

GM Food & Feed – Comments from the Public

Comments received on Starch potato EH92-527-1

The total number of the received comments is 15, but the authors of three of these comments did not agree that their comments could be published on the present website.

1. private person, UK
2. my choice, SE
3. University of Helsinki, FI
4. private person, SE
5. private person, DE
6. Greenpeace, SE
7. Consiglio dei Diritti Genetici, IT
8. GLOBAL 2000 / Friends of the Earth Austria, AT
9. private person, DE
10. ifrik, NL
11. Biodynaaminen yhdistys – Biodynamiska föreningen ry, FI
12. Greenpeace EU Unit, BE

1. Organisation: none
Country: United Kingdom

Comments on the following points:

b. Food Safety Assessment:
Toxicology

It is not enough to say that the potato appears similar to the parent cultivar, therefore it is inherently safe. Starlink corn proved that this is not a viable assumption.

No evidence is provided in the application to rule out unexpected effects due to the GM insertion, and no safety data is provided on the potatoes. Yet experimental GM potatoes have resulted in entirely unpredicted outcomes in the past – for example a potato modified to have low levels of the NAD-malic enzyme showed increase starch content, which the researchers could not explain.

Allergenicity

see above.

Others

Consumers in the EU have indicated very clearly that GMOs are not acceptable. There is no market for GMOs in the EU and therefore it is an unacceptable risk for absolutely no potential benefit.

Furthermore; growing these crops in the EU will open the door to GMOs produced and tested in other countries and under different testing regimes which may (and generally are) much less rigorous and GM-friendly. (eg LL rice and Starlink corn).

Approving this product for consumption in the EU will give thje US a mechanism to challenge the EUs moratorium on GM products and open the door to a flood of GM-containing products and commodities from the US.

3. Environmental risk assessment

The assesment write off any risk associated with cross-contamination by pollen.

In one study (kogsmyr, I. (1994) Gene dispersal from transgenic potatoes to conspecifics: A field trial. Theoretical and Applied Genetics 88: 770– 774.) outcrossing levels of 31% at 1000m were recorded, possible due due to pollen beetles.

It is also assume, quite optimistically, that any tuber remnants will be destroyed by winter cold. With increasingly mild winters due to climate change, this risk has not been adequately addressed.

For these reasons, the separation distance must be at least 1.5km between the trial and the nearest non-GM potato crop.

6. Labelling proposal

I fully endorse all objection made in the representation from Friends of the Earth on application for a part B consent from BASF Plant Science to release genetically modified potatoes with improved resistance to *Phytophthora infestans* (Application Reference 06/R42/01) in October 2006.

source: <http://www.gmwatch.org/archive2.asp?arcid=7159>

2. Organisation: my choice

Country: Sweden

Comments on the following points:

a. Assessment:

Molecular characterisation

No more GMO with the plants.

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

Stop all GMO experiments.

b. Food Safety Assessment:

Toxicology

I don't want GMO food.

Allergenicity

Think about the future of the world.

Nutritional assessment

Save the potatoes from GMO.

Others

It's a big experiment of the world.

3. Environmental risk assessment

Stop all GMO with potatoes.

4. Conclusions and recommendations

I don't want to be scared when I eat if it's possibly genetically modified.

5. Others

Who gives the industries the right to experiment with the organism?

6. Labelling proposal

It's all about the money.... Who cares.

3. Organisation: University of Helsinki

Country: Finland

Comments on the following points:

b. Food Safety Assessment: Toxicology

Eläinkokeet suppeita, rotilla ilmenneiden verisolu-, perna- ja kilpirauhasmuutosten perusteella olisi tehtävä laajemmat ja pitkäaikaisemmat kokeet. Kokeet on toistettava eläimillä, joiden elinikä on useita vuosia ja altistus tehdään useiden vuosien ajan. Rotat ja hiiret, jotka ovat ihmistä huomattavasti kestävämpiä ravinnon toksineille ja epäpuhtauksille, eivät indikoi riittävästi gm-perunan toksisuutta. Toksisuuskokeita olisi tehtävä useiden vuosien ajan mm. kantaville sioille ja tutkittava muutoksia sekä emissä että porsaissa.

Allergenicity

Allergiaominaisuus tulee esille vasta altistuksen jälkeen, voi kehittyä vuosien kuluessa, joten allergiaominaisuuksien testausta ei voida pitää luotettavana.

Nutritional assessment

Erityisesti 2-tyyppin diabetes lisääntyy koko ajan Euroopassa. GM-peruna voi olla ravinnossa syöjän tietämättä. Pienikin ero vaikutuksessa veren sokerin nousuun voi olla haitallista. Esim. raskaan olevien naisten heikentynyt glukoosinsieto - veren sokeripitoisuus voi nousta helposti liian korkealle "tietämättä" varoa. Puutteellisen tutkimuksen vuoksi ei tule hyväksyä ihmisravinnoksi, eikä rehuntuotantoonkaan koska sekoittumista ihmisravinnoksi tarkoitettuun ruokaperunaan ei voida luotettavasti estää.

3. Environmental risk assessment

Peruna listätään kasvullisesti. Sadosta jää aina mukuloita peltoon, ja gm-peruna voi saastuttaa sen jälkeen viljeltävän muuntelemattoman perunan ja sitä kautta vopi tapahtua tahatonta saastuttamista, jonka kustannukset jäävät yksittäisen viljelijän kannettavaksi. Myös villieläimet voivat kuljetta mukuloita viljelypellon ulkopuolelle, esimerkiksi peurat, villisiat, varikset. Gm-perunan tuottajan läheisyydessä sijaitseva luomutilat kärsivät saastumisriskistä. GM-perunan oikeuksien omistaja ja markkinoillesaattajat olisi saatava taloudelliseen vastuuseen muuntelemattomalle perunalle tapahtuvan saastunnan riskeistä, mikäli gm-peruna saatetaan markkinoille. Riskiä ei voida kattaa julkisin varoin, koska on pelkästään kauppapoliittisin, yksittäisen yrityksen intresseihin perustuva saastuminen (oikeuksien haltija/markkinoille saattaja).

4. Conclusions and recommendations

Toksikologiset, ravitsemukselliset ja allergologiset selvitykset eivät ole riittäviä muuntogeenisen perunan markkinoille laskemisen sallimiseksi. Hakijalta on edellytettävä

tarkempia ja paremmin toteutettuja testejä, joiden tulokset on saatettava julkisesti nähtäville mitään salaamatta ja mitään muuntelematta.

5. Others

Ei hyväksytä kaupalliseen käyttöön

Translation:

b. Food Safety Assessment:

* Toxicology

The limited tests conducted on the basis of blood cell, spleen and thyroid changes observed in rats should be expanded and carried out over longer periods. Tests should be repeated on animals several years old and exposure should last several years. Rats and mice, which are considerably more resistant to toxins and impurities in foods than humans, do not give an adequate indication of the toxicity of GM potatoes. Toxicity tests should be carried out over several years, including on pregnant pigs, and changes should be monitored in both sows and piglets.

* Allergenicity

Allergenicity comes out only after exposure and can develop over years, so that allergenicity tests cannot be considered reliable.

* Nutritional assessment

Type-2 diabetes in particular is increasing throughout Europe. GM-potatoes can be present in food without the eater being aware. Even if they cause only a small increase in blood sugar, this can be harmful. For example, pregnant women have lower glucose tolerance – the blood sugar level can easily rise to too a high level, creating an "unknown" risk. In the absence of adequate research, GM potatoes should not be approved as food for humans, nor in fodder, because mixing with potatoes intended for human consumption cannot be prevented reliably.

3. Environmental risk assessment

Potatoes are vegetatively propagated. After the harvest, tubers are always left in the field and GM potatoes can contaminate non-GM potatoes grown afterwards, causing unintentional contamination, the costs of which have to be borne by the individual farmer. Wild animals, such as reindeer, wild boar and crows, can also carry the tubers out of the field. Farms producing natural produce situated in the vicinity of a producer of GM-potatoes run the risk of contamination. The holder of GM-potato rights and marketers should bear financial liability for the risk of contamination of non-GM potatoes, if GM potatoes are placed on the market. The damage cannot be covered by public funding, because the contamination is purely the result of commercial interests (holder of rights/marketer).

4. Conclusions and recommendations

The toxicological, nutritional and allergenicity studies are not sufficient to allow the GM potato to be introduced onto the market. Applicants must be required to carry out more

detailed and better conducted tests, the results of which should be made public, without any concealment or manipulation.

5. Others

Not approved for commercial use

4. Organisation: None
Country: Sweden

Comments on the following points:

a. Assessment:
Others

Don't modify potatoes genetically.

6. Labelling proposal

Don't modify potatoes genetically.

5. Organisation: none
Country: Germany

Comments on the following points:

6. Labelling proposal

Liebe Leute von der EU, zuerst einmal ist es eine Unverschämtheit, Ihre Veröffentlichungen in einer nicht landesüblichen Sprache zu verfassen. Das nächste Mal die Veröffentlichung, sowie dieses Formular bitteschön auch in deutsch. Ich widerspreche hiermit grundsätzlich jeder Zulassung gentechnisch veränderter Nahrungsmittel. Es ist bekannt, daß Zulassungsunterlagen durch die großen Konzerne regelmäßig gefälscht werden, es ist bekannt, daß ehemalige Mitarbeiter der großen Konzerne in Entscheidungspositionen auch der EU sitzen, es ist ebenfalls bekannt, daß EU-Abgeordnete auch in Entscheidungspositionen 'Ruhegehälter' von Großkonzernen beziehen. Aufgrund dieser Tatsachen kann ausgeschlossen werden, daß jegliche Entscheidungen der EU NICHT dem Wohle des Volkes dienen. mfg Manfred Frimmel

Translation:

6. Labelling proposals

Dear People at the EU,

First of all, it is outrageous that your publications are not in a normal language of the country. Next time please send the publication and this form also in German.

I am fundamentally against any approval of GM foods. It is well-known that approval documentation is regularly falsified by the large concerns, that former employees of those large concerns are now in decision-making positions also in the EU, and that MEPs also in decision-making positions receive "retirement pensions" from large concerns. In view of these facts we can rule out the possibility that decisions taken by the EU will NOT be to the benefit of the people*.

Regards

Manfred Frimmel

* Translator's note: the writer seems to have written the opposite of what he intended. I suggest reading the last sentence without the "NOT".

6. Organisation: Greenpeace

Country: Sweden

Comments on the following points:

a. Assessment:

Molecular characterisation

The molecular data contains numerous irregularities, including several additional unintended fragments. These fragments make the probability of unexpected and unpredictable effects even more likely. The most serious effect of these fragments is that they create an open reading frame (ORF). This means that the DNA can be read (or transcribed), i.e. it could be active. And indeed, it is. ORF 4 is transcribed to the RNA level. This is one step away from producing an unintended protein.

The protein could be produced if conditions change within the potato (e.g. under environmental stress such as drought). Or, the ORF could interfere with the plant's own metabolism, affecting the production and composition of plant proteins. Therefore, it is entirely possible that this GE potato could produce new proteins, or alter existing plant proteins. These unintended or altered proteins would have implications for human food safety if the potatoes became mixed with those intended for human consumption.

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

This GE potato alters a metabolic pathway, that of starch production. Therefore, any changes in metabolism must be treated as potentially adverse effects. These changes are apparent in changes in compositional analysis. Of particular relevance are the unintended changes in sugar content as these are likely to be directly related to the intended changes in starch metabolism. The compositional analysis reveals several unexpected alterations in the potato metabolism:

As EFSA state “In addition to the intended alterations in starch composition of the GM potato, some statistically significant differences between the GM potato and its control were observed each year, including a decrease in yield and dry matter and an increase in sucrose content...and vitamin C content.... Other differences were also noted during single years, but not consistently throughout the three years, such as decreases in glycoalkaloid levels of solanine and chaconine in potato EH92-527-1 during two years.”

Unexpected effects are of utmost importance in potatoes as they have a very complex secondary chemistry, including the production of toxic compounds. The genetic engineering of potatoes is well documented to give rise to unexpected effects:

Birch, A.N.E., Geoghegan, I.E., Griffiths, D.W. & McNicol, J.W. (2002) The effect of genetic transformations for pest resistance on foliar solanidine-based glycoalkaloids of potato (*Solanum tuberosum*). *Annals of Applied Biology*, 140, 143-149. Kuiper, H.A., Kleter, G.A., Noteborn, H.P.J.M. & Kok, E.J. (2001) Assessment of the food safety issues related to genetically modified foods. *The Plant Journal*, 27, 503-528. Matthews, D., Jones, H., Gans, P., Coates, S. & Smith, L.M. J. 2005. Toxic secondary metabolite production in genetically

modified potatoes in response to stress. *Journal of Agricultural and Food Chemistry* 53: 7766-7776.

Experimental GE potatoes to alter carbohydrate levels (in this case sugar rather than starch) found unexpected changes in the levels of toxic compounds in potatoes when they were exposed to stresses such as disease or drought. The authors of the study concluded: "It is clear that genetic manipulation of carbohydrate metabolism and pathogen resistance often leads to changes in the profile of plant defense compounds [i.e. toxins] present in the organs of potato plants including the tubers... At the present time, the mechanisms behind the changes observed in this study are not clear but may include direct effects due to changes in the hexose pool and/or indirect effects due to changes in the susceptibility of the plants to infection and infestation."

Despite this, EFSA simply state

"The GMO Panel concludes that the observed differences are unlikely to cause adverse health effects."

If the fruit juice and fruit water and/or pulp are to be spread on fields, soil, livestock and wild organisms will be exposed to the GE potato. However, even though significant differences have been found with the chemical composition of GE potatoes, their potential is disregarded. No studies have been conducted biogeochemical processes, e.g. soil carbon and nitrogen turnover, although any change in microbial ecology could affect soil fertility and be important.

There are no assurances of human food safety should these potatoes become mixed with conventional potatoes. Nor are there any assurances for animal feed safety, nor safety for the by-products to be spread on the fields. Alterations of the levels of normal plant toxins are to be expected. If the levels of these toxins increase, there could be dangers to animal and human health.

b. Food Safety Assessment: Toxicology

In animal feeding trials, significant differences were noted but disregarded by EFSA:

"In female animals, statistically significant differences in white blood cells and spleen weight were noted between animals that were fed the transgenic potato and those given a diet containing the parental cultivar. However, these differences fell within the range of values observed in animals fed the standard rodent laboratory diet. Moreover, these changes were not accompanied by any changes in other lymphoid organs besides the spleen."

These significant differences should have been fully investigated to see if they are of importance to human and animal health.

3. Environmental risk assessment

The list of insects, bacteria and fungi that interact with potatoes in Europe is extremely long. It is likely that potato cultivation plays a role in European agro-ecology. However, there is no systematic analysis of the possible risks to biodiversity from this GE potato. In particular,

long terms sub chronic effects and effects at different trophic levels should be considered. The changes in metabolism make it likely that would be changes in the interaction of insect-potatoes and this could have effects up eh food chain.

However, EFSA disregard this important impact of cultivation of the potato. EFSA simply state that “The results of field studies suggest neither greater susceptibility nor greater resistance to pests and diseases than non-GM potato lines.”

This assessment is from an agronomic rather than biodiversity perspective. This is unacceptable. EFSA do not even make possible adverse effects on biodiversity (for example, by selecting key indicator insect species) the subject of case-specific monitoring.

The ecological implications of cultivation of this GE potato remain unknown.

4. Conclusions and recommendations

EFSA’s opinion of the suitability of GE potato with altered starch composition is inadequate. There are many irregularities that could have implications for food safety. These irregularities are simply dismissed by EFSA.

In conclusion: 1) The molecular data demonstrates that it is entirely possible this GE potato could produce new proteins, or alter existing plant proteins. These unintended or altered proteins would have implications for human food. 2) Compositional data shows unexpected changes in potato chemistry. Alterations of the levels of normal plant toxins are to be expected. If the levels of these toxins increase, there could be dangers to human and animal health. 3) Significant differences found in toxicological studies should be fully investigated to see if they are of importance to human and animal health. 4) The ecological implications of cultivation of this GE potato remain unknown. Effects on biodiversity have not been considered. 5) Antibiotic resistance is unacceptable.

6. Labelling proposal

The GE potato contains an nptII gene for resistance to the antibiotic, kanamycin. This has potential to transfer from plant material to microbes in the soil, during cultivation or afterwards as potato juice is to be used as a fertilizer. Gene transfer would increase bacterial resistance to this antibiotic, reducing the effectiveness of this antibiotic.

EFSA simply state consider “any additional contribution from potential transfer to soil microbes is considered to be insignificant.”

Antibiotic resistance is unacceptable.

7. Organisation: Consiglio dei Diritti Genetici

Country: Italy

Comments on the following points:

a. Assessment:

Molecular characterisation

Concerning the insert (repeated sequences and palindromes) and genomic insertion site configuration (into a highly repeated region), it would be necessary to verify the insert stability also after sexual reproduction, although such a procedure isn't common in agriculture. Moreover, regarding the previous molecular characterization of the insert, which has been continuously revised since 1998, leading to continuously revised incoherency, a third party molecular analysis is strongly suggested.

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

The potato EH92-527-1 was grown in trials in many locations, but only in Sweden: we believe that these tests are not representative of the whole European area where this kind of potato could be grown. Moreover, the compositional analysis show that there are statistically significant differences in some compounds, between the GM potato and the conventional potato used as control. It means the biochemical pathway of the potato EH92-527-1 has been changed.

b. Food Safety Assessment:

Toxicology

Toxicological analysis on rats show clear and worrying physiological and morphological modification: for example there are statistically significant differences in leukocytes and in the weight of the spleen between female of rats fed with potato EH92-527-1 and conventional potato; there is an increase in problems at the thyroid in male fed with potato EH92-527-1. For all these reasons there are reasonable doubts on the food safety of the GM potato we are considering.

Allergenicity

No allergenic analysis were made. The absence of allergenicity was demonstrate using deductive studies. We believe there should be analysis using the whole plant to verify the possibility of allergenicity.

3. Environmental risk assessment

Considering the characteristics of the GM potato EH92-527-1 and scope of the notification (no cultivation) there should not be many environmental risks. There should be a particular

attention to avoid the vegetative propagation, that is possible if there should be the permanence in the soil of little parts of potato.

6. Labelling proposal

We believe that the documentation we could obtain from EFSA is lacking: after request to EFSA we didn't receive the documents referred to the requests made by Member States and by GMO Panel.

8. Organisation: GLOBAL 2000/Friends of the Earth Austria

Country: Austria

Comments on the following points:

a. Assessment:

Molecular characterisation

We have no access to scientific data but only to "statements" of the applicant and EFSA. Thus we only can comment on the statements but not on the quality of the scientific data. The molecular characterization is not completed Open reading frames and their transcription are not described in details . Inconclusive illogic Assessment by EFSA EFSA says that there are up to 18 open reading frames. No information is given if this open reading frames are transcribed i.e. are producing RNAs. In the risk assessment of NK603 (EFSA 2003) EFSA touches the issue of risks from RNAs transcribed from open reading frames of the insert. In contrast to the opinion of EFSA on NK603 (EFSA 2003) EFSA is silent on risks of RNAs transcribed form open reading frames. EFSA gives no reason why risks from RNAs are not addressed in the risk assessment of the GM-starch potato.

References EFSA (2003) Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Notification (Reference CE/ES/00/01) for the placing on the market of herbicide-tolerant genetically modified maize NK603, for import and processing, under Part C of Directive 2001/18/EC from Monsanto. The EFSA Journal 10: 1-13

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

No scientific data was presented but only interpretations by EFSA and BASF the applicant.

b. Food Safety Assessment:

Toxicology

Although EFSA states "since it cannot be excluded that the GMO potato and derived products may be used as or may be present in food" no assessment of long term impacts i.e chronic toxicity test = 24 months studies as required by directive 2001/18/EC There is no assessment of and regulation 178/2002 has been undertaken. "cumulative long term effects on human health" (Annex II Directive 2001/18) and Article 14, Regulation EC178/2002, Chronic toxicity test = 24 month studies are lacking. Thus this application does not meet the legal requirements of Directive 2001/18/EC and Regulation EC178/2002, Article 14.

Allergenicity

The allergenicity assessment is insufficient. (Spok et al 2005)

EFSA soley focus on allergenicity of proteins and does no investigate potential allergenicity of RNAs of the insert and from RNAs of the 18 open reading frames. Since 20 years it is

known that also RNAs can trigger allergic reactions (NAGPAL 1987). At least 18 new RNA molecules in the GM-potato which can trigger allergic reactions have not been investigated. Besides that RNA very quite heat stable. This new RNAs will reach consumers (starchy food products) and livestock (by products of the processing is determined as feed).

References: Nagpal S, Metcalfe DD, Rao PV (1987) Identification of a shrimp-derived allergen as tRNA. *The Journal of Immunology* 138(12): 4169-4174. Spok A, Gaugitsch H, Laffer S, Pauli G, Saito H, Sampson H, Sibanda E, Thomas W, van Hage M, Valenta R (2005) Suggestions for the assessment of the allergenic potential of genetically modified organisms. *Int Arch Allergy Immunol* 137(2): 167-180.

Others

The applicant and EFSA want consumers and politicians make believe the GM potato is mainly for industrial purposes. But this is false. The applicant states that amylopectin the main source of the potato is used in starchy food products. BASF says that BASF intends the use in non food starch industry but it does not preclude to sell amylopectin to the food industry. Thus amylopectin from the GM potato will find its way to the consumer.

3. Environmental risk assessment

* here is no case by case risk assessment of environmental effects. EFSA has based its decision on assumptions but not on hard scientific facts. * There is no assessment of "cumulative long term effects on human health, soil fertility, flora fauna" (Annex II Directive 2001/18)) Thus this applications does not meet the legal requirements. Instead of testing effects on non-target organisms EFSA is citing tests on susceptibility of the GM potato. Such tests are so called product development tests, to investigate the performance of the crop. But based on the information provided of BASF and EFSA it was not investigated how the potato is effecting the abundance and survival of non target organisms. It is a non scientific way how EFSA wants to sell product performance test as test on the effects of the environment. It seems EFSA is promoting the potato rather than making an assessment.

4. Conclusions and recommendations

Conclusion are based on assumptions and not on scientific hard data. Important data on chronic toxic effects etc. see above is missing. Thus the conclusion made by EFSA is wrong. On the bases that mayor data is lacking the safety of the GM potato as compared to its parental non Gm cultivar cannot be assured.

The potato contains a kanamycin resistant gene. In accordance with article 4 (2) of Regulation Nr. 2001/18/EC on the deliberate release into the environment of genetically modified organisms, the identifying and phasing out of antibiotic resistance markers in GMOs should take place by the 31 December 2004 in the case of GMOs placed on the market according to part C (see also Comment form Danish Competent Authority (Danish Forest and Nature Agency)). As the potato contains a kanamycin resistant gene the approval of the potato would be against the law..

Furthermore uncertainties have not been addressed by EFSA. This infringes against COMMISSION DECISION (2002/623/EC) of 24 July 2002 establishing guidance notes

supplementing Annex II to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/269/EEC

Summary: 5 very important risk issues were not addressed by EFSA

1. long term effects on human health
2. long term effects on environment
3. molecular characterization of the insert
4. Risks from RNAs on the immune system
5. Allergenic effects of RNAs from open reading frames of the Gm potato

5 very important legal requirements are not met by European Food Safety Authority (EFSA) while assessing the GM potato of BASF

1. Annex II Directive 2001/18/EC (no long term effects on human health)
2. Annex II Directive 2001/18/EC (no long term effects on environment)
3. Article 14 Regulation 178/2002 (no long term assessment human health)
4. Article 4 (2) Directive 2001/18/EC (no phase out of products carrying antibiotic marker kanamycin)
5. COMMISSION DECISION (2002/623/EC) (no uncertainty assessment)

General conclusion. The approval of the genetically modified potato EH92-527-1 with altered starch composition, for production of starch and food/feed uses from BASF is neither scientific nor legally justified. Council Directive 90/220/EEC

6. Labelling proposal

There are a number of member states comments which are scientifically valid. The way EFSA responds to the comments of member states (e.g. response on comments from Austria, Germany, Denmark) is not based on science. EFSA downplays risk issues raised from member states but does not provide any scientific reference to justify the downplaying response. When EFSA is allowed to continue to provide scientific opinions in such an unscientific way and not to sort out different scientific views the whole procedure of risk assessment is not in line with legal requirements on a science based decision.

9. Organisation: private
Country: Germany

Comments on the following points:

a. Assessment:
3. Environmental risk assessment

Due it is not shure that all possible risks that may occure when planting GMO out in nature, I recomend to research this first as complete as possible before allowing setting free this GMO. See also the report of the European Communities - Measures Affecting the Approval and Marketing of Biotech Products (DS291,DS292,DS293 28January 2005)

10. Organisation: ifrik
Country: The Netherlands

Comments on the following points:

a. Assessment:
Molecular characterisation

The transgenic insert created a number of Open Reading Frames (ORFs), one of which (ORF4) has been transcribed. This is only one step away from the actual translation into a novel protein. Even though this protein could not found in the potato plants tetested, it cannot be excluded that the mRNA of ORF4 will be translated in other circumstances. The potential ORF4 protein has high similarity to two bacterial proteins, one of which is the bleomycin resistance protein. Bleomycin is used in cancer treatment.

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

In contrast to other GM crops modified to produce an additional protein as Bt toxin or for herbicide tolerance, this GM potato is modified in such a way that a normal pathway to produce starch is blocked. This means that precursors accumulate in the cells. Higher sugar levels confirm this, but it is unclear how that effects on the plant metabolism and what happens with the accumulating sugars that cannot be turned in starch any more. If the fruit juice and fruit water and/or pulp are to be spread on fields, soil, livestock and wild organisms will be exposed to the GM potato. However, even though significant differences have been found with the chemical composition of GE potatoes, their potential is disregarded. No studies have been conduced biogeochemical processes, e.g. soil carbon and nitrogen turnover, although any change in microbial ecology could affect soil fertility and be important.

b. Food Safety Assessment: Toxicology

Only two feeding studies were conducted. Both trials used potato products, so there is no toxicological study with the fresh tubers. During cultivation, wild animals can feed on the fresh tubers, and in cases of contamination farm animals and humans can also consume fresh tubers. It is therefore not sufficient that only studies are conducted with potato products. In a 90-day feeding study with rats with as little as 5% freeze dried potatoes in the diet. Still, significant differences were noted but disregarded by EFSA. The GM potato is modified to change its metabolism, and changes in composition were recorded. It is therefore essential that significant differences in toxicology studies are followed up in order to exclude that these differences are caused by changes in the GM potato metabolism. In the other trial, 2x16 cows were fed with potato pulp for 8 weeks to measure weight gain. This study has been criticized for a number of methodological mistakes. It only focused on the nutritional value of the GM potato measured in weight gain, but did not record any toxicological parameters and can therefore not be used to evaluate whether the GM potato is safe for consumption. This study only shows that there are no bigger acute or short term effects from the consumption of GM potato pulp. The two feeding trials are insufficient to declare the GM potato safe for consumption.

3. Environmental risk assessment

Antibiotic resistance The GM potato contains an nptII gene for resistance to the antibiotics kanamycin, neomycin, paromomycin, ribostamycin, butirosin, gentamicin B and geneticin (G418). Antibiotic resistance has potential to transfer from plant material to microbes in the soil, during cultivation or afterwards as potato juice is to be used as a fertilizer. Gene transfer would increase bacterial resistance to this antibiotic, reducing its effectiveness. Neomycin is used in veterinary treatment. Kanamycin is listed in the WHO Essential Medicines Library as a drug against multi-drug resistant tuberculosis. This kind of tuberculosis is a growing problem worldwide and the potential need to use kanamycin should therefore be taken seriously.

Impacts on biodiversity The list of insects, bacteria and fungi that interact with potatoes in Europe is very long, but the information provided as e.r.a. is insufficient to assess possible impact on the environment. Only one environmental trial is provided, studying the number of arthropods in trail plots. This study has a number of flaws, but the worst is probably that in this trial – designed to study insects – the potato plants were repeatedly treated with insecticides. In addition data is provided from variety testing suggesting that there is "no greater susceptibility nor greater resistance to pests and diseases, nor is there a change in sensitivity to a number of potato associated viruses." This study is obviously a performance study of the GM potato's pest and disease susceptibility. It therefore focuses on the GM potato but not on the actual effects on the organisms in question. Only a summary of the results is provided but no raw data – and the notifier points out that they themselves do not have access to this data. The assumption is put forward, that "none of the modifications will make the potatoes more or less attractive to insects, mammals or birds" but there is no data to back this. The composition of the GE potato is different with higher sugar and Vitamin C levels, and there is no study about the attractiveness of this modified potato. None of the feeding studies were conducted with the fresh potato tubers, so these studies give no indication on possible effects on mammals in the wild. No studies at all were conducted with birds.

Decomposition The different starch composition can also result in a different decomposition. EFSA state in its opinions that "GM tubers have a different starch composition, and therefore may be decomposed by a changed microbial community." These effects are not studied at all, but need to be studied as part of an e.r.a.

The lack of appropriate information makes it impossible to judge the environmental impacts of this GMO.

11. Organisation: Biodynaaminen yhdistys ry - Biodynamiska föreningen ry. Country: Finland

a. Assessment:

Others

Biodynaaminen yhdistys ry ilmoittaa kantanaan geeniperuna EH92-527-1 suhteen seuraavaa: Maatalous ei tällaista perunaa tarvitse eikä kukaan viljelijä sitä halua. Ainoa joka sitä tarvitsee on BASF markkinoidensa kasvattamiseen. Kymmenen rotan populaatiolla suoritettu 90 päivän ruokintakoe ei anna ei mitään luotettavaa tietoa perunan mahdollista haittavaikutuksista. Viitteet haitallisista muutoksista edellyttäisivät vähintään kolmen sukupolven koettaa huomattavasti suuremmalla populaatiolla. Me emme jaa tiedemiesten uskoa perunan harmittomuuteen pitkän ajan käytössä. Koska tästä geenimuunnellun perunan mahdollisista haittavaikutuksista ja ympäristöriskeistä ei ole riittävästi tieteellistä tutkimusta, vaadimme että perunaa ei saa laskea viljelyyn ja markkinoille.

Translation:

Biodynaaminen yhdistys ry (Biodynamic Association.) will express as its opinion of the GM potato EH92-527-1 as follows:

The agriculture does not need a potato such as this and none of the farmers wants it. The only one who needs it is BASF in order to grow its markets. The feeding test of 90 days with the population of 10 rats does not give any reliable information about the possible ill-effects of the potato. The references of the harmful alterations would provide at least a test with a considerably bigger population during three generations. We do not share the scientists' belief in the harmless nature of the potato in a long standing use. Because there is no sufficient scientific research about the possible harmful alterations and environmental risks of this GM potato, we demand that the GM potato will not be brought under cultivation or put on the market.

12. Organisation: Greenpeace EU Unit Country: Belgium

a. Assessment: Molecular characterisation

The molecular data demonstrates that it is entirely possible this GE potato could produce new proteins, or alter existing plant proteins. These unintended or altered proteins would have implications for human food safety if the potatoes became mixed with those intended for human consumption.

The molecular data contains numerous irregularities, including several additional unintended fragments. These fragments make the probability of unexpected and unpredictable effects even more likely. The most serious effect of these fragments is that they create an open reading frame (ORF). This means the DNA can be “read” (or transcribed), i.e. it could be active. And indeed, it is. ORF4 is transcribed to the RNA level. This is one step away from producing an unintended protein.

Instead of this raising the alarm on this GE potato, EFSA state

“Extensive studies indicated that, although ORF4 transcript is detectable in the GM potato, there is no corresponding translation into a protein, confirming expectations from the molecular characterisation of ORF4.”

But this is a gross oversimplification. The protein could be produced if conditions change within the potato (e.g. under environmental stress such as drought). Or, the ORF could interfere with the plant’s own metabolism, affecting the production and composition of plant proteins.

Therefore, it is entirely possible that this GE potato could produce new proteins, or alter existing plant proteins. These unintended or altered proteins would have implications for human food safety if the potatoes became mixed with those intended for human consumption.

b. Food Safety Assessment: Toxicology

Compositional data shows unexpected changes in potato chemistry. Unexpected effects are of utmost importance in potatoes as they have a very complex secondary chemistry, including the production of toxic compounds. The genetic engineering of potatoes is well documented to give rise to unexpected effects (Birch, A.N.E., Geoghegan, I.E., Griffiths, D.W. & McNicol, J.W. (2002) The effect of genetic transformations for pest resistance on foliar solanidine-based glycoalkaloids of potato (*Solanum tuberosum*). *Annals of Applied Biology*, 140, 143-149).

Alterations of the levels of normal plant toxins are to be expected. If the levels of these toxins increase, there could be dangers to human and animal health. Significant differences found in

toxicological studies should be fully investigated to see if they are of importance to human and animal health.

This GE potato alters a metabolic pathway, that of starch production. Therefore, any changes in metabolism must be treated as potentially adverse effects. These changes are apparent in changes in compositional analysis. Of particular relevance are the unintended changes in sugar content as these are likely to be directly related to the intended changes in starch metabolism. The compositional analysis reveals several unexpected alterations in the potato metabolism:

As EFSA state “In addition to the intended alterations in starch composition of the GM potato, some statistically significant differences between the GM potato and its control were observed each year, including a decrease in yield and dry matter and an increase in sucrose content...and vitamin C content.... Other differences were also noted during single years, but not consistently throughout the three years, such as decreases in glycoalkaloid levels of solanine and chaconine in potato EH92-527-1 during two years.”

Experimental GE potatoes to alter carbohydrate levels (in this case sugar rather than starch) found unexpected changes in the levels of toxic compounds in potatoes when they were exposed to stresses such as disease or drought. The authors of the study concluded: “It is clear that genetic manipulation of carbohydrate metabolism and pathogen resistance often leads to changes in the profile of plant defense compounds [i.e. toxins] present in the organs of potato plants including the tubers... At the present time, the mechanisms behind the changes observed in this study are not clear but may include direct effects due to changes in the hexose pool and/or indirect effects due to changes in the susceptibility of the plants to infection and infestation.” (Matthews, D., Jones, H., Gans, P., Coates, S. & Smith, L.M. J. 2005. Toxic secondary metabolite production in genetically modified potatoes in response to stress. *Journal of Agricultural and Food Chemistry* 53: 7766-7776.)

Despite this, EFSA simply state

“The GMO Panel concludes that the observed differences are unlikely to cause adverse health effects.”

If the fruit juice and fruit water and/or pulp are to be spread on fields, soil, livestock and wild organisms will be exposed to the GE potato. However, even though significant differences have been found with the chemical composition of GE potatoes, their potential is disregarded. No studies have been conducted on biogeochemical processes, e.g. soil carbon and nitrogen turnover, although any change in microbial ecology could affect soil fertility and be important.

In animal feeding trials, significant differences were noted but disregarded by EFSA:

“In female animals, statistically significant differences in white blood cells and spleen weight were noted between animals that were fed the transgenic potato and those given a diet containing the parental cultivar. However, these differences fell within the range of values observed in animals fed the standard rodent laboratory diet. Moreover, these changes were not accompanied by any changes in other lymphoid organs besides the spleen.”

These significant differences should have been fully investigated to see if they are of importance to human and animal health.

Several member states have demanded a monitoring plan regarding food and feed. However, the EFSA GMO Panel has stated that «the opinion of the applicant that a post-market monitoring of the GM food/feed is not necessary (...) is shared by the GMO panel ». This is unacceptable.

Allergenicity

The GM potato contains an antibiotic resistance marker gene (ABRM) which leads to resistance to a range of antibiotics, inter alia kanamycin and neomycin. This has potential to transfer from plant material to microbes in the soil, during cultivation or afterwards as potato juice is to be used as a fertilizer. Gene transfer would increase bacterial resistance to this antibiotic, reducing the effectiveness of this antibiotic.

In the comments and opinions submitted by Member States for the approval of the GM potatoes for food and feed uses under Regulation 1829/2003, competent authorities from several member states have expressed their concerns regarding the use of the ABRM gene in the GM potato.

According to EFSA, the use of the nptII gene in transgenic plants represents no safety risk to human health and the environment, as the above mentioned antibiotics have only been used to a minor extent in human and veterinary medicine. However, according to the WHO, the antibiotics kanamycin, neomycin and gentamicin are by no means regarded as insignificant, but rather have been classified as “critically important” (Critically important antibacterial agents for human medicine for risk management strategies of non-human use, WHO, 2005).

According to Art. 4 of Directive 2001/18, ABRM in GMOs which may have adverse effects on human health and the environment should have been phased out by the end of 2004. The deadline passed two years ago, and no official declaration has been made. This is unacceptable and no GMO with ABRM should be authorised until the European Commission has ensured that the requirements under 2001/18 are met.

3. Environmental risk assessment

The ecological implications of cultivation of this GE potato remain unknown. Effects on biodiversity have not been subject of the risk assessment.

The list of insects, bacteria and fungi that interact with potatoes in Europe is extremely long. It is likely that potato cultivation plays a role in European agro-ecology. However, there is no systematic analysis of the possible risks to biodiversity from this GE potato. In particular, long terms sub chronic effects and effects at different trophic levels should be considered. The changes in metabolism make it likely that would be changes in the interaction of insect-potatoes and this could have effects up the food chain.

Several member states raised concerns that there are no studies about the safety of the GM potato to plant-associated organisms and to biochemical processes, nor are there data available from the whole of Europe.

The EFSA GMO Panel simply stated that « from the information supplied by the applicant, and from studies of relevant literature, there are no indications that this potato will cause adverse environmental impacts in the EU» and “the results of field studies suggest neither greater susceptibility nor greater resistance to pests ...and diseases ... than non-GM potato lines.” EFSA refers to the company’s field studies, mainly performed in Sweden, on research

on the agronomic performance of the GM potato which is completely irrelevant for the environmental risk assessment of the GM potato on insects, wildlife and soil.

EFSA do not even make possible adverse effects on biodiversity (for example, by selecting key indicator insect species) the subject of case-specific monitoring.

4. Conclusions and recommendations

There are no assurances of human food safety should these potatoes become mixed with conventional potatoes. Nor are there any assurances for animal feed safety, nor safety for the by-products to be spread on the fields. Alterations of the levels of normal plant toxins are to be expected. If the levels of these toxins increase, there could be dangers to animal and human health. The GM potato contains an antibiotic resistance marker gene which is unacceptable.

Potatoes are considered low risk plants for coexistence since the probability of gene flow between the GE potato and conventional potato is regarded as minimal. However, all potato crops have volunteer growth. These volunteers can produce tubers, which could end up in the human food chain. GM potato regrowth due to overwintering of volunteers is a serious issue and would contaminate future crops. Furthermore, contamination due to accidental spillage or release of tubers during transport and handling needs cannot be ignored.

GM potato EH92-527-1 should not be authorised on the grounds of poor quality of the data submitted by the applicant, low scientific standards, lack of adequate monitoring and lack of EU-wide safeguards against GM contamination in place. The fact that this potato will not be used for human consumption, but for industrial compounds, should in no case be an excuse to compromise on the environmental and health risks assessment.