Public Comments for Part C Notification C/SE/96/3501 (deadline 03/03/2003)
Potato variety EH92-527-1 with modified starch content, Amylogene HB

Dear everybody,

My name is [redacted], I live in [redacted]. I do not want any genetically modified products in my country. Being a scientist myself, I do not believe that the scientists involved in these projects know what the full consequences of their tests may be. They may do no harm – or they may do a lot of harm. No one knows. Before this is fully established there should be no allowance for products derived from genetically modified plants (or animals), nor any tests in the free environment.

As a consumer of farm products, like meat, I will not eat anything even slightly associated with genetically modified products and I crave that such products are labelled in such a way that the everyday shoper can easily recognise them and avoid them. This should be the case also if say the cow itself isn't modified, but the grass or starch it has been eating, even to the slightest percentage.

I believe that if this was a petition, the majority of the [redacted] people would sign it.

Sincerely yours

[redacted]

3rd February 2003

Dear Sir,

Objection to application to market GM potato EH92-527-1 in Europe

Notification number: C/SE/96/3501
Member State: Sweden
Notification date: 3/2/2003
Notifier: Amylogene HB
GMO: Potato variety EH92-527-1 with modified starch content

We are totally opposed to this application, since the only publiushed tests we have seen show that GM potatoes are potentially damaging to public health.

Plesew register this objection, and inform us as to the progress of this application.

[redacted]

Notification number: C/SE/96/3501
Member State: Sweden
Notification date: 3/2/2003
Notifier: Amylogene HB
GMO: Potato variety EH92-527-1 with modified starch content

Dear Sirs,

I am opposed to the application to market this genetically modified potato in Europe because of the proven likelihood of horizontal gene transfer of the modified trait to other plants and animals and because of its intended use as aminal feed. Genetically modified DNA is persistent in the mammalian gut and there is no proof of the safety of allowing this GM material to enter the food chain,

Yours faithfully,

[redacted]

To: guy.van-den-eede@jrc.it
Re:
Member State of notification: Sweden
Notification number: C/SE/96/3501
Name of the product (commercial and other name): EH92-527-1 is the name of the potato line.
Date of acknowledgement of notification: 6 August 1996
Notifier: Amylogene HB

Sir/Madam

[redacted]ject most strongly to the notification to cultivate this GM potato line in [redacted] (or in the rest of Europe) or to use any GM material in animal feed or to spread it on the land. This variety is clearly not substantially equivalent to the non GM equivalent variety Prevalent. Significant differences to the parental variety were found in vitamin C, sucrose and fructose levels that were present at higher levels in the GM line.
The notification states that: "Pulp derived from the GM potato line was also used in a heifer feeding trial. Groups of 16 animals were fed for up to 8 weeks with a diet that included pulp produced from GM or non-GM potato material. The pulp constituted slightly more than 30% of the total feed calculated on a dry weight basis. There were no conspicuous differences in feed intake between animals fed on pulp derived from GM or non-GM potatoes. No statistically significant differences in heifer weight gain were detected. No effects of pulp derived from the GM potato line were observed on animal health and intestinal functions."
It is impossible to comment without seeing any raw data or further details of the feeding trial but clearly feeding GM potato pulp for only up to 8 weeks is unlikely to provide evidence of good health and safety in heifers in the long term .
We are particularly concerned that eleven open reading frames (ORFs) detected have no significant homologies to known coding regions.
We have major concerns that the GMO contains the nptII gene that confers antibiotic resistance to kanamycin and neomycin. These antibiotics still have a useful application in medicine. Aminoglycocides are bactericidal and active against some gram-positive and many gram-negative bacteria. Kanamycin is used prior to endoscopy of the colon and rectum and to treat ocular infections. It has been found to be effective against E coli 0157 without causing release of verotoxin. Neomycin is useful to treat infections of the skin. It seems pointless to give consent to market a GMO when Regulation (27) of the Genetically Modified Organisms (Deliberate Release) Regulations seeks to phase out antibiotic resistant markers in commercial GM crops by 31 December 2004 "which may have adverse effects on human health and the environment".

We cannot even start to imagine the risks associated with the presence of known and unknown amino-acids in the GM line. ORF4 has been singled out in the notification for further assessment as the first 50 amino acids are homologous to the bleomycin resistance protein that has a chemotherapeutic use in cancer treatment. The notifier believes that a functional bleomycin protein is not present in the GM-line but does admit that "this does not preclude the possibility that expression of ORF4 results in the production of a novel polypeptide in the plant, although database searches do not indicate significant homologies between ORF4 amino acid sequences and known allergens." These same concerns apply to the other amino acids detected in EH92-527-1 potato line. There are just too many unknowns in this GM line to be sure that the GMO is safe to release into te environment.
Moreover the ease with which potatoes are able to produce regenerative material makes it a difficult agricultural crop to control in subsequent crops and plants can emerge ten years later. Pollination is mediated by insects that include bumblebees. However we have seen no evidence that the pollen is safe for beneficial insects.
Moreover small mammals and insects are able to move potato seed whilst tubers might be moved by larger mammals (eg rats and deer) and birds at distances far greater than that which might be anticipated in conventional separation distances employed to secure potato purity standards. There is no evidence presented regarding the safety of small mammals eating tubers or seed, of invertebrates eating roots or sucking the sap, or by uptake of DNA by soil micro-organisms.
Whilst it is possible that the plants will have a modified amount of the existing sugar and starch which is within the range found in commercially grown non-transgenic potato varieties, this does not mean that other unknown hazards to health might not exist as a result of the unpredictability of the insertion of the transgenic material into the plant genome.
We request that the European Union rejects the notification of this GMO.
Thank you.
Yours faithfully

[redacted]

Notification number: C/SE/96/3501
Member State: Sweden
Notification date: 3/2/2003
Notifier: Amylogene HB
GMO: Potato variety EH92-527-1 with modified starch content

As a member of the [redacted] public, I write to ask you not to allow the marketing of this potato. There is a virtual absence of studies to examine the safety of GM food, which is not made easy by the lack of labelling in countries like USA. I am opposed to any release of GM food until it is proven safe and reliable studies have been carried out. I believe that GM food should be submitted to the same rigorous examination that it would undergo if a drug.

I understand that the potato residue will be used for cattle fodder and again as far as I can see no feed trails have been performed on the effect of feeding GM material to cattle who are then eaten by humans.

Very little is available on the environmental impact of the GM potato and horizontal gene movement.

Until and unless further studies are conducted and shown to be safe I hope you will not give permission to market.

Thanks

[redacted]

Hello,

I'm against/will never buy any product that has been geneticly modified.

If theese products will come out in the market I really hope that it will be clear on the label what kind of product it is!!! The worste thing you can do is to leave our choice out. What about your kids? Will they be able to choose??

The companies that will introduce theese products must PROVE that there is no chance of unexpected happenings.
How can they do this?????

Will it be like always = you earn the money and we pay?
With money or health.

[redacted]

-----Original Message-----
From: [redacted][mailto:[redacted]
Sent: 12 February 2003 11:14
To: guy.van-den-eede@jrc.it
Subject: C/SE/96/3501

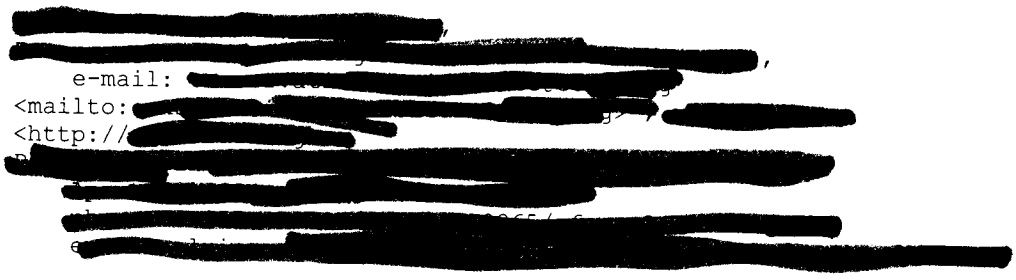
The approval of GM cultivars tolerant to environmental friendly herbicides (glyphosate, gluphosinate, among others) o similar improvments, will have, in our view, several important advantages, as follows:

It will certainly enhance the acceptance / adoption of conservation practices, since weed control will be much easier / efficiency with those GM cultivars than with conventional cultivars. This has been clearly what has happened in USA and others countries in the past 4 to 6 years.

Very likely conservation agricultural techniques will have to be adapted everywhere in Europe to reduce soil erosion and increase organic matter content, as a result of the development of the Soil Protection Strategy designed by the DG-Environment (Communication 2002 Final "Towards a thematic strategy for soil protection....."

Generally, with the acceptance of GM cultivars tolerant to environmental friendly herbicides the overall use of herbicides will be much better for the environment than the current use of herbicide. Reason: soil acting herbicides (pre-plant and pre-emergence soil applied herbicides will be much less used in the future....herbicide residues in soil and water will consistently decrease.....etc.). This is in agreement with the EU Commission Strategy "Toward a sustainable use of pesticide..."

In summary, European agriculture / farmers will benefit from the use of GM cultivars tolerant to herbicides or resistance to some insects. It has happened so elsewhere in the world... Let us keep an close eyes how things evolve ... if some problems occur we will face it... if no problems occur (as expected after so rigorous / strict regulations/ clearance procedure even better..)



-----Original Message-----
From: [redacted] [mailto[redacted]]
Sent: Sunday, February 16, 2003 12:42
To: guy.van-den-eede@jrc.it
Subject: Deliberate releases and placing on the EU market of GMOs

Dear Mr. Vandeneede

On behalf of the [redacted] under Article 24 of the new Directive we are objecting to the 13 applications: -
C/NL/98/11
C/ES/00/01
C/GB/02/M3/03
C/SE/96/3501
C/BE/96/01
C/BE/98/01
C/BE/99/01
C/GB/99/M5/2
C/ES/97/01
C/ES/96/02
C/DE/96/5
C/NL/00/10
C/DE/00/8

We object to these for the following reasons: -

· There is no market for the GMO in Europe. The majority of the public have rejected all GMO derived food, feed and industrial products. This has been accepted by the major supermarkets by ensuring that the no longer supply GM food.

· The GMO has been assessed on the basis that the GMO is substantially equivalent to the non-GM equivalent. This is clearly not the case, is unproven and is in conflict with taking the precautionary approach to new technology.

· No feeding studies have been undertaken to assess toxicity of the plant/food/feed product on non-target organisms, on livestock or on humans.

· GMOs that contain genes expressing resistance to antibiotics, that may have adverse effects on human health and the environment, must be phased out by 31 December 2004 for marketing purposes. As all antibiotics have a useful application, there is no point in approving any GMO expressing resistant genes.

· The monitoring plans proposed for the cultivation of GMOs in Europe rely on implementing Good Agricultural Practice. In the light of experience from countries where GM crops are grown, GAP cannot be relied upon to prevent contamination of the food chain or of the environment.

· The monitoring plans are inadequate or non-existent in that the objectives of Directive 2001/18/EC are not met.
These are to: - confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GMO or its use in the environmental risk assessment are correct, and - identify the occurrence of adverse effects of the GMO or its use on human health or the environment which were not anticipated in the environmental
risk assessment.

· Matters of liability for damage have yet to be settled. Labelling and traceability measures still to be agreed. As such issuing a marketing approval would be premature.

[redacted]

-----Original Message-----
From [redacted] [mailto:[redacted]
Sent: Tuesday, February 18, 2003 12:33
To: guy.van-den-eede@jrc.it
Subject: objection

Subject: Applications to market GMOs in the European Union

Notification No.	Member State
C/NL/98/11	Netherlands
C/ES/00/01	Spain
C/GB/02/M3/03	United Kingdom
C/SE/96/3501	Sweden
C/BE/96/01	Belgium
C/BE/98/01	Belgium

C/BE/99/01	Belgium
C/GB/99/M5/2	United Kingdom
C/ES/97/01	Spain
C/ES/96/01	Spain
C/DE/96/5	Germany
C/DE/00/8	Germany
C/NL/00/10	Netherlands
C/ES/99/02	Spain
C/ES/01/01	Spain
C/DE/98/6	Germany
C/ES/98/01	Spain
C/DE/02/9	Germany

Dear Sir/Madam,

I am objecting to all of the above applications on the following grounds:

The [redacted] an independent, cross-party, democratically elected body, after taking evidence from all of the [redacted], found that growing GM crops was against the precautionary principle due to insufficient evidence to show that growing GM crops is safe in terms of human health.

This lack of testing and evidence on the health and safety of GM crops led the Committee to recommend that further toxicological testing was required along the lines of those applied to pharmaceutical products.

As there is no liability legislation in existence at present, there would be no redress for any adverse health effects. Therefore, the responsibility for the protection for public health falls on the member states to whom these applications have been made.

Until further toxicological testing has been carried out, and full and specific liability legislation has been implemented, the GM applications outlined above should not be given further Consents.

The full report, which includes further strong criticisms especially of the current Risk Assessment Procedures, is available from the [redacted]

[redacted]

I request that this report with our objections (to the applications listed) is circulated.

Yours faithfully

[redacted]

[redacted]

Yours faithfully

[redacted]

-----Original Message-----
From: [redacted] [mailto [redacted]]
Sent: Tuesday, February 18, 2003 17:23
To: guy.van-den-eede@jrc.it
Subject: objection

With thanks

Yours faithfully

[redacted]

[redacted]

18/02/03

Yours faithfully

[redacted]

Yours faithfully

[redacted]

Yours faithfully

[redacted]

Yours faithfully

[redacted]

****

[redacted]

Yours faithfully

[redacted]

Yours faithfully

[redacted]

Yours faithfully

[redacted]

Yours faithfully

[redacted]

Yours faithfully

[redacted]

[redacted]

Yours faithfully

[redacted]

Yours faithfully

[redacted]

Yours faithfully,

[redacted]

Yours sincerely,

[redacted]

[redacted]

[redacted]

18/02/03

Yours faithfully

[redacted]

Yours faithfully

[redacted]

Yours faithfully,

[redacted]

Yours faithfully

[redacted]

Yours faithfully

[redacted]

Yours faithfully

[redacted]

Yours faithfully

[redacted]

Yours faithfully

[redacted]

Yours faithfully

[redacted]

Yours faithfully

[redacted]

Yours faithfully

[redacted]

Yours faithfully

[redacted]

Yours faithfully,

[redacted]

Address: [redacted]

Yours faithfully

[redacted]

Yours faithfully

[redacted]

Yours faithfully

[redacted]

-----Original Message-----
From: [redacted] [mailto:[redacted]]
Sent: Tuesday, February 18, 2003 17:37
To: guy.van-den-eede@jrc.it
Subject: C/SE/96/3501

See [redacted] comments attached

[redacted]

Visit the [redacted] web site at: [redacted]

[redacted] **Comments on Marketing Application C/SE/96/3501: Modified Starch Potatoes, Amylogene**

[redacted]

General comments:

1. It is impossible for people to comment properly on the Part C applications without the full dossiers being available. This is because the summary contains unsupported assertions which require the supporting data to be able to be judged properly. It is not feasible for those wishing to comment to contact the Member State notifying the application. **Unless the Commission makes dossiers readily available, the public consultation process will be little more than a token gesture and will fuel public cynicism.**

2. The EC's regulations on labelling and traceability have not yet been finally agreed and implemented. These have considerable implications for the way in which GMOs that are to be imported into and used in Europe. They also demand specific animal feed safety assessment. **The Commission should not allow any applications to**

import GMOs for any uses until the labelling and traceability regulations are in place.

3. There are no provisions for environmental or economic liability in place. The proposed Environmental Liability Directive has not yet been agreed and, therefore, should any adverse effects arise, the companies involved would be absolved from liability and the state(s) affected would be responsible for any restoration. In the case of economic loss, in the UK at least, if contamination arises of non-GM or organic crops, food or feed, gaining compensation for loss of organic status or non-GM premium would be impossible. **The Commission should not allow any applications to market GMOs until the environmental liability provisions are in place. In those countries where economic losses from GM contamination are not covered by existing liability laws (the UK at least), marketing of GMOs should not be allowed until they are in place.**

Specific comments

4. The GM potato contains an antibiotic resistance gene (NPTII) – to neomycin and kanamycin. The potato pulp residues are intended to be fed to cattle. Whilst it may be argued that neomycin and kanamycin are not important in human medicine (with the exception of drug resistant TB), this is not the case in veterinary medicine. The NPTII gene (coding for resistance) plays no function in the final product and should have been removed but has not been. Whilst the risks of transfer of the resistance gene to bacteria in may be low, this cannot be ruled out. That the isolated NPTII protein degrades in artificial rumenal fluid is not reassuring as it will not be consumed by animal in this form. In potato pulp, the protein may be protected from digestion, for example. GeneWatch believes that antibiotic resistance genes should not be allowed in GMOs which are to be placed on the market. Any risk of transfer of antibiotic resistance genes to disease causing organisms (probably animal diseases) is not justifiable.

5. The monitoring plans proposed are impossible to assess based on the information provided in the SNIF.

6. All the experimental data come from trials in Sweden, yet the application covers the whole of Europe. A full assessment of the applicability of the data to other environments is needed.

[redacted]**does not believe that marketing consent should be awarded at the present time or on the basis of the information provided in the application.**

-----Original Message-----
From: [redacted] mailto[redacted]
Sent: Tuesday, February 18, 2003 19:10
To: guy.van-den-eede@jrc.it
Subject: Applications to market GMOs in the European Union

To

European Commission
DG Joint Research Centre
Institute for Health and Consumer Protection
Biotechnology and GMOs Unit
B-1049 Brussel
Belgium
by email guy.van-den-eede@jrc.it

BASIC LETTER and LIST OF APPLICATIONS
Subject: Applications to market GMOs in the European Union
Notification No. Member State
C/NL/98/11 Netherlands
C/ES/00/01 Spain
C/GB/02/M3/03 United Kingdom
C/SE/96/3501 Sweden
C/BE/96/01 Belgium
C/BE/98/01 Belgium
C/BE/99/01 Belgium
C/GB/99/M5/2 United Kingdom
C/ES/97/01 Spain
C/ES/96/01 Spain
C/DE/96/5 Germany
C/DE/00/8 Germany
C/NL/00/10 Netherlands
C/ES/99/02 Spain
C/ES/01/01 Spain
C/DE/98/6 Germany
C/ES/98/01 Spain
C/DE/02/9 Germany

Dear Sir,

I am objecting to all of the above applications on the following grounds:

1. Need for containment

I am familiar with the operations of the Biotech industry and I have designed a number of plants to process genetically modified organisms for the production of active ingredients used in the pharmaceutical industry. The basic prinicple of all applications was to ensure that no genetically modified organisms or or parts thereof, in particular their DNA, could leave the plant. In order to ensure that barriers were incorporated into the process ensuring that all life tissue would be killed and that organsiams were broken up into small parts before any genetic information or life tissue could enter uncontrolled areas, this includes the environment. Substances from these

processes were single chemical entities purified in a multi stage process. The only substance to leave the plant was the desired active ingredient, usually an organic macromolecule.

In my opinion it is dangerous to allow GMOs to be released to the environment without adequate and thorough testing. Because testing can only cover some aspects of potential dangers it is common -and in this instance advisable- NOT TO ALLOW the release of any GMO into the environment until

firstly there is a definitive need for the effects of the GMO that cannot be achieved by means of cenventional crops or organisms. Increased profits and longer shelf life of produce is not a valid reason for introducing potentially harmful substances into the food chain.

secondly a risk analysis has been carried out and the benefits of the GMO clearly outweigh the risks.

2. General concerns I share with other parties (as copied from a pre-written response):

"The [redacted] an independent, cross-party, democratically elected body, after taking evidence from all of the [redacted] found that growing GM crops was against the precautionary
principle due to insufficient evidence to show that growing GM crops is safe in terms of human health.
This lack of testing and evidence on the health and safety of GM crops led the Committee to recommend that further toxicological testing was required along the lines of those applied to pharmaceutical products.
As there is no liability legislation in existence at present, there would be no redress for any adverse health effects. Therefore, the responsibility for the protection for public health falls on the member states to whom
these applications have been made.
Until further toxicological testing has been carried out, and full and specific liability legislation has been implemented, the GM applications outlined above should not be given further Consents.
The full report, which includes further strong criticisms especially of the
current Risk Assessment Procedures, is available from the [redacted]

Should you have any further queries please do not hesitate to contact me.

Yours faithfully

[redacted]

[redacted]

[redacted]

-----Original Message-----
From: [redacted] [mailto:[redacted]
Sent: Tuesday, February 18, 2003 19:24
To: guy.van-den-eede@jrc.it
Subject: GM concerns

Please find attached a letter expressing our concern regarding forthcoming GM approvals in the European Union.

Yours,
[redacted]

European Commission
2003
DG Joint Research Centre
Institute for Health and Consumer Protection
Biotechnology and GMOs
UnitB-1049
Brussels
Belgium

18th February

Subject: Applications to market GMOs in the European Union

Notification No.	Member State
C/NL/98/11	Netherlands
C/ES/00/01	Spain
C/GB/02/M3/03	United Kingdom
C/SE/96/3501	Sweden
C/BE/96/01	Belgium
C/BE/98/01	Belgium
C/BE/99/01	Belgium
C/GB/99/M5/2	United Kingdom
C/ES/97/01	Spain
C/ES/96/01	Spain
C/DE/96/5	Germany
C/DE/00/8	Germany
C/NL/00/10	Netherlands
C/ES/99/02	Spain
C/ES/01/01	Spain
C/DE/98/6	Germany

C/ES/98/01 Spain
C/DE/02/9 Germany

Dear Sir/Madam,

I am objecting to all of the above applications on the following grounds:the [redacted] an independent, cross-party,democratically elected body, after taking evidence from all of the [redacted] found that growing GM crops was against the precautionary principle due to insufficient evidence to show that growing GM crops is safe in terms of human health.

This lack of testing and evidence on the health and safety of GM crops led the Committee to recommend that further toxicological testing was required along the lines of those applied to pharmaceutical products. As there is no liability legislation in existence at present, there would be no redress for any adverse health effects. Therefore, the responsibility for the protection for public health falls on the member states to whom these applications have been made.Until further toxicological testing has been carried out, and full and specific liability legislation has been implemented, the GM applications outlined above should not be given further Consents.

The full report, which includes further strong criticisms especially of the current Risk Assessment Procedures, is available from the [redacted]
clerk:
[redacted]

I request that this report with our objections (to the applications listed) is circulated.

Yours faithfully,

[redacted]

-----Original Message-----
From: [redacted] mailto:[redacted]
Sent: Tuesday, February 18, 2003 20:37
To: 'guy.van-den-eede@jrc.it'
Subject: Comments relating to the recent applications for GMOs to be marketed within the EU

European Commission - DG Joint Research Centre
Institute for Health and Consumer Protection

Biotechnology and GMOs Unit

Dear Sir/Madam,

I wish to formally lodge my great concern about the following applications that have been made by a number of agrochemical companies requesting that the following GMOs can be marketed in the EU. The corresponding notification number is listed alongside the name of the products that this e-mail refers to.

Roundup Ready Oilseed Rape, event GT73 (C/NL/98/11)
Roundup Ready Maize, event NK603 (C/ES/00/01)
Genetically modified maize NK603 x MON 810 (C/GB/02/M3/03)
Potato variety EH92-527-1 with modified starch content (C/SE/96/3501)
Oilseed rape Ms8xRf3 (C/BE/96/01)
Glufosinate tolerant soybeans A2704-12 and A5547-127 (C/BE/98/01)
Roundup Ready sugar beet (C/BE/99/01)
Glufosinate Tolerant oilseed rape T45 (C/GE/99/M5/2)
Roundup Ready cotton line derived from Event 1445 (C/ES/97/01)
Insect-Protected cotton line derived from Event 531 (C/ES/96/02)
Glufosinate tolerant Oilseed Rape Falcon, GS40/90pHoe6/Ac (C/DE/96/5)
Roundup Ready Sugar Beet (Beta Vulgaris) derived from Event H7-1 (C/DE/00/8)
Lepidopteran resistent and glufosinate tolerant 1507 Maize (C/NL/00/10)
MaisGard/Roundup Ready maize GA21 x MON810 (C/ES/99/02)
Lepidopteran resistent and glufosinate tolerant 1507 maize (C/ES/01/01)
Glufosinate tolerant Oilseed Rape Liberator pHoe6/Ac (C/DE/98/6)
Roundup Ready maize line GA21 (C/ES/98/01)
Lepidopteran resistent Maize MON 863 x MON 810 (C/DE/02/9)

I do not believe that any of these products should be eligible for marketing, sale, growing, or consumption by humans or animals in the EU for the following reasons:

There is no market for these GMOs in Europe. The majority of the public have consistently rejected all GMO derived food, feed and industrial products.
The commission should listen to the public when deciding on all future applications for GMOs to be marketed in the EU. If there is no consumer demand for these products why should they be granted marketable status, bearing in mind the unknown short and long term affects of these products on human and environmental health?

These GMOs has been assessed on the basis that the GMO is "substantially equivalent" to the non-GM equivalent. The principle of "Substantially" is deeply flawed, as acknowledged by an increasing number of independent scientists. To enable GMOs assessed under the "substantially equivalent" principle to be marketed in the EU is in conflict with taking the precautionary approach to new technology. The precautionary principle is key if we are to take environmental and human health seriously.

No independent feeding studies have been undertaken to assess toxicity of the plant/food/feed product on non-target organisms, on livestock or on humans.

Any of these GMOs that contain genes expressing resistance to antibiotics, may have adverse effects on human health and the environment, and existing legislation requires these to be phased out by 31 December 2004 for marketing purposes. As all antibiotics have a useful application, there is no point in approving any GMO expressing resistant genes.

The monitoring plans proposed for the cultivation of GMOs in Europe rely on implementing Good Agricultural Practice (GAP). In the light of experience from countries where GM crops are grown, GAP cannot be relied upon to prevent contamination of the food chain or of the environment. Please look at the experience within North America where the majority of GMOs are currently grown. There is widespread contamination of native plants/crops, and in some regions such as Saskatchewan, it is impossible to grow non-GM crops that have not been contaminated via cross-pollination with GM varieties or via gene flow. Mixing of GM and non-GM crops has occured at the milling, packaging, processing stages.

The monitoring plans are inadequate or non-existent in so far as that the objectives of Directive 2001/18/EC are not met. These are to:
- confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GMO or its use in the environmental risk assessment are correct, and
- identify the occurrence of adverse effects of the GMO or its use on human health or the environment which were not anticipated in the environmental risk assessment

Matters of liability for damage have yet to be settled. Labelling and traceability measures still to be agreed. As such issuing a marketing approval would be premature.

In light of the extremely important issues that I have raised above, I do not support the opinions made by the "lead member states", which recommend that these products should be allowed for marketing within the EU. I believe that it would be extremely premature and unwise for any of these products to be granted marketable status at this time.

Yours sincerely,

[redacted]

-----Original Message-----
From: [redacted][mailt[redacted]
Sent: Wednesday, February 19, 2003 12:29
To: guy.van-den-eede@jrc.it
Subject: Fwd: Comments on applications to market GMO foods in the EU

> Subject: Comments on applications to market GMO foods in the EU
>
> European Commission-DG Joint Research Centre,
> Institute for Health and Consumer Protection, Biotech. and GMOs Unit
>
> Re the following notifications: C/ES/99/02; C/ES/01/01; C/DE/98/6;
> C/ES/98/01; C/DE/02/9; C/NL/98/11; C/ES/00/01; C/GB/02/M3/03;
> C/SE/96/3501; C/BE/96/01; C/BE/98/01; C/BE/99/01; C/GB/99/M5/2;

> C/ES/97/01; C/ES/96/02; C/DE/96/5; C/DE/00/8; C/NL/00/10 and any
> further GM notifications that may be added later to this list, I
would
> like to make the following comments:
> 1) As Michael Meacher our Agriculture Minister said, mankind has
lived
> on this planet for about a quarter of a million years and has managed
> to feed without GM foods --- they are NOT necessary..
> 2)There is no demand for them. The European public has rejected and
> conclusively shown that they do not want GM foods.
> 3)Their assessment as equivalent to non GM foods is unproven and
> evidence is appearing that this is not the case therefore the
> precautionary principle should apply.
> 4)No long term independent feeding studies for toxicity or effects on
> health in humans or animals have been carried out so again the
> precautionary principle should apply.
> 5)As liability for damage caused by GM crops has not yet been decided
> any approval for these crops would be premature.
> 6) As a consumer of organic foods, I believe the growing of GM crops
> outdoors would very rapidly make the growing of organic crops
> impossible. I therefore feel my right of choice as a citizen would be
> infringed.
> Yours sincerely,
>
> [redacted]
> [redacted]
> [redacted]
> [redacted]

-----Original Message-----
From: [redacted]
Sent: Wednesday, February 19, [redacted]
To: guy.van-den-eede@jrc.it
Subject: Against GMOs

European Commission - DJ Joint Research Centre
Institute for Health and Consumer Protection
Biotechnology and GMOs Unit

Dear Madam/Sir,

I am very concerned about the introduction of genetically modified seeds for a variety of purposes in Europe, and I very strongly ask you to reconsider whether the products which are now being pushed into European countries by GMO producers such as Bayer and Monsanto are a) safe - not only for humans, but also animals, plants and the habitat in general; whether they allow biotech giants to control the European farmers with their produce, c) whether the ever more blurred separation line between food production and medicinal production is not an extremely dangerous path to tread.

Last not least: what on earth is it good for? It is not going to feed more people, and if we were in any way serious about decreasing the plight of less developed countries then we ought to think about a fair distribution of the world's abundance. The vast majority of people in Europe are adverse to GM products, be these food, feed or ingredients for industrial use. It is only democratic to listen to them!

From earlier experience we ought to know how perilous the introduction of new technology can be; in the case of GMO's it would be absolutely devastating, because this time we would not even be able to clean up after the fact. Once Europe is contaminated with antibiotic-resistant genes and God knows what else we cannot simply apologize to the generations to come by shrugging our shoulders:" We didn't know any better." I am simply a mother and a citizen of Europe, not a specialist in chemistry, so I have to rely on the experts to be acting from their intergrity and to look at the issue at hand and not at political and economic implications - or a safe and well-paid job!

To be specific:
I seriously object to giving the green light to any of the applications that have been coming in and are now being pushed into some European market. At the moment these are:
The notification numbers C/NL/98/11
C/ES/OO/01
C/GB/02/M3/03
C/SE/96/3501
C/BE/98/01
C/BE/99/01
C/GB/99/M5/2
C/ES/97/01
C/ES/96/02
C/DE96/5
C/DE/00/8
C/NL/00/10

I would be glad to get some confirmation about the receipt of my comments.

Yours sincerely, [redacted]

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[redacted]

From [redacted]

European Commission – DG Joint Research Centre,
Institute for Consumer and Health Protection,
Biotechnology and GMOs Unit.

Dear Sir/Madam,

Re. Consultations on Applications to EU to market GMOs.

I wish to object to the following Applications to market GMOs within the EU.

Yours sincerely,

[redacted]

1. C/NL/98/11. Monsanto. Roundup Ready oilseed rape. GT73.
   I do not agree with the opinion of the Netherlands competent Authority that the product is safe. My reason is that I do not believe that the use of a plant mosaic virus as a promoter is desirable especially if it is fused with a soil bacterium. Insufficient research has been carried out on the effects of these constructs on soil ecology.
   References. Mae Wan Hoe, Angela Ryan and Joe Cummins, "Cauliflour Mosaic Virus Promoter – A recipe for Disaster?" Microbial Ecology in Health and disease" 1999. 11 194-197.
   (This paper has been criticised but not satisfactorily answered).
   Philip J. Dale and others, "Plants rendered herbicide – susceptible by cauliflour mosaic virus-elicitated suppression of a 35S promoter-regulated transgene". 2000 Nature Biotechnology. Vol. 18 No.9 995—999.

2. C/GB/02/M3/03. Monsanto GM Maize NK603 –MCN 810
   I object to the use of the cryIA(b) insect control protein derived from Bacillus thuringiensis.
   Firstly, it has already been reported that insects and insect pests will develop a resistance to this protein. It is used as a natural insecticide in the organic farming industry in limited quantities in order to avoid the development of such resistance. Any unconstrained source could deprive the organic farmers of a valuable aid and could inflict substantial financial damage to their production levels.
   Secondly, neither humans nor animals likely to be fed maize have been subjected to a continued diet that contains this protein.
   Reference. Nagui H. Fares, Adel K. El-Sayad of the Departments. of Zoology and Entomolgy at Ain Sams University, Cairo on Natural Toxins, Vol. 6 issue 6, 1998, described feeding studies on mice with the same protein incorprated into potatoes. Detectable lesions were found in the ileum of those mice fed with GM potatoes and those fed with the endotoxin itself. No lesions were found in those fed with non GM potato.

2. C/SE/96/3501. Amylogene HB. Potato variety EH92-527-1 with modified starch content.
   I object to the use of the npt II gene which confers resistance to Kanamycin. This is in direct contravention of the intentions of the EU Directive 2001/18/EC and will shortly be illegal.
   I also object to the use of the pulp after extraction as animal feed without far more extensive trials to determine the physiological effects. We are not told whether the industrial processing will add any additional chemicals to the residual pulp.

3. C/BE/98/01. Bayer Bioscience. Glufosinate tolerant soybeans A2704-12 and A5547-127.
I object to the use of the cauliflour mosaic virus in the construct as it is a potential hazard.
References: Mae Wan Hoe, Angela Ryan and Joe Cummins. Microbial Ecology in Health & Disease. 1999. 11 194-197
(This paper has been criticised but not satisfactorily answered).
Philip J. Dale and others, "Plants rendered herbicide – susceptible by cauliflour mosaic virus-elicitated suppression of a 35S promoter-regulated transgene". 2000 Nature Biotechnology. Vol. 18 No.9 995—999.

I object to the use of glufosinate herbicide. I consider it is too toxic for general use and is likely to affect soil ecology..
References.
Evaluation of Glufosinate Ammonium 1990. No. 33 Pesticides Safety Directorate.
Glufosinate Ammonium Fact Sheet. 1998. PesticidesTrust.
Effects of Glufosinate Ammonium on microbial populations and enzyme activities in soils. B.S. Ismail et al, Faculty Press Cambridge 1995.

4. C/GB/99/MS/2. Bayer Cropscience. Glufosinate Tolerant Oil Seed Rape.T 45.
I object to the use of the cauliflour mosaic virus in the construct. I consider it to be a potential hazard.
References: Mae Wan Hoe, Angela Ryan and Joe Cummins. Microbial Ecology in Health & Disease. 1999. 11 194-197
(This paper has been criticised but not satisfactorily answered).
Philip J. Dale and others, "Plants rendered herbicide – susceptible by cauliflour mosaic virus-elicitated suppression of a 35S promoter-regulated transgene". 2000 Nature Biotechnology. Vol. 18 No.9 995—999.

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Glufosinate Ammonium Fact Sheet. 1998. PesticidesTrust.
Effects of Glufosinate Ammonium on microbial populations and enzyme activities in soils. B.S. Ismail et al, Faculty Press Cambridge 1995.

5. C/ES/97/01. Monsanto. Roundup Ready cotton line from 1445.
I object to the inclusion of both the nptII and aad genes that confer resistance to kanamycin and to spectinomycin and streptomycin. This is against the intention of the EU Directive 2001/19/EC and will very soon be illegal.

5. C/DE/96/5. Bayer Cropscience. Glufosinate tolerant oilseed rape
I object to the use of the cauliflour mosaic virus as a promoter. I consider it is a potential hazard.
References: Mae Wan Hoe, Angela Ryan and Joe Cummins. Microbial Ecology in

Health & Disease. 1999. 11 194-197
(This paper has been criticised but not satisfactorily answered).
Philip J. Dale and others, "Plants rendered herbicide – susceptible by cauliflour mosaic virus-elicitated suppression of a 35S promoter-regulated transgene". 2000 Nature Biotechnology. Vol. 18 No.9 995—999.

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References.
Evaluation of Glufosinate Ammonium 1990. No. 33 Pesticides Safety Directorate.
Glufosinate Ammonium Fact Sheet. 1998. PesticidesTrust.
Effects of Glufosinate Ammonium on microbial populations and enzyme activities in soils. B.S. Ismail et al, Faculty Press Cambridge 1995.

6. C/DE/00/8. KWS SAAT Monsanto/ Roundup Ready Sugar Beet. Event H7-1.
I object to the use of any plant mosaic virus for the same reasons as the cauliflour mosaic virus. I consider that they pose a potential threat to safety.
References: Mae Wan Hoe, Angela Ryan and Joe Cummins. Microbial Ecology in Health & Disease. 1999. 11 194-197
(This paper has been criticised but not satisfactorily answered).
Philip J. Dale and others, "Plants rendered herbicide – susceptible by cauliflour mosaic virus-elicitated suppression of a 35S promoter-regulated transgene". 2000 Nature Biotechnology. Vol. 18 No.9 995—999.

-----Original Message-----
From: [redacted]
Sent: 20 February 2003 20:49
To: guy.van-den-eede@jrc.it
Subject: Comment - Notification Number: C/SE/96/3501 (potato)

European Commission - DG Joint Research Centre
Institute for Health and Consumer Protection
Biotechnology and GMOs Unit
guy.van-den-eede@jrc.it

Sir,

Notification Number: C/SE/96/3501
Member State: Sweden
Date of Publication: 3/2/2003
Notifier: Amylogene HB
Name of the product: Potato variety EH92-527-1 with modified starch content

[redacted] strongly objects to the notification to cultivate
this GMO potato line in Europe or to use any GMO material in animal feed.

This variety is clearly not substantially equivalent to the non-GMO equivalent variety. Significant differences to the parental variety were found in vitamin C, sucrose and fructose levels that were present at higher levels in the GMO line. Moreover, 98% of the starch is amylopectin starch, thus it is obviously not "substantially equivalent"!

There are just too many uncertainties in this GMO potato to be sure that the GMO is safe to release into the environment. We are especially concerned about antibiotic resistance. We have major concerns that the GMO potato contains genes antibiotic resistance to kanamycin and neomycin, part of the aminoglycocide family of important antibiotics that have a useful application in medicine. Aminoglycocides are bactericidal and active against some gram-positive and many gram-negative bacteria, including P. Aeruginosa, Klebsiella, Staphylococcus and E. Coli.

High level mutational resistance to these important antibiotics can occur in a single step, and when it occurs, there is resistance to all aminoglycocides, including newer ones like gentamicin, tobramycin, amikacin and netilmicin. The pressure of antimicrobic use is already high in hospitals and in human medicine, and should not be aggravated in society by GMO crops. Reports of antibiotics in streams and rivers (from sewage) are alarming enough. The trend in Europe is also to ban by 2005 the unnecessary use of antibiotics in animal feed, which we have demanded for a long time.
Antibiotics as growth promoters have been banned in Sweden since the 1980's and there is a high level of awareness among the general public about these problems.

EU Regulations seeks to phase out antibiotic resistant markers in commercial GMO crops by 31 December 2004 "which may have adverse effects on human health and the environment". The FAO/WHO Codex Alimentarius also has agreed on a similar policy.

We note that the Swedish company has frequently and in writing declared that it is researching the possibility of developing the GMO potato further, in order to get rid of the antibiotic resistance gene. We see no reason why they should get approval for this "first generation" product, which clearly is a rather crude and old-fashioned example of genetic engineering.

We note that there are also risks associated with the presence of known and unknown amino acids in the GMO line. ORF4 has been singled out in the notification for further assessment, as the first 50 amino acids are homologous to the bleomycin resistance protein that has a chemotherapeutic use in cancer treatment, such as Hodgkin's disease. The notifier believes that a functional bleomycin protein is not present in the GMO-line but does admit that "this does not preclude the possibility that expression of ORF4 results in the production of a novel polypeptide in the plant, although database searches do not indicate significant homologies between ORF4 amino acid sequences and known allergens."

If we understand the application correctly, it appears that the notifier wants this product to be used as animal feed but not human food. We reject this type of "split approval" and considers it is a

highly controversial tactic. We have understood from the U.S. that such limitations are impossible to enforce, as the Starlink case clearly proved. A GMO should not be allowed as feed only.

We disagree that the Amylogene GMO potato is "substantially equivalent" to the non-GMO parent and, as such, the GMO should not be approved. This concept is not only unscientific but also potentially dangerous because the present analytical methods used for establishing equivalence do not allow for the discovery of new antinutrients, toxins and allergens formed as the unintended consequence of the genetic transformation of the crops. We urge you to refer to the precautionary principle, and reject a marketing approval.

Regards,

[redacted]

-----Original Message-----
From: [redacted]
Sent: Friday, February 21, 2003 14:41
To: guy.van-den-eede@jrc.it
Subject: GMO notifications

Regarding the following new notifications for GMOs :

C/NL/98/11
C/ES/00/01
C/GB/02/M3/03
C/SE/96/3501
C/BE/96/01
C/BE/98/01
C/BE/99/01
C/GB/99/M5/2
C/ES/97/01
C/ES/96/02
C/DE/96/5
C/DE/00/8
C/NL/00/10

I am extremely worried that no long term studies have been done into the toxicity or otherwise of the plant/food/feed to any humans, livestock or non-target organisms from the GMOs applied for release above.

As the labelling and traceability measures have not yet even been approved it would seem unjustifiable to give market approval in advance.

Yours sincerely,

[redacted]

-----Original Message-----
From: [redacted]
Sent: Friday, February 21, 2003 23:44
To: guy.van-den-eede@jrc.it
Subject: Applications to market GMOs in the European Union

European Commission
DG Joint Research Centre
Institute for Health and Consumer Protection
Biotechnology and GMOs Unit
B-1049
Brussels

Directive 2001/18/EC
Applications to market GMOs in the European Union

I wish to object to the undernoted applications (18 in total) on the following grounds

1. there is a lack of evidence that the growing of GM crops and the consumption of GM food, including from animals fed with GM feeds, are compatible with the interests of human health.

2. toxicological testing is required using the same rigour as applied to pharmaceuticals.

3. before any consideration is given to approvals under the Directive, a regime of unambiguous legal liabilty for adverse impacts on health and the environment should be in place in upon the promoters, growers, marketers, and distributors of GM derived products.

4. on the basis of the above, no responsible authority would grant any of these applications.

Yours faithfully

[redacted]

This objections refers to the following notifications:-
C/NL/98/11 Netherlands
C/ES/00/01 Spain
C/GB/02/M3/03 United Kingdom
C/SE/96/3501 Sweden
C/BE/96/01 Belgium
C/BE/98/01 Belgium
C/BE/99/01 Belgium
C/GB/99/M5/02 United Kingdom
C/ES/97/01 Spain
C/ES/96/01 Spain
C/DE/96/5 Germany
C/DE/00/8 Germany
C/NL/00/10 Netherlands
C/ES/99/02 Spain
C/ES/01/01 Spain

C/DE/98/6 Germany
C/ES/98/01 Spain
C/De/02/9 Germany

Dear Sir

I object to the GMO applications listed below for the following reasons: -

· There is no market for the GMO in Europe. The majority of the public have rejected all GMO derived food, feed and industrial products.

· The GMO has been assessed on the basis that the GMO is substantially equivalent to the non-GM equivalent. This is clearly not the case, is unproved and is in conflict with taking the precautionary approach to new technology.

· No feeding studies have been undertaken to assess toxicity of the plant/food/feed product on non-target organisms, on livestock or on humans.

· GMOs that contain genes expressing resistance to antibiotics, that may have adverse effects on human health and the environment, must be phased out by 31 December 2004 for marketing purposes. As all antibiotics have a useful application, there is no point in approving any GMO expressing resistant genes.

· The monitoring plans proposed for the cultivation of GMOs in Europe rely on implementing Good Agricultural Practice. In the light of experience from countries where GM crops are grown, GAP cannot be relied upon to prevent contamination of the food chain or of the environment.

· The monitoring plans are inadequate or non-existent in that the objectives of Directive 2001/18/EC are not met. These are to:
- confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GMO or its use in the environmental risk assessment are correct, and
- identify the occurrence of adverse effects of the GMO or its use on human health or the environment which were not anticipated in the environmental risk assessment

· Matters of liability for damage have yet to be settled. Labelling and traceability measures still to be agreed. As such issuing a marketing approval would be premature

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NOTIFICATIONS RECEIVED by 15 Feb. 03
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Notification Number: C/NL/98/11
Member State: Netherlands
Date of Publication: 22/01/2003
Notifier: Monsanto

Name of the product: Roundup Ready (glyphosate tolerant) oilseed rape, event GT73
Deadline for public comments: 22/02/2003

Product: GT73 has been genetically engineered from the parental oil seed rape line (Westar) to contain two genes that confer tolerance to the herbicide glyphosate (ie Roundup). One is the CP4-EPSPS gene from Agrobacterium fused with a modified figwort mosaic virus 35S promoter, a chloroplast transit peptide (CTP) sequence from Arabidopsis thaliana and a terminator region from the pea rbcS E9 gene. Together, these sequences permit the plant to continue to synthesise these amino acids when sprayed with glyphosate. The other gene sequence is the gox (glyphosate oxidoreductase) gene from Ochromobactrum anthropii, a soil bacterium, fused with a modified figwort mosaic virus 35S promoter, a chloroplast transit peptide sequence from Arabidopsis thaliana and a terminator region from the pea rbcS E9 gene. The gox gene has been modified to improve the affinity of the enzyme for glyphosate (the gox variant GOXv247). The resultant protein is a novel protein that differs by 3 amino acids to the normal gox protein. Together, these sequences permit the plant to breakdown glyphosate to aminomethylphosphonic acid and glyoxylate, thereby inactivating the herbicide. These were transferred using Agrobacterium-mediated transformation.

Purpose: Import and use only NOT for cultivation (an application for cultivation has been submitted to France for consideration)
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Notification Number: C/ES/00/01
Member State: Spain
Date of Publication: 22/01/2003
Notifier: Monsanto
Name of the product: Roundup Ready (glyphosate tolerant) maize, event NK603
Deadline for public comments: 22/02/2003

Product: This corn has been genetically engineered to contain a gene cassette containing a modified corn EPSPS gene fused to a chloroplast transit peptide (CTP) sequence which has been derived from sequences obtained from corn and sunflower, the actin 1 promoter and first intron from rice and the 3' untranslated region of the nopaline synthase gene (NOS 3') from the Ti plasmid of Agrobacterium.

Purpose: the import and use of Roundup Ready (glyphosate tolerant) maize, event NK603 as an animal feed only (not cultivation or human food).

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Notification Number: C/GB/02/M3/03
Member State: United Kingdom
Date of Publication: 22/01/2003
Notifier: Monsanto
Name of the product: Genetically modified maize NK603 × MON 810
Deadline for public comments: 22/02/2003

Product: The product is maize (Zea mays) seeds of a herbicide tolerant, insect resistant GM hybrid (NK603 X MON810) derived from conventional crossing of two genetically modified maize lines. The insect resistant parent GM maize line is MON 810 and the herbicide tolerant parent GM

maize line is NK603. The hybrid, NK603 X MON810, has characteristics of both parent lines. It is therefore modified for:
i) expression of the cryIA(b) insect control protein derived from the common soil bacterium Bacillus thuringiensis subsp. kurstaki. Expression of the protein in the plant provides control of the European Corn Borer (Ostrinia nubilalis) and certain other Lepidopteran insect pests such as pink borer (Sesamia cretica), as this protein is toxic to these insect pests.
ii) tolerance to the herbicide glyphosate by the insertion of a modified maize gene, CP4 EPSPS, which encodes the enzyme 5-enolpyruvylshikimate-3-phosphate (EPSPS).

Purpose: The scope of the application is only for the importation of maize seed into the EU, for use as for any other maize including in animal feed and industrial processing to non-viable products. The scope does not include cultivation of maize NK603 X MON810 in the EU.

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Notification Number: C/SE/96/3501
Member State: Sweden
Date of Publication: 3/2/2003
Notifier: Amylogene HB
Name of the product: Potato variety EH92-527-1 with modified starch content
Deadline for public comments: 3/3/2003

* NB the nptII gene is expressed which confers resistance to the antibiotic kanamycin.

Product: The product is one transgenic line (EH92-527-1) of potato (Solanum tuberosum ssp. tuberosum L.). The potato has been genetically modified so that 98% of the starch in the tubers is amylopectin starch, and only 2% is amylose starch. Non-transgenic potato tubers contain two types of starch, amylose and amylopectin, at a ratio of 1:4. The potato has been genetically modified by the insertion of the following genes:
1) the granule bound starch synthase (gbss) gene, from S. tubersum. This gene is inserted in the anti-sense orientation and is strongly expressed in the tubers, pollen, and root tips. Insertion of the gbss gene in the anti-sense orientation suppresses expression of the endogenous gbss gene and consequently reduces production of the granule bound starch synthase enzyme which is required for the production of amylose starch.
2) the nptII gene which confers resistance to the antibiotic kanamycin. This gene is under the control of the nos promoter and terminator and is expressed in leaf tissue and to some degree in tuber tissue.

Purpose: The product is intended to be cultivated for the production of seed potatoes and potatoes for industrial processing into starch. Potato pulp generated from industrial processing will be used for animal feed, and the potato juice used for agricultural irrigation or treated as sewage. The potato is intended to be grown for the production of raw material for the starch industry. The GM potato will be used for the production of a specific starch quality and will therefore be grown without contamination with other starch potatoes. Seed potato production will be carried out mainly in Sweden, but may also be considered in other parts of the EC where starch potatoes are grown. This may include the UK.

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Notification Number: C/BE/96/01
Member State: Belgium
Date of Publication: 7/2/2003
Notifier: Bayer BioScience
Name of the product: Oilseed rape Ms8xRf3 [line grown in UK farmscale trials]
Deadline for public comments: 7/3/2003

Product: The product consists of male sterile line (MS8) and fertility restorer line (RF3) of oilseed rape (Brassica napus L.oleifera cultivar Drakkar), and hybrid oilseed rape derived from them by conventional breeding methods. The male sterile line was genetically modified by the insertion of the barnase gene which confers male sterility, and the fertility restorer line was modified by insertion of the barstar gene which encodes fertility restoration by inhibiting the function of the barnase gene when expressed in the presence of the product of the barnase gene. Both genes are controlled by the PTA29 promoter which limits expression of the inserted genes to the anthers (in the oilseed rape flower). Both the male sterile and fertility restorer lines also contain the bar gene which encodes tolerance to the herbicide glufosinate ammonium.

Purpose: The product is intended for cultivation, importation, food and feed use, and industrial processing. Specifically the scope of the application involves, (1) the growing and multiplication of seed and for placing on the market; (2) field cropping for seed production for feed, food and industrial uses of non-living processed products; and (3) for import of seed for processing for food, animal feed and industrial uses.

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Notification Number: C/BE/98/01
Member State: Belgium
Date of Publication: 7/2/2003
Notifier: Bayer BioScience
Name of the product: Glufosinate tolerant soybeans A2704-12 and A5547-127
Deadline for public comments: 7/3/2003

Product: Glufosinate tolerant soybeans expressing the pat gene. Cauliflower Mosaic Virus 35S promoter and terminator genes.

Purpose: Import for use by processing industry.

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Notification Number: C/BE/99/01
Member State: Belgium
Date of Publication: 7/2/2003
Notifier: Monsanto; Syngenta Seeds
Name of the product: Roundup Ready sugar beet [line grown in UK farmscale trials]
Deadline for public comments: 7/3/2003

Product: The recipient plant is the sugar beet breeding line A1012. The resulting transformation event is termed T9100152. Event T9100152

expresses two new genes, cp4 epsps and uidA (the GUS marker), and part of the gox gene. Cp4 epsps renders the sugar beet plant tolerant to the herbicide glyphosate. The dossier says that the nptII gene that confers antibiotic resistance to the useful amiloglycoside group of antibiotics were not incorporated into the sugar beet genome. The promoters used to drive the expression of the genes are considered to be constitutive, i.e. the genes are expressed in all cells in the GM beet plant. This means that the effects of genetic elements such as P-e35S and the cauliflower mosaic virus promoter genes should be assessed. This plant also has the uidA gene which codes for the enzyme beta -D-glucuronidase (GUS) which acts as a marker for plant transformation. beta -D-glucuronidase catalyses a catabolic reaction in plants, animals and people. It breaks down a group of substances known as beta -D-glucuronidases, which also occur in vertebrates, to D-glucuronate. Therefore, this enzyme, which is constantly produced by the plant, is able to find substrates to breakdown in the tissues of animals and people.

The notification paper says that "The shift from traditional sugar beet herbicides to glyphosate will result in increased flexibility in application and potentially more efficient weed control. What impact this may have on the biodiversity - insects and flora - was examined in a large scale experiment conducted in UK (Coghlan, 2002). The experiments suggest that the careful use of GM Roundup Ready sugar beet event T9100152 - C/BE/99/01 13 technology can encourage wildlife diversity in GM crops that has been lost in conventional crops."

This was the much hyped study "good for skylarks" that was much criticised by conservationists as it proved nothing except that it is possible to implement a spraying regime with Roundup that leaves weeds between rows of GM sugar beet that can be zapped a few weeks later. No account was taken of the fact that beneficial insects that might be feeding on flowers or plants will be sprayed at the same time! Whilst any weeds left to advance to seed formation would be a future "weed" problem for control in the next crop.

Purpose: This application includes the cultivation and use of RR sugar beet in the European Union (EU) as any other sugar beet, including feed use.

==========
Notification Number: C/GB/99/M5/2
Member State: United Kingdom
Date of Publication: 10/2/2003
Notifier: Bayer CropScience
Name of the product: Glufosinate Tolerant oilseed rape T45
Deadline for public comments: 10/3/2003

Product: The product is a spring oilseed rape (Brassica napus) cultivar (line T45) and all progeny derived from conventional breeding between the GM cultivar and non-transgenic lines, and between the GM cultivar and the transgenic line Topas notified in application C/GB/95/M5/1. The GM oilseed rape is genetically modified to be tolerant to the herbicide glufosinate ammonium by insertion of a synthetic pat gene (derived from a natural gene from the soil bacterium Streptomyces viridochromogenes). The inserted gene is under the control of the 35S promoter/terminator

system from Cauliflower Mosaic Virus and is therefore expressed throughout the plant.

Purpose: The scope of the application is for the importation of seed into the EU for industrial processing only. The seed will be imported for commercial oil crush. The by-product, meal, will be utilised as animal feed.
The scope of the application does not include cultivation of the GM plant.

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Notification Number: C/ES/97/01
Member State: Spain
Date of Publication: 14/2/2003
Notifier: Monsanto
Name of the product: Roundup Ready cotton line derived from Event 1445
Deadline for public comments: 13/3/2003

** NB The genes nptII, which confers resistance to the antibiotic kanamycin, and the aad gene, which confers resistance to the antibiotics spectinomycin and streptomycin, have also been inserted into this cotton line.

Product: The product is one transgenic line (1445) of cotton (Gossypium hirsutum) cultivar Coker 312. The product consists of plants and seeds of line 1445 and any progeny derived by conventional breeding with non-GM cotton lines. The cotton has been genetically modified for tolerance to the herbicide glyphosate by the insertion of the CP4 EPSPS gene cassette.
The gene nptII, which confers resistance to the antibiotic kanamycin, and the aad gene, which confers resistance to the antibiotics spectinomycin and streptomycin, have also been inserted into cotton line 1445. The nptII gene is expressed in the leaves and seeds of the cotton. The aad gene is controlled to its indigenous bacterial promoter and is therefore not expressed in the GM cotton.

Purpose The product will be marketed as seed for cultivation in the EU for growth, breeding, and processing into non-viable products. The scope of the application also includes the importation of the GM cotton seed into the EU, and the use of the by-products of industrial processing for animal feed.
The application does not cover using the product for human food.

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Notification Number: C/ES/96/02
Member State: Spain
Date of Publication: 14/2/2003
Notifier: Monsanto
Name of the product: Insect-Protected cotton line derived from Event 531
Deadline for public comments: 13/3/2003

** NB The genes nptII, which confers resistance to the antibiotic kanamycin, and the aad gene, which confers resistance to the antibiotics spectinomycin and streptomycin, have also been inserted into cotton line 531.

Product: The product is one transgenic line (531) of cotton (Gossypium hirsutum) cultivar Coker 312. The product consists of seeds of line 531 and any progeny derived by conventional breeding with non-GM cotton lines. The cotton has been genetically modified to be resistant to certain lepidopteran insect larvae by the insertion of the cryIA(c) gene which is expressed throughout the plant. The genes nptII, which confers resistance to the antibiotic kanamycin, and the aad gene, which confers resistance to the antibiotics spectinomycin and streptomycin, have also been inserted into cotton line 531. The nptII gene is expressed in the leaves and seeds of the cotton. The aad gene is controlled to its indigenous bacterial promoter and is therefore not expressed in the GM cotton.

Purpose The product will be marketed as seed to be cultivated in the EU for growth, breeding, and processing into non-viable products. The scope of the application also includes the importation of the GM cotton seed into the EU, and the use of the by-products of industrial processing for animal feed.
The application does not cover using the product for human food.

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Notification Number: C/DE/96/5
Member State: Germany
Date of Publication: 14/2/2003
Notifier: Bayer CropScience
Name of the product: Glufosinate tolerant Oilseed Rape Falcon, GS40/90pHoe6/Ac
Deadline for public comments: 13/3/2003

Product: The product is genetically modified oilseed rape (Brassica napus) derived from transformation event Falcon GS40/90pHoe6/Ac, and progeny resulting from conventional breeding with non-transgenic lines. The oilseed rape is genetically modified by the insertion of the pat gene which confers tolerance to the herbicide glufosinate ammonium. The gene in under the control of the 35S promoter from Cauliflower Mosaic Virus which results in its expression throughout the plant.

Purpose: The product will be used for cultivation for both commercial seed production, for breeding and marketing, and the production of grain for feed, food and industrial uses. The scope of the proposed use also includes importation of GM oilseed rape seed into the EU for food, animal feed and industrial processing. Because oilseed rape is grown in UK agriculture, it is likely that this GM oilseed rape will be grown in the UK if it receives the necessary regulatory approval.

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Notification Number: C/DE/00/8
Member State: Germany
Date of Publication: 14/2/2003
Notifier: KWS SAAT; Monsanto
Name of the product: Roundup Ready Sugar Beet (Beta Vulgaris) Derived from Event H7-1
Deadline for public comments: 13/3/2003

Product: gene cassette encoding one protein CP4 EPSPS that confers herbicide tolerance. The 35S promoter is taken from the Figwort Mosaic Virus.

Purpose: cultivation and use as food/feed

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Notification Number: C/NL/00/10
Member State: Netherlands
Date of Publication: 14/2/2003
Notifier: Pioneer Hi-Bred; Mycogen Seeds
Name of the product: Lepidopteran resistant and glufosinate tolerant 1507 Maize
Deadline for public comments: 13/3/2003

Product: GM maize grain derived from B.t Cry1F maize line 1507, genetically modified to express CRY1F protein, conferring resistance to certain lepidopteran insect pests, and PAT protein, conferring tolerance to glufosinate-ammonium herbicide.

Purpose: Import of 1507 maize for use as any other maize including processing and use as food and feed, but not for cultivation.

Yours sincerely

-----Original Message-----
From: [redacted]
Sent: 27 February 2003 11:34
To: gmoinfo-comments@jrc.it
Subject: C/SE/96/3501

European Commission
DG Environment
c/o JRC
By email gmoinfo-comments@jrc.it

Market approval application genetically modified potatoe
Your notification number C/SE/96/3501

Velt appreciates the opportunity to comment on this notification. We strongly object to the application for the following reasons.

The Commission initiative to restart the approval process for a number of older marketing applications interferes in an unfortunate way with the ongoing review and renewal of the overall GMO legislation. Even though the deliberate release directive itself has now entered into force in its new version, there is still a lack of functional regulation in a number of other respects.

We cannot approve of any further marketing applications before a complete set of EU regulations are in force covering the whole chain of production from seed to table. This means that:

ß Legislation under preparation must be completed and come into force (food/feed, traceability/labelling, and seed).

ß The issues of "co-existence" between GMO producers and agriculture as a whole must be resolved in a manner which does not create new restrictions or costs for existing production, either in the organic or the non-organic sector. As a minimum, this requires regulation of liability and the creation of economic guarantees, e g by requiring mandatory liability insurance.

Yours sincerely

[redacted]

-----Original Message-----
From: [redacted]
Sent: 28 February 2003 10:56
To: gmoinfo-comments@jrc.it
Subject: C/SE/96/3501

Please find enclosed an opinion from the [redacted]

/Sincerely

[redacted]

28 February 2003

European Commission
DG Environment

c/o JRC
By email gmoinfo-comments@jrc.it

Market approval application genetically modified starch potato
Your notification number C/SE/96/3501

The [redacted][1] appreciates the opportunity to comment on this notification. We strongly object to the application for the following reasons.

General

The Commission initiative to restart the approval process for a number of older marketing applications interferes in an unfortunate way with the ongoing review and renewal of the overall GMO legislation. Even though the deliberate release directive itself has now entered into force in its new version, there is still a lack of functional regulation in a number of other respects.

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Specific

The application concerns a variety containing antibiotic resistance genes as marker genes. [redacted] cannot under any circumstances accept that plants with antibiotic resistance are approved for use outside closed laboratories.

The application covers use of the potato pulp as cattle feed. The applicant does not indicate that any serious feeding trials have been carried out which would support the safety of such use, especially over a longer period. The 8-week trial referred to is obviously insufficient to detect health implications.

We can also not see that the applicant has showed how it will be ensured that the GM starch will not enter the human food chain.

[redacted]

Yours sincerely

[redacted]

-----Original Message-----
From: [redacted] [mailto:[redacted]
Sent: 01 March 2003 18:03
To: guy.van-den-eede@jrc.it; gmoinfo-comments@jrc.it
Subject: Market approval application genetically modified plants

Market approval application for gm plants.

I appreciate the opportunity to comment these notification. I strongly object to the application for the following reasons.

The Commission initiative to restart the approval process for a number of older marketing applications interferes in an unfortunate way with the ongoing review and renewal of the overall GMO legislation. Even though the deliberate release directive itself has now entered into force in its new version, there is still a lack of functional regulation in a number of other respects.

We cannot approve of any further marketing applications before a complete set of EU regulations are in force covering the whole chain of production from seed to table. This means that:

ß Legislation under preparation must be completed and come into force (food/feed, traceability/labelling, and seed).

ß The issues of "co-existence" between GMO producers and agriculture as a whole must be resolved in a manner which does not create new restrictions or costs for existing production, either in the organic or the non-organic sector. As a minimum, this requires regulation of liability and the creation of economic guarantees, e g by requiring mandatory liability insurance.

Yours sincerely

[redacted]

-----Original Message-----
From: [redacted] [mailto:[redacted]
Sent: 02 March 2003 16:53
To: gmoinfo-comments@jrc.it
Subject: C/SE/96/3501

C/SE/96/3501
Sweden
3/2/2003
Amylogene HB
Potato variety EH92-527-1 with modified starch content

Sweden, 2 March 2003

Sir/Madam,

I am a citizen of EU. Thank you for giving me this opportunity to make a comment on the GMO notification.

During these years of GMO debate, I have witnessed that some of the government officials who had served on the matter of GMO have changed their side and gotten positions in the GMO industry. One ex-Swedish agriculture agency official is now working for Monsanto. Another ex-Swedish agriculture agency official is working for Svalof Weibull (the company that owns the Amylogene company).

Many citizens have expressed their opinions about GMO to the Swedish agriculture agency, while these people were serving the government, without knowing that they would be working for Monsanto or Svalof Weibull. I think this is a part of the big problem in our society. We should avoid such things Americans have called "revolving door" to happen in Europe. Having mentioned this, I would like to say that as a citizen of EU member states, I feel a little better that now JRC can listen to us citizens' voices. I hope you will not change your position to work for the GMO industry.

Since you have not yet published the risk assessment, I have to make comments on the Amylogene's GMO potato using the information provided as SNIF. I think it will be better if JRC makes a rule that as long as both SNIF and RA are not on the table, JRC will not draw the deadline for public comments. We citizens are also busy as you all are, so in order to not give us two separate deadlines, please consider to make a single deadline for each notification.

According to SNIF, this product is applied for paper production and feed use, not for placing on the market for food uses of whole potatoes or derived starch.

I have a problem with this split notification. I support the dual-use clause which requires a GM product to be approved as food and feed where it is likely to be used for this purpose. (Article 29 of the Commission's proposal on GM feed and food.)

"Learning from the US experience with StarLink, the proposal provides that GMOs likely to be used as food and feed can only be authorised for both uses or not at all." (Press release from the European Commission, Brussels, 25 July 2001- Commission improves rules on labelling and tracing of GMOs in Europe to enable freedom of choice and ensure environmental safety - Authorisation procedure)

This GM crop must not be approved by EU, because it contains antibiotic resistance gene. A Swedish GMO authority Gentekniknamden has also expressed its serious concern on the matter of GM potato with antibiotic resistance gene in 1998. Also WHO and Codex are against antibiotic resistant marker genes. The company has defended the use of such marker genes, saying they exist already in nature, for example in soil bacteria. It is not a logical defence because people do not eat soil. Even though the potato will be used as feed, there is a risk that it may also accidentally be used as food, without safeguards. Finally, should the marker gene be taken up by the animal, it will be a health risk for consumers who eat the meat or drink the milk.

This GM potato is clearly not substantially equivalent to the non GM equivalent variety. In the matter of food security as well as food safety, it is time to recognise the importance of keeping Europe GMO free. Co-existence is not at all possible. Please do not approve Amylogene's
Potato variety EH92-527-1.

Sincerely,

[redacted]

-----Original Message-----
From: [redacted] [mailto:[redacted]]
Sent: 02 March 2003 21:43
To: gmoinfo-comments@jrc.it
Subject: C/SE/96/3501

I am very concerned about the potential acceptance in Europe of this GM potato. As a grower I am very aware of the complexity of the eco-system that we work with and as a member of the farming community have seen the devastation wrought by poorly made decisions, regarding animal feed deregulation, leading to BSE. Having read the report for the proposed GM potato release, my concerns are greater. In the report there are various statements which highlight the uncertainty of the science. Page 12 states the "this makes it extremely unlikely, but not impossible that ORF4 is expressed in the GM potato plant as a polypeptide." Then it states that "positive reactions occurred with leaf protein extracts to which recombinant ORF4 protein was added." On page 13 we read that "it is very unlikely that an unstable insert would result in a stable inhibition of amylase production over several consecutive generations" Further on we read that "there are not any plants of the plant where the expression of the npt11-gene can be completely excluded ".Then we read that the modified potato contains an npt11 gene for kanamycin resistance with the potential for transfer from plant material to microbes in the soil." All these statements show the uncertainty of the new release. You should act on the precautionary principle. Finally it is claimed that the "characteristics of EH92-527-1 and significant equivalency to the parental variety do not introduce any risks to human health." This

statement is not substantiated. It is however known that the introduction of new genes into DNA can cause unexpected changes in plants, some of which have been dangerous to human health. These statements give cause for doubt as to the safety of releasing these GM changes into the eco-system. The appearance of "superweeds in the United States shows that there could be serious problems in both the agricultural and natural environment. As far as I am aware, there have been no tests conducted for this GM potato regarding its effect on soil life, insects, birds or other aspects of the natural food chain. It would be irresponsible for you to allow release of this new GM potato into the wider environment, from which it is not possible to recall the genes, as has been shown in previous reports on gene spread. Yours sincerely [redacted]

-----Original Message-----
From: [redacted] [mailto:[redacted]
Sent: 02 March 2003 22:36
To: gmoinfo-comments@jrc.it
Subject: C/SE/96/3501

This is a new version of an earlier e-mail, which includes comment on GM entering the human food chain.
I am very concerned about the potential acceptance in Europe of this GM potato. As a grower I am very aware of the complexity of the eco-system that we work with and as a member of the farming community have seen the devastation wrought by poorly made decisions, regarding animal feed deregulation, leading to BSE. Having read the report for the proposed GM potato release, my concerns are greater. In the report there are various statements which highlight the uncertainty of the science. Page 12 states the "this makes it extremely unlikely, but not impossible that ORF4 is expressed in the GM potato plant as a polypeptide." Then it states that "positive reactions occurred with leaf protein extracts to which recombinant ORF4 protein was added." On page 13 we read that "it is very unlikely that an unstable insert would result in a stable inhibition of amylase production over several consecutive generations" Further on we read that "there are not any plants of the plant where the expression of the npt11-gene can be completely excluded ".Then we read that the modified potato contains an npt11 gene for kanamycin resistance with the potential for transfer from plant material to microbes in the soil." All these statements show the uncertainty of the new release. You should act on the precautionary principle. Finally it is claimed that the "characteristics of EH92-527-1 and significant equivalency to the parental variety do not introduce any risks to human health." This statement is not substantiated. It is however known that the introduction of new genes into DNA can cause unexpected changes in plants, some of which have been dangerous to human health. Although this GM potato is not intended for human consumption, I note that it is expected that some will be fed to animals and thus would be entering the human food chain. The above statements give cause for doubt as to the safety of releasing these GM changes into the eco-system. The appearance of "superweeds in the United States shows that there could be serious problems in both the agricultural and natural environment. As far as I am aware, there have been no tests conducted for this GM

potato regarding its effect on soil life, insects, birds or other aspects of the natural food chain. It would be irresponsible for you to allow release of this new GM potato into the wider environment, from which it is not possible to recall the genes, as has been shown in previous reports on gene spread. Yours sincerely [redacted]

-----Original Message-----
From: [redacted] [mailto[redacted]]
Sent: Thursday, February 27, 2003 11:39
To: guy.van-den-eede@jrc.it
Subject: GM marketing notifications made to the EU and products already approved

European Commission - DG Joint Research Centre
Institute for Health and Consumer Protection
Biotechnology and GMOs Unit

I am writing about the following notifications for marketing under Directive 2001/18/EC and about the products already approved under 90/220/EEC.

I am appalled to see what is happening.

There is no market for these products in the EU. The public consistently rejects them.

The concept of substantial equivalence has been discredited as a means of comparison.

The precautionary approach adopted by the EU means that we should refrain from taking unquantifiable risks, which all these are.

There is no means of ascribing liability in place yet.

Labelling and traceability measures have still to be agreed.

Some of these products contain an antibiotic resistance marker, even though these will be phased out by 31 December 2004 for marketing purposes, so there is no excuse for approving such products.

The monitoring plans are inadequate and play straight into the hands of an industry which wants to penetrate the European market at any cost.

No proper feeding tests have EVER been held, as you will be fully aware. Arpad Pusztai, the only person to carry out a proper research programme in the public domain, was dismissed, his research was rejected and disinformation was spread about him, his methodology and the results he had found.

It is extremely difficult for the public to respond to this way of seeking approval, which favours industry methods and basically facilitates the defiance of democracy and public opinion.

We now know that cross pollination causes resistance problems in weeds

plus resistant volunteers, with multiple resistance also featured.

We know that claims for increased yields are extremely debateable.

We know that in the UK for instance, co-existence between GM crops, conventional and organic crops is basically impossible without contamination of the conventional and organic food streams.

I am particularly horrified to see the list of already approved products contains vaccine expressing plants and extremely frivolous applications for carnation colour and lasting properties. The former has huge implications for our health. The example of ProdiGene in the US is a timely warning. There is simply no excuse for the carnation applications.

Sincerely,

[redacted]

Notification Number: C/NL/98/11
Notification Number: C/ES/00/01
Notification Number: C/GB/02/M3/03
Notification Number: C/SE/96/3501
Notification Number: C/BE/96/01
Notification Number: C/BE/98/01
Notification Number: C/BE/99/01
Notification Number: C/GB/99/M5/2
Notification Number: C/ES/96/02
Notification Number: C/DE/96/5
Notification Number: C/DE/00/8
Notification Number: C/NL/00/10

GMO PRODUCTS - APPROVED UNDER DIRECTIVE 90/220/EEC as of March 2001

1. Vaccine against Aujeszky's disease
2. Vaccine against rabies
3. Tobacco tolerant to bromoxynil
4. Vaccine against Aujeszky's disease (further uses)
5. Male sterile swede rape resistant to glufosinate ammonium (MS1, RF1)
6. Soybeans tolerant to glyphosate
7. Male sterile chicory tolerant to glufosinate ammonium
8. Bt-maize tolerant to glufosinate ammonium (Bt-176)
9. Male sterile swede rape tolerant to glufosinate ammonium (MS1, RF1)
10. Male sterile swede rape tolerant to glufosinate ammonium (MS1, RF2)
11. Test kit to detect antibiotic residues in milk
12. Carnation lines with modified flower colour
13. Swede rape tolerant to glufosinate ammonium (Topas 19/2)
14. Maize tolerant to glufosinate ammonium (T25)
15. Maize expressing the Bt cryIA(b) gene (MON 810)
16. Maize tolerant to glufosinate ammonium and expressing the Bt cryIA(b)
gene (Bt-11)
17. Carnation lines with improved vase life
18. Carnation lines with modified flower colour

-----Original Message-----
From: [redacted] [mailto[redacted]
Sent: 03 March 2003 13:11
To: gmoinfo-comments@jrc.it
Subject: C/SE/96/3501

I would like to submit a few comments on the Amylogene Potato Clone EH92-527-1 notification.
- It does not make clear how organic farmers will be protected from contamination (and hence from losing their certification).
- It does not present any proof as regards genetic stability of the genetic modification.
- It does not present any safety net as regards unexpected ecological damage.
- It does not present any scientific study / reference as regards human long term toxicity potential in case, through accidental contamination, this genetic modification enters the human food chain.
As such, I conclude Amylogene should not be allowed to grow these potatos in the EU.
Sincerely,
--
[redacted]

-----Original Message-----
From: [redacted]
Sent: 04 March 2003 10:28
To: gmoinfo-comments@jrc.it
Subject: C/SE/96/3501

1- **The public has 30 days** after the publication to make comments. If the notification has been published on the 3/2/2003, we can submit our comments until the 5/3/2003.

2-**The Commission shall also make available to the public the so-called "assessment reports".** That is a crucial point to make a comment.

Thanks

[redacted]

Before undertaking a placing on the market a notification shall be submitted to the competent authority of the Member State where such a GMO is to be placed on the market for the first time. Also in this case, amongst other information, and without prejudice to Article 25 of Directive 2001/18/EC, the Commission shall immediately make

available to the public a "summary notification information format" (SNIF). **The Commission shall also make available to the public the so-called "assessment reports". The public may make comments on the Part C SNIFs** and on the assessment reports to the Commission **within 30 days** and the Commission shall immediately forward the comments to the competent authorities. Finally, for all GMOs which have received written consent for placing on the market or whose placing on the market was rejected, the assessment reports carried out for these GMOs and the opinion(s) of the Scientific Committees consulted shall be made available to the public. Also the consent itself including the conditions specified, and the Commission Decision (if any) including the conditions specified, have to be made public by the Member States.