Public Comments for Part C Assessment Report to Notification C/SE/96/350

Potato variety EH92-527-1 with modified starch content

> -----Original Message-----
> From: [redacted]
> Sent: 31 May 2004 16:40
> To: gmoinfo-comments@jrc.it
> Subject: Comment on Assessment Report C/SE/96/3501
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> Please find attached [redacted] technical comments on the GE potato
> clone EH92-527-1.
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> ----------
> [redacted]

mailto:gmoinfo-comments@jrc.it Subject=Comment on Assessment ReportC/SE/96/3501

[redacted] technical comments on: notification for placing the potato clone EH92-527-1, being genetically modified for increased content of amylopectin, on the market (C/SE/96/3501)

[redacted] is opposed to the deliberate release of GE crops regardless whether the release occurs within or outside the EU. This application is for the cultivation of GE potato intended for industrial use and animal consumption. There are important implications for both the environment and animal health associated with this maize which should result in a rejection of this application.

This particular application should be rejected on the grounds that:

1. **The molecular data shows many irregularities, including rearrangements, deletions and a transcribed reading frame.**
2. **The compositional analysis shows many significant differences attributed to yield. The GE potatoes are certainly not "substantially equivalent".**
3. **The ecological interactions of the GE potatoes have not been investigated.**
4. **The potato contains the antibiotic resistance marker gene, nptII.**
5. **There are no feeding trials, even though the application includes use of a by-product for animal feed.**
6. **Cultivation could contaminate non-GE potato crops.**

7. **There could be contamination of human food – with repercussions similar to the Starlink debacle.**

1) Molecular data

The molecular data contains numerous irregularities. The most serious is that an open reading frame (ORF 4) is transcribed to the RNA level. This is one step away from producing an unintended protein/peptide. The complex post transcriptional and post translational modifications that occur in eukaryotes may prevent detection of a translation product. Some proteins are formed in large molecular precursors to proteins, which are then cut to yield the final protein or proteins. These are then cut down to a final protein or proteins by specialised enzymes or proteases[1]. This process could occur within the protein(s) formed by the open reading frame (or at least, no evidence has been presented to suggest this has not happened). **Therefore, it is entirely possible that proteins other than those analysed for are produced by the open reading frame but these have not been detected, as they have not been looked for.**

The e.r.a. acknowledges that the deletions and rearrangements during the GE process may cause changes:
"*The integration itself could theoretically lead to changes that could influence the estimation of health and environmental risks. The risks that are connected with changes in the T-DNA at the introduction into the plant and a potential introduction of DNA from the vector outside the T-DNA can be dismissed after a complete sequencing of the introduced DNA and analyses of potential presence of DNA from the vector outside T-DNA. Endogenous genes may also have been knocked out, have changed expression level, or been fused with other endogenous genes, as a consequence of the introduction of the T-DNA.*"

But then says that this is not of consequence because "*This could happen as a consequence of T-DNA introduction in an already present gene or by rearrangements in connection with the introduction itself.*" and "*Such effects may also arise as a consequence of normal mutations and are thus nothing that especially distinguishes EH92-527-1 from conventional potatoes.*" However, in this GE potato, such rearrangements are under the control of a strong promoter, raising the possibility that they are expressed to an extent that they wouldn't be in a non-GE variety.

There do not, as yet, appear to have been any investigations on whether rearrangements of the DNA adjoining the insert have been undertaken. Flanking sequences at both ends of the primary insert and each unintended fragment must be compared with genomic sequences from the non-GE line to establish whether or not there are further rearrangements of the genome.

2) Compositional analysis

The are several significant differences noted in the compositional chemistry, in addition to the intended modification to starch. These include: vitamin C, saccharose, glucose and fructose, nitrates, digestible fibres, chlorogenic acid. These differences are all attributed to yield, which itself it attributed to the changes made by the genetic modification. However, this is an unverified assumption. The hypothesis should be

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[1] see, e.g. Lewin, B. (2000) Genes VII. Oxford University Press, Oxford, UK.

backed up, e.g. with a mass balance of the biochemical pathways involved. It is critical that the large number of significant differences should be examined in further depth. Even taking yield into account, there are significances differences in the vitamin C. The potatoes cannot be considered "substantially equivalent", especially as yield has been taken into consideration in the comparison.

If the potato pulp is to be used as animal feed, the differences in chemical composition would be extremely important on a weight basis, regardless of yield. Therefore, the differences in chemical composition, must be evaluated independently of yield.

What else might vary?
Potatoes have a very complex secondary chemistry. The genetic engineering of potatoes is well documented to give rise to unexpected effects[2,3,4]. With all these differences in chemical composition, there could be other, as yet, unanalysed components that may vary in an undesirable way. This GE potato, like other GE organisms, is subject to unexpected and unpredictable effects and should therefore not be released into the environment.

3) Ecological Interactions
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 analysis of the possible risks to biodiversity from this GE potato. No biodiversity studies appear to have been conducted during field trials. This is a major flaw in the risk assessment process. If a risk is not identified, it cannot be assessed.

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 conduced biogeochemical processes, e.g. soil carbon and nitrogen turnover. The e.r.a. simply states "*A detailed investigation of effects on the micro-flora before placing on the market or in a monitoring program would not be proportional to the possible risk from the putative detection of a minor difference in micro-flora composition.*"
However, any change in microbial ecology could affect soil fertility and be of the utmost importance.

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[2] Documented in 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. Table 6.
[3] 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.
[4] 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.

4) Antibiotic resistance

Appendix 1 of the dossier states "*The results from this study indicate that intact DNA fragments possibly can be found in the pulp directly after the starch processing. The DNA fragments can remain intact if the pulp is stored cold, while the DNA fragments probably degrades fast if pulp is stored at room temperature.*" Therefore, DNA from the GE potato, including the kanamycin resistance gene nptII, could be spread over the fields thus potentially increasing bacterial resistance to this antibiotic. The use of antibiotic marker genes is unacceptable.

5) Animal feed

It states clearly in the SNIF (pg. 2), the main application (pg. 37) and the e.r.a. (11 – Health risk assessment), that the potato pulp is to be used as an animal feed. However, no feeding trials or toxicity tests have been conducted. This is simply unacceptable, especially as the differences in chemical composition noted above would be extremely important on a weight basis, regardless of yield.

6) Contamination of non GE potato crops

Whilst potatoes may not form hybrids with wild relatives in the EU, there is still a risk of contamination, both of non GE potatoes and potatoes intended for human/animal food uses:

"*The [potato] crop is planted with seed tubers rather than true seed so a GM contaminant would not be transmitted to progeny crops. However in less developed areas of the world TPS has a considerable number of benefits and as such has been utilised in commercial potato production (Askew, 1993) so that cross-pollination could lead to contamination of subsequent crops. In addition varieties prone to producing fertile berries would be exposed to contaminating GM pollen, providing a source for GM volunteers.*

Volunteer potatoes appear to occur in virtually all crops to a greater or lesser extent on all farms where potatoes are grown in the rotation (Askew, 1993). The risk of a GM potato plant being integrated with a conventional crop could arise if volunteer tubers and plants are allowed to persist. In crop production systems, volunteer tubers and plants are usually removed with the production practices that are normally used for potatoes and the crops that succeed potatoes in the rotation though this can be difficult to achieve, especially in areas of TPS production. In recent years, the combination of reduced herbicide rates throughout the rotation due to declining arable margins, a succession of mild winters and the use of vigorous potato varieties has increased the numbers of volunteer potatoes."[5]

7) Contamination of human food - lessons from Starlink

It is incredible that the EC would consider authorising a GE crop intended for industrial/animal feed use, but not human use. Have regulatory authorities nothing

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[5] Eastham, K. & Sweet, J. (2002) Genetically modified organisms (GMOs): the significance of gene flow through pollen transfer. European Environment Agency (EEA). Copenhagen, Denmark. March 2002.

the Starlink debacle[6] in 2000 in North America? A crop not authorised for human use by the regulatory authorities, it can still end up in human food. Aventis' Starlink was not approved for human consumption, only for animal feed and industrial purposes but was found to be present in corn taco shells and other corn products leading to a withdrawal of over 300 corn products in 2000. In addition, traces of Starlink corn were found in corn products in Japan and Korea. It is not known how Starlink came to be in the human food chain, it may have been a mix-up at a mill, cross-pollination or a framer passing off corn intended for animal use to get a higher price[7]. This episode proves that GE crops cannot be controlled, a risk assessment cannot be conducted for extreme or unlikely events or human error. The precautionary principle should be used and the GE potato rejected.

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[6] Segarra, A.E. & Rawson, J.M. (2001) StarLink™ Corn Controversy: Background. CRS (Congressional Research Service) Report no. RS20732. Available at: http://www.cnie.org/nle/crsreports/agriculture/ag-101.cfm

[7] Boyce, N. (2000) Taco trouble. New Scientist, 7th October 2000, p. 6.

> -----Original Message-----
> From: [redacted]
> Sent: 03 June 2004 14:18
> To: gmoinfo-comments@jrc.it
> Subject: Comment on Assessment ReportC/SE/96/3501
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> Please find attached the [redacted] comments on C/SE/96/3501.
>
>
> [redacted]
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> Visit the [redacted] eb site at [redacted]
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Comments by [redacted] to 2001/18/EC marketing application reference C/SE/96/3501

(June 2004)

[redacted] has a number of concerns regarding the application C/SE/96/3501 for GM potato line EH92-527-1 made under Part C of Directive 2001/18/EC. Our concerns reflect both the regulatory procedures and the quality of the application. Specifically our concerns are;

- **pulp from the potatoes will be fed to livestock and therefore the application should be made under Regulation (EC) No.1829/2003.**

- **starch is commonly used in the food industry, indeed it is the intention of BASF Plant Science GmbH to ultimately use this amylopectin within food. Consent should not therefore be given until a full food safety assessment has been undertake and authorisation has been received under Regulation (EC) No.1829/2003.**

- **GM crops should containing an antibiotic resistance marker genes should not be given consent under part C of 2001/18/EC or under Regulation (EC) No.1829/2003.**

- **the field trials do not properly assess the direct and indirect effects of the GM potatoes on the surrounding flora and fauna and have been carried out within only one EU country.**

- **there has not been a satisfactory explanation of the differences in composition between the GM and non-GM potatoes.**

The application should be made under Regulation (EC) No.1829/2003 on genetically modified food and feed.

BASF Plant Science Holding GmbH clearly state a number of times that the pulp derived from the potato line EH92-527-1 will be fed to livestock as feed. This pulp would be considered a GM feed by the EU. It therefore should be subject Regulation (EC) No.1829/2003

Additionally, in the 'Market Introduction Plan' the application states ;

So far the amylopectin starch is intended to serve the paper industry, mainly the paper producers and chemical companies working in the area of paper chemicals. After the amylopectin starch is placed on the market it is highly likely that starch processors as well as customers will find new areas of application. This was also the case for maize amylopectin starch...

... Currently amylopectin starch from maize is used in non-food as well as in food applications. It is expected that these markets currently served by maize amylopectin starch will be addressable by potato amylopectin starch too. While exploration of such uses may be envisaged, it is the intention of BASF Plant Science to serve the non-food starch markets with the amylopectin starch derived from event EH92-527-1.

This passage clearly states that BASF Plant Science intend to ultimately use the amylopectin starch for a wide variety of uses inlcuding food. Whilst they indicate it is not intended as a food product, they do not give a strict undertaking that it will not be used for human food. If the ultimate aim is to use the amylopectin starch as a human food this application should be made under Regulation (EC) No.1829/2003.

The use of antibiotic resistance gene NptII

The use of antibiotic resistance genes within the GM potato line EH92-527-1, is unnecessary for the final product. There have been a number of concerns raised about the use of these genes[8]. BASF Plant Science Holding GmbH argue that the amount of protein produced by this gene is so low as to have no effect even if it were to be transferred to soil borne bacteria or mammalian guts. However, the use of NptII gene, as a marker gene in the development of GM crops, is very common. If many GM crops containing the NptII were to be grown within a given region associated risks and effects would be greatly increased.

GeneWatch considers there is no justification to allow the use of antibiotic resistance marker genes within commercial GM crops.

Field trials do not look at ecological interactions.

Any GM crops to be grown in the EU must undertake a full ecological impact assessment. BASF Plant Science Holding GmbH provide details of the field trials carried out (Annex 19-24). Furthermore they state in the Environmental Risk Assessment: (Section 2. V) that:

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[8] Advisory Committee on Novel Foods and Processes. 1994. "Report on the use of antibiotic resistance markers in GM food organisms". July 1994.

".....all interactions with organisms revealed to be unchanged in the different field trials. The observations included a wide range of organisms interacting with potatoes, viruses, bacteria, fungi, insects, snails and worms."

However, the trial data sheets indicate, the observations of the viruses, bacteria, fungi, insects, snails and worms have all been based around their effect on the potato. i.e. did these organisms cause more or less damage to the GM potatoes . This approach gives no insight into the effect of the GM potatoes on the above organisms.

Field trials are limited to Sweden

The field trials have all been conducted within Sweden. The application states that currently starch potatoes are additionally grown in Germany, The Netherlands, France, Denmark, Finland and Austria. Ecological studies should be carried out to reflect the different growing regions. Additionally any consent given should be restricted to those regions where full ecological studies have been undertaken.

Altered composition other than amylose/amylopectin ratio.

Analysis by BASF Plant Science demonstrates that there are a number of compositional differences between the (Page 19-33, Annex III Update). Specifically noted is a difference in Vitamin C levels. Whilst a possible explanation is put forward that this difference is attributable to the alteration in mono- and disaccharides, no work has been done to confirm or deny this possibility.

From: [redacted]
Sent: 03 June 2004 19:03
To: gmoinfo-comments@jrc.it
Subject: Comment on Assessment ReportC/SE/96/3501

[redacted]

COMMENTS TO THE ASSESSMENT REPORT OF THE SWEDISH COMPETENT AUTHORITY ON THE PLACING ON THE MARKET ACCORDING TO NOTIFICATION C/SE/96/3501

General aspects:

a.. There is no possibility to verify the given information, for lack of appropriate bibliographical references

b.. In the swedish report the environmental risk assessment is referred only to the swedish environment, although the application concerns all EU countries. Moreover, ERA is referred only to the potato variety Prevalent.

Technical comments:

Molecular characterisation

We retain, according with the EFSA GMO panel[1], that it is necessary to supply:

- the position of all coding and non-coding sequences really inserted in the plant genome,

- sequence data of the inserted material and of the flanking 5′ and 3′ regions. Information on flanking sequences should be sufficient to allow identification of potential chimeric ORFs generated at the junctions of the insert and the plant DNA

- Applicants should provide statistically analysed data, from a representative number of generations (vegetative or generative propagation), to demonstrate the inheritance pattern and stability of the trait(s) introduced (including the expression of corresponding proteins under representative environmental conditions).

Data from the sequencing of the whole inserted DNA-sequence, showed a point mutation in the ORF of the nptII gene. Contrary to the swedish assumption that the mutation can not affect protein function, a paper on the nptII mutation (Kocabiyik e Perlin, 1992[2]) demonstrated that same mutations can change the substratum specificity of the enzyme.

Assessment of use in animal feeds

- statistically significant differences in the composition between GM line and non-transgenic control hybrid have been reported[3]. Even if these modification fell within the range reported for the non-GM test hybrid they suggest us that potential unintended effect due to genetic modification should be occur. So we retain, according with the EFSA GMO panel[4], that the whole GM food/feed should be tested. The testing programme should include at least a 90-day toxicity study in rodents.

- We retain the feeding study with ruminants has been too short to obtain biological relevant data;

Assessment of environmental risk

- Fields trials of the GM potato has exclusively been effected in Sweden. There aren't evidence of the behaviour of GM potato in other environment of the EU territory where GM potato could have different fitness.

- Phytosociologicals studies of the possible wild relative of GM potato presents in the environmental has not been reported.

- Conclusion of the post release monitoring are referred only to the climatic condition present in Sweden. It is possible that in different climatic conditions, such conclusion will be different, how for example a prolongation of the times of persistence of the GM potato in the field. Guide-line for prevent such risk should be fournished.

- The system that has been established by Notifier for separation, control, and documentation, called Identity Preservation System (IPS), in order to assure quality is not sufficient to prevent the risk of cultivation of GM potato. For example, it's not consider the risk connected to unintentional spillage of GM plant.

- If a phytosociological study has not been effected how is it possible affirm that the interaction among the GM potatoes and wild relative doesn't give origin to fertile progeny? Moreover to evaluate vertical gene flow the Swedish Competent Authority consider only the variety Prevalent, while the application of authorization is for the production of new seed potatoes derived from classical breeding with other commercial variety.

- Presence of ORF4 and ORF 1 (nptII gene) could increase the risks associate with the Horizontal gene flow

- Analysis of the risk referred to increase of the competitive ability considers only the territorial and climatic situation of the North Europe. The analysis of the environmental risk cannot be considered sufficient for the entire EU territory.

- Unintended spillage of GM potato in South Europe clime could cause hazard on non-target organisms if potato volunteers take place.

- Impact on biogeochemical processes due to the cultivation of GM potato doesn't been excluded.

Surveillance and monitoring plane

- Monitoring plan should indicate the responsibility in the case that unlikely changes of the potato and effects that have not been anticipated in the risk assessment take place.

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[1] DRAFT GUIDANCE DOCUMENT FOR THE RISK ASSESSMENT OF GENETICALLY MODIFIED PLANTS AND DERIVED FOOD AND FEED April 2004 Prepared by the Scientific Panel on Genetically Modified Organisms of the European Food Safety Authority p. 15-17.

[2] Kocabiyik, D. e Perlin, M.H. 1992 FEMS Microbiol. Lett. 72, 619-624.

[3] Assessment Report point 5.2 pag.7

[4] DRAFT GUIDANCE DOCUMENT FOR THE RISK ASSESSMENT OF GENETICALLY MODIFIED PLANTS AND DERIVED FOOD AND FEED April 2004 Prepared by the Scientific Panel on Genetically Modified Organisms of the European Food Safety Authority p. 24.

> -----Original Message-----
> From: [redacted]
> Sent: 03 June 2004 19:36
> To: gmoinfo-comments@jrc.it
> Subject: Comment on Assessment ReportC/SE/96/3501
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> please find attached the comments from [redacted]
> [redacted] on SE/96/3501
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> THese personal opinions do not necessarily reflect the policy of
> [redacted]
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[redacted]

Comments from [redacted] on the application for marketing consent under 2001/18 (SE-96-3501) of high amylopectin GM potato EH92-527-1 by BASF Plant Science Gmbh

03 June 2004

Summary

[redacted] is writing to object to the placing on the market of BASF 's GM potato modified for starch production for the following reasons:

- The GM potato has not undergone sufficient safety testing to ensure that it is safe for use in human food and animal feed, yet it is proposed that byproducts from industrial starch production will be used for animal feed and contamination of the human food chain appears to be extremely likely, even certain.
- The molecular characterization indicates that novel proteins could be produced and that the GM potato is not substantially equivalent to its non GM progenitor.
- The GM potato contains the antibiotic resistance marker gene nptII.
- The possibility of contamination of the human food chain is treated with complacency and the prevention measures are wholly inadequate – the proposals will not prevent GM potatoes entering the human food chain through contamination of seed crops.
- There is no assessment of the indirect effects of the GM potato on organisms in the agricultural ecosystem.
- There is no assessment of the effects on soil organisms and biogeochemical processes of growing the GM potatoes and disposal of processing waste on agricultural land.

[redacted] is astonished that, in the light of the Starlink contamination case in the United States, an application is being considered which would potentially allow commercial production of a GMO which has not been assessed for its safety for human consumption. Until such time as full safety testing has been conducted, including long term toxicity, carcinogenicity and immunotoxicity tests, this product should not be approved for commercial cultivation as it cannot be guaranteed that it will not enter the human food chain. Until sufficient testing has been conducted, it would be highly irresponsible of the Commission and member states to approve commercial production of this GMO.

Molecular characterisation

The GM potato EH92-527-1 has been modified to contain the kanamycin resistance gene NptII, and the antisense gene *gbss,* causing the potato to alter its starch metabolism away from amylose and in favour of amylopectin. However, the molecular data contains numerous irregularities including the identification of 18 open reading frames in the insert. In the case of ORF 4, in which the first 50 amino acids are homologous to the bleomycin resistance protein, transcription to the RNA level was demonstrated in both leaves and tubers of the EH92-527-1. The complex post transcriptional and post translational modifications that occur in eukaryotes may prevent detection of a translation product. Some proteins are formed in large molecular precursors to proteins, which are then cut to yield the final protein or proteins. These are then cut down to a final protein or proteins by specialised enzymes or proteases[9]. This process could occur within the protein(s) formed by the open reading frame and there does not appear to have been any investigation to rule out this possibility.

The environmental risk assessment by the company acknowledges that "*The presence of other coding sequences could lead to direct effects on the phenotype and to toxic or allergenic effects by expressing additional proteins and peptides. In addition, transfer of such a sequence could entail indirect effects in the recipient*

[9] see, e.g. Lewin, B. (2000) Genes VII. Oxford University Press, Oxford, UK.

organisms." Although the novel polypeptide transcribed from ORF 4 was not detected in analyses, even the company does not rule out the possibility that this could alter with time – "*Whereas the data satisfy the argumentation on safety of the line today, there remains some risk for future exposure.*"

The assessment report by the Swedish authorities acknowledges that the deletions and rearrangements during the GE process may cause changes:

"*The integration itself could theoretically lead to changes that could influence the estimation of health and environmental risks. ... Endogenous genes may also have been knocked out, have changed expression level, or been fused with other endogenous genes, as a consequence of the introduction of the T-DNA.*"

But then goes on to argue that this does not need to be investigated further because this can happen during natural mutations. However, in the GM potato, rearrangements would under the control of a strong promoter, raising the possibility that they are expressed to a greater extent. Flanking sequences at both ends of the primary insert and each unintended fragment must be compared with genomic sequences from the non-GE line to establish whether or not there are further rearrangements of the genome.

Antibiotic resistance marker gene.

The GM clone EH92-527-1 contains the kanamycin resistance gene nptII. [redacted] is opposed to the commercial approval of GM organisms containing antibiotic resistance marker genes in the light of the concerns about horizontal gene transfer to micro-organisms in the soil, in humans and in animals. [redacted] considers that there is simply no justification to allow the use of antibiotic resistance marker genes within commercial GM crops, as this could compromise the medical and veterinary use of these important drugs.

Safety for food and feed

[redacted] is concerned that the safety assessment for this GMO is not sufficient, particularly in light of the potential for unexpected effects revealed in the molecular characterisation. As a general principle Friends of the Earth considers that approval for commercial cultivation should not be granted until such time as full safety testing, including long term testing for carcinogenicity and immunotoxicity, has been carried out to the highest standard. In this case the quality of testing is inadequate not least because it seems to be assumed that there will not be human consumption. But that cannot be guaranteed because of the large possibilities for contamination of the human food chain. This approach is not acceptable and does not provide sufficient protection to consumers in the EU.

It is clear that the modification has caused major changes in the metabolism of the potato; potatoes normally produce starch of around 85 % amylopectin and 15 % amylose, but the modification leads to 98 % amylopectin production and only 2 % amylose. Considering that carbohydrates can make up more than 80% of the dry matter content of the potato, this is not an insignificant alteration in composition and represents a significant change in the plant metabolism. The company also suggests that the starch content of the leaves may be altered, indicating the significance of the modification in relation to the plant's metabolism. In fact, BASF 's own field trials found large, consistent and significant differences in yield and dry matter content between the GM potato and unmodified progenitor Prevalent. Differences in vitamin C content, nitrate, fructose and saccharose were also observed. In all cases the

company stated that it could not rule out that these observations were a consequence of the changes in starch metabolism caused by the genetic modification. (Annex III update page 24 and Annex II update, annex 29). In the case of significant difference in fibre content, the company noted that *"It is probable that the modification of the starch synthesis also affects parts of the constituents included in the analysis of digestible fibres, e.g. retrograded amylose."*

In other words: the modification has caused major changes to the metabolism of the plant; the GM potato cannot be considered substantially equivalent to the non GM potato; it should be investigated fully and full toxicity testing should be carried out.

Finally, it is clear that the Scientific Committee on Plants opinion on the safety of BASF's GM potato is not sufficient to assume safety for human consumption – in fact it states clearly that food use approval would require additional consideration by scientific advisors. The opinion makes no comment on the safety of the GMO in the case of accidental human consumption of whole tubers, for example through contamination of the food chain, and so cannot be considered sufficient to cover this possibility.

Contamination

The identity preservation system is inadequate to prevent contamination of the food chain. The entire system will be industry managed and there does not appear to be any independent monitoring or measures to ensure compliance, particularly at the farm level where contamination is most likely to occur. For example, there appears to be no independent monitoring to ensure the accidental spillage and contamination of harvesting equipment does not occur. Simply stating that the grower should ensure that this won't happen is not sufficient to ensure compliance.

The grower is only required to grow a non-potato crop for one year after growing the GM crop, despite the fact that BASF 's notification states that *"Potato plants have been found in the fallow following cultivation of modified potatoes and in the subsequent 3 years without potatoes"* (SNIF para 32 p). In many seed-potato producing areas, only short breaks are used between crops and so it is entirely possible that seed crops could be grown in the second and third years after the GM crop. Volunteer GM potatoes in a later seed crop for food use potatoes would lead to contamination of the human food chain. Seed potato production is limited to specific geographical areas within the EU, and farmers in these areas specialize in seed potato production, so it is likely that a farmer growing seed potatoes for BASF could later grow seed potatoes for food use. Potentially, the commercial production of these GM potatoes could lead to long term contamination of potato production in the EU.

The applicant is suggesting an annual production of 50 000 to 75,000 tonnes of potato per year in a number of EU countries, and this implies a large area will have to be used for seed potato tuber production. The proposals by the applicant are clearly insufficient to ensure that contamination of seed crops will not occur and the applicant only suggests that procedures will 'avoid' contamination, not completely prevent it. In 2001, food manufacturers in Japan were forced to withdraw snack products which had been made with imported potatoes contaminated with Monsanto's Bt potato (which was not approved in Japan). [redacted] is concerned that, since contamination in Japan occurred in the case of unapproved imported GM potatoes, the likelihood of contamination will be very high for GM potatoes approved for domestic cultivation in the EU.

The environmental risk assessment makes no consideration of this issue, and no risk management has been proposed.

Cross pollination

The applicant suggests that only a 5m separation distance is required around GM potato fields, despite the fact that it accepts that pollen bearing plants, though uncommon, will occur. The applicant states that "*According to available publications and our own studies pollen dissemination is limited to around 3 m*", yet this appears to be based on studies using small scale field trials – an approach which has been largely discredited when considering cross pollination from farm scale commercial plantings. Furthermore, the applicant dismisses the one study (from Sweden) which used a field size pollen source and found pollination up to a distance of 1 km [10], claiming methodological inaccuracies. However, a recent analysis by experts from the UK's National Pollen Research Unit[11] did not agree and concluded that the high rates of pollination in the Swedish study may have been due to the activities of pollen beetles (*Meligethes aeneus*), which move in large numbers and can fly over long distances. The NPRU researchers point out that more research is needed into the effects of different pollinators and the long distance movement of pollen between potato crops. Some varieties (eg Desiree) are highly prolific producers of seed, and volunteer potatoes from seed can occur in following crops and could represent a source of GM contamination into the food chain, particularly because farmers would be unaware that their crop contained GM potatoes grown from seed. This issues must be investigated further before approval can be granted.

Ecological effects

Annex II of Directive 2001/18 requires that the environmental risk assessment includes information on and consideration of:

"Potential immediate and/or delayed environmental impact resulting from direct and indirect interactions between the GMHP and target organisms, such as predators, parasitoids, and pathogens (if applicable)."

"Possible immediate and/or delayed environmental impact resulting from direct and indirect interactions of the GMHP with non-target organisms, (also taking into account organisms which interact with target organisms), including impact on population levels of competitors, herbivores, symbionts (where applicable), parasites and pathogens."

"Possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of the GMO release(s)."

However, BASF have not provided any evidence that they have investigated potential delayed impacts on target and non target organisms despite acknowledging that wild mammals and birds may feed on potatoes and that a range of aphids and leaf

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[10] Skogsmyr I (1994) Gene dispersal from transgenic potatoes to conspecifics: a field trial *Theoretical and applied genetics* 88: 770-774

[11] True R & J Emberlin (2000) *Pollen dispersal in the crops maize (zea mays), oilseed rape (brassica napus ssp loeifera), potatoes (solanum tuberosum), sugar beet (beta vulgaris ssp vulgaris) and wheat (triticum aestivum) - Evidence from publications.* A report for the Soil Association from the National Pollen Research Unit.

hoppers are herbivores of potatoes – insects which a e important food sources for birds and beneficial insects. There has been no ecol gical assessment of the GM potatoes; no attempt to establish if there were any adverse effects on herbivores feeding on the GM crop. Instead, the data presented relates only to the effect on the potato of certain species, such as viruses, bacteria, fungi, insects, snails and worms –in other words whether these organisms cause more or less damage to the GM potatoes. This is a standard agronomic assessment of the resistance of the GM potato to pests, but it does not constitute an environmental assessment of the impact of the GM potato on the receiving ecosystem. An approval for commercial cultivation based on this evidence would not provide the protection to the environment that is required by Directive 2001/18.

Similarly, the assessment of the impact on soil ecosystems and biogeochemical processes is missing, despite the fact that BASF proposes that waste material will be applied to agricultural land. The company states that 'For none of the field trials an unexpected performance of the subsequent crops was reported" (Annex III update, p) and therefore no further investigations of the effect on soil organisms were conducted. This does not represent an adequate consideration of the impacts of both growing the crop, and applying waste material after processing, on soil ecosystems.

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