# HIDDEN UNCERTAINTIES

# What the European Commission doesn't want us to know about the risks of GMOs



**April 2006**

## Executive Summary

Following a legal request by Friends of the Earth, the European Commission has released new documents that question the safety of genetically modified foods and crops. The papers form the basis of the European Communities' (EC) scientific arguments in the current trade dispute at the World Trade Organisation (WTO).

At the same time as the papers were written, the Commission not only broke Europe's six year moratorium on new GM foods, but also made member states vote twice on proposals that would have forced member states to lift their national bans on certain GM products. In addition the Commission has commercialised 31 varieties of GM maize since September 2004. In all cases the Commission informed member states and the public that the GM foods or crops were "completely safe".

These new documents however show a different picture; one of uncertainties, lack of data and subjective judgements that have to be made about the safety GM crops and food. They reveal that at the same time as taking a pro-GM line with the public, the Commission was presenting evidence behind closed doors in the dispute at the WTO, that:

- there are substantial scientific concerns about the safety of GM foods and crops;
- new and complex risks are emerging;
- the risks to human and animal health can not be excluded;
- serious concerns remain about the environmental safety of growing GM crops;
- the environmental risks of GM organisms (GMOs) will vary according to the region and its environment;
- biotechnology companies provided poor quality applications and research in their applications to market GMOs;
- the Commission had considerable reservations about the risk assessments conducted by the European Food Safety Authority (EFSA) which undertakes independent risk assessments of GM crops and foods as part of the approvals process.

In this report we illustrate these issues using extracts from the Commission's evidence to the WTO dispute panel. In its own words, the Commission makes it clear that it "*has taken its task of providing science based comments very seriously, and has relied only on the most up-to-date science available*." The report focuses in particular on the questions over the environmental safety of both herbicide- and insect-tolerant crops, the only GM crops that the industry has brought to market.

The WTO documents could well prove to be the turning point in the debate over the safety of GM foods and crops. The uncertainties presented by the EC raise serious questions as to whether GM foods should be consumed by the public, or whether GM crops should be allowed to be grown. It is clear that their long-term safety cannot be currently guaranteed.

**Below we make a number of recommendations for urgent changes that need to be made to the way the Commission deals with GM crops and foods. Because of the seriousness of the issues, we are calling for an immediate suspension of the GMO approvals process, and a halt to the sale of GM foods and feeds and commercial cultivation until these issues are resolved.**

### The EFSA

The manner in which such uncertainties are concealed is most obvious when the opinions of the EFSA are contrasted with those of the precautionary approach the Commission was forced into taking when having to deal with the WTO dispute process. The EFSA opinions do not examine the uncertainties, methodological problems or gaps in data and the Commission's starkly different

presentation of the issues and explicit criticism of the EFSA show that changes are urgently needed. **The EFSA should be required to revise its presentation of the available data when it undertakes GMO risk assessments. They should document the uncertainties, gaps in knowledge and assumptions used in coming to a conclusion. All past assessments, including those of the Scientific Committee on Plants which are still relevant, should be revised and presented in this way.**

**The Precautionary Principle**

The regulation of GMOs in Europe requires a precautionary approach to be followed. In situations where serious harm may arise, lack of evidence of the harm arising should not prevent action being taken to prevent harm. As the Commission's evidence to the WTO dispute shows, there is the potential for serious and irreversible harm from the use of GMOs, considerable uncertainty exists and gaps in knowledge are extensive. Normally the Commission conceals the extent of this from the public and member states when it accepts the advice of the EFSA. In giving the biotechnology industry, rather than the environment, the benefit of the doubt , the Commission is failing to implement the precautionary principle as required in law. **The Commission must acknowledge that under a precautionary approach to environmental protection, bans or restrictions on GM crops are legitimate. It must also prioritise environmental protection, not the biotech industry, in its interpretation of the implications of uncertainties and gaps in knowledge.**

**Member state assessments of GMOs**

The EC has laid out very clearly, particularly in relation to the risks to non-target species from Bt crops and the difficulties of containing oilseed rape and sugar beet, how sensitive risk assessments of GMOs are to different environments and environmental protection priorities. For example, information on the susceptibility of European non-target species is extremely limited at best and non-existent at worst for most species. **European countries should ban the use of Bt crops until data is available that clearly demonstrates that the relevant non-target species are not at risk. In their implementation of the Environmental Liability Directive, member states should ensure that all species and habitats are included and that the very poor risk assessments currently being used to justify consents cannot be used as a defence.**

**Coexistence of GM and non-GM crops**

Co-existence, according to the Commission, is both extremely difficult and a matter of environmental protection as well as an economic issue. **The Commission should withdraw its flawed Recommendation to member states on coexistence which emphasises that coexistence is simply an economic issue. Instead the Commission should start a process for Europe wide measures that aim to prevent any GM contamination, contain strict economic liability measures to back this up and allow member states and regions to ban GMOs if they pose an unacceptable risk to their environments.**

**Public confidence in the European Commission**

The publication of this report on the Commission's previously concealed views on the risks of GMOs signifies a turning point in the politics of GMOs in Europe. The contrast between the public and private views of the European Commission on the risks of GMOs is staggering and will seriously dent public and member states' confidence in their ability to act fairly. All the evidence reveals a Commission policy of favouring the interests of the biotechnology industry over protecting the environment and human health. **A fundamental change in the way in which the European Commission acts in relation to GMOs is now required. This new approach must place protection of the environment and public safety at the heart of decision making over GMOs - as it should be under the precautionary principle, and abandon all bias towards biotechnology industry interests. The Commission must ensure that the EFSA changes it risk assessment practice; support member states that wish to ban or restrict GMOs; and end approvals of GMOs when member states are not in agreement.**

# 1 Introduction

**The public face of the European Commission…**

"*..no GMOs are allowed on the EU market unless they have been proved to be completely safe*." Mariann Fischer Boel, Commissioner for Agriculture and Rural Development, 10 March 2006.[1]

"*GM sweet corn has been subject to the most rigorous pre-marketing assessment in the world. It has been scientifically assessed as being as safe as any conventional maize. Food safety is therefore not an issue..”* David Byrne, Commissioner for Health and Consumer Protection, 19 May 2004.[2]

**…but behind closed doors, a different story:**

*“It is apparent from the scientific advice now before the Panel, that there is no unique, absolute, scientific cut off threshold available to decide whether a GM product is safe or not (the risk assessment end point).”*

“ *on the basis of existing research…it is impossible to know whether the introduction of GM food had had any human health effects other than acute toxic reactions*. European Communities submission to World Trade Organisation dispute panel, 28 January 2005.[3]

In May 2004, the European Commission approved the first genetically modified (GM) food for import since 1998 - despite most member states refusing to support the application. The GM sweet corn, called Bt11, was approved for importation and sale as food or animal feed,. The Commission used its legal powers to break the six year moratorium on the approval of new GM crops or foods in Europe because of pressure from a challenge at the World Trade Organisation by the USA, Canada and Argentina, the world's largest GM crop producers. In its announcement about the approval, the Commission told the public that the GM sweet corn was safe. There was no mention of uncertainties or doubt. This unwavering confidence in the safety of GM crops and foods has continued to dominate the public face of the Commission. And since then, the Commission has approved another seven GM foods and feeds for import into Europe, each one after member states had failed to agree over their safety or environmental impact. In addition the Commission has added 31 varieties of Monsanto's MON810 maize since September 2004 onto the EC's Common Catalogue of seeds, making them available to farmers across the EU to grow.

However, documents previously kept secret reveal that the Commission is in fact fully aware of the uncertainties, lack of data and judgements that have to be made about the safety GM crops and food. The documents, released to Friends of the Earth by the Commission following a legal request, show that at the same time as taking a pro-GM line with the public, including pushing through approvals and trying to force member states to lift national bans on GM crops and foods, the Commission was presenting evidence behind closed doors in the dispute at the WTO, that:

- there are substantial scientific concerns about the safety of GM foods and crops;

[1] Commission reports on national measures to ensure co-existence of genetically modified crops with conventional and organic farming. European Commission press release, 10 March 2006. http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/06/293&format=HTML&aged=0&language=EN&guiLanguage=en

[2] Commission authorises import of canned GM-sweet corn under new strict labelling conditions – consumers can choose. European Commission press release,19 May 2004 http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/04/663&format=HTML&aged=1&language=EN&guiLanguage=en

[3] European Communities - Measures affecting the approval and marketing of biotech products (DS291, DS292, DS293). Comments by the European Communities on the scientific and technical advice to the panel. 28 January 2005.

- new and complex risks are emerging;
- the risks to human and animal health can not be excluded;
- serious concerns remain about the environmental safety of growing GM crops;
- the environmental risks of GMOs will vary according to the region and its environment;
- biotechnology companies provided poor quality applications and research in their applications to market GMOs;
- the Commission had considerable reservations about the risk assessments conducted by the European Food Safety Authority (EFSA) which undertakes independent risk assessments of GM crops and foods as part of the approvals process.

**The Commission and the GM trade dispute**

In May 2003 the United States, Canada and Argentina made a formal complaint to the World Trade Organisation (WTO) about Europe's precautionary stance on genetically modified organisms, claiming it was a barrier to trade and violated international trade rules. The US led coalition claimed that Europe had:
• refused to approval to a number of new GM foods,
• stopped processing applications for new GMOs,
• not taken action to stop EU member states banning GM products.

During the dispute, a panel of independent scientific experts was set up to report on whether there were scientific grounds for Europe's position. The papers released to Friends of the Earth formed the EC's comments on the scientific advice submitted to the WTO panel, backing up the EC's defence in the dispute and were dated February and March 2005. The papers were presented on behalf of the European Communities but were prepared by the European Commission which acts as its executive arm.

The WTO published an Interim Report on the dispute in February 2006, which was leaked to Friends of the Earth - http://www.foeeurope.org/biteback/WTO_decision.htm. A final decision is expected

In this report we illustrate these issues using extracts from the Commission's evidence to the WTO dispute panel. In its own words, the Commission makes it clear that it "*has taken its task of providing science based comments very seriously, and has relied only on the most up-to-date science available*." The report focuses in particular on the questions over the environmental safety of both herbicide- and insect-tolerant crops, the only GM crops that the industry has brought to market.

After revealing the information that the Commission failed to present to the public, we consider its implications for:
- the role of the EFSA in GMO risk assessments;
- the precautionary approach enshrined in EC legislation;
- member state assessments of GMOs;
- "coexistence" of GM and non-GM crops;
- public confidence in the Commission.

The authors of this report have attempted not to take the quotations cited out of their general context. Throughout this report we refer to the European Commission and the European Communities (EC) interchangeably.

## 2 Uncertainties and gaps in knowledge

Whilst the EC continually reassures the public that GMOs are completely safe, one of the main arguments used by the EC throughout its case is that there are "*large areas of scientific uncertainty*" (para 31), scientific disagreement and huge gaps in our knowledge - "*some issues have not yet been studied at all*"(para 32). The following excerpts give examples of just how uncertain the EC is about the safety of GM foods and crops. Any reference to "experts" refers to the panel of independent scientific experts that the WTO panel employed to help them with the case (their report has not been made public).

### 2.1 Evolving science

*"It is also striking that the experts confirm how little was known on so many of the relevant issues only 10 to 15 years ago, and how much the scientific understanding of many of these issues has developed since then, including in international fora such as the Codex. Developments identified by the experts include the identification of previously unsuspected areas of risks and impacts, or identification of flaws in the way risk assessments may have been conducted in the past, both issues which are still moving very fast forward today.* "(para 33)

### 2.2 Controversy

*"…it is noteworthy that there is extensive disagreement between the experts or with independent scientists. This indicates a clear lack of consensus in the scientific circles on the issues at stake in these proceedings."* (para 36)

### 2.3 Judging when the scientific information is sufficient

*"It is apparent from the scientific advice now before the Panel, that there is no unique, absolute, scientific cut off threshold available to decide whether a GM product is safe or not (the risk assessment end point)."* (para 38)

### 2.4 Availability of risk mitigation and risk management tools

"*… it is apparent that the introduction of any GM product into the environment may cause an irreversible effect under certain conditions, in particular if a particular product, or a particular genetic modification, has the ability to maintain or spread itself into the environment. Therefore, if uncertainties remain for a particular product that may have these characteristics, any available mitigation measure may be considered on policy grounds to be inadequate. This is especially the case if the effects are irreversible*." (para 41)

### 2.5 Surveillance and food safety

*"However, in the absence of exposure data in respect of chronic conditions that are common, such as allergy and cancer, there simply is no way of ascertaining whether the introduction of GM products has had any other effect on human health."* (para 45)

Given the widespread public concern about the risks of GM crops and foods and the fact that the precautionary principle underpins EU law , it is critical that this extent of scientific uncertainty and ignorance is taken into account in the decision making process. When there is no certainty, judgements have to be made about what level of risk is acceptable. This requires open public debate and then political decisions. By routinely hiding uncertainties over the risks of GMOs from the public, the Commission conceals that it is taking political decisions in favour of the GM industry.

## 3 Health impacts

On the 19th July 2004, Margot Wallström, Commissioner for the Environment, defended the Commission's decision to approve a variety of GM maize, NK603, for import saying: "*The NK603 maize has been subject to a rigorous pre-market risk assessment. It has been scientifically assessed by the European Food Safety Authority as being as safe as any conventional maize. Its safety is, therefore, not in question* ..." [4]

Despite Commissioner Wallström's confident statement, a much more complex picture of the difficulties of assessing human health impacts was presented to the WTO dispute panel in December 2005 – that the amount of available information restricts the conclusions that can be drawn; improved testing for allergenicity is needed; and antibiotic resistance genes may pose unacceptable risk.[5]

### 3.1 Limited information

*"... on the basis of existing research...it is impossible to know whether the introduction of GM food had had any human health effects other than acute toxic reactions. Therefore it is impossible to comment on any changes that might have occurred since 1998.* "(para 777)

Here the Commission presents evidence that only acute toxic reactions from consuming GM foods can be excluded so far. While sudden serious illness or death is considered highly unlikely, other, more complex, health effects such as development of cancer, immune responses, or chronic toxicity can not be ruled out on the basis of the current data. The same is said to be true for animal health risks.

"*As regards food safety, even if some GM products have been found to be safe and approved on a large scale..., the lack of general surveillance and consequently of any exposure data and assessment, means that there is no data whatsoever available on the consumption of these products – who has eaten what and when. Consequently, one can accept with a high degree of confidence that there is no acute toxicological risk posed by the relevant products, as this would probably not have gone undetected – even if one cannot rule out completely acute anaphylactic exceptional episodes. However, in the absence of exposure data in respect of chronic conditions that are common, such as allergy and cancer, there simply is no way of ascertaining whether the introduction of GM products has had any other effect on human health."* (para 45)

"*It is finally critical to note that, as regards animal health impacts of GM plant or other GM products (impacts on animals used for food, breeding animals, or even on all relevant non domesticated organisms from the animal kingdom), or as regards target or non target animal feed safety, there is not yet much specific risk assessment guidance developed by international expert consultation or organisations. It is important to consider that the lack of identification of human health risks in the risk assessment of a GM plant used as food, does not necessarily correlate with an absence of risks on target or non target animals in the framework of feed safety, in particular for non mammals. This relates to, among others, differences in animal physiology and metabolism, parts/products of crop plants that are consumed, processing, and exposure (intake) levels...Consequently, indirect environmental or human health effect that may arise from direct impacts on animal health or GM plant*

[4] GMOs: Commission authorises import of GM-maize for use in animal feed. European Commission press release, 19 July 2004
http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/04/957&format=HTML&aged=1&language=EN&guiLanguage=en

[5] Unless otherwise stated, the quotations in this report come from '*European Communities – Measures affecting the approval and marketing of biotech products (DS291, DS292, DS293). Comments by the European Communities on the Scientific and Technical Advice to the Panel*', Geneva, 28 January 2005

*induced imbalance in the animal interactions with the ecosystem is still a largely an unexplored area.*" (para 65)

### 3.2 Allergenicity

In relation to the risks of creating new allergens, the Commission emphasises the need for new testing protocols, such as immunization experiments, because those currently used are not sufficient to exclude possible health impacts.

"*Even if a given protein per se does not represent an allergen, its expression in another host organism may indirectly upregulate the expression of potential allergens. It is therefore recommended to compare the engineered plant/plant product with that of the parent/wildtype plant/plant product regarding IgE reactivity to establish whether the transgenic organism represents a more potent allergen source than the parent/wildtype organism for already sensitized patients. The potentially increased ability of the transgenic organism versus the parent/wildtype organism to induce de novo IgE responses (i.e. allergic sensitization) needs to be compared by immunization experiments*." (para 717)

The Commission also raises fundamental questions about the scientific basis of what would constitute normal risk assessment practice for allergenicity as conducted by the EFSA and others saying:

*"The 'sound scientific evidence'...consists only on checking protein homologies with existing allergens and a study of the isolated purified transgene product in a simulated gastric fluid. Based on this, Bt proteins are degraded within minutes. However, today we know that when embedded within transgenic plant material Bt-proteins can pass even through the intestinal tract of cows..."* (para 304)

### 3.3 Conclusion

The evidence presented and questions raised by the Commission with the WTO dispute panel, raise serious questions about confidence that can be placed in EFSA's GMO risk assessments . These risk assessments are ever more important because of the new centralised approvals system under the Food and Feed Regulation (1829/2003) which assessed the safety of GMOs for food and feed. And it is EFSA's risk assessments and opinions which the Commission relies on to back up its decisions to ultimately authorise GMOs.

## 4 Environmental safety and Bt crops

*"Unfortunately, as has been shown eloquently by the experts' replies, there is still considerable lack of familiarity with many ecological systems and interactions occurring both in cultivated and natural environments."* (para 56)

The European Commission's submission to the WTO dispute panel exposes even larger gaps in our knowledge over the environmental impacts of growing GM crops. Only two GM crops have been approved for growing in Europe, Syngenta's Bt176 maize and Monsanto's MON810 maize. Both of these crops are insect resistant and are engineered to produce a toxin, called Bt, that kills a particular pest or pests. These two varieties of GM maize have been grown mainly in Spain, although Bt176 has now been taken off the market following health concerns because if also contains a resistance gene to the commonly used antibiotic, ampicillin. Applications have also been made to grow several other Bt insect resistant crops in Europe.

The Commission's evidence, as presented to the WTO dispute panel, highlights considerable uncertainty. One of the most important questions relates to whether the Bt toxin in the plant may have harmful effects on non-target organisms. Another issue is whether the use of Bt crops will cause pests to become resistant and make the use of Bt sprays by organic farmers ineffective.

### 4.1 Non-target organisms

*"It is a reasonable and lawful position to say that no Bt crops can be planted until there is information on all potential non-target organisms in the soil…" (para 702)*

Harm to non-target species includes the possible reduction in populations of species of wildlife or heritage value, such as rare butterflies or moths and disturbances to soil microflora – vital for healthy ecosystems. As the quotes below illustrate, the Commission presented much evidence that Bt plants may create new risks for non target organisms and that the risks are unique and can result in unpredictable effects, especially in the soil.

The Commission claimed that it would be reasonable to prevent Bt crops being grown until impacts on soil organisms are more fully investigated. Yet it has done nothing to stop Bt crops being grown in Europe, it is unclear even whether the Commission has even informed member states growing Bt crops of these concerns, and instead has tried to force countries that have national bans on Bt crops to lift them.

*."… a GM crop, where a new Bt gene is introduced into its genome, leads to lots of unpredictable interactions... No one can scientifically claim to be able to predict all consequences of the presence and functioning of a new gene (and even less for several) in a genome which has never been exposed or contained this gene. The potential hazard here is not a consequence of the action of modification the plant genome, but of the fact that it generates high levels of unpredictability. The risk here may not come from the genetic modification itself, but from the extreme unpredictability of the direct and indirect effects of the introduction of a new gene(s) and gene product(s) into the plant genome and its gene expression. This cannot be compared to conventional maize, where such new combinations have ever occurred."* (para 152)

*"The current state of Bt environmental risk assessment in Europe shows that there were and still are considerable grounds for concern about the toxin Bt, especially non-target effects, which have only been addressed in recent years and which still continue to produce large amount of data."* (para 128)

*"…There are numerous possible ways that Bt maize could be toxic (i.e. have an adverse effect on the receiving organism following acute or chronic exposure) when Bt maize is grown under European field conditions."* (para 137)

*"Several examples...of unintended or unanticipated effects arising from transformation of transgenic crops, show that plant metabolites involved in ecological interactions with non-target organisms can be changed during production of Bt crops, and have the potential to influence the toxicity of Bt toxins by unpredictable toxicological interactions as part of the complex diet consumed by herbivores."* (para 143)

"*Scientific uncertainty is increased due to the ongoing scientific debate over the most appropriate testing methods and scales (spatially and temporally) useful to determine realistic ecological effects of Bt crops...In reality, the non target herbivore will consume the Bt toxin produced by the homologous Bt-expressing plant, which may therefore be different in molecular structure, size, posttranslational modifications, and biological activity to the artificially produced "surrogate" Bt toxin*." (para 145)

"*Bt toxin exposure routes for non target organisms, like insect pollinators, predators and parasitoids, are frequently multi-trophic, not simply bi-trophic that is, they arise from indirect complex and network interactions. Simplified bi-trophic testing systems, based on eco-toxicological models (as featured in many non target methods using a purified Bt toxin in artificial diets for non target insects) are now not considered by many experts to be ecologically realistic for assessing multitrophic interactions of Bt crops over several insect generations and spanning at least three trophic levels..."* (para 146)

*"… There are undoubtedly effects on at least some non-target organisms. It may reasonably be anticipated that as more species are tested, more effects will be found. This supports the view it is very difficult to be sure that all appropriate NTO* [non target organism] *effects have been tested for."* (para 700)

The complexities of soil ecosystems and the difficulties of determining the effects on soil organisms were emphasised by the Commission

*"As regards unintended effects of Bt maize on non target organisms, a very recent paper shows some effects of the maize expressing the Bt toxin on soil nematodes, which are site and season specific effects..."* (para 125)

*"The effects detected on nematodes was also found by other authors, although no one yet understands why the effect happens (less nematodes under Bt maize in some soils/regions / tillage regime combinations). It may be related to root exudation, plant composition, altered moisture below Bt maize plants, altered trophic interactions of a food source for nematodes, or any other effect directly or indirectly related to the expression of the Bt toxin…It strikingly shows evidence of continued scientific uncertainties and regional differences on soil ecology as regards non target effects of Bt maize... "* (para 126)

*"The discussion about soil organisms nicely illustrates the difficulties in terms of sufficiency and NTO [non target organism] effects. It is a reasonable and lawful position to say that no Bt crops can be planted until there is information on all potential non-target organisms in the soil, particularly given that scientists do not know much about most of the organisms in the soil (they cannot be reared and it is not known what they feed on)."* (para 702)

*Effects (either directly to the non-target organism, or indirectly to non-target organisms via simple or complex trophic interactions in the food web) of the Bt toxin itself, or of the Bt crop as a whole, on non-target insects which provide important 'ecological services' in agro-ecosystems.*

*In several of the above non-target studies on Bt crops, the possibility is raised from a scientific viewpoint that sub-lethal effects detected in small scale or short term studies (e.g. lab or contained glasshouse) could possibly be exacerbated by longer term exposure (i.e. over a growing season encompassing multiple generations of non-target insect species) and by toxic interactions between expressed Bt toxins and other components of the non-target target organisms normal diet…"* (paras 140-142)

### 4.2 Effects of organic farming

A major concerns over growing Bt crops is that insect pests will become resistant to the Bt toxin over time. The Commission goes into some detail about this problem and whether establishing "insect refuges" – areas planted with non Bt crops to prevent resistance from building up, are sustainable. In addition, because Bt sprays are used by organic farmers to control pests the EC argues that if resistance in the pests builds up organic farmers may no longer be able to use this tool for pest control.

"*If the pests exposed to Bt maize develop resistance to the toxin, then other pesticides will have to be used, on Bt corn but also on non GM crops where the same Bt protection is used against these pests. This would obviously be an adverse impact, on the environment, and on the required change of agronomic practices for these non GM crops. This would be the case, for instance, for organic farming of tomato, which can be damaged by the same pest as Bt maize*" (para 26, EC's Further Evidence)

### 4.3 Conclusions

According to the Commission's evidence to the WTO dispute panel, there is considerable uncertainty and many serious gaps in our knowledge about the possible environmental effects of growing Bt crops in Europe. Harm to non-target species is a real possibility. Relevant data is needed and is often absent. However, as described later, the bodies providing the Commission with expert advice (the EFSA and previously the Scientific Committee on Plants) these uncertainties are not detailed in assessments conducted by.

## 5 Environmental safety and herbicide tolerant crops

*"… it can easily be taken for granted that the large scale application of broad spectrum herbicide in farmland area will cause wide-spread and serious disruption of trophic structures and food webs as the food basis of all species feeding on anything but the crop is eliminated at least temporarily and locally. The severity of this effect will be a function of the area sprayed and the frequency of applications…"* (para 366)

The second GM trait that the biotech industry has commercialised is herbicide tolerance (HT). These are crops genetically modified to be tolerant to either Monsanto's glyphosate (Roundup) or Bayer's glufosinate (Liberty), both of which are broad spectrum herbicides – meaning they are meant to kill off all other plants in the field sprayed, apart from the GM crop. The UK's farm-scale trials showed that the growing these crops using their accompanying herbicide could lead to significant harm to farmland wildlife compared to the non-GM equivalent, and some applications to grow herbicide tolerant crops in Europe have been withdrawn as a result, such as Bayer's GM oilseed rape. However, Monsanto has now applied to grow Roundup Ready soybeans in Europe, some of the insect-resistant maize crops are also herbicide resistant, and GM oilseed rape has been approved for import and processing which will inevitably lead to accidental releases through spillage during transport.

In its submission to the WTO dispute panel, the EC highlights how difficult it will be to control many GM crops, how the emergence of herbicide tolerant weeds may lead to increases in the use of other herbicides and the potential for adverse impacts on soil flora and fauna.

### 5.1 Genetic pollution and GM 'pests'

In the risk assessment of GM crops, important questions include whether it will be possible to contain the crop and introduced genes. The EC submission underlines how difficult and potentially impossible this may prove to be, especially for species such as oilseed rape and sugar beet which may be among the next GM crops to be grown in Europe. The Commission emphasises the negative consequences of a GM crop cross-breeding with related species and/or becoming established as a weed itself.

*"…a plant with an herbicide resistance will easily become a pest if the herbicide is widely used. The consequence is that the same HT should not be introduced in different species that may be used in the same agricultural system, if no potential adverse consequences are to be expected."* (para 163)

"*Some species, like rapeseed, are already very aggressive outside and inside cultivated fields…introducing resistance to important herbicides in certain species may certainly lead to significant spread and impacts. A problematic (worst) strategy would then be to introduce HT to several of the same relevant herbicides in one plant species with weediness potential. Cross hybridization would rapidly lead to the existence of multi-resistant plants which would then become major pests…the fast appearance of such plants has already been demonstrated in Canada, and proves extremely difficult to manage."* (para 164)

*"Concerning sugar beets, their easy hybridization with wild relatives give birth to very invasive weeds in Europe. Introducing resistances to herbicides in cultivated beets would also lead to significant agro-environmental impacts, as it would also rapidly lead to HT weeds, probably within a couple of years."* (para 165)

*"However, until recently, the plants had to develop these resistance mechanisms at least by themselves. Since the introduction of HT crop plants, we actually put HT resistance genes actively out into the agro-ecosystem and make them available to any crop relative. All it takes ever since for related weeds, notably often bad competitors already, is to take these offered HT genes up, they do not even have to develop them anymore. This shortcuts the resistance development process of related and unrelated weeds significantly. In addition, we increase the selection pressure*

*tremendously by exclusively spraying the complementary herbicide."* (para 168)

*"One should consider that some crops have a high potential for dispersal and long term establishment, especially crops like oilseed rape, which can be influenced by a range of environmental and agronomic factors. GM oilseed rape will behave in the same way. In addition crops like oilseed rape and beet have wild relatives with which they can hybridise. Thus the presence of these related species will result in hybrid formation and introgression of genes into these wild species. The wild population can then act as a potential reservoir over space and time for transgenes or can become a weed in HT crops."* (para 181)

"*A retrospective study has been carried since 1996 in Selommes (Loir et Cher, France). The aim was to determine the origin of feral populations in road and field borders around a silo and the impact of border management practices on their persistence. In summary, this study demonstrates that seeds do disperse a lot. A field of rapeseed produces about 75000 seeds per square meter. About 10% are lost during harvest and transportation. It has been shown that these seeds establish all around the fields and roads where they are transported and that the plants could live and reproduce outside of the fields. It was demonstrated that some plants found outside the fields corresponded to genotypes which had not been cultivated for more than 10 years."* (para 183)

*"… as of now, only the nearest steps of out-crossing to the next and most compatible relatives (for example, Brassica rapa for oilseed rape) have been considered and researched in the context of GM plants. However, multiple transgene out-crossing events via several relatives of crop plants have not been studied in any great detail to our knowledge and none of the experts addressed this gap of knowledge." (para 207)*

"*Studies showed that gene introgression occurred potentially creating additional problems for conventional beet seed producers. This is because the introduction of GM beet may result in flow of transgenes to wild beets, where they are incorporated into these wild populations. Subsequent flow of transgenes from wild beet to non-GM beet seed crops could introduce these genes into beet seed and weed beet contaminants of beet seed. This could have important implications for the seed industry."* (para 386)

*"The European Communities would also note that if imported seeds entered into cultivated fields (directly through seed dispersal or by pollen flow from feral plants to cultivars), their development could then be maintained in the case of farm-saved seeds (more than 30 % of the French cultivars)."* (para 670)

*"… the European Communities considers oilseed rape (OSR) a crop with weedy potential, especially in other broad leaved crops in arable rotations. Introduction of herbicide tolerance into OSR further reduces options for managing it and thus it could be argued that, under certain circumstances (e.g. existing use of the specific herbicide), its pest or weed status is increased by the introduction of HT traits and requires additional measures to manage it. Likewise some related species are also weeds and their weediness could be enhanced by the introduction of HT traits via gene flow. The European Communities thus concurs with… the fact that specific measures should be taken to control a "potential pest" and that "management options become more challenging and more complicated when the pest population has genes for several types of herbicide resistance". Furthermore, as this "potential pest" could spread out of the GM farms, control should also be applicable by non-GM farmers in order to be efficient. However, some of these management options may be difficult to implement (especially in non-GM farms), have higher costs and/or less desirable environmental impacts."* (para 318)

*"…Oilseed rape has many characteristics of a weed: high seed set, high seed dormancy, variable germination, competitive under fertile growing conditions, etc. In addition GMHT rape has the ability to*

*grow in subsequent non-GM rape crops even when grown after several years interval, resulting in potential impurity problems. In addition if the HT gene transfers to existing related weeds, they in turn can become problematic weeds of the HT crop since the specific herbicide will not control them."* (para 319)

### 5.2 Herbicide resistance

If herbicide tolerant crops are used widely, it is likely that herbicide tolerant weeds will evolve. This will result in the use of more toxic herbicides to control those weeds, as has already been widely documented in Canada, where herbicide tolerant GM crops have been grown for a number of years. The Commission explains how this will have negative environmental as well as agricultural impacts, emphasising some of the uncertainties involved.

*"Resistance to the herbicides glufosinate and glyphosate is also an issue that has been raised... Glyphosate is already one of the most widely used herbicides in the world and so how significantly the additional usage on HT crops would speed up the evolution of tolerant weeds is difficult to predict. Some resistance has already been found and some have argue that increased usage on HT crops will accelerate the evolution of resistance. This would initially be an agricultural problem but could be become an environmental issue if it results in an increased usage of herbicides with much worse environmental profiles…"* (para 198)

*"… Today, Canadian farmers do have to carefully select the herbicides they can use and with no resistance management plan in place, this situation will worsen from year to year. For Europe and oilseed rape, the gene flow issue and its possible consequences for ecosystems (spread of transgenes, reservoir function, multiple pathways of spread) and agricultural practice (resistance issues, stacking, weediness, coexistence) are still being fully and rigorously thought through in all the consequences. The situation in Europe for oilseed rape is sufficiently complex, so that there remains uncertainties which are likely not to allow experts to get a full grasp of all the consequences in the limited time available."* (para 208)

### 5.3 Effects on the soil

Another consequence of using herbicide tolerant plants together with the relevant herbicide is that the chemical will have a damaging effect on the soil microflora and fauna.

*"Soil systems react quite sensitively to chemical inputs, but because agricultural soils are already highly disturbed and often quite poor in biodiversity, and only productive with significant external inputs of agrochemicals, changes are not easily detectable, certainly not for lay people… While, it might be true that the two named herbicides [glyphosate and glufosinate] are less toxic than say Atrazine, it is a normative judgement to imply that this would justify the more intensive use of a less toxic one. This may sound like a choice between two adverse situations, for which it is not clear whether one is better than the other. However, no long-term data (> 3 years) and systematically recorded field experience is available to date on development of soil microflora and –fauna under large-scale use of GM HT crops and repeated applications of glufosinate or glyphosate."* (paras 244 and 245)

*"Some data however, do emerge from the use of glyphosate resistant soybeans in the US and some of these findings do rather point in the direction of a change in soil microbial activity towards favouring fungi over bacteria. For example Kremer et al. (2000) found that in soils repeatedly treated with glyphosate and grown to glyphosate resistant soybeans, soybeans significantly fell victim to a Fusarium fungus causing 'damping off'. It would in fact be rather surprising if such intensive use of one chemical would NOT cause a change in the microbial communities. The experience from Canada and the US also clearly show that the use of the respective herbicides complementary to GM HT crops do increase significantly with the production of the respective HT crops."* (para 246)

### 5.4 Conclusions

The UK farm-scale evaluations with GM HT crops had already revealed how damaging the use of broad spectrum herbicides may be to farmland wildlife. In its submission to the WTO, the Commission points to may other potential environmental problems likely to result from HT crops being grown. However, the Commission and its advisors gloss over these issues in public or when conducting risk assessments of GM crops, even when the same concerns are expressed by member states.

## 6 Regional differences in risk

"*The Commission has a legal obligation to make sure that the existing regulatory framework governing the release of GMOs is correctly applied by Member States. That is why we proposed to lift the current bans or restrictions on certain GMOs in Austria, France, Germany, Greece and Luxemburg*". Stavros Dimas, Commissioner for the Environment, 24 June 2005.[6]

Several countries in Europe have banned certain GM products even though these had been approved in Europe. These national bans formed part of the WTO challenge by the US, Canada and Argentina. The European Commission has tried to force countries to lift these national bans because they say that they are not justified under the regulatory system in Europe.

However, in the privacy of the WTO dispute process, the Commission argued that environmental impact assessment can not be simply translated from one country or region to another. The EC criticised the practice of using risk assessment results from non-European countries to justify approvals in Europe and stressed the need for regionally-relevant data.

*"It is not scientifically reasonable to simply translate and extrapolate the limited risk assessment results on the toxicity of Bt maize to human and non-target organisms from USA, Australia or some other non-European countries because the*
*- regional growing environments,*
*- scales of farm fields,*
*- crop management practices,*
*- local/regional target and non-target species considered most important in the agro-ecosystem,*
*- interactions between cultivated crops, and*
*- surrounding biodiversity*
*could each be different from published non-European studies and could differ substantially between regions and countries within the EC."* (para 139)

"…*Indeed, toxicity and environmental impact data on other species (e.g. regionally appropriate non target insects, including other non-domesticated herbivores) and regional environments (local growing regions in Spain) would be needed to accurately determine toxicity and environmental impacts to local Spanish fauna of Bt corn Cry1F and its degradation products (i.e. resulting from ingestion by herbivores and decomposition in the soil of plant material and root exudates). Even for target pest species from different countries or regions, sensitivities to expressed Bt toxins vary widely. Hence it can be reasonably expected that the same (species-specific and even population-specific variability in sensitivity to Bt toxins) will apply to local non target species that could be affected by this Bt toxin e.g. local butterflies of conservation concern or of heritage value.."* (para 448)

The Commission has acknowledged the enormous difficulties of having a single risk assessment which can be applied to the whole of the EU. This raises important questions about how the EFSA can take into account national and regional environmental differences and whether member states or regions need to be given the power to decide whether a risk is acceptable according to their own local conditions and environmental protection needs. The Commission is legally obliged, under the precautionary principle that underpins the regulations, to protect the environment and human health, not approve GM products.

[6] Brussels/Luxembourg, GMOs: Commission reaction on Council votes on safeguards and GM maize MON863. European Commission press release, 24 June 2005
http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/05/793&format=HTML&aged=1&language=EN&guiLanguage=en

## 7 Poor quality data provided by the industry

The Commission's submission to the WTO is critical of the quality of the information supplied by industry in support of its marketing applications for GM crops. When the EC provided evidence in support of Italy's national ban on Bt11 maize, it said:

"*The information requested and supplied from the company was mixed, scarce, delivered consecutively all over years, and not convincing. The quality of the dossier can therefore be considered as not sufficiently informative, taking into consideration the specific legislator's chosen level of protection. The major weaknesses of the dossier relate to :*

> *No sufficient experimental evidence to assess the safety;*
> *Compositional data insufficient for a product directly consumed by human;*
> *No in vivo experiments conducted on laboratory or farm target animals with grain of the event "sweet maize";*
> *Field maize used as a control - grain material was spiked with Bt proteins (resulting in poor and unsatisfactory experimental conditions);*
> *Further experiments performed on ruminants using the whole plant silage or stalk have no meaning for the safety assessment.*

*Taking into account the legislator's chosen level of protection, these issues could be considered to have justified requests for further evidence on the safety of the product."*
(paras 762 and 763)

## 8 The realities of "co-existence"

*"Efficient and cost-effective strategies to ensure co-existence are vital to ensure a practical choice between GM and non-GM produce for farmers and consumers. This is not a question of health or environmental protection, because no GMOs are allowed on the EU market unless they have been proved to be completely safe"*. Mariann Fischer Boel, Commissioner for Agriculture and Rural Development, 4 April, 2006.[7]

Probably the most controversial current debate on GMOs in Europe is over what measures countries can take to control or prevent contamination from GM crops. This is known as the "coexistence" between GM, conventional and organic farming. Causes of contamination include cross-pollination, spillage of seed or mixing at various times after harvest. The extent to which coexistence is feasible is intensely divisive but in public at least, the Commission is encouraging the view that national measures to manage contamination are practicable and will not bring additional costs. However, in their submission to the WTO, the EC shows that it is only too familiar with the difficulties of adopting strategies for mitigation of risks from GM contamination.

*"…Knowing agricultural practice, compliance would be low and hardly* [sic] *to enforce. Not least of all, it would put quite a burden on the farmers, and potentially also increase the exposure of farmers to less innocuous chemicals, with all the related human health consequences, and it would not eliminate the risk after all"* (para 215)

*"The measures for maintaining low levels of HT oilseed rape on farms will be the most difficult to implement and will require very stringent measures to maintain volunteers at low levels and restrict gene flow. Temporal separation of non-GM rape from GM rape will be several years (8-10?) and spatial separation and sanitary measures will be needed."* (para 217)

*"This would mean that all farmers (both GM and non-GM) should comply with mitigation measures if we intend to mitigate the spread of herbicide resistance. This is technically feasible but not easy to implement under the current legal framework. This would also lead to extra costs for non-GM farmers".* (para 232)

In public, the Commission also emphasises that coexistence is only an economic problem because the environmental and safety concerns are already dealt with in the GMO approvals process. However, when Canada and Argentina raised this issue in the WTO dispute, the Commission strongly argues that coexistence is also an environmental problem.

"*Argentina and Canada naively assert that there is no problem managing HT volunteers but fail to recognise the major issue of GM admix in non GM rape crops, for which there is no available management…The Complainants consider such admixture as an agronomic problem and not an environmental one. But it constitutes an agronomic and/or economic harm to neighbours' or subsequent crops and thus should be viewed as environment harm*." (para 21, EC's Further Evidence)

The Commission also highlights the problems arising in Canada through contamination. "*It is well established that in Canada HT-canola has become effectively a pest…Furthermore, pedigree seed is contaminated, effectively bringing organic or GM-free canola production to a halt in large areas of Canada (eg Manitoba) – likely irreversibly…The fact that multiple HT stacking is occurring is not*

[7] Experts gather in Vienna to discuss co-existence of genetically-modified crops with conventional and organic farming. European Commission press release, 4 April 2006. http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/06/427&format=HTML&aged=0&language=EN&guiLanguage=en

*disputed anymore…In this case, other herbicides would enable proper management. Notably, with the use of the herbicides with worst impacts, that the applicants for marketing HT-crops originally started out claiming to get away from. This undermines the original claimed benefits of improved environmental safety by using a less toxic herbicide, but also imposes it use for non GM crop users*." (para 23, EC's Further Evidence)

## 9 At odds with EFSA

One of the most striking aspects of the EC submissions is that they frequently criticise the European Food Safety Authority (EFSA) and its assessments of the safety of GM foods and crops, even though the Commission relies on these evaluations to make recommendations to member states. The Commission has also continually used EFSA opinions to justify its decisions to approve new GM foods and feeds for import following a lack of agreement between member states.

Here we give examples of the Commission's private opinion on the quality of evidence and uncertainties in relation to two GM maize varieties, Bt11 and 1507, which have been considered by the EFSA. Both varieties of maize are insect resistant, although each contains a different Bt toxin gene, and are the subject of national bans in Austria and Hungary. The EFSA's official opinions on Bt11 and 1507 maize, and their opinions on the Austrian and Hungarian invocations of the 'safeguard clause'[8], dismiss concerns and studies that show negative impacts. However, in its evidence to the WTO, the EC challenge many of the judgements made by the EFSA:

*"The publication by Zwahlen et al (2003) on earthworms was apparently criticised by EFSA in July 2004 as not being conclusive and definitive… The cited criticisms by EFSA should at least have required that further follow-on scientific investigations were performed (precautionary approach after some evidence of adverse effects to an important soil NT organism), not that the scientific evidence should be dismissed and the potential risk to earthworms ignored."* (para 696)

"*The European Communities agrees...on the likelihood of Bt toxin entering the soil ecosystem (via plant debris and/or root exudates) and being more (not less) likely to cause harm to soil organisms (e.g. collembolan that consume plant remains in the soil) than residues from Bt sprays applied to foliage, where UV breaks down Bt toxin in foliar sprays quickly…The EFSA also made comparisons between growing Bt crops with risks from using Bt sprays (the latter are known to be UV unstable, contain different toxins, only present on leaf surfaces etc) that have been subsequently criticised…The EFSA also appeared to discount linked evidence that in GM maize lines lignin content was unintentionally altered, leaving open possible long term effects on GM crop decomposition and nutrient cycling."* (also para 696)

Furthermore, the Commission brings attention to the fact that the Bt toxin can accumulate in the food chain and cause much more complex negative effects than taken into account by the EU advisory bodies so far.

*" ...The European Communities considers that it is now clear that Bt toxin could accumulate in Bt-resistant herbivores (e.g. caterpillars which are able to ingest the Bt toxin and thus accumulate it and/or its metabolites without dying), and so pass the Bt toxin and/or its metabolites to organisms higher up the food web (e.g. to predators and parasitoids which feed on Bt-resistant herbivores). This point involving multi-trophic interactions was not dealt with by the SCP [*Scientific Committee on Plants[9]] *in its analysis of risks to non-target organisms in the environment, at least not in a manner reflecting the specific legislator's concerns."* (para 692)

EFSA's opinions for Bt11 and 1507 maize state that *"No evidence of accumulation of Bt toxins in the food chain has been reported and is not expected as the toxin is an easily degradable protein."*

In another example of a staggering divergence of views, EFSA's opinions for Bt11 and 1507 maize rely on studies of monarch butterflies in the USA as evidence that impacts on non-target butterflies in

[8] http://www.efsa.eu.int/science/gmo/gmo_opinions/1046_en.html and http://www.efsa.eu.int/science/gmo/gmo_opinions/507_en.html

[9] The expert advisory committee used by the Commission before the establishment of the EFSA.

the EU will be negligible – not one European study is mentioned. EFSA states that, "*Maize, a recently introduced species into Europe, is not a significant food source for endemic lepidoptera and impacts due to pollen dispersal are likely to be transient and minor as demonstrated by studies on monarch butterflies in the USA.*[10]

The Commission's contrasting view of the need for geographically relevant data is that:
"…*Indeed, toxicity and environmental impact data on other species (e.g. regionally appropriate non target insects, including other non-domesticated herbivores) and regional environments (local growing regions in Spain) would be needed to accurately determine toxicity and environmental impacts to local Spanish fauna of Bt corn Cry1F and its degradation products (i.e. resulting from ingestion by herbivores and decomposition in the soil of plant material and root exudates). Even for target pest species from different countries or regions, sensitivities to expressed Bt toxins vary widely. Hence it can be reasonably expected that the same (species-specific and even population-specific variability in sensitivity to Bt toxins) will apply to local non target species that could be affected by this Bt toxin e.g. local butterflies of conservation concern or of heritage value.."* (para 448)

Furthermore, several studies from the USA and Canada, one of which looks at cotton, not maize, are cited as evidence by EFSA of the lack of impact on soil microorganisms and to counter findings of slow degradation of Bt maize in soil. In contrast, the EC submission clearly states what is needed:

"*The views summarised in these cited publications focus on the need for multitrophic testing, using real Bt crops in realistic testing conditions, tested with regionally appropriate non-target species, likely to be exposed to Bt toxin or metabolites. These views arise from accumulating scientific knowledge over the period from the mid 1990s until today. Scientific uncertainties on effects of Bt crops on non-target species or ecological functions were (and still are) identified and are being addressed by many international scientists*." (para 147)

And again in relation to indirect effects of Bt on beneficial insects, the EFSA's view is:
"*Thus, a reduction in prey either by cultivation of Bt maize or by insecticides may negatively effect the food source of predators like Chrysoperla carnea (Hilbeck et al. 1998a,b). However, current knowledge on toxicity and exposure give sufficient scientific evidence that Bt maize poses no risk to this predator (Dutton et al. 2003a, b; Romeis et al. 2004)."* (EFSA opinion on 1507)

The EC takes a different line.
"*The two sets of studies differ widely in most of their approaches and are thus not comparable in this way. The Romeis et (2004) study on Bt Cry1Ab toxin cited by Canada is recognised to be scientifically flawed in several ways (e.g. use of surrogate Bt toxin not shown to be identical to Bt toxin in the GM crop, use of artificial diet not suitable for normal development and leading to high control mortalities, compounding effects of starvation on Bt treatment effects, use of very short term exposures which do not reflect GM crop trophic interactions in ecologically realistic ways*." (para 31, EC's Further Evidence)

The divergent views of the EFSA and the Commission in public, and the Commission in private illustrate the very subjective nature of the GM risk assessment system and how the outcome depends on the relative importance that it placed on environmental protection versus the approval of the product. When environmental protection is prioritised, as the Commission had to do in arguing its case at the WTO, the uncertainties, lack of data and methodological limitations of studies come to the fore. If more weight is put on commercial interests of industry, environmental protection is marginalised. However it is important to note that under the European legal framework, which is based upon the precautionary principle, the priority for the Commission is the protection of the environment and health

[10] http://www.efsa.eu.int/science/gmo/gmo_opinions/827_en.html

and any attempts by the Commission to push through GMOs whilst sidelining these impacts must be treated with the utmost seriousness.

Another implication of biased risk assessments is in relation to liability for environmental harm. Companies may be able to rely on a consent to grow or import a GMO as a defence against being required to pay for remediation. Therefore, an inadequate risk assessment acts in the economic interests of the GM industry in both the short and long term.

## 10 Conclusions

The WTO documents obtained by Friends of the Earth, show that the Commission fully appreciates the extent of the uncertainties and gaps in knowledge that exist in relation to the safety of GM crops. However, the Commission normally keeps this uncertainty concealed from the public whilst presenting its decisions about the safety of GM crops and foods as being certain and scientifically based.

**Below we make a number of recommendations for urgent changes that need to be made to the way the Commission deals with GM crops and foods. Because of the seriousness of the issues, we are calling for an immediate suspension of the GMO approvals process, and a halt to the sale of GM foods and feeds and commercial cultivation until these issues are resolved.**

### 10.1 The EFSA

The manner in which such uncertainties are concealed is most obvious when the opinions of the EFSA are contrasted with those of the precautionary approach the Commission was forced into taking when having to deal with the WTO dispute process. The EFSA opinions do not examine the uncertainties, methodological problems or gaps in data and the Commission's starkly different presentation of the issues and explicit criticism of the EFSA show that changes are urgently needed. **The EFSA should be required to revise its presentation of the available data when it undertakes GMO risk assessments. They should document the uncertainties, gaps in knowledge and assumptions used in coming to a conclusion. All past assessments, including those of the Scientific Committee on Plants which are still relevant, should be revised and presented in this way.**

### 10.2 The Precautionary Principle

The regulation of GMOs in Europe requires a precautionary approach to be followed. In situations where serious harm may arise, lack of evidence of the harm arising should not prevent action being taken to prevent harm. As the Commission's evidence to the WTO dispute shows, there is the potential for serious and irreversible harm from the use of GMOs, considerable uncertainty exists and gaps in knowledge are extensive. Normally the Commission conceals the extent of this from the public and member states when it accepts the advice of the EFSA. In giving the biotechnology industry, rather than the environment, the benefit of the doubt , the Commission is failing to implement the precautionary principle as required in law. **The Commission must acknowledge that under a precautionary approach to environmental protection, bans or restrictions on GM crops are legitimate. It must also prioritise environmental protection, not the biotech industry, in its interpretation of the implications of uncertainties and gaps in knowledge.**

### 10.3 Member state assessments of GMOs

The EC has laid out very clearly, particularly in relation to the risks to non-target species from Bt crops and the difficulties of containing oilseed rape and sugar beet, how sensitive risk assessments of GMOs are to different environments and environmental protection priorities. For example, information on the susceptibility of European non-target species is extremely limited at best and non-existent at worst for most species. **European countries should ban the use of Bt crops until data is available that clearly demonstrates that the relevant non-target species are not at risk. In their implementation of the Environmental Liability Directive, member states should ensure that all species and habitats are included and that the very poor risk assessments currently being used to justify consents cannot be used as a defence.**

### 10.4 Coexistence of GM and non-GM crops

Co-existence, according to the Commission, is both extremely difficult and a matter of environmental protection as well as an economic issue. **The Commission should withdraw its flawed Recommendation to member states on coexistence which emphasises that coexistence is**

**simply an economic issue. Instead the Commission should start a process for Europe wide measures that aim to prevent any GM contamination, contain strict economic liability measures to back this up and allow member states and regions to ban GMOs if they pose an unacceptable risk to their environments.**

### 10.5 Public confidence in the European Commission

The publication of this report on the Commission's previously concealed views on the risks of GMOs signifies a turning point in the politics of GMOs in Europe. The contrast between the public and private views of the European Commission on the risks of GMOs is staggering and will seriously dent public and member states' confidence in their ability to act fairly. All the evidence reveals a Commission policy of favouring the interests of the biotechnology industry over protecting the environment and human health. **A fundamental change in the way in which the European Commission acts in relation to GMOs is now required. This new approach must place protection of the environment and public safety at the heart of decision making over GMOs - as it should be under the precautionary Principle, and abandon all bias towards biotechnology industry interests. The Commission must ensure that the EFSA changes it risk assessment practice; support member states that wish to ban or restrict GMOs; and end approvals of GMOs when member states are not in agreement.**