Amflora
Facts

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Content

	page
1. Background information "Amflora – a starch is born"	2
2. Amflora: Supported by the new German government	4
3. Amflora: Approval process	5

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Amflora - a starch is born!

Amflora is a genetically improved potato developed to produce a specific natural starch (amylopectin) needed for industrial applications, for example in paper manufacturing, the textile and adhesives industries.

Amylopectin and Amylose

Amylopectin

Amylose

- Amylopectin is a highly branched polymer with excellent thickening properties
- Amylose is an essentially linear polymer which tends to form gels

Benefits of Amflora for the industry

- creates additional value for the starch potato farmers in Europe
- reduces production costs
- is a natural renewable resource
- reduces the use of oil-based chemicals

The “making of” Amflora

The request to develop a potato like Amflora goes back to an unmet need of the starch industry. While a potato produces starch consisting of two components (amylopectin and amylose) only one (amylopectin) provides the desired functionality required by many technical applications.

With the tools of plant biotechnology developed in Leuven, Belgium and Cologne, Germany, BASF developed a potato which only produces this single starch component - pure Amylopectin.

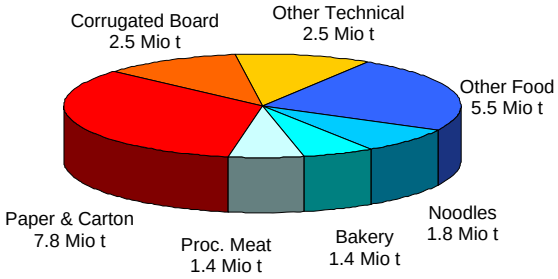
The name “Amflora”

The potato’s name is derived from the Greek word for starch “amylon” and the Latin word for flower “flora”.

The starch market

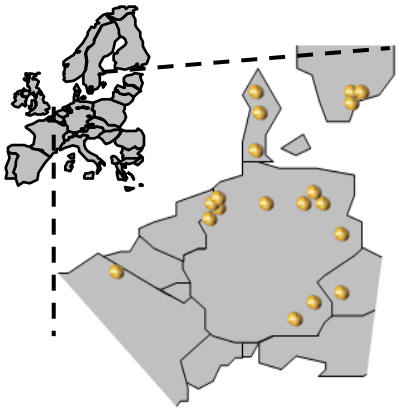
Starches derived from special potatoes, maize or tapioca, are used for food and technical applications like paper manufacturing, the textile and the adhesives industries.

These technical applications account for 56% (12.9 Mio t) of the global starch consumption of 23 Mio tones.



The potato starch industry

Europe accounts for 80% of the global potato starch production. The main potato starch cultivation regions and potato starch processing countries are Germany, the Netherlands, France, Denmark, Poland and Sweden.



The European potato starch industry

- provides direct income to over 14.000 farmers
- financially supports more than 4.000 employees families
- factories are located in rural areas and play an important socio-economic role in their regions

Amflora safety

In Europe, genetically improved crops undergo a rigorous

Amflora's role for the starch industry

Currently the European starch industry is subsidized by the EU in order to remain competitive on the global market. The EU subsidies for potato starch will stop in 2012.

To meet this challenge, this industry needs to focus on products with higher value. Amflora can help to increase the competitiveness of the potato starch farmers and industry, as it generates an added value of 2.000 €/ha for the starch industry.

Example: The paper making industry

Amflora starch will be marketed for technical applications. In the paper industry Amflora starch can improve the quality of paper and reduce the cost of the paper making process.

Paper making and the environment

Fibers, fillers, and starch are the main components of paper. The extraction of fibers from wood is the most energy- and water-consuming and costly process in paper making.

The use of waste paper as a fiber source is highly advantageous, as it requires much lower inputs in terms of water, energy and forest resources.

However, the use of waste paper is limited because paper strength decreases with increasing waste paper content.

Amflora - helping the environment

The highly branched structure of Amflora starch has several advantages for paper making, as it binds fibers more efficiently and allows using a higher rate of waste paper in the process.

Amflora starch, therefore, can help to save water, energy and raw material in the paper production.

safety assessment by the European Food Safety Authority (EFSA). An approval will only be granted if through extensive studies it can be verified, that:

- the molecular information for the desired trait has been correctly introduced (by an array of molecular analytical methods)
- no toxins or allergens have been generated (shown by different methods including a set of animal feeding studies)
- the crop characteristics, e.g. morphology, growth, germination, tuber composition (e. g. vitamins, amino acids, minerals) remain unaffected by the introduced trait as compared to conventional potato varieties
- interaction with animals or insects as well as the physical environment remains unaffected as compared to conventional potato varieties (in large field trials)

In June 2009 EFSA confirmed its previous assessments from 2005 and 2007 that Amflora is as safe for humans, animals and the environment as any conventional potato.

Amflora and other agricultural crops can be grown together

- because potatoes have no wild relatives in Europe and are multiplied vegetatively by tubers so there is no possibility for out-crossing
- potatoes are not frost tolerant and usually do not survive European winters

Quality-assuring cultivation

In order to maintain the special quality of its starch Amflora will be cultivated and processed separately from conventional potatoes:

- from seed potato through the starch processing in an Identity Preservation System
- identity and purity of products monitored and audited at all stages of process
- system thoroughly tested under real-life conditions
- contract farming only, no free sales of Amflora

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Amflora
Supported by the new German government

The new German government, a coalition of Christian Democrats and Liberals, is committed to the promotion of biotechnology in general and supports the approval of Amflora in particular.

As it is written in the Coalition Agreement of October 24, 2009:

“Biotechnology is an important sector with a promising future for research, industry and agriculture. It is already established the world over.

We therefore want to tap into the accountable potential offered by green genetic engineering. The overriding aim of German genetic engineering legislation remains the protection of people and the environment.

We support a more scientific approach and efficient approval of genetically modified organisms (GMO) at EU level.

We lay the legal foundations for the German federal states to be able to act within a standard framework across Germany to flexibly and independently define the spacing required between fields planted with genetically modified crops and those with conventional or organic crops.

We are waiting for the outcome of court proceedings on the decreed cultivation ban on the MON810 genetically modified corn variety. **We support the cultivation of the Amflora genetically modified starch potato for commercial and industrial use.**

In order to deliver a for economic and monitoring purposes practicable application of the zero tolerance level defined in EU law for GMOs not licensed in the EU, we will alter genetic engineering legislation and the German law regulating the implementation of the European provisions in the field of GMOs. We will establish an authorization for defining official methods of sampling and detection.

To create comprehensive consumer transparency, we aim for positive labeling (process labeling) at European level.”

Amflora
Approval process

- 08/1996 — submission of application for approval of cultivation, processing, industrial use and feed use of the pulp (a by-product of starch manufacturing) according to Directive 90/220/EEC
- 1998-2004 — "de facto"-moratorium on the approval of genetically modified (GM) plants in Europe, change of legislation
- 01/2003 — complementation of application according to Directive 2001/18/EC
- 03/2005 — submission of application according to Regulation (EC) No. 1829/2003 for food and feed use; purpose:
  - to guarantee – in line with the precuationary principle – the safety of Amflora for humans, animals and the environment
  - to allow the pulp to be used for animal feed
- 12/2005 — change of scope of application according to Directive 2001/18/EC to cultivation, processing and industrial use
- 12/2005 — scientific opinion by the European Food Safety Authority (EFSA) confirming the safety of Amflora for humans, animals and the environment

for cultivation, processing and industrial use in accordance with Directive 2001/18/EC (details):

- 12/2006 — vote in the Regulatory Committee on the proposed decision of the European Commission to approve Amflora for cultivation and industrial use in Europe in accordance with Directive 2001/18/EC; following outcome:

  134 votes in favor
  109 votes against
  78 abstentions

- 07/2007 — vote in the Council of Ministers for Agriculture on the proposed decision of the European Commission to

approve Amflora for cultivation and industrial use in Europe in accordance with Directive 2001/18/EC; following outcome:

130 votes in favor
119 votes against
96 abstentions

- 05/2008 orientation debate about GMOs in the EU Commission: For GMOs containing an antibiotic resistance marker gene, such as Amflora containing nptII, the Commission asked EFSA to analyse further scientific evidence on the effects of these GMOs on the environment and human health until September 30, 2008. The Commission will adopt the pending decision *if and when* EFSA has confirmed the safety of the products. To our best knowledge, there is no scientific evidence that questions the safety of Amflora.

- 07/2008 BASF Plant Science filing an action with the European Court of First Instance in Luxembourg against the EU Commission for failure to act.

- 07/2008 Instead of the requested deadline of September 30, 2008 for the delivery of the consolidated opinion on antibiotic resistance markers, EFSA extended the deadline until December 15, 2008.

- 12/2008 The deadline for delivery of the consolidated opinion from EFSA was again postponed, until March 31, 2009.

- 06/2009 EFSA reiterates earlier assessments that Amflora is safe for humans, animals and environment

- next step approval by the European Commission

for restricted use as food and animal feed in accordance with Regulation (EC) No 1829/2003:

- 10/2007 vote in the Standing Committee of the Food Chain and Animal Health on the proposed decision of the European Commission to approve Amflora for restricted use as food and animal feed in accordance with Regulation (EC) No 1829/2003, i.e.

  - animal feed manufactured from Amflora (for the use of the pulp, see above, as animal feed)
  - all other animal feed / foodstuff based on Amflora up to a limit of 0.9% and only, if accidentally and

technically unavoidable

Following outcome:

123 votes in favor
133 votes against
89 abstentions

- 02/2008 vote in the Council of Ministers for Agriculture on the proposed decision of the European Commission to approve Amflora for restricted use as food and animal feed in accordance with Regulation (EC) No 1829/2003 (see above); following outcome:

  131 votes in favor
  166 votes against
  48 abstentions

- 06/2009 EFSA reiterates earlier assessments that Amflora is save for humans, animals and the environment

- next step approval by the European Commission