fusarium spp. in grains of transgenic Bt maize hybrids, their isogenic counterparts, and commercial varieties*, Plant Breeding

The solution: Bt toxin

Bt toxin is a collective term for a family of toxins produced in nature by the soil bacterium *Bacillus thuringiensis* (this is where the abbreviation Bt comes from). This bacterium is present throughout the world. There are various strains of the *Bacillus thuringiensis,* each of which produces another form of Bt toxin. Each of these forms has a specific effect on certain types of insects. The Cry1 form is toxic for the larvae of specific moths, and Cry3 for certain types of beetles.

In its free form, Bt toxin is a so-called protoxin. It is not active and is therefore harmless. The characteristic of the toxin is that it becomes active only when it ends up in the stomach and intestinal tract of certain insects. The insects' stomach enzymes cut off a piece of the Bt toxin, which will convert the protoxin into an active toxin (Schnepf, 1998). Once activated, the Bt toxin attaches itself to the cell membranes in the stomach and intestinal canal of the insect. There, it upsets the composition of the cell membranes – the cells are ruptured and start leaking. The cells break, and the stomach and intestinal tract can no longer function properly. The insect dies. Subsequently, the bacterium can start feeding on the dead insect.

Bacillus thuringiensis produces spores – dormant survival structures which resist the most extreme external influences. It is in these spores that the Bt toxin accumulates. Mixtures of *Bacillus thuringiensis* spores containing various Bt toxins are used in agriculture as an insecticide, also in organic agriculture.

In contrast to some of the other chemical pesticides, Bt is not toxic to humans. The Bt toxin becomes active only if the substance gets into the intestines of specific insects. Here there are specific receptors that are unique for these insects and with which the toxin can bind.

The Bt toxin in MON810

In MON810, a gene is inserted that codes for the production of the Bt toxin, indicated with the code Cry1Ab. This is an toxin that is toxic to the European corn borer and the various types of the *Sesamia* moth genus.

E. Schnepf et al., 1998, *Bacillus thuringiensis and Its Pesticidal Crystal Proteins*, Microbiology and Molecular Biology Reviews

The corn rootworm *Diabrotica virgifera* in the area around Zaventem should not be confused with the European corn borer

The European corn borer *(Ostrinia nubilalis)* should not be confused with the corn rootworm (*Diabrotica virgifera*). Now and then, the Flemish media reports about small populations in Belgium, including around Zaventem airport – these bugs literally fall off airplanes. The corn rootworm is not sensitive to the MON810 Bt toxin. The MON863 corn variety – which is also a Monsanto Bt corn, but containing a different Bt toxin – is developed to resist this bug (FAVV, 2009).

FAVV (Federal Agency for the safety of the food chain), **2009**. *Phytosanitary aspects, Illnesses and Plagues, Maize rootworm*

MON810 is a group of tens of varieties

Monsanto developed the MON810 corn variety in the 1990s. Once such a variety is created, an intensive refinement program starts with the goal of deriving as many different varieties as possible from it. Each region needs its own variety adapted to the local soil and climatic circumstances. Thus, there are MON810 varieties that grow well close to the Canadian border, and others that flourish in warmer climates. Therefore MON810 is not a single corn variety: it is the name for tens of corn varieties, derived from the MON810 line. In Spain today, there are more than 100 MON810 corn varieties on the market. The majority of these are included not only in the Spanish but also in the European list of crop varieties (European Commission, 2009). Monsanto was not alone in bringing MON810 varieties onto the market: around ten other seed companies also adopted Monsanto's technology under license.

European Commission, 2009*: Common EU catalogue of varieties of agricultural plant species*
http://ec.europa.eu/food/plant/propagation/catalogues/index_nl.htm

Economic interest

The importance of corn as an agricultural crop

After wheat and rice, corn is the third most cultivated crop worldwide. It is mostly used as a base for forage. Additionally, corn is also processed in food in the form of corn flour, sweeteners, starch and alcohol, or the corn grain is offered as a vegetable or as popcorn. In 2007, the surface area for the cultivation of corn was 158 million hectares worldwide. As a comparison: this is 51 times the surface area of Belgium or almost three times the total surface area of France.

FAO *(Food and Agriculture Organization of the United Nations)*
(http://faostat.fao.org/site/567/DesktopDefault.aspx?PageID=567#ancor)

Bt corn: big in the world, unassuming in the EU

According to the data of the agrobiotechnology industry, 41 million hectares of genetically modified corn were grown worldwide in 2009. This is almost a quarter of all corn grown in the entire world. In the USA alone, a surface area of 20 million hectares of Bt corn was cultivated. In the EU, the cultivation of Bt corn is much more limited. In 2009, there were 94,750 hectares of MON810 in the EU. This is 12% less than the 107,719 hectares grown in 2008, and represents about 2% of the total European corn production. In 2009 the bulk of MON810 was in Spain, but there were also cultivations on a much more reduced scale in the Czech Republic, Portugal, Romania, Poland, and Slovakia.

James, Clive. 2009. *Global Status of Commercialized Biotech/GM Crops: 2009. ISAAA Letter No. 41. ISAAA: Ithaca, NY.*

Yield advantages for the cultivation of the MON810 crop

Why do farmers choose for MON810? Farmers want guarantees that at the end of the growing season they will be able to harvest what they sowed. However, insect plagues, weeds or weather circumstances can ruin their harvests. Therefore farmers look for ways of increasing the “harvest certainty”. That is why you can see the additional fee paid by farmers for Bt seeds as some kind of insurance.

In places where the European corn borer is a plague for corn growers (such as the USA, Canada, Spain, Southern Germany or Italy), farmers can ensure a good yield by replacing conventional corn varieties with MON810 plants. This is the most important motive for farmers to sow MON810. By planting MON810, they improve their chances of having a good harvest.

In the European Union, Spain is the country with the longest experience in cultivating Bt corn. Scientific research shows that, in normal circumstance, farmers' income increases by 15% with Bt corn. This is mainly due to the fact that farmers use half the amount of pesticides with Bt corn than with conventional corn (Gomez-Barbero, 2008). Since the plant produces its own pesticide, farmers can save on spraying. In areas like Zaragoza, where the European corn borer is particularly prevalent, farmers earn up to 135 Euros more per hectare with the cultivation of Bt corn. This is not only due to savings on pesticides, but also because of a significant yield increase. In other regions the profit for farmers is much more reduced, sometimes even just a few Euros per hectare.

Also, the quality of MON810 corn can offer advantages. Since the plants are less damaged by the corn borers, moulds have less chance of infecting corn plants. On average, Bt plants contain lower levels of mycotoxins, leading to forage that contains fewer harmful substances. In addition, when using corn for conversion into biofuel, Bt corn is better than normal corn because of the low quantities of mycotoxins, since those molecules are also harmful for the microorganisms that must convert the starch in the corn into ethanol.

Gomez-Barbero, M; Berbel, J; Rodriguez-Cerezo, E; *Bt corn in Spain - the performance of the EU's first GM crop*, Nature Biotechnology

Political importance of MON810

European approval for sale, growth and consumption

MON810 is developed by the agrobiotechnology company Monsanto, and in 1998 it was one of the first genetically modified plants to be allowed for cultivation in the European Community. Based on the market request filed by Monsanto, the European Union decided it was unlikely that MON810 would have negative effects on the environment or on consumer's health. As far as the safety of food and feed is concerned, the EU decided that MON810 is as safe as comparable conventional corn.

A European market approval of a genetically modified organism is only valid for maximum 10 years. Consequently, Monsanto submitted a request for a renewal of the MON810 approval. After studying the request documentation and the existing scientific literature, EFSA, the European Agency for Food Safety, maintained the original conclusion that it is unlikely for MON810 to have negative consequences for the environment, especially if suitable measures are taken to prevent the exposure of non-harmful moths and butterflies to the pollen of MON810.

The European decision procedure

If a producer wants to bring a genetically modified crop onto the EU market, he must submit a marketing request. The decision procedure is as follows:

1. The first decisional right lies with the 'Standing Committee for the food chain and animal health', consisting of representatives of the member states and the European Commission. If this committee does not succeed in reaching a decision (for or against) on the basis of a qualified majority, then the request will go to the European Council of Ministers.
2. The request is put to the vote of the European Council of Ministers. If the Ministers cannot reach a decision for or against on the basis of a qualified majority, the dossier is referred to the European Commission.
3. If neither the Permanent Committee nor the European Council of Ministers can reach a decision, then the European Commission will have to take the final decision. Based on the available scientific information, the European Commission will determine whether it will be allowed onto the European market.

EFSA 2009. *Scientific Opinion of the Panel on Genetically Modified Organisms on applications (EFSA-GMORX-MON810)*, The EFSA Journal 1149: 1-84.

Political controversy: European member states vs. the European Commission

There is no consensus on the cultivation of the corn variety MON810 among the European member states. Over the years, France, Germany, Austria, Hungary, Greece and Luxembourg have prohibited the cultivation of MON810 on their territory, against the existing European market approval.

Such a local ban is possible if the member state can show well-founded reasons why the cultivation of the crop in the environmental circumstances of its country could pose a danger for the environment, and/or new scientific proof arises that would make the previous consent seriously questionable. The legal basis for a local prohibition is constituted by the so called "safeguarding clause" included in the European directive 2001/18/EC, which forms the legal framework for bringing genetically modified organisms needed for cultivation onto the market.

EFSA has examined one by one the scientific publications on which the member states base their decisions. It has not found any convincing proof justifying a revocation of the admission of MON810 onto the market.

Publications quoted by the member states	**Remarks by EFSA**
Resistance of the 'pink bollworm' in Bt cotton (The Morin et al., 2003)	Crops, Cry-proteins, insects and environment are not representative of the GM corn cultivation
Negative effects of Bt corn on earthworms (Zwahlen et al., 2003)	'The way the study was set up does not allow it to be ruled out that the loss of weight by earthworms was due to other factors
Slow decomposition of Bt toxin in soil (Zwahlen et al., 2003)	Nothing indicates that Bt toxin from GM corn behaves differently from Bt toxin used in conventional Bt spraying substances
Spreading of Bt toxin in the soil through the roots of the corn (Saxena et al., 2002)	Nothing indicates that Bt toxin from GM corn behaves differently from Bt toxin used in conventional Bt spraying substances

This creates a problem of legal certainty. On the one hand, according to the European legislation, MON810 is allowed for cultivation and consumption, but on the other hand various countries prohibit its cultivation. In order to solve this problem, the European Commission has already tried twice to revoke the local ban, but without success. As with the decision on approval requests, it will be the European Council of Ministers who will have to decide whether the local ban is legal. And despite the fact that EFSA has asserted repeatedly that the new information does not justify an adaptation of their original advice, it has still not been possible to obtain a qualified majority vote that would force a withdrawal of the ban on local cultivation.

If EFSA does not find any scientific reasons for revising the approval of MON810, why do several EU member states keep resisting its cultivation? That is not an easy question to answer, but it is politics, not science, that plays the decisive role. As shown by the Eurobarometer, the population in these countries has very little confidence in biotechnology. No more than 20% of the people of the countries concerned is in favor of GMOs in food. It is clear that the politicians base their decision on the public opinion in their country, notwithstanding the scientific consensus about the safety of MON810.

The Eurobarometer is a series of surveys performed on behalf of the European Commission in order to estimate public opinion in the EU member states. This should help the Commission in preparing texts, taking decisions and making an evaluation of its work. The attitude of Europeans towards genetically modified organisms is one of the recurring topics of the Eurobarometer.

EFSA *(European Food Safety Authority): Reactions on clause France, Germany, Austria, Hungary, Greece and Luxembourg*

Eurobarometer: *Europeans and Biotechnology in 2005: Patterns and Trends*

Impact on people and environment

Is human and animal consumption of Bt toxin safe?

Bt toxins have been used safely as a means for protecting plants for a long time. They are used as a biopesticide on a large scale, for example in organic agriculture. Up to 80% of all organic pesticides are based on Bt (Lewis, 1997). To date, this use has not had any harmful consequences for human and animal health. Also, the consumption of genetically modified crops that produce Bt appears to be as safe as for the conventional varieties of corn. This also applies to MON810 (Hammond, 2006). The first European approval of MON810 dates back to 1998. Over the years, experts from the EFSA, the European Food Safety Authority, have examined the file multiple times. Conclusion: nothing indicates that MON810 is less safe or less healthy than conventional corn.

Meanwhile, MON810 is cultivated on several millions hectares per year. The crop is mainly used as animal feed. Research carried out up to the present time has not been able to determine any negative effects on human and animal health, nor on plants.

W. J. Lewis, J. C. van Lenteren, Sharad C. Phatak, and J. H. Tumlinson; 1997; *A total system approach to sustainable pest management*; PNAS

Hammond, BG ; Dudek, R ; Lemen, JK; Nemeth, MA; 2006; *Results of a 90-day safety assurance study with rats fed grain from stalk borer-protected corn*; FOOD AND CHEMICAL TOXICOLOGY

What are the effects of Bt corn on other organisms?

The action of Bt toxin is quite specific. It is only toxic for the insect to be fought, and sometimes for other types that are closely related to that insect. Research over several years has shown that the cultivation of Bt corn does not have any negative effects on the soil or on biodiversity if compared with conventional cultivation (Romeis, 2008). The types and number of spiders and insects in corn fields with Bt plants were consistently higher than in fields where the European stalk borer was fought with insecticides.

What applies to the current varieties of Bt corn does not necessarily apply to other genetically modified crops. A risk assessment is required for each new crop that is brought onto the market.

Romeis et al. (2008) *Assessment of risk of insect-resistant transgenic crops to nontarget arthropods*. Nature Biotechnology

MON810 is deadly for a moth, the European corn borer. Is the plant harmful for other butterflies?

MON810 was specifically bred to kill the European corn borer – a moth. This is why a great deal of scientific research has been performed in order to determine the effects on other butterflies (Pimentel, 2000). From laboratory tests, it has emerged that the sensitivity to Bt toxin varies from species to species. When, in laboratory conditions, caterpillars are fed high amounts of the toxin, some species are negatively affected. However, in field tests no proof has been found that MON810 is harmful for butterflies or moths other than the European corn borer (*Ostrinia nubilalis*) and the moths of the *Sesamia* genus.

Why is there such a difference between the laboratory tests and the tests in field conditions? The caterpillar of the European stalk borer lives inside the corn plant. The caterpillars of other butterflies, such as the cabbage white or the peacock, do not eat corn plants. They only sporadically come into contact with the Bt toxin, for example from pollen coming from neighboring plants. The quantity of MON810 pollen that caterpillars or butterflies eat under natural circumstances does not appear to have any effect on the health of the insects. On the contrary, the exposure of butterflies to Bt in fields with Bt corn is in any case much lower than in fields where Bt is used as a conventional spraying substance.

Pimentel, DS; Raven PR; 2000 *Bt corn pollen impacts on nontarget Lepidoptera: Assessment of effects in nature*, PNAS

Effects on the American monarch butterfly

Towards the end of the 1990s, American scientists at Cornell University published a study on the effects of the genetically modified corn line Bt176 on the caterpillars of the monarch butterfly (Losey, 1999). From laboratory studies, it emerged that those caterpillars were sensitive to Bt toxin when they were fed with the pollen of Bt176 plants. Bt176 was a corn variant that had been brought onto the market by the agrochemical company Syngenta. These results were followed by a whole new series of studies (Zangerl, 2001). And what did those reveal? In field conditions, the larvae of certain butterflies (but not the monarch butterfly) appeared to grow more slowly if they came into contact with Bt176 pollen. With other Bt corn varieties, this was not observed. The reason for this is that in Bt176 the Bt toxin was mostly produced in the pollen of the corn plant. This is not the case with other varieties of Bt corn, such as MON810 or Bt11. Partly because of these studies, shortly after the start of the new millennium, Bt176 was taken off the market. Up to the present time, the population of monarch butterflies in the United States has not fallen as a consequence of the enormous cultivation of Bt corn. The concentrations of Bt toxin getting into nature through pollen appear to be too low to have a measurable effect.

Losey J.E et al.; 1999 *Transgenic pollen harms monarch larvae*, *Nature*

A. R. Zangerl, et al.; 2001; *Effects of exposure to event 176 Bacillus thuringiensis corn pollen on monarch and black swallowtail caterpillars under field conditions* *PNAS*

Consequences for other plants because of the cultivation of MON810

One of the arguments often heard against the use of genetically modified crops is the possible spreading of the newly introduced genes to wild plants in nature – so-called “outcrossing”.

This is why companies or researchers wanting to introduce a genetically modified plant into the environment (for experiments or for commercial cultivation) have to perform a thorough risk analysis. Among other things, they need to examine whether there are wild plants that could take up the new genes, for example by transfer of the pollen through wind or insects. This risk is present in places where there are species closely related to the genetically modified crops.

Corn (*Zea mays*) originated from Central America. The crop is derived from the teosinte plant present in wild nature. After thousands of years of selection and refinement, modern corn bears little resemblance to that wild plant. In Europe, corn does not have any uncultivated relatives, so the spreading of genes from genetically modified maize to wild plants is not a problem there. Neither wild maize plants nor genetically modified plants can survive in the European climate.

In Central America, however, in countries such as Mexico, outcrossing to wild plants and to the original corn species is a serious issue. In Mexico the teosinte plant grows in the wild, and farmers grow a broad spectrum of varieties (landraces). The modern corn species are bred based on these landraces. They are very important as a source of genetic diversity. Characteristics of these landraces can be introduced into modern species by means of conventional crossings.

In 2001, the scientific journal Nature published the results of a study by ecologist Ignacio Chapela, from the University of California, Berkeley, showing that various landraces from the Oaxaca region in Mexico contained traces of genetically modified maize (Quist, 2001). At that point a controversy broke out. Critics pointed to serious mistakes in Chapela’s research (Kaplinski, 2002). The scientific journal Nature even declared that if they had discovered the mistakes earlier, they would never have published the results (Metx, 2002, *footnote*). Chapela admitted his mistakes, but continued to support his conclusion that genetically modified material had ended up in landraces in Mexico. Subsequent studies produced various results. In some studies no spreading of genes was found, while in other studies it was (Piñero-Nelson, 2009). Whether there is true contamination of land races in Mexico, is still a matter of debate (Schoel and Fagan, 2009).

The presence of Bt corn in Mexican landraces would be illegal. The corn was not authorized to be cultivated. But whether Bt corn was a bigger threat for the Mexican landraces than other non-genetically modified commercial corn varieties is open to question. Any commercial variety coming from elsewhere that is outcrossed with the local Mexican strains can have an impact on those landraces. The more interesting the characteristics of this commercial variety, the greater the possibility that people will keep working on it. There is a possibility that certain characteristics of landrace varieties will be pushed away. Therefore, the protection of the genetic diversity of landraces is mainly a matter of introducing species from elsewhere in an intelligent manner, whether they are genetically modified or not.

David Quist & Ignacio H. Chapela, 2001; *Transgenic DNA introgressed into traditional maize landraces in Oaxaca, Mexico, Nature*

Kaplinsky N, Braun D, Lisch D, et al., 2002; *Biodiversity (communications arising): Maize transgene results in Mexico are artefacts, Nature*

Metz M & Fütterer J, 2002; *Biodiversity (Communications arising): Suspect evidence of transgenic contamination (see editorial footnote), Nature*

Piñeyro-Nelson, A, 2009; *Transgenes in Mexican maize: molecular evidence and methodological considerations for GMO detection in landrace populations, Molecular Ecology*

Schoel B, Fagan, J, 2009 *Insufficient evidence for the discovery of transgenes in Mexican landraces, Molecular Ecology*

Is there a difference between Bt toxin in corn and Bt toxin in plant treatment products?

The active ingredients in Bt plants and Bt plant treatment products have similar effects. The researchers that introduced the bacterial gene for the toxin into plants have adapted that gene. This appeared to be necessary because the original bacterial genes produced toxins that were not active enough in the plant. In order to correct this activity, scientists cut out superfluous parts. The useful parts that guarantee the action of the toxin were preserved (Schnepf, 1998).

E. Schnepf et al., 1998, *Bacillus thuringiensis and its Pesticidal Crystal Proteins*, Microbiology and Molecular Biology Reviews

What does the Gilles-Eric Séralini 2009 study prove?

At the end of 2009, the study by French scientist Gilles-Eric Séralini made worldwide headlines. He had reanalyzed Monsanto's original safety data and had come to the conclusion that there were indications that genetically modified corn could have consequences on the health of test animals, but he could not find a statistically significant proof of toxicity. The European Food Safety Autority (EFSA), concluded that the study has a number of methodological mistakes, and consequently that it does not offer any new data.

de Vendômois JS, Roullier F, Cellier D, Séralini GE.; 2009; *A Comparison of the Effects of Three GM Corn Varieties on Mammalian Health*, Int J Biol Sci

EFSA: GMO Panel deliberations on the paper by de Vendômois et al.

The 2008 Austrian study on Bt corn

In the fall of 2008, the Austrian Ministry of Public Health (Bundesministeriums für Gesundheit, Familie und Jugend) came up with alarming news. Mice fed for generations with the corn variant NK603 x MON810, appeared to have fewer offspring in a study by the animal nutrition specialist Jürgen Zentek, from Veterinary Medicine in Vienna, Austria (Velimorov A, 2008)

During the presentation of the study, the chief author Jürgen Zentek underlined that the results were still provisional and had yet to be confirmed. The results were presented at a press conference. This is unusual in the scientific world. Normally, such research is first presented to other scientists, before it can appear in scientific publications. And indeed, this will never happen again: in 2010 Austria withdrew the study, because scientists were not able to draw statistically relevant conclusions from the data.

NK603 x MON810 is a corn variety that was developed by Monsanto. It is a conventional cross between the genetically modified lines NK603 and MON810, and combines the characteristics of both varieties. NK603 is resistant to herbicides, and its active substance is glyphosate, with the most famous example being Roundup. MON810 is resistant to the European stalk borer.

The presentation of the study caused conflicting reactions. For the environmental organization Greenpeace, the study shows that genetically modified food is a threat to fertility. The organization used the study as a weapon to argue for the complete dismissal of the biotech industry (Greenpeace, 2008).

Velimirov A, Binter C and Zentek J., 2008 *Biological effects of transgenic maize NK603xMON810 fed in long-term reproduction studies in mice. Report, Forschungsberichte der Sektion IV, Band 3. Institut für Ernährung, and Forschungsinttitut für Biologischen Landbau, Vienna, Austria*

Greenpeace, 2008, GMOs potential threat to fertility, http://www.greenpeace.org/seasia/en/press/releases/gmos-potential-threat-to-ferti

Gunjan Sinha, 2009, *Up in Arms* - Nature Biotechnology

EFSA, 2008, *Request from the European Commission related to the safeguard clause invoked by Austria on maize MON810 and T25 according to Article 23 of Directive 2001/18/EC. Question No EFSA-Q-2008-314.* **The EFSA Journal** *http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/gmo_op_ej891_austrian_safeg_clause_MON810_T25_maize_en.pdf?ssbinary=true*

Consequences for agriculture

Can insects become resistant to Bt toxins?

If harmful insects are treated with the same pesticides year after year, there is a risk that they may become insensitive to them. This risk is also present for Bt plants. Even though laboratory tests have shown that insects can become resistant to Bt toxins, this has not yet been observed in the field. Caution is of the essence.

It is in the interest of seed producers, GM growers, conventional and organic farmers to avoid as far as possible the emergence of resistant insects.

There are various ways to avoid resistance:

- **Shelters**
  Strips of non-Bt plants are cultivated alongside cultivations with Bt crops. In these shelters Bt sensitive insects can reproduce unrestrained. If an insect of the Bt field were to survive because of developing some resistance, this will be 'diluted' in the pool of non-resistant insects. In this way the creation of resistant insects is postponed, because this could only happen as a result of mating between two insects that had developed some resistance.
- **Crop rotation**
  Because of crop rotation, corn is not cultivated in the same field year after year, so genetically modified corn is only sown every few years. In the intervening years, other crops are cultivated and a possibly resistant insect does not have the selection pressure of maintaining itself or increasing in number.
- **High dose**
  Bt toxin in the plant is produced in a high dose. If the toxin were produced in a low dose, barely above the lethal dose, it would be easier for an insect to develop resistance to it.

The co-existence of conventional, organic and transgenic corn

Can MON810 or other genetically modified corn be cultivated together with corn cultivated according to conventional or organic methods? There is a fear that small quantities of genetically modified corn will be found in corn cultivated according to conventional or organic methods, as a consequence of a natural exchange between two adjacent fields or other forms of mingling. A relatively small mingling could already lead to problems in practice. If a harvest is genetically modified for more than 0.9%, then it should be labeled as genetically modified when it is brought onto the market. For farmers of conventional corn, this can lead to problems when this genetically modified corn has a lower market value. They will suffer economic damage because of an unwanted mingling. For organic cultivation too,

unwanted mingling is a problem. If traces of GMOs in the harvest of an organic farmer are found to be above a given threshold value (0.9%), then that harvest will lose its organic certification and it must be mentioned that GMOs are present. And this too will lead to economic damage. The European Organic Regulation 834/2007 prohibits the deliberate use of GMOs in organic agriculture.
In order to decrease the risk that genetically modified corn varieties are mixed with conventionally or organically cultivated corn, the European member states have drafted legislation: the so called co-existence rules. Co-existence refers to the side-by-side existence of conventional, organic and biotechnical agriculture. Farmers and consumers must have the ability to choose the agricultural methods and products they prefer.
The unwanted presence of genetically modified crops in conventional or organic products cannot be completely excluded. In order to keep this risk as low as possible, strict measures are needed during cultivation, harvest, transportation, storage and processing.

The way in which this co-existence is modeled is left to the governments of the individual member states. In Flanders, the co-existence decree was approved by the government and parliament in 2009 (Belgian Government Gazette, 2009). A number of matters are laid down in this decree:

- Farmers who want to cultivate GM crops must inform the neighboring farmers in a timely manner.
- Farmers who can invoke a real economic interest and who would like to cultivate the same crop (but not genetically modified) within a set isolation distance can object.
- Objections are dealt with by a committee.
- Contractors must be trained and everybody performing actions related to cultivation of a GM crop must be informed.
- Specific measures are laid down for each crop, such as maintaining an isolation distance with regard to other lots with the same crop, and cleaning sowing and harvesting machines after they have worked on a GM lot. In Flanders, the isolation distance for the cultivation of corn is 50 meters.
- If, despite the measures taken, the farmer still finds GMOs in his harvest within a reporting distance and he suffers an economic loss because of this, then he can submit a request for compensation. Allocated payments come out of a fund fed by the contributions of GMO farmers.

If, in a conventional corn harvest, a farmer has more than 0.9% GMOs and he does not put the corn onto the market but feeds it to his own animals, then normally this is not considered an economic loss.

3 April 2009 *Decreet houdende de organisatie van co-existentie van genetisch gemodificeerde gewassen met conventionele gewassen en biologische gewassen*, (Decreeing the organization of the co-existence of genetically modified crops with conventional crops and organic crops), Belgian Government Gazette

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