Friends of the Earth Europe

WHAT'S WRONG WITH AN EFSA OPINION

In 2005 the European Food Safety Authority published its first opinion on the environmental aspects of growing genetically modified crops in Europe. The opinion concerned the application by Pioneer Hi-Bred to grow a GM maize called 1507. Shortly afterwards, the EFSA issued an opinion on the cultivation of Syngenta's Bt11 maize. The two opinions are virtually identical.

Friends of the Earth believes that the EFSA has failed to fully address the long term impacts of growing GM crops in Europe. These two opinions question the competence of EFSA on environmental issues. References are quoted out of context, research showing possible negative impacts is either ignored or sidelined, and every concern raised by member states is dismissed.

In this publication, Friends of the Earth has annotated the 1507 maize opinion to show its inadequacies and lack of transparency. The comments added are limited to the environmental aspects of the application and are indicative of what is wrong with the EFSA opinions. Similar comments can be made about the opinion on Bt11.

Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the notification (Reference C/ES/01/01) for the placing on the market of insect-tolerant genetically modified maize 1507 for import, feed and industrial processing and cultivation, under Part C of Directive 2001/18/EC from Pioneer Hi-Bred International/Mycogen Seeds

(Question No EFSA-Q-2004-0)

Opinion adopted on 19 January 2005

5. Environmental risk assessment

5.1 Issues raised by the Member States

(1) Direct and indirect effects of the Cry1F toxin on non-target organisms, specifically soil biota, arthropods, parasitoids of maize pests, butterflies, and other invertebrates, should be addressed; (2) more information on the general surveillance and monitoring of non-target effects was requested; in addition, a more detailed insect resistance management plan was demanded; (3) the lack of knowledge concerning the occurrence of lepidoptera and their sensitivity to the Cry1F toxin in and around maize fields was emphasised; (4) concerns about

> Fifteen (out of seventeen) national authorities raised the issue of effects of the Bt maize on non-target organisms. Several member states commented that no information was provided on the presence of Lepidoptera in European maize fields, their likely exposure or susceptibility to the Cry1F protein. This data is recommended as an initial screen to determine what should be investigated further (Wolt et al, 2003), but even this was not provided by the applicant.

potential harm to endangered Lepidopteran species were expressed and the possible need to protect endangered butterfly species was emphasised; (5) it was recommended that there should be consideration of potentially altered lignin contents and the biodegradability of plant litter as well as possible long-term persistence of the Cry1F protein; (6) dietary toxicity studies on non-target insects carried out with microbially-derived Cry1F protein were questioned due to a potentially higher toxicity of the toxin produced by GM plants8; (7) it was argued that the implications of the presence and use of *pat* gene, in addition to the *cry*1F gene, should be considered both in the environmental risk assessment (ERA) and in the post-market environmental monitoring plan (PMEM); (8) it was mentioned that the use of glufosinate in association with 1507 maize should be restricted to the regime used in the UK Farm Scale Evaluation trials; (9) the issue of outcrossing between GM and non-GM crops and related impacts on the co-existence of these crops was raised.

5.2. Evaluation of relevant scientific data

5.2.1. Potential unintended effects on plant fitness due to the genetic modification

Maize is highly domesticated and not generally able to survive in the environment without cultivation. Maize plants are not winter hardy in many parts of Europe. They have lost their ability to release seeds from the cob and they do not occur outside cultivated or disturbed land in Europe, despite cultivation for many years. In addition, there are no cross-compatible wild relatives in Europe, and gene flow via pollen is largely restricted to neighbouring crops. 1507 maize has no altered survival, multiplication or dissemination characteristics except in the presence of glufosinate. The Panel is of the opinion that the likelihood of unintended environmental effects due to the establishment and spread of 1507 maize will be no different to that of traditionally bred maize.

5.2.2. Potential for gene transfer

A prerequisite for any gene transfer is the availability of pathways for the transfer of genetic material, DNA in case of horizontal gene transfer and pollen in case of vertical gene flow through cross-pollination.

Exposure of microorganisms to transgenic DNA derived from GM maize plants takes place in the environment during natural decay of transgenic plant material, such as GM plant parts, in agricultural areas and/or pollen in nearby natural ecosystems as well as in cropped fields. Transgenic DNA is a component of some or most of the food and feed products derived from the GM maize. Therefore microorganisms in the digestive tract of humans and animals (domesticated animals and other animals feeding on fresh and decaying GM plant material) may be exposed to transgenic DNA.

Transgenic pollen is shed and distributed from cultivated GM hybrids or from plants resulting from the adventitious presence of GM kernels in conventionally bred maize seeds. A further but less likely pathway of dispersal of transgenic maize pollen is the flowering of volunteer GM maize plants originating from accidental seed spillage during transport and/or processing. For *Zea mays* any vertical gene transfer is limited to other maize plants as populations of sexually compatible wild relatives of maize are not known in Europe.

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8 This issue is addressed in section 4.2.3.1.

Maize is winter-hardy in parts of southern Europe and should require a separate consideration of the risks. Member states specifically raised this matter in their responses to the application. The Panel relies for part of its safety conclusion upon maize being killed by cold weather – if this is a safety requirement then it should be a condition of the release that the GM maize cannot be cultivated in those areas where it would not be killed off by cold weather

Glufosinate ammonium herbicide is already used for weed control in the EU, and its use is likely to extend if glufosinate tolerant GM crops (not just maize) are approved. What are the current rates of volunteer maize in following crops, and land adjoining agricultural habitats and roadside verges? What additional control measures would be required to control herbicide tolerant maize? What is the environmental impact of these measures? What would be the potential for contamination of following or adjacent non-GM crops?

(a) Plant to bacteria gene transfer

Based on present scientific knowledge and elaborated recently in more detail (EFSA, 2004c), gene transfer from GM plants to bacteria under natural conditions is extremely unlikely, and would occur primarily through homologous recombination in microbes.

The *cry*1F gene and the *pat* gene expressed in the 1507 maize are under the control of eukaryotic promoters with limited if any activity in prokaryotic organisms. Genes under control of prokaryotic regulatory elements conferring the same traits as expressed in the GM plants are widespread in microorganism in natural environments.

Taking into account the origin and nature of these genes and the lack of selective pressure in the intestinal tract and/or the environment, the likelihood that horizontal gene transfer would confer selective advantages or increased fitness on microorganisms is very limited. For this reason it is very unlikely that genes from 1507 maize would become established in the genome of microorganism in the environment or human and animal digestive tract. In the very unlikely event that such a horizontal gene transfer would take place, no adverse effects on human and animal health and the environment are expected as no principally new traits would be introduced into microbial communities.

(b) Plant to plant gene transfer

The extent of cross-pollination to conventionally bred hybrids will mainly depend on the scale of accidental release and/or adventitious presence in conventional seeds.

As shown in several field trials there are no indications for an altered ecological fitness of the GM maize in comparison to conventionally bred hybrids with similar genetic background. The herbicide resistance trait can only be regarded as providing a selective advantage where and when glufosinate-ammonium containing herbicides are applied, *i.e.* mainly on arable land. Insect protection against lepidopteran pests is also not regarded as providing a selective advantage for maize in Europe, as the survivability is mainly limited by the absence of a dormancy phase, susceptibility to fungi and susceptibility to cold climate conditions. Therefore, as for any other maize cultivars, it is considered very unlikely that volunteers could survive until subsequent seasons or would establish undesirable populations under European environmental conditions.

What is the impact of insect resistance if one of these limiting factors (eg cold climate conditions) is removed?

5.2.3. Interactions between the GM plant and target organisms

According to the statement made by the Scientific Committee on Plants (SCP, 1999) and in line with Annex II of Directive 2001/18/EC the Panel considers that the evolution of resistance in target pests is an environmental and agronomic concern. Up to now, resistant *Ostrinia nubilalis* or *Sesamia nonagrioides* have not been found in fields in the US or in Europe (Evans 2002, Tabashnik *et al*., 2003, Bourguet *et al*., 2003, Farinós *et al*., 2004). Although laboratory tests showed that corn borer populations are capable of developing some degree of tolerance to the Cry1Ab protein (Huang *et al*. 2002), laboratory selection and F2 screening to generate highly resistant *O. nubilalis* strains have failed so far (Bourguet, 2004). However, another lepidopteran pest (*Plutella xylostella*) has developed resistance to *Bt* toxins (Tabashnik *et al*., 2003). The Panel concludes that large scale cultivation of 1507 maize over several years will increase the selection pressure on corn borers, which might result in the development of resistance. This could have several consequences including the use of alternative phytosanitary measures to control the pest including involving the use of insecticides other than *Bt* toxins. The Panel agrees that the likelihood of occurrence is low since, under field conditions and several years of

This study does not look at resistance in depth – the review is intended to look at environmental risks associated with root exudation of Bt. It refers to the “still largely unquantified risk factor” of increased resistance to Bt.

“Unequivocal evidence” has also been provided that cotton bollworms (Helicoverpa armigera) bred from field survivors of a Cry1Ac resistance screening procedure, are resistant to Cry1Ac (Gunning et al, 2005).

“…it is very difficult or impossible to generalise or extrapolate between studies, even within one country and for one GM crop event. This enforces the scientific arguments for regionally specific, case-by-case studies of GM crop impacts performed over several (preferably 3 or more) growing seasons in the same region." (EC in the WTO dispute)

cultivation, no resistance has been reported. However, cultivation of *Bt* maize in Europe is currently on a small scale and limited to a few geographic regions. Thus it is difficult to predict future responses of corn borer populations in Europe. Therefore, the Panel advises that potential target pest resistance development should be monitored under case-specific monitoring using the methods submitted by the applicant as part of their general surveillance plan.

5.2.4. Interactions of the GM plant with non-target organisms

(a) Effects on predators and parasitoids of the target organisms

The abundance of non-target predators preying upon the target organisms *Ostrinia* or *Sesamia* will vary with the abundance of their prey. 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). Most field studies confirm that predator and parasitoid abundances and biocontrol functions are very similar in *Bt* and non-*Bt* fields (Candolfi *et al*. 2004, Pons & Stary, 2003, Musser & Shelton, 2003). Reductions of population densities of specialist *Ostrinia* predators and parasitoids are expected as this pest is the target to be controlled in *Bt* maize fields. Bourget *et al.* (2002) and Siegfried *et al.* (2001) have found that populations of specific natural enemies of *Ostrinia* are less abundant in *Bt* maize fields than in non-*Bt* maize fields. This is not thought to be due to the direct effects of the Cry toxin consumed while predating or parasitizing *Ostrinia* but is due to decreased availability of specific prey. Results of field studies comparing the effects of *Bt* maize with insecticide treatments against the target pest, show that broad-spectrum insecticides, like pyrethroids, reduce abundances of a range of predator and parasitoid species not specific to *Ostrinia*. Such effects have not been reported in *Bt* maize.

(b) Effects on other non-target organisms

It is well documented that a range of lepidopteran species may be affected by *Bt* toxins and some may be present in maize fields (Schmitz *et al*., 2003; for a review see Evans 2002). However, exposure of any populations of lepidoptera to the toxin is restricted to those consuming the *Bt* plant or its products. In the vicinity of the *Bt* maize field larvae may be most exposed to the toxin when *Bt* maize pollen is deposited on plants on which they are feeding. 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 (Dively *et al*., 2004). Published studies investigating potential effects of GMOs due to the expression of *Bt* toxins have been mainly performed with maize *Bt*11 and *Bt*176, both producing CryIAb. Generally similar effects on the environment due to the presence of different *cry* genes can be expected, however, the severity of potential effects will depend on the expression of the relevant gene and the toxicity of the resulting toxin. Hellmich *et al.* (2001) compared the toxicity of different *Bt* toxins and reported a >10.000 times lower toxicity of the Cry1F toxin (as produced in 1507 maize) on monarch butterfly first instars as compared with other Cry toxins (*e.g.* CryIAb). On the other hand, according to the data presented in the respective dossiers, Cry1F concentration in 1507 maize pollen is higher in comparison with CryIAb concentration in *Bt*11 pollen (1.3 ng Cry toxin mg-1 plant protein in *Bt*11 pollen compared with 160 ng Cry protein mg-1 plant protein in 1507 maize pollen). However, Hellmich *et al.* (2001) showed that monarch larvae were not affected by a diet consisting of 1507 maize pollen. Considering toxicity and exposure of Cry1F, the Panel agrees with the assessment of the applicant that risk of exposure of non-target lepidoptera to harmful toxin concentrations via 1507 maize pollen is negligible and that adverse impacts on populations are very unlikely.

Dutton study looks at Dipel Bt spray, not Bt maize. In the WTO case the EC argued that the Romeis study was “scientifically flawed in several ways” (surrogate BT toxin used, artificial diet led to high control mortalities, use of short term exposures which do not reflect GM crop trophic interactions in ecologically realistic ways etc).

This study uses very small plot sizes which will not be equivalent to larger plots or fields (see Prasifka et al, 2005). “Scale of testing has a major impact on environmental impact assessment…" (EC in the WTO dispute)

This is misleading – the paper found that the toxic effect of Bt maize pollen was caused by monarch larvae ingesting maize pollen that had fallen on milkweed plants, rather than the maize itself.

Unsupported statement. Which European Lepidoptera species *do* feed on maize? Are these declining species? What proportion of their diet does maize represent? What importance do these species have for higher organisms?

The monarch butterfly is a North American species. This is not sufficient to demonstrate safety of the Cry1F toxin. Data from more extensive studies on Cry1Ab shows that high tolerance of one species cannot be taken as an indication for other species, with the range of toxicity for 50% mortality of the different Lepidoptera species studied being 0.8 ng/ml (first instar Monarch butterfly larve) to 107,000 ng/ml (neonate Spodoptera exigua) (van Frankenhyzen & Nystrom, 2002).

What are the likely exposure rates of European Lepidoptera? Are the feeding patterns and behaviour of the monarch butterfly comparable with the European species present in maize fields? Are European species more or less susceptible to Cry1F than the monarch butterfly?

Three year experimental studies of *Bt* maize (*Bt*176 expressing CryIAb) in Spain did not show effects on mortality, developmental and pre-reproductive times, fecundity, and intrinsic rate of population increase comparing the offspring of apterous aphids maintained on *Bt* or non-*Bt* maize for several generations (Lumbierres *et al*., 2004), which is in line with the absence of *Bt* toxin in the phloem (Raps *et al*., 2001).

Direct and indirect effects of GM plants in general on animals higher in the food chain including both invertebrates and vertebrates (birds, mammals) have been discussed in some publications (Kjellson & Strandberg, 2001; Firbank *et al.* 2003) No indications of intoxication have been reported or are indicated from first and second tier exposure studies or from feeding studies with diets containing *Bt* toxin. It should also be considered that under field conditions most animals higher in the food chain would be eating diets consisting of a range of food sources.

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 most situations the toxin appears to be degraded through passage of the gut, although detectable amounts of the *Bt* toxin can still be found in faeces and therefore pass into the environment. In cattle, the influence of CryIAb transgenic maize on rumen bacterial microflora was investigated compared with isogenic material through analysis of 497 individual bacterial 16S rDNA sequences. In principle, specific bacterial species could be identified in all bovine rumen extracts, but no significant influence of *Bt* maize feed (*Bt* 176) was found on the composition of the microbial population (Einspanier *et al.* 2004). It therefore appears that the environmental impact of *Bt* toxin through manure is negligible, as only very small amounts of the toxin are expected to be excreted to the environment through manure and significant long-lasting changes in the composition of microbial communities of the manure seem unlikely.

Reduction of prey/feed abundance can be a consequence of many types of crop management practices. The Panel has no reason to consider that 1507 maize will cause changes to non-target species that differ significantly from those caused by conventional farming.

5.2.5. Potential interaction with the abiotic environment and potential effects on biogeochemical processes

As a consequence of the cultivation of *Bt* maize the respective *Bt* toxins will be incorporated into the soil (root exudates, *Bt* toxin containing plant material like plant litter and pollen). Some scientific publications indicate that this might affect soil organisms. Assumptions were raised that the *Bt* toxin may persist and accumulate in soil during cultivation of *Bt* maize in subsequent years. Therefore, both direct and indirect impacts of the toxin or the *Bt* maize (*e.g.* potential increase of lignin content in combination with a possible delay in decomposition) on non-target organisms and soil function should be considered (Saxena *et al.* 2002, Zwahlen *et al.* 2003a). There was a concern that *Bt* maize might negatively affect species other than lepidoptera and consequently biodiversity. The suggested species range comprises soil and plant associated insects in food chains including those involved in plant decomposition.

Herman *et al.* (2002) showed that Cry1F produced in recombinant *Pseudomonas fluorescens* rapidly decomposed in soil studied under laboratory conditions which is in line with other publications on the degradation of Cry proteins in soil (Glare & O´Callaghan, 2000). Further data on potential effects of *Bt* plants are mainly available from maize expressing CryIAb such as *Bt*11. However, as effects of *Bt* plants expressing different Cry proteins are considered to be comparable, the GMO Panel takes published data on other *Bt* maize cultivars into account. Saxena & Stotzky (2001) reported Cy1Ab had no apparent effect on earthworms and nematodes in a 45-days study. Zwahlen *et al.* (2003b) reported a 200-day study investigating the impact of transgenic *Bt* maize event *Bt*11 (expressing Cry1Ab) on immature and adult *Lumbricus terrestris* in a single worst-case laboratory study and in a single small scale field test. At the end of the laboratory test the earthworms showed a significant weight loss of 18%

Directive 2001/18 requires the risk assessment to consider indirect impacts. EFSA has only considered direct toxicity to higher organisms.

What about the animals which are not "eating diets consisting of a range of food sources"? How important is the target organism and non-target Lepidoptera in their diets?

With no assessment of the impact on European Lepidoptera, there can be no assessment of whether key species are affected or whether such species are important to higher organisms. Lepidoptera larvae are important food sources for declining bird species as well as most granivorous bird species (Wilson et al, 1996, Campbell et al, 1997, University of East Anglia, 2002)

What role does the target species play in the diets of higher organisms? How important are these species in the diet of higher organisms? What is their conservation status? It is essential that the indirect effects on biodiversity are properly investigated, and the requirements of 2001/18 are met.

The discussion of this paper states: "these results should be considered as being preliminary, as only one species of earthworm and only total numbers of culturable bacteria, fungi, protozoa and nematodes were evaluated. More detailed studies on the composition and diversity of these groups of organisms are necessary…to confirm the absence of the effect of the Cry1Ab toxin on biodiversity in soil"

Harwood et al, 2005, report the presence of Cry1Ab endotoxin in arthropod predators in Bt maize agroecosystems, indicating movement into higher trophic levels.

The EC stated at the WTO: "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)."

They also concluded: "Further experiments, lasting longer than 200 days, are necessary to confirm this effect. As well as a potentially adverse effect of the Bt toxin, another reason could be unanticipated changes in the plant quality due to the genetic transformation… Further, we recommend that other life history traits and fitness parameters, such as longevity, development time from hatch to sexual maturity, numbers of cocoons produced, fertility and survival of offspring should be investigated."

The EC at the WTO stated: "EFSA should at least have required that further follow-on scientific investigations were performed…not that the scientific evidence should be dismissed and the potential risk to earthworms ignored."

(compared with their initial weight) when fed (*Bt*+) maize litter whereas a weight gain of 4% occurred with non-GM control maize. No difference was found in the higher tier small scale field test. Due to the experimental design, the authors stated that they were unable to exclude the possibility that the weight loss of earthworms fed with Bt maize in the laboratory test was due to other factors.

The effects of 1507 and Bt11 maize on soil microbial community structure were assessed in growth chamber experiments using three soil types with different textures (Blackwood & Buyer, 2004). Very few significant effects on soil microbial communities due to the presence of the *Bt* toxins were found, whereas the soil type significantly influenced the composition of the soil microflora. Similarly, other studies on transgenic plants expressing Cry toxins did not reveal any negative, long-lasting impact on the soil or plant-associated microorganisms (Flores *et al.*, 2005; Devare *et al.*, 2004; Donegan *et al.*, 1995). Koskella & Stotzky (2002) reported that Bt proteins showed no toxicity to bacteria, fungi and algae. Turrini *et al.* (2004) reported that root exudates of *Bt*176 corn significantly reduced hyphal growth of arbuscular mycorrhizal fungi, a group of organisms that is fundamental for soil fertility and plant nutrition. In the same study, *Bt*11 did not affect the plant-mycorrhiza symbiosis (Turrini *et al.*, 2004). Blackwood & Buyer (2004) did not detect an effect due to the cultivation of 1507 maize on the abundance of arbuscularmycorrhizal fungi.

For Bt11 maize, it has been suggested that biodegradation and mineralisation of plant litter was delayed by a higher lignin content (Zwahlen *et al*. 2003a, Saxena & Stotzky, 2001a). Zwahlen *et al*. (2003a) published the results of two field studies in the temperate maize-growing region of Switzerland investigating the degradation of Cry1Ab toxin in transgenic *Bt* maize leaves during autumn, winter and spring periods. Each of the two field trials (in 1999/2000 and 2000/2001) covered a period of 200 days. The results suggest that *Bt* toxin is not completely degraded within the period tested. The authors discuss their findings in the light of potential differences in lignification (Saxena & Stotzky, 2001a), although lignin content was not determined. A more comprehensive study suggests that the extent of lignification of Bt transgenic maize (several lines derived from MON 810 and *Bt*11) does not differ from the non-transgenic controls (Jung & Sheaffer, 2004). Compositional analysis provided by the applicant on 1507 maize of the lignin-containing acid and neutral detergent fibre content in forage, as well as the lignin precursors *p*-coumaric acid and ferulic acid in kernels, did not indicate altered lignification.

A four-year study on the decay of transgenic maize *Bt* toxin (event *Bt*176) was published (Hopkins & Gregorich, 2003). The authors followed the rate at which the toxin in *Bt*-maize leaves decomposed in soil from a field in which *Bt*-maize had been cultivated for four years. The results suggested that much of the *Bt* toxin in crop residues is highly labile and quickly decomposes in soil, but that a small fraction may be protected from decay in relatively recalcitrant residues. It is known from experience with conventional *Bt* sprays, that *Bt* toxins as crystals can persist in soils, *e.g.* for at least 28 months (Vettori *et al.*, 2003). Recently, the decomposition of different plant species expressing *Bt* toxins was analysed in laboratory experiments and results were discussed in relation to lignin contents and potential environmental consequences (Flores *et al.*, 2005). Generally, *Bt* plants showed less decomposition than non-*Bt* plants. However, this effect was not clearly related to lignification or reduced microbial activity in soil. The authors concluded that lower decomposition rates may be beneficial as organic matter derived from plants would persist for a longer period improving soil structure and reducing erosion. In addition, Flores *et al.* (2005) discussed potential effects on target and non-target insects due to the longer persistence of *Bt* toxins in soil. In relation to soil organic content, it has been shown that even distinct increases in decomposition resistant compounds such as lignin result in only modest increases in organic carbon in the topsoil. Changes in soil management have a much more pronounced effect (Sessitsch *et al.*, 2004). Considering the available information on potential effects of *Bt* plants on the soil environment and in particular on soil non-target organisms, adverse effects due to slightly altered decomposition rates are unlikely.

They conclude that the effects in this short-term experiment are small and longer-term investigations are necessary.

They found that 2 Bt **cotton** lines "frequently caused significant although transient" increases in total bacterial and fungal populations. Concluded change in microbial species composition may be of ecological significance, and additional research needed.

The study concludes: "a smaller, but significant, amount is present in decomposing residues, some of which are likely to have persisted from the previous year or earlier"

These studies do not answer the question as to why Bt maize decomposes more slowly, they simply suggest that altered decomposition rates may not be due to lignin content.

This is misleading. The authors *suggested* this, but there is no evidence to *conclude* this. They state "The ecological and environmental relevance of these observations is also not clear", and they point out that "the longer persistence of the biomass of Bt plants would extend the time that the toxins are present in soil and, thereby, could enhance the hazard to non-target organisms and the selection of toxin-resistant target insects". The authors propose two possible outcomes of lower decomposition rate, but do not weight one as more likely than the other.

This study concludes that the effects "in this short term experiment" are small, and "longer-term investigations are necessary"

This study concludes that "Additional research…is required because of the wide range and complexity of possible targeted and non-targeted direct and indirect effects of novel crop traits on soil processes and because of the increasingly large land area cultivated with transgenic crops."

This study also concludes that "There is a surprising lack of quantitative information on the total load of Bt in soil beneath transgenic crops, thus pointing to the need for more research in this area".

The published results from laboratory and field trials showed that on short to medium time scales (up to 3 years) and under field conditions, the effects on soil functions and biodiversity (Blackwood & Buyer 2004; Motavelli *et al.*, 2004; Evans, 2002) does not exceed the range of the "natural" variability. No conclusive evidence has yet been presented that currently released transgenic *Bt* resistant crops are causing significant direct effects on the soil environment. The effects of transgenic *Bt* maize in these experiments were small, if they existed at all. In addition, the available data do not indicate a chain of events that might result in long-term effects. Therefore, it seems likely that in commercial cropping conditions, where crop rotations are used, the consequences of effects on soil functions and soil organisms are negligible. However, long -term effects may become detectable in cultivation systems without crop rotation where repeated cropping of 1507 maize might result in accumulation of effects.

However, the EC in the WTO dispute highlighted the uncertainty in this area: "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."

Should the requirement for crop rotation not be a condition on the marketing consent?

5.2.6. Potential impacts of the specific cultivation, management and harvesting techniques

The environmental risk assessment made no comparisons of the environmental profile of the use of glufosinate on maize in comparison with other herbicides. Indeed, this would be difficult to do because of the range of other herbicides used and the range of agricultural systems and environments in which maize is grown and the wide diversity of weed species and associated flora and fauna that will be found in maize fields. Glufosinate is a contact, non-persistent and non-systemic broad-spectrum herbicide with activity against a wide range of plants though some tolerance occurs in some *Viola* species and some species of grasses. In the UK Farm Scale Evaluation study the glufosinate herbicide programmes studied on farms resulted in reduced biodiversity in spring oilseed rape but had less impact on biodiversity than the standard herbicide programmes used on maize (Champion *et al*. 2003). The most commonly used comparator in maize was atrazine for which authorisations had to be withdrawn in most EU countries by 10 September 2004 (EC, 2004a). However other herbicides were used and a recent report (Perry *et al.*, 2004) indicated that regimes applying glufosinate either had a better or similar biodiversity impact compared with these herbicides.

The re-analysis of FSE data based on sites where triazine herbicides were not used was based on only just four samples, and in some cases just two, so any conclusions drawn in this study are highly speculative.

The Panel considers that the presence of the *pat* gene and the use of glufosinate is not likely to give an increased impact on biodiversity in most situations. The Panel therefore comes to the conclusion that case specific monitoring regarding any consequences due to the application of glufosinate in combination with the cultivation of 1507 maize is not required. The Panel, however, recommends that observation of general weed abundance and diversity should be included in the general surveillance plan.

5.3. Conclusions

The notification C/ES/01/01 for 1507 maize is for cultivation, and thus the environmental risk assessment and the monitoring plan have to consider the environmental impact of full scale commercialisation. The Panel is of the opinion that no significant risk has been identified in the environmental risk assessment with the exception of resistance development of the target insects, which affects the case-specific monitoring plan.

1507 maize has no altered survival, multiplication or dissemination characteristics except in the presence of glufosinate. The Panel agrees with the assessment that the likelihood of unintended environmental effects due to the establishment and spread of 1507 maize will be no different from that of traditionally bred maize.

Judging from the available data delivered either by the applicant or by literature survey, the likelihood of adverse effects on non-target organisms or on soil function is foreseen to be very low.

The Panel considers that the presence of the *pat* gene and the use of glufosinate is not likely to give an additional botanical diversity effect compared to other herbicides.

The safety of residues of glufosinate applied to 1507 maize and of any metabolites has to be evaluated under a different Directive (EC, 1991) before market approval, and is therefore not within the remits of this opinion.

The Panel is aware that glufosinate containing herbicides are currently being evaluated within the framework of the above mentioned Directive (EC, 1991).

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