

Miljø- og Planlægningsudvalget  
MPU alm. del - Bilag 5  
Offentligt

**GREENPEACE**

Att.: Folketingets miljø- og planlægningsudvalg  
Ang.: EU-miljørådsmøde 10/3 2005  
Nyt GMO moratorie på kommerciel dyrkning

Til orientering

Greenpeace har idag sendt brev til Miljøministeren med appel om, at Danmark på EU rådsmødet (miljø) den 10. marts tager initiativ til, at rådet suspenderer godkendelsesprocessen for gensplejsede organismer til kommerciel udsætning.

Se venligst vedlagte dokumenter:

- a) Greenpeace-brev til miljøministeren
- b) Greenpeace pressemeddelelse
- c) Greenpeace baggrundspapir om manglende overvågningsplan for MON810
- d) Greenpeace baggrundspapir om WTO-sagen anlagt af USA angående EU's *de facto* moratorium

Med venlig hilsen,

Dan Hindsgaul  
Greenpeace



To : Environment Minister Connie Hedegaard  
Cc : Agriculture Minister Hans Chr. Schmidt

Copenhagen, 15 February 2005

Re : GMOs – 10<sup>th</sup> March Environment Council

Dear Minister,

The previous European Commission has taken decisions on GMOs which could harm the environment, create an economic burden for the farming and food sector and prevent the EU from implementing appropriate standards for environment and consumers protection in Europe. Greenpeace therefore urges you to take action against the lack of monitoring plan for GM maize MON 810 and against the Commission's attempt to lift national safeguard clauses on GMOs (see below).

In the absence of a legislation on the adventitious presence of GMOs in conventional seeds, in the absence of minimum EU legal requirements on the « co-existence » of conventional, organic and GM crops, GMO cultivation in the EU would create an economic burden and job losses for the European food sector. Besides, outstanding issues remain regarding the risk assessment, the post-market monitoring and the risk management of GMOs, and the proper implementation of the legal requirements of Directive 2001/18/EC on deliberate release of GMOs in the environment.

Greenpeace therefore urges you to initiate a discussion at the 10<sup>th</sup> March 2005 Environment Council and to call for a suspension of the approval process of GMOs for cultivation.

Yours sincerely,

Dan Belusa og Dan Hindsgaul, Greenpeace

### **1) Lack of monitoring plan for GM maize MON 810**

On September 8, 2004, the European Commission decided to put 17 varieties derived from genetically modified maize MON 810 in the Common EU Catalogue of Varieties of Agricultural Plant Species. In its press release IP/04/1083, David Byrne, Commissioner for Health and Consumer Protection, states: "*As required by Directive 2001/18/EC, Monsanto, the authorisation holder of MON 810, provided a monitoring plan which was positively evaluated by the Scientific Committee on Plants and approved by Member States in the Regulatory Committee.*"

In contradiction with this statement, Greenpeace investigations revealed that the only monitoring plan available is a paper presented by Monsanto in 1995 when they originally applied for market permission. This paper ("Insect Resistance Management Plan for Insect-Protected Maize") only takes in account the possibility of growing resistance in population of corn borers after exposure to the Bt maize. It does not cover any of the scientific issues discussed since the approval of this GM maize in 1998 and which should be taken into account by the new Directive 2001/18/EC, e.g. structure of the genome after integration of the foreign gene, risks for non target organism, changes in the secondary metabolic pathway of the plants and the excretion and accumulation of Bt toxin into the soil.

This Commission's decision had already drawn criticism from 15 Member States at the 18<sup>th</sup> October 2004 Agriculture Council, on the ground that it was taken before the publication of

the Commission's report on experience with the Member States' implementation of the rules governing co-existence. On 19<sup>th</sup> January 2005, Hungary invoked Article 23 of Directive 2001/18/EC on safeguard clauses to forbid the cultivation of this GM maize.

Greenpeace urges you to follow Hungary's example and to forbid the cultivation of this GM maize on the Danish territory as neither the notifier nor the Commission have provided a monitoring plan in line with Directive 2001/18/EC requirements. Besides, some outstanding questions remain in the risk assessment of this GM maize, whose authorisation will expire by 17<sup>th</sup> October 2006 and, provided the company reapply for market permission, will have to be re-assessed in 2006.

## **2) Withdrawal of Commission's proposals on national safeguard clauses**

In the 29<sup>th</sup> November 2004 Regulatory Committee, 11 to 14 countries voted against the Commission's proposals to lift the national safeguard clauses enacted by five Member States on some GMOs authorised at the EU level under the old legislation Directive 90/220/EC, namely GM maize Bt 176, MON810, T25 and GM oilseed rape MS1/RF1, Topas19/2. According to our information, the Denmark was among 7 to 10 countries that abstained.

In our opinion, a decision to lift the safeguard clauses under the pressure from the Commission would put the European Union in a position to lose the case at the World Trade Organisation (WTO) initiated by the US, Canada and Argentina<sup>i</sup>. The US has lodged a complaint against these national safeguard clauses and against the alleged failure of the Commission to force their lifting even though EU scientific committees had given opinions against the clauses. In its defence<sup>ii</sup>, the Commission is arguing that the opinions of EU scientific committees « *have no formal overriding effect on the opinions of the corresponding national [scientific] committees* », and that it has to take into account scientific disagreements between Member States as well as the scientific uncertainties linked to GMOs.

The EU would appear to be acting in contradiction with its own arguments if it now requests a lifting of these national measures, appearing to admit that the US is right to ask Members States who retain these safeguard measures to be condemned. In a letter to the president of the Commission dated 7<sup>th</sup> December 2004, the government of Austria points out that both the Commission and Member States will loose if the Commission re-submits these proposals to the Council of Ministers, and that such a move will only trigger more polarisation between EU countries. Austria has therefore asked the Commission to withdraw their proposals until the WTO case is decided and until the re-assessment of the GMOs targeted by the safeguard clauses, which have to be re-assessed by 17<sup>th</sup> October 2006, is finished. Austria also points out the absence of a decision on seed purity and of co-existence measures across the EU.

In a comitology procedure, the Commission is free to withdraw its proposal at any point. Greenpeace indeed urges you to ask the Commission to withdraw their proposals on the national safeguard clauses.

Attachment: Fact Sheet on lack of monitoring plan for MON810

Notes:

<sup>i</sup> European Communities – Measures Affecting the Approval and Marketing of Biotech Products (WT/DS/291, 292 and 293)

<sup>ii</sup> Oral Statement by the European Communities at the First Meeting of the Panel with the Parties – Geneva, 2 June 2004. §39 of the Oral Statement states that : « *Second, these committees only reply to specific questions put to them and thus their opinions are not exhaustive, they do not necessarily cover all issues at stake. Also, the committees only provide advisory opinions and their views do not*

*necessarily have to be homogenous. In particular, and contrary to what was alleged today by Argentina and Canada, the views of the European Communities's scientific committees, now regrouped under the European Food Safety Authority, have no formal overriding effect on the opinions of the corresponding national committees. Indeed, in several instances, at the national level subsequent studies have been carried out which have demonstrated conclusively that concerns expressed by the Member States were justified. Thus, the resolution of any scientific differences in the assessment of GMOs and GM products has ultimately to be sought by the political instances in the risk management phase taking into account all relevant scientific information, including studies, reports and opinions from outside the EC. »*

## Pressemeddelelse

### Greenpeace afslører urent trav i EU om GMO-majs

**Geneve/København, 15. februar 2005** – Greenpeace rettede i dag en skarp kritik mod EU-kommissionen for at tilsidesætte EU's egne regler for udsættelse af gensplejsede organismer (GMO). Sagen drejer sig om de 17 varianter af den såkaldte Monsanto 810 Bt-majs (MON810), der som de første GMO-afgrøder den 8. september 2004 blev sat på den fælles europæiske sortsliste, hvorefter de kan anvendes i hele EU. Greenpeace-undersøgelser viser, at der i modstrid med EU's udsætningsdirektiv 2001/18 og udtalelser fra kommissionen, ikke findes en tilstrækkelig overvågningsplan for MON810.

“Det er ren vildledning, når EU-kommissionen påstår, at denne Monsanto-majs opfylder de betingelser om overvågningsplaner, som er foreskrevet i udsætningsdirektivet,” siger Christoph Then, GMO-ekspert i Greenpeace International. “Sandheden er, at der kun findes Monsanto's egen overvågningsplan fra 1995, og at der siden er kommet nye alarmerende videnskabelig dokumentation frem om risici for miljø og dyreliv ved Bt-afgrøder. Greenpeace opfordrer medlemslandene til at tage initiativ til at forhindre kommerciel dyrkning af Monsanto's GMO-majs, ligesom Ungarn netop har gjort.”

Greenpeace har fået indsigt i en email-korrespondance mellem en tysk journalist og daværende talskvinde for EU-kommissionen (sundhed og forbrugerbeskyttelse) Beate Gminder. Efter at have rykket for overvågningsplanen gentagne gange, fik journalisten at vide af Beate Gminder, at der rigtig nok var tale om Monsanto's egen overvågningsplan fra 1995, men at der nu forelå en opdateret plan. Samme indtryk fik man fra EU-kommissionens pressemeddelelse i september 2004, hvoraf det fremgik, at overvågningsplanen fra Monsanto opfyldte alle de nye kriterier. Men forespørgsler til tyske, danske og østrigske myndigheder afslører altså nu, at denne opdaterede plan ikke findes.

GMO-majsen MON810 producerer det såkaldte Bt-toxin (som normalt kun findes i bakterier), som er indspejset for beskytte planten mod en særlig type majsboerbille. Monsanto's overvågningsplan fra 1995 fokuserer kun på risikoen for opbygning af Bt-resistens i majsboerbiller, men ikke på andre potentielt negative miljøkonsekvenser såsom ophobning af Bt i jorden samt et øget pres på sommerfuglearter.

Afsløringerne kommer samme dag som parterne i WTO-sagen om EU's *de facto* GMO-moratorium mødes med videnskabelige eksperter i den kontroversielle handelstvist anlagt af USA. Her forventes EU at forsvare sit juridiske og administrative system for at godkende GMO-planter med henvisning til blandt andet forsigtighedsprincippet.

“Hvis kommissionen vil beholde nogen form for troværdighed EU-kommissionen, så må handle i Bruxelles som de taler i Geneve,” siger Daniel Mittler, WTO-ekspert i Greenpeace International. “Europa må forsvare miljøet og forbrugerne mod transnationale selskaber som Monsanto, som kun varetager egne snævre økonomiske interesser. Så længe EU-kommissionen ikke handler, så må medlemsstaterne selv tage initiativ til at stoppe denne GMO-majs.”

Den nuværende EU-lovgivning tillader medlemslande at indføre nationale forbud mod import og dyrkning af GMO, hvis der kan dokumenteres ny videnskab om mulige risici. Ungarn har allerede indført et nationalt forbud mod MON810 i januar, og igår udtalte den slovakiske miljøminister, at også Slovakiet vil følge trop. Greenpeace har i dag sendt et brev til miljøminister Connie Hedegaard om, at Danmark gør det samme, og Danmark (fortsat) stemmer imod alle godkendelser til kommerciel dyrkning af GMO.

**For yderligere information, kontakt venligst:**

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Brevet til miljøministeren samt de to baggrundspapirer – “Monitoring of genetically engineered crops: European Commission fails to protect EU Member States” og “The assault on Biosafety – The WTO dispute on GMO’s” – kan fås ved henvendelse til Greenpeace eller downloades fra [www.greenpeace.dk](http://www.greenpeace.dk)

# GREENPEACE

## **Monitoring of genetically engineered crops: European Commission fails to protect EU Member States**

Greenpeace accuses the European Commission of exposing EU Member States to the irreversible risks of genetically engineered (GE) crops and of undermining relevant safety regulations within the EU.

Monsanto's GE maize (MON810) produces a toxin derived from a bacterial gene. This toxin is meant to kill certain pest insects. The European Commission is misleading EU Member States when it asserts that MON810 has been thoroughly assessed and monitored for environmental risks and meets all the necessary requirements under current EU legislation.

Greenpeace's investigations show that an adequate monitoring plan does not exist, and diverse publications make it clear that closer monitoring of this GE maize is highly relevant for the EU Member States if MON810 is to be grown commercially.

### **A catalogue of confusion**

May 2004 saw the first indications that the European Commission intended to approve the listing of 17 varieties of Monsanto's MON810 GE Maize in the Common EU Catalogue of Varieties of Agricultural Plant Species. Listing in the Common Catalogue means the seed can be easily commercialised, sold to farmers and grown all over Europe. Therefore, this was an important step, since it would be the first time for any GE variety to be so listed.

The decision to list MON810 should have been dependent on the provision of a plan by Monsanto to monitor the cultivation of the GE maize in accordance with EU Directive 2001/18. This Directive provides the legal framework within the EU for regulating the release of GMOs into the environment and it requires a monitoring plan of the plants that are to be grown commercially in order to collect relevant data concerning their potential risks to the environment (see below).

In this regard, a German journalist contacted Mrs. Beate Gminder, the European Commission Spokeswoman for Health and Consumer Protection, by e-mail in May 2004 to obtain information about the monitoring plans for MON810.

In her answer of 25 May, Mrs. Gminder advised that a decision on listing MON810 was still pending. She explained that before taking any decision the monitoring plan would be issued to the EU Scientific Committee on Plants and to the Regulatory Committee of the Member States for further discussion. MON810 would only be entered in the Common Catalogue if the monitoring plan was regarded as being sufficient under Directive 2001/18.

On 14 July, the journalist again asked Mrs. Gminder when the relevant monitoring plan of Monsanto would be submitted to the Member States. On 15 July, Mrs. Gminder replied that all Member States had now been provided with the relevant

information. However, upon request, neither the German Ministry of Agriculture nor other relevant German authorities could find any specific documents. Subsequently, Mrs. Gminder was contacted again on 23 July, and asked how the monitoring plans had been submitted. In her answer by e-mail on the same day, she explained that the relevant information had already been provided to the Member States under EU Directive 90/220, and that there was an additional update to the monitoring plan.

This answer is crucial. In 1998, MON810 obtained its first European market approval, necessary for later registration in the Common Catalogue, under European Directive 90/220. This older regulation did not require detailed monitoring. It has since been replaced by Directive 2001/18, which requires a much greater level of monitoring. This is the first indication that not all parts of the monitoring plan have been written in accordance with the more recent legislation contained under Directive 2001/18.

To add to the confusion, in a final e-mail to the same journalist on 24 September, Mrs. Gminder clarified that the monitoring plan was originally issued in 1995, in the context of the market authorisation of 1998, and was updated according to the new 2001/18 regulations as necessary. Gminder wrote, "*The monitoring plan fulfils the requirements of 2001/18 and the seed catalogue.*"

Greenpeace attempted to get hold of the updated monitoring plan and made several requests to the German national authorities (the Federal Agency for Consumer Protection and Food Safety). These authorities finally sent two letters (dated 16 December, 2004 and 24 January, 2005) stating that there was no updated monitoring plan for MON810. The only available document was the original monitoring plan already presented by Monsanto in 1995 in the context of the old legislation and the first application for market authorisation in 1998.

The relevant expert from the German Federal Agency for Consumer Protection and Food Safety stated on 24 January, 2005: "*Meanwhile, I have the response about the monitoring plan that was issued to the Commission in the context of the decision to list 17 genetically engineered maize corn varieties of MON810 to the Common European Seeds Catalogue. (...) A first reading shows that it is the document that was already presented for the first market application. To the knowledge of the Federal Agency for Consumer Protection and Food Safety there is no further information concerning monitoring of the cultivation of MON810.*"

That there was no updated monitoring plan was confirmed to Greenpeace by relevant state authorities of Austria and Denmark. The only paper available is the old paper from Monsanto from 1995, and this is not sufficient to fulfil the requirements of current legislation.

### **Seeds of untruth**

In September 2004, MON810 was published in the Common Catalogue by the European Commission, becoming the first GE variety ever inscribed in the Common Catalogue. A European Commission press release from 8 September announced this news (IP/04/1083), quoting David Byrne, Commissioner for Health and Consumer Protection at the time: "*The maize has been thoroughly assessed to be safe for human health and environment. It has been grown in Spain for years without any known problems.*" The press release further states: "*As required by Directive 2001/18/EC, Monsanto, the authorisation holder of MON 810, provided a monitoring plan which was positively evaluated by the Scientific Committee on Plants and approved by Member States in the Regulatory Committee.*"



The investigations made by the journalist, which have been provided to Greenpeace, and Greenpeace's own investigations, show that both the statements made by Mrs. Gminder and the press release of the European Commission can only be considered to be severely misleading and incorrect.

### **Basic principles of monitoring**

According to Directive 2001/18, every case needs specific monitoring and general surveillance because adverse effects might occur during growing of GE crops that were not or could not be anticipated during risk assessment (Directive 2001/18/EC Annex VII). In October 2002, the Council decided upon relevant Guidance Notes (EU Council, 2002/811/EC). In the "Objectives" of these notes the following benchmarks are given:

*"The environmental risk assessment aims, on a case by case basis, to identify and evaluate potential adverse effects of the GMO, either direct or indirect, immediate or delayed, on human health and the environment arising from its placing on the market. This assessment may also need to take account of potential long-term effects associated with the interaction with other organisms and the environment. [...]"*

In subsequent paragraphs, the guidance notes explain two basic concepts of the monitoring concept, case specific monitoring (1.3.1) and general surveillance (1.3.2):

*"Case-specific monitoring serves to confirm that scientifically sound assumptions, in the environmental risk assessment, regarding potential adverse effects arising from a GMO and its use are correct.*

*The approach should:*

- *focus on all the potential effects on human health and the environment identified in the risk assessment, taking into account i.e. different locations, soil types, climatic conditions, and*
- *define a specified time period in which to obtain results.*

*In contrast to case-specific monitoring, general surveillance should:*

- *Seek to identify and record any indirect, delayed and/or cumulative adverse effects that have not been anticipated in the risk assessment,*
- *Be carried out over a longer time period and possibly a wider area.*

*The type of general surveillance, including locations, areas and any parameters to be measured, will largely depend on the type of unanticipated adverse effect is being surveyed. For example, any unanticipated adverse effects on the cultivated ecosystem such as changes in bio-diversity, cumulative environmental impacts from multiple releases and interactions may require a different approach to general surveillance of other effects arising from gene transfer."*

### **Resistance to the facts – what the Monsanto monitor plan misses**

Greenpeace has obtained the monitoring plan from Monsanto that was provided by the company in 1995 and adopted by the Member States in 1998. The monitoring plan only considers one issue - the possible emergence of resistance to Bt-toxin in European corn borer populations. The European corn borer is an insect pest which can lead to some economical disadvantages under certain circumstances in fields with maize corn. The MON810 contains the so-called Bt- toxin (which normally only occurs in bacteria, *Bacillus thuringiensis*) which is intended to protect the plants

against specific the corn borer. The monitoring plan doesn't touch on other possible impacts on the environment that the plant could have.

A significant number of scientific studies, published after the market authorisation in 1998, show that beside the possible emergence of resistance in the corn borer, there is an alarmingly broad range of other possibly harmful effects in these GE plants. The effects mentioned in these publications are highly relevant for any monitoring plan in accordance with the Guidance Notes 2002/811/EC, if the plants are grown commercially<sup>1</sup>:

- As reported by Hernandez et al. (2003), detailed analysis of the genome suggested that the insertion of the transgene results in substantial deletion and/or rearrangement of plant genomic DNA at the insertion site. This effect is not reflected in the original application filed by Monsanto.
- A scientific study, conducted over a period of 2 years under field conditions and published in August 2004 (Dively, et al, 2004), in which monarch butterfly larvae were exposed to pollen from MON810, showed that over 20% fewer larvae reached the adult butterfly stage than in the control group. Before this research, MON810 was regarded as containing levels of the Bt toxin in its pollen too low to cause adverse effects on non-target insects. Earlier studies had shown no short-term effects. Another study showed that larvae of the Eurasian peacock butterfly have a similar susceptibility to the Bt toxin (Felke and Langenbruch 2003).
- Research further suggested that transgenic Bt plants could also be harmful to organisms that feed upon pests exposed to the toxins. Swiss laboratory studies, for example, have demonstrated that the mortality of Green Lacewing (*Chrysoperla carnea*) larvae almost doubled after ingesting European corn borers fed on GM maize (Hilbeck et al 1999). *Chrysoperla* is not only a non-target organism but also a beneficial insect for pest control in organic agriculture.
- The Cry1Ab protein expressed in MON810 is supposed to be specifically toxic only to Lepidoptera larvae, but studies show that it is also toxic to other insects such as beetles. In a field study conducted in 2001 to assess the potential impact of transgenic sweetcorn on several beneficial insects, including predatory coccinelids, chrysopids and anthocorids, scientists found a significant trend of lower densities of these insects in Bt maize, compared to non-Bt maize (Woldet al 2001).
- A study conducted by the German Max Planck Institute of Jena in 2003 compared specific plant defence mechanisms of MON810 with a comparable (isogenic) line. The spectrum of volatile compounds used by the plants to defend themselves against pest insects showed significant differences which will have to be studied further<sup>2</sup>. Volatile compounds are important components of the secondary metabolic pathway in plants. They are used as a communication tool and alarm system against pest insects. If a maize plant is attacked by corn borers for example, it produces a specific profile of volatile substances that attract the natural enemies of the corn borer. If this

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<sup>1</sup> For further points of criticism on the risk assessment of MON810 see also Greenpeace Technical Comments, GREENPEACE 2003

<sup>2</sup> <http://www.biosicherheit.de/mais/228.doku.html>

composition is changed, it might not only make the plants more susceptible to pest insects, but also affect beneficial insects such as honey bees in their potential to pollinate. Further, it might be a signal that other unintended compounds are being produced by the plant or that metabolic pathways are disrupted (see also Firn and, Jones 1999).

- Bt residues in the soil are another established aspect of Bt plants that are relevant for assessment of the impact of Bt plants to the environment. Bt toxins are exuded by the roots of Bt crops (Saxena, et al, 2002). These toxins do not degrade quickly but persist in the soil, being absorbed into soil particles whilst remaining physiologically active for up to several months (Zwahlen, et al 2003). The long-term, cumulative effects of the continued growth over several years of GM plants expressing toxins are important and should be considered part of the risk assessment (Marvier, 2002; Andow and Hilbeck, 2004)
- Data for levels of lignin in MON810 and nine other commercially grown hybrids of Bt maize are reported in a paper from 2001. Levels of lignin were between 33% and 97% higher in GM lines compared to non-GM lines, whether grown in the laboratory or in the field. The paper raises several questions concerning the environmental impacts and the possible impact of feeding these plants (Saxena and Stotzky, 2001). In general the change in lignin content and the findings on volatile compounds (see above) are a indication that secondary metabolic pathways in MON810 are affected by genetic manipulation on several levels (see also Firn and Jones, 1999).

It is abundantly clear that these potential risks are relevant for monitoring under Directive 2001/18 (and the guidance note of the Council 2002/811/EC), and that they are not addressed in any way by the monitoring plan presented by Monsanto ten years ago in 1995. Under no circumstances can this old monitoring plan be seen as sufficient under current European regulations.

Why the Commission has ignored all these facts and decided to list MON810 in the Common Catalogue in September 2004 is unclear. Greenpeace and Friends of the Earth tried to warn the European Commission in 2003 with a report showing that GE maize grown in Spain<sup>3</sup> was taking place with an alarming lack of monitoring. The small amount of analysis that has been performed is largely concerned with the build up of resistance to Bt in insect populations and has found highly variable results (Farinós et al., 2004). There was no official data available on the exact area planted with GE crops, nor was there an independent analysis of GE crops' results, in agronomic terms, of the possible appearance of resistance in pest insects, of the unwanted impacts on non-target species and soil ecosystem, or of the effects of antibiotic resistance gene on animals and humans. (Greenpeace and Friends of the Earth, 2003). Contamination events have been reported, but not fully investigated (Greenpeace and Friends of the Earth, 2003; Brookes and Barfoot, 2003; 2004, Alcade, undated).

Nevertheless the experience of the Spanish cultivation of the MON810 GE Maize was presented by the former Commissioner for Health and Consumer Protection David Byrne as a central reason for the decision of the Commission: "*The maize has been thoroughly assessed to be safe for human health and environment. It has been grown in Spain for years without any known problems.*" (European Commission press release from 8 September 2004 (IP/04/1083)).

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<sup>3</sup> MON810 was already listed in the Spanish seeds catalogue

### **Stop the growing and authorisation of GMOs in Europe**

It is not too late to stop the cultivation of MON810. Since the risk assessment of MON810 carried out in 1998, a lot of important new scientific data has been published, and the authorisation of MON810 should now be revoked or stopped by EU Member States in accordance with the so-called "Safeguard clause" (Article 23 of Directive 2001/18):

*"Where a Member State, as a result of new or additional information made available since the date of the consent and affecting the environmental risk assessment or reassessment of existing information on the basis of new or additional scientific knowledge, has detailed grounds for considering that a GMO as or in a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, that Member State may provisionally restrict or prohibit the use and/or sale of that GMO as or in a product on its territory."*

The Government of Hungary has already taken this approach in January 2005, banning the cultivation of MON 810. In addition the environmental committee of the Slovak parliament demanded a national ban on 1 February, 2005. It is now up to other Member States to take similar initiatives. This active approach from individual Member States seems necessary as the European Commission is increasingly pushing for the commercialisation of GE crops, even when individual Member States are reluctant to do so:

- The Commission pushed for market authorisation of GMOs several times even in those cases where a majority of EU Member States voted against the authorisation and where major uncertainties in the risk assessment of the GMOs were evident.
- The Commission urges Member States to lift national bans for the import and cultivation of GMOs, thus ignoring the concerns of the majority of Member States and their rights to protect the environment and the consumer according to the principle of precaution.
- The EFSA constantly fails to perform the risk assessment on market applications with the necessary scrutiny (see Greenpeace, 2004).

Greenpeace urges all Member States of the European Union to apply the precautionary principle, as this is the basis of the current EU legislation for protecting the environment and consumers in so far as possible. Given current knowledge and uncertainties about the risk of GMOs, no commercial cultivation of GMOs or their use in any food and animal feed should be allowed.

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# GREENPEACE

## **The US Assault on Biosafety – The WTO dispute on GMOs**

On May 13, 2003 the US government threatened consumers, farmers and the environment when it filed a complaint with the World Trade Organization (WTO) against the European Union's de facto moratorium on genetically modified organisms (GMOs), as well as a number of EU member states national bans on GMOs. The moratorium was due to be, and was, lifted however, with the EU food market being closed to GMOs because of consumers rejection. So why the lawsuit? The real target of the US complaint against GMO restrictions is the Cartagena Protocol on Biosafety - the first legally binding global agreement that reaffirms the sovereign right of countries to reject or ban GMOs on the basis of the precautionary principle.

The US action in the WTO tries to prevent developing countries from implementing the Biosafety Protocol, which came into force in September 2003. The WTO has a powerful enforcement mechanism, and losing this case could cost the EU millions of dollars. In 2001, Sri Lanka did not adopt a GMO moratorium, because the US threatened to initiate a similar WTO dispute. By attacking the EU, the US is effectively telling developing countries: "Don't you dare to use your rights under the Biosafety Protocol. If you do so, we will make you pay dearly at the WTO." When the US launched its opposition to complaint GMO restrictions it was joined by the governments of Argentina, Canada and Egypt. A couple of weeks later, Egypt withdrew its support, recognizing "the need to preserve adequate and effective consumer and environmental protection". Egypt was reportedly punished for this brave move as the US subsequently pulled out of a bilateral trade deal.

A WTO "court", called a panel, is made up of three people, which are appointed through a secretive process. The GMO case panel was appointed on March 4<sup>th</sup> 2004. It is made up of Christian Haeblerli (Chair, Switzerland), Mohan Kumar (India), and Akio Shimizo (Japan). All have previous experience with WTO disputes, but little expertise on GMOs.

In its justification for its WTO complaint, the US argues forcefully that GMOs are safe. The panellists recognized that they were not able to address disputes about GMO science. The parties to the dispute agreed, and in August 2004 a search for "scientific experts" to advise the panel started. These experts were appointed in November 2004 and have reportedly submitted their views to the parties in February 2005. The next "hearing" for the case is scheduled for February 21<sup>st</sup>-22<sup>nd</sup> in Geneva. If all goes as planned, a first ruling on the case is expected by July 2005. No matter what the result, there is likely to be an appeal phase.

### **The EU's response: A case of inconsistency**

The European Commission's response to the US complaint has been inconsistent. At the WTO, the EU has stressed scientific uncertainty and referred to the precautionary principle. It has also defended national bans by EU member states, saying that member states have the right to practice precaution and act on national scientific advice (even where it contradicts studies made by EU bodies!). At the same time, the EU Commission has put pressure on member states to lift its national bans and has pushed forward the approval of GMOs in the European Union. It was the Commission that broke the de facto moratorium on the 19<sup>th</sup> May 2004 by approving Bt 11 maize. There was no clear member state mandate for this approval. Greenpeace can now also reveal, that the EU is failing to implement the safety monitoring plans that it claims to have in place for GM varieties such as MON810 (which was approved in 1998, before the moratorium.)

Greenpeace demands that the EU Commission acts in Brussels as it talks in Geneva. The Commission must stop pressuring member states to lift their national bans. It must also stop pressing for further GMO approvals, even though there is no majority among member states to do so. Greenpeace calls on member states to defend their national bans, demand consistency of the Commission, and stop the commercialisation of approved GMOs, such as MON810. This initiative by member states is particularly necessary as the European Food Safety Authority (EFSA) is not applying the necessary scrutiny in risk assessment and is unwilling to apply the precautionary principle; the issue of contamination of organic and conventional agriculture by GMOs is unresolved; no comprehensive monitoring regulation exists; and the commission still has to propose regulation to protect seeds from contamination.

### **The WTO: The wrong institution to decide about our food!**

The WTO has no authority to legislate about the future of our food. This dispute is highly secretive and undemocratic, but the decision affects everybody. The WTO is a trade body with no expertise on the environment. Worse, the WTO has a bad track record on environmental issues. In the WTO debate on the relationship between global environmental rules (MEAs) and trade rules, for example, WTO diplomats cannot even agree on the nature of the negotiations. The WTO's lack of sincerity on the environment is nowhere more plain to see than in its refusal to accept the precautionary principle; a key principle in environmental governance, which allows countries to take action to protect the environment even where there is scientific uncertainty. When governments try to apply the precautionary principle and do the right thing, they are told that they might get into trouble with the WTO. The GE dispute illustrates this perfectly.

The current US assault on global biosafety could be just the first. In 2004, US biotechnology businesses asked a law firm to prepare another WTO complaint against Europe's labelling and traceability laws, which are the real hurdle to GMOs in Europe, as they allow consumers to reject GMOs. Such a case could be filed at any moment.

Greenpeace is a member of the "bite back" campaign, a global coalition calling for the right of farmers and consumers, and not the WTO, to decide what they farm and eat. In May 2004, Greenpeace, together with 14 other groups, also submitted an "Amicus Curiae" brief to ensure that critical science arguments are heard in this case.

### **Further information**

Greenpeace, *The US War on Biosafety*, 2003,  
[http://www.greenpeace.org/international\\_en/multimedia/download/1/306507/0/wto\\_brief\\_final.pdf](http://www.greenpeace.org/international_en/multimedia/download/1/306507/0/wto_brief_final.pdf)  
The "Bite Back" campaign: [www.bite-back.org](http://www.bite-back.org)

The Greenpeace (and others) Amicus Curiae brief:  
<http://www.genewatch.org/WTO/Amicus/PublicInterestAmicus.pdf>

Public Submissions by parties: [http://www.genewatch.org/WTO/WTO\\_Submissions.htm](http://www.genewatch.org/WTO/WTO_Submissions.htm)

WTO: [http://www.wto.org/english/tratop\\_e/dispu\\_subjects\\_index\\_e.htm#gmo](http://www.wto.org/english/tratop_e/dispu_subjects_index_e.htm#gmo)

EU: <http://trade-info.cec.eu.int.docli/html/117666.htm>

### **Contact:**

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# GREENPEACE

Att.: Folketingets miljø- og planlægningsudvalg  
Ang.: EU-miljørådsmøde 10/3 2005  
Nyt GMO moratorie på kommerciel dyrkning

## Til orientering

Greenpeace har idag sendt brev til Miljøministeren med appel om, at Danmark på EU rådsmødet (miljø) den 10. marts tager initiativ til, at rådet suspenderer godkendelsesprocessen for gensplejsede organismer til kommerciel udsætning.

Se venligst vedlagte dokumenter:

- a) Greenpeace-brev til miljøministeren
- b) Greenpeace pressemeddelelse
- c) Greenpeace baggrundspapir om manglende overvågningsplan for MON810
- d) Greenpeace baggrundspapir om WTO-sagen anlagt af USA angående EU's *de facto* moratorium

Med venlig hilsen,

Dan Hindsgaul  
Greenpeace





To : Environment Minister Connie Hedegaard  
Cc : Agriculture Minister Hans Chr. Schmidt

Copenhagen, 15 February 2005

Re : GMOs – 10<sup>th</sup> March Environment Council

Dear Minister,

The previous European Commission has taken decisions on GMOs which could harm the environment, create an economic burden for the farming and food sector and prevent the EU from implementing appropriate standards for environment and consumers protection in Europe. Greenpeace therefore urges you to take action against the lack of monitoring plan for GM maize MON 810 and against the Commission's attempt to lift national safeguard clauses on GMOs (see below).

In the absence of a legislation on the adventitious presence of GMOs in conventional seeds, in the absence of minimum EU legal requirements on the « co-existence » of conventional, organic and GM crops, GMO cultivation in the EU would create an economic burden and job losses for the European food sector. Besides, outstanding issues remain regarding the risk assessment, the post-market monitoring and the risk management of GMOs, and the proper implementation of the legal requirements of Directive 2001/18/EC on deliberate release of GMOs in the environment.

Greenpeace therefore urges you to initiate a discussion at the 10<sup>th</sup> March 2005 Environment Council and to call for a suspension of the approval process of GMOs for cultivation.

Yours sincerely,

Dan Belusa og Dan Hindsgaul, Greenpeace

### **1) Lack of monitoring plan for GM maize MON 810**

On September 8, 2004, the European Commission decided to put 17 varieties derived from genetically modified maize MON 810 in the Common EU Catalogue of Varieties of Agricultural Plant Species. In its press release IP/04/1083, David Byrne, Commissioner for Health and Consumer Protection, states: "*As required by Directive 2001/18/EC, Monsanto, the authorisation holder of MON 810, provided a monitoring plan which was positively evaluated by the Scientific Committee on Plants and approved by Member States in the Regulatory Committee.*"

In contradiction with this statement, Greenpeace investigations revealed that the only monitoring plan available is a paper presented by Monsanto in 1995 when they originally applied for market permission. This paper ("Insect Resistance Management Plan for Insect-Protected Maize") only takes in account the possibility of growing resistance in population of corn borers after exposure to the Bt maize. It does not cover any of the scientific issues discussed since the approval of this GM maize in 1998 and which should be taken into account by the new Directive 2001/18/EC, e.g. structure of the genome after integration of the foreign gene, risks for non target organism, changes in the secondary metabolic pathway of the plants and the excretion and accumulation of Bt toxin into the soil.

This Commission's decision had already drawn criticism from 15 Member States at the 18<sup>th</sup> October 2004 Agriculture Council, on the ground that it was taken before the publication of

the Commission's report on experience with the Member States' implementation of the rules governing co-existence. On 19<sup>th</sup> January 2005, Hungary invoked Article 23 of Directive 2001/18/EC on safeguard clauses to forbid the cultivation of this GM maize.

Greenpeace urges you to follow Hungary's example and to forbid the cultivation of this GM maize on the Danish territory as neither the notifier nor the Commission have provided a monitoring plan in line with Directive 2001/18/EC requirements. Besides, some outstanding questions remain in the risk assessment of this GM maize, whose authorisation will expire by 17<sup>st</sup> October 2006 and, provided the company reapply for market permission, will have to be re-assessed in 2006.

## **2) Withdrawal of Commission's proposals on national safeguard clauses**

In the 29<sup>th</sup> November 2004 Regulatory Committee, 11 to 14 countries voted against the Commission's proposals to lift the national safeguard clauses enacted by five Member States on some GMOs authorised at the EU level under the old legislation Directive 90/220/EC, namely GM maize Bt 176, MON810, T25 and GM oilseed rape MS1/RF1, Topas19/2. According to our information, the Denmark was among 7 to 10 countries that abstained.

In our opinion, a decision to lift the safeguard clauses under the pressure from the Commission would put the European Union in a position to lose the case at the World Trade Organisation (WTO) initiated by the US, Canada and Argentina<sup>i</sup>. The US has lodged a complaint against these national safeguard clauses and against the alleged failure of the Commission to force their lifting even though EU scientific committees had given opinions against the clauses. In its defence<sup>ii</sup>, the Commission is arguing that the opinions of EU scientific committees « *have no formal overriding effect on the opinions of the corresponding national [scientific] committees* », and that it has to take into account scientific disagreements between Member States as well as the scientific uncertainties linked to GMOs.

The EU would appear to be acting in contradiction with its own arguments if it now requests a lifting of these national measures, appearing to admit that the US is right to ask Members States who retain these safeguard measures to be condemned. In a letter to the president of the Commission dated 7<sup>th</sup> December 2004, the government of Austria points out that both the Commission and Member States will loose if the Commission re-submits these proposals to the Council of Ministers, and that such a move will only trigger more polarisation between EU countries. Austria has therefore asked the Commission to withdraw their proposals until the WTO case is decided and until the re-assessment of the GMOs targeted by the safeguard clauses, which have to be re-assessed by 17<sup>th</sup> October 2006, is finished. Austria also points out the absence of a decision on seed purity and of co-existence measures across the EU.

In a comitology procedure, the Commission is free to withdraw its proposal at any point. Greenpeace indeed urges you to ask the Commission to withdraw their proposals on the national safeguard clauses.

Attachment: Fact Sheet on lack of monitoring plan for MON810

Notes:

<sup>i</sup> European Communities – Measures Affecting the Approval and Marketing of Biotech Products (WT/DS/291, 292 and 293)

<sup>ii</sup> Oral Statement by the European Communities at the First Meeting of the Panel with the Parties – Geneva, 2 June 2004. §39 of the Oral Statement states that : « *Second, these committees only reply to specific questions put to them and thus their opinions are not exhaustive, they do not necessarily cover all issues at stake. Also, the committees only provide advisory opinions and their views do not*

*necessarily have to be homogenous. In particular, and contrary to what was alleged today by Argentina and Canada, the views of the European Communities's scientific committees, now regrouped under the European Food Safety Authority, have no formal overriding effect on the opinions of the corresponding national committees. Indeed, in several instances, at the national level subsequent studies have been carried out which have demonstrated conclusively that concerns expressed by the Member States were justified. Thus, the resolution of any scientific differences in the assessment of GMOs and GM products has ultimately to be sought by the political instances in the risk management phase taking into account all relevant scientific information, including studies, reports and opinions from outside the EC. »*

## Pressemeddelelse

### Greenpeace afslører urent trav i EU om GMO-majs

**Geneve/København, 15. februar 2005** – Greenpeace rettede i dag en skarp kritik mod EU-kommissionen for at tilsidesætte EU's egne regler for udsættelse af gensplejsede organismer (GMO). Sagen drejer sig om de 17 varianter af den såkaldte Monsanto 810 Bt-majs (MON810), der som de første GMO-afgrøder den 8. september 2004 blev sat på den fælles europæiske sortliste, hvorefter de kan anvendes i hele EU. Greenpeace-undersøgelser viser, at der i modstrid med EU's udsætningsdirektiv 2001/18 og udtalelser fra kommissionen, ikke findes en tilstrækkelig overvågningsplan for MON810.

“Det er ren vildledning, når EU-kommissionen påstår, at denne Monsanto-majs opfylder de betingelser om overvågningsplaner, som er foreskrevet i udsætningsdirektivet,” siger Christoph Then, GMO-ekspert i Greenpeace International. “Sandheden er, at der kun findes Monsanto's egen overvågningsplan fra 1995, og at der siden er kommet nye alarmerende videnskabelig dokumentation frem om risici for miljø og dyreliv ved Bt-afgrøder. Greenpeace opfordrer medlemslandene til at tage initiativ til at forhindre kommerciel dyrkning af Monsanto's GMO-majs, ligesom Ungarn netop har gjort.”

Greenpeace har fået indsigt i en email-korrespondance mellem en tysk journalist og daværende talskvinde for EU-kommissionen (sundhed og forbrugerbeskyttelse) Beate Gminder. Efter at have rykket for overvågningsplanen gentagne gange, fik journalisten at vide af Beate Gminder, at der rigtig nok var tale om Monsanto's egen overvågningsplan fra 1995, men at der nu forelå en opdateret plan. Samme indtryk fik man fra EU-kommissionens pressemeddelelse i september 2004, hvoraf det fremgik, at overvågningsplanen fra Monsanto opfyldte alle de nye kriterier. Men forespørgsler til tyske, danske og østrigske myndigheder afslører altså nu, at denne opdaterede plan ikke findes.

GMO-majsen MON810 producerer det såkaldte Bt-toxin (som normalt kun findes i bakterier), som er indspejset for beskytte planten mod en særlig type majsboerbille. Monsanto's overvågningsplan fra 1995 fokuserer kun på risikoen for opbygning af Bt-resistens i majsboerbiller, men ikke på andre potentielt negative miljøkonsekvenser såsom ophobning af af Bt i jorden samt et øget pres på sommerfuglearter.

Afsløringerne kommer samme dag som parterne i WTO-sagen om EU's *de facto* GMO-moratorium mødes med videnskabelige eksperter i den kontroversielle handelstvist anlagt af USA. Her forventes EU at forsvare sit juridiske og administrative system for at godkende GMO-planter med henvisning til blandt andet forsigtighedsprincippet.

“Hvis kommissionen vil beholde nogen form for troværdighed EU-kommissionen, så må handle i Bruxelles som de taler i Geneve,” siger Daniel Mittler, WTO-ekspert i Greenpeace International. “Europa må forsvare miljøet og forbrugerne mod transnationale selskaber som Monsanto, som kun varetager egne snævre økonomiske interesser. Så længe EU-kommissionen ikke handler, så må medlemsstaterne selv tage initiativ til at stoppe denne GMO-majs.”

Den nuværende EU-lovgivning tillader medlemslande at indføre nationale forbud mod import og dyrkning af GMO, hvis der kan dokumenteres ny videnskab om mulige risici. Ungarn har allerede indført et nationalt forbud mod MON810 i januar, og igår udtalte den slovakiske miljøminister, at også Slovakiet vil følge trop. Greenpeace har i dag sendt et brev til miljøminister Connie Hedegaard om, at Danmark gør det samme, og Danmark (fortsat) stemmer imod alle godkendelser til kommerciel dyrkning af GMO.

**For yderligere information, kontakt venligst:**

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Dan Hindsgaul, Greenpeace Media, 3393 8660 eller 2810 9021

Brevet til miljøministeren samt de to baggrundspapirer – “Monitoring of genetically engineered crops: European Commission fails to protect EU Member States” og “The assault on Biosafety – The WTO dispute on GMO’s” – kan fås ved henvendelse til Greenpeace eller downloades fra [www.greenpeace.dk](http://www.greenpeace.dk)

# GREENPEACE

## **Monitoring of genetically engineered crops: European Commission fails to protect EU Member States**

Greenpeace accuses the European Commission of exposing EU Member States to the irreversible risks of genetically engineered (GE) crops and of undermining relevant safety regulations within the EU.

Monsanto's GE maize (MON810) produces a toxin derived from a bacterial gene. This toxin is meant to kill certain pest insects. The European Commission is misleading EU Member States when it asserts that MON810 has been thoroughly assessed and monitored for environmental risks and meets all the necessary requirements under current EU legislation.

Greenpeace's investigations show that an adequate monitoring plan does not exist, and diverse publications make it clear that closer monitoring of this GE maize is highly relevant for the EU Member States if MON810 is to be grown commercially.

### **A catalogue of confusion**

May 2004 saw the first indications that the European Commission intended to approve the listing of 17 varieties of Monsanto's MON810 GE Maize in the Common EU Catalogue of Varieties of Agricultural Plant Species. Listing in the Common Catalogue means the seed can be easily commercialised, sold to farmers and grown all over Europe. Therefore, this was an important step, since it would be the first time for any GE variety to be so listed.

The decision to list MON810 should have been dependent on the provision of a plan by Monsanto to monitor the cultivation of the GE maize in accordance with EU Directive 2001/18. This Directive provides the legal framework within the EU for regulating the release of GMOs into the environment and it requires a monitoring plan of the plants that are to be grown commercially in order to collect relevant data concerning their potential risks to the environment (see below).

In this regard, a German journalist contacted Mrs. Beate Gminder, the European Commission Spokeswoman for Health and Consumer Protection, by e-mail in May 2004 to obtain information about the monitoring plans for MON810.

In her answer of 25 May, Mrs. Gminder advised that a decision on listing MON810 was still pending. She explained that before taking any decision the monitoring plan would be issued to the EU Scientific Committee on Plants and to the Regulatory Committee of the Member States for further discussion. MON810 would only be entered in the Common Catalogue if the monitoring plan was regarded as being sufficient under Directive 2001/18.

On 14 July, the journalist again asked Mrs. Gminder when the relevant monitoring plan of Monsanto would be submitted to the Member States. On 15 July, Mrs. Gminder replied that all Member States had now been provided with the relevant

information. However, upon request, neither the German Ministry of Agriculture nor other relevant German authorities could find any specific documents. Subsequently, Mrs. Gminder was contacted again on 23 July, and asked how the monitoring plans had been submitted. In her answer by e-mail on the same day, she explained that the relevant information had already been provided to the Member States under EU Directive 90/220, and that there was an additional update to the monitoring plan.

This answer is crucial. In 1998, MON810 obtained its first European market approval, necessary for later registration in the Common Catalogue, under European Directive 90/220. This older regulation did not require detailed monitoring. It has since been replaced by Directive 2001/18, which requires a much greater level of monitoring. This is the first indication that not all parts of the monitoring plan have been written in accordance with the more recent legislation contained under Directive 2001/18 .

To add to the confusion, in a final e-mail to the same journalist on 24 September, Mrs. Gminder clarified that the monitoring plan was originally issued in 1995, in the context of the market authorisation of 1998, and was updated according to the new 2001/18 regulations as necessary. Gminder wrote, "*The monitoring plan fulfils the requirements of 2001/18 and the seed catalogue.*"

Greenpeace attempted to get hold of the updated monitoring plan and made several requests to the German national authorities (the Federal Agency for Consumer Protection and Food Safety). These authorities finally sent two letters (dated 16 December, 2004 and 24 January, 2005) stating that there was no updated monitoring plan for MON810. The only available document was the original monitoring plan already presented by Monsanto in 1995 in the context of the old legislation and the first application for market authorisation in 1998.

The relevant expert from the German Federal Agency for Consumer Protection and Food Safety stated on 24 January, 2005: "*Meanwhile, I have the response about the monitoring plan that was issued to the Commission in the context of the decision to list 17 genetically engineered maize corn varieties of MON810 to the Common European Seeds Catalogue. (...) A first reading shows that it is the document that was already presented for the first market application. To the knowledge of the Federal Agency for Consumer Protection and Food Safety there is no further information concerning monitoring of the cultivation of MON810.*"

That there was no updated monitoring plan was confirmed to Greenpeace by relevant state authorities of Austria and Denmark. The only paper available is the old paper from Monsanto from 1995, and this is not sufficient to fulfil the requirements of current legislation.

### **Seeds of untruth**

In September 2004, MON810 was published in the Common Catalogue by the European Commission, becoming the first GE variety ever inscribed in the Common Catalogue. A European Commission press release from 8 September announced this news (IP/04/1083), quoting David Byrne, Commissioner for Health and Consumer Protection at the time : "*The maize has been thoroughly assessed to be safe for human health and environment. It has been grown in Spain for years without any known problems.*" The press release further states: "*As required by Directive 2001/18/EC, Monsanto, the authorisation holder of MON 810, provided a monitoring plan which was positively evaluated by the Scientific Committee on Plants and approved by Member States in the Regulatory Committee.*"

The investigations made by the journalist, which have been provided to Greenpeace, and Greenpeace's own investigations, show that both the statements made by Mrs. Gminder and the press release of the European Commission can only be considered to be severely misleading and incorrect.

### **Basic principles of monitoring**

According to Directive 2001/18, every case needs specific monitoring and general surveillance because adverse effects might occur during growing of GE crops that were not or could not be anticipated during risk assessment (Directive 2001/18/EC Annex VII). In October 2002, the Council decided upon relevant Guidance Notes (EU Council, 2002/811/EC). In the "Objectives" of these notes the following benchmarks are given:

*"The environmental risk assessment aims, on a case by case basis, to identify and evaluate potential adverse effects of the GMO, either direct or indirect, immediate or delayed, on human health and the environment arising from its placing on the market. This assessment may also need to take account of potential long-term effects associated with the interaction with other organisms and the environment. [...]"*

In subsequent paragraphs, the guidance notes explain two basic concepts of the monitoring concept, case specific monitoring (1.3.1) and general surveillance (1.3.2):

*"Case-specific monitoring serves to confirm that scientifically sound assumptions, in the environmental risk assessment, regarding potential adverse effects arising from a GMO and its use are correct.*

*The approach should:*

- *focus on all the potential effects on human health and the environment identified in the risk assessment, taking into account i.e. different locations, soil types, climatic conditions, and*
- *define a specified time period in which to obtain results.*

*In contrast to case-specific monitoring, general surveillance should:*

- *Seek to identify and record any indirect, delayed and/or cumulative adverse effects that have not been anticipated in the risk assessment,*
- *Be carried out over a longer time period and possibly a wider area.*

*The type of general surveillance, including locations, areas and any parameters to be measured, will largely depend on the type of unanticipated adverse effect is being surveyed. For example, any unanticipated adverse effects on the cultivated ecosystem such as changes in bio-diversity, cumulative environmental impacts from multiple releases and interactions may require a different approach to general surveillance of other effects arising from gene transfer."*

### **Resistance to the facts – what the Monsanto monitor plan misses**

Greenpeace has obtained the monitoring plan from Monsanto that was provided by the company in 1995 and adopted by the Member States in 1998. The monitoring plan only considers one issue - the possible emergence of resistance to Bt-toxin in European corn borer populations. The European corn borer is an insect pest which can lead to some economical disadvantages under certain circumstances in fields with maize corn. The MON810 contains the so-called Bt- toxin (which normally only occurs in bacteria, *Bacillus thuringiensis*) which is intended to protect the plants



against specific the corn borer. The monitoring plan doesn't touch on other possible impacts on the environment that the plant could have.

A significant number of scientific studies, published after the market authorisation in 1998, show that beside the possible emergence of resistance in the corn borer, there is an alarmingly broad range of other possibly harmful effects in these GE plants. The effects mentioned in these publications are highly relevant for any monitoring plan in accordance with the Guidance Notes 2002/811/EC, if the plants are grown commercially<sup>1</sup>:

- As reported by Hernandez et al. (2003), detailed analysis of the genome suggested that the insertion of the transgene results in substantial deletion and/or rearrangement of plant genomic DNA at the insertion site. This effect is not reflected in the original application filed by Monsanto.
- A scientific study, conducted over a period of 2 years under field conditions and published in August 2004 (Dively, et al, 2004), in which monarch butterfly larvae were exposed to pollen from MON810, showed that over 20% fewer larvae reached the adult butterfly stage than in the control group. Before this research, MON810 was regarded as containing levels of the Bt toxin in its pollen too low to cause adverse effects on non-target insects. Earlier studies had shown no short-term effects. Another study showed that larvae of the Eurasian peacock butterfly have a similar susceptibility to the Bt toxin (Felke and Langenbruch 2003).
- Research further suggested that transgenic Bt plants could also be harmful to organisms that feed upon pests exposed to the toxins. Swiss laboratory studies, for example, have demonstrated that the mortality of Green Lacewing (*Chrysoperla carnea*) larvae almost doubled after ingesting European corn borers fed on GM maize (Hilbeck et al 1999). *Chrysoperla* is not only a non-target organism but also a beneficial insect for pest control in organic agriculture.
- The Cry1Ab protein expressed in MON810 is supposed to be specifically toxic only to Lepidoptera larvae, but studies show that it is also toxic to other insects such as beetles. In a field study conducted in 2001 to assess the potential impact of transgenic sweetcorn on several beneficial insects, including predatory coccinelids, chrysopids and anthocorids, scientists found a significant trend of lower densities of these insects in Bt maize, compared to non-Bt maize (Woldet al 2001).
- A study conducted by the German Max Planck Institute of Jena in 2003 compared specific plant defence mechanisms of MON810 with a comparable (isogenic) line. The spectrum of volatile compounds used by the plants to defend themselves against pest insects showed significant differences which will have to be studied further<sup>2</sup>. Volatile compounds are important components of the secondary metabolic pathway in plants. They are used as a communication tool and alarm system against pest insects. If a maize plant is attacked by corn borers for example, it produces a specific profile of volatile substances that attract the natural enemies of the corn borer. If this

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<sup>1</sup> For further points of criticism on the risk assessment of MON810 see also Greenpeace Technical Comments, GREENPEACE 2003

<sup>2</sup> <http://www.biosicherheit.de/mais/228.doku.html>

composition is changed, it might not only make the plants more susceptible to pest insects, but also affect beneficial insects such as honey bees in their potential to pollinate. Further, it might be a signal that other unintended compounds are being produced by the plant or that metabolic pathways are disrupted (see also Firm and, Jones 1999).

- Bt residues in the soil are another established aspect of Bt plants that are relevant for assessment of the impact of Bt plants to the environment. Bt toxins are exuded by the roots of Bt crops (Saxena, et al, 2002). These toxins do not degrade quickly but persist in the soil, being absorbed into soil particles whilst remaining physiologically active for up to several months (Zwahlen, et al 2003). The long-term, cumulative effects of the continued growth over several years of GM plants expressing toxins are important and should be considered part of the risk assessment (Marvier, 2002; Andow and Hilbeck, 2004)
- Data for levels of lignin in MON810 and nine other commercially grown hybrids of Bt maize are reported in a paper from 2001. Levels of lignin were between 33% and 97% higher in GM lines compared to non-GM lines, whether grown in the laboratory or in the field. The paper raises several questions concerning the environmental impacts and the possible impact of feeding these plants (Saxena and Stotzky, 2001). In general the change in lignin content and the findings on volatile compounds (see above) are a indication that secondary metabolic pathways in MON810 are affected by genetic manipulation on several levels (see also Firm and Jones, 1999).

It is abundantly clear that these potential risks are relevant for monitoring under Directive 2001/18 (and the guidance note of the Council 2002/811/EC), and that they are not addressed in any way by the monitoring plan presented by Monsanto ten years ago in 1995. Under no circumstances can this old monitoring plan be seen as sufficient under current European regulations.

Why the Commission has ignored all these facts and decided to list MON810 in the Common Catalogue in September 2004 is unclear. Greenpeace and Friends of the Earth tried to warn the European Commission in 2003 with a report showing that GE maize grown in Spain<sup>3</sup> was taking place with an alarming lack of monitoring. The small amount of analysis that has been performed is largely concerned with the build up of resistance to Bt in insect populations and has found highly variable results (Farinós et al., 2004). There was no official data available on the exact area planted with GE crops, nor was there an independent analysis of GE crops' results, in agronomic terms, of the possible appearance of resistance in pest insects, of the unwanted impacts on non-target species and soil ecosystem, or of the effects of antibiotic resistance gene on animals and humans. (Greenpeace and Friends of the Earth, 2003). Contamination events have been reported, but not fully investigated (Greenpeace and Friends of the Earth, 2003; Brookes and Barfoot, 2003; 2004, Alcade, undated).

Nevertheless the experience of the Spanish cultivation of the MON810 GE Maize was presented by the former Commissioner for Health and Consumer Protection David Byrne as a central reason for the decision of the Commission: "*The maize has been thoroughly assessed to be safe for human health and environment. It has been grown in Spain for years without any known problems.*" (European Commission press release from 8 September 2004 (IP/04/1083)).

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<sup>3</sup> MON810 was already listed in the Spanish seeds catalogue

### **Stop the growing and authorisation of GMOs in Europe**

It is not too late to stop the cultivation of MON810. Since the risk assessment of MON810 carried out in 1998, a lot of important new scientific data has been published, and the authorisation of MON810 should now be revoked or stopped by EU Member States in accordance with the so-called "Safeguard clause" (Article 23 of Directive 2001/18):

*"Where a Member State, as a result of new or additional information made available since the date of the consent and affecting the environmental risk assessment or reassessment of existing information on the basis of new or additional scientific knowledge, has detailed grounds for considering that a GMO as or in a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, that Member State may provisionally restrict or prohibit the use and/or sale of that GMO as or in a product on its territory."*

The Government of Hungary has already taken this approach in January 2005, banning the cultivation of MON 810. In addition the environmental committee of the Slovak parliament demanded a national ban on 1 February, 2005. It is now up to other Member States to take similar initiatives. This active approach from individual Member States seems necessary as the European Commission is increasingly pushing for the commercialisation of GE crops, even when individual Member States are reluctant to do so:

- The Commission pushed for market authorisation of GMOs several times even in those cases where a majority of EU Member States voted against the authorisation and where major uncertainties in the risk assessment of the GMOs were evident.
- The Commission urges Member States to lift national bans for the import and cultivation of GMOs, thus ignoring the concerns of the majority of Member States and their rights to protect the environment and the consumer according to the principle of precaution.
- The EFSA constantly fails to perform the risk assessment on market applications with the necessary scrutiny (see Greenpeace, 2004).

Greenpeace urges all Member States of the European Union to apply the precautionary principle, as this is the basis of the current EU legislation for protecting the environment and consumers in so far as possible. Given current knowledge and uncertainties about the risk of GMOs, no commercial cultivation of GMOs or their use in any food and animal feed should be allowed.

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# GREENPEACE

## **The US Assault on Biosafety – The WTO dispute on GMOs**

On May 13, 2003 the US government threatened consumers, farmers and the environment when it filed a complaint with the World Trade Organization (WTO) against the European Union's de facto moratorium on genetically modified organisms (GMOs), as well as a number of EU member states national bans on GMOs. The moratorium was due to be, and was, lifted however, with the EU food market being closed to GMOs because of consumers rejection. So why the lawsuit? The real target of the US complaint against GMO restrictions is the Cartagena Protocol on Biosafety - the first legally binding global agreement that reaffirms the sovereign right of countries to reject or ban GMOs on the basis of the precautionary principle.

The US action in the WTO tries to prevent developing countries from implementing the Biosafety Protocol, which came into force in September 2003. The WTO has a powerful enforcement mechanism, and losing this case could cost the EU millions of dollars. In 2001, Sri Lanka did not adopt a GMO moratorium, because the US threatened to initiate a similar WTO dispute. By attacking the EU, the US is effectively telling developing countries: "Don't you dare to use your rights under the Biosafety Protocol. If you do so, we will make you pay dearly at the WTO." When the US launched its opposition to complaint GMO restrictions it was joined by the governments of Argentina, Canada and Egypt. A couple of weeks later, Egypt withdrew its support, recognizing "the need to preserve adequate and effective consumer and environmental protection". Egypt was reportedly punished for this brave move as the US subsequently pulled out of a bilateral trade deal.

A WTO "court", called a panel, is made up of three people, which are appointed through a secretive process. The GMO case panel was appointed on March 4<sup>th</sup> 2004. It is made up of Christian Haeblerli (Chair, Switzerland), Mohan Kumar (India), and Akio Shimizo (Japan). All have previous experience with WTO disputes, but little expertise on GMOs.

In its justification for its WTO complaint, the US argues forcefully that GMOs are safe. The panellists recognized that they were not able to address disputes about GMO science. The parties to the dispute agreed, and in August 2004 a search for "scientific experts" to advise the panel started. These experts were appointed in November 2004 and have reportedly submitted their views to the parties in February 2005. The next "hearing" for the case is scheduled for February 21<sup>st</sup>-22<sup>nd</sup> in Geneva. If all goes as planned, a first ruling on the case is expected by July 2005. No matter what the result, there is likely to be an appeal phase.

### **The EU's response: A case of inconsistency**

The European Commission's response to the US complaint has been inconsistent. At the WTO, the EU has stressed scientific uncertainty and referred to the precautionary principle. It has also defended national bans by EU member states, saying that member states have the right to practice precaution and act on national scientific advice (even where it contradicts studies made by EU bodies!). At the same time, the EU Commission has put pressure on member states to lift its national bans and has pushed forward the approval of GMOs in the European Union. It was the Commission that broke the de facto moratorium on the 19<sup>th</sup> May 2004 by approving Bt 11 maize. There was no clear member state mandate for this approval. Greenpeace can now also reveal, that the EU is failing to implement the safety monitoring plans that it claims to have in place for GM varieties such as MON810 (which was approved in 1998, before the moratorium.)

Greenpeace demands that the EU Commission acts in Brussels as it talks in Geneva. The Commission must stop pressuring member states to lift their national bans. It must also stop pressing for further GMO approvals, even though there is no majority among member states to do so. Greenpeace calls on member states to defend their national bans, demand consistency of the Commission, and stop the commercialisation of approved GMOs, such as MON810. This initiative by member states is particularly necessary as the European Food Safety Authority (EFSA) is not applying the necessary scrutiny in risk assessment and is unwilling to apply the precautionary principle; the issue of contamination of organic and conventional agriculture by GMOs is unresolved; no comprehensive monitoring regulation exists; and the commission still has to propose regulation to protect seeds from contamination.

### **The WTO: The wrong institution to decide about our food!**

The WTO has no authority to legislate about the future of our food. This dispute is highly secretive and undemocratic, but the decision affects everybody. The WTO is a trade body with no expertise on the environment. Worse, the WTO has a bad track record on environmental issues. In the WTO debate on the relationship between global environmental rules (MEAs) and trade rules, for example, WTO diplomats cannot even agree on the nature of the negotiations. The WTO's lack of sincerity on the environment is nowhere more plain to see than in its refusal to accept the precautionary principle; a key principle in environmental governance, which allows countries to take action to protect the environment even where there is scientific uncertainty. When governments try to apply the precautionary principle and do the right thing, they are told that they might get into trouble with the WTO. The GE dispute illustrates this perfectly.

The current US assault on global biosafety could be just the first. In 2004, US biotechnology businesses asked a law firm to prepare another WTO complaint against Europe's labelling and traceability laws, which are the real hurdle to GMOs in Europe, as they allow consumers to reject GMOs. Such a case could be filed at any moment.

Greenpeace is a member of the "bite back" campaign, a global coalition calling for the right of farmers and consumers, and not the WTO, to decide what they farm and eat. In May 2004, Greenpeace, together with 14 other groups, also submitted an "Amicus Curiae" brief to ensure that critical science arguments are heard in this case.

### **Further information**

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The "Bite Back" campaign: [www.bite-back.org](http://www.bite-back.org)

The Greenpeace (and others) Amicus Curiae brief:  
<http://www.genewatch.org/WTO/Amicus/PublicInterestAmicus.pdf>

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