AARHUS
UNIVERSITET
DCA - NATIONALT CENTER FOR FØDEVARER OG JORDBRUG

Til Landbrugsstyrelsen

Levering på bestillingen: ”Summary af Vidensyntese om muligheder og risici for anvendelse af nye planteforædlingsteknikker inden for dansk landbrug”

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Landbrugsstyrelsen (LBST) har i en bestilling dateret d. 26. oktober 2018 bedt DCA – Nationalt Center for Fødevarer og Jordbrug – om at levere et engelsk summary af ” Vidensyntese om muligheder og risici for anvendelse af nye planteforædlingsteknikker inden for dansk landbrug”, samt vurdere ”hvilke konsekvenser domstolens afgørelse forventes at få for dansk landbrug, havebrug og skovbrug, samt planteforædling”.

Summaryet følger nedenfor, og er i vidensyntesen udarbejdet af Professor Henrik Brinch-Pedersen, seniorforsker Per L. Gregersen, forsker Inger Bæksted Holme og lektor Kim Hebelstrup fra Institut for Molekylærbiologi og Genetik v. AU, molekylærbiolog Lotte Hougs fra Fødevarestyrelsen, seniorforsker Birte Boelt fra Institut for Agroøkologi v. AU, seniorforsker Karen Koefoed Petersen fra Institut for Fødevarer v. AU samt seniorrådgiver Morten Gylling fra IFRO v. KU. Professor Henrik Brinch-Pedersen og seniorforsker Per L. Gregersen har forfattet den engelske oversættelse samt tilføjelsen om konsekvenserne af EU dommen. Tilføjelsen er fagfællebedømt af lektor Kim Hebelstrup

Besvarelsen er udarbejdet som led i ”Rammeaftale mellem Miljø- og Fødevareministeriet og Aarhus Universitet om forskningsbaseret myndighedsbetjening af Miljø- og Fødevareministeriet med underliggende styrelser 2018-2021”. Under ID 1.21 i Ydelsesaftale Planteproduktion.

Venlig hilsen

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Summary of Knowledge synthesis on breeding techniques and their effect on Danish agriculture

Baggrund

EU-domstolen afsagde d. 25. juli 2018 kendelse i sagen om regulering af nogle af de nye planteforædlingsteknikker, de såkaldte mutagenese-teknikker. Afgørelsen slår fast, at disse nye præcisionsmutagenese-teknikker skal omfattes af EU's fulde GMO-regulering. EU-landene er delte i deres holdning til GMO og dermed også til de nye teknikker, og der foregår derfor en del drøftelser af domstolens afgørelse og konsekvenser i komiteerne under udsætningsdirektivet. Danmark har i den forbindelse nævnt DCA's Vidensyntese om nye planteforædlingsteknikker og deres effekt på dansk landbrug. EU-Kommissionen har efterfølgende spurgt Danmark, om de kan få tilsendt et summary på engelsk af vidensyntesen.

Landbrugsstyrelsen har derfor bestilt et summary på engelsk på 4-5 sider af DCA's Vidensyntese om nye planteforædlingsteknikker og deres effekt på dansk landbrug. Summaryet skal opdateres i forhold til ny viden, som fx at der nu er faldet dom i sagen om regulering af nogle af de nye planteforædlingsteknikker. Summaryet skal endvidere beskrive, hvilke konsekvenser domstolens afgørelse forventes at få for dansk landbrug, havebrug og skovbrug, samt planteforædling.

Besvarelse

Nedenstående summary er udarbejdet af forfatterne til Vidensyntese om nye planteforædlingsteknikker og deres effekt på dansk landbrug, DCA rapport 127, 2018: Henrik Brinch-Pedersen, Per L. Gregersen, Inger Bæksted Holme, Kim Hebelstrup, Lotte Hougs, Birte Boelt, Karen Koefoed Petersen og Morten Gylling, og oversat til engelsk af Henrik Brinch Petersen og Per L Gregersen.
Tilføjelsen vedr. konsekvenserne af EU dommen er forfattet af Henrik Brinch-Petersen og Per L. Gregersen, fra Institut for Molekylærbiologi og Genetik ved Aarhus Universitet

Summary

This present knowledge synthesis about new plant breeding techniques (NBT), precision breeding and the possibilities in Danish agriculture is divided into a technical part (chapters 1-5) providing background information about plant breeding, mutations, technology within mutation breeding in the past and now, actual examples of precision breeding by NBT in crops and the possibilities for detection of precision-bred crops, if it has been decided to regulate them as GM crops. Next, there is an agricultural part (chapters 7-9) focusing on current challenges in Danish agricultural crops, nursery and forestry and on whether NBT has a potential for contributing. At the end of this part, the economic situation for Danish agriculture with or without NBT is described. Chapter 6 provides a summary of the technical part and a comparison of precision breeding with conventional breeding technologies. Chapter 10 is a summarizing analysis of the potentials of NBT for the agricultural part.

Plant breeding is a discipline for targeted and continuous development of new plant varieties. It

utilizes the genetic variation between individuals within a plant species and combines the desired properties into new and improved varieties. Plant breeding is dependent on genetic variation, and NBT can be used to increase this variation.

However, introducing new variation in a plant species is not a new invention. The new plant breeding techniques are a continuation of an old practice plant breeding has tried to increase the genetic variation by introducing or inducing new properties in our crops. As a basis for the understanding of mutations in plant breeding, the report therefore describes how new variation traditionally has been introduced in the plant breeding material by e.g. chemical or physical treatments, translocation breeding, synthetic hexaploids etc.; techniques that involve comprehensive changes of the plants' genome.

New plant breeding techniques and precision breeding of our crops are relatively new concepts within plant breeding. Actually, new plant breeding techniques comprise a number of technologies that have ermerged over the last decades. At the request of the member states, the European Commission set up a working group in 2007 to evaluate if various new breeding techniques should be covered by the GMO legislation. The working group prepared a list of seven new plant breeding techniques: *Zinc finger nuclease (ZFN) technology, Oligonucleotide directed mutagenesis (ODM), Cisgenesis and Intra-genesis, Grafting on GM-rootstock, RNA-dependent DNA methylation, Agro-infiltration 'sensu stricto' and Reverse breeding.* The ZFN technique is a Site Directed Nuclease (SDN) tool that can produce a mutation at a predetermined position in the plant's genome and not at random positions in the genome where mutations can be potentially harmful. Hence the term precision breeding. Since 2007, a number of new techniques in the same category as ZFN have emerged such as the TALEN and CRISPR/Cas techniques of which in particular the latter has accelerated the development. Specific report focus is on the SDN techniques and in particular the techniques referred to as SDN-1 (a CRISPR technique). SDN-1 techniques are used when the SDN tool makes a break in the DNA strand and the cell repairs the break itself, as it would also do if the break was caused by e.g. UV rays from the sun. Mutations may then occur, if this repair process is not performed perfectly.

Although the SDN techniques are new, there are already a number of examples of how they can be used in crops. For instance crops that by SDN-1 have reached a higher natural disease resistance, improved quality from health-promoting components, low gluten content, and improved utilization of nitrogen – particularly under growing conditions with limited access to nitrogen.

With respect to traceability, it will not be possible to separate mutations resulting from SDN-1 from mutations occurring by traditional means, unless information about their gene sequences is available. This will complicate the control of crops imported from countries that do not require labelling of NBT crops.

It is estimated that SDN-1 has very few potential risks of e.g. unwanted mutations compared with traditional mutation techniques. Mutation breeding as well as the new precision breeding technologies can be considered as additional opportunities for the already existing very efficient and optimized plant breeding of crop plants based on classical hybridization breeding. Precision

breeding in particular is estimated to have great potential as it is precise with respect to positioning of introduced mutations and because the number of off-target mutations can be minimized. Furthermore, it is anticipated that the potential of precision breeding will increase considerably when linked to the continuous knowledge development within basic molecular regulation processes for selection of suitable candidate genes in plants.

Regarding the challenges that Danish plant production faces, the development of robust and high-yielding varieties will continue to play a role in maintaining and increasing the yield and quality of Danish crops. Each crop has its own specific breeding targets, e.g. protein content or digestibility, but across practically all species, the challenges of diseases – and to an increasing extent robustness to climatic conditions – are similar. For both specific targets and the big challenges in relation to resilient plants, precision breeding has potentials for contributing large qualitative leaps in useful properties in new varieties. Even though Denmark is a small country in terms of acreage, the plant production is, to a high extent, characterized by the use of varieties that are adapted specifically to Danish conditions, and the adaptation of cereals to restrictions in use of nitrogen fertilizer is a striking example. Precision breeding has the special potential that it will be possible to add new properties to existing elite varieties relatively easily. In the longer term, it will be a great advantage to both Danish plant breeders and to the Danish plant production in general, because the varieties that have already been adapted to Danish conditions may be further improved. Moreover, NBT will have great potential within vegetatively propagated crops and/or perennial crops (fruit cultures and many ornamental plants) because both mutation breeding and classical crossings involve extended subsequent backcrossing and selection work.

Danish plant breeding is concentrated within specific species that are important to agriculture in Denmark. Within the agricultural area, it is especially the major crops such as wheat, barley, potato, fodder beet and sugar beet, grasses and clover, whereas within horticulture and forestry it is particularly special genera of ornamental plants and conifers for Christmas tree production and greenery cuttings. For some of the minor/medium crops grown in Denmark, e.g. rye, maize, and vegetable crops, breeding of new varieties has more or less ceased, and cultivation is thus based on varieties bred in neighbouring countries. However, for some species there is a certain niche breeding. Therefore, plant breeding finds itself in a significant international competitive situation, which makes it important for Danish companies to have the same technical possibilities for developing breeding activities as the competitors. Globally, the same applies to European and international activities. NBT technologies are expected to play an important role in the development of new varieties in the future, and in order to be internationally competitive, Danish companies will only succeed, if they have access to the same technical possibilities as foreign competitors as well as possibilities of marketing new varieties on the same conditions. An important factor is the possible differences in the public regulation of varieties developed by NBT, which will be of crucial importance to the marketing costs of new varieties.

If precision breeding is exempted from the requirements of the GMO legislation regarding approval, it is estimated that it may be widely used by even minor breeding companies to introduce new properties in plant varieties, as the technique is not costly and does not require large investments. If the plants produced with the new technologies are regulated according to the full EU GMO regulation, it is estimated that only the largest international breeding companies will be able to bear the costs involved in developing new varieties with these technologies. In that case,

it will not be realistic for Danish breeding companies, and thus also, to a large extent, for Danish agriculture to make use of the new technologies. At the same time, Danish farmers will be in a problematic situation if they want to grow crop varieties from countries, where NBT is not regulated as GMO.

Comments, following the decision from the EU court on NBTs, July 2018:

As concluded in the summary above, the status of NBT (SDN1 technologies) with respect to the EU GMO regulation is important for the possibilities of exploiting the potentials of the technologies in future Danish plant breeding. The decision by the EU court that new varieties obtained by SND1 techniques are "subject to the obligations laid down by the GMO Directive", and not exempted as classical mutagenesis, makes it difficult, if not impossible, for Danish plant breeders to make use of the new techniques, due to heavy costs associated with the approval of GM varieties. Realistically, only major companies can afford the costs and, hence, only these companies can probably make commercial use of the new SDN technologies. In a short-term perspective, the influence on the Danish/European plant breeding industry, in particular SMEs, might not be strong, but in a longer perspective this industry will probably be in a weak competitive situation, as it is to be expected that the restrictions on the use of the new techniques will be weaker outside Europe.

The development of crop varieties usually takes many years and, thus, the effects on the market and in agriculture will have an equivalent lag. However, the court decision will probably also make the industry reluctant to enter into research and development directed towards the use of the new techniques. This will most likely aggravate the long term weakening of the Danish/European breeding industry in the global competition.

For some crops and traits, especially ornamentals and garden/vegetable seeds, new cultivars have a shorter developmental horizon, e.g. when it comes to developing new flower colours. Since this is also a global market, the impact of the new techniques on Europe may come sooner than expected, if restrictions on their use, as expected, will be limited in Asia and the US. This raises the issues of detection of genetic modifications introduced by the new techniques. In Europe, they are considered GMO and, thus, subject to strict approval, but, as outlined in the knowledge synthesis report, it is almost impossible to make unambiguous tests for the introduced mutations, since there is no marks distinguishing them from natural mutations/variants. This situation will be even worse in a long-term perspective, when varieties of major European crops with new NBT traits can enter the European market from the surrounding world and be crossed with locally developed varieties. From the regulatory aspect, this situation will not be sustainable and it is not supporting the European plant breeding industry.

All these aspects make the current situation very unclear and untenable for the Danish/European plant breeding industry, and it calls for clarifications at EU regulation level. In response to the unclear situation, the European Commission's Group of Chief Scientific Advisers recently published their advice on gene editing - calling for the GMO Directive to be revised https://ec.europa.eu/info/news/commissions-chief-scientific-advisors-publish-statement-regulation-gene-editing-2018-nov-13_en.