GM Food & Feed – Comments from the Public

Comments received on Maize MON863 x MON810

1. private person, DE
2. private person, NL
3. Lucel, NL
4. Gothenburg University, dept. of Clinical Nutrition, SE
5. Universita Politecnica Marche, IT
6. Friends of the Earth Europe, UK
7. ETC Netcherlands, NL
8. Greenpeace, DE
9. GeneWatch, UK
10. Consiglio dei Diritti Genetici, IT
11. GM Free Cymru, UK

1. Organisation: individual
Country: Germany

Comments on the following points:

4. Conclusions and recommendations
As a consumer, I dont agree with any GMO food and feed like most of the Europeans. I will try my best to keep this kind of food out of my kitchen. I will be deeply disappointed from EFSA if they dont put their weight to strengten consumer rights instead financial interests of Monsanto.

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2. 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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- 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 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*

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

en Genen], soil has never been properly studied in connection with GM organisms and the genes incorporated into them.
Thought is being given to the health of the economy rather than the health of the consumer.

4. Conclusions and recommendations

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 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:

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

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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3. 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/

4. 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.

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6. Labelling proposal

If GMO-products enter the European food market, they must be labeled GMO.

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5. 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 European Convention on Human Rights and Fundamental Freedoms. Specifically, 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 level of tolerance has been raised), a fundamental freedom will be violated. Increasing the number of registered varieties worsens 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. Unfortunately labelling itself does not imply that non-GM maize 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 labelling proposal is considered insufficient.

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

Comments on the following points:

a. Assessment:
- Molecular characterisation

Expression levels of the Cry proteins are of concern. Cry3Bb1 expression in MON863xMON810 is much higher than that of Cry proteins in other GM maize varieties, such as MON810, Bt11, Bt176 (producing Cry1Ab) and even Starlink (producing Cry9C). Expression levels in the hybrid are also higher than those of the parental GM lines - the applicant notes that "Average levels of the Cry3Bb1 protein in tissues of Mon 863xMon 810 were estimated to be 1 -2 fold higher than in Mon 863". Similarly the average level of Cry1Ab was 83% higher in the hybrid (0.84 µg/g fw) than in MON810 parent grains (0.46 µg/g fw). In the case of NPTII, the protein was expressed at a very low level in both hybrid and parent grains (<0.076 µg/g fw) although it was expressed at a higher level in both leaves and forage [1]. EFSA's Opinion concludes that these data to not raise safety concerns, but no evidence is given to support this.
[1] Monsanto. Application for authorisation of MON863xMON810 maize in the European Union according to Regulation EC No 1829/2003 on genetically modified food and feed. Part I – Technical Dossier.

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

Compositional analysis is based on forage and grain obtained from field trials in Argentina, which is considered "representative of major countries exporting maize to the EU". However, maize is imported into the EU from a variety of countries, including Brazil, the USA and South Africa [2], each of which will have markedly different climatic conditions to Argentina.
[2] FAOSTAT data, 2006

b. Food Safety Assessment:

- 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 Cry3Bb1). Yet a recently released EU document [3], states "it can not be excluded that unintended effects may result from hybridisation between the two parental GM events", and "information on the parent lines alone cannot provide full reassurance that the cross will be safe as well." A consideration of allergenicity of the whole GM plant seems essential.
Furthermore, the assessments for Cry1Ab and Cry3Bb1 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 [4] casts doubt on the suitability of such studies to address allergenic potential, and Freese & Schubert [5] found industry procedures often failed to accurately simulate gastric fluid content. Additionally, for Cry1Ab, Chowdhury et al [6] 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 [7] 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 Cry3Bb1.

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 [8] 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 [9], on which EFSA's guidance [10] 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 [11] 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 [12], 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.

[3] 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 [4] 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. [5] Freese W & Schubert D (2004). Safety testing and regulation of genetically engineered foods. In Harding SE (Ed) Biotechnology & Genetic Engineering Reviews 21. [6] 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. [7] 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. [8] www.fao.org/es/ESN/food/pdf/allergygm.pdf [9] www.codexalimentarius.net/download/standards/10021/CXG_045e.pdf [10]

www.efsa.eu.int/science/gmo/gmo_guidance/660_en.html [11]
http://food.gov.uk/multimedia/pdfs/rrd20.pdf and http://food.gov.uk/multimedia/pdfs/rrd21 [12]
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.
[13] Markaverich BM et al (2002) Identification of an endocrine disrupting agent from corn with mitogenic activity Biochemical and Biophysical Research Communications 291: 692-700
[14] 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 [15] Ibid

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3. Environmental risk assessment

Minimal assessment is made of the potential for dissemination and accidental release of MON863xMON810 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 [16]. 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.
EFSA also conclude that the antibiotic resistance gene nptII does not pose a risk to the environment or to human and animal health due to limited use of kanamycin and neomycin in medicine, widespread presence in bacterial populations and low risk of gene transfer from plants to bacteria. But these drugs are still important for specific purposes, such as bowel sterilisation prior to surgery and treatment of neonatal infections.
[16] Papa R. Maize landraces in Europe: a special case for co-existence. http://europa.eu.int/comm/research/biosociety/pdf/rt_papa_abstract.pdf

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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.

7. 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.

4. Conclusions and recommendations

Genetically modified maize MON 863 x MON 810 should not be given the licence for food and feed uses!

8. Organisation: Greenpeace
Country: Germany

Comments on the following points:

a. Assessment:
- Molecular characterisation

Mitochondrial DNA: MON863 unintentionally contains mitochondrial DNA in the transgenic insert which was not part of the original intended insert. No risk assessment has been performed for this unintended DNA sequence and the possible effects. Instead, EFSA (2005a: 6) claims that DNA from organelles (mitochondria, chloroplasts) „acquired during the transformation is established as a normal phenomenon in plant biology and the Panel considered that this would not significantly impact on the present safety assessment..“ This is not the case. The mitochondrial DNA inserted in the MON863 genome is an unintended DNA sequence, and neither part of the nuclear maize genome nor part of the original transgenic insert. As such, it needs to be assessed in a risk assessment. If mitochondria were damaged during the GM transformation to such a degree that their DNA was included in the nucleus, then it is necessary to study possible effects caused by this, as well other possible mitochondrial insert in the rest of the genome.

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

Bt toxin: In each of the three MON863 hybrids, the Cry3Bb1 toxin levels in the kernels are increased compared with those of MON863 itself (29 µg Cry3Bb1/g dry weight in MON863, 37 µg/g dw in MON863 x MON810 x NK603; see table for details). No further study was done on why there is a consistent increase, and whether this indicates other cumulative effects of the four GM traits. Instead EFSA discards them with one sentence: „This reflects variability in gene expression, which may have been influenced, for example, by environmental factors.“ However, no study has been performed to confirm that. In addition, if GMO hybrids with stacked GM traits display such a variability in gene expression: can they be considered stable? Cry1Ab levels in kernels are increased in one hybrid, and decreased in another. Again, no further study is performed.
Composition: several components are different between the original GM maize varieties MON863, MON810 and NK603 and the hybrids cross-bred from them. For each of the three hybrids, EFSA (2005a: 9) states that „a number of statistically significant differences were observed“ but the Opinions give very little details on which components were different. From those data that are included, a significant decrease in linolenic acid in kernels stands out because it appears in both hybrids involving MON863 and MON810. The argumentation used by EFSA to discard the observed statistical significance reduces the whole concept of studying composition differences between control and test group to absurdity:
„Niacin levels decreased from [...] control maize to [...] MON863 x MON810 x NK603 maize, while the latter was slightly outside the background range of commercial varieties [...], but still within the background ranges reported in literature [...] and from previous field trials with maize [...].“ (EFSA 2005d: 10)
„Cry3Bb1 and Cry1Ab protein levels in kernels of MON 863 x MON 810 maize were higher than in the individual MON 863 and MON 810 lines.“„This reflects variability in gene expression, which may have been influenced, for example, by environmental factors.“ (EFSA)
„In the comparisons of data from all four combined sites, a number of statistically significant differences were observed." "Comparison of MON 863 x MON 810 maize with controls, both

single-trait parental lines and various commercial reference hybrids showed statistically significant differences in several compounds.“
„The average level of linolenic acid (C18:3) in kernels of MON863 x MON810 maize was significantly decreased compared with that of all comparators in each separate location: 1.01 ± 0.02 % of total fatty acids in MON 863 x MON 810 compared with 1.17 ± 0.02 % in MON 863, 1.10 ± 0.02 % in MON 810, 1.19 ± 0.02 % in the control, and 1.19 ± 0.01 % in commercial reference lines.“„Panel concludes, therefore, that the difference in linolenic acid is not meaningful from a biological point of view.“

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b. Food Safety Assessment:
- Toxicology

Toxicity: The toxicity studies are based on the assumption that any relevant effect is dose related and that they appear to the same degree in male and female animals. This hypothesis has no scientific basis.
Significant differences are discarded because even though there is a decrease in haemoglobin concentration between non-GM and GM feed, the concentration does not get decreased further with more GM feed. Decreased organ weight were observed in all studies including heart, kidney, thyroid/parathyroid, epididymes and other (not specified) organs. Most of these differences are described as "statistically significant different".
Changes in blood included lower numbers of red blood cells, increased corpuscular hemoglobin for one hybrid and a decrease in another, increased blood urea nitrogen, changes in basophile counts, and an increased neutrophil count.
Other changes included higher feed consumptions of animals feeding fed with two of the three hybrids
Feed conbsumption: „Small deviations in food consumption by females on test diets containing MON 863 x MON 810 were observed as compared with those on the control diet.“
Decreased haemoglobin concentration: „Analysis of the clinical chemistry and pathology data showed statistically significant decreases in mean corpuscular haemoglobin concentration in male animals in the 11% and 33% test diet groups. Values of 32.7 g/dl for the control group, 31.6 g/dl for the 11% group and 31.6 g/dl for the 33% group and therefore these values were not dose-related.“
Different Basephile counts: „Another statistically significant, but slight difference in basophil counts was observed but only in males that received the 11% test diet. The Panel considers the changes observed to be of no toxicological relevance.“
Different organ weights: „Concerning organ weights, some statistically significant differences were observed.“ „For example, lower mean absolute and relative thyroid/parathyroid weights compared with the control group (0.257 g) were observed in female animals of groups fed the 11% (0.200 g) and 33% (0.219 g) test diets.“ „The mean kidney weight relative to body weight was statistically significantly lower in females in the 33% test diet group.“

- Others

Antibiotic Resistance Gene: MON863 contains an GM antibiotic resistance gene (nptII) against kanamycin and neomycin. EFSA seems to be unaware political decisions to stop the use of antibiotic resistance, and instead refers to more then 10 year old studies to claim "a history of safe use" and conclusions predating the EU decision not tu allow antibiotic resistance markers: "This conclusion was based on the limited use of kanamycin and neomycin in human and veterinary medicine, the already widespread presence of this gene in bacterial populations [...] NptII is a well-established selection marker with a history of safe use (Nap et al., 1992; Redenbaugh et al., 1994). This conclusion is consistent with earlier safety evaluations of nptII (SCP, 1998)." (MON863xNK603). „The GMO Panel recently concluded that the use of the nptII gene as a selectable marker did not pose a risk to the environment or to human and animal health.“ (EFSA 2005c: 15)

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3. Environmental risk assessment

Environmental risk assessment: Member States had explicitly asked for effects of the three hybrids on non-target organisms but EFSA declares such studies unnecessary because the application would be for import and processing only. Experiences with GM crops show repeatedly unintended use, experiences with the feed and food industry show repeatedly unintended or even illegal use. Why not expect similar events for these GMOs? Member states also asked for the consequence of water and soil exposure to the Bt toxins present in the GM maize via organic waste material and litter or sewage to be addressed. Such expore occur during processing or through spillage. This was not studied because EFSA considers the amount of toxin to be too low to be of interest. No data are given for this assumption even though EFSA acknowledges that Bt toxin from manure can reach susceptible organisms such as soil coleoptera (EFSA 2005a,b,c,d). No consideration is given to the fact that all studied MON863 hybrids have increased Bt Cry3Bb1 toxin levels.

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4. Conclusions and recommendations

Greenpeace urges you to reject the opinions of EFSA and the authorisation for the hybrids for the following reasons:
Significant changes in plant composition have been disregarded in all MON863 hybrids. · Significant findings in animal feeding studies were found in all hybrids, but have not been sufficiently taken into account. · Unexpectedly, the kernels of the hybrids show higher Cry3Bb1Bt toxin concentrations than those of MON863. These findings have not been investigated. · Environmental risk assessments were only done for the intended use, but not for GM hybrids released through unintended use. No environmental risk assessment was done with the hybrids themselves; instead EFSA based its opinion on the individual GM lines.
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 scrunity 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. Further, Greenpeace is of the opinion that no decision can be taken by the Commission and Member States on the hybrids as long as the problems regarding the MON863 risk assessment have not been addressed by the Commission. Since MON863 itself can not be seen as safe for food or feed products, further authorisations involving this construct would be irresponsible.
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

decleares 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

9. Organisation: GeneWatch UK
Country: United Kingdom

Comments on the following points:

a. Assessment:
- Molecular characterisation

GeneWatch UK's view is that the EFSA opinion is deficient and not fit for purpose because it does not consider the uncertainties, gaps in knowledge and assumptions that are inevitable in any area of science. 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 therisk assessment it does not provide an adequate basis for decision making.

10. 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 MON863) DNA, has been integrated: o in MON810 sequence data and PCR analysis, reported by third party suggest a deletion and/or rearrangement of genomic plant DNA at the insertion site(1) ; o 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; o in MON 863, sequencing data of flanking regions identify DNA with homology with mitochondrial genes, "However, the molecular analysis at both the 5' flank and the 3' flank of the MON 863 event does not differentiate between the integration of insert DNA within a region of mitochondrial DNA that is already present in the nuclear genome and the acquisition of this organelle DNA as part of the primary integration during transformation" (3)
• 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.
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. 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) Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the safety of foods and food ingredients derived from insect-protected genetically modified maize MON 863 and MON 863 x MON 810, for which a request for placing on the market was submitted under Article 4 of the Novel Food Regulation (EC) No 258/97 by Monsanto, The EFSA Journal (2004) 50, 1-25

- Comparative analysis (for compositional analysis and agronomic traits and GM phenotype)
• The sample used in compositional analysis isn't representative cross-section. Furthermore, the notifier analyzed 58 parameters of GM maize MON863 x MON810 grain and the same parameters of conventional maize, and statistically significant differences were observed in 21% of the parameters analyzed. These results demonstrate that metabolic pathways of GM maize MON863 x MON810 are changed. It could have unexpected effects on human and animal health, due to changes in unknown or underestimated metabolites.

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b. Food Safety Assessment:
- Toxicology

Toxicological analyses show a statistically significant decrease in Hb (hemoglobin) values in male mice of test groups, as a significative decrease also in thyroid and kinder weight. It seems to require deeper investigations to evaluate the safety of the GM maize on human and animal health.

- Allergenicity

The GM maize MON863 x MON810 seems to be lacking in allergenicity, but the notifier didn't produce analyses on the whole plant but only deductive arguments.

- Nutritional assessment

The studies on broiler chickens are inadequate to make a deduction on nutritional equivalence of the GM maize MON863 x MON810 with conventional maize.

3. Environmental risk assessment

The E.R.A. seems to be inadequate to evaluate unpredictable effects of GM maize MON863 x MON810 on soil. Further studies on non target organisms and on soil microorganisms are necessary to verify the absence of negative effects on trophic chains and on biogeochemical cycles.

4. Conclusions and recommendations

Surveillance and monitoring plans forecasted from notifier aren't enough to monitor unpredictable effects that notifier didn't evaluate in E.R.A. furnished in the notification. They also seem to be unable to assure the separation between productions of GM, conventional and biological maize.

11. 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 public concerns.
EFSA appears to be quite unconcerned that Monsanto has refused to make MON 810 seed available for further Hungarian research, following recent "uncomfortable" results reported by Professor Darvas and his team. A company which behaves in such a despicable and arrogant fashion is clearly intent upon the suppression of independent science, and it is self-evident that it has something to hide with respect to the environmental impact of MON 810 and its hybrids. At the very least, EFSA should support Hungarian demands for the release of seeds and for a continuation of the Hungarian research, instead of acting as a poodle for a multinational corporation.

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5. Other comments

This variety is also a MON 863 hybrid -- again we are amazed, after all the revelations about Monsanto's obsessive secrecy and obfuscation, and its attempt to prevent its supporting research (including the 90-day rat feeding study) from being examined by independent scientists, that EFSA should now be pressing ahead with this positive opinion. The jury is still out on the question of MON 863 safety, and much more scientific debate (and replication of research) must be conducted before any further authorisations of MON 863 hybrids can be considered.
We urge the EC to reject this opinion.
