Annex 1, EPSO feedback on the roadmap regarding the legislation for plants produced by new genomic techniques.

Web-links and scientific publications referred to in the online submission:

[1] https://ec.europa.eu/food/plants/genetically-modified-organisms/new-techniques-biotechnology/ec-study-new-genomic-techniques_en

[2] Levi, Sebastian (2022): Living standards shape individual attitudes on genetically modified food around the world. In: Food Quality and Preference 95, S. 104371. DOI: 10.1016/j.foodqual.2021.104371.

[3] David L. Ortega, Wen Lin, Patrick S. Ward, Consumer acceptance of gene-edited food products in China, Food Quality and Preference, Volume 95, 2022, 104374, ISSN 0950-3293,https://doi.org/10.1016/j.foodqual.2021.104374

[4] Chicory as a multipurpose crop for dietary fiber and medicinal terpenes' http://chicproject.eu, https://cordis.europa.eu/project/id/760891

[5] https://www.efsa.europa.eu/en/efsajournal/pub/2561

[6] https://www.efsa.europa.eu/en/efsajournal/pub/2943

[7] https://www.efsa.europa.eu/en/efsajournal/pub/6299.

[8]https://gmo-crl.jrc.ec.europa.eu/doc/JRC116289-GE-report-ENGL.pdf

[9] Grohmann, L., Keilwagen, J., Duensing, N., Dagand, E., Hartung, F., Wilhelm, R., Bendiek, J. and Sprink, T. 2019 Detection and identification of genome editing in plants: Challenges and opportunities. Frontiers in Plant Sci: DOI: 10.3389/fpls.2019.00236

On pages two to three in this document, you will find the summary of an attitude survey on NGTs conducted by the Swedish Gene Technology Advisory board. Finally, on pages four and five, you will find a description of how the current GM-legislation affects the Starch company Lyckeby.

Genteknikmnden
The Swedish Gene Technology Advisory Board

Stockholm
October 20 2021

Swedes attitudes towards genome editing in plant breeding surveyed

In short:

1. Swedes have in general little knowledge and awareness about genetics, genetically modified plants and genome editing.

2. The majority of Swedes are positive towards the use of genome editing in plant breeding if the aim is beneficial for the environment and the society. Younger people, well-educated people, men, and people with previous knowledge about CRISPS/Cas9, are in general more positive.

3. The majority of Swedes are also worried about potential risks associated with genome editing.

In a web-based survey from November 2020, the Swedish Gene Technology Advisory Board investigated **Swedes attitudes towards the usage of genome editing in plant breeding**. The Swedish Gene Technology Advisory Board is Governmental authority that gives advice on issues concerning the use of genetic engineering and contributes to public information and debate.

The survey was designed in collaboration with representatives at the Department of Plant Biology at the Swedish University of Agricultural Sciences, and data collection was carried out by Novus, a company that performs market analyses and opinion polls.

The initial questions of the survey were formulated to reflect on participants previous knowledge about gene technology, including CRISPR/Cas9, in plant breeding. The opening questions were followed by a short text about different plant breeding techniques, and additional questions formulated to reflect on their attitudes towards the same.

Summary of the study results:

Previous knowledge

- Every second Swede have heard of CRISPR/Cas9 but only one in ten state they know the technique well. Of those with previous knowledge, 40 percent did hear about the technique in the context of *plant breeding* and 60 percent in *treating disease*.

- One third of the Swedes believe that products from genetically modified plants are as safe as those that derive from other plant breeding techniques.

- Many Swedes are under the impression that genetically modified products are common in their grocery store. Only one in three know these products are very rare.

Attitudes

- One in three Swedes are positive towards the use a gene technology in plant breeding, irrespectively of method (cisgenic or transenic modification, or genome editing). Traditional mutagenesis receives a lower support, just one in five Swedes are positive towards this method.

- Seven out of ten Swedes are positive towards the use of genome editing in plant breeding if the aim is to reduce pesticide usage. Among younger people (between 18-29 years) and people with previous knowledge about CRISPR/Cas9 the support is even higher, between eight and nine out of ten. Other aims with a clear benefit for the society, such as adapt a plant to climate changes or increase nutrition value of a plant, also receive high support from Swedes (64 and 51 percent respectively). The support diminishes when the aim is to change esthetical attributes such as colour of form, then a narrow majority, 59 percent, are against.

- Four out of ten Swedes think it is unethical to not use existing technology, such as CRISPR/Cas9, to solve serious problems faced by the society.

- Despite the fairly high support, nearly three out of four Swedes are worried at some level that genome editing in plant breeding will have a negative impact on our health and the environment. One in five are not at all worried.

- Two out of three Swedes think it is important that food products that derive from plants are labeled to reflect which plant breeding technique have been used (genetic modification, genome editing or traditional mutagenesis).

- One in four Swedes think that genome editing can be used to develop plants for organic cultivation.

- The sub-group more positive towards genome editing in plant breeding are:
  - people with previous knowledge about CRISPR/Cas9
  - younger people (between 18-29 years old)
  - people with a university degree
  - people living in the southern part of the country (where a lot of land is utilised for agriculture).

Final note: This study indicates that an increased awareness about genome editing is positively correlated with acceptance.

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.

Sveriges stärkelseproducenter, förening u.p.a.
Degebergavägen 60-20
SE-291 91 Kristianstad
SWEDEN

Tel: +46 (0)44 28 61 00
Fax +46 (0)44 28 61 09
info@lyckeby.com
www.lyckeby.com

Faktura/Invoicing address
PO Box 45
SE-291 07 Fjälkinge
SWEDEN

Reg. nr/F-skatt/VAT
7362002102
SE 736200210201

An interpretation or new legislation where the outcome of the breeding using new genomic technology as CRISPR-Cas9 is excempted 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

Lyckeby