Comments by GeneWatch UK to 2001/18/EC marketing application reference C/SE/96/3501

(June 2004)

GeneWatch 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.**

1. 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.

2. 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[1]. 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.

3. 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;
"…..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.

4. 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.

5. 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.

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