

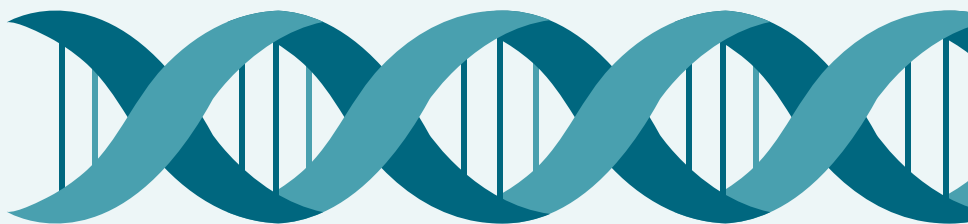
Genome Editing and Agriculture:  
Policy, Practices and Public Perceptions (GEAP3)  
**Policy Briefing 2**

# GENOME EDITING IN AGRICULTURE: THE POLITICS OF REGULATION IN THE EUROPEAN UNION





## Introduction



Genome editing, also known as gene editing, is a technique of genetic engineering that involves the alteration of an organism's genetic structure by adding, deleting, changing or replacing individual nucleotides or sequences of DNA.<sup>1</sup> Genome editing includes several different methods and tools, which can be used by breeders to alter the traits of crop plants and livestock animals. Genome-edited crops and food products are beginning to be commercialised, which raises questions around how the techniques and products of genome editing should be governed.

This briefing discusses the governance of genome editing and its products in the European Union (EU). The future of the EU's rules could have significant implications for agricultural and food systems within the European single market, for the bloc's trading relations with the USA and other countries, and for African countries that want to export agricultural products to European markets. The EU has been under pressure from within and without to change its current approach. Stakeholders from science and industry argue that European regulators should adopt a more permissive approach. Foreign governments, notably the United States, argue that the EU's rules governing genetic engineering techniques are excessively restrictive and constitute a barrier to trade. However, environmentalists and consumer groups insist that stringent regulation of genetic engineering technologies is appropriate, justified and democratically legitimate.

---

<sup>1</sup> DNA stands for deoxyribonucleic acid, a type of molecule often referred to as the genetic 'building blocks' of life.

## Background

---

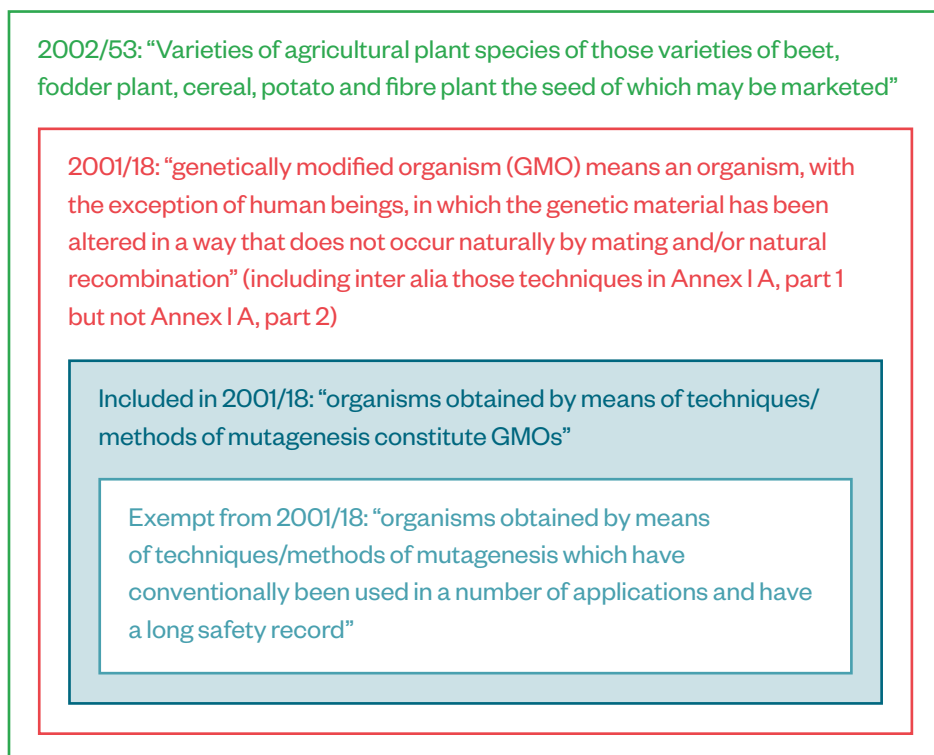
The EU has wrestled for several years with the question, whether genome editing should be regulated in the same way as the previous generation of genetic engineering techniques. In July 2018, the European Court of Justice (ECJ) ruled that genome-edited organisms should be governed under the same rules and protocols that govern the cultivation and marketing of genetically modified organisms (GMOs) within the single market. These rules adhere to the precautionary principle and impose special rules for GMOs, including measures for approval, monitoring, labelling and liability. The court's decision rejected an alternative proposition: that genome-edited organisms should be considered comparable to crop varieties developed using conventional breeding techniques, including mutagenesis, a procedure that uses chemicals or radiation to induce genetic mutations (see Briefing 1). The ECJ concluded that “organisms obtained

by mutagenesis are GMOs”, but excluded those “which have conventionally been used in a number of applications and have a long safety record”.

The legal frameworks governing genetically engineered organisms in the EU include Directive 2001/18/EC, which regulates the deliberate release of GMOs; Regulation (EC) 1829/2003 concerning genetically modified food and feed; Regulation (EC) 1830/2003, which establishes rules on the traceability and labelling of GMOs; and Directive (EU) 2015/412, which governs the scope for EU member states to restrict or prohibit the cultivation of GMOs in their territory. Council Directive 2002/53/EU, on the common catalogue of varieties of agricultural plant species, embraces both conventional plants and GMOs. The diagram in Box 1 delineates the instruments under which GMOs, genome-edited organisms and mutagenic organisms are regulated in the EU.

## Box 1. Mapping the EU legal framework for deliberate release of seeds, and the implication of the 25 July 2018 ECJ Ruling

Source: GEAP3 project.



The diagram shows the scope and exemptions of different EU Directives relating to seed (indicated by the colour of the text – see key below). Implications of the ruling of the court with respect to deliberate release are indicated by the blue surrounding line. On the basis of the ruling, genome-edited crops fall within the shaded area.

Although not shown in the diagram, inclusion and exemption from Directive 2001/18 is identical to inclusion and exemption from Regulation (EC) 1829/2003, (EC) 1830/2003, and (EU) 2015/412.

Key – text taken verbatim from :

Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC - Commission Declaration

Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species

Judgement of the Court (Grand Chamber) 25 July 2018, Case C-528/16

## Debates about the ruling

---

The ECJ ruling brought legal clarity but attracted a range of reactions from different stakeholders. It was welcomed by people and groups that express concerns about genome editing, because it adhered to the precautionary principle. The international peasant organisation *La Vía Campesina*, for instance, celebrated the decision as a “historic victory for peasants and citizens of the EU”, while the European Network of Scientists for Social and Environmental Responsibility (ENSSER) also welcomed the court’s ruling.

Proponents of genome editing techniques, on the other hand, saw the ruling as prohibitive. Scientists expressed concern that embracing genome editing within the legal framework for GMOs would create an impossible situation for regulators, because of the technical difficulty of detecting genome edited organisms. The German science academies and the German Research Foundation (DFG) argue, for instance, that European regulations hamper the development of “urgently needed improved crops to support productive, climateadapted and sustainable agriculture”. The European seed industry organisation Euroseeds complained

that the ECJ ruling made genome editing tools “unavailable for European plant breeding and agriculture”.

Debates about the future regulation of genome editing are still ongoing in the EU. The Netherlands, for instance, proposed a change of EU regulation in 2018 with the aim of exempting genome editing at least partly from GMO regulation. Fourteen EU member states called for a “unified approach” that could exempt some genome editing techniques or products from the GMO rules. Business organisations have called for a move to more “innovation-friendly” regulations, including less complex approval procedures. On 8 November 2019, the European Commission was requested by the EU member states to study “the status of novel genomic techniques under Union law”. The results of this inquiry are expected in Spring 2021. A key issue is how EU rules could affect imported agricultural products, because genome editing is already being used in some countries that export goods to the EU single market, such as the USA (see below).

## The future of genome editing in the EU

---

At least two different pathways can be identified for the future of genome editing policy and regulatory frameworks in the EU. The first path represents the status quo following the ECJ ruling of July 2018: in other words, the continuing regulation of genome-edited products as GMOs in the EU, including the application of strict rules on risk assessment, labelling and traceability. The history of agricultural GMOs in the EU suggests that this pathway would make approval of new genome-edited organisms for commercial use in European agriculture quite unlikely. The most extensively planted GM crop variety in Europe, a transgenic maize variety called MON810, has been cultivated only in a few EU member states. The great majority of cropland in the EU has remained GMO-free, with some member states and regions opting out of the cultivation of MON810 and other GM crops.

A second pathway would involve changing EU rules, for example, so that some or all genome-editing applications would be regulated in similar ways as 'conventional' breeding techniques (including mutagenesis), i.e. less restrictively than GMOs, with less stringent requirements on risk assessment, traceability and labelling. Proponents of genome editing argue for this outcome by highlighting technical distinctions between genome editing and the first generation of GMOs. They believe that these differences could allow genome editing and its products to be perceived as less controversial in Europe (see Briefing 1).

Under either of these scenarios, the option for individual member states to approve (new) techniques of genetic engineering in their

territories could lead to the development of 'genome editing hotspots' in Europe. It appears that the governments of some EU member states do favour allowing the cultivation of GMOs and genome-edited crops, as the proposal by the Netherlands suggests.

Evidence suggests that strong coalitions exist across Europe which would resist genome editing in agriculture, no matter how the technology is framed by proponents or policy makers. Eurobarometer public opinion surveys indicate that most European citizens remain opposed to GMOs, although recent studies are less clear – possibly because the topic of genetic engineering has not been high on the public agenda in recent years. Nevertheless, it can be expected that conflicts over genome editing will escalate if and when commercial applications begin. The history of GMO conflicts suggests that contestation over genome editing is likely to be more intense for food rather than animal feed. Divergences in public opinion among individual EU member states might amplify the tendency for genome editing hotspots to emerge in specific countries or locations.

Divergences in national policy and practice on genome editing could pose a challenge for the integration of the EU's single market. The potential for friction among member states may be exacerbated by upcoming reforms of the Common Agricultural Policy (CAP) and the implementation of the European Commission's proposed Farm-to-Fork Strategy for agriculture and food, which promotes biotechnology as a key tool for achieving sustainability.

## Genome editing and transatlantic trade relations

---

Disagreements over the need for traceability and labelling were at the heart of historical disputes between the EU and the USA over the regulation of GMOs. In the early 2000s, these disagreements led to a formal dispute in the World Trade Organisation (WTO), in which the USA claimed that the EU was illegally restricting its exports of GM products without providing sufficient scientific evidence of harm (the complaint was upheld). GMOs were also a key issue during unsuccessful efforts to negotiate a Transatlantic Trade and Investment Partnership (TTIP) between the EU and USA in the 2010s. These contestations over GMO

governance are likely to be replayed over genome editing. Some American farmers have been cultivating a genome-edited rapeseed (canola) variety ('Falco' from the company Cibus) since 2015 and the possibility of importing this crop into the EU remains uncertain. In May 2020, the USA took further steps towards the deregulation of GMOs and genome editing technologies. Efforts by European regulators to control the flow of genome-edited crop varieties into the EU could be complicated by the current difficulty of identifying some products of genome editing using existing detection techniques.

## Genome editing and the EU after Brexit

---

The United Kingdom's departure from the EU on 31 January 2020 may eventually lead to the UK diverging from EU regulations on biotechnology in agriculture, with implications for the application of genome editing in agriculture and for UK–EU trade in agricultural inputs and products (see Briefing 3). The UK's absence from the EU's internal negotiations about regulation might affect the balance of forces towards a stricter

regulation in the EU, even if there remain other member states within the EU that are likely to continue pushing for more permissive rules. If the UK decides to allow cultivation of GMOs and genome-edited crops, this might reinforce the EU's model of mostly GM-free production on one hand, while on the other hand creating frictions in trade between the EU and the UK.



## EU and sub-Saharan Africa

---

The EU is an important market for agricultural products from sub-Saharan Africa and also an important aid donor and source of technical cooperation for some African countries. This means that EU policies and regulations that govern genome editing in agriculture and food could influence African nations that export agricultural products to Europe, as well as those that participate in EU-funded aid and technical

cooperation programmes affecting agriculture and technology. Of the GM crops currently grown around the world, few have had any commercial potential to be cultivated in African countries for export to European countries. The situation could be different for genome editing techniques, if they are applied to the improvement of horticultural crops, for example, which are produced in Africa for European consumers.

## The GEAP3 Project Policy Hub

The Genome Editing and Agriculture: Policy, Practices and Public Perceptions (GEAP3) network is an international research consortium that brings together social scientists, policy experts and bio-scientists to explore the domestic and international ramifications of the EU's policy and regulatory approach to genome editing in agriculture. The network is exploring and analysing key developments in genome editing and their implications for agriculture through three hubs: policy, practice, and public perceptions.

The GEAP3 Policy hub is exploring systematically the implications of the EU's regulatory approach to genome editing. The hub is examining how competing visions for the governance of genome editing conflict or may be reconciled. For further information on the GEAP3 network and the Policy hub, please visit the project website at

<https://www.geap3.com>

## Other GEAP3 briefings in this series

Briefing 1: Genome Editing in Agriculture: Issues for Policy and Regulation

Briefing 3: Genome Editing in Agriculture: Regulation in the United Kingdom after Brexit

*This briefing was written by Beate Friedrich, Dominic Glover and Adrian Ely.  
September 2020*

## Further reading

Broll, H., et al. (2019) 'European Court of Justice decision for genome editing: Consequences on food/feed risk assessment and detection.' Food Control 104: 288-291. <https://doi.org/10.1016/j.foodcont.2019.05.002>

COUNCIL DECISION (EU) 2019/1904 of 8 November 2019 requesting the 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, and a proposal, if appropriate in view of the outcomes of the study: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D1904&from=EN>

Vives-Vallés, J. A. and C. Collonnier (2020). 'The Judgment of the CJEU of 25 July 2018 on Mutagenesis: Interpretation and Interim Legislative Proposal.' Frontiers in Plant Science 10(1813). <https://www.frontiersin.org/articles/10.3389/fpls.2019.01813/full>

Kawall, K., Cotter, J. & Then, C. Broadening the GMO risk assessment in the EU for genome editing technologies in agriculture. Environmental Sciences Europe 32, 106 (2020). <https://doi.org/10.1186/s12302-020-00361-2>

The European Commission's support for the production of this publication does not constitute an endorsement of the contents, which reflect the views only of the authors, and the Commission cannot be held responsible for any use which may be made of the information contained therein.



BUSINESS  
SCHOOL

SCIENCE POLICY  
RESEARCH UNIT

