GM Food & Feed – Comments from the Public

Comments received on Maize NK603 x MON810

1. private person, UK
2. private person, IT
3. private person, NL
4. private person, supplement 1, NL
5. Wieteke van Dort Productions, NL
6. CPREssex, UK
7. Lucel, NL
8. Gothenburg University, dept. of Clinical Nutrition, SE
9. Universita Politecnica Marche, IT
10. Biodynamic Association, UK
11. Friends of the Earth Europe, UK
12. ETC Netcherlands, NL
13. GLOBAL 2000/Friends ofthe Earth Austria, AT
14. Greenpeace, DE
15. GeneWatch, UK
16. Consiglio dei Diritti Genetici, IT
17. GM Free Cymru, UK

1. Organisation: none
Country: United Kingdom

Comments on the following points:

4. Conclusions and recommendations

This form is too complicated for laypeople to complete. We just DO NOT want GM foods in UK thank you.

6. Labelling proposal

Very Large labels saying this contains GM flour (whatever). Put a smaller limit on foods which may not 'contain GMOs ' but have been contaminated with them.

2. Organisation: Individual
Country: Italy

Comments on the following points:

6. Labelling proposal

I read the information on the website of the EFSA concerning the application GMO UK 2004-01.
The public has the possibility to provide its input to this application but as an individual without the in-depth background knowledge it is impossible to participate.
It is completely unclear to me, for example what the labelling of a product containing NK 603 and MON 810 maize will look like. After spending more than 1 hour to read through some documents and runnunig the search engine of the EUR-LEX website to read the EC No 1829/2003 regulation, I am still not sure about the result of my research. The question what will the labelling of such products will look like remains unanswered.
In this way participation for a consumer is simply impossible. The way the information is provided on the website, the participation of the public is not ensured at all. I am concerned about the democratic deficit of this kind of procedures in general but in this specific case it is even made hard to make use of the very limited existing participatory rights.
If you even do not provide transparent material how do expect a consumer to be able to give an input?
I would appreciate if you could set up a consumer friendly website providing summarized information, so that the outcome of the whole application in case of an authorization will be clear.
So, could you please answer me my question and tell me what the labelling of authorized NK 603 and MON 810 maize products will look like?
Thank you very much.

3. Organisation: individual
Country: The Netherlands

Comments on the following points:

b. Food Safety Assessment:
- Toxicology

These comments concern, *inter alia*, Mon (Monsanto) 810, which uses the Cry1Ab gene of Bacillus thuringiensis, (var. Kurstaki) controlled by a 35S promoter from the cauliflower mosaic virus.
Dr Joseph Cummins, Professor Emeritus of Genetics at the University of West-Ontario warns: "Probably the greatest threat from genetically altered crops is the insertion of modified virus and insect virus genes into crops. It has been shown in the laboratory that genetic recombination will create highly virulent new viruses from such constructions. Certainly the widely used cauliflower mosaic virus [CaMV] is a potentially dangerous gene. It is a pararetrovirus meaning that it multiplies by making DNA from RNA messages. It is very similar to the Hepatitis B virus and related to HIV. Modified viruses could cause famine by destroying crops or cause human and animal diseases of tremendous power."[1]
Translation into Dutch by Jan Storms at:
http://proto.thinkquest.nl/~llb109/meningenvw.html

Villagers in the south of the Philippines suffered mysterious illnesses when a Monsanto GM maize hybrid came into flower; antibodies to the Bt protein (Bt toxin Cry1Ab) in the GM maize were found in the villagers, and there have been five unexplained deaths.
http://www.i-sis.org.uk/GMBanLongOverdue.php

All Bt products, just like any other pesticides used for GM crops or for impregnation of wood (biocides), also contain non-Bt ingredients. These ingredients are trade secrets, and may be the most toxic components in the formula.

- Allergenicity

There are also disturbing similarities between the Cry1Ab protein produced by MON 810 [and] the Cry9C protein in StarLink maize (withdrawn in 2000), which has potential allergenic characteristics.
http://www.genfood.at/download/Greenpeace_2006_impossible-coexistence.pdf

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- Nutritional assessment

- Others

Owing to shortage of time, I have restricted my comments to Mon 810.
The GM maize variety, Mon 810, which was authorised under less stringent regulations and included on the list of varieties in 1998, has never yet been planted by farmers in the Netherlands.

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3. Environmental risk assessment

Bacillus thuringiensis (Bt) is therefore a poison, a toxin, that is incorporated into the maize by means of genetic manipulation. What will happen to the balance of organisms in the soil if it

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[1] *Translator's note*
Quotation taken from http://www.psrast.org/scicomm.htm

ends up there? After all, Bt may well separate out and accumulate in the soil. In fact, as Professor Lucas Reijnders assured us at the public debate on biotechnology and food [*Eten en Genen*], soil has never been properly studied in connection with GM organisms and the genes incorporated into them.

4. Conclusions and recommendations

Thought is being given to the health of the economy rather than the health of the consumer.

A non-GM solution applied Africa: push-pull

In Kenya, an Indian scientist by the name of Dr Zeyaur Khan has developed an alternative to Novartis Bt maize. Every year around half of the maize harvest in Kenya is destroyed by the simultaneous invasion of “witchweed” (striga) and stem borers. The harmful insects are related to the maize borers, which Novartis developed its GM Bt maize to combat. The biotechnology company has already launched a programme for testing and introducing Bt maize in Kenya. Khan's “push-pull” method combats both the weeds and the insects, without chemical pesticides or genetic manipulation.

Khan has slides and a video showing the havoc that can be wrought by the weeds and the stem borers in the maize fields of Kenyan smallholders – depressing pictures of maize plants with limply hanging leaves full of holes, often surrounded by the treacherously beautiful flowers of witchweed, a parasite that grows on the roots of the maize plant. The seeds of the parasite remain active in the ground for ten years or so.

Khan and his team tested more than four hundred types of grass and finally hit on Napier grass, a type that proved to be very attractive to stem borers. A hedge of this type of grass planted around a maize field lures the insects away from the maize. Desmodium was sown between the maize plants in order to make them unattractive to stem borers; it repels the insects and also combats the witchweed, as well as fertilising the soil with natural nutrients. This is the “push-pull” method: the desmodium “pushes” the stem borers out of the maize field and the Napier grass provides the “pull”.

“At last I’ve got real, healthy maize”, sighs a peasant woman in Khan’s video. “I can sell the Napier grass and use the money to pay for my child’s education.” Others buy cattle with the money they earn, thus extending their diet to include milk and meat. More and more farmers are opting for the “push-pull” method in countries such as Uganda, South-Africa, Ethiopia and Malawi. A problem is that the desmodium seed is imported from Australia and is therefore expensive. Farmers in Africa are now cultivating their own desmodium seed and earning some money by selling it.
http://talk2000.en/docu/bmd_101_verslag-conferentie.html

5. Other comments

Dr Erwin Chargaff is one of the founders of modern genetics. “There are two boundaries we should never have crossed” says Dr Chargaff[2], “that of the nucleus of the atom and that of the nucleus of the cell”. He explains: “A bacterium contains as much genetic information as the bible contains words, and a human being as much as fifteen bibles. The genetic engineer replaces perhaps one or two or pages and says that this is not dangerous. He keeps quiet, however, about the fact that he hasn't read the table of contents, that he doesn't know which pages have been replaced, that he has not the slightest notion of how important the contents

[2] *Translator’s note*
I have been unable to find any existing English version of these quotations.

of these page are or of how the contents of these pages fit in with the rest of the book, and moreover has no way of understanding the change of content."

Translation into Dutch by Jan Storms at:
http://proto.thinkquest.nl/~llb109/meningenvw.html

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6. Labelling proposal

All packaging (of such products) should be marked: contains genetically modified ingredients

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4. Organisation: Individual/supplement 1
Country: The Netherlands

Comments on the following points:

b. Food Safety Assessment:
- Toxicology

SUPPLEMENT
http://sify.com/news/fullstory.php?id=14194773 Fragment UNI 1600 sheep die after grazing in Bt cotton field Sunday, 30 April , 2006, 15:00 Hyderabad: Sixteen hundred sheep died in Warangal district after grazing in fields on which Bt cotton had been harvested.
---------- LATEST NEWS
http://www.scoop.co.nz/stories/PO0604/S00067.htm Genetically engineered corn - is it safe? Friday, 7 April 2006, 11:07 am Press Release: Physicians and Scientists for Responsible Genetics Genetically engineered corn - is it safe? New studies run over several years each confirmed concerns about the commercialisation of corn genetically engineered with Cry toxins.1,2,3
One study monitored the quantity of Cry toxins in a variety of genetically engineered corn developed by Monsanto (MON 810).1 This corn variety produces an artificial, truncated version of a Cry toxin derived from the bacterium, Bacillus thuringiensis, and was developed to control Lepidopteron insects.
What this study found was that instead of the Cry toxins acting as they would if sprayed on corn plants - releasing a small quantity of the toxin at a single or several occasions - the engineered plant produced the toxin protein during the whole period of its growth. It was also found that the toxin remained biologically active for several years in a dry plant under moderate temperatures. After harvest, the corn stubble was shown to contain a significant quantity of Cry toxin, which could still be detected in plant residues more than a year later. Traces of the toxin were also found in the soil where it could affect essential soil microorganisms.
The researchers looked at doses of Cry-toxins permitted for use in commercial bio-pesticides, including DIPEL. When they compared these with MON 810 Bt-corn, they found that the engineered corn produced 1500-3000 times more Cry1Ab toxin than the dose in a single treatment using DIPEL.
A second study2 analysed the spread of pollen from the MON 810 corn, choosing an area for the trials where no other corn was grown. It established that a conventional variety of corn grown closer than 800 metres was liable to cross-pollination by the MON 810 transgene/s. It also revealed that MON 810 pollen that settled on nearby weeds affected insects, potentially causing species to recede. The researchers established, for example, that the caterpillars of the Peacock and Comma butterflies were extremely sensitive to Cry toxins, and that the dose permitted for use against European corn borer, Ostrinia nubilalis, is 50-times larger than the sensitivity level of these butterflies.
A third study3 revealed that insects have developed resistance against Cry-toxin and that Bt-corn varieties (incorporating a Cry toxin) could have a relatively short 'viability' time. The extrapolation of this is that it will generate a growth in the number of insect populations on which Bacillus thuringiensis products would no longer work. This would pose a severe problem for organic farming, which relies on it almost exclusively.
References
1. 'Production and decomposition of DK-440 BTY corn,' András Székács, Erik Maloschik, Éva Lauber, László A. Polgár & Béla Darvas, Hungarian Academy of Sciences, Plant Protection Institute, Department of Ecotoxicology and Environmental Analysis, Budapest; Székács, A. et al. (2005) FEBS Journal, 272 Suppl. 1: 508;
http://www.blackwellpublishing.com/febsabstracts2005/abstract.asp?id=41771;

Székács, A. et al. (2006) Abs. 52th Hungarian Plant Protection Days, 52: 32; http://www.fvm.hu/doc/upload/200602/ntn_2006_kiadvany_2006_02.pdf;
Granted by Hungarian Ministries of Education (BIO-00042/2000); Environment & Water (K-36-01-00017/2002, NTE-725/2005).
2. 'Conflicts of DK-440 BTY corn pollen,' Béla Darvas, Éva Lauber & László A. Polgár Hungarian Academy of Sciences, Plant Protection Institute, Department of Ecotoxicology and Environmental Analysis, Budapest.
Darvas, B. et al. (2004) Növényvédelem, 40: 441-449.
Lauber, É. et al. (2006) Abs. 52th Plant Protection Days, 52: 36; http://www.fvm.hu/doc/upload/200602/ntn_2006_kiadvany_2006_02.pdf
Bálint, A. (1980) A vetomagtermesztés genetikai alapjai. Mezogazdasági Kiadó, Budapest. 1-171.
Granted by Hungarian Ministries of Education (BIO-00042/2000); Environment & Water (K-36-01-00017/2002, NTE-725/2005).
3. Béla Darvas & Éva Lauber, Hungarian Academy of Sciences, Plant Protection Institute, Department of Ecotoxicology and Environmental Analysis, Budapest
Darvas, B. et al. (2005) Abs. 51. Növényvédelmi Tudományos Napok, 51: 9; http://www.omgk.hu/ntn2005.pdf
Darvas, B. et al. (2006) Abs. 52. Növényvédelmi Tudományos Napok, 52: 37; http://www.fvm.hu/doc/upload/200602/ntn_2006_kiadvany_2006_02.pdf
Granted by Hungarian Ministries of Education (BIO-00042/2000); Environment & Water (K-36-01-00017/2002, NTE-725/2005).

5. Organisation: Wieteke van Dort Productions
Country: The Netherlands

Comments on the following points:

5. Other comments

It is really like a conspiracy how this disgusting genetic engineered stuff is forced to people and animals. Nobody asked for it. Nobody wants it. Only the concerns who make money of it. This food will poison the environment, animals and people. And who pays the bill if things go wrong?

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6. Organisation: CPREssex
Country: United Kingdom

Comments on the following points:

b. Food Safety Assessment
- Allergenicity

I believe that the rapid increase in allergies is due to chemicals in our food system. GM represents an irreversible threat likely to introduce further allergies at great cost to society and at no cost to perpertrators.

3. Environmental risk assessment

There is a real risk of permanent changes to plants, the consequences of which are ignored by those pushing this technology.

4. Conclusions and recommendations

I am opposed to the continuing dominance of a few multinationals over the world's food chain. Especially as it is only legislation stops them implementing terminator genes. They are not interested in feeding the poor, only the rich and poor farmers will suffer.

7. Organisation: LUCEL
Country: The Netherlands

Comments on the following points:

5. Other comments

More and more scientific evidence is coming to light that suggests that we should not take the "GMO route" because of the menace it poses to public health and the incomes of our farmers and market gardeners.

See the summary below; the attached PDF contains the entire report that Greenpeace published recently in cooperation with Spanish agricultural organisations.

A few important observations:

In almost a quarter of the cases investigated, GM maize was found to have unintentionally reached the land of farmers who did not grow GM crops. The contamination by GM crops was sometimes as high as 12.6 %.
In some cases the farmers in question suffered financial losses as they could no longer sell the contaminated maize at the higher price normally charged for organically-grown and conventional crops.
Three of the cases of contamination concern local maize varieties which, after years of careful selection, are no longer usable for cultivation. These cases show how contamination by GM organisms is a threat to biodiversity and to the few varieties that are still in the hands of the farmers.

At the end of this message there is a notice informing us that we can have our comments published on an EU website against the authorisation of Monsanto GMO maize varieties.

TAKE THIS OPPORTUNITY OF MAKING YOUR OPINION KNOWN!
http://europa.eu.int/comm/food/food/biotechnology/authorisation/public_comments_en.htm

We have until 2 May to take this opportunity. You can consult the attached articles (also in PDF format) by Stephan Timmermans for guidance in forming your opinion.

Forward this information to people who are also concerned about the EU's GMO policy. It might help people who are not aware of this danger to realise what is at stake. Thank you in advance for your support.

I have posted a few Internet links where you can find a great deal of information on why GMO is not a sustainable solution. I hope you will take a look at the sites so you can decide for yourself.

Yours sincerely, Sjoerd Smits sjoerdsmits@home.nl

PS: I got the information on the Greenpeace report from the e-zine at http://www.biotheek.be. You can subscribe to it yourself free of charge. You have to search the Internet yourself for the rest of the information, and I would recommend that everyone does this!

Here is a link to a Dutch translation of an article in English [published in the Independent on Sunday] according to which feeding rats genetically modified corn may lead to internal abnormalities and affect the blood.

http://talk2000.nl/mediawiki/index.php/Genmais_geeft_rat_afwijkingen_-_onderzoek_van_Monsanto

And here is a link to an explanation in Dutch of the case for a GM-free sustainable world.

http://www.talk2000.nl/mediawiki/index.php/ISP_rapport%3B_ingekorte_NL_samenvatting

On the basis of the study by Schoustra (conducted at the Agricultural University of Wageningen), it can be expected that, in the long term, crops made resistant by means of genetic modification (GMOs) will be of no USE whatsoever. http://www2.wau.nl/pers/04/111wu.html

At the end of this message it is also stated that we can keep up-to-date on GMO information on an EU website:

http://www.gmo-compass.org/eng/home/

Biotheek Netknipsels #152 – 5 april 2006

[Item No 152 of *Biotheek Netknipsels* – a Belgian bionews site]

Europe –GMO contamination in Spain: a warning for Europe

In cooperation with a number of other environmental organisations (1), Greenpeace has published today a new report, entitled “Impossible coexistence”. Seven years of GMOs have contaminated organic and conventional maize. The report deals in depth with specific examples in Catalonia and Aragón.

According to Greenpeace, the continuing cultivation of genetically manipulated crops in Spain is causing contamination on a massive scale and threatening farmers’ incomes, and must be halted as a matter of urgency. In its new report, entitled “Impossible Coexistence”, Greenpeace also shows how GM crops in Spain – the only EU country that grows GMOs on a large scale – are undermining diversity in agriculture and consumer choice.

Impossible Coexistence is based on thoroughgoing research, including laboratory tests of samples taken from the maize fields of 40 organic and conventional farmers.

A number of important observations:

In almost a quarter of the cases investigated, GM maize was found to have unintentionally reached the land of farmers who did not grow GM crops. The contamination by GM crops was sometimes as high as 12.6 %.
In some cases the farmers in question suffered financial losses as they could no longer sell the contaminated maize at the higher price normally charged for organically-grown and conventional crops.
Three of the cases of contamination concern local maize varieties which, after years of careful selection, are no longer usable for cultivation. These cases show how contamination by GM organisms is a threat to biodiversity and to the few varieties that are still in the hands of the farmers.

Greenpeace urges the Spanish Government to call an immediate halt to the growing of GM crops in that country. There is no regulatory framework whatsoever for monitoring GMOs from the laboratory to the table.

You can download “Impossible coexistence” at:

www.greenpeace.org/international/press/reports/impossible-coexistence
<http://www.greenpeace.org/international/press/reports/impossible-coexistence>

(1) The report was written by Greenpeace in cooperation with the agricultural organisation *Assemblea Pagesa* and the pressure group *Plataforma Trangènics Fora!.*

Source: Greenpeace, 4 April 2006

Europa - Genetically modified maize - your chance to comment

Four opinions from the European Food Safety Authority (EFSA) on genetically modified maize for food and feed uses were published on April 3. The EFSA opinions follow requests from biotechnology company Monsanto to put four types of insect-protected and glyphosate (herbicide) -tolerant maize on the EU market.
The public may make comments on these opinions
<http://europa.eu.int/comm/food/food/biotechnology/authorisation/public_comments_en.htm> for 1 month, in accordance with Regulation (EC) No 1829/2003 on genetically modified food and feed. The comments received on previous opinions may also be consulted via this page.

The EFSA opinions relate to industry requests to place on the market food or feed containing genetically modified maize. The four types of maize are the following:
· Genetically modified maize "NK603xMON810" (e.g. maize grains) or food and feed (e.g. flour, oil) produced from this maize.
· Genetically modified maize "MON863xMON810" (e.g. maize grains) or food and feed (e.g. flour, oil) produced from this maize.
· Genetically modified maize "MON863xNK603" (e.g. maize grains) or food and feed (e.g. flour, oil) produced from this maize.
· Genetically modified maize "MON863xMON810xNK603" (e.g. maize grains) or food and feed (e.g. flour, oil) produced from this maize.

Comments on the four EFSA opinions may be provided until 2 May by filling the provided forms. To respond to the opinions, please visit the following web page:
http://europa.eu.int/comm/food/food/biotechnology/authorisation/public_comments_en.htm
<http://europa.eu.int/comm/food/food/biotechnology/authorisation/public_comments_en.htm

For more information on DG Health and Consumer Protection's work on genetically modified food and feed, click here:
http://europa.eu.int/comm/food/food/biotechnology/index_en.htm
<http://europa.eu.int/comm/food/food/biotechnology/index_en.htm

For more information on EFSA, click here: http://www.efsa.eu.int <http://www.efsa.eu.int/>

Source: Sanco news, 5 April 2006

EU launches website with information on GMOs

Now that the European Union is allowing more scope for genetically modified organisms (GMOs), consumers can expect to find ever-increasing quantities of GMO products in the supermarkets. The vociferous debate between those in favour and those against has led to uncertainty among consumers about how to approach GMOs. They therefore need an independent, scientific source of information. The EU has provided this in the form of *GMO Compass*, an independent English-language website financed by the European Union.

GMO Compass provides information on the purpose, applications and use of GMOs, and also deals with evaluation, the safety of GMOs for health and the environment, and the

status of authorisations for GMOs. The site also contains information needed to understand the regulations on the labelling and traceability of GMOs, and a detailed glossary of important terms in biotechnology. The EU and *GMO Compass* are endeavouring to make an objective contribution to the forming of consumer opinion. The website provides a forum for open dialogue between experts and the general public.

The website will soon contain specific information on the situation in Germany, Finland, the United Kingdom, the Netherlands and Austria, giving an overview of the GM debate in those countries. There are links for each country to important local websites. More country information is to be added before the end of this year.

Website: http://www.gmo-compass.org/eng/home/

8. Organisation: Gothenburg University, dept. of Clinical Nutrition
Country: Sweden

Comments on the following points:

b. Food Safety Assessment:
- Nutritional assessment

All modified organisms are subject to the same problem, and our common tools for analysis are too dull to recognize them. When we analyse foods for nutritional properties we only characterize macronutrients (carbohydrates, fats, proteins) and vitamins and minerals. These are the compounds of which we know at least enough to determine minimal needs for the human organism. But, when it comes to optimal function and prevention of the major killers of western societys, that is cardiovscular diseases, cancer and type 2 diabetes, a substantial and complex interplay of other bioactieve compounds are involved. There are at least 10.000 of these identified, but their specific functions are still beeing studied and just beginning to be understood. It is evident from large studies, which has showed that inclusion of fruit and vegetables, but not purified essential vitimins, protect against cardiovascular disease and cancer, that these compounds are of utter importance for humans. Now, the problem with GMO-foods is that we don't even know which of these bioactive compounds to look for when to make an nutritional assessment. What we do know is that altering the genetic structure of foods may change the types and amounts of these compuonds and that will have effects we can not forsee.

4. Conclusions and recommendations

This product should not be used either as food or feed.

6. Labelling proposal

If GMO-products enter the market of food in Europe, they must be labeled as GMO.

9. Organisation: Università Politecnica Marche
Country: Italy

Comments on the following points:

4. Conclusions and recommendations

legally and ethically the commercialisation of GM cops is not acceptable until it can be proven without any reasonable doubt that the diffusion of GM maize will not affect farmers growing non-GM varieties or consumers will to buy non-GM maize products. I argument that GM contamination of non-GM crops at both the producer and consumer side is a breach of a fundamental civil right as contained in the Euroepan Convention on Human Rights and Fundamental Freedoms. Specifibally, of: Art. 4 "no one shall be required to perform forced or compulsory labour". The diffusion of many glyphosate-resistant maize varieties could be acceptable only if the risk of contamination will not impose to any farmer a non-intentional GM-contaminated crop. Art. 9 "Everyone has the right to freedom of thought, conscience and religion". I argue that the way GM maize is produced renders it incompatible with the fundamental values and integrity of certain individuals or groups. GM contamination could violate the right of each individual or group to make freely his/her food choices. If 100% GM-free food will prove difficult to achieve on the field or in the market, even at organic grade (since the levl of tolerance has been raised), a fundamental freedom will be violated. Increasing the numeber of registered varieties worsen the problem.

6. Labelling proposal

Labelling is very relevant and indeed is a useful tool provided producers and consumers could effectively choose between GM and non-GM products. Unfortunatley labelling itself does not imply that non-GM maise will be available on the market in sufficient quantities (now and in the future) in order not to violate the fundamental freedom of those who want to choose GM-free food or GM-free inputs. Actually, the high risk of cross-pollination on the field and of contamination in the supply chain (as demonstrated in the high tolerance levels used to officially label food as containing GMOs) imposes interferences and restrictions of one's food choices which are ethically, legally and politically unbearable. Therefore the current labeling proposal is considered insufficient.

10. Organisation: Biodynamic Association
Country: United Kingdom

Comments on the following points:

a. Assessment:
- Molecular characterisation

1. I don't believe that enough is understood on the interactive effect of introduced or modified genes within the DNA structure itself.

3. Environmental risk assessment

4. There are still articles being written about the success with defeating the cotton bollworm in India when Ihave personal experience of the disaster that it has created in India.. when such distortions of truth are presented by the companies what credibility can there be about anything they say.

5. Other comments

2. The whole presentation of GM plants has been done in such a way that it seems the priority is more about making high profits than any concern about the ethics or environmental effects of the plants. So many lies & distortions have been presented it is difficult to believe that any genuine concern for the environment exists. 3. Socially & legally there are bizarre presentations, by gm companies, of culpability by farmers whose plants have been invaded without permission by gm plants.

6. Labelling proposal

It is vital that labelling is done so that a real choice is available to consumers. In this way there can be avalid universal decision can be made on whether it is ok or not.

11. Organisation: Friends of the Earth Europe
Country: United Kingdom

Comments on the following points:

a. Assessment:
- Molecular characterisation

EFSA's earlier Opinions for NK603 [1] noted that new unintended RNA sequences were present in the genome of NK603, but speculative and largely unsupported assumptions were made about their safety. It was stated that the unpredicted transcription "is *not expected* to have a regulatory function", but no evidence was supplied to support this claim. In describing the transcription it is stated that "This *could* create 2 or more mRNA species, a smaller one at 1.4 kb (predicted as the cp4 epsps L214p transcript) and a larger species at >1.4 kb (a product *likely* to be the result of incomplete termination at the NOS 3' genetic element due to "read through")" [our emphasis]. 'Read through' transcription is dismissed because it is routinely observed in many plant genes, yet there is evidence that it can shut down neighbouring genes [2]. The new Opinion for NK603xMON810 does not consider these issues to pose a safety risk, but gives little justification for this conclusion.
[1] Opinions of the Scientific Panel for NK603 in relation to 258/97 and 2001/18 http://www.efsa.eu.int/science/gmo/gmo_opinions/catindex_en.html [2] Kusaba M et al (2003) Low glutelin content1: A dominant mutation that suppresses the glutelin multigene family via RNA silencing in rice Plant Cell 15(6):1455-1467

- Comparative analysis (for compositional analysis and agronomic traits and GM phenotype)

EFSA's earlier Opinions for NK603 [3] found a difference in the stearic acid composition of NK603 compared to non-GM maize in one year, but not the other. This is not considered to be of biological significance due to additional tests that did not find "conclusive differences requiring further studies". It is not stated whether further statistically significant differences were found – further detail would be useful to explain why the compositional difference was not thought relevant. The new Opinion for NK603xMON810 does not explore this issue in any more detail.
All compositional analyses for NK603xMON810 and its comparator were carried out in France, which is considered to be representative for maize growing regions within the EU. Yet maize is grown in a wide range of EU countries – grain production takes place in Austria, Belgium, Czech Republic, France, Germany, Greece, Hungary, Italy, Luxembourg, Netherlands, Poland, Slovakia, Slovenia and Spain [4]. Maize is also grown for forage in cooler countries such as the UK. Furthermore, as the application is for import only, it would seem necessary to provide information from countries in which maize is exported, for example as in the applications for MON863xMON810, MON863xNK603 and MON863xMON810xNK603, where data from Argentina is provided.
[3] Opinions of the Scientific Panel for NK603 in relation to 258/97 and 2001/18 http://www.efsa.eu.int/science/gmo/gmo_opinions/catindex_en.html [4] FAOSTAT data, 2006

b. Food Safety Assessment:
- Toxicology

The EFSA Opinion for NK603xMON810 states "Given the functional properties of the proteins, the GMO Panel considers that interactions between the expressed proteins are unlikely", and that "because no relevant changes in compositional analysis were detected no

further safety assessment of new constituents in NK603xMON810 is warranted". EFSA therefore reject a Member State request for a 90-day toxicology study in rats to confirm the safety of NK603xMON810 maize.
But this is at odds with a recently released EU document produced for the WTO dispute [5], which states "it can not be excluded that unintended effects may result from hybridisation between the two parental GM events", and "the intended hybrid must be subject to separate evaluation including additional data from appropriate feeding trials". It points out that "information on the parent lines alone cannot provide full reassurance that the cross will be safe as well. For example, the introduced genetic material and the products that are derived from this genetic material (eg enzymes), may interact with each other within the conventional cross of GM lines", with examples cited for GM crosses where features distinctive from the parental lines were seen and gene silencing. Insufficient evidence has been provided by EFSA to justify dismissing calls for toxicology tests on the hybrid maize.
Additionally, evidence for the safety of the Cry1Ab protein expressed in MON810 is based upon testing of a surrogate protein produced by E. coli. The use of surrogate proteins has been criticised, as different proteins can be produced by plants and bacteria even when transformed with the same gene, and so tests using such surrogates may not reflect the toxicity of the plant-produced protein [6].
[5] Paras 546, 536, European Communities – Measures Affecting the Approval and Marketing of Biotech Products: Comments by the European Communities on the Scientific and Technical Advice to the Panel. http://www.foeeurope.org/biteback/EC_case.htm [6] Freese W & Schubert D (2004). Safety testing and regulation of genetically engineered foods. In Harding SE (Ed) Biotechnology & Genetic Engineering Reviews 21.

- Allergenicity

Allergenicity assessment is based purely upon the proteins expected to be expressed by the inserted genes in the two separate parent lines (Cry1Ab and CP4 EPSPS). As explained above, unintended effects must be considered as a result of hybridisation between the two GM parental events, and so a consideration of allergenicity of the whole GM plant seems essential.
Furthermore, the assessments for Cry1Ab and CP4 EPSPS are themselves flawed. The assessments are based purely on indirect evidence such as analysis of sequence homology and pepsin resistance of bacterial surrogate proteins. But a recent study by Spök et al [7] casts doubt on the suitability of such studies to address allergenic potential, and Freese & Schubert [8] found industry procedures often failed to accurately simulate gastric fluid content. Additionally, for Cry1Ab, Chowdhury et al [9] found that the protein can pass through the digestive tract and be detected in the faeces of farm animals – so the "rapid and extensive degradation" observed in pepsin studies cited in the Opinion may not occur in reality. Additionally, Prescott et al [10] found that a genetically modified pea containing a protein not previously associated with immune reactions provoked immune responses in mice, as well as priming them to react to other foods. This is thought to be due to post-translational modification of the protein – an effect that would not be picked up by the indirect testing used for Cry1Ab and CP4 EPSPS.
Yet EFSA's opinion states that they are "not aware of any new information on allergenicity that requires a change in this opinion", and that they are "not aware of any new, validated tests that produce additional relevant or accurate information on possible allergenicity of the proteins". But the FAO/WHO Expert Consultation [11] that sought to establish a reliable methodology to assess the allergenicity of GM foods recommended targeted serum screening and immunogenicity testing in animal models for all GM foods, even from sources not known to be allergenic. Yet the Codex guidelines [12], on which EFSA's guidance [13] is based, only suggest the use of such tests where the source of the introduced gene is considered allergenic, or there are consistent indications of sequence homology to known allergens, which seems remiss based on the findings of Prescott et al.

There is currently no validated and widely accepted animal model for allergenicity testing, so clearly further research is needed – a fact acknowledged by recent calls for research [14] from the UK's Food Standards Agency for bioinformatic and proteomic techniques to identify potential allergens in novel food, and methods to study post-translational modification of transgenic proteins compared with native equivalents. Until research in this area is completed, it seems premature to conclude a low probability of allergenicity.
This is further backed up by the EU's WTO dispute document [15], which states "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."
Concerns that the allergenicity of the whole crop could have been altered are dismissed in the Opinion, stating that the issue "does not appear relevant to the Panel since maize is not considered a common allergenic food". Yet this ignores the potential for unintended effects that could occur as a result of hybridisation between the GM parental lines, as discussed above. Additionally, as maize consumption increases, particularly in processed foods, consumers could be widely exposed to the GM maize, so even uncommon allergic reactions could become an issue due to wide exposure.
Finally, the EFSA Opinion dismisses the fact that the Cry1Ab protein has been shown to act as an adjuvant, yet gives little evidence or reasoning to justify this. It is simply stated that "the adjuvant effect of Cry proteins, observed after high dosage intragastric or intranasal administration will not raise any concerns regarding allergenicity caused by maize consumption or contact. Furthermore, maize is not a common allergenic food, and only a rare cause of occupational allergy may occur".
Bearing in mind the lack of allergenicity testing carried out, the decision that no post-market monitoring of the GM food/feed is regarded as necessary seems unwise.
[7] Spök A et al (2005). Suggestions for the assessment of the allergenic potential of genetically modified organisms. International Archives of Allergy and Immunology 137:167-80. [8] Freese W & Schubert D (2004). Safety testing and regulation of genetically engineered foods. In Harding SE (Ed) Biotechnology & Genetic Engineering Reviews 21. [9] Chowdhury EH et al (2003). Detection of corn intrinsic and recombinant DNA fragments and Cry1Ab protein in the gastrointestinal contents of pigs fed genetically modified corn Bt11. J. Anim. Sci 81(10):2546-2551. [10] Prescott VE et al (2005). Transgenic expression of bean alpha-amylase inhibitor in peas results in altered structure and immunogenicity. Journal of Agricultural and Food Chemistry 53:9023-30. [11] www.fao.org/es/ESN/food/pdf/allergygm.pdf [12] www.codexalimentarius.net/download/standards/10021/CXG_045e.pdf [13] www.efsa.eu.int/science/gmo/gmo_guidance/660_en.html [14] http://food.gov.uk/multimedia/pdfs/rrd20.pdf and http://food.gov.uk/multimedia/pdfs/rrd21 [15] Para 717, European Communities – Measures Affecting the Approval and Marketing of Biotech Products: Comments by the European Communities on the Scientific and Technical Advice to the Panel. http://www.foeeurope.org/biteback/EC_case.htm

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- Others

Article 14(4) of Regulation 178/2002 explicitly states that regard must be given to not only short-term effects, but effects on subsequent generations, cumulative toxic effects and the effects on health sensitive consumers. But there is no mention of long-term effects in EFSA's Opinion. Yet compounds in maize have been linked with both carcinogenic and endocrine disrupting effects. For example, maize products have been shown to disrupt the oestrous cycle of rats, either by consumption or through exposure in bedding [16], extracts of fresh

maize and maize cob products have been shown to stimulate breast and prostate cancer cell proliferation in vitro, with sensitivity occurring at µMolar concentrations [17] and research identified a mixture of THF-diols in maize that produce endocrine disrupting effects at concentrations 200 times lower than those of classical plant estrogens [18]. A thorough assessment must be carried out to determine whether the production of these newly identified carcinogenic and endocrine disrupting compounds has been increased as a consequence of genetic modification.

[16] Markaverich BM et al (2002) Identification of an endocrine disrupting agent from corn with mitogenic activity Biochemical and Biophysical Research Communications 291: 692-700
[17] Markaverich BM et al. (2002) A novel endocrine-disrupting agent in corn with mitogenic activity in human breast cancer and prostatic cancer cells. Environmental Health Perspectives 110: 169-177 [18] Ibid

3. Environmental risk assessment

Minimal assessment is made of the potential for dissemination and accidental release of NK603xMON810 because the application is for import only. But this ignores the experience of Mexico, where despite the fact that only food and feed imports of GM maize were allowed, local landraces of maize were found to be contaminated with GM constructs. It is suggested that GM maize grains sold as food or feed were inadvertently planted, and no evidence is given to show that this will not occur in Europe. Maize seed saving is still practised in Europe, and maize landraces are still cultivated that represent a valuable source of genetic variation and an important cultural heritage. Cultivation of traditional landraces has been documented in Italy, Spain, Portugal, France and Romania [19]. Although the EFSA Opinion "advises that appropriate management systems should be in place to restrict seeds… entering cultivation", this does not appear to be an absolute requirement, and no further detail is given as to how this will be achieved in practice.

[19] Papa R. Maize landraces in Europe: a special case for co-existence.
http://europa.eu.int/comm/research/biosociety/pdf/rt_papa_abstract.pdf

5. Other comments

General comments

The 30 day opportunity for public comment is already a major constraint on providing detailed comments on application. Releasing four applications simultaneously seriously impacts on the ability to fully engage in this process, and should not be repeated. Furthermore, there does not appear to be any notification system in place for when new applications are placed on http://europa.eu.int/comm/food/food/biotechnology/authorisation/public_comments_en.htm - at the very least the ability to sign up to an email alert system should be implemented.

Access to full applications is still only available via multiple downloads from the EFSA extranet following specific requests for permission to view individual dossiers. No information is provided on EFSA's webpage about how to obtain these dossiers, making public participation in the decision making process more difficult. Public access to these documents must be made easier, making it clear that documents are available and, at the very least, creating a single, downloadable Zip file for each dossier.

The recent EC support for improvements in scientific consistency and transparency in EFSA's decision making is very welcome, but the suggested practices need to be implemented now. Opinions released for public comment must be revisited to ensure that EFSA, for example, provides more detailed justifications for dismissing Member State objections, and explicitly addresses potential long-term effects and biodiversity issues in risk assessments. All assumptions made must be made explicit, and the reasoning behind conclusions reached must be fully detailed.

12. Organisation: ETC Netherlands
Country: The Netherlands

Comments on the following points:

3. Environmental risk assessment

All GMOs pose a true environmental risk because we cannot control their behaviour/spread in the environment. Besides, glyphosate-tolerant plants cause and additional threat as they encourage greater usage of environmentally non-friendly plant protection agents.

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4. Conclusions and recommendations

Genetically modified maize NK603 x MON810 should not be given the licence for food and feed uses!

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13. Organisation: GLOBAL 2000/Friends of the Earth Austria
Country: Austria

Comments on the following points:

a. Assessment:
- Molecular characterisation

No molecular charakterisation of the insert has been undertaken. EFSA refers to the molecular charaterisation of the singel event assesment. This is a violation of the CASE by CASE principle. Nobody knows if the the stacked event has the same charateristics at the molecular level as the single event. More importatnt unintended fragments a result of the insertion process have never been assessed espacially RNA sequences transcribed from these fragments have never undergone a valid risk assessment.

- Comparative analysis (for compositional analysis and agronomic traits and GM phenotype)

The scientific bases for the assessment is not known. EFSA uses the comparative analyses as an decision tool and not as a starting point. EFSA tries to link comparative analyses with the safety of a GM crop whithout citing any references which would have shown that it is possible to extrapolate from a comparative analyses to the safety of a GM food i.e toxicolocical effects.

b. Food Safety Assessment:
- Toxicology

EFSA GMO Panels has failed to address 1 long term effects, 2 effects on subsequent generations and 3 cumulative toxic effects which all are legally required by Article 14. of Regulation EC No 178/2002 Furthermore uncertainties have not been documented. The documentation of uncertainties in the risk assessment is required by EFSAs own Guidance documenton risk assessment and is required by Directive 2001/18/EG Annex 2 Guidance notes (published as Decison 623/2002/EG). The assessment of uncertaities is key for risk managers to make a balanced deciosn on the bases what is known and what is not known. EFSA has not assessed risk by RNA which are build from unintended fragments detected in NK603. EFSA has provided a personal opinion but not an assessment on the scientific bases.

- Allergenicity

EFSA has failed to adress the allegenic potential on a case by case bases. The protein of the plant was not assessed. EFSA has reffered to the assessment in the single Events NK603 and mon 810. In NK603 EFSA has not assessed the alergenic potential but refered to the assessment of previous notifications without given any references which notification EFSA is refferring to. This is a violation of the CASE by CASE principle of the risk assessment! The CASE by CASE principle is the ey princible in the risk assessment of GMOs. Furthermore the asessment of the allergenic potential of the whole plant has not been adressed.
The evaluation of the allergenic potential is outdated see (Spoek A, Gaugitsch H; Laffer S, Pauli G, Saito H, Sampso H, Sibanda E, Thomas W, Hage vn M, Valenta R (2005) Suggestions for the assessment of the Allergenic Potential of Genetically Modified Organisms. Int. Arch. Allergy Immunol. 137:167-180) EFSA has provided a personal opinion but not an assessment on sound scientific bases.

3. Environmental risk assessment

EFSA uses scientifically flawed stuies liek Romeis et al EFSA has not undertaken any relevant exposurre analyses. EFSa has not described those species within or near the maize filed which might be exposed to the BT-maize toxin via pollen or other roots of exposure. Du to the lack of a valid exposure analyses the hazard for exposed species was not analysed. EFSA has provided a personal opinion but not an assessment on sound science and reliable data.

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4. Conclusions and recommendations

EFSA has provided a personal opinion but not an assessment on sound science and reliable data.

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14. Organisation: Greenpeace
Country: Germany

Comments on the following points:

a. Assessment:
- Molecular characterisation

Copy number and molecular characterisation of NK603 and MON810 NK603 shows molecular irregularities such as an additional and modified EPSPS inserts, rearrangements and additional chloroplast DNA, as confirmed by EFSA.
MON810 contains a truncated cry1Ab gene through truncation of the gene cassette (Agbios GM Database http://www.agbios.com/dbase.php). The native Cry1Ab protein has a molecular weight of 131 kD while the inserted, plant expressed cry1Ab gene codes for a truncated protein with a molecular weight of 91 kD, as confirmed by Western blot analysis of MON810 tissue extracts. The significance of this difference in the molecular weight has not been evaluated for environmental or food safety. Concerns about the NOS terminator in the genome of MON810, have been raised, and EFSA considers them "resolved" but no further details are given. It therefore still is an open question and concern.
The hybrid NK603xMON810 was only tested for the presence of the transgenic inserts of both parent lines and hybrid, but no further study was done about the stability of the transgenic constructs in the hybrid or possible interactions on a genomic level. Similarly, no study has been performed of the flanking regions to determine whether rearrangement has occurred during development of the hybrid. EFSA only considers the trait phenotypes for its further assessment.
It is not adequate that molecular data are presented for the GE parental lines rather than the as levels of, e.g. antinutrients may change in the hybrid or there may be possible interactions between the two parental lines at the molecular level. Such concerns were expressed by the UK ACRE (ACRE/02/M4 Minutes of the 81st meeting of ACRE May 2002. Item 3.1. Available at: http://www.defra.gov.uk/environment/acre/meetings/02/020523m.htm). Especially, it should not be assumed that the two genetic inserts act independently. How far away are the inserts from one another on the genome? On separate chromosomes or the same? This may be important as the promoter from the first genetic insert could affect expression of the second insert down stream. In addition, has transgene stability been established for the hybrid?

- Comparative analysis (for compositional analysis and agronomic traits and GM phenotype)

Compositional data: Even the very limited data provided for transgene expression and composition analysis show a high variability and statistically significant differences in the composition analysis of NK603xMON810. Geographical differences and simply inconsistencies between fields are given as a reason to discard these findings, whilst these differences could well be due to genetic engineering.
According to the Summary (Summary of the dossier EFSA GMO UK 2004-01 (2005), available at: http://www.efsa.eu.int/science/gmo/gm_ff_applications/more_info/486_en.html) and the EFSA opinion ((Question No EFSA-Q-2004-086). The EFSA Journal (2005) 309, 1-22.), NK603xMON810 was only compared in a field trial to a "non-transgenic control hybrid (generated from similar, though not identical parent lines) and five different non-transgenic commercial maize hybrids" but not to NK603, MON810 and/or an isogenic line. Due to the omission of NK603 and MON810 in the field trials for the comparative analysis, it is impossible to investigate whether the cross-breeding of two GE varieties resulted in an interaction of the different GE proteins, as well as with the herbicide and/or its metabolites.

EFSA refers to a positive approval of MON810 and NK603 but the compositional data existing in both the Monsanto MON810 safety assessment (Monsanto (2002) Safety Assessment of Yieldgard Insect-Protected Corn Event MON810. Available at: http://www.monsanto.com/monsanto/content/our_pledge/yieldgardcorn_product.pdf) and the Monsanto NK603 safety assessment (Monsanto (2002) Safety Assessment of Roundup Ready Corn Event NK603. Available at: http://www.monsanto.com/monsanto/content/our_commitments/roundupcorn_product_NK603.pdf) are of exceptionally poor quality. For MON810, proximate analysis, amino acid composition, fatty acid composition, tocopherol, calcium and phosphorus determinations are all made on samples pooled from different field sites. Similarly, for NK603, all analyses are based on pooled samples from the US and also pooled samples from the EU (numbers of samples are not supplied). Such pooled data would mask any differences between sites. In addition, for MON810 values are compared to literature values rather than control sister lines. Such data are not statistically sound and would be wholly unacceptable for a peer-reviewed scientific journal and in no sense establishes any similarities in composition with non-GE maize.

Field trials in France are of no relevance for imported GE maize: NK603xMON810 was grown in field trials in three locations during one season (2000) in France to assess the transgenic expression and the compositional analysis. However, the transgene expression or compositional analysis of NK603xMON810 produced in France or anywhere else in the EU is not of relevance to the application for food and feed, import and processing because NK603xMON810 will not be cultivated within the EU but only imported.

EFSA's opinion gives no information regarding where this maize will be cultivated. Nor are there any studies about transgene expression or compositional analysis of NK603xMON810 from any of the growing regions from where the maize is proposed to be imported into the EU.

Field trials in France can be used as an indication, but they give no information about the transgene expression and compositional analysis in the actual growing regions. As indicators, these tests show a high variability (in transgene expression) and even statistically significant differences (for some compounds tested). EFSA explains this with geographical difference. It is therefore reasonable to assume even greater differences if NK603xMON810 is grown in very different climatic conditions on other continents. Field trial data from France are therefore inadequate to give relevant information and to exclude significant differences

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b. Food Safety Assessment:
- Toxicology

Food safety is unknown Greenpeace applied for access to Monsanto's feeding studies of MON810 with rats and broilers. Even after the competent authority in Germany granted this, Monsanto refuses access and has taken matter to court. Concerns about the food and feed safety of MON810 were raised after similar feeding studies with another Bt maize produced by Monsanto showed negative health effects. Without re-evaluation of these data, it can not be assumed that MON810 is safe for food and feed. A decision can certainly not be taken while Monsanto actively withholds such vital information from the public.

Also for NK603xMON810, the results of a 42-day feeding study are described as finding "no biological meaningful differences were observed." This indicates that differences were found, and that (based on the EFSA's usage of such terms) and no indication is given why EFSA does not consider them relevant or what these differences where. Member states had requested a 90-day feeding study of NK603xMON810 instead of only using data from the individual studies with MON810 and NK603, but this was refused by EFSA. Member states also requested information about the mortality rate of broiler chickens fed with NK603xMON810, but this was also not further investigated.

In addition no feeding studies were done with NK603xMON810 grown under herbicide application which could show effects that might arise from the Cry1Ab toxin and the herbicide glyphosate or its metabolites, even if the transgenic proteins do not interact themselves.

3. Environmental risk assessment

No risk assessment for Bt (Cry1Ab) in the soil: The possible transfer of Bt (Cry) toxins from animal feed through the manure into the soil has been documented in the scientific literature, and EFSA confirms that by stating that “little Cry toxin would survive to pass out in faeces.”
EFSA assumes that only little Cry toxin will be passed out in faeces, that this would be degraded due to microbial proteins and that therefore the amount of Cry toxins and the possible effects on non-target organisms would be too low to require any kind of risk assessment. Neither EFSA nor the applicant support this assumption with any data or published studies. However, published, peer-reviewed studies have shown that pigs (Chowdhury, E.H., Kuribara, H., Hino, A., Sultana, P., Mikami, O., Shimada, N., Guruge, K.S., Saito, M. and Nakajima, Y. 2003. Detection of corn intrinsic and recombinant DNA fragments and Cry1Ab protein in the gastrointestinal contents of pigs fed genetically modified corn Bt11. Journal of Animal Science, 81: 2546-2551) and cattle (Einspanier, R., Lutz, B., Rief, S., Berezina, O., Zverlov, V., Schwarz, W. and Mayer, J. 2004. Tracing residual recombinant feed molecules during digestion and rumen bacterial diversity in cattle fed transgene maize. European Food Research and Technology 218: 269-273.) fed GE crops excrete some GE DNA and large fragments of the Bt protein. The excretion of large fragments of Bt protein from animals fed GE crops is of environmental concern as, despite being fragmented, the Bt toxins retain their toxicity (Chowdhury et al. 2003. op. cit).
Even if some further degradation is reasonable to assume, an environmental risk assessment cannot be left out based on vague assumption.
Since the survival of Cry toxin in manure was documented no studies were undertaken to investigate: 1. the survival rate of Cry toxin in the gut of cows, pigs, chickens or other animals that are supposed to feed on NK603xMON810 or any other Bt maize 2. the degradation of Cry toxins in manure and the transfer rate into soil 3. which non-target organisms would come into contact with Bt toxin in manure and whether they would be negatively affected by it.
Without any kind of study or data the accepted survival of Cry toxins in the animal gut cannot be discarded as ‘would be too low to matter.’

4. Conclusions and recommendations

The import and the use for food and feed of the GE hybrid NK603xMON810 in the EU should be refused on the grounds that:
1) The molecular characterisation from both parental lines shows irregularities, including open reading frames, missing “stop” codons and truncated constructs possibly producing truncated proteins. 2) Compositional analysis from field trials shows high variability attributed to geographic differences and statistically significant differences. Compositional data for the parental lines provided by Monsanto are of exceptionally poor quality. On this basis, there is no evidence for any claim to substantial equivalence. 3) Field trials in France are of no relevance for imported GE maize 4) There is no risk assessment for Cry1Ab in the soil 5) Food safety is unknown
On these grounds it is evident from the (unsatisfactory) risk assessment that there are many remaining uncertainties relating to this application. The risk assessment from EFSA should (according to preamble 9 in the regulation) be followed by a risk management decision by the Community, under a regulatory procedure ensuring close cooperation between the Commission and the Member States. The risk management decision is (according to article 7(1) in the regulation) drafted by the commission. Based on the many remaining uncertainties and statistically significant differences, the Commission must put forward a draft risk management decision, which on grounds of precaution, refuse approval.
The EFSA has consistently shown a lack of scrutiny on GMO applications and it fails to conduct a full risk assessment as requested by EU legislation. Greenpeace considers therefore that the current authorisation process for GMOs should be stopped, and that the

risk assessment and risk management procedures performed by the EFSA and the Commission must be reviewed.

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5. Other comments

Greenpeace demands full publication of all original data, especially data from feeding trials, to allow independent assessment of the applications.
General remarks on EFSA work: EFSA has a poor understanding of the concept of „statistical significant difference“. In statistics, a result is significant if it is unlikely to have occurred by chance. In a study to compare a test and control group this means that the difference is caused by the trait or treatment that is different in both groups, and that each test object/animal can be identified as belonging to either of these groups. EFSA repeatedly declares statistical significant differences as not relevant because they (a) say that even as there is a statistical difference, there is in fact no difference, because the data overlap or because the data are similar enough etc (3), or they declare the results as not of biological relevance. In the first case that interpretation goes against exactly the point that "statistical significance" makes: that there is a difference. In the second case, the unscientific argument of "biological relevance" reduces the whole test to meaninglessness because EFSA basically says that the test as such was not designed to give any relevant information anyway. In this case it would be necessary to repeat the tests with a different values for significance and power, but not to discarded the results as „irrelevant“. Unexpected differences between test and control group, and especially such obvious ones as the increased Cry3Bb1 levels, can be indicators for underlying changes in the plant physiology caused by the transgenic inserts. EFSA, however, seem to consider Bt levels and plant components as some kind of static list of components of a food and feed product and not as indicators for the physiology of a living organisms

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15. Organisation: GeneWatch UK
Country: United Kingdom

Comments on the following points:

a. Assessment:
- Molecular characterisation

Our view is that the EFSA opinion does not consider the uncertainties, gaps in knowledge and assumptions that are inevitable. An explanation of these areas is required in the EFSA'a own guidance document e.g. ‘The final risk characterisation should result in informed qualitative, and if possible quantitative, guidance to risk managers. It should explain clearly what assumptions have been made during the risk assessment, and what is the nature and magnitude of uncertainties associated with establishing these risks.’ (p51)
In practice, a proper risk assessment, having laid out the uncertainties, gaps in knowledge and assumptions, the opinion should consider the importance of these and how the reasoning behind the decision on the risk assessment. The opinion should consider the quality of data, problems with methodologies and some assessment of the statistical power of data provided to be able to detect differences in comparative analysis. Yet no such approach is adopted.
Because of these serious shortcomings in the scientific conduct of the risk assessment it does not provide an adequate basis for decision making.

16. Organisation: Consiglio dei Diritti Genetici
Country: Italy

Comments on the following points:

a. Assessment:
- Molecular characterisation

• Molecular characterization of single events highlighted that during the transformation process several unexpected sequences, showing homology with mitochondrial (MON810) and chloroplast (NK603) DNA, has been integrated. Moreover, sequence data and PCR analysis, reported by third party suggest a deletion and/or rearrangement of genomic plant DNA at the insertion site(1) .
• MON810 maize has been obtained by transformation using a solution of 2 vectors: PV-ZMBK07 and PV-ZMGT10 (2) . Indeed, the EFSA opinion reported only of one, the PV-ZMBK07 vector, no data has been provided to exclude integration of DNA from the PV-ZMGT10 vector according the recommendations of the Scientific Committee on Plants.
• In conclusion, molecular characterization of the single events, showed the presence of unexpected sequences at the insertion locus, including sequences not present in the vectors used for the transformations. We retain, that these data don't allow concluding that the genotypic alterations, observed or potential, don't produce any phenotypic effect in the transformed maize line. In order to better investigate this hypothesis, we consider that should be necessary to apply profiling technologies (transcriptomics, proteomics, metabolomics). Without these analysis, the food/feed safety assessment should be performed very accurately in order to consider the unpredictable effects on human and animal health. However, we retain that selection of commercial events should be performed more stringently to prevent the presence of unexpected sequences with unknown functions.
(1) Hernandez M, Pla M, Esteve T, Prat S, Puigdomenech P and Ferrando A. A specific real-time quantitative PCR detection system for event MON810 in maize YieldGard based on the 3'-transgene integration sequence. Transgenic Research 2003, 12, 179-89. (2) Opinion of the Scientific Committee on Plants Regarding the Genetically Modified, Insect Resistant Maize Lines Notified by the Monsanto Company (NOTIFICATION C/F/95/12/02)

- Comparative analysis (for compositional analysis and agronomic traits and GM phenotype)

• Trial fields where the plant grew were in France. Compositional analysis were made on samples originated from those fields. It seems to be inadequate, because France isn't representative of all European cultivation areas. • Statistically significant differences were observed between maize MON810 x NK603 and control hybrids, in 56 cases on 236 studied (23.78%). In particular, differences were observed in phosphorus and oleic acid. It could mean that metabolic pathway of the GM maize were changed, so it seems better to do deeper studies to be able to say that there are no differences between conventional and GM maize.

b. Food Safety Assessment:
- Toxicology

• GMO-Panel didn't require toxicological analysis on the new event, but they considered the previous analysis on singular events enough to conclude that GM maize MON810 x NK603 is safe for human and animal health. This conclusion seems superficial and not conclusive.

- Allergenicity

• There isn’t production of IgE, but analysis on mice demonstrated that protein Cry12Ab can have adjuvant effects, so more studies seem necessary to exclude any potential allergenic effect of the GM maize MON810 x NK603.

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3. Environmental risk assessment

• More consequences could derivate from an accumulation of Cry toxins in the soil, from the genetic horizontal transfer, from unintentional dispersal or bad use of GM seeds that could be used for cultivation. It requires to be considered from the GMO-Panel. • The E.R.A. seems to be inadequate. More studies on effects on non target organisms, soil microorganisms, biogeochemical cycles and biodiversity seem necessary to conclude that GM maize MON810 x NK603 is safe for environmental. • More monitoring plans are necessary to evaluate eventually unintentional effects on soil. The notifier didn’t present an adequate monitoring plan.

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17. Organisation: GM Free Cymru
Country: United Kingdom

Comments on the following points:

4. Conclusions and recommendations

We are frankly amazed that following the heavy criticism of the GMO Panel's working methods, its conduct of science and its heavy dependence upon the "advocacy science" submitted in support of approval applications, it has pressed forward with this "positive opinion." That does not show a great deal of sensitivity. Concerns about the Panel have come from NGOs, from European Environment Ministers, and from within the Commission. Also, there are large unanswered questions about the toxicity of MON 810 and its hybrids that are not adequately investigated -- it is a Bt variety, and it is becoming increasingly clear from research in India, Australia and elsewhere that mammal deaths and allergic reactions in humans (not to mention the dramatic crop failures of Bt cotton) indicate that ALL Bt varieties may be quite dangerous. It is foolhardy in the extreme to press ahead with approvals for Bt varieties such as this (either for planting in the EU, or for food / feed use) until all these questions are adequately resolved through scientific debate. EFSA pretendss that environmental issues are irrelevant in this case; but it does have a brief to consider environmental egffects, and it would be dishonest for ity to say if the environmental effects are outside the EU, that is none of our concern." Countries including Hungary, Austria and Poland also have concerns about MON 810, and these concerns have not yet been adequately explored. We therefolre urge the EC not to act upon EFSA's positive opinion in this case, in recognition of the widespread calls for a "freeze" on further GM authorizations pending further research and in-depth investigations of national and publ;ic concerns.