Public Comments for Part C Notification C/FR/96/05/10 (deadline 30/07/2003)
Insect resistant Bt11 maize

-----Original Message-----
From: [redacted]
Sent: 07 July 2003 13:24
To: SNIF comments
Subject: Comment on SNIF C/FR/96/05/10

Ref: Notification Number C/FR/96/05/10
Member State: France
Date of Publication: 30/06/2003
Notifier Syngenta Seeds
Name of the product: Insect resistant Bt11 maize

Description of the traits and characteristics which have been introduced or modified, including marker genes and previous modifications:
Bt11 maize contains two genes introduced by genetic modification techniques:
- Glufosinate ammonium tolerance gene: pat (phosphinothricin-acetyl-transferase) under the control of the CaMV 35S promoter and the nos termination region
- Insect resistance gene: cryIAb, under the control of the 35S promoter and the nos3' termination region.

Sir

[redacted]object most strongly to the proposed use of Bt11 maize that would replace existing varieties of maize (field and sweet varieties) in conventional agriculture. This maize will be grown and consumed by animals and humans. The maize will be used as grain and silage to feed animals (such as chickens, cows and pigs). Maize will also be used as raw - material in the industrial transformation process (starch and semolina industries, distilling etc) and in the manufacture of products used for animal and human consumption, including sweetcorn.

1 SNIF of poor quality
Firstly we must object to the lack of detail available in the SNIF accompanying this application to market Bt11 maize. It is impossible to make valuable comments when we are provided with no evidence whatsoever that would assure the safety of feeding the maize line to humans and livestock whilst the evidence relating to the impact of the GMO on non-target pollinators is selective. The monitoring plan is not included for consultation.

2 Not substantially equivalent to nearest isogenic maize variety
The Canadian Food Inspection Agency reported (Determination of Environmental Safety of Event 176 Bt Corn) on a similar (same?) line that expressed cry1Ab protein and glufosinate tolerance that

"comparisons of protein, fat, fibre and ash concentration of corn grain and whole plant material from each PNT line and its respective parent line were made. In both the grain and the whole plant, there were occasional significant differences in fat and protein content between a

PNT line and its respective nonmodified control, but these differences were inconsistent (ie., the PNT line was sometimes higher, and sometimes lower in fat or protein than its control)."

The fact that results varied so much should have set alarm bells ringing, but instead the GMO line was deemed substantially equivalent to the closest non-GM isogenic maize variety!

3 Potential for harm
The Bt 11maize has been genetically modified to express cry1Ab protein, conferring resistance to certain lepidopteran insect pests, such as the European corn borer and Sesamia spp., and PAT protein, conferring tolerance to glufosinate-ammonium herbicide.

We believe that the genetic modification process has the potential to cause great harm to the environment not least of all because Bt tolerant pests are now proliferating in areas where Bt maize crops are grown whilst herbicide resistance of weeds will surely follow. Moreover research has shown that Cry1Ac protein has increased the fitness of certain Bt resistant pests.
Researchers from [redacted] [Could Bt transgenic crops have nutritionally favourable effects on resistant insects? Ecology Letters, (2003) 6: 167-169] showed that insect larvae can use the engineered toxin as a supplementary food source. They found that toxin-resistant larvae of the Diamondback Moth developed faster and had a greater pupal weight in the presence of the toxin. This could be a genetic effect, linked indirectly to the presence of a resistance allele but more simply, could be due to resistant insects enhancing their ability to survive and digest the toxin.

4 Negative impact on pollinators and beneficial predators
Although the toxins expressed in Bt-corn pollen are supposed to be specific for Lepidoptera, several studies raise questions about Bt effects on pollinators and beneficial predators. Documentation for the EPA registration shows that pollen from Bt corn has no effect on survival of either larval or adult domesticated bees (USEPA 1999). However, some unexpected effects of transgenic plants on domesticated bees have been reported. For example, one preparation of Bt (var. tenebrio-nis), reported to be specific for Coleoptera, caused significant mortality in domesticated bees (Vandenberg 1990).

Another study indicated that PAT proteins produced in transgenic rapeseed pollen (and present in Bt 11 maize) and targeted for Coleoptera and Lepidoptera interfered with learning by domesticated bees (Picard-Nioi et al. 1997). These studies raise concerns about the precision of genetic transformations and the unintended side effects of genetic transfers.

In addition, although wild bees provide a substantial amount of the pollination in many systems, they apparently were not tested for registration of Bt corn. We are not aware of any studies that have examined the impact of Bt pollen on wild bees.

Negative effects were also observed in Collembola fed Bt 11 leaf protein (5 % mortality at 0.088 mg Cry1Ab /kg soil) while Collembolans fed with non-Bt maize protein were not adversely affected.

Green lacewings (Chrysoperla carnea), which are insect predators of insect pests, were killed by ingesting European corn borers (Ostrinia nubilalis) reared on Bt maize [Hilbeck, A., Baumgartner, M., Fried, P. M. & Bigler, F. Environ. Entomol. 27, 480-487 (1998)]

5 Gene stacking and insect resistance
Good crop management abroad has not prevented gene stacking of herbicide resistance traits in GM crops whilst concerns about Bt resistance is growing. For example, in the United States, Environmental Protection Agency officials wanted to reduce the risk of rootworm developing a tolerance to Bt maize by requiring Monsanto to ensure that 20 percent of the acreage where the seeds are planted is kept as a buffer zone. The zone would be a refuge for rootworms that won't be in contact with the pesticide. EPA officials expect the unexposed rootworms to mate with those exposed to the Bt bacterium, which should prevent the insects from passing on their tolerance and help the pesticide remain effective. Gregory Jaffe, biotech director at the Center for Science in the Public Interest, warned recently that setting aside 20 percent of the acreage to prevent resistance development isn't enough. He said at least half the acreage should be set aside for the buffer zone as an extra precaution.

6 Absence of an Insect Resistance Management plan
It is of agronomic and economic importance to prevent insect resistance to Bt11. As such an Insect Resistance Management plan should accompany the application.

7 Negative impact on livestock and human
With regard to the potential risk of feeding Bt11 maize to humans and livestock there have been no studies undertaken that are published. We are aware that contrary to popular belief that the GMOs would be broken down during processes and cooking, this has not occurred. Also contrary to popular belief, GMOs are not broken down in the acidic environment of the stomach.

Transgenic material has been identified in intestinal cells, the blood, the liver, the spleen and the faeces of mice. Transgenes have been found in bacteria in the intestines of humans, mice and bees.

Three feeding studies of GM food (rather than feeding studies involving the novel protein extract) have shown pathological changes to the stomach and intestines of mammals. As the first symptoms likely to arise from ingesting the Bt11 maize would appear as a digestive disorder, this might go unrecognised and impossible to diagnose. Bleeding from the gut might arise alarm bells should necrosis of the cells and inflammation of the alimentary canal take place, particularly where the recipient is already debilitated.

We quote from an abstract (pasted in below) on research into a mice feeding trial of transgenic potatoes that carry the Cry1 gene and the endotoxin itself:

"Although mild changes are reported in the structural configuration of the ileum of mice fed on transgenic potatoes, nevertheless, thorough tests of these new types of genetically engineered crops must be made to avoid the risks before marketing."

It appears that their advice has not been followed in the case of Bt11 maize.

8 Persistence of cry1Ab gene in soils

Deepak Saxena, Saul Flores and G. Stotzky demonstrated that Bt exudes from the roots of GM maize. They showed that Bt toxin is released into the rhizosphere soil in root exudates from Bt maize where it remained active in the soil binding rapidly and tightly to clays and humic acids. The bound toxin retained its insecticidal properties and was protected against microbial degradation by being bound to soil particles, persisting in various soils for at least 234 days (the longest time studied), as determined by larvicidal bioassay. Unlike the bacterium, which produces the toxin in a precursor form, Bt corn contains an inserted truncated cry1Ab gene that encodes the active toxin.

9 No European market

It is absolutely clear from all the polls on European public opinion that not only has GM food/feed been rejected by the majority of the public, that they do not want GM crops grown in the countryside. As such it is most important that GM free areas are attached as a condition of consent for the commercial growing of Bt 11 maize. As the European corn-borer is not a problem in most parts of Europe and certainly not in the UK at the moment, Bt11 maize will not be grown in the UK. However with global climate change, we cannot rule out that the corn-borer might not move to Britain. We request that Bt11 maize is restricted from cultivation in the UK in order to protect the country's thriving and expanding organic sweetcorn and fodder maize market where any contamination with transgenic material will make the crop unmarketable as organic.

10 Post market monitoring plan inadequate

There is plenty of evidence of harm to the environment, to mammals and to insects from Bt maize, and even more evidence that damage might be done to biodiversity as a result of the glufosinate ammonium tolerance trait and changing farming practices if the Bt line is cultivated in Europe.

No study of the effects on human health have been undertaken. However, as a result of the Newcastle (UK) trial, we do know that transgenes from volunteers fed one meal of GM soya will remain intact in the human stomach and enter bacteria in the intestines. This evidence goes against all predicted expectations and, as such, the industry should be required to take liability for any damage caused to human health and to the environment. The fact that the biotech industry have strongly fought off moves to label GM presence in foods sold in the USA and Canada as well as attempting to scupper EU labelling and traceability rules whilst accepting no responsibility for damage, it is clear that the BIOTECH INDUSTRY HAVE NO CONFIDENCE THAT THEIR PRODUCT IS SAFE.

The environmental risk assessment for Bt11 maize did not anticipate any adverse effects on human health or the environment. For this reason no case-specific monitoring has been recommended. Notwithstanding the fact that Good Agricultural Practice has not prevented insect and herbicide resistance becoming a global problem, we believe that monitoring will be inadequate to pick up any adverse impacts on heath and the

environment until it is too late to reverse the problem created. This MUST be addressed in the application - general surveillance is not enough.

11 Safer alternatives
There are many natural enemies that will attack the European corn-borer that include ladybirds and predacious mites that feed on eggs and young larvae. Many birds will dig out and eat overwintering larvae in crop debris. There are parasitic wasps that attack eggs. There is no need to grow this Bt maize line - there are much safer alternatives.

[redacted] request that member states reject the application from Syngenta to market the GMO in Europe.

Yours sincerely

[redacted]

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Natural Toxins Volume 6, Issue 6, 1998. Pages: 219-233
Published Online: 29 Jun 1999
Research Article

Fine Structural Changes in the Ileum of Mice Fed on -Endotoxin-Treated Potatoes and Transgenic Potatoes Nagui H. Fares 1, Adel K. El-Sayed 2
1Department of Zoology, Faculty of Science, Ain Shams University, Cairo,
Egypt
2Department of Entomology, Faculty of Science, Ain Shams University, Cairo,
Egypt

Abstract The present work has been designed to study the effect of feeding on transgenic potatoes, which carry the CryI gene of Bacillus thuringiensis var. kurstaki strain HD1, on the light and electron microscopic structure of the mice ileum, in comparison with feeding on potatoes treated with the -endotoxin isolated from the same bacterial strain. The microscopic architecture of the enterocytes of the ileum of both groups of mice revealed certain common features such as the appearance of mitochondria with signs of degeneration and disrupted short microvilli at the luminal surface. However, in the group of mice fed on the -endotoxin, several villi appeared with an abnormally large number of enterocytes (151.8 in control group versus 197 and 155.8 in endotoxin and transgenic-treated groups, respectively). Fifty percent of these cells were hypertrophied and multinucleated. The mean area of enterocyte was significantly increased (105.3 µm2 in control group versus 165.4 µm2 and 116.5 µm2 in endotoxin and transgenic-treated groups, respectively). Several forms of secondary lysosomes or auotophagic vacuoles were recognized in these cells. These changes were confirmed with the scanning electron microscope which revealed a remarkable increase in the topographic contour of enterocytes (23 µm in

control group versus 44 µm and 28 µm in endotoxin and transgenic-treated groups, respectively) at the divulged surface of the villi. The basal lamina along the base of the enterocytes was damaged at several foci. Several disrupted microvilli appeared in association with variable-shaped cytoplasmic fragments. Some of these fragments contained endoplasmic reticulum, as well as ring-shaped annulate lamellae. In addition, the Paneth cells were highly activated and contained a large number of secretory granules. These changes may suggest that -endotoxin-treated potatoes resulted in the development of hyperplastic cells in the mice ileum. Although mild changes are reported in the structural configuration of the ileum of mice fed on transgenic potatoes, nevertheless, thorough tests of these new types of genetically engineered crops must be made to avoid the risks before marketing.
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-----Original Message-----
From: [redacted]
Sent: 20 July 2003 12:05
To: gmoinfo-comments@jrc.it
Subject: Comment on SNIF C/FR/96/05/10

Ref: Notification Number C/FR/96/05/10
Member State: France
Date of Publication: 30/06/2003
Notifier: Syngenta Seeds
Name of the product: Insect resistant Bt11 maize

Dear Sir,

After reading the above Notification, I can only conclude that the quality of information given by Syngenta is of an unacceptable standard.

Syngenta states that it does "not anticipate any adverse effects on human health or the environment" and has not therefore dealt with Bt11 maize as case-specific. The information supplied is consequently of an unacceptably general nature and omits or misrepresents many factors which require your consideration, for example:

A. The Level of Knowledge is Disguised

It is clear from a close reading of the Notification that the wording is carefully chosen to make an impression that considerably more knowledge has been amassed than is actually specified e.g.

- very little of the information given actually refers to Bt11 maize, but describes studies on non-GM maize (e.g. sections 27, 22b, 22c), other Bt maize (e.g. section 24), or isolated Bt toxin, which is unlikely to have been derived from any maize plant (e.g. sections 24, 25)
- the only relevant studies of the Bt11 maize seem to be of fertility (e.g. section 22a) which, of course, is a vital commercially consideration, persistence (e.g. section 33h) which is commercially

sensitive, and superficial morphology (e.g. section 22b); the presence of scientific testing in any other area is unspecified and may not have been carried out adequately or, indeed, at all

- variations of gene expression in different plant tissues are described; these could indicate instability but this does not seem to have been investigated (e.g. section 21)
- a reference is made to the low frequency of potential genetic transfer into soil bacteria because the latter do not take up "non-homologous plant DNA" (section 23); since the engineered DNA inserted into the Bt11 maize is copied from, and cloned in, bacteria this statement actually indicates a danger of gene transfer due to homology rather than the opposite as suggested
- pollen contamination "would only constitute a fraction of the harvest" (e.g. section 23) could refer to 0.9% or 99%; if it had been tested, Syngenta would be able to specify the potential in more exact terms
- 'no evidence' , or 'no reports', of adverse effects on human health (e.g. sections 24,32.33), or 'no evidence of differences' (section 33b) do not indicate the extent of the parameters examined; these statements might simply mean that the subject has not been studied at all

B. Omissions

- inappropriate answers are given in several sections: for example, section 37 does not answer the question, section 25 asks a question on "animal feedstuffs" and is answered by references to human food use assessments; in other words the questions have not been answered
- management plans for insect resistance are not specified (e.g. sections 7 and final)
- management plans for co-existence with organic crops are not considered
- long-term soil monitoring is not considered

It would appear the Notification has been at best carelessly assembled and at worst deliberately designed to mislead. I trust the European Commission will fulfill its duty of care and reject this application by Syngenta to market Bt11 maize in Europe.

Yours faithfully,

[redacted]

-----Original Message-----
From: [redacted]
Sent: 25 July 2003 13:21
To: gmoinfo-comments@jrc.it
Subject: Comment on SNIF C/FR/96/05/10

Is it possible to have the evaluation report and the notification of the french competent authority for the syngenta placing in the market document C/FR/96.05.10, in order to send my comments?

Thank you very much
[redacted]

-----Original Message-----
From: [redacted]
Sent: 29 July 2003 00:27
To: gmoinfo-comments@jrc.it
Subject: C/FR/96/05/10

TO - THE BIOTECHNOLOGY AND GMOS UNIT, THE INSTITUTE FOR HEALTH & CONSUMER PROTECTION, DG JOINT RESEARCH CENTRE, EUROPEAN COMMISSION.
I attach a copy of my objection to application no C/FR/96/05/10. It is in RTF.
[redacted]

[redacted]
28.7.03

Biotechnology and GMO's Unit.
Institute for Health and Consumer Protection
European Commission – DG Joint Research Centre.

Dear Sir,

Re. Application by Syngenta Seeds AG to market Bt11 maize seed.
Ref. C/FR/96/05/10

I wish to object to this application for the following reasons:

1. The Application itself is inadequate and does not fully answer all the questions . It relies on evidence presented to the original application in 1996 which is only referred to by its serial number, and which was only considered in the light of Directive 90/220/EEC. This current application and supporting evidence in the Dossiers C/F/96.05.10 and UK/C/96/M4/1 should be assessed under the more exacting Directive 2001/18/EC.

2. In section 7 it is stated that "An insect resistance management plan will be associated with the Bt11 maize". No details are given. This would be an essential part of the post-monitoring plan required, details should be given

3. In section 9 (ii) it is stated that the pollen dispersal is "limited" and that the pollen grain life is "short". This statement is inaccurate as maize pollen can disperse for up to 800 metres . Pollen survival depends on weather conditions and can be as long as 24 hours. *(Pollen Dispersal, Report for the Soil*

Association, UK by the National Pollen Research Institute, University College, Worcester, UK, Dr Rob Treu and Professor Jean Emberlin. Jan. 2000)

4. Section 21. No details are given as to the levels of either the PAT gene or the Btk protein that have been found in various parts of the plant, notably the kernel and pollen.

5. Section 23. It is stated that soil bacteria do not take up non-homologous plant DNA at "appreciable" frequencies, quoting *Nielson et al*, 1997. *Frank Gebhard and Kornelia Smalla* also showed that this could occur in bacteria with homologous sequences. What evidence is there that there are no such soil bacteria that could be transformed by the Bt11 maize?

6. Sections 24 and 25. The evidence in the Dossier UK/C/96/M4/1 should be supplied.
No human or animal feeding trials appear to have been carried out. This GMO contains an insecticide expressed within the edible parts of the maize plant. Both humans and animals will be eating a compound which is toxic to certain species of insects. The results of toxicity trials to other insect species, notably bees, are not provided. The study carried out by *Fares and El-Sayad, Ain Sams University, Cairo, Natural Toxins. Vol 6 issue 6,* 1998, have shown that potato containing the same Bt gene when fed to mice produced detectable lesions in the ileum, as did the endotoxin itself. The repetition of similar trials should be an essential safety test for any GMO containing the Bt gene. Have they been carried out?

7.. Section 31. The Environmental Impact Assessment should be supplied in full.

8.Section 32 c. What steps have been taken to investigate possible effects on human healthg in the USA?

9. In my view the toxicity of the herbicide Glufosinate is still under question. It is a neurotoxin and there is evidence of effects on pregnant rats. It has been shown to have effects on soil fungi (*Ahmed & Malloch Ecosystems and Environment 1995 and Can.Journal Bot. 1995)* and if it reaches the water table it is toxic to aquatic life.

Yours sincerely,

[redacted]

-----Original Message-----
From: [redacted]
Sent: 2[redacted] July 2003 22:41
To: gmoinfo-comments@jrc.it
Subject: Comment on SNIF C/FR/96/05/10Ref: Notification Number C/FR/96/05/10

I object most strongly to the proposed use of Bt11 maize for cultivation in Europe and for food and animal feed.

1 Summary dossier of poor quality
Firstly I must object to the lack of detail available in the summary dossier that accompanies this application to market Bt11 maize. It is impossible to make valuable comments when I am provided with no

evidence whatsoever that the GM variety is safe to eat. There is no monitoring plan included and this is a breach of the Regulations.

2 Not substantially equivalent to nearest isogenic maize variety
The Canadian Food Inspection Agency reported (Determination of Environmental Safety of Event 176 Bt Corn) on a similar (same?) line that expressed cry1Ab protein and glufosinate tolerance that

"comparisons of protein, fat, fibre and ash concentration of corn grain and whole plant material from each PNT line and its respective parent line were made. In both the grain and the whole plant, there were occasional significant differences in fat and protein content between a PNT line and its respective nonmodified control, but these differences were inconsistent (ie., the PNT line was sometimes higher, and sometimes lower in fat or protein than its control)."

The fact that results varied so much should have set alarm bells ringing, but instead the GMO line was deemed substantially equivalent to the closest non-GM isogenic maize variety!

3 Potential for harm
The Bt 11maize has been genetically modified to express cry1Ab protein, conferring resistance to certain lepidopteran insect pests, such as the European corn borer and Sesamia spp., and PAT protein, conferring tolerance to glufosinate-ammonium herbicide.

I believe that the genetic modification process has the potential to cause great harm to the environment not least of all because Bt tolerant pests are now proliferating in areas where Bt maize crops are grown whilst herbicide resistance of weeds will surely follow. Moreover research has shown that Cry1Ac protein has increased the fitness of certain Bt resistant pests. Researchers from Imperial College, England [Could Bt transgenic crops have nutritionally favourable effects on resistant insects? Ecology Letters, (2003) 6: 167-169] showed that insect larvae can use the engineered toxin as a supplementary food source. They found that toxin-resistant larvae of the Diamondback Moth developed faster and had a greater pupal weight in the presence of the toxin. This could be a genetic effect, linked indirectly to the presence of a resistance allele but more simply, could be due to resistant insects enhancing their ability to survive and digest the toxin.

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I ask that member states reject the application from Syngenta to market the GMO in Europe.

Yours

[redacted]

-----Original Message-----
From: [redacted]
Sent: 30 July 2003 09:17
To: gmoinfo-comments@jrc.it
Subject: Comment on SNIF C/FR/96/05/10Ref: Notification Number C/FR/96/05/10

I wish to object to the proposed use of Bt11 maize for cultivation in Europe and for food and animal feed. It is unfortunate that the deadline for objections is today because we in the UK have not had time to digest the full implications of growing GM here in the light of recent reports. There are too many unanswered questions, for example researchers from [redacted] [Could Bt transgenic crops have nutritionally favourable effects on resistant insects? Ecology Letters, (2003) 6: 167-169] showed that insect larvae can use the engineered toxin as a supplementary food source.

Proceeding with a crop that is later found to cause problems would do great harm public confidence in farming. I hope this application can be deferred for 12 months to be considered in more detail.

[redacted]

-----Original Message-----
From: [redacted]
Sent: 30 July 2003 12:43
To: gmoinfo-comments@jrc.it
Subject: Comment on SNIF C/FR/96/05/10Ref:
NotificationNumberC/FR/96/05/10

Dear Sir,

Comment on SNIF C/FR/96/05/10Ref: Notification
Number C/FR/96/05/10

I write on behalf of the organization [redacted]. We object most strongly to the proposed use of Bt11 maize for cultivation in Europe and for food and animal feed.

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The Bt 11maize has been genetically modified to express cry1Ab protein, conferring resistance to certain lepidopteran insect pests, such as the European corn borer and Sesamia spp., and PAT protein, conferring tolerance to glufosinate-ammonium herbicide.

I believe that the genetic modification process has the potential to cause great harm to the environment not least of all because Bt tolerant pests are now proliferating in areas where Bt maize crops are grown whilst herbicide resistance of weeds will surely follow.
Moreover research has shown that Cry1Ac protein has increased the fitness of certain Bt resistant pests.
Researchers from [redacted] [Could Bt transgenic crops have nutritionally favourable effects on resistant insects? Ecology

Letters, (2003) 6: 167-169] showed that insect larvae can use the engineered toxin as a supplementary food source. They found that toxin-resistant larvae of the Diamondback Moth developed faster and had a greater pupal weight in the presence of the toxin. This could be a genetic effect, linked indirectly to the presence of a resistance allele but more simply, could be due to resistant insects enhancing their ability to survive and digest the toxin.

4 Negative impact on pollinators and beneficial predators
Although the toxins expressed in Bt-corn pollen are supposed to be specific for Lepidoptera, several studies raise questions about Bt effects on pollinators and beneficial predators. Documentation for the EPA registration shows that pollen from Bt corn has no effect on survival of either larval or adult domesticated bees (USEPA 1999). However, some unexpected effects of transgenic plants on domesticated bees have been reported. For example, one preparation of Bt (var. tenebrio-nis), reported to be specific for Coleoptera, caused significant mortality in domesticated bees (Vandenberg 1990).

Another study indicated that PAT proteins produced in transgenic rapeseed pollen (and present in Bt 11 maize) and targeted for Coleoptera and Lepidoptera interfered with learning by domesticated bees (Picard-Nioi et al. 1997). These studies raise concerns about the precision of genetic transformations and the unintended side effects of genetic transfers.

In addition, although wild bees provide a substantial amount of the pollination in many systems, they apparently were not tested for registration of Bt corn. I am not aware of any studies that have examined the impact of Bt pollen on wild bees.

Negative effects were also observed in Collembola fed Bt 11 leaf protein (5 % mortality at 0.088 mg Cry1Ab /kg soil) while Collembolans fed with non-Bt maize protein were not adversely affected.

Green lacewings (Chrysoperla carnea), which are insect predators of insect pests, were killed by ingesting European corn borers (Ostrinia nubilalis) reared on Bt maize [Hilbeck, A., Baumgartner, M., Fried, P. M. & Bigler, F. Environ. Entomol. 27, 480-487 (1998)]

5 Gene stacking and insect resistance
Good crop management abroad has not prevented gene stacking of herbicide resistance traits in GM crops whilst concerns about Bt resistance is growing. For example, in the United States, Environmental Protection Agency officials wanted to reduce the risk of rootworm developing a tolerance to Bt maize by requiring Monsanto to ensure that 20 percent of the acreage where the seeds are planted is kept as a buffer zone. The zone would be a refuge for rootworms that won't be in contact with the pesticide. EPA officials expect the unexposed rootworms to mate with those exposed to the Bt bacterium, which should prevent the insects from passing on their tolerance and help the pesticide remain effective. Gregory Jaffe, biotech director at the Center for Science in the Public Interest, warned recently that setting aside 20 percent of the acreage to prevent resistance development isn't enough. He said at least half the acreage should be set aside for the buffer zone as an extra precaution.

6 Absence of an Insect Resistance Management plan
It is of agronomic and economic importance to prevent insect resistance to Bt11. As such an Insect Resistance Management plan should accompany the application.

7 Negative impact on livestock and human
With regard to the potential risk of feeding Bt11 maize to humans and livestock there have been no studies undertaken that are published. We are aware that contrary to popular belief that the GMOs would be broken down during processes and cooking, this has not occurred. Also contrary to popular belief, GMOs are not broken down in the acidic environment of the stomach.

Transgenic material has been identified in intestinal cells, the blood, the liver, the spleen and the faeces of mice. Transgenes have been found in bacteria in the intestines of humans, mice and bees.

Three feeding studies of GM food (rather than feeding studies involving the novel protein extract) have shown pathological changes to the stomach and intestines of mammals. As the first symptoms likely to arise from ingesting the Bt11 maize would appear as a digestive disorder, this might go unrecognised and impossible to diagnose. Bleeding from the gut might arise alarm bells should necrosis of the cells and inflammation of the alimentary canal take place, particularly where the recipient is already debilitated.

8 Persistence of cry1Ab gene in soils
Deepak Saxena, Saul Flores and G. Stotzky demonstrated that Bt exudes from the roots of GM maize. They showed that Bt toxin is released into the rhizosphere soil in root exudates from Bt maize where it remained active in the soil binding rapidly and tightly to clays and humic acids. The bound toxin retained its insecticidal properties and was protected against microbial degradation by being bound to soil particles, persisting in various soils for at least 234 days (the longest time studied), as determined by larvicidal bioassay. Unlike the bacterium, which produces the toxin in a precursor form, Bt corn contains an inserted truncated cry1Ab gene that encodes the active toxin.

9 No European market

It is absolutely clear from all the polls on European public opinion that not only has GM food/feed been rejected by the majority of the public, that they do not want GM crops grown in the countryside. As such it is most important that GM free areas are attached as a condition of consent for the commercial growing of Bt 11 maize. As the European corn-borer is not a problem in most parts of Europe and certainly not in the UK at the moment, Bt11 maize will not be grown in the UK. However with global climate change, we cannot rule out that the corn-borer might not move to Britain. We request that Bt11 maize is restricted from cultivation in the UK in order to protect the country's thriving and expanding organic sweetcorn and fodder maize market where any contamination with transgenic material will make the crop unmarketable as organic.

10 Post market monitoring plan inadequate

There is plenty of evidence of harm to the environment, to mammals and to insects from Bt maize, and even more evidence that damage might be done to biodiversity as a result of the glufosinate ammonium tolerance trait and changing farming practices if the Bt line is cultivated in Europe.

No study of the effects on human health have been undertaken. However, as a result of the Newcastle (UK) trial, we do know that transgenes from volunteers fed one meal of GM soya will remain intact in the human stomach and enter bacteria in the intestines. This evidence goes against all predicted expectations and, as such, the industry should be required to take liability for any damage caused to human health and to the environment. The fact that the biotech industry have strongly fought off moves to label GM presence in foods sold in the USA and Canada as well as attempting to scupper EU labelling and traceability rules whilst accepting no responsibility for damage, it is clear that the BIOTECH INDUSTRY HAVE NO CONFIDENCE THAT THEIR PRODUCT IS SAFE.

The environmental risk assessment for Bt11 maize did not anticipate any adverse effects on human health or the environment. For this reason no case-specific monitoring has been recommended. Notwithstanding the fact that Good Agricultural Practice has not prevented insect and herbicide resistance becoming a global problem, we believe that monitoring will be inadequate to pick up any adverse impacts on heath and the environment until it is too late to reverse the problem created. This MUST be addressed in the application - general surveillance is not enough.

11 Safer alternatives
There are many natural enemies that will attack the European corn-borer that include ladybirds and predacious mites that feed on eggs and young larvae. Many birds will dig out and eat overwintering larvae in crop debris. There are parasitic wasps that attack eggs. There is no need to grow this Bt maize line - there are much safer alternatives.

I ask that member states reject the application from Syngenta to market the GMO in Europe.

Yours sincerely,

[redacted]

-----Original Message-----
From: [redacted]
Sent: 30 July 2003 18:58
To: gmoinfo-comments@jrc.it
Subject: Comment on SNIF C/FR/96/05/10

Ref: Notification number C/FR/96/05/10

Application to grow Bt-11 maize commercially in the EU.

We fully support the detailed objections already made known to you by [redacted]. We have the following general objections to make to the inclusion of a further Bt maize for commercial crop growing in the EU.

1. When Bt is used selectively as a toxic spray on plants, it is limited to targeting harmful pests for brief periods.

Introduced as a Cry protein the genetically modified Bt maize remains toxic at all times and throughout the plant. It is harmful to beneficial insects and lepidoptera, to animals fed it [1], and not least to humans, who may be allergic to the CryBt protein, with severe, and possibly fatal consequences.

The StarLink episode in the US bears this out. This has however, been discounted by the regulators, on the grounds that unlike the other Bt maize authorised, it had only been approved for animal feed. In the meantime, they have not sought to establish what effects the several variations of the CryBt maize might have either on animals or for humans.

2. No EU approval should be given:

a) without a detailed submission by the applicant of the foreign genetic sequences introduced into the natural plant, and their known effects on humans, animals, and in the environment.

b) without making available independent properly conducted and peer reviewed safety tests, and without independent substantiated documentary evidence for the applicant's claims that the potential effects in the environment are zero.

c) by accepting the interested applicant's own dossier as evidence of no harm. By making assumptions that the GM crop "poses no [or very low] risk in terms of human health and environmental safety" [2], and by doing so without requiring proper full scientific investigation.

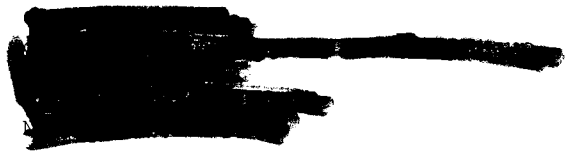
3. We much regret that the present EU regulatory system fails to uphold the public interest, promoting instead that of the agrobiotech industry, as the records show.

The authorisation of the deliberate release of GMOs is, almost without exception, agreed. Whether the GM crop has the pat or other foreign genes, the Cry Bt gene, the CaMV as promoter, as terminator, whether it has Antibiotic Resistance Markers. It is apparent that at the same time, both valid reasons and substantiated evidence which show the contrary effects are dismissed or ignored.

We are told that applications undergo 'rigorous safety assessment', when clearly this is no more than opinion based on the applicant's own

data. While 'Substantial Equivalence' is a non-scientific concept designed for marketing purposes and to avoid both labelling and safety testing. Common sense alone shows that it is meaningless - a BSE cow would be 'substantially equivalent' to a non-BSE cow.

We trust that this application for the commercial growing of Bt 11 maize in the EU will this time receive responsible consideration, and accordingly be rejected.



[1] In 2002 a pig farmer in Iowa, USA, found farrowing rates in his sow herd dropped nearly 80%. It became apparent that pig farmers within a 15 mile radius had suffered similarly. The 'Iowa Farm Bureau Spokesman' reported 'a common denominator' and that the herds had been fed the same Bt maize hybrids, which had high levels of Fusarium mould. The problem disappeared when the farmers switched back to non-GM maize.

[2] ACRE has in the past approved a Bt crop as not environmentally relevant to the UK but pointed out that there might be implications for migratory birds in the areas where it would be grown in the EU.