The consequences of the ECJ ruling for the European market – Greetje van Heezik & Fleur Tuinzing-Westerhuis

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The European Court of Justice ruled on 25 July 2018 that organisms obtained by mutagenesis plant breeding technique are GMOs and should, in principle, fall under the GMO Directive, in a surprising move that went contrary to the Advocate-General's non-binding opinion.

What is your first impression of the ruling?

If you take AG Bobek's opinion in consideration, the outcome of the ruling is rather radically different. However, when looking at the text of the GMO Directive (Directive 2001/18), it comes as less of a surprise. The European Court of Justice (ECJ) is the interpreter of the European Union law and not a policy maker. It is indeed a conservative ruling, but it is consistent with the case law relating to the restrictive interpretation of exemptions to the general rule. Particularly where the precautionary principle applies, like it is the case for the GMO Directive 2001/18. Taking the intention of the legislator as a starting point, the ECJ held that exemption for the existing techniques cannot be interpreted in a dynamic way given the importance the legislator assigned to the monitoring of the developments of GMOs.
The fact that the European Commission was reluctant to intervene in the discussion of such a sensitive topic, exacerbated the existing gap in society between the legal text and its perception. While AG Bobek advocated a dynamic interpretation, the Grand Chamber stuck very closely to the text of Directive 2001/18 and the intention of the legislator as expressed in the recitals of the directive, stating that GMOs cannot be placed on the market without explicit approval and that the exemption to that rule must be interpreted very restrictively.

Is it usual that the European Court of Justice (ECJ) dismisses the opinion of the Advocate General?

It is not usual. In most of the cases the ECJ follows the opinion of the Advocate General. However, it can happen that the court ruling deviates, especially in sensitive cases attributed to the Grand Chamber with thirteen judges involved instead of the more common chambers of five or three judges. Contrary to the United States, there is no system of dissenting opinion in

Europe. Hence, the ECJ will formulate one ruling based on consent within the court. The risk of different opinions that have to be aligned is of course higher when more judges are involved.

Following the Court's ruling, how are new mutagenesis techniques going to be regulated?

After the ruling's interpretation of the Directive 2001/18, new mutagenesis techniques have to undergo the whole regulatory procedure and can thus only be released into the environment or placed on the market after an extensive risk assessment. The consequence of the ruling is that the ECJ's interpretation is supposed to be the interpretation of Directive 2001/18 that had to be given from the start. Therefore, the regulatory requirements are supposed to have applied also prior to this ruling as new mutagenesis techniques have never been exempted. In some cases, the ECJ limits the effect of its ruling in time, but in this case it did not.
The impact it will have for the food industry is that producers will face great administrative hurdles to prove the safety of a product and, subsequently, consumers need to be convinced to purchase the product that must be labelled as a GMO product. Once a technique is compliant with the Directive 2001/18, Member States have to accept all its implications with regard to the internal market (free movement) and can no longer take unilateral restrictive measures. However, the ECJ underlines in its ruling that Member States can individually regulate the exempted conventional breeding techniques for which no harmonising EU rules are in place.

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How about non-mutagenesis techniques and other methods of plant genome editing?

The ruling only refers to mutagenesis techniques and does not give an interpretation of other techniques. However, it can be deducted from the ruling that the assessment of other techniques must go through the following steps. Firstly, it requires an evaluation if the changes caused by the respective technique can occur naturally (does the technique fall under the definition of GMO). Secondly, one needs to check if the technique is listed under Annex I A in the Directive 2001/18 as resulting in a GMO or as exempted under Annex I B. Lastly, it depends on the explicit exemptions based on the environmental risk assessments referred to in Annex II.
Based on the ruling, the exemptions from all the obligations within the GMO Directive such as the safety assessment, the labelling or monitoring, have to be interpreted restrictive, while we have yet to see where exactly to draw the line.

How does the ECJ ruling change the status quo with regards to NBTs?

In society the perception of what is considered a GMO has changed while it has not in legal terms. Traditional as well as new techniques have already been considered as such. The ECJ ruling makes clear that NBTs have never been exempted from the scope of the GMO rules whereas the traditional mutagenesis methods have.
Therefore, the most significant change of the ruling was to resolve uncertainties concerning which techniques fall under the strict regime of GMOs and which ones are exempted. As said, the legal interpretation of Directive 2001/18 though, should have always been like this since the ECJ has not limited the effect of its ruling in time. Therefore, the ruling has severe consequences for already existing products produced with NBTs. If a product has been developed using one of the new mutagenesis techniques falling under the scope of the Directive at a

certain stage, it has to undergo a risk assessment before it can be marketed and, additionally, it has to be labeled as GMO. Hence, the responsibility to trace back the applied methods resides within the plant breeders, growers and other stakeholders along the value chain. As a consequence, given the major investments for the safety assessment and labelling requirements, it will be harder to develop profitable business applications which make it worthwhile bringing certain products on the market.

How would the Court's answer to the third question, stating that Member States are free to subject organisms resulting from mutagenesis techniques which have conventionally been used, in compliance with EU law, to the obligations laid down by the GMO Directive or to other obligations, would affect the internal market, and more precisely the free movement of goods?

The third question of the French court (Conseil d'État) is referring to the room of manoeuvre of the Member States to adopt additional restrictive measures. Such measures can only apply for methods which are exempted in Article I B in the Directive 2001/18 and thus not covered by harmonised European Union rules. Given the restrictive interpretation of the exemption by the ECJ, national measures restricting the free movement are only possible with respect to products resulting from traditional mutagenesis techniques. Hence, this question lost relevance due to the ruling. Nevertheless, the ECJ points out that any national measures must comply with the free movement of goods which is not an absolute right. Even though Article 34 of the Lisbon Treaty states that restrictions on imports by Member States are not allowed, Article 36 provides an exemption from this prohibition if the restriction is necessary to meet, inter alia, concerns of human health or the environment. Member States wishing to introduce even stricter rules for GMOs, i.e. by submitting the exempted techniques to the GMO rules, are likely to invoke these exceptions. Although the ECJ does not explicitly refer to the precautionary principle in this context, a Member State invoking the exceptions is required to put forward scientific evidence demonstrating the alleged dangers before being able to implement any restrictive measures. Therefore, in theory national restrictive measures are possible, however, in practice it will be a big hurdle respective Member States are facing.
When it comes to the free movement of goods, regarding products produced with NBTs, Member States have to be compliant with the GMO rules and cannot provide a possibility for a third party to bring a product to the market without undergoing a formal approval procedure provided for by Directive 2001/18. Thus, the product cannot be marketed until the respective Member State notifies the European Commission and all the other Member States and an approval decision is adopted. Only after this procedure the product can be placed on the European market and no individual Member State is allowed to block it.
Resuming, national restrictive measures are only possible with regard to (products resulting from) traditional breeding techniques. Since they do not fall under the scope of the Directive, Member States can block these products under the premise that they provide sound scientific evidence.

Do you see any legislative developments following the ECJ ruling?
Even though it is an immense political hurdle to overcome, a modification of Directive 2001/18 or a new legislation is currently the only way for policy makers to realign the interpretation of the ECJ with the existing practice. Additionally, the European Commission can provide specific rules and guidance with regard to exempted techniques for stakeholders, based on the text of the ruling. What could happen at a later stage is that policy makers realise the severe consequences of the ruling or its subsequent developments and thus decide to facilitate the risk assessment for new techniques, enabling a modification of Directive 2001/18 in favour of the NBTs. However, at the moment NBTs have to undergo the individual authorisation procedure.
While research and development have the possibility to continue inside the EU, products cannot be released into the environment or put on the market. Even if companies relocate their activities outside of the EU, the developed products must undergo a risk assessment before

entering the European market. For instance, the United States or China are more liberal in terms of risk assessment, but it does not grant them access to the European market.
After the ECJ ruling, it is now up to the industry to provide sound evidence that certain new techniques of mutagenesis are as safe or even safer than traditional ones. In the current political climate such evidence seems to be required in order to enable a modification of Annex I B of the GMO Directive 2001/18 by the European legislator existing in an extension of the exemption to NBTs. The European Commission has been reluctant to take position so far, but, given the impact of the ruling and the interests of the various sectors in facilitating the NBTs, it is likely that there will be discussions in the respective directorates of the European Commission, in the Council and the European Parliament with regard to the possible steps that can be taken following the ECJ ruling.

Greetje van Heezik specialises in EU law and competition law, including State aid and market and government regulations. She advises companies and public bodies on the State aid aspects of strategic projects and public-private partnerships. Greetje also advises companies on the compatibility of business practices and various types of collaboration with the competition rules and a very wide range of EU regulations on agrifood, including the common organisation of the agricultural markets, food law, biocides, pesticides, and with regard to other medicinal products, medical devices and hazardous substances (REACH). She has specific expertise on the interaction between the rules for the common organisation of markets and competition. Greetje is also involved in several national and European proceedings on matters related to her areas of specialisation. She has particular experience litigating before the European Court of Justice and the General Court of the European Union. Before joining Houthoff, she worked at the Legal Service of the European Commission for 8 years and the Ministry of Agriculture, Nature and Food Quality.

Fleur Tuinzing-Westerhuis specialises in technology related Intellectual Property matters, with a focus on patents and plant variety rights. In her daily practice, Fleur represents a wide variety of domestic and international companies that are active in technology intensive business sectors, such as Agrifood and Biotech. Fleur is an experienced patent litigator and has, as one of only a hand full of lawyers in the Netherlands, extensive experience in litigation relating to national and Community plant variety rights. Furthermore, Fleur assists clients in implementing Customs seizure actions based on the EU Anti-Piracy Regulation. Over the past 10 years, Fleur has litigated in various cases before the Dutch Courts, the Dutch Board of Plant Varieties and the Office for Harmonization in the Internal Market.

What is plant breeding?

Plant breeding is the art and science of changing the traits of plants in order to produce desired characteristics to improve the overall function of various plants and crop systems.

With the predicted growth in the global population and the effects of climate change, varieties with increased yields and resistance to drought and disease are critical if we are to provide enough food for future generations. Plant breeding is one of the tools that will help us achieve sustainable crop production in the long term.

About the NBT Platform

The NBT Platform is a coalition of SMEs, large industry representatives and members of prominent academic and research institutes. Its aim is to provide policy makers and stakeholders with clear and precise information on NBTs and to generate awareness about their benefits for the European economy and society.

More information on www.nbtplatform.org, or contact us via info@nbtplatfform.org.