Friends of the Earth Europe

Friends of the Earth Europe comments on 1507 maize.

Response to European Food Safety Authority GMO Panel opinions for Commission questions EFSA-Q-2004-072 and EFSA-Q-2004-087

Summary

Friends of the Earth Europe is extremely concerned about a number of deficiencies and limitations of the scientific opinions provided by the European Food Safety Authority (EFSA) Scientific Committee on Genetically Modified Organisms (GMO Panel) with respect to 1507 GM maize. Friends of the Earth Europe is concerned that:

Many of the GMO Panel's conclusions appear to be based upon assumption rather than evidence.

They dismiss every issue raised by member state national authorities, even when these are requests for additional evidence.

The GMO Panel has failed to undertake a full consideration of the indirect effects of the GMO on the wider environment, as required by Directive 2001/18, and as raised by almost all of the member states who provided comments on this application.

Friends of the Earth recommends that the application for 1507 maize should not be taken further until these matters are resolved. In addition, future risk assessment opinions should delineate clearly: the extent to which conclusions are based on evidence; where areas of uncertainty lie; the assumptions being used by the committee.

A summary of findings is listed below:

1. There are clear limits to the GMO Panel opinions.

- The opinions are limited in scope because the GMO Panel did not consider the issues and concerns relating to the 'coexistence' of GM and non-GM agriculture.

- In every case where the member state authorities raised concerns or requested more information, the GMO Panel has dismissed these and agreed with the position of the applicant.
- The GMO Panel did not given adequate consideration to geographical and climatic differences across the EU.

2. The risk assessment relating to molecular characterization is based on insufficient evidence and rests upon several assumptions.

- The genetic transformation is very complex. Based on the evidence provided by the applicant, the GMO panel is unable to rule out the possibility of deletions/rearrangements to the native genome.
- It is proposed that the insertion event will not lead to unintended effects because it is likely to be in a non-coding region. There appears to be no evidence in support of this proposition, and the scientific literature suggests that a large proportion of gene inserts occur in, or near, endogenous plant genes.
- It is proposed that the compositional and agronomic analyses support the conclusion that deletions/rearrangements have not resulted in unintended effects. However, the compositional analyses show significant differences between the GM and non-GM comparators. The agronomic data is not even as detailed as that required for variety registration.
- The Panel suggests that deleted genes would be complimented by commercial hybrids. This implies that the GMO Panel is assuming only 'knock out' deletions could have occurred, as gene fusions, mis-expression, antisense and suppression effects could not be complemented. It implies that the use of heterozygous commercial hybrids is a safety requirement.
- Insufficient data is provided by the applicant to rule out the possibility of novel fusion proteins. Only the direct toxicity of such proteins is considered; no consideration is given to possible metabolic disruption or interference arising from their expression.

3. The member states appear to require higher evidence standards for a conclusion of food/feed safety. The GMO Panel appears to reach safety conclusions on the basis of evidence that member states deem insufficient.

4. The GMO Panel has given an entirely inadequate consideration of the indirect effects on biodiversity of 1507 maize.

- All but two member states raised concerns about the effects of 1507 maize on non- target organisms, and many queried the lack of data provided by the applicant. However, the GMO Panel, despite this lack of data, still found in favour of the applicant's assessment.
- The GMO Panel's conclusions only serve to raise serious questions which cannot be answered from the opinions. Which European Lepidoptera species feed on maize? Are these declining species? What proportion of their diet does maize represent? How crucial for survival of populations in different regional areas is

the food provided by maize plants? 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?

- Directive 2001/18 requires the risk assessment to consider "*possible immediate and/or delayed environmental impact resulting from direct and indirect interactions of the GMHP with non-target organisms, (also taking into account organisms which interact with target organisms)"* (Annex II D.2.6). However, the GMO Panel only appears to consider food chain effects in terms of direct toxicity to higher organisms, and hardly examines the risks due to reductions in food supply.
- There are important questions that cannot be answered from the GMO panel opinion: What role does the target species of 1507 maize play in the diets of higher organisms? Which non-target Lepidoptera will be affected by the Bt maize? How important are these species in the diet of higher organisms? What is the conservation status of these higher organisms?

Conclusion

Friends of the Earth Europe has serious concerns about the opinions of the GMO Panel in relation to 1507 GM maize. The scope of the opinion is limited and does not cover all relevant issues. It does not address all of the concerns raised by member states. Many of the conclusions appear to rest upon assumption rather than evidence. It does not appear that the consideration of indirect effects on the environment meet the requirements of directive 2001/18.

Friends of the Earth is not reassured by the scientific opinions provided by the GMO panel. In fact, the opinions themselves raise a number of concerns, not just about the GMO itself, but about the quality of advice being provided by the panel. The EFSA makes judgments on issues that are of enormous public concern, their opinions have huge political significance and could effect the environment in 25 countries. In that context, Friends of the Earth Europe believes that the opinions must be required to meet the highest standards of evidence and intellectual rigor. We do not consider that these standards have been met.

1. Limits of the GMO Panel opinions.

1.1. The opinions are limited in scope because the GMO Panel did not consider the issues and concerns relating to the 'coexistence' of GM and non-GM agriculture.

Throughout the European Union, there are concerns about the agricultural and economic impacts of the cultivation of GM maize. In particular, there remains uncertainty as to whether GM crops can be grown without compromising the choice to grow non-GM and organic crops ('coexistence'). In addition, there are a large number of unresolved practical difficulties, such as liability, compensation for economic loss, the nature and scale of required separation measures. A report by the European Environment Agency classifies maize as a "*medium to high risk crop for pollen mediated gene flow from crop to crop.*"[1]

However, the GMO Panel opinion specifically does not address the issues around 'coexistence' and contamination of non-GM crops, because consideration was only given to whether the genetic modification would confer altered ecological fitness. The only statement that can be seen as relevant to this controversial and difficult issue is

"*The extent of cross-pollination to conventionally bred hybrids will mainly depend upon the scale of accidental release and/or adventitious presence in conventional seeds*"[2].

This is unlikely to assist member states in reaching their decisions on this matter.

Friends of the Earth Europe has, through a freedom of information request, obtained comments provided by member states on 1507 maize. From these documents it appears that five member states raised concerns and objections related to 'coexistence' issues, and the lack of EU agreed legislation on this matter. Therefore, it should not be argued by the Commission that the EFSA opinions have dealt with all the concerns raised by member states; they clearly have not.

1.2. In every case where the member state authorities have raised concerns or requested more information, the GMO Panel has dismissed these and agreed with the position of the applicant:

Member states raised diverse and extensive scientific concerns about the 1507 maize application. In many instances, objections to its approval were based upon concern that inadequate levels of scientific information had been provided, or that inadequate methodology had been used during scientific investigations conducted by the applicant. In other words, many concerns relate to the quality of the scientific data supporting the application. Although the GMO Panel state that they requested additional information

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[1] Eastham K & Sweet J (2002) *Genetically modified organisms (GMOs): The significance of gene flow through pollen transfer* European Environment Agency, Copenhagen.

[2] Opinion of the GMO Panel 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. *The EFSA* journal 181:1-33. para 5.2.2(b)

from the applicant, it is not at all clear from the opinions what this additional information related to, and whether it addressed the concerns raised by member states.

Despite this, in every case the GMO Panel has concluded that member state concerns can be dismissed. Astonishingly, there is not one instance in which the panel agrees with the member state authorities, even when the concerns relate to lack of evidence. In fact, the GMO panel concludes in both opinions that

"*the information available for 1507 maize addresses the outstanding questions raised by member states*."

This highlights the clear differences in approach between the EFSA and the member state authorities – many member state authorities appear to take a significantly more precautionary approach than the GMO panel. What the GMO panel has provided is its own scientific opinions; as such, they are not necessarily definitive and are clearly not the only scientific opinions about the quality of the application.

Article 30.4 of Regulation 178/2002 requires the EFSA to cooperate with national authorities to resolve or clarify differences of scientific opinion. Friends of the Earth Europe recommends that no decisions be taken regarding 1507 maize until such time as the member states have given their response to the EFSA opinion, and outstanding concerns about data gaps in the application have been resolved.

1.3. The opinions are limited in scope because the GMO Panel has not given adequate consideration to geographical and climatic differences across the EU.

In its summary of the environmental risk posed by 1507 maize, the GMO panel concludes that "*no unintended environmental effects due to the establishment and spread are anticipated*". This is based, in part, on the statement that "*maize is winter-hardy only in parts of southern Europe*"[3]. The fact that maize behaves differently in southern environments than it does in northern ones should require a separate consideration of the risks and Member states specifically raised this matter in their responses to the application. This is of particular concern as the Panel relies for part of its safety conclusion upon maize being killed by cold weather. If the GMO Panel is using this as a safety requirement, then it should be a condition of release that the GM maize cannot cultivated in those areas where it would not be killed off by cold weather.

The GMO Panel also bases its conclusion upon the fact that "*1507 maize has no altered survival, multiplication or dissemination characteristics except in the presence of glufosinate."* Yet 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. Given that maize survives over winter in southern Europe, and that GM

[3] Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the notification (Ref 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. *The EFSA journal* (2005) l81: 1-33 (summary p.2)

seeds can be disseminated beyond fields during harvest, transport and by wildlife, it is disturbing that not even cursory consideration has been given to the potential consequences. For example, 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?

Similarly, the GMO Panel concludes that insect resistance would provide no competitive advantage to volunteer maize because "*survivability is mainly limited by the absence of a dormancy phase, susceptibility to fungi and susceptibility to cold climate conditions."*[4] However, it does not assess the impact of insect resistance if one of these limiting factors (cold climate conditions) is removed.

In the absence of answers to such questions, Friends of the Earth Europe is concerned that the GMO Panel may have based its conclusions on insufficient evidence and that the risk to southern European countries has not been properly assessed. In the absence of such evidence it would seem clear that the GM maize should not be released in areas where it will not be limited by cold weather.

2. The molecular characterization risk assessment is based on insufficient evidence

2.1 The genetic transformation is very complex. Based on the evidence provided by the applicant, the GMO panel is unable to rule out the possibility of deletions/rearrangements to the native genome.

The data provided by the applicant shows that the transformation event in 1507 maize is complex. In addition to the *pat* gene and the *cry*1F gene, conferring herbicide tolerance and insect resistance respectively, 1507 maize also contains:

- a second, truncated copy of the *cry*1F gene (335 bp) located at the 5' end of the insertion
- A large number of fragments of insert DNA, including incomplete sequences of the *pat* gene, the maize ubiquitin promoter and the mannopine sythase terminator.
- A total of 24 open reading frames (ORF), including ORF4 (630 bp) which is located within the insertion site and ORF 3 (753bp) which spans the junctions between the inserted DNA and the maize DNA.
- Fragments of chloroplast DNA and sequences with similarity to retrotransposons in the border region of the insert.

Friends of the Earth Europe considers that given the complexity of the insertion event, especial attention should be given to establishing that unexpected impacts on the host genome have not occurred. The applicant appears to have conducted a gross characterization of the insert using southern blotting followed by sequencing of the insert

[4] Opinion of the Scientific Panel on Genetically Modified Organisms *op cit 4.* para 5.2(b)

identified. However, southern blotting frequently fails to identify all transgene insert fragments, especially in organisms (such as maize) with large genomes[5].

A recent literature review[6] has highlighted that genetic modification has the potential to cause unintended alterations, including deletions and rearrangements, of the host genome, and that transformation-induced mutations occur both at insertion sites and elsewhere in the genome of modified plants. Particle bombardment typically leads to highly complex transformations, as well as deletion or rearrangement of host sequences[7].

In consideration of this aspect of the transformation, the GMO Panel states that "*No data documenting the intactness of the insertion site were shown. Therefore a direct comparison of the insertion locus and the respective site in the recipient plant is not possible*."[8] In other words, the applicant did not present any direct evidence relating to deletions and alterations of the host genome. The GMO Panel themselves conclude that, based on the evidence presented, "*it cannot be assumed that DNA deletions have not occurred during the transformation process*."[9].

In what could be read as a defence of the applicant's failure to provide the relevant evidence, the GMO panel state that *'The design of PCR primers to provide unequivocal evidence that sequences detected in the flanking regions of the 1507 insert are also found as continuous sequences in the recipient plant is in general technically difficult."*
It is difficult, but not impossible. Considering the importance of the issue, technical difficulty should not rule out the provision of evidence.

The possibility of deletions and rearrangements cannot be ruled out using the evidence presented by the applicant, and the GMO Panel does not rule out the possibility. Instead, three reasons are given as to why, in the committee's view, "*undiscovered adverse effects*" are "*unlikely*."

2.2 It is proposed that the insertion event is likely to be in a non-coding region. There appears to be no evidence in support of this proposition, and the scientific literature suggests that a large proportion of gene inserts occur in, or near, endogenous plant genes.

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[5] see for example, Makarevitch I, Svitashev SK and Somers DA (2003) Complete sequence analysis of transgene loci from plants transformed via microprojectile bombardment *Plant Molecular Biology* 52: 421-432

[6] Wilson A, Latham J and Steinbrecher R (2004) *Genome scrambling – Myth or reality? Transforamtion-induced mutations in transgenic crop plants* EcoNexus, Brighton, UK. www.econexus.info

[7] See, for example: Shimizu K et al (2001) *Plant J* 26: 375-384; Makarevitch I et al (2003) *Plant Molecular Biology* 52: 421-432. For a review see Wilson A et al (2004) *op cit*.

[8] Opinion of the GMO Panel 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. *The EFSA* journal 181:1-33. para 2.2.2 Opinion of the GMO Panel on an application (reference EFSA-GMO-NL-2004-02) for the placing on the market of insect-tolerant genetically modified maize 1507, for food use. *The EFSA journal* 182: 1-22 para 2.2.2

[9] para 2.2.2

The GMO Panel states that if rearrangements/deletions do occur, this would not have any impact because *"a large proportion of the maize genome consists of non-coding sequences*"[10]. It is surprising that the GMO Panel should use this argument, given that, in the case of agrobacterium-mediated transformations, there is now evidence that a large proportion of T-DNA inserts occur in, or near, endogenous plant genes[11]. While there have been few studies examining the location of insertions resulting from particle bombardment, as was used for 1507 maize, there is no evidence to suggest that the situation should be different. No evidence is provided by the applicant to confirm whether or not the insertion site is in a non-coding region of the genome.

The validity of the GMO Panel's position would require additional information proving that particle bombardment insertion loci generally occur outside coding regions, in other words that they behave differently to agrobacterium-mediated transformations. However, given the sparse literature on this subject, and the lack of supporting evidence, it seems inappropriate to base a risk assessment upon such an assumption.

2.3. It is proposed that the compositional and agronomic analyses support the conclusion that deletions/rearrangements have not resulted in unintended effects. However, the compositional analyses show significant differences between the GM and non-GM comparators. The agronomic data is not even as detailed as that required for variety registration.

Secondly, the GMO Panel states that the comparative analysis and agronomic data "*show no indication of adverse effects.*" The data from comparative analyses of composition show statistically significant differences in levels of potassium, linoleic acid, linolenic acid, tocopherols, manganese, stearic acid, oleic acid, cysteine, methionine and vitamins B1 and B2. The GMO Panel dismisses these findings because they do not occur in every year and growing location. This implies an assumption that all changes to the host genome will be expressed in every situation and will be uniform across all growing conditions. However, it is just as possible that unintended effects will become apparent during interaction with environmental factors.

In addition, it is not clear that the agronomic data is sufficiently detailed to allow detection of subtle effects. At one point, the opinion even relies upon the "*general appearance of the plants*" to support the contention that the transformation has not resulted in unintended effects. Many of the characteristics measured (lodging, vigour) appear more useful for establishing agronomic value of the variety, rather than detecting subtle changes as a result of modification. In fact, the agronomic data presented by the applicant is nowhere near as extensive as required to establish distinctness, uniformity and stability for the purposes of variety registration. The applicant provides measurements of 14 characteristics, only 3 of which are even relevant to the 33

[10] para 2.3

[11] See, for example: Jeong D-H et al (2002) *Plant physiology* 130: 1636-1644; Szabados et al (2002) *Plant Journal* 32: 233-242; Dong J et al (1996) *Molecular breeding* 2: 267-276; Koncz C et al (1989) *Proc Nat Acad Sci USA* 86: 8467-8471

measurements required for testing of distinctness, uniformity and stability as required by EU law.

2.4. The Panel suggests that deleted genes would be complimented by commercial hybrids. This implies that the GMO Panel is assuming only 'knock out' deletions could have occurred, as gene fusions, mis-expression, antisense and suppression effects could not be complemented. It implies that the use of heterozygous commercial hybrids is a safety requirement.

The GMO Panel states that *"deleted components will, in most cases, be complemented in commercial hybrids."* This suggests that the Panel is arguing that the heterozygosity of commercial hybrids is requisite for safety. This would require a condition on the marketing consent. Even if achieved, the safety rests upon complementing genes being fully dominant under all environmental conditions, and that the only unintended effect of the transformation has been 'knock-out' deletions. However, particle bombardment can also lead to gene fusions, mis-expression, antisense and suppression effects, which cannot be complemented.

2.6. Insufficient data is provided by the applicant to rule out the possibility of novel fusion proteins. Only the direct toxicity of such proteins is considered; no consideration is given to possible metabolic disruption or interference arising from their expression.

The presence of open reading frames indicates the possibility of novel fusion proteins being produced. Again, the applicant provided insufficient data to allow this to be ruled out and the GMO panel does not, in fact, rule out this possibility. Yet, in consideration of the effects of the fusion proteins, the applicant and the GMO Panel appear to focus only on the sequence homology with known allergens or toxic proteins. While this is of course an essential test, no consideration is given to possible metabolic disruption or interference arising from the expression of these proteins.

It appears that the GMO Panel opinions rests heavily on assumption, which are not clearly delineated as such. If the GMO cannot be properly assessed for its risks – in this case due to the complexity of the transformation event – then it should not be approved.

It is probable that a thorough investigation of the possible impacts of this complex transformation event, including the ORFs, would be extremely difficult at this time. However, Friends of the Earth Europe does not consider this provides allowable grounds for a failure to do so. If the GMO cannot be properly assessed for its risks – in this case due largely to the complexity of the transformation event – then it should not be approved until such time as the evidence is provided. It is simply not acceptable to excuse failure to do a proper risk assessment on the grounds that it is technically difficult. A more rigorous approach would have the added benefit of encouraging applicants to submit GMOs whose transformations have been adequately characterized and which really are as straightforward as claimed.

3. The member states appear to require higher evidence standards for a conclusion of food/feed safety. The GMO Panel appears to reach safety conclusions on the basis of evidence that member states deem insufficient.

The applicant has not conducted long term safety testing of 1507 maize, and several member states raised this point, as well as other specific concerns about the evidence on food and feed safety. For example, member states requested that the applicant supply: additional information from feeding trials using ruminants, laying hens, fish and crustaceans; evidence on the safety of the whole GMO, including forage, not just the expressed novel proteins; evidence of long term, chronic safety tests. These requests came from a number of different national authorities, and taken collectively indicate serious concerns about the quality and extent of the food and feed safety data supplied by the applicant.

In contrast, the GMO Panel, despite its earlier conclusion that it could not rule out unintended effects on the native genome, appears content with the partial food/feed safety data provided by the applicant. It does not support any of the member states' requests for additional information. The contrasting approaches are exemplified by consideration of the 90 day rat feeding study. Several member states raised queries about raised serum counts of eosinophil leukocytes in female rats fed 33% 1507 maize. Additional data was requested from the applicant. Although it does not appear from the GMO Panel opinion that they received additional information, the Panel concludes that the observed differences are not "biologically relevant." The member state concerns are dismissed, and the Panel finds in favour of the applicant.

Several of the conclusions of the GMO Panel raise further questions. For example, the toxicity assessment is an acute oral toxicity study using mice. Yet there is evidence in the scientific literature that Cry proteins may be immunogenic[12]. It is argued that the Cry1F protein is broken down by high temperatures and pressures during processing - but both humans and animals eat maize products (sweetcorn, crimped grain, silage) which undergo minimal processing. It is argued that the Cry1F protein is rapidly broken down in gastric fluid, yet the data also show that a trypsin resistant core survives in intestinal fluid for the full duration of testing (120 minutes).

Astonishingly, the GMO Panel appears to consider that none of the additional information requests from member states are justified and that none of the concerns raised are valid. Again, it appears that there are major differences of approach and

[12] See: Vazquez RI et al (1999) Bacillus thuringiensis Cry1Ac protoxin is a potent systemic and mucosal adjuvant. *Scand J Immunol*. 49:578-84; Vazquez-Padron RI et al (1999) Intragastric and intraperitoneal administration of Cry1Ac protoxin from Bacillus thuringiensis induces systemic and mucosal antibody responses in mice. *Life Sci.* 64:1897-912; Moreno-Fierros L et al (2000) Intranasal, rectal and intraperitoneal immunization with protoxin Cry1Ac from Bacillus thuringiensis induces compartmentalized serum, intestinal, vaginal and pulmonary immune responses in Balb/c mice. *Microbes Infect* 2: 885-9

evidence standards between the panel and the member states. Article 30.4 of Regulation 178/2002 requires the EFSA to cooperate with national authorities to resolve or clarify differences of scientific opinion. Friends of the Earth Europe recommends that no decisions be taken regarding 1507 maize until such time as these differences of approach have been resolved.

4. The GMO Panel has given an entirely inadequate consideration of the indirect effects on biodiversity of 1507 maize.

4.1 All but two member states raised concerns about the effects of 1507 maize on non- target organisms, and many queried the lack of data provided by the applicant. However, the GMO Panel, despite this lack of data, still found in favour of the applicant's assessment.

Friends of the Earth Europe has obtained, through a freedom of information request, comments from member states on the application made for cultivation of 1507 maize. Out of seventeen national authority comments provided, fifteen raised the issue of effects of the Bt maize on non-target organisms, such as European Lepidoptera, predatory insects, soil organisms and parasitoids. In particular, 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 expressed by 1507 maize. This data is recommended as an initial screen to determine what should be investigated further[13], but even this was not provided by the applicant.

4.2 The GMO Panel's conclusions only serve to raise serious questions which cannot be answered from the opinions.

Once again, the GMO Panel "agrees with the assessment of the applicant". It effectively dismisses the concerns of member states, doing so largely on the basis of inference, rather than data. For example, the opinion states "*It is well documented that a range of lepidopteran species may be affected by Bt toxins and some may be present in maize fields.*"[14] But it goes on to argue that this does not matter because "*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*".

Friends of the Earth Europe is extremely concerned that this quality of statement should have been allowed to proceed from an EFSA committee. Firstly, the statement that maize is not a food source for European Lepidoptera appears to be unsupported and lacks the clarity and the precision required of a risk assessment. It simply raises questions that cannot be answered from the GMO panel opinion: Which European Lepidopteran species *do* feed on maize? Are these declining species? What proportion of their diet does maize represent? How crucial for survival of populations in different regional areas

[13] Wolt JD et al (2003) A screening level approach for nontarget insect risk assessment: Transgenic Bt corn pollen and the monarch butterfly (Lepidoptera : Danaidae) *Environmental Entomology* 32: 237-246
[14] para 5.2.4(b)

is the food provided by maize plants? What importance do these species have for higher organisms, such as birds during the breeding season?

Similarly, the second half of the statement simply raises further questions: 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?

The UK farm scale evaluations of GMHT crops noted that adult butterflies were recorded visiting eight weed genera within maize fields and between 32% and 70% of recorded visits were to the maize plants themselves[15]. Many common arable plants are larval food plants for European Lepidopteran species[16], and the field conditions under which these European plants grow should not be assumed to be consistent with those in the mid-western United States, considering the huge landscape diversity of the twenty five member countries.

4.3 Directive 2001/18 requires the risk assessment to consider "*possible immediate and/or delayed environmental impact resulting from direct and indirect interactions of the GMHP with non-target organisms, (also taking into account organisms which interact with target organisms)*" (Annex II D.2.6). However, the GMO Panel only appears to consider food chain effects in terms of direct toxicity to higher organisms, and barely examines the risks due to reductions in food supply.

In fact the entire consideration of indirect risks to higher organisms through loss of food sources appears to consist of a couple of sentences in section 5.2.4., including the statement that "*most animals higher in the food chain would be eating diets consisting of a range of food sources*." What about the animals left out by this statement - how important is the target organism, and non-target Lepidoptera, in their diets?

This lack of consideration can only be described as shocking. As there is no assessment of the impact of the insect resistant maize on European Lepidoptera, there can be no assessment of whether key species are affected, nor any consideration of whether such species are important to higher organisms, such as breeding birds. This is more than an academic consideration - several reviews of the data relating to UK bird species have concluded that Lepidoptera larvae are important food sources for declining bird species as well as important nestling food for most granivorous bird species[17].

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[15] Houghton AJ et al (2003) Invertebrate responses to the management of genetically modified herbicide-tolerant and conventional spring crops. II. Within-field epigeal and aerial arthropods. *Phil Trans R Soc London B* 358: 1863-1877

[16] see http://www.funet.fi/pub/sci/bio/life/warp/food-plants-a.html

[17] See for example: Wilson et al (1996) *The diet of bird species of lowland farmland: a literature review* University of Oxford & RSPB, Sandy, UK; Campbell LH et al (1997) *A review of the indirect effects of pesticides on birds* JNCC report No.227. JNCC, Peterborough; University of East Anglia et al (2002) *Modelling the effects on farmland food webs of herbicide and insecticide management in the agricultural ecosystem* DEFRA, UK. Campbell LH et al (1997) *A review of the indirect effects of pesticides on birds* JNCC report No.227. JNCC, Peterborough

Even if European wildlife was booming, the GMO Panel opinion would hardly constitute an adequate risk assessment for all higher organisms living in diverse conditions across twenty five countries. Given that there has been a serious decline in biodiversity associated with agricultural areas for several decades, it is even more alarming. There are important questions that cannot be answered from the GMO panel opinion: What role does the target species of 1507 maize play in the diets of higher organisms? Which non-target Lepidoptera will be affected by the Bt maize? How important are these species in the diet of higher organisms? What is the conservation status of these higher organisms?

The GMO Panel opinion does not fulfil the requirements of 2001/18 and does not provide adequate protection of European wildlife. In this respect, it falls well below the standards expected of a premier scientific body in the European Union. Such an important matter cannot be dismissed in a couple of paragraphs – it is essential that the indirect effects on biodiversity from introducing Bt maize are properly investigated before any decision is made. In this respect, Friends of the Earth Europe considers that the GMO Panel opinion does not meet the evidence standard requirements of Directive 2001/18.

5. Conclusion

Friends of the Earth Europe has serious concerns about the opinions of the GMO Panel in relation to 1507 GM maize. The scope of the opinion is limited and does not cover all relevant issues. It does not address all of the concerns raised by member states. Many of the conclusions rest upon assumption rather than evidence. It does not appear that the consideration of indirect effects on the environment meet the requirements of directive 2001/18.

Friends of the Earth is not reassured by the scientific opinions provided by the GMO panel. In fact, the opinions themselves raise a number of concerns, not just about the GMO itself, but about the quality of advice being provided by the panel. The EFSA makes judgments on issues that are of enormous public concern, their opinions have huge political significance and could effect the environment in 25 countries. In that context, Friends of the Earth Europe believes that the opinions must be required to meet the highest standards of evidence and intellectual rigor. We do not consider that these standards have been met.