

## **ANNEX 4**

### **USER GUIDE AMYLOPECTIN POTATO EH92-527-1**

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# Amflora

A starch is born



**User Guide**

**Amylopectin Potato EH92-527-1**

 **BASF**

The Chemical Company

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## 1. Starch potatoes and starch production

Potato production for starch extraction is an important source of income for many farms. Starch potatoes contribute to the income of about 14,000 farms across Europe. Furthermore, there are approximately 4,000 people employed in the starch processing industry, which is mainly located in rural regions with weak infrastructures. The main regions of starch potato production can be found in Germany, the Netherlands, France, Denmark, Poland, Sweden, Finland, Austria and the Czech Republic. These countries account for more than 90% of the EU's total starch production. So far, starch production has been organized in close cooperation and through long-term contracts between farmers and starch processors.



In the EU, potato starch production is regulated until 2012 by a quota system. The starch quota permits production of up to 1.95 million tons per year in the EU, a level which has not however been reached in the last few years. After 2012 subsidies of 66.32 € per ton of starch will no longer apply at farmer level. This translates into a reduced income of 500 € to 600 € per hectare of starch potato production. Subsidies of 22.25 € per ton of starch will also be removed at factory level. To keep potato starch production competitive, cost reductions or even better starch-based products of a higher value are urgently needed for the farmers as well as the factories.

Starch potatoes are currently grown on 250,000 hectares in the EU, producing 10 million tons of starch potatoes. Starch potato production in Germany today accounts for one-third of total potato production. Almost 2.8 million tons of potatoes were grown for starch production in Germany in 2008. About 80% of the world's potato starch is produced in the EU.



## 2. Amflora – the potato

Starch in a conventional potato tuber is a mixture of two components – amylopectin and amylose. Both components are polymers made up of glucose units, but they differ dramatically in their physical-chemical characteristics: amylopectin thickens and amylose gels. For many industrial applications, only the thickening amylopectin component is required, while the gelling amylose component is undesirable since it interferes in a number of applications. Nevertheless, the process of separating amylopectin and amylose is energy intensive and not economically viable. Today in most industrial processes, starch is first chemically modified to reduce the tendency of the amylose to gel. This is a process which consumes chemicals, water and energy.

**Amflora** offers a preferred solution for the potato starch industry as well as the environment. Its starch is composed almost exclusively of amylopectin. Therefore, **Amflora** combines the superior properties of potato-based starches with the excellent thickening functionality of pure amylopectin. Potato starch is superior to, for example, wheat and corn starch due to its higher molecular weight and its lower fat and protein content.



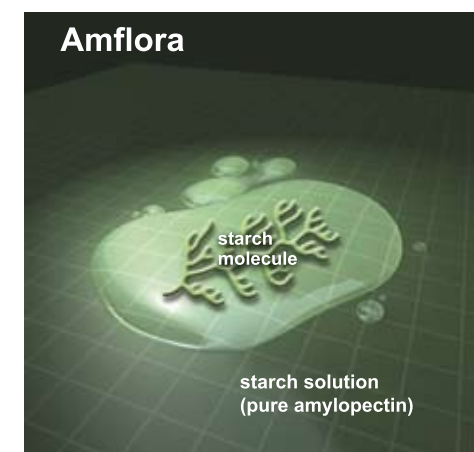
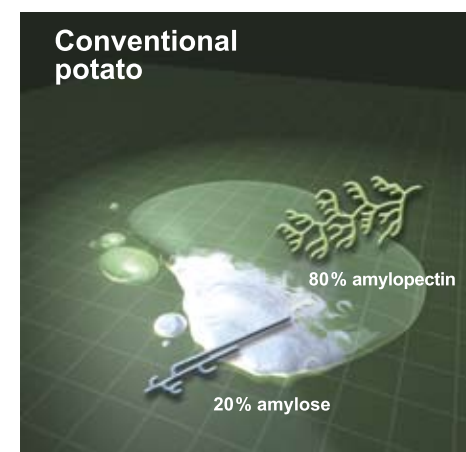
Pure amylopectin potato starch delivers unique, novel textures combined with high viscosity, stability and clarity. This innovative starch is used in paper, adhesives, textiles, and construction materials.

The idea behind **Amflora** was developed by experts in the potato starch industry. It is a European product designed to strengthen the competitiveness of the potato starch industry (which is mainly based in Europe) over other starch sources, e.g. corn. Therefore, high value potato starch products such as the starch derived from **Amflora** meet the needs of European starch processors and starch potato farmers.

**Amflora** is a potato variety of the medium late to late maturity group, has medium tuber yields and stable, high starch content in the form of pure amylopectin. It does not have any particular soil requirements and also tolerates drought and heat quite well. Pre-germination is recommended due to the medium dormancy nature of **Amflora**.

**Amflora** was made using molecular biology methods developed in the 1980s by researchers at the University of Ghent and the Max Planck Institute for Plant Breeding Research in Cologne.

In **Amflora**, the gene encoding the key enzyme for the synthesis of amylose, the granule bound starch synthase (GBSS), was switched off using the so-called antisense method through which a mirrored copy of the GBSS gene was reinserted into the genome of the potato. Apart from the intended change in the composition of its starch, **Amflora** maintains all the characteristics of its mother variety, the starch potato variety Prevalent.





### 3. Amflora – the starch

Increasing international competition and the phasing out of EU subsidies in 2012 are presenting major challenges for potato starch production. **Amflora** offers the potato starch value chain real alternatives to create more value per hectare and improves the competitiveness of starch processors.

**Compared with starch derived from conventional potatoes or from cereals, Amflora's pure amylopectin starch offers many improved properties:**

- high viscosity
- high transparency
- high molecular weight
- no complexing
- thickening without gelling
- flexible films
- high swelling rate
- solubility < 100°C
- low impurities

These properties result in improved product performance at high concentrations. By using starch derived from **Amflora** some technical application processes may be operated at lower temperatures and some modifications to the starch might only be necessary in part or not at all (e.g. chemical modification for starch stabilization).



The use of **Amflora**-derived starch can improve the performance of starch in various segments of non-food applications such as paper production (fiber and filler retention in the wet end, surface treatment and high-gloss coating).



Starch derived from **Amflora** also presents advantages in adhesive solution. In addition it is beneficial for yarn sizing and subsequent processes during weaving. Furthermore, there are several benefits from using pure amylopectin starch in the construction industry, such as sprayable concrete and other building materials.



## 4. Amflora identity preservation

Thanks to its numerous advantages in technical applications, starch derived from **Amflora** has a higher added value than conventional potatoes. To preserve this value, it is important that **Amflora** is kept separate from other potatoes throughout the whole production process, from seed potato production to starch production. Therefore, BASF Plant Science has developed an identity preservation system which describes documents and controls measures and processes throughout the production of **Amflora** and starch derived from **Amflora**, ensuring strict separation from conventional potatoes and potato starch.

As **Amflora** is produced in a closed loop system, **Amflora** remains within the potato starch value chain. **Amflora** will not be traded commercially because every grower undertakes to deliver the starch potatoes to the starch processor who contracted him to grow **Amflora**. With the identity preservation system and the closed loop production system, the quality and purity of **Amflora** will be maintained, while at the same time **Amflora** will be prevented from entering the food potato segment.

## 5. Amflora production

Production of **Amflora** builds upon existing processes to keep it as practical and reliable as possible. Seed potato producers, starch potato farmers and starch producers are integrated in the process according to their core competencies. This production system also ensures that authorization conditions and monitoring requirements are met and provides for full identity preservation.

BASF Plant Science is the provider of the trait as well as the corresponding variety protection right. BASF Plant Science ensures that seed potato production runs smoothly. The identity preservation system which was developed by BASF will be constantly applied throughout the whole process by each member in the value chain and controlled by BASF Plant Science.

### Amflora seed potato production

BASF Plant Science contracts multipliers via a service contract to multiply **Amflora**. Thereby, BASF Plant Science always retains ownership of all seed and pre-basic seed. Certified seed is produced by the multiplier exclusively for BASF Plant Science. The multiplier will not obtain a sales license and thus is not allowed to sell seed to third parties. Nonetheless, multipliers are allowed to use third parties via service agreements to meet their contractual volumes with BASF Plant Science. They are not allowed to use the material provided for breeding purposes and they are not allowed to extract amylopectin from the potatoes. This procedure ensures the high quality of **Amflora** seed potatoes.

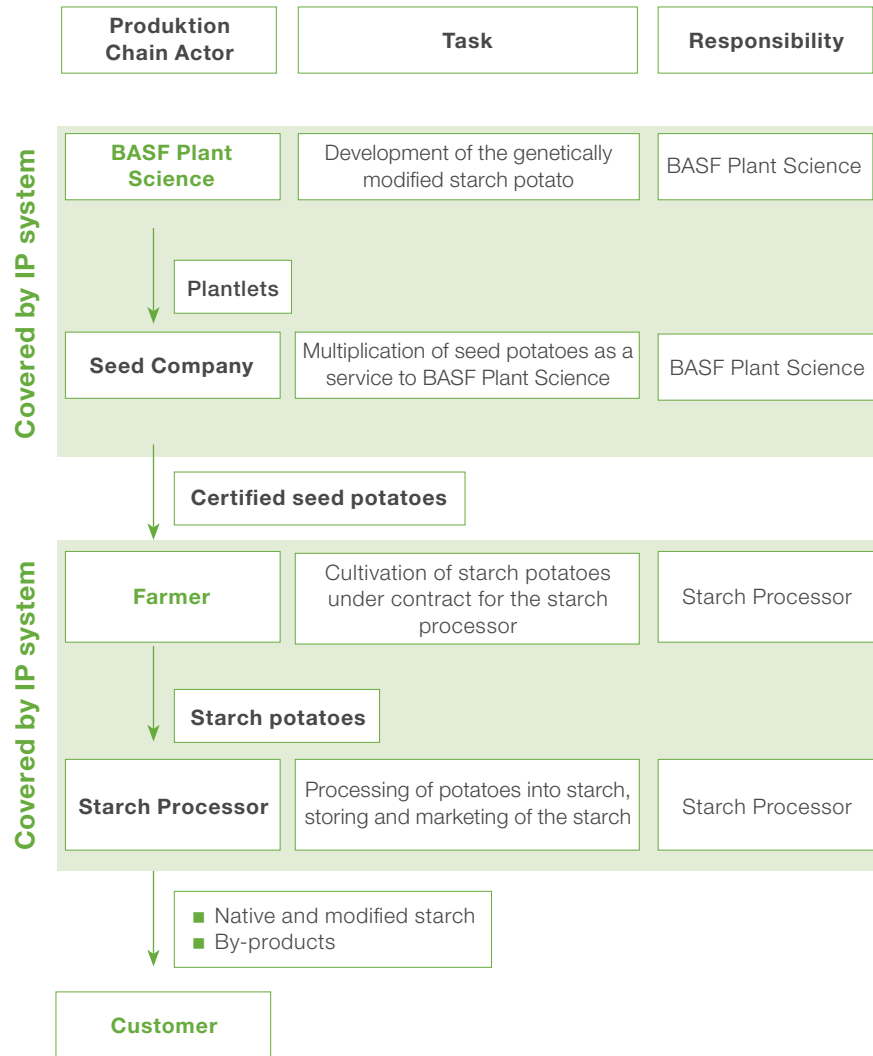


### Growing Amflora starch potatoes

Based on the applicable starch quota, starch processors plan their starch production volumes and order the seed potato quantities accordingly from BASF Plant Science. BASF Plant Science ensures that the starch potatoes that are produced can be processed and starch processors order seeds according to their planned volumes. BASF Plant Science ensures that seed potatoes are delivered to starch processors in good time before planting. The starch processors identify reliable and experienced farmers to grow **Amflora**. BASF Plant Science ensures via audits that the requirements of the identity preservation system are met. The contract between the starch processor and the farmers encompasses cultivation and harvesting of the starch potatoes.

The farmer, producing starch potatoes does not contractually acquire ownership of the **Amflora** potatoes. He provides a service to the starch processor, who is the owner of the **Amflora** seed potatoes transferred from BASF Plant Science to the starch processor and of the starch potatoes harvested by the farmer. After harvesting, the farmer delivers all starch potatoes to the starch processor and the potatoes will be processed accordingly. The farmers are not allowed to multiply or sell the starch potatoes to third parties.

## Closed-loop production of **Amflora**



## 6. Safety of **Amflora**

The safety of **Amflora**, or amylopectin potato EH92-527-1, as it is called in the regulatory documents, was confirmed in a series of research studies in the laboratory and in the field put together for a submission to the regulatory authorities of the European Union. These studies addressed effects on human health, animal health and the environment. In its assessments, the European Food Safety Authority (EFSA) concluded in December 2005 that **Amflora** is as safe as any conventional potato for the proposed uses.

**Safety for human and animal health**  
 Food and feed safety of **Amflora** was proven by analyzing the composition of **Amflora** tubers, as well as the by-products of starch processing, the starch and the pulp. In addition, feeding studies with rats and cows demonstrated that **Amflora** is as safe and nutritious as any conventional potato.

Furthermore, the safety of the selection marker nptII for humans, animals and the environment was reconfirmed by the European Food Safety Authority in June 2009. The rationale for this conclusion is the diminishing small probability of a gene transfer from a plant to a bacterium (horizontal gene transfer) on one hand, and the ubiquitous prevalence of the nptII gene in soil bacteria on the other hand.





## 7. Environmental safety

An environmental risk assessment was conducted on possible impacts on the environment from cultivating **Amflora**, and it concluded that **Amflora** is as safe as conventional starch potatoes. The European Food Safety Authority (EFSA) summarized this in their scientific opinion as follows: 'Potato rarely survives outside the cultivated environment and there is no indication of enhanced weediness or invasiveness of potato EH92-527-1. Potato has no cross-compatible wild relatives in Europe.'



Since it is vegetatively propagated and the natural exchange of genetic material is only possible with other varieties of potato, there is negligible risk to the environment of any transgenic flow. Therefore, no unintended environmental effects due to the establishment and spread are anticipated. In the unlikely event that horizontal transfer of gene sequences occurs between the GM potato and bacteria, the bacteria would not pose any additional risk to human health or the environment. No adverse effects on plant-associated organisms and soil function have been observed or would be likely from cultivation of the potato EH92-527-1.'

## 8. Regulatory framework for GM crops in the EU

The EU has strict legislation regulating the cultivation and use in food and feed of GM products, including Directive 2001/18/EC for the deliberate release of GMOs into the environment (repealing Directive 90/220/EEC) and Regulation (EC) No 1829/2003 on GM food and feed. Additionally, the subject of labeling and traceability is covered in Regulation (EC) No 1830/2003 and requires labeling for food and feed containing GM material above 0.9%.

## 9. Approval for **Amflora** in the European Union

In August 1996, BASF Plant Science (formerly Amylogene) submitted a notification to the competent authority of Sweden regarding the market launch of amylopectin potato EH92-527-1 according to Directive 90/220/EEC. The original notification C/SE/96/3501 covered cultivation, processing into industrial starch and use in feed. On January 24, 2003, and in accordance with the new Directive 2001/18/EC, the notification was supplemented and thereafter received a positive assessment by the Swedish competent authority. The notification included an environmental risk assessment and a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC, in line with the intended use of the product. In December 2005, the scope of the notification was limited to cultivation and production of starch for industrial uses.

The European Food Safety Authority (EFSA) evaluated the notification and on December 7, 2005 adopted a positive scientific opinion, concluding that **the potato EH92-527-1 is unlikely to have an adverse effect on human health or the environment in the context of its proposed uses<sup>1</sup>**.

After consideration by the Regulatory Committee on December 4, 2006 and the Council of Agricultural Ministers on July 16, 2007, amylopectin potato EH92-527-1 (variety name **Amflora**) was approved by the European Commission on March 2, 2010 for cultivation and processing in accordance with Directive 2001/18/EC (Commission Decision, 2010)<sup>2</sup>, which adopted the proposals with authorization for ten years. Amylopectin potato EH92-527-1 is listed in the Community Register<sup>3</sup>. Furthermore, on February 28, 2005, BASF Plant Science GmbH submitted an application for food and feed approval of amylopectin potato EH92-527-1 in accordance with Regulation (EC) No 1829/2003 via the competent authority of the United Kingdom.

<sup>1</sup> <http://www.efsa.europa.eu/en/scdocs/scdoc/323.htm>

<sup>2</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:053:0011:0014:EN:PDF>

<sup>3</sup> [http://ec.europa.eu/food/dyna/gm\\_register/index\\_en.cfm](http://ec.europa.eu/food/dyna/gm_register/index_en.cfm)

<sup>4</sup> <http://www.efsa.europa.eu/en/scdocs/scdoc/324.htm>

After consideration by the Standing Committee on the Food Chain and Animal Health (SCFAH) on October 10, 2007 and the Council of Agricultural Ministers on February 18, 2008, the European Commission on March 2, 2010 approved feed produced from amylopectin potato EH92-527-1 (variety name **Amflora**)

and the adventitious or technically unavoidable presence in food or other feed products in accordance with Regulation (EC) No 1829/2003 (Commission Decision, 2010)<sup>5</sup>. Amylopectin potato EH92-527-1 is listed in the Community Register<sup>6</sup>.

## 10. Approval with conditions

The consent for cultivation, processing and industrial use of **Amflora** was issued by the Swedish competent authority on March 31, 2010 and is subject to a set of conditions that are specified in the Commission decision from March 2, 2010. The consent remains valid for ten years. **Amflora** potato tubers require labeling such as 'this product contains

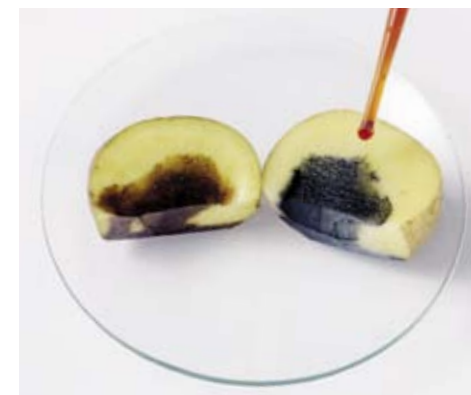
genetically modified EH92-527-1 potato' or 'genetically modified organisms' and 'not for human consumption'. In addition, the label needs to indicate that **Amflora** contains an altered starch composition. A monitoring plan is to be implemented including case-specific monitoring, general surveillance and an identity preservation system.

<sup>5</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:053:0015:0018:EN:PDF>

<sup>6</sup> [http://ec.europa.eu/food/dyna/gm\\_register/index\\_en.cfm](http://ec.europa.eu/food/dyna/gm_register/index_en.cfm)

## 11. Detection method

An event-specific method for quantification of amylopectin potato EH92-527-1 (variety name **Amflora**) using real-time PCR has been validated by the European Commission Joint Research Centre (JRC). It was published on the Community Reference Laboratory (CRL) website on September 14, 2006<sup>7</sup>. Certified reference material (ERM<sup>®</sup>-BF421) is available from the Institute of Reference Materials and Measurements (IRMM)<sup>8</sup> and as AOCS 0406 from the American Oil Chemists' Society (AOCS)<sup>9</sup>.



A rapid and simple test which can be performed readily in the field allows **Amflora** to be distinguished from conventional potatoes. Potatoes are cut in half and the fresh surfaces are sprayed with Lugol's solution (Lugol's iodine). In conventional potatoes, the surfaces will show a blue color indicating the presence of amylose in the potato starch. In **Amflora**, due to the lack of amylose in its starch, the surfaces will show a brownish color. It should be noted, however, that this test does not allow **Amflora** to be distinguished from other potato varieties which produce pure amylopectin, e.g. Eliane which is produced by AVEBE.



<sup>7</sup> <http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm>

<sup>8</sup> [http://irmm.jrc.ec.europa.eu/html/reference\\_materials\\_catalogue/index.htm](http://irmm.jrc.ec.europa.eu/html/reference_materials_catalogue/index.htm)

<sup>9</sup> <http://www.aocs.org/tech/crm>

## 12. Traceability, labeling, unique identifier



Operators handling or using amylopectin potato EH92-527-1 tubers and derived feeds in the EU are informed of the legal obligations regarding traceability and labeling, as indicated in Regulation (EC) No 1830/2003 and in the conditions of market launches. The unique identifier of amylopectin potato EH92-527-1 is BPS-25271-9.



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