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Swedish Board of Agriculture

Consequences of the EC-ruling according to Swedish companies and research groups

In order to collect information on the consequences of the EU Court of Justice (ECJ) ruling, the Swedish Board of Agriculture (SBA) have contacted a number of organisations, companies and research institutes with an interest in plant breeding, plant research and agriculture. We requested information regarding if the ruling will affect them and in that case how and to what extent. The organisations, companies and institutes that answered are listed in Table 1 together with a short introduction about them. The information that we received is summarised in this document.

Additionally, we have added information from a cost analysis performed by the Swedish National Reference Laboratory (NRL) for GMOs, which is a part of the National Food Agency. The analysis contains a cost estimate for necessary investments and analyses.

Some key points:

- The use of targeted mutagenesis within the EU is likely to be very limited when regulated as GMO. This, since the EU GMO legislation entails long and expensive authorisation procedures.
- It is less likely to receive funding for research within the EU when the chances for a practical use of the results are reduced because the resulting product is considered GMOs.
- Research project using targeted mutagenesis to achieve new or improved crops or food products have already been changed or paused. Collaboration with research institutes and businesses abroad will decrease.
- Products with an improved environmental profile will not reach the market. It will be more difficult to achieve a sustainable and resilient agriculture and forestry in a changing climate without this important tool for plant breeding.
- Made investments in patent, staff, research, product development and knowledge will be lost. Production and marketing of some products will most likely be redirected to countries outside the EU.
- Countries that do not regulate organisms produced with targeted mutagenesis as GMO will have advantages in both commercial and research opportunities compared to the EU.

Consequences of the EU Court of Justice ruling on new techniques of mutagenesis (case C-528/16)

In what context are the new breeding techniques important?

Among the answers, it was pointed out that the access to different methods is necessary for successful breeding. The methods are combined in different ways depending on for example the genetic regulation of the desired traits. A spectrum of methods are used, including traditional selection of (phenotypic) traits, selection based on germplasm (e.g. genomic selection), transferring of genes (genetic modification) and new techniques of targeted mutagenesis. It was pointed out that all of these tools are necessary in a plant breeder's tool box to, in the best way possible, solve the difficult problems that we are facing. Genome editing is considered to have great potential to increase breeding efficiency when it comes to improvement of plant traits and increasing the genetic diversity.

Targeted mutagenesis does not replace conventional cross breeding but it is rather a complementing tool for efficient and successful plant breeding. The greatest benefit of this technique is obtained when handling one or a few traits in already high-performing varieties. The technique enables fine adjustment of gene expression to optimise the phenotypic effect in the crop (Mumm, 2013). With genome editing such as CRISPR/Cas9, it is possible to mutate only a few determined base pairs in the genome. This can be done without integrating any external DNA in the genome. In this way, genetic variation in specific characters can be introduced into elite varieties without simultaneously transferring genetically linked DNA or other unwanted DNA. This means that a number of generations of backcrossing to a parental line can be skipped in contrast to what is the case with conventional cross breeding or breeding through random mutagenesis.

According to the European Seed Association (ESA), two generations of back crossings are often enough when targeted mutagenesis is used, while seven are needed for conventional breeding (Information material from P. Jorasch). However, this presumes that a suitable elite material is already available, that you have enough knowledge about gene sequences, their biological functions, and that you have identified suitable targets for mutagenesis.

A research team from Brazil, Germany and USA has recently demonstrated domestication of a new tomato relative over the course of only one generation through CRISPR-editing of six different loci that control for example fruit size, fruit number and content of nutrients (Zsögön *et al*., 2018). However, in practice, a number of generations (up to five) of greenhouse testing of the material, is needed to control the quality of the introduced trait. This is also needed to ensure that the crop has an added value for growers and the industry.

In summary, targeted mutagenesis as a method has great potential to shorten the time to produce new varieties with specific traits when using elite material as starting material. However, this remains to be demonstrated in practice.

Ongoing projects involving “new” techniques of mutagenesis

Specific ongoing projects are described below and have been divided by crop. In addition, there are other ongoing projects within the area of new breeding techniques in both the industry and academia. There are also ongoing collaborations with international companies who use methods of genome editing such as oligonucleotide directed mutagenesis (ODM) and CRISPR/Cas9.

Potato

There is an ongoing project regarding the production of new potato varieties for the Swedish starch industry. This involves mainly the use of CRISPR/Cas9 without introducing any new DNA into the genome. In this context, amylose potato with modified starch quality is mentioned. The potato works as a prebiotic and has a low glycemic index. Additionally, naturally stable potato starch for food applications is being developed, thus avoiding the otherwise usually necessary chemical modification to make it stable.

Starch producers in Sweden and northern Europe uses potato as raw material. Unlike maize, potato does not have the natural variation in starch quality necessary to obtain starch with special characteristics, e.g. high amylose content. We are therefore dependent on import of these types of starch. Such production in northern Europe would be important for both food production and the production of bioplastic from high amylose potato, which can replace a part of the fossil oil that is used for the production of plastic today. This would contribute to an increased competitiveness and employment in Swedish agriculture and industry production and have a positive effect from a climate and environmental point of view.

Breeding for resistance to potato late blight is also carried out by using CRISPR/Cas 9 to knock out genes whose expression contribute to facilitate infection. Positive preliminary results suggest that this could be a good way of obtaining good food potato with lasting resistance. This has, despite great efforts, not yet been achieved through traditional breeding, due to difficulties of combining many traits. With genome editing, all other agronomic and quality traits can be retained which is important in potato breeding since backcrossing is not possible. Resistance to pathogens is important to decrease the use of pesticides in potato cultivation, which makes up a large part of the general pesticide use in agriculture.

Another project aims at decreasing glycoalkaloids in potato which leads to a decreased content of unhealthy substances and thereby increased food safety.

Modified potato protein is also mentioned in the context of ongoing projects. This leads to an increased extractability of food graded highly nutritional protein.

Studies on autophagy; basic research on recycling of cellular components, is also carried out and could potentially lead to increased yield and resistance traits.

Lepidium Campestre

One of the ongoing projects regard domestication and breeding of *Lepidium Campestre* for improved cultivation properties, oil content and oil composition. For this, a combination of crosses and traditional selection, genomic selection and genome editing with CRISPR/Cas9 have been used.

Due to limitations in the natural variation of some critical traits, genome editing has proven to be indispensable, especially to improve the fatty acid composition and to reduce the levels of substances that make the pressed seed cakes (a bi-product from the oil production) unsuitable for feed.

L. Campestre grows in the wild in e.g. Sweden and has the potential to be grown as an oil crop farther north than what is possible with existing oil crops. Growing this species as a new oil crop could contribute to the survival of the agribusiness in the whole country, especially in the northern parts.

Barley

In barley, breeding is carried out for resistance to net blotch, a common and important disease that is usually treated with chemicals. Resistant varieties are not available. The project involves trying to mutate the genes that increase the susceptibility to the fungus by the use of CRISPR/Cas9.

Another ongoing project regards resistance to virus spreading bird cherry-oat aphids. The aphid is an increasing, climate related problem and is treated with pesticides. Resistant varieties are not available.

Rapeseed

Development of non-glaucous rapeseed lines is carried out through genome editing to improve pathogen resistance and to reduce spraying with chemicals.

Projects starting from 2019 involving “new” techniques of mutagenesis

Potato

One project aims at an efficient use of an industrial side stream for circular bio-based economy for food graded protein of premium quality. The breeding goal of another project regards starch content, granular size and structure by elucidating mechanisms of initiation and differentiation of starch synthesis.

Rapeseed

The mentioned projects regard:

-Elimination of anti-nutrient factors in the pressed seed cakes for both feed and food use.

-Characterisation of the rapeseed enzyme DGAT, a key enzyme for quality and quantity of the seed oil.

Cost Action PlantEd

The newly EU financed project PlantEd (Genome editing in plants- a technology with transformative potential) aims at networking and research coordination between 70 participants from 24 countries.

Consequences of the ECJ ruling on ongoing and future projects

The preconditions of the PlantEd project are changed to the worse if Europe loses expertise in plant editing. There will be decreasing opportunities for Swedish research to benefit from this and other networks if research and development in the area are moved to countries outside the EU.

One university department states that there has been no immediate change of ongoing projects. It is however likely that the ruling will entail a loss of interest from the industry regarding involvement and financing. This probably also applies to other financiers, similar to what is the case with projects involving traditional genetic modification. Financiers increasingly require a direct and apparent social relevance and practical application of proposed projects. The use of GMO techniques could be considered to be of low social relevance, even if they are considered to be the most effective and relevant tools.

For another research group, with a focus on plant breeding for the food sector, the ruling has had more direct consequences. In some project proposals, the original idea of using genome editing has been changed to using less optimal methods and some projects have not started at all.

If the ruling is to be followed with no regard to the development of technologies since 2001, one company will be forced to terminate ongoing projects. This will lead to the loss of a large portion of the knowledge, products and technology that have been developed.

For research groups primarily working with basic research, the ruling will not change the direction of their project much. Since the funding is not aimed at developing new crops, the researchers can basically work as before. However, in a few cases, there were plans for field trials with genome edited plants. If such trials are now considered as GMO trials it is doubtful that they will be executed, since the administration is both time consuming and expensive.

If new breeding techniques are considered to give rise to GMOs, it will, in the best-case scenario, mean both increased costs and project delays. In the worst-case scenario, many projects will no longer be economically feasible.

Consequences for analysis according to the Swedish NRL

The National Food Agency (NFA) in Sweden states that the strategies and costs for analysis are determined completely by whether information on the actual genetic change is available or not. In cases where an application for approval of a genome edited crop exists, the technique for analysis (quantitative real time PCR), which is already in place at the NFA, could be used in most cases. If there are only a few mutations, it could be difficult to develop a PCR method that is specific enough. However, that burden lies upon the applicant who has to provide a functioning detection method, in accordance with the application procedure. When the method is collaboratively tested, and is performing according to the demands, the method ought to be able to become implemented in the same way as the existing methods for detection of transgenic GMOs. The cost to detect a specific transformation event is, according to the NFA, approximately 100 EUR/sample.

In cases where there is DNA sequence information available for an unauthorised genome edited crop, but where an application for approval is missing, it would be possible to develop PCR based methods for certain genetic changes. If the changes regard single nucleotides, DNA sequencing methods are likely necessary. Traditional sequencing technique (Sanger) would not work for samples where there is DNA from both genetically modified and conventional crops. Next generation sequencing (NGS) is a technique which is being increasingly used and the technique could be used to detect and identify known genome edited crops, even in samples with different genotypes. The drawbacks of the technique are high costs for analysis per sample, long response times and the need of access to high quality reference genomes. Interpretation and analysis of NGS-data also requires competence in bioinformatics and systems to handle the large amount of data that the technique entails, which today is lacking at the NFA. The simpler NGS instruments today cost about 100,000 EUR and a rough estimate of the cost is more than 1,950 EUR/sample. In addition, the recruitment of bioinformaticians will be necessary which means approximately 73,000 EUR per year in salary. If the modification only comprises one or a few nucleotides, it will also not be possible to determine whether the modification is a result of a spontaneous mutation or if the modification has been induced by traditional or new (genome editing) technique.

If no information on the mutation is available when it comes to an unauthorised genome edited crop, the prospects for detecting the mutation is almost non-existent. Additionally, no realistic possibilities for analysis are available today. The development of PCR methods is not possible if no DNA sequence information is available. The use of whole genome or exome sequencing to identify unknown mutations in the genome of higher plants would require constantly updated pan-genomic reference databases, which is considered unrealistic. The cost of analysis per sample would be immensely high and in the case of a potential find of a mutation, it would still not be possible to determine whether the mutation arose spontaneously or was induced.

Analysis and control

At the moment, no effects are seen when it comes to trading of tree based products in relation to analysis and control, but this could change.

Future problems are predicted with international exchange of plant material, when the outside world does not intend to regulate mutagenesis where no external DNA is present in the end product. If there is no reason to label research material as regulated material in the country of origin, we have no possibility to control if mutagenesis with methods that are regulated in the EU has taken place at some point. This creates a legal and credibility problem given that the quality of products is currently guaranteed by analysis.

When research and plant breeding are moved outside of the EU, there is a risk that the crops that were originally developed in EU countries will be imported back into the EU. This could partly be the case for seeds for cultivation within the EU but also for consumer ready products. Since there are no detectable differences between crops that have been developed with modern and traditional plant breeding techniques, it is questioned how the control of such import would be possible. There is a risk that food and ingredients produced with the new techniques of mutagenesis, will still be on the EU market, in spite of the efforts of the EU to limit the use of these techniques.

If a genome edited crop would after all be produced, the current EU legislation for traceability and labelling of GM crops would obstruct commercialisation since it will be very difficult to produce a method to identify and distinguish mutations when only one or a few nucleotides have been changed. In practice, the ruling therefore means a ban on genome edited crops.

Environmental consequences

One of the university departments cannot see that the use of genome editing, where no foreign or recombinant DNA is integrated in the plant, would cause environmental effects that differ from mutagenesis obtained with “older” techniques. On the contrary, these techniques are a more efficient way of obtaining desired effects with a higher degree of precision.

It will become more difficult to produce new plant varieties with higher quality, improved resistance, improved uptake of nitrogen and phosphorous and the production will be delayed if the new breeding techniques cannot be used. The use of chemicals in agriculture will continue for a longer time and might even increase (with increasing leakage to water) as compared to if we would have been able to use targeted techniques to improve the resistance of plants to diseases etc. The agriculture in Sweden as well as in the rest of the EU will thereby become less sustainable, from both an ecological and economical point of view.

There is also a risk that we will be stuck with crops developed without the goal of favouring ecosystem services and the environment, goals which we have in

Swedish plant breeding and in EU countries with higher demands on environmental sustainability.

The loss of investments in plant breeding due to the ECJ ruling could result in a less climate-adjusted agriculture that cannot persevere in a changing and erratic climate. To be able to meet the challenges that we are facing in the environmental area and with a changing climate, we need varieties with increased resistance to different pests, an improved use of plant nutrients, efficient use of water, tolerance to drought and flooding and adjustments to changes in cultivation systems. In a warmer climate, the risks of pests and fungal infections are increased. Additionally, we need a greater access to perennial crops which can be adapted to our cultivation technique and give a high yield. This could also increase the content of humus and bind more carbon to meet the climate goals and decrease the leakage of plant nutrients.

One of the ways to increase the biological diversity is to use a more diverse set of crops. The loss of investment in plant breeding might risk obstructing this development. By decreasing the efficiency in agriculture, more land will be needed to cultivate the food and feed that we need. A decreased efficiency in forestry will decrease the possible biomass that is available to develop the bio-based economy. Both of these effects will likely have negative consequences for the climate and the environment.

When it comes to potato, the use of chemicals for cultivation and production can be decreased substantially with the development in modern plant breeding. The crops that have been developed with new methods of mutagenesis have a significantly lower impact on the climate and environment than the current potato varieties. A decreased use of chemicals will not be accomplished without the use of new techniques to improve the potato crop. Today, we use a couple of thousand tons of fossil-based chemicals for the modification of our food starch. This use would become unnecessary with the new potato varieties. When it comes to cultivation, there are ongoing projects to decrease the amount of plant protection products by half. In development projects that use targeted mutagenesis, an effect has been achieved that is 100 times larger than the tons of chemicals that have been saved. A large part of the work on sustainability of the company has been done on development of new potato crops with the help of new techniques of mutagenesis.

Difficulties of reaching specific, political sustainability goals without using the new techniques of mutagenesis have also been addressed. In relation to this, the FN's Agenda 2030 and the 1.5°C goal in the Paris Agreement, the EU sustainable development strategy and the Swedish government's food strategy have been mentioned. The latter clearly points out that plant breeding is a strategic investment that is needed to create long-term competitiveness in Swedish agriculture.

Economic consequences

Economic effects on businesses

One company states that more than 10 million EUR invested in research and development of crops and techniques during the last years will now be lost due to the ruling. In addition, many years of competence building will be lost due to the ruling. Market release of GM starch in not an option due to the high costs for trials, production, control and monitoring. More important though is the lack of tolerance for GM labelled products on the EU market.

Manufacturing of naturally storage stable starch is a breakthrough that dramatically changes the use of potato starch compared to existing raw materials. The effect of the ruling is that it has marginalized potato as raw material for industrially manufactured foods. That will result in an enormous financial impact on their business. They now need to consider moving the manufacturing of the product outside the EU, either physically or through license agreements.

Another company states that in both short and long term, there will be less opportunities to sell projects or to develop products that could be marketed.

The feed industry in Sweden and in the EU is a large importer of vegetable produce. The asynchrony between approval of GM commodity in the EU and exporting countries is causing significant problems for the feed industry today. The problems will increase when more countries decide not to regulate genome-edited crops as GMOs.

Economic effects for research institutes

Turning academic progress into product requires companies in the sector, which have both the possibility and willingness to invest. These will now gradually disappear. This will affect the possibilities to obtain research funding for more research in agriculture and forestry, both nationally and from the EU. According to previous experience, project applications involving GMOs have not been prioritised because they would not lead to any practical applications in Europe.

One of the universities state that a high percentage of the staff is fully or partially financed through projects that include genome editing. They might not be able to keep all staff and will lose competence. The budget of the department for projects involving genome editing is approximately 850,000 EUR for 2019. The same university has so far purchased equipment for approximately 180,000 EUR due to genome editing projects specifically. Even though some of the equipment could be used for other purposes, the main application relates to work with genome editing.

A DNA-free genome editing project in potato is carried out by what is equivalent to 3.5 full time positions a year. The project is financed until 2021 but unless the legal situation is changed, it is not likely that this prominent research will continue in Sweden for long.

Economic effects due to GM notification requirement

The cost of obtaining an approval for market release of a GM crop or product in the EU is in the range of 6-15 million EUR to meet all regulatory requirements. When genome editing falls within the scope of Directive 2001/18/EG, this means that the costs of developing plants with new properties where such techniques are used in practice become so high that companies within the EU abstain from it. To this can be added the uncertainty in the decision-making process regarding whether the EU will allow cultivation of varieties that have genome edited traits.

The direct economic cost of the regulatory process for GMOs in the EU is very extensive and affects the use of the new methods of mutagenesis, since only the largest and most resourceful companies can afford to complete the process. According to information from Monsanto in 2011, it costs on average about 100 million USD to bring a genetically modified crop to the market, using maize as an example (Mumm, 2013). Of that, the cost of complying with regulatory requirements and reaching market approval for a GM crop has been estimated on average 6,788,000 EUR (3,820,000 – 10,388,000 EUR). Much of the costs result from the requirements of field trials to evaluate environmental effects and phenotypic comparisons with corresponding conventional lines (Food Chain Evaluation Consortium, 2010). Estimations from EuropaBio result in similar figures with costs for GMO approval in the EU of around 7-10 million EUR per event (EuropaBio, 2011). A survey from 2007 of four major international seed companies showed that regulatory compliance in ten different jurisdictions varied between 6 million USD to over 15 million USD for insect resistant or herbicide tolerant GM maize (Kalaitzandonakes *et al.*, 2007). Another survey from 2011 of six major international seed companies showed that the regulatory costs specific for the US market are on average over 35 million USD, or about a quarter of the total R & D costs (McDougall, 2011). A review of approximately 50 different studies from all over the world, about regulatory compliance costs for one event on one market, showed that this varies widely across countries. On average, the cost is 7.8 million USD, with the lowest cost being 53,000 USD and the highest 14.8 million USD (Phillips, 2013). With the ECJ ruling, the costs for a genome edited crop would be of the same magnitude.

Marketing of genome edited products is only economically feasible for the big multinational companies. However, in 2012 and 2013, BASF and Monsanto announced that they will discontinue their R & D activities on plant biotechnology in Europe as a result of the restrictive application of GMO legislation (AgbioInvestor, 2018).

Application is also restrictive to the extent that only one GM crop is currently authorized for cultivation in the EU and a relatively small number of GM products (about 65-70) are approved for import. In the EU, it usually takes between 4 and 8 years to get market approval for import of a GM product and often much longer to obtain authorization for commercial cultivation of GMOs.

If crops produced with targeted mutagenesis are regulated as GMOs, there are only small chances to obtain marketing approval for the cultivation of these crops or for use of the products. It also means that the time required to obtain marketing approval for these will be equivalent to what has been the case for conventional GMOs.

Socioeconomic effects

The ruling will have negative effects on the national economy when it comes to both plant and animal production. It is counter-productive to make it more difficult to use a technique with high precision and with several benefits compared to “older” techniques. Genome editing is a brilliant example of technical development being the most important factor to be able to deal with challenges regarding food supply, resource management, climate adaptation and the environment.

A socioeconomic analysis of the costs of refraining from genetically engineered crops in Swedish agriculture was published in 2011. The analysis indicated that the lack of acceptance of genetically modified herbicide tolerant sugar beet, herbicide tolerant rapeseed and potato blight resistant potatoes entails missing out on a potential socio-economic gain of approximately 27 million EUR per year and a reduced use of cultivable land of 10,000 hectares. For the whole EU, this would amount to about 2 billion EUR and saving an area of about 645,000 hectares per year (Fagerström & Wibe, 2011). It is likely that the potential gains for genome edited crops would be equivalent to this.

The EU Commission's Research Service, the Joint Research Centre (JRC), has estimated that each year a GM crop or GM product is delayed can cost anywhere from 700,000 to 70 million EUR in lost income (Food Chain Evaluation Consortium, 2010).

Plant breeding is of central importance for development of a sustainable and viable farming. It creates values in the chain from farm to fork for farmers, the food industry and consumers and for growth and competiveness in Sweden. Additionally, we will have to increase the production to meet a growing demand. We also have to increase the domestic production of protein feed and protein crops and varieties that are adjusted to the conditions of different regions. If research and plant breeding is limited, the range of protein crops is also decreased.

Plant breeding creates possibilities for innovation and job opportunities, which in turn results in possibilities for export of safe products with an added value. The ruling limits the possibilities of choosing the new techniques for plant breeding and this has already created doubts about new projects. Is it worth spending time, effort and money on something that might not reach the market? It is stated that we are losing momentum on a matter that should be pursued forcefully to tackle the challenges we have in front of us.

The decision regarding the regulation of targeted mutagenesis is likely to affect the establishment and maintaining of international companies on the European market. There is a risk of losing collaborators, companies and researchers from academic institutions as they now choose to cooperate with institutions outside the EU. In the long term, this may lead to losing promising young researchers who choose to place their research in countries where genome edited organisms are not regulated as GMOs.

Effects on trade

All imports of seeds for sowing from countries where cultivation of genome edited crops is not regulated will become difficult. It cannot be excluded that there could be seeds modified with new methods of mutagenesis in all seed lots imported to the EU, regardless of the plant species. There might be a need to set up special inspection programs for this. Since it will not be possible to determine the potential presence of genome edited unauthorised seeds by genetic analysis, you may need a system for certification of the entire seed production chain. This will obviously become more expensive for the importer. Since the cultivation of genome edited plants will not be allowed, unless it has been authorised, the requirements for seed purity will be high. It should be emphasized again that, currently, there is no control system that can determine whether a single point mutation has occurred naturally or by genome editing. The same scenario as described above is the case for trade with plant based commodities.

Loss of competitiveness within the agriculture sector

The competition is increased at a global level where the United States, and also to an increasing extent the major Asian economies, over time will have a large impact on the ability of the EU to compete. The EU imports approximately 32.5 million tons of soybean and soy flour from mainly Argentina, Brazil and the United States, and around 5 million tons of rapeseed and rapeseed oil from mainly Australia, Canada and Ukraine. A genome edited rapeseed has already been marketed in Canada and the United States and genome edited soybean and maize are in the pipeline (BioVox website). China is also important when it comes to research and development of gene edited crops. China is primarily invested in rice and is almost dominating the patents related to CRISPR/Cas9 technology.

When Swedish and European farmers do not have access to varieties with the same traits as in other countries, they have weakened their competitiveness in agriculture and forestry internationally. This effect will not only be noted in the cultivation of major crops such as wheat, rye, maize and rapeseed but also for different specialty crops, not the least for vegetables and other crops where not many examples of the use of GMO technology have been seen. In animal production, we will lose competitiveness through increased costs for feed in the EU compared to countries that do not regulate gene edited crops.

One company risks finding itself in a worse position, competitively, due to the ECJ-ruling, compared to farmers outside of the EU. This is due to both wanted traits not being acquired with new techniques of mutagenesis, and to increased costs for analyses and control of imported raw material for feed.

One association states that if the EU chooses not to benefit from new genome editing techniques, we will lose our competitiveness in the long run. We will be dependent on imported commodities both when it comes to food and seeds for sowing. We will also lose control of plant breeding. Food from other regions of the world will most likely be cheaper and have a more secure production.

As developments are taking place at a rapid pace, smaller regions such as northern Europe will not be interesting for the major plant breeding companies outside the EU. This means that crops adapted for northern Europe will fall behind in development. One consequence of this is that countries in northern Europe will lag behind in competitiveness, a trend that is already a fact today. When plant breeding can no longer be maintained in an efficient and modern way in the future, these parts of the world will fall behind even further. For the countries in the north, there is a risk that the consequences will be greater than for the countries in central Europe.

The United States, Canada and additional countries have decided that genome edited plants are not regulated as GM plants. Overall, this means more disadvantages for European plant breeding. So far, European plant breeders have, for their overseas development and marketing of varieties in crops such as maize and rapeseed, been dependent on licenses from biotechnology companies that have patented GMO properties in these crops. With that comes costs for controls and separation of GM and non-GM crops. Now we are faced with the same situation in a variety of other crops such as wheat, oats, potatoes and sugar beet, if we still want to be able to market varieties in these crops successfully outside the EU.

Loss of competitiveness within the research community

Plant breeding is an international operation. Exchange of research results and genetic material is a major part of any practical research. The ruling brings about obstacles that will weaken the collaboration of Swedish and European researchers with non-EU countries. Difficulties of predicting the consequences are expressed but also a fear that the consequences will be considerable.

There is a great risk that all research and knowledge in the area will be transferred to non-EU countries. As a consequence, Swedish and European initiatives will be transferred to companies in non-EU countries that are able to apply the knowledge that has been developed. Modern plant breeding technology will in time replace traditional plant breeding and the conclusion is that the EU will soon be dependent on the competence and financial interests of other countries. There is a risk that the multinational companies will have patented most applications and we will be dependent on these companies for access to applications interesting for Swedish conditions.

As described previously, several research projects involving genome editing have changed direction or been put on hold. Even if projects would be resumed, the research would be delayed compared to that of international competitors. With the competition that prevails, this could mean that we will lose our head start towards other researchers who can now publish and patent their results before the Swedish researchers. In the long run, the consequences will be less opportunities for financing. Furthermore, there will be other conditions for licensing of technology and its applications.

One large research group states that they had plans to apply for research funding to develop new varieties for practical use. This concerned, for example, investments in forestry, agriculture and horticulture in north of Sweden. The research group had begun to contact stakeholders, but the plans were brought to an end since it is not plausible that they, at this stage, could convince commercial actors and research financiers about this. The GMO legislation has, for many years, meant that they were prevented from translating their basic research findings into farm- and forestry practice. They had hoped that this situation could partially be resolved with the use of genome editing. It is still unclear to what extent their international collaborations will be affected. In the short term, it does not mean any dramatic differences, but a research centre in the EU is of course less attractive as a partner now than it would have been otherwise. There were also plans of a lectureship to better utilize the opportunities that they thought would be realised but which will not happen now.

Consumer´s choice

Consumers are making increasingly specific demands for vegetables and other foods. This could regard the absence of substances that may cause allergies, such as gluten, or an altered content of other specific components which have positive or negative health effects. Higher demands are made on food safety, i.e. a guaranteed supply even in the case of disturbances in food production. In these respects, it will be difficult for the agricultural sector to live up to the wishes and demands of the consumers, unless plant breeding has access to all new methods and technologies.

Chemically modified starch has to be declared, in accordance with current legislation, with an E-number in the ingredient list of foods. The consumer demand for clean label (E-number free) products in the EU is strong and will be further enhanced over time. Currently, in the UK, 44% of the sales of modified starch for food comprises of clean label. It is based on raw materials other than potatoes (mainly maize) because, due to plant cell structure, it is possible to develop naturally storage stable starch using traditional plant breeding. Due to a lacking acceptance of GM labelled products, it is considered impossible to sell GM labelled starch. It is also stated that there is a risk that the debate is distorted, so that the new techniques are questioned on completely partial and unscientific grounds.

Legal uncertainties

In almost all the responses that the SBA received, it was stated that, for a legislation to be meaningful, there has to be reasonable possibilities to control compliance. This, among other things, will result in that the trust in EU as an institution and its ability to develop its legislation will become damaged.

In one of the responses it was written that the decision of the court has created legal uncertainty for the researchers. Could researchers bring plants with them when they move outside the laboratory or the country? What will the research groups do in the future when they get research material, which might have been produced with genome editing, sent to them from colleagues or stock centres in other countries? Would they commit crimes if they would handle such material outside of their GMO facility, if they do not even know whether the material is genome edited or not? How would they communicate this to their employees? Many questions remain unanswered. For many researchers, the ruling is perceived as very problematic and it creates a great deal of uncertainty in their daily operations.

Table 1. Organisations/institutes that that have contributed with information

Organisation/Institute	**Purpose**
Föreningen Foder och Spannmål	An industry association for companies manufacturing and trading with *e.g.* feed, cereals, seeds, fertilizers and plant protection products. The association currently has about 60 members, both from individual companies and cooperative associations.
Lantbrukarnas Riksförbund	The Federation of Swedish Farmers is an interest and business organisation for the green industry with approximately 140,000 individual members.
Lantmännen Lantbruk	Lantmännen is an agricultural cooperative and Northern Europe's leader in agriculture, machinery, bioenergy and food products. It is owned by 25,000 Swedish farmers, has 10,000 employees with business in about 20 countries and a turnover of approximately 4 billion EUR/year. Lantmännen Lantbruk, which is the agricultural sector of Lantmännen, has 10 plant breeding programs for the production of new varieties for the benefit of farmers, the industry and consumers.
Mistra Biotech	A research program focusing on the use of biotechnology in plant and livestock breeding to contribute to environmentally, socially and economically sustainable Swedish agriculture. The program started in 2012 and involves about 60 researchers specialised in natural science, ethics and social science.
Sveriges Stärkelseproducenter	An economic association and owner of *e.g.* the company Lyckeby Starch AB. The association has a turnover of approximately 180 million EUR per year and has about 600 employees. It is owned by approximately 800 farmers and about half of those cultivate starch potato. Sustainable enterprise is an important part of the business strategy and the association is world leading within the development of sustainable starch potato.
Sveriges Utsädesförening	A non-profit association for issues regarding plant breeding and seeds for sowing. The association has about 250 members spanning everything from plant breeding research to plant breeding, seed production, agriculture and an involved general public.
Swedish University of Agricultural Sciences,	The department has around 100 employees and is a part of the research centre Umeå Plant Science Centre

Department of Forest Genetics and Plant Physiology	(UPSC)*. The department conducts research in plant physiology, ecophysiology, plant molecular biology, forest genetics and forest biotechnology.
Swedish University of Agricultural Sciences, Department of Plant Biology	The department develops fundamental knowledge about developmental processes and defence in plants for application in agriculture and forestry.
Swedish University of Agricultural Sciences, Department of Plant Breeding	The Department of Plant Breeding carries out research, pre-breeding and the production of varieties in a number of crops with the goal to contribute to a sustainable production of food, feed and bio-based materials. A great deal of effort is invested in the development of modern breeding methods such as genome editing. The department is also highly involved in the spreading of information and in questions regarding the policy of different breeding techniques.
Swedish University of Agricultural Sciences, Grogrund	Grogrund is a knowledge centre initiated by the Swedish government. The centre gathers the academia and business to develop skills to, in accordance with the objectives of the national food strategy, ensure the availability of varieties for sustainable and competitive agricultural and horticultural production in Sweden.
SweTree Technologies AB	A plant and forest biotechnology company providing products and technologies to improve the productivity and performance properties of plants and wood for forest owners and fibre related industries
Umeå University, Department of Chemistry	The department has more than 200 employees. Research at the department includes three major areas: biological chemistry, environmental and biogeochemistry and technical chemistry. The department is a part of Umeå Plant Science Centre (UPSC)*.
Umeå University, Department of Plant Physiology	The department has around 100 employees and is a part of the research centre Umeå Plant Science Centre (UPSC)*. Their main activity is academic research in experimental plant biology, with the goal of understanding all aspects of plants in relation to the environment that they live in.
*Umeå Plant Science Centre, UPSC	UPSC is a "centre of excellence" and one of the most prominent research environments for plant research in Europe. About 40 research groups work in UPSC with

	large international element with over 40 nationalities represented. Virtually all groups use genetically modified plants in some part of their research. In recent years, many groups have also started to use genome-editing techniques. The main part of the research at UPSC is basic research, but some projects have a more applied nature. In 2014, researchers at UPSC were the first ones to ask the Swedish Board of Agriculture about their views on the regulatory status of genome editing.

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