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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[1]:

- 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[2]. 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 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

[1] For further points of criticism on the risk assessment of MON810 see also Greenpeace Technical Comments, GREENPEACE 2003

[2] http://www.biosicherheit.de/mais/228.doku.html

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 (Saxenaand 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[3] 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)).

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.*"

[3] MON810 was already listed in the Spanish seeds catalogue

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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