

**ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES:
PAPER FOR POSTAL CONSULTATION**

**2001/18 APPLICATION FOR THE HIGH AMYLOPECTIN GM POTATO CLONE
EH92-527-1: REFERENCE C/SE/96/3501**

Issue

This paper seeks the Committee's views on additional information provided by the applicant in relation to this application under the deliberate release directive 2001/18/EC. Members are asked if this information provides satisfactory answers to the concerns raised when the dossier was first considered in May 2004.

Background

1. An application for deliberate release of this GM potato clone under Regulation (EC) 2001/18 was considered by postal consultation in 2004 and discussed at the ACNFP meeting in May 2004. This clone is not intended for direct human consumption and the derived starch will only be used in non-food applications. The ACNFP considered the molecular characterisation and human health aspects of the above application and in a letter to the ACRE Secretariat (Annex 1) expressed concern regarding two issues:
 - a) A full analysis of the flanking regions on either side of the insertion site has not been provided, as would be the case with as would be required for crops destined to enter the food chain. Although a thorough identification preservation system is outlined in the dossier, the Committee considered that there is still the potential for contamination in the human food chain, in particular, the possibility of volunteers which can persist for many years in subsequent crops.
 - b) The Committee noted the applicant's introductory statement that "*EH92-527-1 is not intended for direct human consumption and the derived starch will only be used in non-food applications*". Nevertheless, the Committee felt it important to remind the applicant that growers of this potato clone must be made aware of their obligations to ensure that neither the crop nor any of its by-products should enter the human food chain. If this were the case, a separate assessment would need to be conducted under Regulation 1829/2003 on GM food and feed.
2. The applicant has determined the structure and flanking DNA sequence of the complete T-DNA insert as integrated into the genome of the amylopectin potato clone EH92-527-1 has been determined (Annex 2, page 5). The data generated by the applicant are attached in Annex 3.
3. The applicant has also carried out a bioinformatic analysis of the potato chromosomal region flanking the insertion event in this clone using BLAST

searches of DNA databases (Annex 4). Using this approach the applicant has concluded that the only significant homology was to known potato sequences. In addition, the flanking sequences do not contain any known functional ORFs (Open Reading Frames) and no ORFs had been interrupted or created as a result of the insertion event.

4. The applicant states that whilst all effort will be made to avoid contamination of the human food chain, it cannot be excluded that trace amounts may be present in other potato products. Though the applicant does not consider this a safety issue, and questions the need for an application under Regulation (EC) 1829/2003 for unintended food use, they state their intention to submit such an application (Annex 2: section 3.3.1, page 29). (Note: Without authorisation under the GM food and feed regulation the presence of any material from EH92-528-1 potatoes in food or feed products, at any level, would be illegal)

Committee action required

5. Members are asked whether they are content with the applicant's response to their earlier concerns over this application. Responses are requested by **12 January 2005** at the latest, but earlier responses would be welcome.

Secretariat

January 2005

Annexes attached:

Annex 1 – Letter to the ACRE Secretariat regarding the 2001/18 application for genetically modified potato clone EH92-527-1 ref. C/SE/96/3501.

Annex 2 – Reply to comments and objections raised under Directive 2001/18/EC in accordance with article 15.

Annex 3 – Insert structure and flanking DNA sequence of potato event EH92-527-1 (**confidential**).

Annex 4 – Bioinformatic analysis of potato chromosomal region flanking the insert of potato event EH92-527-1 (**confidential**).

Documents available on request

- Quantification of NPTII protein in leaves, pulp, starch and tubers of potato event EH92-527-1. (Annex 3 to the BASF response)
- Reference document of Member States comments and objections (Appendix 1 to BASF response) (**confidential**).
- Detailed results of BLAST searches (Appendices A-D of BASF response) (**confidential**).

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

Letter to the ACRE Secretariat regarding the 2001/18 application for genetically modified potato clone EH92-527-1 ref. C/SE/96/3501.

**Secretariat
January 2005**

ANNEX I

Dr Steven Hill – *By e-mail*
ACRE Secretary
3/H10 Ashdown House
123 Victoria Street
London, SW1E 6DE

28th May 2004

Dear Steven,

2001/18 application for genetically modified potato clone EH92-527-1 ref. C/SE/96/3501

The Advisory Committee on Novel Foods and Processes has considered the molecular characterisation and human health aspects of the above application.

The Committee was concerned that a full analysis of the flanking regions on either side of the insertion site has not been provided (as would be required for crops destined to enter the food chain). Although a through identification preservation system is outlined in the dossier, the Committee considered that there is still the potential for contamination in the human food chain, in particular, the possibility of volunteers which can persist for many years in subsequent crops.

The Committee noted the applicant's introductory statement that "*EH92-527-1 is not intended for direct human consumption and the derived starch will only be used in non-food applications*". Nevertheless, the Committee felt it important to remind the applicant that growers of this potato clone must be made aware of their obligations to ensure that neither the crop nor any of its by-products, including products recovered from the effluent of the starch extraction process, should enter the human food chain. If this were the case, a separate assessment would need to be conducted under Regulation 1829/2003.

Yours sincerely,

Dr Sonia Molnar. Room 515B Aviation House, 125 Kingsway, Holborn, London, WC2B 6NH. Tel: 020 7276 8571, GTN: 276 8571, Switchboard: 020 7276 8000, Fax: 020 7276 8564 E-mail: sonia.molnar@foodstandards.gsi.gov.uk

A handwritten signature in black ink, appearing to read 'S. Molnar', written in a cursive style.

Sonia Molnar.

cc. Mike Gasson (ACNFP Chair)
Sandy Lawrie (ACNFP Secretary/FSA)
Clair Baynton (FSA)
David Jefferies (FSA)

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

Reply to comments and objections raised under Directive 2001/18/EC in
accordance with article 15. (Annex available on request)

**Secretariat
January 2005**