



To:

Sabine Juelicher, Director for Food and Feed Safety, Innovation, DG SANTE

Irene Sacristán Sánchez, Head of Unit for Biotechnology, DG SANTE

CC:

Carina Knorpp, Ministry of Enterprise and Innovation, Sweden

Jerker Stattin, the Permanent Representation of Sweden to the EU

Maria Ulfvarson Dahlman, Ministry of the Environment, Sweden

Stockholm, 4 October 2021

Dear Director,

Dear Head of Unit,

Feedback on intended initiative to modernize Legislation for plants produced by certain NGTs

DG SANTE has opened a period on September 24, 2021, to provide feedback on an intended initiative to modernize the Legislation for plants produced by certain NGTs. The Plant Node is therefore taking the opportunity to submit the following feedback. The Plant Node is a project serving as a knowledge hub on modern plant biotechnology, specifically gene editing, and affiliated to the Royal Swedish Academy of Agriculture and Forestry (KSLA). Further information is available on [Växtnoden](https://www.vaxtnoden.se) | [Kungl. Skogs- och Lantbruksakademien \(ksla.se\)](https://www.kungl.skogs-och-lantbruksakademien.se)

Earlier this year the Plant Node has requested the European Commission to provide clarification on the legal status of NGTs in two letters on 15 February and 27 May. The Plant Node now takes the opportunity to illustrate consequences of how NGTs are regulated for innovative, new food products and entrepreneurial companies.

The Plant Node has asked Lyckeby to describe how different scenarios would affect the planned development and market introduction of their gene edited potato starch (enclosed memo). Lyckeby developed this potato in collaboration with a small start-up company, SolEdit AB, using CRISPR-Cas9 technology to achieve a pure amylopectin starch to meet demands from food industry on a natural ingredient with stabilizing properties for different food products. This starch quality is now offered to the market after chemical modification. There is also a potato variety with this quality that has been developed after traditional mutagenesis, but with a yield drag that has made the marketing unattractive. Lyckeby is a cooperative company, owned by some 600 farmers in southern Sweden. The company was involved in the development and marketing of the genetically modified potato Amflora up to when the marketing stopped 10 years ago.

This new gene edited amylopectin potato starch could be marketed in the EU already in 2024, according to Lyckeby. This would make it the first European gene edited product on the EU market as far as we understand. There is a pronounced interest in this starch also in other markets such as UK, USA and Asian countries. The company's second product, potato starch with increased amylose content for reduced digestibility, is still in the development pipeline.

In short, Lyckeby describes that the present regulation is stopping the company from producing and marketing this innovative starch in the EU. Even if plant varieties obtained with NGTs and corresponding to varieties developed with traditional mutagenesis or other plant breeding technologies are exempted from regulation, labelling requirements for use of products as ingredients could become a severe hindrance to marketing in the EU.

Therefore, Lyckeby is presently looking into the possible production of this new innovative starch outside the EU, either in a Joint Venture or in a licensing arrangement, in order to be able to meet the interest in different markets.

The memo from Lyckeby is interesting since it describes the planning situation for a company that has invested heavily in this new technology and the strategy choices it now has to evaluate. It is quite clear that the outcome will depend on how EU will regulate NGT based plants and plant products. It is unusual that companies are this open on their strategic plans in a setting that will be available also for other actors in their markets.

Lyckeby and SolEdit are good examples of entrepreneurial companies with innovative products in the pipeline, based on NGTs. DG SANTE has already demonstrated that the present interpretation of the regulation of genetically modified plants is a hindrance for the development of such products. This is a seriously detrimental situation in need of a constructive solution, if the European Community shall be able to reap the benefits of these new technologies.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Annika Åhnberg', with a stylized flourish at the end.

Annika Åhnberg
Chair Växtnoden

Possibilities with new genomic technology at Lyckeby

Background

Lyckeby has been working with CRISPR-Cas9 on potato since 2014. The work has been done in close collaboration with the Swedish University of Agricultural Sciences (SLU). Lately most of the work was moved to the start-up company SolEdits AB, created in collaboration with SLU.

So far the work has been concentrated on functional properties of potato starch, meaning either pure amylopectin starch with good stability or high amylose starch with properties as a resistant starch with good health benefits.

Pure amylopectin starch is something that is existing in a number of starch raw materials such as corn, rice and barley. Lately there is also tapioca coming on the market. In potato there are existing varieties, but those have been made with traditional mutagenesis and have too low production capacity and quality to be commercially attractive.

The type of amylopectin is essential as it governs the freeze/thaw stability. In some crops, such as barley, the starch is good enough for this purpose while in most other crops you still need to chemically modify in order to have the property you need. Ordinary amylopectin in potato has rather bad properties concerning freeze/thaw stability and is chemically modified to meet the quality demands. With natural freeze/ thaw stability we do not need to chemically modify the starch to have this effect. It is required to declare chemically modified starch as an ingredient with E-number on the label of food products.

On high amylose starch we have a similar situation with examples of other raw materials having this type of starch. Ongoing work is focused on understanding what is possible within potato.

Products to be commercialized

The amylopectin starch we have developed using CRISPR-Cas9 in potato is comparable to barley and thus has a very high quality.

If we would convert our full production of chemically modified starches to natural storage stable amylopectin potato starch we would save about 5 000 tons of chemicals and a lot of energy in Sweden alone.

With this starch we can offer E-number free potato starch with the same properties as chemically modified starch to our customers in the food industry. Many consumers are hesitant to buy processed food with E-numbers on the list of ingredients, and therefore food industry is trying to avoid or reduce E-numbers on the label.

The new potato varieties are under development in a seed potato programme to multiply seed potatoes. We expect to be able to go commercial in about 2- 3 years meaning that we will have this starch on the market in 2024. If that will be possible depends on the legislation in EU. If the interpretation of the current situation is that new genomic technology like CRISPR-Cas9 is classified and regulated as GMO, this will stop the project in EU.

An interpretation or new legislation where the outcome of the breeding using new genomic technology as CRISPR-Cas9 is exempted the same way as the outcome from traditional mutagenesis would solve the problem. A limitation in scope, that we can use technology that result in genetic alterations within the context of crossable species would be a natural borderline for GMO. Labelling has been mentioned as an alternative to inform consumers. This can work when the product is sold as such. When the product is used as an additive in food in small amounts, it will not work as it means that all ingredient lists of the finished product needs to be changed. Looking at regulations outside EU, labelling is not required.

Since we have a Joint Venture outside EU in Russia with modification of starch we are now preparing for the possibility to produce there instead. There is also an interest from countries in Asia to license the technology. We would, of course, prefer to produce and market this new starch quality ourselves, but licensing the technology to a partner in Asia could be an alternative to be able to meet a strong market demand for the product. We expect to have a strong market interest for E-number free starches in most of the world, especially in UK, Asia and North America. UK is currently the market with largest proportion of E-number free starches. We see a strong growth of the demand for E-number free starches also in EU, but to be able to meet that growth also with potato starch we need our new potato varieties.

New development

We are now initiating projects on disease resistance in potato. Late blight disease is causing lots of problems in potato cultivation. To handle it, spraying with fungicides is common practice. By creating resistance towards this disease in potato, we can reduce the use of fungicides significantly. We will also create much better possibilities to grow organic potato. Furthermore, there are many other potato diseases where the technology would benefit resistance breeding.

Kristianstad, September 17, 2021



Hans Berggren
CEO