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Jordbruks verket

Swedish Board of Agriculture

Follow-up from PAFF-meeting on September 11, 2018

At the meeting, the Member States were asked to provide the Commission with information on several issues regarding “new” gene editing techniques/new breeding techniques and the recent European Court of Justice (ECJ) ruling. The Swedish Board of Agriculture (SBA) answers the questions as we perceived them below:

Sweden has no registered varieties in the national or common catalogue, which have been produced by using “new” techniques of mutagenesis. However, in relation to the ECJ ruling, it might be interesting to mention that there are spontaneously mutated herbicide tolerant varieties (ALS inhibited) registered.

Before the court ruling, we received questions regarding a potential future registration of a potato edited with CRISPR/Cas9. Allegedly, the mutation is identical to a naturally occurring mutation found in maize.

Regarding plants produced by “new” techniques of mutagenesis, we have no knowledge of plans of market release outside the EU.

As far as we know, there are no ongoing field trials in Sweden with plants produced with “new” techniques of mutagenesis. Additionally, we have not received any new questions or applications regarding field trials with such plants.

The SBA has interpreted the Directive on three occasions due to questions from one company and two universities. We concluded that Cibus rape seed created with ODM in 2012 was exempted from the Directive. The questions from the universities in 2015 regarded thale cress modified in different ways by using CRISPR/Cas9. Our conclusion was that plants containing new or foreign DNA were GMOs while plants that did not contain such DNA were exempted from the GM regulation.

Since the ECJ ruling, we have received some questions, primarily from researchers and businesses but also from the media. Naturally, they want to know how the SBAs earlier interpretation stands against the new ruling and what the consequences of the ruling will be. The SBA has found it difficult to give an answer since we think that, instead of clarifying the legal situation, the ECJ ruling has created additional questions. We also find it difficult to understand the risk based arguments used in the ECJ ruling.

Several articles have been published in a wide variety of media in which the writers are highly concerned about the ECJ ruling and point to the negative consequences it entails, for example the risk of competence disappearing from the EU. Six headmasters of Swedish universities have also written a joint statement urging politicians in Sweden and the EU to take action for a science based legislation. They state that the ECJ ruling threatens the future provision of food and the task of decreasing the negative effects of agriculture on the environment.

The SBA´s questions to the Commission

Detection and quantification

We found the EURL document to be very clarifying regarding the possibilities and limitations of analytical determination of whether a crop has emerged with new mutagenesis methods or with conventional or spontaneous mutations. The SBA is very concerned about the legal certainty of such analyses and what conclusions that can be drawn from the analyses. Additionally, we are also concerned about the amount of resources that will be needed to perform the controls.

1. We would like the Commission to do a cost analysis which takes into account the costs for the laboratories, control authorities and operators to perform these types of controls and to produce and keep such databases of genetic information updated. We would also like the Member States to be involved in this process.

Since it seems difficult to detect minor mutations through analysis we were wondering about the possibility for a potential applicant to be able to fulfil the requirements necessary to apply for market release in the EU. If it is not possible, or very difficult to have a specified protocol for the detection of small mutations that have been introduced in a genome, this will be like a kind of ban on the use of goods produced with new techniques.

2. Will the Commission ask the EURL for an assessment of the possibility to fulfil the requirement of having a detection protocol for a notification for market release for the kind of mutations that can be achieved with new techniques?

Definition of “GMO” in other regulations

In Directive 2009/41/EC on the contained use of genetically modified microorganisms, mutagenesis is excluded, just as in Directive 2001/18/EC, but there is no equivalence to recital 17. That means that a bacterium modified through a gene editing technique, such as CRISPR/Cas9, is exempted from the GM-regulation when used contained but that it becomes a GMO when released into the environment. Since there has previously been a field trial with genetically modified microorganisms in Sweden, it is possible that such trials

will also be performed in the future. Therefore, it needs to be clear, for all parties involved, what is exempted from the requirements in the GM legislation.

3. Has the Commission considered if any revision in other regulations is necessary due to the ECJ ruling?

The meaning of recital 17

Since the court is largely inclined to recital 17, we must relate to this and discuss what it might mean when a technique "has been used conventionally in a number of applications and has a long safety record". For example, when it comes to new methods of mutagenesis, there are publications from before 2001. However, is the use of the method in microorganisms relevant or does it have to be used in plants? Do cell cultures count or does it have to be in whole organisms? How long will it take before a technique has a "*long*" safety record? How should the phrase "*used in a number of applications"* be interpreted? Must the technique have been used in both plants and in microorganisms? Or does it mean that the technique must have been used in several plant species or that the technique perhaps created several different traits even though the traits were only in one and the same species?

What constitutes a technique or method also needs to be clarified. If the word "method" does not mean the molecular change but rather the process by which the change is achieved, does that mean that e.g. CRISPR/Cas9 should be considered as one method? For example, you can achieve different types of molecular changes with CRISPR/Cas9. Would each type of change then be a different method?

Furthermore, if "method/technique" means the process by which a molecular change is achieved, then it is the method that matters and not the organism in which it was used. Would the consequences then be that when we try to determine when a method was first used (to be able to determine if a method has a "long" safety record) it does not matter in which context it was used? The Competent Authorities should be able to answer these kind of questions.

4. Will the commission take an initiative for such detailed discussions?

A legislation in a frozen state?

In the interpretation that the SBA did in 2015, we concluded that mutagenesis in itself is a technique. We used recital 17 to interpret Directive 2001/18/EC as meaning that the mutagenesis exemption applies to the molecular processes that occur in traditional mutagenesis and not the method of obtaining the mutations. We concluded that gene editing is one type of mutagenesis and we found no basis in the Directive, to differentiate between different techniques of mutagenesis, notably because the end results are similar or even identical. Since the goal of the Directive is to protect human health and the environment *when*

genetically modified organisms are deliberately released in to the environment we concluded that it is the safety of the organism that is relevant and not the safety of the process by which you produce the organism.

If it is not the change in the resulting plant that is of importance but rather the process by which you achieve the change, that could entail that e.g. new chemicals for the induction of mutations also would be considered as new techniques/methods. It would also mean that one would automatically consider any improvement in methodology to carry a higher risk even when the actual change in the organism might be identical to what has been previously achieved with an "old" and safe method.

5. Does the Commission interpret the ECJ ruling in such a way that all development in methodology should automatically lead to a regulated GMO?

The risk aspect

The ECJ ruling gives rise to questions regarding when something should be considered to carry an increased risk. For example, is it not reasonable to presume that molecular changes that are exactly the same would carry the same risk, no matter how they were produced? If the safety of an organism cannot be determined based on the molecular changes that it contains and by comparison to other organisms which are known to be safe and which contain the same molecular changes, then how is that supposed to be done?

Since the same process might induce different molecular changes, would we then need a database of each molecular change that has been produced through each available method of mutagenesis to be able to figure out if an organism is safe or if it needs to be tested for its safety?

6. Is there a procedure on how to determine the risks or the safety of a method?

Risk of trade disruption

A number of WTO members have previously questioned EU legislation on genetically modified organisms. At least USA and Japan have announced that they do not consider mutations produced by new gene editing techniques to lead to regulated GMOs. The document from EURL clearly shows the issues that might arise with the control. High costs for analyses and uncertainty with the results could be regarded as trade barriers. Especially in those cases where there are no differences between a variety that has been produced through spontaneous mutations and a variety where the same mutation has been produced by gene editing.

7. Will the Commission analyse the consequences of the ECJ ruling in relation to the WTO agreements?

With regards to all of the questions above, we urge the Commission to work towards finding a solution to the situation that the ECJ ruling has caused.