

PBI Advocacy Brief for Euroseeds Members (07-05-2021)

Introduction

On July 25th 2018 the Court of Justice of the European Union (ECJ) rendered its long awaited Judgment on the scope of Directive 2001/18 on the deliberate release into the environment of genetically modified organisms (GMO Directive). The ECJ concluded that only plants resulting from conventional, random mutagenesis breeding methods (such as e.g. radiation or chemical mutagenesis) qualify for the exemption laid down in Annex IB of the GMO Directive, even if plants from newer, targeted mutagenesis breeding methods are genetically identical.

In November 2019, the Council of the European Union requested the EU-Commission to submit a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law. This Commission study was published on 29 April 2021.

The Commission repeatedly has underlined that the views of Member States and the European Parliament will be decisive in determining possible ways forward. It is therefore our specific goal to build broad coalitions with Euroseeds members and other stakeholders to maximise outreach and advocacy to member states and the European Parliament, specifically in relation to the Parliaments report on the Farm to Fork Strategy and possible Council Conclusions still under the Portuguese Presidency end of June 2021.

Next Steps and Follow-up as to NGT Study and Commission Letter to Portuguese Council Presidency:

- Action needs to be taken in the field of NGTs, to address the current challenges that were at the origin of the Council request, and are further confirmed by the study.
- The Commission intends to initiate a policy action **on plants derived from targeted mutagenesis and cisgenesis** which will entail carrying out an impact assessment. The action will
 - aim at a proportionate regulatory oversight for the relevant plant products by adapting the risk assessment and authorisation procedures and the labelling/traceability requirements.
 - maintain the objectives of the current legislation as regards a high level of protection of human and animal health and the environment.
 - be fully aligned with the objectives of the European Green Deal and the Farm to Fork Strategy, including the development of a proposal for a legislative framework for sustainable food systems.
 - should allow reaping benefits from innovation by enabling safe NGT products to contribute to the sustainability and resilience of the EU agri-food system.
- The impact assessment will look into the design of a proposal that combines high levels of safety with clear added value to society and the environment.

Process:

- The Commission will engage in a wide-ranging communication effort to share its results and to discuss its outcome with the Council (26-27 May and end of June), the European Parliament and stakeholders in dedicated meetings (19 May) to gather views on the follow-up.
- The Commission expects to publish an inception impact assessment in the third quarter of 2021, building on the study and the exchanges with the co-legislators and stakeholders.
- The impact assessment will follow and will include further consultation of all interested parties.

Our policy request: A differentiated legal proposal for plants resulting from NGTs

New Genomic Techniques (NGTs*¹) applications are versatile and can be used in the development of a wide range of different products. One type of products are GMOs (e.g., using genome editing tools to introduce a transgene). However, other types of NGT derived plants are similar to those that could occur in nature or produced by conventional breeding methods, e.g. by induced random mutagenesis.

Based on the Euroseeds Position on Plant Breeding Innovation (PBI) which was adopted in 2018, we ask for an amendment of the Directive 2001/18/EC to exclude those plants & products generated using NGTs which are indistinguishable from conventionally bred plants as to the criteria of the [Euroseeds PBI position](#).

With this, the European Seed Sector takes a differentiated approach not asking to exclude NGTs from GMO regulations in general, but only those applications of NGTs that result in conventional-like plants. Other applications that result in transgenic products (GMO) would still be covered by the GMO legislation.

This differentiated regulatory approach will require a targeted amendment of the GMO Directive 2001/18 that excludes conventional-like NGT-plants from its definition and adapts Annex IB accordingly. It will align the EU's policy and rules with those established and being developed in the rest of the world; it will also create legal certainty for EU operators by avoiding that Member States adopt individual national rules for products resulting from conventional, random mutagenesis.

¹ Definition as to the EU-Commission: "New Genomic Techniques are techniques capable to alter the genetic material of an organism that have emerged or have been mostly developed over the past two decades." This includes the so-called New Breeding Techniques like genome editing (Crispr)

Such an amendment will reflect the current scientific knowledge and technological progress since the original drafting of the legislation and will be proportionate to risk.

Table of Content:

Verification of the regulatory Status of NGT products.....	4
Transparency/Freedom of Choice to Customers	4
Access to relevant IP	5
Detection and Identification of conventional like NGT plants.....	6
Safety of conventional-like NGT plants	8
Responsibility of plant breeders	8
Unintended Effects/Off-targets.....	9
The EU Farm to Fork Strategy and benefits of plant breeding innovation	11
Communication	13
The International Regulatory Landscape and Impacts on Trade.....	13
Commission Study on NGTs.....	15
Legal Background	15

The following Chapters of our Advocacy Brief include several main messages from the NGT study according to relevant policy aspects that are publicly and critically discussed in the context of NGTs. They also include main outcomes of the NGT study as well as agreed Euroseeds positions and background information.

Verification of the regulatory Status of NGT products

NGT Study: The study mentions that a number of non-EU countries require some product-based exemptions to apply only if the applicants demonstrate that certain criteria are fulfilled, e.g. the absence of foreign material in the final product. In some cases, the scope of the exemption is limited to specific organisms, e.g. plants.

Euroseeds Position:

As to our policy request above, we advocate for a differentiated approach not asking to exclude NGTs from GMO regulations in general, but only those applications of NGTs that result in conventional like products. Other applications that result in transgenic products (GMO) would still be covered by the GMO legislation. In order to evaluate and assess the regulatory status of a plant resulting from NGTs (GM/non-GM), a verification process might be established.

- Due to the long-term investments and the duration of variety development and in order to gain legal clarity, Euroseeds supports a process that allows for an early exchange with regulators on the legal status (GM/non-GM) of an NGT derived variety under development.
- Euroseeds also proposes a practical verification/ validation of that status as part of the variety registration process. Such validation should ideally be the responsibility of the variety registration office, based on a clear set of defined criteria, strict timelines and mutual recognition of decisions between Member States. Member States/the EU may organise this also by involving the relevant GM authorities, i.e. variety registration office and GM authority.

Transparency/Freedom of Choice to Customers

NGT Study: In particular, the organic and GM-free premium market sector reported that they might face threats from coexistence with new genomic techniques and, therefore, any consideration of NGT products outside the scope of the current GMO regulatory framework would deal a severe blow to their value chain and risk damage consumer trust in their sector. Stakeholders have opposing views, both on the need to continue labelling NGT products as GMOs and on the effectiveness of such labelling in informing consumers.

Member States emphasized that there can be no valid traceability without a valid analytical strategy and that no enforcement is possible without the necessary legal certainty and evidence that would stand up in court. Other traceability systems mentioned (paper trail, databases) were all subject to various limitations.

Euroseeds Position:

The European seed sector strongly supports and respects farmers' freedom of choice and interest in information. We are of the opinion that any transparency requirements regarding compliance control and customer choice can be fulfilled in a predictable, reliable and harmonized way without putting respective conventional-like NGT plant varieties under the strict and cumbersome GMO labelling obligations.

- To practically support and facilitate informed choice, Euroseeds is committed to provide information on all varieties obtained with NGTs and available on the national variety lists and the European Common Catalogues.
- This commitment includes varieties that have been developed with classical breeding methods but where the pedigree includes at least one variety that has been developed with NGTs.
- Euroseeds is of the opinion that such information shall be publicly accessible without any cost to customers.
- Such information will allow full freedom of choice to those farmers and growers and value chains that do not wish to or, based on private standards, do not allow the use of NGTs in their production.
- Euroseeds points out that such information can only be supplied to the best knowledge of each individual company and based on the information shared by all companies (Disclaimer).

Access to relevant IP and the role of patents on breeding innovation

NGT Study: The study acknowledges the benefits of patents and licensing in promoting innovation and the development of new genomic techniques and their products. However, these same aspects (together with high business concentration) can also act as a barrier to market entry for SMEs and can limit access to new technologies and to genetic material, e.g. for breeders and farmers. Further investigations regarding the effect of IP on different business models are announced.

Euroseeds Position:

Euroseeds confirms its [position on Intellectual Property Rights](#) in relation to plants and seeds. Euroseeds firmly reiterates its principal position that broad access to IP protected breeding technologies and resulting commercially available plant genetic material is an important precondition and objective of the sector to bring innovation to all markets. Such access shall be granted under fair, reasonable and non-discriminatory (FRAND) conditions in the most practical and effective manner.

- Euroseeds acknowledges uncertainties expressed by breeders as regards accessibility and conditions of access to key technologies and commercially available plant varieties falling under the scope of patents in relation to latest plant breeding methods in general and gene editing in particular. Euroseeds also acknowledges concerns expressed by other stakeholders in relation to the impact of patents on latest breeding methods on the structure of the plant breeding sector and on the diversity of its product development.
- However, patent protection also offers opportunities and benefits for the innovators of NGTs. Patents enable patent holders to recoup costs, which are - in case of GMO regulation – even higher. Patents disclose information on the patented technology which can also provide benefits to others.

- Before the background of the Euroseeds position on IP rights, Euroseeds promotes and actively supports the development of broadly agreed mechanisms and rules to enable access to patent protected breeding technologies and resulting commercially available plant genetic material via industry IP licensing platforms.
- Euroseeds specifically points to the International Licensing Platform Vegetable in relation to plant traits that has already been agreed and the industry's on-going discussion on a similar approach for agricultural species which are supported by Euroseeds.
- **GMO regulation and patentability** are two different matters and the two pieces of legislation also seek different purposes (The purpose of GM regulation is to protect human health and the environment whereas the patent system is designed to stimulate innovation in all fields of technology). It is well possible that a technique does not qualify for being regulated under the Directive 2001/18 but it can still meet the patentability criteria (novelty, inventive step, industrial applicability and enabling disclosure) and thus be eligible for patent protection.
- **Farm saved Seeds (FSS):** EU Directive on the protection of biotechnological inventions includes in its Articles a FSS exemption. The extent and the conditions of this exemption are defined by referring to Article 14 of the CPVR Regulation. Therefore, the FSS exemption that applies under patent law in all EU Member States is exactly the same as the FSS exemption under the Community plant variety rights system.
- **Transparency about patented varieties:** The lack of transparency in the field of patents was the driver for Euroseeds to develop [PINTO](#) (Patent Information and Transparency On-line) in 2013. PINTO is a publicly available database where patent holders and licensees provide information about the varieties marketed in the European Economic Area which may fall under the scope of patents. All Euroseeds members support PINTO and the transparency it creates.

Further Information on NGTs and IP: Questions and Answers prepared by Euroseeds CIPR: <https://intranet.euroseeds.eu/f/67678>

Detection and Identification of conventional like NGT plants

The procedures for the validation of detection methods as part of the market authorisation application process for NGT plant products are currently in principle the same as for the current conventional GMOs.

NGT Study: Under the current EU regulatory system, there are implementation and enforcement challenges, in particular related to the detection and differentiation of NGT products that do not contain any foreign genetic material. This is a problem for enforcement authorities, operators and applicants.

The lack of reliable detection methods is also a concern for stakeholders, as it affects agri-food operators' ability to verify compliance with the EU legislative framework. This has potential implications for legal liability, compliance costs, the risk of fraud and consumer trust.

EFSA concluded that mutations introduced by genome editing (SDN-1, SDN-2) are of the same type as those obtained with conventional breeding techniques. As things stand, certain genome-edited products have no unique features that could be the focus of specific methods. There is a need to explore ways of addressing this basic problem.

Euroseeds Position:

For market control, considering the current knowledge and state of the art of GMO testing, it is highly unlikely for enforcement laboratories to be able to detect the presence of unauthorised conventional-like NGT derived plant products in food or feed entering the EU-market without prior information on the altered DNA sequences. Also, current detection methods cannot distinguish how the genetic change in a plant occurred (NGT or conventional breeding) and with that if a plant (product) in fact is a regulated GMO.

These detection and identification challenges are of major concern for EU member states who are responsible for the enforcement of the GMO regulation and for market control.

- **“Some NGT applications result in GMO plants while other applications deliver plants equivalent to and indistinguishable from conventionally bred plants”** - NGT applications are versatile and can be used in the development of a wide range of products. One type of products are GMOs (e.g., using genome editing tools to introduce a transgene). However, other types of NGT derived plants are similar to those that could occur in nature or produced by conventional breeding methods, including induced random mutagenesis.
- **“Most NGT plants do not have specific genetic signatures in the same fashion as transgenic events”** - NGT applications that result in plants that are similar or indistinguishable to that which could occur in nature or produced by conventional breeding methods do not result in “events” with a specific genetic signature in the same manner as GMOs. Other applications of NGTs do not result in the insertion of DNA sequences in the final product, rather simply influence the outcome from the crossing of two breeding lines or varieties.
- **“With prior knowledge of the specific genetic change and a reference genome for comparison, sequence modifications are detectable. However, current detection methods cannot distinguish how the genetic change occurred”** - While not producing a unique genetic sequence combination in the same manner as GMOs, it is technically feasible to detect small specific DNA sequence change resulting from NGTs like genome editing in a sample derived from identical source material (seed or grain). However, without additional information, it is not possible to determine whether a specific sequence change is a result of spontaneous or induced mutation, breeding or genome editing. DNA sequence changes from different mutagenesis methods can be similar or even identical. Consequently, the detection of a particular DNA sequence alone may not uniquely identify a specific technology, product, or developer in the same way a GMO event specific detection does. Detection and identification challenges are amplified when samples subject to analysis come from multiple sources and are heterogenous, rather than from a single plant or seed.

The following documents contain more background information about the challenges to detect and distinguish conventional-like plants resulting from genome editing specifically.

[CONCEPTS AROUND DETECTION METHODS AND GENOMEEDITED CROPS](#) (Prepared by: CLI Plant Breeding Innovation Project Team and ISF Working Group Plant Breeding Innovation)

[FAQ'S ON DETECTION AND UNIQUE IDENTIFICATION](#) (Prepared by: CLI Plant Breeding Innovation Project Team and ISF Working Group Plant Breeding Innovation)

The European Network of GMO Detection Laboratories (ENGL) published also a [Report on Detection challenges with a specific view on the EU regulatory Detection Requirements](#).

Safety of conventional-like NGT plants

NGT Study: NGTs constitute a diverse group of techniques, each of which can be used in various ways to achieve different results and products. Therefore, safety considerations depend on the technique, how it is used and the characteristics of the resulting product and cannot be made on all techniques as a whole. A purely safety-based risk assessment may not be enough to promote sustainability and contribute to the objectives of the European Green Deal and in particular the 'farm to fork' and biodiversity strategies; benefits contributing to sustainability would also need to be evaluated², so an appropriate mechanism to accompany risk assessment may be required.

Euroseeds Position:

Many NGT products could be obtained also by using conventional breeding techniques albeit with less precision, less efficiency and, in a much more time-consuming way. Where the resulting geno- and phenotype is comparable to results from conventional breeding, the risk on human/animal health and on environment is also similar to conventionally-bred plants. This is why these plants would not require a specific pre-market risk assessment.

Responsibility of plant breeders

All partners of the agricultural production chain take their individual responsibilities to contribute to an environmentally safe production of safe feed & food of high quality. Responsibility for product safety is always linked to the specific product developed for marketing. Breeders may thus be considered responsible for varieties with "safe" genetics intended for feed & food production. A comprehensive regulatory framework for EU-breeders, seed producers, processors etc. is already in place

Public and private breeders develop varieties and these varieties are propagated through seeds. Today around 45.000³ varieties are available for farmers in the EU (around 3.500 new varieties each year) and the seeds of these varieties are mostly used to produce feed & food or food components.

² Plant breeding already proofed to contribute to sustainability (http://www.plantetp.org/system/files/publications/files/hffa_research_paper_plant_breeding_eu.pdf) the new plant breeding study from Steffen Noleppa will confirm this. The evaluation of sustainability must be based on sound scientific criteria and not lead to a politicized product approval system.

³ <https://www.gnis.fr/en/plant-variety-databases/>

Plant breeding is often said to be a process not (only) of selection, but (foremost) of elimination. Any off-types, unstable lines, or lines showing characteristics such as significant differences in nutrient content, detrimental responses to environmental stresses, diseases, or the presence of other undesirable traits are discarded as soon as they are identified. The generation of genome-wide variation is the basis of plant breeding whether by crossing or induced mutation (e.g. with NGTs). This is addressed within well-established practices for crop improvement and by breeders best practices which document relevant phenotypic characteristics.

The environment in which a crop is grown often plays a significant role in affecting plant characteristics, such as the levels of certain anti-nutrients, overall yield and flowering. Therefore, the trialling process occurs over multiple geographies and multiple years in order to observe that potential variability, keeping only those varieties that will meet consumer and grower expectations and show reliable performance under different environmental conditions.

Independent of the breeding technology used, potential commercial varieties are tested for:

- Geographic and agricultural/horticultural production system adaptation
- Performance characteristics, relative to existing commercial varieties
- Processing characteristics appropriate for that crop, such as milling for wheat, sugar yield for sugar beets, oil quality for canola and sunflower or storage characteristics for fruits and vegetables
- End-user characteristics (as appropriate for that crop), such as protein content or bread-making characteristics for wheat, oil quality for oilseed rape or flavour characteristics for vegetables and fruits
- Regardless of the tools used for breeding, the goal is always the same: To first create genetic diversity in a population of plants and through multiple years of field trials and testing to develop new plant varieties that reliably produce safe food with desired characteristics.

The comprehensive regulatory framework for EU-breeders, seed producers, processors et.al. which is already in place, includes a.o.

- Protocols for DUS and VCU testing
- Common catalogue of varieties of agricultural plant species and marketing of vegetable seed 2002/53-57:
- Seed Marketing Directives (...)
- Plant Health Regulation (EU) 2016/2031
- Seed Treatment Regulation (EC) No 1107/2009
- General Environmental Liability 2004/35/CE
- General Food Law
- Novel Food Regulation (it needs to be noted that a novel food developed from an NGT derived plant could be captured by the EU novel food regulation if it would not result in a GMO)

Unintended Effects/Off-targets

NGT Study: *In terms of specificity, there is general agreement among Member States and EFSA that SDN technology is a substantial improvement over random genetic modifications and that several approaches have been developed to improve method specificity. Nonetheless, the Member State*

opinions put forward different considerations on off-target modifications, e.g. concerning their type, extent, effect and need for assessment. EFSA noted that recently published experimental evidence confirmed that the off-target mutations potentially induced by NGTs are of the same type as, and fewer than, mutations in conventional breeding, including spontaneous mutations and those produced by physical and chemical mutagenesis.

Euroseeds Position:

Unintended effects are, as the term suggests, effects other than those which are desired, resulting from the employment of a technique, like an NGT. Unintended effects can be caused by unintended mutations, which in conventional breeding result from spontaneous or classical induced mutations (irradiation, chemicals) and can be numerous, occur at random locations, and not possible to control. With genome editing, off-target mutations can also occur, however they are much less numerous, and can be mitigated with the proper design of genome editing reagents, which are continuously being improved.

- NGTs may be accompanied by few unintended effects. However, in general NGTs, like genome editing show a much lower number or complete lack of unintended mutations as compared to organisms obtained via conventional breeding techniques, e.g. random mutagenesis by chemicals or radiation.
- In addition, backcrossing following the transformation process can be used to remove these potential off-target mutations from the final product.
- The EFSA GMO panel concluded that the analysis of potential off-targets would be of very limited value for the risk assessment.

More information on unintended/off-target Effects:

ISF/CLI Paper on Genome Editing and off-target effects: <https://intranet.euroseeds.eu/f/67628>

ISF/CLI paper on whole genome sequencing and off-target identification:
<https://intranet.euroseeds.eu/f/67627>

SAM Note, Explanatory Note, New techniques in agricultural biotechnology, 2017
<https://publications.europa.eu/en/publication-detail/-/publication/103eb49f-4047-11e7-a9b0-01aa75ed71a1/language-en/format-PDF/source-94584105>

Applicability of the EFSA Opinion on site-directed nucleasestype 3 for the safety assessment of plants developed using site-directed nucleases type 1 and 2 and oligonucleotide-directed mutagenesis: <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2020.6299>

The EU Farm to Fork Strategy and benefits of plant breeding innovation

NGT Study: Several of the plant products obtained from NGTs have the potential to contribute to the objectives of the EU's Green Deal and in particular to the 'farm to fork' and biodiversity strategies and the United Nations' sustainable development goals (SDGs) for a more resilient and sustainable agri-food system.

Euroseeds Position:

Seeds are the key input for farmers in Europe and worldwide. It is estimated that more than 50%*⁴ of all productivity gains are due to improved varieties resulting from sophisticated plant breeding. Euroseeds is convinced that in order to be successful, an EU Farm to Fork Strategy must place plant breeding, related scientific advances and technological innovations at the very core of its considerations and consequent supportive measures.

- For example, new plant varieties increase and secure crop yields while reducing the use of plant protection products, fertilizers and other inputs; improve plant health and qualities; prolong the shelf life of fresh produce thereby supporting healthier diets and addressing food waste. In this way, plant breeding is contributing to a sustainable intensification of agriculture to protect and preserve scarce natural resources.

Why Plant Breeding Innovation and Seeds matter....



Examples & Resources:

The Euroseeds Survey on New Breeding Techniques

The results of a survey among 62 private plant breeding companies conducted by Euroseeds confirms the enormous interest of companies in using new breeding techniques (NBTs) for a wide range of crop species and traits and the negative impact of the current regulatory situation in the EU on companies' decisions for investments in NBT-related R&D activities for the EU market and beyond.

Main Conclusions:

⁴ http://www.plantetp.org/system/files/publications/files/hffa_research_paper_plant_breeding_eu.pdf

- There is huge interest from EU plant breeding companies to apply new breeding methods like genome editing. Small & medium sized EU operators are much more dependent on an innovation enabling EU regulatory framework than bigger operators with R&D facilities outside the EU.
- Innovation enabling frameworks specifically support small & medium sized plant breeding companies. Also the EU Ethics Group acknowledges that any additional risk assessment requirements would impose a high regulatory burden which may disproportionately impact small companies.
- The survey shows that innovative breeding methods like genome editing are developed for application to all kind of crops & vegetables. This can help to increase crop diversity for EU agriculture by making crops future smart.
- Innovative crop breeding is key to help meeting the goals of the EU Farm to Fork strategy. EU plant breeders are ready to develop a diversity of climate-smart and sustainable crops and vegetables using the latest breeding methods like genome editing.
- The 2018 ECJ ruling subjecting innovative mutagenesis breeding under the cumbersome GMO regulations already had a negative effect on plant breeding innovation. Many companies reduced or stopped their R&D efforts for the EU market.

Full Study here: <https://www.frontiersin.org/articles/10.3389/fpls.2020.582011/full>

Communication tools and social media messages here: <https://intranet.euroseeds.eu/f/67704>

Examples for Crops resulting from Genome editing:

- Crispr potato with improved starch - more sustainable starch production using less energy; clean food label <https://www.euroseeds.eu/app/uploads/2020/03/19.0357-CRISPR-Potato-Infographic.pdf>
- Innovation to preserve tradition – fungi resistant grape vine – sustainable wine production using less pesticides <https://www.euroseeds.eu/app/uploads/2020/06/20.0278.1-Innovation-to-preserve-tradition-fungi-resistant-grape-vine.pdf>
- Plant Breeding Innovation for a more sustainable tomato production video <https://vimeo.com/478816422>
- PILTON - Fungi Resistant Wheat – more sustainable bread production using less pesticides: <https://pilton.bdp-online.de/?lang=en>

Euroseeds contribution to the Farm to Fork strategy and related agricultural topics

<https://www.euroseeds.eu/app/uploads/2020/04/20.0102.3-Euroseeds-contribution-to-the-Farm-to-Fork-strategy-and-related-agricultural-topics.pdf>

Euroseeds contribution to the Biodiversity strategy

<https://www.euroseeds.eu/app/uploads/2021/03/20.0143.8-Euroseeds-contribution-to-the-biodiversity-strategy.pdf>

Sustainable Agriculture: the role of Plant Breeding Innovation <http://scienceforglobalpolicy.org/wp-content/uploads/6037d0bc53ad4-SA-Plant%20Breeding%20Innovation.pdf>

Communication

Communication resources and the Cribsheet for social media messages are accessible here:
<https://intranet.euroseeds.eu/f/58901>

The International Regulatory Landscape and Impacts on Trade

NGT Study: *In light of the different regulatory oversight for NGTs in other countries, enforcement difficulties could lead to trade limitations and disruptions, and put EU operators at a competitive disadvantage, with further negative consequences. This could also lead to the creation of technical barriers to trade, potentially leading to disputes between the EU and its trade partners. Regulatory barriers would particularly affect small and medium-sized enterprises (SMEs) and small-scale operators seeking to gain market access with new genomic techniques, even though many Member States and stakeholders see opportunities for them in this sector.*

Euroseeds Position:

The seed sector is an international acting business. Countries should take into account the global impacts that different regulatory processes may have on global seed movement, exchange and access to germplasm globally, agriculture, trade and research collaborations.

- Countries should agree on the criteria for regulatory oversight. There may be differences in how they can be incorporated into current policies and regulations.
- When considering the criteria for the scope of regulatory oversight, the question is not whether there is adequate regulation of foods and plants but rather the extent to which a specific pre-market review and clearance process is justified for conventional-like plant varieties developed through the latest plant breeding methods.
- The risk is to create another system of patchwork regulations and asynchronous decisions repeating some of the mistakes of GMO regulation. This would create an environment in which only the largest seed companies will have the financial capability to manage the costs related to regulation.
- The predictability of the policy approach is the process used to determine whether a product is within or outside the scope of existing biotechnology/GMO regulations. The process should be predictable and timely, taking into account existing regulatory mechanisms for improved plant varieties, such as variety registration and national seed laws and regulations. Alignment across countries can be facilitated through alignment of:
 - (a) definitions
 - (b) standard information requests needed to make determinations
 - (c) timelines
 - (d) recognition of other countries' scope decisions.

Resources:

Plant breeding innovation: Consistent criteria for the scope of regulatory oversight

<https://www.worldseed.org/wp-content/uploads/2018/06/Plant-breeding-innovation-Consistent-criteria-for-the-scope-of-regulatory-oversight.pdf>

The global need for plant breeding innovation <https://intranet.euroseeds.eu/f/67729>

Commission Study on NGTs

In **November 2019**, The Council of the European Union requested the Commission ([Council Decision \(EU\) 2019/1904](#)) to submit, by 30 April 2021, “a study in light of the Court of Justice’s judgment in Case C-528/16 regarding the status of **novel genomic techniques** under Union law” (i.e. Directive 2001/18/EC, Regulation (EC) 1829/2003, Regulation (EC) 1830/2003 and Directive 2009/41/EC).”

The [study](#) will deal with:

- A state-of-play on the implementation and enforcement of the GMO legislation, as regards NGTs, based on 1) contributions from targeted [consultations of the Member States and stakeholders](#); 2) work of the European Union Reference Laboratory, together with the European Network of GMO Laboratories, on the [detection of products obtained by new mutagenesis techniques](#).
- Information on the status and use of NGTs in plants, animals and micro-organisms for agri-food, industrial and pharmaceutical applications.
- An overview on the risk assessment of plants developed through new genomic techniques, prepared by the [European Food Safety Authority \(EFSA\)](#), based on its own previous and ongoing work and on work carried out at national level (link available soon).
- An overview of current and future scientific and technological developments in new genomic techniques as well as of new products that are, or are expected to be marketed, prepared by DG [Joint Research Centre \(JRC\)](#).

In addition, the study will take into account an analysis of the ethical and societal implications of gene editing that is being developed by the [European Group on Ethics in Science and New Technologies](#).

More Information here: https://ec.europa.eu/food/plant/gmo/modern_biotech/new-genomic-techniques_en

Legal Background

On July 25th 2018, the Court of Justice of the European Union (CJEU) rendered its long awaited Judgment on the scope of Directive 2001/18 on the deliberate release into the environment of genetically modified organisms (GMO Directive).

The CJEU determined in essence whether organisms obtained by mutagenesis are genetically modified organisms (GMOs) and when such organisms are subject to the obligations laid down by the GMO Directive. The CJEU also ruled on the option for Member States to define their own GMO regime.

The ruling of the European Court of Justice (ECJ) in case [C-528/16](#) interprets the [EU Directive 2001/18](#) on the deliberate release of GMOs in a way that:

- all plants obtained by any form of mutagenesis breeding are GMOs as defined by Article 2(2),
- only plants resulting from conventional, random mutagenesis breeding methods (such as e.g. radiation or chemical mutagenesis) qualify for the exemption laid down in Annex IB, even if plants from newer, targeted mutagenesis breeding methods are genetically identical even for those plants to which the mutagenesis exemption of Annex IB applies,
- Member States may still lay down national rules subjecting plants resulting from conventional mutagenesis to similar obligations as the GMO Directive.

Euroseeds analysis of the ruling is available here: <https://intranet.euroseeds.eu/f/29974>