

Application for
Amylopectin Potato Event EH92-527-1
according to Regulation (EC) No 1829/2003

PART II SUMMARY

PART II SUMMARY**A. GENERAL INFORMATION****1. Details of application**

a) Member State of application	United Kingdom
b) Application number	Not available at time of application.
c) Name of the product (commercial and other names)	The application is for genetically modified amylopectin potato event EH92-527-1. The name AMFLORA has been assigned to the variety. The unique identifier is BPS-25271-9.
d) Date of acknowledgement of valid application	Not available at time of application.

2. Applicant

a) Name of applicant	BASF Plant Science GmbH
b) Address of applicant	BASF Plant Science GmbH Carl-Bosch-Str. 38 D-67056 Ludwigshafen Germany
c) Name and address of the person established in the Community who is responsible for the placing on the market, whether it be the manufacturer, the importer or the distributor, if different from the applicant (Commission Decision 2004/204/EC Art 3(a)(ii))	For placing on the market of the genetically modified amylopectin potato within a closed-loop (identity preservation) system: BASF Plant Science GmbH Carl-Bosch-Str. 38 D-67056 Ludwigshafen Germany The products from genetically modified amylopectin potato EH-92-527-1 will be placed on the market by the starch processor as is applicable for products from conventional starch potatoes.

3. Scope of the application

- ☒ GM plants for food use
- ☒ Food containing or consisting of GM plants
- ☒ Food produced from GM plants or containing ingredients produced from GM plants
- ☒ GM plants for feed use
- ☒ Feed containing or consisting of GM plants
- ☒ Feed produced from GM plants
- ☐ Import and processing (Part C of Directive 2001/18/EC)
- ☐ Seeds and plant propagating material for cultivation in Europe (Part C of Directive 2001/18/EC)

4. Is the product being simultaneously notified within the framework of another regulation (e.g. Seed legislation)?

Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
If yes, specify	

5. Has the GM plant been notified under Part B of Directive 2001/18/EC and/or Directive 90/220/EEC?

Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
If <i>no</i> , refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC	

6. Has the GM plant or derived products been previously notified for marketing in the Community under Part C of Directive 2001/18/EC or Regulation (EC) 258/97?

Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
If yes, specify Notification C/SE/96/3501 according to Directive 2001/18/EC.	

7. Has the product been notified in a third country either previously or simultaneously?

Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
If yes, specify	

Table relating to A.5. Information on previous releases notified under Part B of Directive 90/220/EEC**List compiled January 2003**

Year	Notification No.	Authorizing Country	Location	Duration (Dates)	Purpose	Size
1993	Dnr 22-4314/92	Sweden	Teckomatorp	26 April-27 Sept.	Observation trial	30 plants
1994	Dnr 22-4363/93	Sweden	Teckomatorp	27 April-7 Oct.	Observation trial	75 plants
1994	Dnr 22-4363/93	Sweden	Händene	16 May-22 Sept.	Seed production	0.1 ha
1994	Dnr 22-4363/93	Sweden	N. Sunderbyn	15 June-22 Sept.	Seed production	21,000 plants
1995	Dnr 22-28/95	Sweden	Häljarp	10 May-4 Oct.	Official trial	250 m2
1995	Dnr 22-28/95	Sweden	Fjälkinge	18 May-13 Oct.	Official trial and Starch production	0.5 ha
1995	Dnr 22-28/95	Sweden	Händene	13 May-1 Oct.	Seed production	0.2 ha
1995	Dnr 22-28/95	Sweden	Habo	27 May-9 Oct.	Seed production	1.3 ha
1995	Dnr 22-28/95	Sweden	N. Sunderbyn	12 June-14 Sept.	Seed production	1.3 ha
1996	Dnr 22-530/96	Sweden	Häljarp	15 May-3 Oct.	Official trial	250 m2
1996	Dnr 22-530/96	Sweden	Skepparslöv	17 May-14 Oct.	Official trial	250 m2
1996	Dnr 22-530/96	Sweden	Fjälkinge	7 May-9 Oct.	Official trial and Starch production	1.35 ha
1996	Dnr 22-530/96	Sweden	Habo	5 June-3 Oct.	Seed production	3.5 ha
1996	Dnr 22-530/96	Sweden	Flaskebo	6 June-10 Oct.	Seed production	3.5 ha
1996	Dnr 22-530/96	Sweden	Händene	15 June-3 Oct.	Seed production	1.0 ha
1996	Dnr 22-530/96	Sweden	N. Sunderbyn	10 June-19 Sept.	Seed production	2.5 ha
1996	Dnr 22-530/96	Sweden	Tegsnäset	15 June-24 Sept.	Seed production	2.0 ha
1997	Dnr 22-1782/97	Sweden	Axeltofta	14 May-3 Oct.	Official trial	200 m2
1997	Dnr 22-1782/97	Sweden	Ronneby	26 May-25 Sept.	Official trial	270 m2
1997	Dnr 22-1782/97	Sweden	Skepparslöv	12 May-14 Oct.	Official trial	270 m2
1997	Dnr 22-1782/97	Sweden	Halltorp	16 May-early Oct.	Starch production	2.8 ha
1997	Dnr 22-1782/97	Sweden	Bergkvara	16 May-early Oct.	Starch production	8.0 ha
1997	Dnr 22-1782/97	Sweden	Ljungbyholm	16 May-early Oct.	Starch production	4.0 ha
1997	Dnr 22-1782/97	Sweden	Ljungbyholm	16 May-early Oct.	Starch production	4.0 ha
1997	Dnr 22-1782/97	Sweden	Ljungbyholm	17 May-early Oct.	Starch production	4.4 ha
1997	Dnr 22-1782/97	Sweden	Ljungbyholm	16 May-early Oct.	Starch production	2.8 ha
1997	Dnr 22-1782/97	Sweden	Ljungbyholm	16 May-early Oct.	Starch production	1.3 ha
1997	Dnr 22-1782/97	Sweden	Ljungbyholm	16 May-early Oct.	Starch production	2.1 ha
1997	Dnr 22-1782/97	Sweden	Mörbylånga	20 May-early Oct.	Starch production	4.5 ha
1997	Dnr 22-1782/97	Sweden	Mörbylånga	15 May-3 Oct.	Starch production	2.5 ha
1997	Dnr 22-1782/97	Sweden	Söderåkra	24 May-early Oct.	Starch production	1.5 ha
1997	Dnr 22-1782/97	Sweden	Vassmolösa	15 May-3 Oct.	Starch production	2.0 ha
1997	Dnr 22-1782/97	Sweden	Vassmolösa	16 May-early Oct.	Starch production	2.3 ha
1997	Dnr 22-1782/97	Sweden	Ramdala	17 May-early Oct.	Starch production	1.6 ha
1997	Dnr 22-1782/97	Sweden	Ronneby	20 May-early Oct.	Starch production	4.0 ha
1997	Dnr 22-1782/97	Sweden	Ronneby	26 May-early Oct.	Starch production	3.2 ha
1997	Dnr 22-1782/97	Sweden	Skara	20 May-20 Sept.	Seed production	6.5 ha
1997	Dnr 22-1782/97	Sweden	Skara	7 May-8 Sept.	Seed production	7.4 ha
1997	Dnr 22-1782/97	Sweden	Lidköping	19 May-20 Sept.	Seed production	7.7 ha
1997	Dnr 22-1782/97	Sweden	Lindärva	7 May-5 Sept.	Seed production	7.0 ha

1997	Dnr 22-1782/97	Sweden	Umeå	12 June-21 Sept.	Seed production	1.5 ha
1997	Dnr 22-1782/97	Sweden	Granö	4 June-25 Sept.	Seed production	2.0 ha
1997	Dnr 22-1782/97	Sweden	N. Sunderbyn	4 June-21 Sept.	Seed production	2.3 ha
1998	Dnr 22-2519/98	Sweden	Axeltofta	7 May-1 Oct.	Official trial	175 m2
1998	Dnr 22-2519/98	Sweden	Skepparslöv	11 May-19 Oct.	Official trial	216 m2
1998	Dnr 22-2519/98	Sweden	Ramdala	14 May-7 Oct.	Official trial	202 m2
1998	Dnr 22-2519/98	Sweden	Sölvesborg	4 May-15 Oct.	Starch production	20 ha
1998	Dnr 22-2519/98	Sweden	Sölvesborg	2 May-13 Oct.	Starch production	2 ha
1998	Dnr 22-2519/98	Sweden	Sölvesborg	20 May-14 Oct.	Starch production	1.75 ha
1998	Dnr 22-2519/98	Sweden	Mörum	10 May-10 Oct.	Starch production	4.5 ha
1998	Dnr 22-2519/98	Sweden	Åhus	15 May-14 Oct.	Starch production	12 ha
1998	Dnr 22-2519/98	Sweden	Sölvesborg	20 April-28 Sept.	Starch production	6 ha
1998	Dnr 22-2519/98	Sweden	Fågelmara	10 May-12 Oct.	Starch production	2 ha
1998	Dnr 22-2519/98	Sweden	Ramdala	17 May-14 Oct.	Starch production	2 ha
1998	Dnr 22-2519/98	Sweden	Lyckeby	5 May-5 Oct.	Starch production	1.1 ha
1998	Dnr 22-2519/98	Sweden	Fågelmara	10 May-8 Oct.	Starch production	5 ha
1998	Dnr 22-2519/98	Sweden	Ljungbyholm	10 May-3 Oct.	Starch production	4 ha
1998	Dnr 22-2519/98	Sweden	Färjestaden	10 May-5 Oct.	Starch production	3 ha
1998	Dnr 22-2519/98	Sweden	Ramdala	10 May-10 Oct.	Starch production	8 ha
1998	Dnr 22-2519/98	Sweden	Mörbylånga	20 May-13 Oct.	Starch production	1.5 ha
1998	Dnr 22-2519/98	Sweden	Mörbylånga	10 May-18 Oct.	Starch production	5 ha
1998	Dnr 22-2519/98	Sweden	Jämjö	20 May-15 Oct.	Starch production	9 ha
1998	Dnr 22-2519/98	Sweden	Kallinge	11 May-5 Oct.	Starch production	4 ha
1998	Dnr 22-2519/98	Sweden	Jämjö	10 May-8 Oct.	Starch production	6 ha
1998	Dnr 22-2519/98	Sweden	Färjestaden	20 May-12 Oct.	Starch production	4.5 ha
1998	Dnr 22-2519/98	Sweden	Mörbylånga	10 May-4 Oct.	Starch production	2.9 ha
1998	Dnr 22-2519/98	Sweden	Ljungbyholm	14 May-13 Oct.	Starch production	7 ha
1998	Dnr 22-2519/98	Sweden	Ronneby	20 May-5 Oct.	Starch production	2.5 ha
1998	Dnr 22-2519/98	Sweden	Kallinge	20 May-9 Oct.	Starch production	5 ha
1998	Dnr 22-2519/98	Sweden	Kallinge	23 May-3 Oct.	Starch production	2 ha
1998	Dnr 22-2519/98	Sweden	Ramdala	20 May-8 Oct.	Starch production	4.3 ha
1998	Dnr 22-2519/98	Sweden	Mörbylånga	2 May-2 Oct.	Starch production	8 ha
1998	Dnr 22-2519/98	Sweden	Bergkvara	10 May-5 Oct.	Starch production	3 ha
1998	Dnr 22-2519/98	Sweden	Ramdala	23 May-1 Oct.	Starch production	1.5 ha
1998	Dnr 22-2519/98	Sweden	Fågelmara	20 May-7 Oct.	Starch production	3.8 ha
1998	Dnr 22-2519/98	Sweden	Jämjö	10 May-6 Oct.	Starch production	4.5 ha
1998	Dnr 22-2519/98	Sweden	Vassmolösa	16 May-3 Oct..	Starch production	2.5 ha
1998	Dnr 22-2519/98	Sweden	Ljungbyholm	10 May-8 Oct.	Starch production	5 ha
1998	Dnr 22-2519/98	Sweden	Lyckeby	13 May-10 Oct.	Starch production	4.5 ha
1998	Dnr 22-2519/98	Sweden	Mörbylånga	3 May-8 Oct.	Starch production	4 ha
1998	Dnr 22-2519/98	Sweden	Mörbylånga	10 May-10 Oct.	Starch production	6 ha
1998	Dnr 22-2519/98	Sweden	Mörbylånga	10 May-7 Oct.	Starch production	5.5 ha
1998	Dnr 22-2519/98	Sweden	Ronneby	10 May-13 Oct.	Starch production	5 ha
1998	Dnr 22-2519/98	Sweden	Ronneby	10 May-8 Oct.	Starch production	4 ha
1998	Dnr 22-2519/98	Sweden	Vassmolösa	7 May-5 Oct.	Starch production	3.5 ha
1998	Dnr 22-2519/98	Sweden	Trekanten	18 May-8 Oct.	Starch production	6 ha
1998	Dnr 22-2519/98	Sweden	Lyckeby	20 May-2 Oct.	Starch production	2 ha
1998	Dnr 22-2519/98	Sweden	Mörbylånga	8 May-7 Oct.	Starch production	7 ha
1998	Dnr 22-2519/98	Sweden	Halltorp	5 May-4 Oct.	Starch production	5 ha

1998	Dnr 22-2519/98	Sweden	Vassmolösa	20 May-18 Oct.	Starch production	4.5 ha
1998	Dnr 22-2519/98	Sweden	Ljungbyholm	15 May-14 Oct.	Starch production	1.5 ha
1998	Dnr 22-2519/98	Sweden	Ramdala	20 May-12 Oct.	Starch production	5 ha
1998	Dnr 22-2519/98	Sweden	Vittskövle	9 May-5 Oct.	Starch production	4.5 ha
1998	Dnr 22-2519/98	Sweden	Vassmolösa	11 May-20 Oct.	Starch production	3 ha
1998	Dnr 22-2519/98	Sweden	Mörbylånga	10 May-12 Oct.	Starch production	3 ha
1998	Dnr 22-2519/98	Sweden	Asarum	18 May-18 Oct.	Starch production	4 ha
1998	Dnr 22-2519/98	Sweden	Jämfö	20 May-22 Oct.	Starch production	2 ha
1998	Dnr 22-2519/98	Sweden	Ljungbyholm	16 May-19 Oct.	Starch production	10 ha
1998	Dnr 22-2519/98	Sweden	Bräkne Hoby	11 May-17 Oct.	Starch production	2.9 ha
1998	Dnr 22-2519/98	Sweden	Ronneby	18 May-13 Oct.	Starch production	2.5 ha
1998	Dnr 22-2519/98	Sweden	Olofström	10 May-16 Oct.	Starch production	1.5 ha
1998	Dnr 22-2519/98	Sweden	Ramdala	11 May-8 Oct.	Starch production	3 ha
1998	Dnr 22-2519/98	Sweden	Jämfö	15 May-14 Oct.	Starch production	1 ha
1998	Dnr 22-2519/98	Sweden	Sölvesborg	27 April-5 Oct.	Starch production	5 ha
1998	Dnr 22-2519/98	Sweden	Vollsjö	1 May-29 Sept.	Seed production	7 ha
1998	Dnr 22-2519/98	Sweden	Skara	17 May-1 Oct.	Seed production	4 ha
1998	Dnr 22-2519/98	Sweden	Skara	14 May-28 Sept.	Seed production	5 ha
1998	Dnr 22-2519/98	Sweden	Händene	22 May-25 Sept.	Seed production	8 ha
1998	Dnr 22-2519/98	Sweden	N. Härene	16 May-28 Sept.	Seed production	11.5 ha
1998	Dnr 22-2519/98	Sweden	Lidköping	18 May-23 Sept.	Seed production	7.5 ha
1998	Dnr 22-2519/98	Sweden	Skallmeja	15 May-20 Sept.	Seed production	7.2 ha
1998	Dnr 22-2519/98	Sweden	Entorp	15 May-20 Sept.	Seed production	4 ha
1998	Dnr 22-2519/98	Sweden	Boxholm	27 May-5 Oct.	Seed production	8.9 ha
1998	Dnr 22-2519/98	Sweden	Skara	19 May-9 Oct.	Seed production	6 ha
1998	Dnr 22-2519/98	Sweden	Granö	6 June-24 Sept.	Seed production	1.5 ha
1998	Dnr 22-2519/98	Sweden	Granö	6 June-27 Sept.	Seed production	1.7 ha
1998	Dnr 22-2519/98	Sweden	Flurkmark	18 June-22 Sept.	Seed production	1.5 ha
1999	Dnr 22-1087/99	Sweden	3 sites	5 May-18 Oct.	Yield trial	600 m2
1999	Dnr 22-1087/99	Sweden	75 sites	20 April-Oct.	Starch production	319 ha
1999	Dnr 22-1087/99	Sweden	12 sites	2 May-early Oct.	Seed production	57.3 ha
2000	Dnr 22-1019/00	Sweden	24 sites	17 April-Oct.	Starch production	136.2 ha
2000	Dnr 22-1019/00	Sweden	7 sites	9 May-end Sept.	Seed production	25.6 ha
2001	Dnr 22-1019/00	Sweden	7 sites	11 May-22 Oct.	Seed production	4.9 ha

8. General description of the product**a) Name of the recipient or parental plant and the intended function of the genetic modification**

The parental plant is potato (*Solanum tuberosum*) variety Prevalent. An introduced granule bound starch synthase (*gbss*) gene from *Solanum tuberosum* in antisense relative to the *gbss* promoter leads to a decrease in amylose content and a concomitant increase in amylopectin content in tuber starch of amylopectin potato clone EH92-527-1. The expression of neomycin phosphotransferase II by the nopaline synthase promoter from *Agrobacterium tumefaciens* confers tolerance to kanamycin.

b) Types of products planned to be placed on the market according to the authorisation applied for

The scope of the application includes amylopectin potato clone EH92-527-1 and products of the starch processing for food and feed use (please see A.3).

Products of the starch processing of amylopectin potato event EH92-527-1 are intended to be placed on the market for feed use in the same way as products of any conventional starch potato.

Cultivation, processing, handling and feed use of by-products of the starch processing for amylopectin potato clone EH92-527-1 as for any conventional starch potato are covered under the scope of notification C/SE/96/3501 according to Directive 2001/18/EC.

Since it cannot be excluded that amylopectin potato event EH92-527-1 and products derived from EH92-527-1 potato may be used as or may be present in food, this application aims to demonstrate safety and to ensure that such presence would not be considered unauthorised. It is not the intention of the applicant to place on the market amylopectin potato EH92-527-1 and products of the starch processing for food use.

c) Intended use of the product and types of users

Like conventional starch potatoes amylopectin EH92-527-1 potatoes are not intended for direct human consumption, but solely for use in the starch production industry. The starch potatoes are grown by the farmer under contract and made available to the starch processor. The starch processor provides the starch to his customer for the uses indicated on the label accompanying the product (amylopectin starch for non-food uses only). Other by-products of the starch processing are provided to the respective users (e.g. farmers use the fruit juice as fertilizer and the pulp as animal feed, protein concentrates derived from the fruit juice can also serve as animal feed) as for any conventional starch potato.

d) Specific instructions and/or recommendations for use, storage and handling, including mandatory restrictions proposed as a condition of the authorisation applied for

Amylopectin EH92-527-1 potatoes will be used, stored, processed and handled as any conventional starch potatoes. No mandatory restrictions are proposed as a condition of the authorisation, except for the use of the derived amylopectin starch, which is intended to be marketed for non-food uses only and will be labelled accordingly.

Any product derived from EH92-527-1 potato that is during use, storage or handling found to be unintentionally present in the food chain, will be labelled and channelled according to applicable EU legislation, in particular Regulation (EC) No 1829/2003.

e) Any proposed packaging requirements

Amylopectin EH92-527-1 potatoes and products of the starch processing will be packaged as any other conventional starch potatoes and starch potato processing products.

f) A proposal for labelling in accordance with Articles 13 and Articles 25 of Regulation ((EC) 1829/2003. In the case of GMOs, food and/or feed containing or consisting of GMOs, a proposal for labelling has to be included complying with the requirements of Article 4, B(6) of Regulation (EC) 1830/2003 and Annex IV of Directive 2001/18/EC

Product name: name variety is AMFLORA

Specification of the traits introduced by genetic modification: ‘Amylopectin potato, authorized according to Directive 2001/18/EC – Reference C/SE/96/3501. In addition to amylopectin enrichment, a tolerance to kanamycin (*nptII*) has been introduced’.

Product description: ‘Seed potatoes of genetically modified potato derived from transformation event EH92-527-1’ or ‘starch potatoes of genetically modified potato derived from transformation event EH92-527-1’.

Unique identifier: BPS-25271-9

Reference to public registers: A reference to one or more public registers, as indicated by competent authorities, where the public can obtain information on the GMO will be included.

Provider: Name and address of breeder/distributor (see point 2.c)

Use indications: ‘The amylopectin potato is intended for starch production. It is not intended for food use.’

Labelling and traceability: According to Regulation (EC) 1829/2003 and (EC) 1830/2003 operators handling or using foods and feeds produced from amylopectin potato event EH92-527-1 are required to be aware of the legal obligations regarding traceability and labelling. The applicant will communicate such obligations to all parties involved in the processing. In processing the amylopectin starch from the EH92-527-1 potato, feed products will be obtained. These will be labelled according to Regulation (EC) 1829/2003 with ‘produced from genetically modified potato’.

g) Unique identifier for the GM plant (Regulation (EC) 65/2004; does not apply to applications concerning only food and feed produced from GM plants, or containing ingredients produced from GM plants)

The unique identifier is BPS-25271-9.

h) If applicable, geographical areas within the EU to which the product is intended to be confined under the terms of the authorisation applied for. Any type of environment to which the product is unsuited

Not applicable.

9. Measures suggested by the applicant to take in case of unintended release or misuse as well as measures for disposal and treatment

Any product derived from amylopectin potato clone EH92-527-1 that is during use, storage or handling found to be unintentionally present in the food chain, will be labelled and channelled according to applicable EU legislation, in particular Regulation (EC) No 1829/2003.

**B. INFORMATION RELATING TO (A) THE RECIPIENT OR (B)
(WHERE APPROPRIATE) PARENTAL PLANTS****1. Complete name**

a) Family name	<i>Solanaceae</i>
b) Genus	<i>Solanum</i>
c) Species	<i>tuberosum</i>
d) Subspecies	<i>tuberosum</i>
e) Cultivar/breeding line or strain	Prevalent
f) Common name	Potato

2 a. Information concerning reproduction

(i) Mode(s) of reproduction	Potato reproduce mainly vegetatively via tubers, known as seed tubers or seed potatoes. Reproduction is also possible sexually via botanical seed. Under field conditions selfing is most likely with 80 to 100 % of the seeds formed due to selfing.
(ii) Specific factors affecting reproduction	Potato tubers can persist in the soil, however under European conditions (cold wet soils) plants rapidly become infected with a range of viral and fungal diseases. Though due to sensitivity to frost the survival of tubers also depends upon winter temperature. Most cultivated <i>S. tuberosum</i> subsp. <i>tuberosum</i> cultivars show a reduced pollen fertility or even pollen sterility, such that their fertility in general is reduced. Flower and berry development is very rare. Most (> 95%) buds and flowers abort prematurely. In very exceptional cases when flowers are developed they are very small and malformed. Also anthers are malformed and contain almost no viable pollen (OECD, 1997).
(iii) Generation time	The generation time of potato is one year.

2 b. Sexual compatibility with other cultivated or wild plant species

The recipient potato variety Prevalent is compatible with other cultivated potato varieties as well as with true seedling plants produced by hybridisation between potato varieties, including their vegetative progenies, which all belong to the species <i>Solanum tuberosum</i> .

The tetraploid *Solanum tuberosum* is not compatible with the wild related species *S. nigrum* (deadly nightshade) and *S. dulcamara* (woody nightshade) occurring in Europe.

3. Survivability

a) Ability to form structures for survival or dormancy

Potatoes survive as tubers or as seed.

b) Specific factors affecting survivability

Tubers are destroyed by a frost period of 25 hours at -2°C or a frost period of five hours at -10°C . They may survive the winter in the soil in most parts of Europe. Survivability is also limited by cultivation practices such as ploughing, harrowing, application of herbicides and by competition from other crops in the crop rotation. Botanical seed over-winter regardless of temperature. Their survival depends on cultivation practices and crop rotation. Usually routine agricultural practices like ploughing, harrowing, herbicide application and competition in crop rotation eliminate emerging volunteer plants.

Outside the field, potato seedlings have difficulty establishing, as they are at a competitive disadvantage with other plants. In general, the potato is not known as a coloniser of unmanaged ecosystems. It is not able to compete with other species such as grasses, trees and shrubs.

4. Dissemination

a) Ways and extent of dissemination

The extent of pollen dispersal in potato is related to the species of insect pollinator concerned, weather conditions and the fertility of the cultivar. Potato produces no nectar so honey-bees are usually not attracted to the flowers. Bumblebees instead are contributing to pollination, however they travel only short distances so that the majority of pollen – if present – is deposited in the immediate surroundings of the pollen source.

Potato is mainly self-pollinating. Pollen dispersal via wind is possible and may lead to minimal dispersal of pollen beyond the immediate vicinity of the potato field.

Dissemination of tubers and botanical seed is normally limited to the area of cultivation. Tubers may be spread during transportation and handling, but in general these plants will not establish themselves due to unfavourable environmental conditions.

b) Specific factors affecting dissemination

See 4a.

5. Geographical distribution and cultivation of the plant, including the distribution in Europe of the compatible species

Potatoes are found in agricultural areas throughout Europe. Wild related species, *Solanum nigrum* and *S. dulcamara*, are found throughout Europe, but efficient incompatibility barriers prevent hybridisation between those and *S. tuberosum*.

6. In the case of plant species not normally grown in the Member State(s), description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts

Potatoes are normally grown in the Member States, while the cultivation of starch potato varieties for the purpose of starch production within the EU quota system is limited to only a subset of Member States.

7. Other potential interactions, relevant to the GM plant, of the plant with organisms in the ecosystem where it is usually grown, or used elsewhere, including information on toxic effects on humans, animals and other organisms

Potato interacts with a range of organisms like aphids, beetles, nematodes, many microorganisms, virus and viroids as well as pathogenic fungi. The main toxic or anti-nutritional substances in potatoes are glycoalkaloids and nitrates. Glycoalkaloids which in high concentrations are toxic, are found in harmful amounts mainly in the above ground parts of the plant - stems, leaves and fruits. Nitrates are found in the entire plant and are considered anti-nutritional.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION**1. Description of the methods used for the genetic modification**

Plasmid DNA was introduced into the potato lines by *Agrobacterium*-mediated gene transfer technology. In this case a binary vector system was used where the T-DNA, containing the genes that are to be transferred, is found on one plasmid while the DNA mobilising functions are found on a modified Ti-plasmid. Leaf discs from potato were transformed after which *A. tumefaciens* was eliminated with Claforan (500mg/l). Shoots were then generated under selection on kanamycin containing medium (50mg/l). *A. tumefaciens* can be considered eliminated since the culturing of shoots on non-selective medium does not lead to bacterial growth. This is standard technology for potato transformation.

2. Nature and source of the vector used

Agrobacterium tumefaciens strain LBA4404 containing Ti-plasmid pAL4404 was used for transformation of potato. In pAL4404 the T-DNA and the 'oncogenic' traits are deleted. The binary vector, which functioned as a carrier of the traits that have been transferred to plant tissue is derived from pBIN19. pBIN19 can be propagated both in *E. coli* as well as *A. tumefaciens* and contains a T-DNA that is limited by the right and left border sequences from pTiT37. Outside the T-DNA border sequences a gene for kanamycin resistance is located that allows for selection in bacteria. This gene, however, is not transferred to the plant.

3. Size, source (name) of donor organism(s) and intended function of each constituent fragment of the region intended for insertion

The potato cultivar Prevalent was transformed with the plasmid pHoxwG, which is derived from the vector pBIN19.

Table 1 presents the size, the intended function and the origin of each constituent of the T-DNA of pHoxwG.

Size	Function	Origin
1-372	pTiT37 fragment with right border sequence (RB) including the 5' untranslated part of a nopaline synthase gene (Pnos), functional as a promoter in plants.	<i>Agrobacterium tumefaciens</i>
373-1356	Tn5 fragment with neomycine phosphotransferase II (<i>nptII</i>) coding sequence (385-1179)	Can be isolated from different bacteria, among others <i>Escherichia coli</i>
1357-1568	Ti-plasmid fragment	<i>Agrobacterium tumefaciens</i>
1569-1824	pTiT37 fragment including the 3' untranslated part of a nopaline synthase	<i>Agrobacterium tumefaciens</i>

	gene (nospA), functional as a polyadenylation sequence in plants	
1825-2496	M13mp19 fragment with polylinker sequences	Phage M13 modified for laboratory use
2497-3486	Genomic <i>gbss</i> fragment (Pgbss) functional as a promoter in plants	<i>Solanum tuberosum</i>
3487-3500	Cloning remainders from M13mp19	Phage M13 modified for laboratory use
3501-3511	Cloning remainders from pJRD184	Synthetic sequence
3512-5455	Genomic <i>gbss</i> fragment, inserted in reversed orientation in relation to the promoter sequence	<i>Solanum tuberosum</i>
5456-5701	Cloning remainders from pJRD184	Synthetic sequence
5702-5978	pTiT37 fragment including the 3' untranslated part of a nopaline synthase gene (nospA), functional as a polyadenylation sequence in plants.	<i>Agrobacterium tumefaciens</i>
5979-6559	M13mp19 fragment with polylinker sequences.	Phage M13 modified for laboratory use
6560-6637	pTiT37 fragment including left border sequence (LB).	<i>Agrobacterium tumefaciens</i> .

D. INFORMATION RELATING TO THE GM PLANT**1. Description of the trait(s) and characteristics, which have been introduced or modified**

An introduced granule bound starch synthase (*gbss*) gene from *Solanum tuberosum* in antisense relative to the *gbss* promoter leads to a decrease in amylose content and a concomitant increase in amylopectin content (> 98 %) in tuber starch of amylopectin potato clone EH92-527-1. The expression of neomycin phosphotransferase II by the nopaline synthase promoter from *Agrobacterium tumefaciens* confers tolerance to kanamycin.

2. Information on the sequences actually inserted or deleted**a) The copy number of all detectable inserts, both complete and partial**

Amylopectin potato clone EH92-527-1 contains one single insert present as an inverted repeat in a tail-to-tail arrangement with two right border regions as junctions to the potato chromosomal DNA as revealed by extensive molecular characterisation.

b) In case of deletion(s), size and function of the deleted region(s)

Not applicable.

c) Chromosomal location(s) of insert(s) (nucleus, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its determination

The insert of amylopectin potato clone EH92-527-1 is integrated into the nuclear genome of potato. The integration of the insert was confirmed by extensive molecular characterisation including the DNA sequence of flanking genomic regions. The recombinant *gbss*-gene has inhibited the expression of the chromosomal endogenous *gbss*-gene and the modified trait has been shown to be stable over several tuber generations.

d) The organisation of the inserted genetic material at the insertion site

The insert in EH92-527-1 comprises the 5' untranslated region of a nopaline synthase gene (*p-nos*) functional as a promoter in plants, the *nptII* (neomycin phosphotransferase II) coding sequence (Tn5 derived), the 3' untranslated part of a nopaline synthase gene (*t-nos*), a potato *gbss* (granule bound starch synthase) promoter fragment, a *gbss* coding region fragment in antisense orientation. All of the above elements including the *gbss* coding region fragment have been inverted, duplicated and joined directly tail-to-tail during integration. No genetic elements outside of the T-DNA borders of the vector pHoxwG were transferred to the EH92-527-1 potato.

3. Information on the expression of the insert**a) Information on developmental expression of the insert during the life cycle of the plant**

Amylopectin potato clone EH92-527-1 carries a *gbss* gene fragment in antisense relative to the *gbss* promoter from *Solanum tuberosum*, which leads to the inhibition of expression of the endogenous *gbss* gene in potato tubers during tuber development. No new protein is expressed. The selectable marker gene neomycin phosphotransferase II is under the

control of the nopaline synthase promoter from *Agrobacterium tumefaciens*. The expression level of APH(3')II was investigated in developing potato leaves. Though the protein is expressed in young leaves, leaf expression of APH(3')II decreased to non-quantifiable amounts with age of the plant.

b) Parts of the plant where the insert is expressed

The genetic modification in amylopectin potato clone EH92-527-1 is intended to inhibit the expression of the endogenous *gbss* gene and thereby reducing the synthesis of amylose in the potato tuber. EH92-527-1 potatoes were analyzed for the presence of the GBSS protein. In conventional potato starch the GBSS protein constitutes approximately 80 % of the extractable protein. The GBSS protein is not detectable in clone EH92-527-1. APH(3')II protein was detectable in tuber and leaves of potato clone EH92-527-1. Tubers contained approx. 31 ppb or ng APH(3')II/g fresh weight (6.82 ng APH(3')II/mg protein).

4. Information on how the GM plant differs from the recipient plant in

a) Reproduction

Comparative observations regarding flowering frequencies, fruit setting and tuber formation in amylopectin potato clone EH92-527-1 and the recipient variety Prevalent have not revealed any biological significant differences. Based on these results and knowledge of the genetic modification it can be concluded that there are also no differences regarding mode or frequency of reproduction or dissemination between EH92-527-1 and the recipient clone.

b) Dissemination

See 4a.

c) Survivability

The survivability of potatoes in Europe mostly depends on the sensitivity to cold temperatures as well as to infections based on cold and wet soil conditions. No difference in frost tolerance between the recipient clone and EH92-527-1 were recorded. Tubers submitted to artificial frosts in the laboratory did not show any behaviour deviating from those of the recipient variety Prevalent. In field trials it has been shown that establishment and development of potato plants are comparable to the recipient clone, above as well as below ground.

d) Other differences

No other differences were observed.

5. Genetic stability of the insert and phenotypic stability of the GM plant

Amylopectin potato clone EH92-527-1 has been vegetatively propagated by way of cuttings and via tubers. Based on multiplication over several generations the inserted trait was found to be stable as has been shown via analysing the composition of tuber starch from EH92-527-1 during three consecutive years. The insert has been stably integrated into the potato genome, which was demonstrated by DNA sequence analysis over multiple years.

6. Any change to the ability of the GM plant to transfer genetic material to other organisms**a) Plant to bacteria gene transfer**

As demonstrated by Southern analysis no genetic elements outside of the right and left border region of the T-DNA in construct pHoxwG that could affect the mobility of DNA have been inserted into amylopectin potato clone EH92-527-1. Therefore no changes as compared to conventional starch potatoes are expected in the ability of EH92-527-1 potato to transfer genetic material to bacteria.

b) Plant to plant gene transfer

Genetic material can be transferred to other potato varieties by pollen, which could result in hybrids containing the genetic modification. The amylopectin potato clone EH92-527-1 is compatible with other cultivated potato varieties belonging to the same species, *Solanum tuberosum*. *S. tuberosum* is not compatible to any of its relatives present in Europe, *S. nigrum* and *S. dulcamara*. No changes in flower morphology have been observed for EH92-527-1 that could indicate a change in the ability to produce and release pollen. Therefore no changes compared to conventional starch potatoes regarding the transfer of genetic material to other potato varieties is expected.

7. Information on any toxic, allergenic or other harmful effects on human or animal health arising from the GM food/feed**7.1 Comparative assessment****Choice of the comparator**

Amylopectin potato clone EH92-527-1 was compared to its mother variety Prevalent and conventional starch potatoes.

7.2 Production of material for comparative assessment**a) number of locations, growing seasons, geographical spreading and replicates**

Multiple field trials have been conducted in Sweden in regions representative with regard to environmental conditions for the cultivation of conventional starch potatoes. Comprehensive data sets are provided for field trials carried out in 1996, 1997 and 1998 at three locations and in 4 replicates per year.

b) the baseline used for consideration of natural variations

Published literature data for conventional starch potatoes as well as table potatoes together with analysis of the mother starch potato variety served as a baseline for evaluation of natural variation.

7.3 Selection of compounds for analysis

Dry matter, protein, ash, fibre, digestible fibre, fat, starch and sugar, chlorogenic acid, glycoalkaloid, vitamin C, nitrate and mineral ion contents have been quantified in tubers of potato event EH92-527-1 and in the mother variety Prevalent. Compositional analyses are also provided for the potato pulp (crude protein, ash, fibre, digestible fibre, mineral ion content), fruit juice and fruit water (dry matter, acidity, mineral ion content) derived from

the starch extraction process.

7.4 Agronomic traits

Agronomic characteristics of the amylopectin potato event EH92-527-1 and the recipient variety Prevalent have been compared in the years 1993 to 1996 in field trials in Sweden as well as in variety trials in 1995 and 1996 in Sweden. Growth characteristics have been observed during the conduct of all field trials. No significant differences between EH92-527-1 and the comparator variety Prevalent were observed.

7.5 Product specification

Amylopectin potato clone EH92-527-1 shows an increase of amylopectin in potato tuber starch to > 98 % and confers tolerance to kanamycin.

Southern Blot or PCR techniques can be employed for the detection and identification of the inserted nucleotide sequences. Iodine staining can be used to detect the amylopectin trait in individual potato tubers. An event-specific PCR-based detection method allows quantitative detection of amylopectin potato event EH92-527-1.

7.6 Effect of processing

Processing of amylopectin potato clone EH92-527-1 for starch will essentially be the same as for commercial starch potatoes. The processes applicable in the potato starch industry can be summarized as the following: In high speed rasping machines the potato cells are broken open and the starch is freed yielding extraction rates of 96 to 98 %. Discoloration of the potato mash is avoided by the addition of sulfur dioxide containing water. The starch is being extracted via centrifugation and concentrated in hydrocyclone units, yielding the fruit juice, the pulp and the starch slurry. Further refining and washing in hydrocyclones as well as drying results in the dry starch and the fruit water.

Any effects of the processing of amylopectin potato clone EH92-527-1 on derived starch and by-products are not expected to be any different from any effects of the processing of conventional starch potatoes on the equivalent by-products.

7.7 Anticipated intake/extent of use

The amylopectin potato clone EH92-527-1 is intended to be used as any other commercial starch potato for the industrial production of starch. Its unique quality regarding the amylopectin content will be ensured and protected by the implementation of an identity preservation system. Like other commercial starch potatoes, EH92-527-1 potatoes are not intended for human consumption, but solely for use in the starch production industry. The derived amylopectin starch is intended to be placed on the market for non-food uses e.g. in the paper industries. The starch processing by-products (fruit juice and pulp) will be placed on the market to be used as any conventional starch potato by-products as fertilizer and in animal feed.

7.8 Toxicology

7.8.1 Safety evaluation of newly expressed proteins

Amylopectin potato clone EH92-527-1 contains a granule bound starch synthase gene fragment in antisense, which does not lead to the expression of a new protein in the plant, further it contains the selectable marker gene neomycin phosphotransferase II, being expressed at low levels throughout the potato plant. APH(3')II protein was detectable in pulp, raw tuber and leaves but not in starch samples of potato clone EH92-527-1. As published in literature there are no indications of acute toxicity for APH(3')II protein

based on oral gavage studies in mice. Further the degradability of APH(3')II protein in ruminal fluid was tested. Considering the low expression levels of APH(3')II in potato in tubers and stolons, an intake for humans nearing zero (starch potatoes are not intended for human consumption, purified starch derived from EH92-527-1 does not contain the APH(3')II protein), a limited intake for animals via pulp and the rapid degradation of the protein in rumens the total exposure is negligible.

7.8.2 Testing of new constituents other than proteins

The traits introduced into potato event EH92-527-1 are a decrease in amylose content in starch with a concomitant increase in amylopectin and tolerance to kanamycin. Thus no new constituents other than the APH(3')II protein are formed due to the introduction of those traits and no further evaluation is required.

7.8.3 Information on natural food and feed constituents

Comprehensive compositional analysis were performed for amylopectin potato event EH92-527-1. Statistically significant differences were identified for fructose, saccharose, vitamin C (increase relative to the comparator Prevalent) and total glycoalkaloids (decrease relative to the comparator Prevalent), but remained well within the ranges of natural variation for conventional starch potatoes. The amylopectin potato clone EH92-527-1 only differs in its ratio of amylose and amylopectin in the tuber. Based on extensive characterisation of EH92-527-1 starch the natural constituents of tuber starch amylose and amylopectin in EH92-527-1 are equivalent in their characteristics to the comparator variety Prevalent. Any differences are solely related to the altered quality of the starch due to it being an amylopectin type starch with the corresponding biochemical and biophysical characteristics.

7.8.4 Testing of the whole GM food/feed

Amylopectin potato clone EH92-527-1 differs substantially in its content of amylose from its mother variety and conventional starch potatoes due to the introduced trait that is intended to suppress the expression of granule bound starch synthase and thereby leads to a reduction of the amylose fraction in potato tuber starch to less than 2 %. Neither the molecular, nor the compositional or phenotypic analysis point to the potential occurrence of any unintended effects with regard to human or animal health. Food and feed safety has been confirmed via a 90-day rat feeding study with the unprocessed EH92-527-1 potato as feed ingredient and a bovine study conducted with EH92-527-1 potato pulp.

7.9 Allergenicity

7.9.1 Assessment of allergenicity of the newly expressed protein

The potato clone EH92-527-1 has been modified to produce a significantly higher level of the naturally occurring starch amylopectin. This was achieved through the anti-sense inhibition of the gene encoding the granule bound starch synthase protein (GBSS) that is responsible for amylose biosynthesis. The neomycin phosphotransferase gene functions as selectable marker. The potential allergenicity of APH(3')II protein has been investigated on numerous occasions where simulated mammalian digestion studies have been submitted for evaluation as well as studies where its amino acid sequence has been compared with known allergens. None of this has revealed any potential for APH(3')II protein to be a food allergen. In addition the safety of this protein including its potential allergenicity has also been considered on numerous occasions in the peer reviewed scientific literature. The product derived from amylopectin potato clone EH92-527-1 will be a highly purified amylopectin starch, which is already used as a food ingredient in

numerous applications. There is no reason to expect the product considered here to be any more or less of a potential allergen than the product presently used in food.

7.9.2 Assessment of allergenicity of the whole GM plant or crop

There are no indications that other changes have occurred that influence the allergenicity of the whole crop. No adverse effects have been reported during the development and handling of EH92-527-1, as potatoes or during processing. Should the high amylopectin starch potato be inadvertently consumed the data supporting its equivalence to the non-modified parent variety would indicate that it is no more of a potential allergen than the non-modified parent.

7.10 Nutritional assessment of GM food/feed

7.10.1 Nutritional assessment of GM food

Taking together the characteristics of the EH92-527-1 potato, its compositional characteristics due to the introduced trait, the anticipated intake and exposure and the presence and safe use of the starch component amylopectin in our food supply the EH92-527-1 potato is considered to pose negligible risk to human health.

7.10.2 Nutritional assessment of GM feed

The results of the supportive feeding study together with the compositional analyses of the potato tubers as well as the derived by-products show that there are no biologically relevant differences in the nutritional and compositional properties of amylopectin EH92-527-1 potatoes compared to conventional starch potatoes. They thus confirm the conclusion that amylopectin potato clone EH92-527-1 is as nutritious and safe as conventional starch potatoes when its products are used in animal feed applications as any other starch potato products.

7.11 Post-market monitoring of GM food/feed

As any conventional starch potato the EH92-527-1 potatoes are not intended for human consumption. The intended use of the starch is for non-food applications, e.g. in paper industries. The amylopectin potato EH92-527-1 is compositionally and nutritionally equivalent to conventional starch potatoes except for the introduced traits. The starch component amylopectin is already present in our food supply with all starchy foods and therefore would not constitute a new component to the human diet, nor is the exposure to amylopectin changed in any significant degree, which would affect long-term nutritional and health status of individuals. Further none of the characteristics of the starch potato have been changed in a way that would be measurable in animal feed or are intended to have an effect on animal feed as shown in the heifer feeding study. The by-products of EH92-527-1 potato processing are used as any other starch potato processing by-products in animal feeding. No post-market monitoring of GM food and feed is required. However, the general surveillance of some selected parameters relating to animal feed are included in the post-market monitoring plan, which is part of notification C/SE/96/3501 for amylopectin potato event EH92-527-1 according to Directive 2001/18/EC.

8. Mechanism of interaction between the GM plant and target organisms (if applicable)

Not applicable.

9. Potential changes in the interactions of the GM plant with the biotic environment resulting from the genetic modification

Amylopectin potato clone EH92-527-1 is substantially equivalent to conventional starch potatoes except for the introduced traits of increased amylopectin content in tuber starch and tolerance to kanamycin as selectable marker. Both the starch component amylopectin and the APH(3')II protein have a safe history of use and do not confer any change in the interactions with the biotic environment as compared to the parental variety. Cultivation, processing, and feed use of processing by-products as well as starch for non-food uses of amylopectin potato clone EH92-527-1 are covered under the scope of notification C/SE/96/3501 according to Directive 2001/18/EC. The scope of the current application includes amylopectin potato clone EH92-527-1 and products of the starch processing for food and feed use.

9.1 Persistence and invasiveness Please see Point 9.
9.2 Selective advantage or disadvantage Please see Point 9.
9.3 Potential for gene transfer Please see Point 9.
9.4 Interactions between the GM plant and target organisms Please see Point 9.
9.5 Interactions of the GM plant with non-target organisms Please see Point 9.
9.6 Effects on human health Please see Point 9.
9.7 Effects on animal health Please see Point 9.
9.8 Effects on biogeochemical processes Please see Point 9.
9.9 Impacts of the specific cultivation, management and harvesting techniques Please see Point 9.

10. Potential interactions with the abiotic environment

Amylopectin potato clone EH92-527-1 is substantially equivalent to conventional starch potatoes except for the introduced traits of increased amylopectin content in tuber starch and tolerance to kanamycin as selectable marker. Both the starch component amylopectin and the APH(3')II protein have a safe history of use and do not confer any change in the interactions with the abiotic environment as compared to the parental variety. The scope of the current application includes amylopectin potato clone EH92-527-1 and products of

the starch processing for food and feed use. Cultivation, processing and feed use of processing by-products as well as starch for non-food uses of amylopectin potato clone EH92-527-1 are covered under the scope of notification C/SE/96/3501 according to Directive 2001/18/EC.

11. Environmental monitoring plan (not if application concerns only food and feed produced from GM plants, or containing ingredients produced from GM plants)

The scope of the current application includes amylopectin potato clone EH92-527-1 and products of the starch processing for food and feed use. Cultivation, processing and feed use of processing by-products as well as starch for non-food uses of amylopectin potato clone EH92-527-1 are covered under the scope of notification C/SE/96/3501. Notification C/SE/96/3501 includes a post-market monitoring plan for the placing on the market (cultivation) of amylopectin potato event EH92-527-1 in accordance with Annex VII to Directive 2001/18/EC and further supplemented by the guidance notes in Council Decision 2002/811/EC.

11.1 General (risk assessment, background information)
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Please see Point 11.

11.2 Interplay between environmental risk assessment and monitoring

Please see Point 11.

11.3 Case-specific GM plant monitoring (approach, strategy, method and analysis)
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Please see Point 11.

11.4 General surveillance of the impact of the GM plant (approach, strategy, method and analysis)

Please see Point 11.

11.5 Reporting the results of monitoring
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Please see Point 11.

12. Detection and event-specific identification techniques for the GM plant

A quantitative event-specific detection method and control materials have been provided to DG Joint Research Centre, Unit Biotechnology and GMOs, according to Regulation (EC) No 1829/2003.

E. INFORMATION RELATING TO PREVIOUS RELEASES OF THE GM PLANT AND/OR DERIVED PRODUCTS**1. History of previous releases of the GM plant notified under Part B of the Directive 2001/18/EC and under Part B of Directive 90/220/EEC by the same notifier**

a) Notification number
See table to point A.5. with regard to previous releases notified under Part B of Directive 90/220/EEC.
b) Conclusions of post-release monitoring
Different experimental purposes have been pursued for the field trials performed in Sweden ranging from observation trials, yield trials and official variety registration trials, to seed potato production and starch production trials. During and post trial observations on performance, management and potential impact have been performed and results have been reported to the Swedish Board of Agriculture. None of the observations made revealed any unexpected effect or behaviour of amylopectin potato event EH92-527-1.
c) Results of the release in respect to any risk to human health and the environment (submitted to the Competent Authority according to Article 10 of Directive 2001/18/EC)
Post-trial observations did not provide any evidence that amylopectin potato clone EH92-527-1 is likely to pose any risk of adverse effects to human health and the environment.

2. History of previous releases of the GM plant carried out outside the Community by the same notifier

a) Release country
No environmental releases have been carried out outside of the European Community with amylopectin potato clone EH92-527-1.
b) Authority overseeing the release
Not applicable.
c) Release site
Not applicable.
d) Aim of the release
Not applicable.
e) Duration of the release
Not applicable.
f) Aim of post-releases monitoring
Not applicable.
g) Duration of post-releases monitoring
Not applicable.

h) Conclusions of post-release monitoring

Not applicable.

i) Results of the release in respect to any risk to human health and the environment

Not applicable.

3. Links (some of these links may be accessible only to the competent authorities of the Member States, to the Commission and to EFSA):

a) Status/process of approval

The status of the notification according to Directive 2001/18/EC is publicly accessible under http://gmoinfo.jrc.it/gmc_browse.asp. The 45-day period according to Article 15 (1) concluded on 27 January 2005.

b) Assessment Report of the Competent Authority (Directive 2001/18/EC)

The assessment report for notification C/SE/96/3501 is available at http://gmoinfo.jrc.it/gmc_browse.asp.

c) EFSA opinion

The positive opinion on amylopectin potato clone EH92-527-1 by the Scientific Committee on Plants is available at http://europa.eu.int/comm/food/fs/sc/scp/index_en.html. There is no EFSA opinion available yet.

d) Commission Register (Commission Decision 2004/204/EC)

Not available yet.

e) Molecular Register of the Community Reference Laboratory/Joint Research Centre

The information will be made available at <http://gmo-crl.jrc.it/>.

f) Biosafety Clearing-House (Council Decision 2002/628/EC)

The link to the biosafety clearing house is <http://bch.biodiv.org/>.

g) Summary Notification Information Format (SNIF) (Council Decision 2002/812/EC)

The SNIF for notification C/SE/96/3501 is available at http://gmoinfo.jrc.it/gmc_browse.asp.