GM Food & Feed – Comments from the Public

Comments received on Maize MON863 x NK603

1. private person, NL
2. Lucel, NL
3. Gothenburg University, dept. of Clinical Nutrition, SE
4. Universita Politecnica Marche, IT
5. Friends of the Earth Europe, UK
6. ETC Netcherlands, NL
7. GLOBAL 2000/Friends ofthe Earth Austria, AT
8. Greenpeace, DE
9. GeneWatch, UK
10. Consiglio dei Diritti Genetici, IT
11. GM Free Cymru, UK

1. Organisation: Individual
Country: The Netherlands

Comments on the following points:

b. Food Safety Assessment:
- Toxicology

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.

Glyphosate is a herbicide, of which the toxicity has not been tested sufficiently, I do not want glyphosate on my plate. Genetically modified crops non-resistant to glyphosate, should be protected by hoods. The genetically modified maize that has been made resistant to glyphosate, receives the full dose of herbicide when sprayed.

Fragment Weedkiller may boost toxic fungi 12:16 14 August 2003 Exclusive from New Scientist Print Edition. Andy Coghlan A widely used herbicide encourages the growth of toxic fungi that devastate wheat fields, laboratory studies by scientists working for the Canadian government suggest. If further studies confirm that the herbicide, glyphosate, increases the risk of fungal infections - which are already a huge problem - farmers might be advised to use it less.

That could be a major blow for backers of genetically modified wheat in Canada, because the first GM variety up for approval in Canada is modified to be glyphosate-resistant. If it gets the go-ahead, there is likely to be an overall increase in glyphosate use.

The potential problem was spotted during a five-year study of plant diseases headed by Myriam Fernandez of the Semiarid Prairie Agricultural Research Centre run by Agriculture and Agri-Food Canada in Swift Current, Saskatchewan. She noticed that in some fields where glyphosate had been applied in spring just before planting, wheat appeared to be worse affected by fusarium head blight - a devastating fungal disease that damages grain and turns it pink.

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

Deadly toxins In Europe alone, fusarium head blight destroys a fifth of wheat harvests. The fungi that cause the disease also produce toxins that can kill humans and animals.

"We found higher levels of blight within each tillage category when glyphosate had been used," says her colleague Keith Hanson.

And his lab study showed that Fusarium graminearum and F. avenaceum, the fungi that cause head blight, grow faster when glyphosate-based weedkillers are added to the nutrient medium.

But the investigators warn against jumping to conclusions. "We're deferring judgement until we have all the data," says Hanson. Analysis of the last four years of data from the study is not yet complete, Fernandez stresses.

KNIP Zie verder; http://www.newscientist.com/article.ns?id=dn4051

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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 en Genen*], soil has never been properly studied in connection with GM organisms and the genes incorporated into them.

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4. Conclusions and recommendations

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

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

We do not want any genetically modified crops

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:
http://proto.thinkquest.nl/~llb109/meningenvw.html

6. Labelling proposal

All packaging (of such products) should be marked: contains genetically modified ingredients. I do prefer not to have any genetically modified food and feed at all.

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

2. 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/

3. 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.

6. Labelling proposal

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

4. 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.

5. 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 MON863xNK603 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)

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 [3], each of which will have markedly different climatic conditions to Argentina.
[3] FAOSTAT data, 2006

b. Food Safety Assessm
- Allergenicity

Allergenicity assessment is based purely upon the proteins expected to be expressed by the inserted genes in the two separate parent lines (Cry3Bb1 and CP4 EPSPS). Yet a recently released EU document [4], 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 Cry3Bb1 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 [5] casts doubt on the suitability of such studies to address allergenic potential, and Freese & Schubert [6] found industry procedures often failed to accurately simulate gastric fluid content. Additionally, Prescott et al [8] 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 Cry3Bb1 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 [9] 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 [10], on which EFSA's guidance [11] 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 [12] 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 [13], 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.

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.

[4] 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 [5] 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. [6] Freese W & Schubert D (2004). Safety testing and regulation of genetically engineered foods. In Harding SE (Ed) Biotechnology & Genetic Engineering Reviews 21. [7] 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. [8] 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. [9] www.fao.org/es/ESN/food/pdf/allergygm.pdf [10] www.codexalimentarius.net/download/standards/10021/CXG_045e.pdf [11] www.efsa.eu.int/science/gmo/gmo_guidance/660_en.html [12] http://food.gov.uk/multimedia/pdfs/rrd20.pdf and http://food.gov.uk/multimedia/pdfs/rrd21 [13] 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 [14], 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 [15] 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 [16]. 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.

[14] Markaverich BM et al (2002) Identification of an endocrine disrupting agent from corn with mitogenic activity Biochemical and Biophysical Research Communications 291: 692-700
[15] 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 [16] Ibid

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3. Environmental risk assessment

Minimal assessment is made of the potential for dissemination and accidental release of MON863xNK603 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 [17]. 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.

[17] 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.

6. 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

4. Conclusions and recommendations

Genetically modified maize MON863 x NK603 should not be given the licence for food and feed uses!

7. 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)

* Comparative analysis
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

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.

4. Conclusions and recommendations

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

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)
Stearic acid: „Compositional data for maize NK603 from two growing seasons revealed a minor, but statistically significant difference for the stearic acid content (C18:0) in kernels compared to non GM maize in one year, but not in the other year.“
„A number of statistically significant differences were observed in the comparisons of the composition of kernels from MON 863 x NK603 and its control.“
Increased arachidic acid: „The Panel therefore considers the observed consistent differences in arachidic acid content as small in size and not meaningful from a biological point of view.“

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
Higher feed intake: “With regard to feed consumption, the average daily intake per animal was statistically significantly higher during various weeks in the male and female 33% test groups. However, the ranges of individual values overlapped with each other.”
Lower heart weight: „Lower mean heart weight and heart/brain ratio in male rats fed 11% MON 863 x NK603 compared with the controls.“
Less red blood cells and Increased corpuscular hemoglobin concentration: „With regard to haematology parameters, the only observed statistically significant differences were lower values for mean red blood cell count and higher values for mean corpuscular hemoglobin in male rats fed 11% MON 863 x NK603 compared with the control group.“
Increased blood urea nitrogen: „The value for mean blood urea nitrogen was statistically significantly higher in female rats in the 11% test group than in the control 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)

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.

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 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.

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 the risk 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 (MON863) and chloroplast (NK603) DNA, has been integrated: 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" (1)
• 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) 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 all material used for the analyses come from four trial fields located in Argentina. It seems to us that Argentine country isn't representative of the all countries that export maize in Europe. Furthermore, compositional analyses tell us that 14% of the samples analyzed show significative differences between GM maize MON863 x NK603 and control hybrids (42 parameters on 310). Especially, 9 parameters (4 amino acids , 3 fatty acids, iron and ferulic acid) presented significative differences in every trial field.

b. Food Safety Assessment:
- Toxicology

• Toxicological analyses show statistically significant differences in daily food consumption and hematological parameters like Hb (hemoglobin), erythrocytes number, urea.., and anomalies in some organs like hearth. It seems to us that safety of GM maize MON863 x NK603 should be further investigated. These data seem worrying.

- Allergenicity

• GM maize MON863 x NK603 seems to be lacking in allergenicity, but the notifier didn't produce analyses on the whole plant but only deductive arguments.

3. Environmental risk assessment

• E.R.A. doesn't calculate unintentional dispersal or bad use of GM seeds that could be used for cultivation. Furthermore, GMO-Panel didn't require analysis on the new event, but they considered the previous analysis on singular events enough to conclude that GM maize MON863 x NK603 is safe for environment. It seems inadequate because it doesn't study potential effects derived from import and processing of GM maize.
• The E.R.A. seems to be inadequate to evaluate unpredictable effects of GM maize MON863 x NK603 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:

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4. Conclusions and recommendations

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.

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5. Other comments

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.
Until such time as those concerns have been addressed, and action taken to deal with them, EFSA should NOT issue any further opinions, and the EC should simply refuse to act upon them, citing ongoiung scientific uncertainty as its justification. It would also be disingenuous of the EC to approve this and other varieties on the basis of EFSA advice, after the leaks showing that it has -- internally ay least -- considerable doubts about the safety of GM crops and foods.
