European Union Law Working Papers

No. 28

Between Innovation and Precaution: Which Treatment for New Plant Breeding Technologies? The European Perspective

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2018
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Abstract

This paper delineates, from a legal perspective, the main contours of the debate on New Plant Breeding Techniques (NPBTs) that is currently occurring on the European level. It describes and analyses the legal tools held by European regulators and the European judges who will define the legal status of these plant technologies.

NPBTs’ practical uses will depend on their legal status in European Union law. The question is whether the organisms produced by these NPBTs are genetically modified in the sense of Directive 2001/18/EC or not, and if those techniques must be regulated as such, or should be exempted from evaluation.
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1. Introduction

In the past 10,000 years since humans began to engage in agriculture, a variety of techniques to select and introduce desirable traits in plants used for food and feed emerged. These plant breeding techniques result in either a stable or a transient alteration of the plant genome or its expression (phenotype), and vary in the extent of change experienced by the organism.¹

Legal doctrine distinguishes two main groups of breeding techniques, CBT and ETGM. Conventional breeding techniques (CBT) are “those techniques, the use of which (with the exception of animal somatic cloning) predates the use of ETGM [established techniques of genetic modification] and the products of which combine traits which pre-exist in the genetic potential of the 'parent' organisms.”² While the CBT benefit from a long history of safe use and therefore fall out of the scope of the specific requirements relating to genetically modified organisms (GMOs), the ETGM are subject to strong European regulation.

Aside from the classical division between CBT and ETGM, a series of new plant breeding techniques (NPBTs) emerged in the 1990s and continue to develop even now. A characteristic common to the NPBTs is that these targeted methods are free from the dynamics of biological evolution, which is based on the random production of variants and subsequent selection. In other words, the methods make it possible to accelerate the selection of cultivated varieties.³

The NBPTs are also applied to animals and micro-organisms. However, this paper only covers plant technologies, specifically the breeding of cultivated (i.e. not wild) plant varieties.

There is an urgent call for legal certainty relating to NPBTs, emphasized by the fact that some plants produced with these new genetic engineering techniques are already on the market despite the lack of clarity regarding their legal status. The practical use of the NPBTs will depend on their legal status, according to the law of the European Union. The question is whether the organisms produced by these NPBTs are genetically modified in the sense of Directive 2001/18/EC or not, and if those techniques must be regulated as such, or should be exempted from evaluation.

This paper does not aim to give a legal opinion of how NPBTs should be regulated. Its purpose is to delineate the main lines of the debate that currently takes place on the European level and to describe and analyse the tools held by the European regulators and/or the European judges who will define the legal status of NPBTs.

To assess the legal status of NPBTs, consideration will first be given to the regulation of GMOs under Directive 2001/18/EC. Second, this analysis will parse the main legal issues concerning NPBTs to better understand the different tools that may influence the awaited final decision on their legal status.

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2. The regulatory framework for genetically modified organisms (GMOs)

An analysis of the scope of GMO regulation in the EU will also constitute a necessary framework for a future legal assessment of NPBTs.

2.1. History and applicable legislation


In the 1990s, a rigorous discussion took place on the international level regarding the questions raised by transgenic technology. The conclusions of this public and political debate materialised in the Cartagena Protocol on Biosafety. Its objective is “to contribute to ensuring

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an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology.”


2.2. Definition of a GMO: scope and interpretation

In order to assess the legal qualification of the NPBTs correctly, consideration must be given to the regulation of GMOs under the Directive. Article 2 of the Directive defines a genetically modified organism as “an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.” This definition remains unchanged since the first generation of directives. A cumulative analysis through three different levels, as developed below, must be undertaken to assess whether an organism is subject to the requirements of the Directive. The Cumulative Multilevel Analysis table produced by the NBT Platform provides for a useful overview of this analysis process and is attached in Annex 1 of this paper.

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13 Art. 2 (2) Dir. 2001/18/EC, op. cit.
2.2.1 Genetic modifications within the scope of the Directive

According to Article 2 (2) (a), genetic modification occurs using the techniques listed in Annex I A, part 1. These techniques include some recombinant DNA applications that involve the insertion of a nucleic acid molecule capable of continued propagation, direct introduction of heritable material prepared outside the organism, and certain cell fusion or hybridisation techniques. This enumeration requires further explanation of some essential terms.

Concerning the hereditability of the genetic material, the Court of Justice of the European Union (CJEU) has ruled in Bablok and Others v Freistaat Bayern that:

“The definitions of organism and GMO given by Directive 2001/18 necessarily imply that the genetic information included is capable of being transferred specifically to a suitable recipient for the purposes of recombination. Recital 4 in the preamble to Directive 2001/18 supports such an analysis. That directive thus seems to endorse conclusively two criteria which go together, namely viability and fertility, and not merely a transfer of DNA which is no longer capable of playing a role in reproduction.”

Another important question is interpreting the legislative intent underlying language regarding incorporations that “do not naturally occur.” “Naturalness” is currently the subject of rigorous discussions in the context of NPBTs and divides stakeholders. Some argue that it includes alterations which can possibly occur in nature even if they are the result of human intervention, while others see the human intervention in those incorporations as preventing

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15 CJEU, C-442/09, Bablok and Others v Freistaat Bayern, I-07419 (2011), § 55. See also § 59, 60 and 62.
16 NBT Platform, op. cit., 5.
any naturalness of the process. This distinction will be of deep interest when assessing the legal qualification of NPBTs (see below).

The words “at least” of article 2 and “inter alia” of Annex I A indicate clearly the non-exhaustive character of this list. It is the reason why unknown or not commonly established techniques at the time of adoption of the Directive might fall within its scope. Therefore, the reference to the Annex leaves substantive room for interpretation of the definition of a GMO. From a historical perspective, it is important to note that the inter alia approach and the resulting possibility of covering new techniques reflects a compromise that takes into consideration a demand of the Commission (in the context of the review of Directive 90/220/EEC). Indeed, the Commission had required “the possibility of adapting all annexes of the Directive through a Regulatory Committee” to ensure that the provisions are based on the latest stage of scientific experience and knowledge. Its demand was unsuccessful. Nevertheless, the review gave an indicative character to the list of Annex I A, part 1, thus leaving room for interpretation.

2.2.2. Techniques other than genetic modification

Article 2 (2) (b) of the Directive further excludes from the qualification of genetic modification the techniques listed in Annex I A part 2. These are, on the condition that they do not fall into the scope of Art. 2 (2) (a), in vitro fertilisation, and natural processes such as conjugation, transduction, transformation, and polyploidy induction.

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17 Prof. Dr. Dr. T. M. SPRANGER, Legal Analysis of the applicability of Directive 2001/18/EC on genome editing technologies, commissioned by the German Federal Agency for Nature Conservation, October 2015, 17, available at https://bfn.de/fileadmin/BfN/agrogentechnik/Dokumente/Legal_analysis_of_genome_editing_technologies.pdf
18 Prof. Dr. Dr. T. M. SPRANGER, op. cit., 15.
20 Prof. Dr. Dr. T. M. SPRANGER, op. cit., 16.
2.2.3. Genetic modification techniques outside the scope of the Directive

Article 3 provides that certain techniques of genetic modification listed in Annex I B fall
automatically out of the scope of the Directive. It thus represents an exception to the rule of
Article 2 and Annex 1 A, as indicated in the title of the article (“Exemptions”). These
techniques are mutagenesis and cell fusion “of plant cells of organisms which can exchange
genetic material through traditional breeding methods.”

It should be noted that the dynamic application of Annex I A Part 1 does not apply here: the
list in Annex I B is exhaustive, meaning that no other technique of genetic modification can
be automatically excluded from the scope of the Directive. However, “mutagenesis” refers to
any production of mutations in the genome of an organism and is subject to broad
interpretation. Recital 17 is helpful for understanding the underlying reason for those
exemptions:

“This Directive should not apply to organisms obtained through certain techniques of genetic
modification which have conventionally been used in a number of applications and have a
long safety record.” (own underlining)

Read together, Article 3 and Recital 17 intend the exemption to only apply to conventional
breeding techniques. The question is whether mutagenesis also includes a new breeding
technique: site-directed mutagenesis.

21 Prof. Dr. Dr. T. M. SPRANGER, op. cit., 23.
22 Annex I B, Dir. 2001/18/EC, op. cit.
23 Prof. Dr. Dr. T. M. SPRANGER, op. cit., 12, 24.
24 Recital 17 of the Dir. 2001/18/EC, op. cit.
2.3. The requirements concerning GMOs

The cultivation and the marketing of GMOs in the European Union trigger legal obligations on the national and European level.

2.3.1. The requirements under the Directive

The Directive imposes various specific obligations based on mitigating health and environment risks identified in an evaluation of GMOs designed to be cultivated. These obligations include marketing authorisation\textsuperscript{25}, biological traceability\textsuperscript{26}, coexistence with plants produced by CBT, compulsory labelling\textsuperscript{27} and obligations relating to the information to the public.\textsuperscript{28}

The evaluation process is organised first on a national level and then on the European level. The competent national authority designated by the Member State examines the notification of the transgenic event for compliance with the requirements of the Directive, and forwards the summary of the dossier to the Commission and the competent authorities of the other Member States, which may present their own observations. The national authority makes the final decision, in light of these observations.\textsuperscript{29} If authorized, the transgenic event will be inserted in different varieties of the species, and it will be registered in the catalogue of the Member State concerned.\textsuperscript{30}

\textsuperscript{25} Articles 4 and 5 Dir. 2001/18/EC, op. cit.
\textsuperscript{26} Article 4 (6) and Annex IV Dir. 2001/18/EC, op. cit.
\textsuperscript{27} Article 21 Dir. 2001/18/EC, op. cit.
\textsuperscript{28} Article 24 Dir. 2001/18/EC, op. cit.
\textsuperscript{29} Articles 6 and 11 Dir. 2001/18/EC, op. cit.
\textsuperscript{30} Haut Conseil des Biotechnologies, Comité scientifique, \textit{Avis sur les nouvelles techniques d’obtention de plantes}, op. cit., 20.
GMOs which are only designed to be eaten or used (but not cultivated) are evaluated under Regulation 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.\textsuperscript{31}

This is a very long and costly process, which together with the rather negative perception of GMOs as consequence of such a laborious process, explains why some actors (cited below) are trying to narrow, as much as possible, the scope of the definition of GMOs under the Directive.\textsuperscript{32}

2.3.2. National legislation concerning GMOs

Article 4 of the Directive enumerates the obligations of Member States regarding GMOs, and these obligations will further be transposed into national legislation.

Member States have the obligation to ensure that no unauthorised GMO is deliberately released or placed on the market. For instance, this includes ensuring that the competent authority organises inspections or other controls. They are also responsible for enforcing the Directive in case of a release of the GMO without authorisation. They can determine the penalties applicable to breaches of national provisions adopted pursuant to the Directive.\textsuperscript{33}

The Directives contain a so-called “safeguard clause” according to which the Member States may reject GMOs that were approved on the European level in case of new scientific information about adverse effects on human health or the environment.\textsuperscript{34}

\textsuperscript{31} Regulation (EC) No 1829/2003, \textit{op. cit.}
\textsuperscript{32} In that sense, F. HARTUNG, J. SCHIEMANN, \textit{op. cit.}, 745: “[It is] obvious that successful adoption of an agricultural biotechnological technique in the EU will only occur when the resulting organism does not fall under or is excluded from the GMO legislation.”
\textsuperscript{33} Article 33 Dir. 2001/18/EC, \textit{op. cit.}
\textsuperscript{34} Article 23 Dir. 2001/18/EC, \textit{op. cit.}
2.4. The precautionary principle in relation to GMOs and its impact on NPBTs regulation

This precautionary approach was originally introduced for environmental purposes by the Rio Declaration (1992):

“where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.”

The Cartagena Protocol on Biosafety (2000) applied the precautionary approach to

“the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.”

The principle is part of the primary law of the European Union in Article 191 (2) TFEU. It stipulates that

“Union policy on environment (…) shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental should as a priority be rectified at source and that the polluter should pay.”

36 Article 1 of the Cartagena Protocol on Biosafety to the Convention on biological diversity, op. cit.
The precautionary approach was already a central point in first-generation directives. With Directive 2001/18/EC, it becomes a principle, occupying an even more important position. The Directive delivers indeed an essential role to the precautionary principle, opening her first article with those terms:

“In accordance with the precautionary principle, the objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment”.

This makes some commentators argue that the entire Directive illustrates a concretisation of the precautionary principle.38

Within Directive 2001/18/EC, Recital 6 and Article 1 emphasize the importance of this principle when implementing the Directive. Indeed, the principle functions as a basis for restricting the use of new technologies through preventive decision-making in the case of risk for human health and environment.39 The Commission describes its content as follows:

“where the scientific data do not permit a complete evaluation of the risk, recourse to this principle may, for example, be used to stop distribution or order withdrawal from the market of products likely to be hazardous.”40

In particular, the invocation of the principle depends on three conditions: the identification of potentially adverse effects, the evaluation of the scientific data available and the extent of scientific uncertainty.41 It will involve, as a prerequisite, an assessment of risks, development

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37 According to the Commission, the principle needed to be ensured in the implementation of Directive 90/220/EEC. See also CJEU, C-6/99 – Association Greenpeace France and Others v. Ministère de l’Agriculture et de la Pêche and Others (2000), ECR I-6031, §41 sq ; Prof. Dr. Dr. T. M. SPRANGER, op. cit., 34.

38 Prof. Dr. Dr. T. M. SPRANGER, op. cit., 35.

39 Prof. Dr. Dr. T. M. SPRANGER, op. cit., 36.


41 Ibidem
of a risk management strategy, and information on potential harm.\textsuperscript{42} The precautionary principle is thus a principal scientific evaluation, which is meant to be the basis for taking proportionate measures.\textsuperscript{43}

In the context of NPBTs, innovation is often presented as a counter-balancing principle to precaution. Some stakeholders of NPBTs even talk about the innovation “principle.”\textsuperscript{44} However, contrary to the precautionary principle, innovation is not legally a principle and cannot be put on the same level as the precautionary principle.\textsuperscript{45}

The main discussion amongst stakeholders concentrates on how far the precautionary principle should apply. Numerous benefits of biotechnologies motivate innovation in plant breeding: “improving crop and vegetable resource efficiency, building climate change resilience, increasing fruit and vegetable storability and shelf life, increasing yields, improving plants' nutritional qualities and transforming food systems so that they need fewer inputs and have less of an environmental impact.”\textsuperscript{46} This makes some argue that the principle could “undermine itself in preventing innovative technologies that allow for precaution in the first place.”\textsuperscript{47} On the other hand, sceptics of NPBTs point to the lack of knowledge about those techniques, arguing that the precautionary principle should be applied in a way that NPTBs can be regulated under GMO rules.\textsuperscript{48}


\textsuperscript{44} KWS SAAT SE, op. cit., 1. The « innovation principle » was mentioned several times during the conference on Modern Biotechnologies in Agriculture.

\textsuperscript{45} R. STEINBRECHER, on behalf of the European Network of Scientists for Social and Environmental Responsibility (ENSSER), at the conference on « Modern Biotechnologies in Agriculture – Paving the way for responsible innovation », op. cit.


\textsuperscript{47} KWS SAAT SE, op. cit., 4.

Rather than opposing precaution and innovation, which legally do not have the same weight and do not automatically contradict each other, the proportionality principle seems to be an effective tool for ensuring that the precautionary principle is applied in a balanced way. The proportionality principle generally sets out a principle of adequacy of means to the desired goal.49

3. The legal status of NPBTs

It is of the utmost importance to clarify the legal status of NPBTs. In the absence of a common interpretation of the definition of GMOs, the temptation is strong for the Member States to interpret the Directive in their own way, even though the Commission advised them to forbid any uncontrolled release pending its decision on the question.50 For instance, the German Federal Office of Consumer Protection and Food Safety (BVL) has classified, in two decisions on 5 February 2015 and 1 June 2015 RTDS, oilseed rape as not falling into the scope of the German Gentechnikgesetz, the implementation act of the Directive. This decision was contradicted by the Commission in a letter of 26 June 2015.51 Similarly in 2015, the Swedish Board of Agriculture ruled that some plants developed through CRISPR-Cas gene editing did not fall within the definition of a GMO.52

49 Haut Conseil des Biotechnologies, Comité économique, éthique et social, op. cit., 36.
51 Prof. Dr. L. KRÄMER , Legal questions concerning new methods for changing the genetic conditions in plants, September 2015, available at https://www.testbiotech.org/sites/default/files/Kraemer_Legal%20questions_new%20methods_0.pdf
The French judge expressed this urgent call for legal certainty, asking the Court of Justice to clarify in a preliminary ruling whether a variety of herbicide-resistant rapeseed obtained through NPBTs should fulfil the requirements of the Directive for GMOs.53

After a brief overview of new plant breeding techniques, we will consider the French preliminary question. The question of who will finally define the legal status of the NPBTs also deserves attention.

3.1. Overview of NPBTs

An exhaustive scientific overview of the new techniques in agriculture is provided by the SAM Explanatory Note, cited above. We therefore restrict our analysis to the main characteristics of NPBTs.

As told by the SAM in the Explanatory Note for the Commission, there is a very diverse range of NPBTs. They should therefore not be considered as one homogeneous group of techniques, “some of which are substantially different from established transgenic approaches in their way of introducing traits to an organism. Some are a refinement of CBT and insert genetic material that is derived from a sexually compatible species, while some nevertheless are used in combination with ETGM”54. In addition, some NPBTs refer to tools, while others are processes and others, products. A categorisation is therefore not in accordance with

54 European Commission, Scientific Advice Mechanism (SAM), New Techniques in Agricultural Biotechnology, op. cit., 17 and 56.
However, NPBTs share a common trait: they are less time-consuming and less expensive than CBT.\textsuperscript{56}

NPBTs can be divided between genome editing techniques and techniques that do not edit the genome. Whereas the CBT lead to random mutation of many genes simultaneously and the ETGM randomly inserted new genes, new genome editing techniques can precisely modify or replace entire genes. This concerns both closely and distantly related organisms.\textsuperscript{57} It is achieved with the aid of the cell’s Deoxyribo-Nucleic Acid (DNA) recombination/repair system, activated with the use of a site-directed nuclease (SDN), exogenous nucleic acid molecule (oligonucleotide), or the combination of both.\textsuperscript{58} Those techniques include Oligonucleotide Directed Mutagenesis (ODM) which use oligonucleotides for the induction of targeted mutations in the genome, and the three applications of Site-Directed Nucleases which imply cutting the DNA at selected target sites (SDN1, SDN2 and SDN3).\textsuperscript{59}

Techniques that do not edit the genome are intended to temporarily change the gene expression patterns in order to adjust the traits of an organism. They include cisgenesis and intragenesis, agro-infiltration, epigenetic modification with RNA-dependent DNA methylation, reverse breeding, synthetic biology, and gene drives.\textsuperscript{60}

The new genome editing techniques ODM, SDN1 and SDN2 do not result in end products containing exogenous DNA and are comparable to the CBT of mutation breeding and sexual crosses, whereas SDN3, cisgenesis and intragenesis (which do not edit the genome)

\textsuperscript{55} Pr. J. BUJNIČKI, on behalf of the Scientific Advice Mechanism (SAM), at the conference organised by the European Commission on «Modern Biotechnologies in Agriculture – Paving the way for responsible innovation», \textit{op. cit.}
\textsuperscript{56} European Commission, Scientific Advice Mechanism (SAM), \textit{New Techniques in Agricultural Biotechnology, op. cit.}, 90.
\textsuperscript{57} European Commission, Scientific Advice Mechanism (SAM), \textit{New Techniques in Agricultural Biotechnology, op. cit.}, 25.
\textsuperscript{58} European Commission, Scientific Advice Mechanism (SAM), \textit{New Techniques in Agricultural Biotechnology, op. cit.}, 56.
\textsuperscript{59} European Commission, Scientific Advice Mechanism (SAM), \textit{New Techniques in Agricultural Biotechnology, op. cit.}, 58.
\textsuperscript{60} European Commission, Scientific Advice Mechanism (SAM), \textit{New Techniques in Agricultural Biotechnology, op. cit.}, 25.
intentionally produce end products containing exogenous nucleic acids.\textsuperscript{61} This important distinction between techniques which can be used to insert foreign DNA and those which cannot, was stressed by Pr. J. BUJNICKI on behalf of the Commission's Scientific Advice Mechanism (SAM), at the conference on Modern Biotechnologies in Agriculture, in Brussels 28\textsuperscript{th} September 2017.\textsuperscript{62}

\section*{3.2. The main friction points in the interpretation of the legislation}

The most significant legal issues concerning NPBTs are outlined here. These are highlights in current discussions, such as the conference on Modern Biotechnologies in Agriculture and in numerous reports, legal opinions, or press articles.

\subsection*{3.2.1. Process-oriented vs. Product-oriented definitions of GMO}

On behalf of the Commission, Mr. Borg answered in Parliament that the evaluation of NPBTs was complex because the definition of GMO in the EU legislation was referring both to the characteristics of the organism obtained and to the techniques used.\textsuperscript{63}

Some argue that the Directive is \textit{de lege lata} process-oriented and not result-oriented. This is reflected in the legal analysis commissioned by the German Federal Agency for Nature Conservation which insists that the Directive refers to techniques respectively methods, contrary to the regulatory approach of countries like the United States of America. In this

\textsuperscript{61} European Commission, Scientific Advice Mechanism (SAM), \textit{New Techniques in Agricultural Biotechnology}, \textit{op. cit.}, 89-90.

\textsuperscript{62} Pr. J. BUJNICKI, on behalf of the Scientific Advice Mechanism (SAM), at the conference organised by the European Commission on « Modern Biotechnologies in Agriculture – Paving the way for responsible innovation », \textit{op. cit.}

\textsuperscript{63} Answer given by Mr Borg on behalf of the Commission, Parliamentary questions, 17 October 2014, \textit{available at} http://www.europarl.europa.eu/sides/getAllAnswers.do?reference=E-2014-006525&language=EN
viewpoint, the lack of detectability that characterizes certain NPBTs such as ODM would not prevent the techniques from activating the regulation regime of the Directive.64

Others argue that the Directive is product-oriented, or at least that it should be amended in this way. Sorting plants by the function of their product means evaluating them according to the new trait and/or product rather than the technique used to create this new trait. This view is shared by a range of bodies, including the European Academies Science Advisory Council (EASAC)65, the Julius Kühn Institut (Germany)66, the UK Biotechnology and Biological Sciences Research Council (BBSRC)67, and the European Plant Science Organisation (EPSO).68 Those who adhere to this interpretation often claim that the Directive needs a new interpretation, because it could not consider the NPBTs at the time it was enacted. In fact, some preparatory documents show that the question did arise at the time of the drafting of Directive 2001/18. In particular, the question about site-directed mutagenesis arose as the possible exemption of certain "second generation GMOs" without insertion of foreign DNA.69

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64 Prof. Dr. Dr. T. M. SPRANGER, op. cit., 41 and the literature therein mentioned.
66 F. HARTUNG, J. SCHIEMANN, op. cit., 743.
3.2.2. The techniques which should be regarded as GMO-generating

According to most of the unions promoting small and medium-scale farmers\textsuperscript{70}, environmental organizations\textsuperscript{71}, and certain consumer associations\textsuperscript{72}, all NPBTs imply a direct and intentional intervention in genomes by means of new techniques and are thus a novelty (by way of being protected by a patent). Hence, the German Federal Agency for Nature Conservation considers it is crucial that “the modifications are carried out purposefully and lead to the incorporation of material into a host organism in which these nucleic acid molecules do not occur naturally.”\textsuperscript{73}

For these actors, Directive 2001/18 was specifically designed to frame the novelty of genetic modification techniques in terms of health and environmental risks. The completeness of the health and environmental assessments provided for in Directive 2001/18 and the mandatory nature of the traceability, coexistence and information management systems it offers are, in their opinion, the best guarantees against uncertainties and risks associated with the new varieties produced by NPBTs.

Those who support an approach based on the analysis of the biological characteristics of the products of NPBTs argue that only the latter must allow for the choice of the relevant regulatory framework. The French Haut Conseil des Biotechnologies enumerates the positions

\textsuperscript{70} See for instance the intervention of Guy Kastler on behalf of Via Campesina, at the conference on « Modern Biotechnologies in Agriculture – Paving the way for responsible innovation », \textit{op. cit.}


\textsuperscript{73} See for instance the intervention of C. UDSEN on behalf of the Danish Consumer Council, at the conference on « Modern Biotechnologies in Agriculture – Paving the way for responsible innovation », \textit{op. cit.}

\textsuperscript{73} Prof. Dr. Dr. T. M. SPRANGER, \textit{op. cit.}, 46.
of different agencies and national authorities in this respect. For the British Advisory Committee on Releases to the Environment (ACRE), only cisgenesis and intragenesis are to be considered GMOs. The Dutch Commission on Genetic Modification (COGEM) considers cisogenesis out of the scope of GMOs, arguing that it only involves same-species or cross-compatible species. The Swedish Board of Agriculture declared that the CRISPR/Cas9 technique is out of the scope of GMOs, as the German Zentrale Kommission für die Biologische Sicherheit (ZKBS) did with Zinc finger nuclease (ZFN) and ODM. As for the Environment Agency Austria, it stresses the necessity of a case-specific risk assessment.

The New Techniques Working Group, set up by the European Commission and composed by nationally appointed scientists, considers organisms developed through cisgenesis and intragenesis as falling under the Directive, but did not find a common position on the legal status of most of the other NPBTs. The European Food Safety Authority (EFSA) “concluded that the existing guidelines for risk assessment applicable to GM plants were also appropriate for cisgenic and intragenic plants, and for the ZFN-3 technique”.

The two main approaches described above, which are currently supported in public debates, set important limits on the specificities of NPBTs. Therefore, it could be desirable, as suggested by the French Haut Conseil des Biotechnologies, to create an intermediary framework for NPBTs. The Council notices that neither the national Catalog nor the Directive appear to be entirely satisfactory frameworks to respond to the diversity of NPBTs, their specificities and to jointly respect the principles of precaution and proportionality. The various socio-economic impacts of NPBTs and the uncertainties that characterize them make

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74 Haut Conseil des Biotechnologies, Comité économique, éthique et social, op. cit., 34.
It is necessary to evaluate the introduction or the modification, via a NPBT, of one (or several) trait(s) in a given species. This evaluation would be carried out on a case by case basis, include the analysis of the socio-economic impacts and the ethical stakes, use a benefits / risks approach, and take into consideration the new purpose(s) of the variety.\textsuperscript{78}

In a similar line, the Scientific Advisory Mechanism of the Commission promotes a case-by-case basis assessment of safety, based on several criteria: specific mutations, unintended effects, species in which the mutation is introduced, environment in which the end product is used, agricultural practice applied, planned use and exposure.\textsuperscript{79}

3.2.3. The degree of risk

Some argue that NPBTs merely accelerate natural processes and insert genetic information in a more precise way, which reduces the probability of unintended effects in comparison with CBT.\textsuperscript{80} They pretend that it is only about an acceleration of natural processes. Others point out the fact that those modifications can be multiplied indefinitely, that their consequences are not known yet and that the slow speed of nature is a protection and limitation of the danger.\textsuperscript{81}

The question raises whether the scientific conclusions about the risks of NPBTs should precede the regulation. However, there is obviously an important pressure coming from the industry concerned with the new techniques. The scientists endorse a lot of pressure and obviously lack the tools to cope with the difficulty of evaluating a product \textit{ex ante}. They claim

\textsuperscript{78} Haut Conseil des Biotechnologies, Comité économique, éthique et social, \textit{op. cit.}, 36 sq, 55-56. This opinion summarises the main legal opinions and takes a step back due to its recent character. It is meant to influence the future French position about NPBTs and will of course also have an influence on the coming European decision on the matter.

\textsuperscript{79} Pr. J. BUJNICKI, at the conference on « Modern Biotechnologies in Agriculture – Paving the way for responsible innovation », \textit{op. cit.}

\textsuperscript{80} NBT Platform, Legal Briefing Paper, \textit{op. cit.}; A. VAN TUNEN, on behalf of Keygene, at the conference on « Modern Biotechnologies in Agriculture – Paving the way for responsible innovation », \textit{op. cit.}

\textsuperscript{81} C. UDSEN, on behalf of the Danish Consumer Council, at the conference on « Modern Biotechnologies in Agriculture – Paving the way for responsible innovation », \textit{op. cit.}
not to have sufficient cognitive and human resources. It could be ineffective to regulate without sufficient knowledge about the risks. Indeed, the purpose of regulation is to prevent risks.

3.2.4. Consumers’ information and protection

Most actors agree on the necessity of transparency for consumers, who must be aware of the techniques that are used and know what consequences their use implies for alimentation. Consumers’ information presupposes a labelling system which indicates the technique used to modify the genes(s).

Regulation is likewise a *sine qua non* element for biotechnology and for social acceptance. People expect regulation to be a guarantee for safety, and indeed, the text of Article 1 of the Directive reveals a general acceptance of the preponderance of safety as a main objective.

“In accordance with the precautionary principle, the objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment.”

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82 C. NOIVILLE, on behalf of the French High Council of Biotechnologies, at the conference on « Modern Biotechnologies in Agriculture – Paving the way for responsible innovation », *op. cit.*
83 T. BABUSCIO, on behalf of COCERAL, at the conference on « Modern Biotechnologies in Agriculture – Paving the way for responsible innovation », *op. cit.*
84 A. DELAHAYE, farmer and EPP member in the European Parliament, at the conference on « Modern Biotechnologies in Agriculture – Paving the way for responsible innovation », *op. cit.*
85 H. DELGADO ROSA, Director for natural capital in DG Environment, European Commission, at the conference on « Modern Biotechnologies in Agriculture – Paving the way for responsible innovation », *op. cit.*
86 J. GUTELAND, S&D member of the European Parliament, at the conference on « Modern Biotechnologies in Agriculture – Paving the way for responsible innovation », *op. cit.*
3.2.5. Which regulation should apply?

Almost all actors agree on the fact that regulation is needed, especially concerning genome editing technologies which have great promise. As to which regime should apply, opinions differ.

The French Haut Conseil des Biotechnologies has listed four possible regimes that could apply, exclusively or simultaneously, to NPBT:

- The national regime, which regulates conventional breeding techniques, ensures that once the new plant variety has been approved by the national authority, it can be further marketed in all Member States.
- The Directive regime, together with its requirements for GMOs, has been described supra.
- The Novel Food Regulation organises an assessment, also at European level, of foods or ingredients placed on the market after 15 May 1997 which have new characteristics but are not GMOs. This assessment concerns the possible toxicity of the product and its nutritional composition.
- The Protocol of Cartagena requires an agreement procedure for Living Modified Organisms (LMOs), the establishment of mechanisms for the collection and exchange of information, support for state-level implementation of legislation to ensure safe movement of LMOs and verification of compliance by the latter. On European level, it is implemented by Regulation (EC) No 1946/2003 of the European Parliament and

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87 R. STEINBRECHER, on behalf of the European Network of Scientists for Social and Environmental Responsibility (ENSSER), at the conference on « Modern Biotechnologies in Agriculture – Paving the way for responsible innovation », op. cit.
88 Haut Conseil des Biotechnologies, Comité économique, éthique et social, op. cit., 19-23.
90 Cartagena Protocol on Biosafety to the Convention on biological diversity, op. cit.
of the Council of 15 July 2003 on transboundary movements of genetically modified organisms.\(^91\)

### 3.2.6. The industrial property of NPBT products

The issue of industrial property of products derived from NPBTs arose in several reports, as well as in the September 2017 conference.\(^92\) It raises several questions that remain unresolved. In order to be able to patent plant crossings, precise and reliable detection and identification of the products of new techniques must be possible. However, the genetic information of a plant issued from conventional breeding techniques could possibly be the same as the genetic information of a plant issued from NPBTs, since some NPBTs imitate, in a more efficient way, what nature does.\(^93\) A major problem with NPBTs consists of the difficulty and sometimes the impossibility of identifying the source of the change in the product.\(^94\) Consequently, there is uncertainty on how to make sure that crossings that are completely natural will not be unfairly patented, because it is impossible to distinguish natural mutations from induced mutations.\(^95\)

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\(^{92}\) i.a. Haut Conseil des Biotechnologies, Comité économique, éthique et social, op. cit., 43-45; G. KASTLER, on behalf of Via Campesina, and J. HUITEMA, VVD/ALDE member of the European Parliament and farmer, at the conference on « Modern Biotechnologies in Agriculture – Paving the way for responsible innovation », op. cit.

\(^{93}\) G. KASTLER, on behalf of Via Campesina, at the conference on « Modern Biotechnologies in Agriculture – Paving the way for responsible innovation », op. cit.

\(^{94}\) Pr. J. BUJNICKI, at the conference on « Modern Biotechnologies in Agriculture – Paving the way for responsible innovation », op. cit.

\(^{95}\) Haut Conseil des Biotechnologies, Comité économique, éthique et social, op. cit., 24.
This is a problem of coexistence between conventional and new breeding techniques. The detection and identification of the products of new techniques is important to guarantee the freedom of choice of those who do not want to use NPBTs.96

3.3. Who decides?

To the question whether NPBTs should be included in the scope of GMOs, Commissioner Andriukaitis told the European Parliament:

“The decision to include or exclude a technique from the scope of Directives 2001/18/EC and 2009/41/EC depends only on the interpretation of the definition of Genetically Modified Organisms/Genetically Modified Microorganisms and of the conditions for exemption provided for in the two Directives.”97

Consequently, an essential question is who is legally entitled to provide the interpretation of GMOs.

3.3.1. The European Court of justice and the interpretation of EU law

Article 267 TFEU entitles the Court of Justice of the European Union to give preliminary rulings concerning the interpretation of the Treaties. As the commissioners often repeated in the context of NPBTs, it is the sole prerogative of the Court to provide a binding

96 J. PLAGGE, on behalf of IFOAM EU group, at the conference on « Modern Biotechnologies in Agriculture – Paving the way for responsible innovation », op. cit.
interpretation of EU law. Next, a brief analysis of the questions asked by the French Council of State to the CJEU will be given in order to assess what kind of answer the Court might provide.

The preliminary question arose when some associations and workers’ unions challenged the legality of article D.531-2 of the French Environment Code, which states that organisms which originated from mutagenesis are out of the scope of GMO regulations. The Council of State, confronted with a serious difficulty of interpreting EU law, has sent four questions to the CJEU.

First, the Council of State asks whether mutagenized organisms (in particular those obtained by the new techniques of site-specific mutagenesis such as, for example, ODM or SDN1, which uses different types of proteins (ZFN, TALEN, Cas9) are GMOs subject to the rules laid down by Directive 2001/18, or whether it should be considered that these organisms obtained by mutagenesis, or only some of them (those obtained by conventional mutagenesis methods existing prior to the adoption of the Directive) are exempted from the precautionary impact assessment and traceability measures provided for in this Directive. It is consequently for the Court to determine whether the NPBT-mutagenesis should receive a different regime from that of conventional mutagenesis.

Second, the Council of State asks whether the varieties obtained by mutagenesis are "genetically modified varieties" subject to the rules laid down in the Directive 2002/53/EC.

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relating to the inscription of genetically modified varieties in the common catalog of agricultural plant species.

In the event that the Court excludes the organisms obtained by mutagenesis from the scope of Directive 2001/18, the subsidiary question is whether Member States are prohibited from subjecting these mutagenized organisms to all or part of the obligations laid down by the Directive (or any other obligation) or if the States have, on the contrary, a margin of discretion in defining the system which may be applied to mutagenized organisms. The question of the flexibility that the Member States could have regarding the classification of those organisms as GMOs is even more important, given that the margin of discretion at stake might apply to NPBTs other than mutagenesis.

In addition, in the event that the Court excludes the organisms obtained by mutagenesis from the obligations of taking precautionary impact assessment and traceability measures under the Directive, the Council of State would challenge the move’s validity regarding the precautionary principle laid down in Article 191 (2) TFEU. Indeed, the precautionary principle, as part of the primary law of the European Union, takes precedence over the Directive, which is part of secondary law. The Court is therefore asked to estimate whether there is a conflict of laws resulting from the evolution of what is considered a mutagenized organism.

Even if the scope of the Court’s answer would provide for an essential clarification of the Member States’ margin of appreciation and of the precautionary principle relating to NPBTs, it could not simply be generalised to the other new techniques. The impact of a negative
ruling on genetic engineering in general remains unclear. Therefore, there will, in any case, still be space for political decision.  

3.3.2. Which role for the European Commission?

On the demand of the Commission, the SAM High Level Group of Scientific Advisors presented an Explanatory Note on 28 April 2017 on New Techniques in Agricultural Biotechnology. The Note is intended to give guidance to the national authorities and offers a scientific overview of the new techniques in agriculture, rather than a legal analysis of those techniques. Indeed, contrary to what was expected by numerous stakeholders as well as the European Parliament, the SAM does not take a position on the legal status of NPBTs. In accordance with the scoping paper, the SAM insists on the fact that “the Note is explanatory and so does not take a position or make recommendations to policy makers with respect to the techniques under discussion.”

However, one must not underestimate the impact of a scientific advice of this size. To assess whether NPBTs fall under the Directive or not, the European judge needs sufficient scientific understanding of the techniques. Besides, a ruling of the ECJ does not prevent the European legislator from amending the legislation in the course of political decisions. Therefore, the
final word encompassing all the existing and future new techniques will likely be given to the Commission, together with the European Parliament. The Court ruling will probably only be received as an interpretation of EU law limited in time, pending a political arbitration.  

The remarks and conclusions stemming from the conference on Modern Biotechnologies in Agriculture, which took recently place under auspices of the Commission, will certainly influence the court’s judgement and future legislation.

Conclusion

It is evident from this analysis that the legal issues concerning NPBTs are numerous and subject to different interpretations of the existing regulatory framework of modified organisms. This could explain why there is no clear answer yet for the regulatory regime of NPBTs on European level.

The NPBTs represent a turning point in biotechnology, which makes it necessary to rethink the legal framework for plant breeding. Even though the gene modifications they operate in some cases are confined to the reproduction of mutations that happen naturally, the artificial aspect of human intervention in plant breeding is to be seriously considered. It represents a massive, impending issue that would be dangerous not to take into account if the legislation is kept as it is. Indeed, given the divergent interpretations of the definition of GMOs, there is a

106 C. NOIVILLE, on behalf of the French High Council of Biotechnologies, at the conference on « Modern Biotechnologies in Agriculture – Paving the way for responsible innovation », op. cit.
risk that Member States might implement EU law in contradicting ways. This would produce
dangerous imbalances within the European market.

Whatever the answer of the CJEU regarding the preliminary question, the political pressure
for amending the current regulation is such that the European legislator needs to react. The
new legal framework will have to consider all interests at stake: the protection of consumers’
health, the freedom of organic and conventional farmers not to use the new techniques and not
to be impacted negatively by NPBTs products, the accession of small and medium enterprises
to the technology, etc. According to the precautionary principle, a serious consideration of
those interests implies that regulation should not precede sufficient scientific information. The
stakes at issue – human health and environmental protection – are too serious to take the
liberty of releasing NPBTs products without a prior case-by-case evaluation. In addition, the
fact that it can be impossible to distinguish between induced or natural mutations in a product
is problematic for industrial property issues.

The legal assessment of NPBTs, in all their diversity, represents generally a complex
evaluation which the European legislator will only be able to do effectively if he balances
precaution with the proportionality principle.
Annex 1: NBT analysis under Directive 2001/18/EC