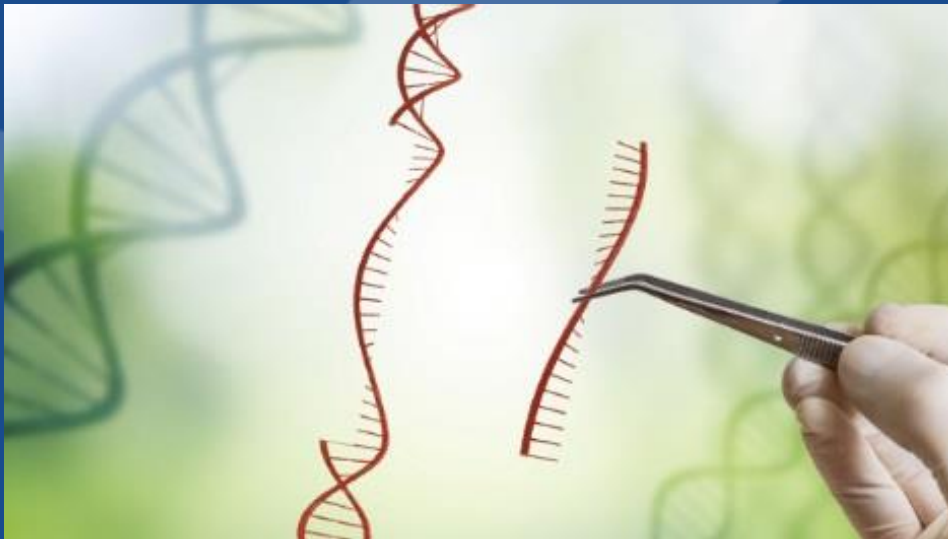


Prospects for Regulation of Gene-Edited Crops Post-Brexit



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The past: Atomic Gardening



1961

In 1959 Muriel Howorth formed the Atomic Gardening Society, “a cultural body for the guidance of atomic plant-mutation experiments”. She sold irradiated seeds and published “Atomic Gardening for the Layman”.

GM: Exclusions

Annex IB:

Techniques/methods of genetic modification yielding organisms to be excluded from the Directive

- i) **mutagenesis**,
- ii) cell fusion of plant cells of organisms which can exchange genetic material through traditional breeding methods.

Legal question

- Status of gene editing, GM or a form of mutagenesis?
- Case referred by France to the European Court of Justice in October 2016
- Preliminary judgement Jan 2018
- Final verdict July 2018

ECJ Case C-528/16: 18th Jan 2018

“organisms obtained by mutagenesis are, in principle, exempted from the obligations in the Genetically Modified Organisms Directive”

“Member States are free to adopt measures regulating such organisms provided they respect overarching principles of EU law”

Final decision expected summer 2018

Realpolitik:

The German coalition agreement, Feb 2018

We reject patents on plants and animals. Likewise, the cloning of animals for food production. We stick to the seed purity. We will regulate a genetic engineering ban nationwide (opt-out directive of the EU).

Following the pending decision of the European Court of Justice (ECJ) on the new molecular biology breeding technologies, we will make arrangements at European or, where appropriate, national level to ensure the precautionary principle and freedom of choice.

ECJ Verdict, 25th July 2018

Organisms obtained by mutagenesis are GMOs and are, in principle, subject to the obligations laid down by the GMO Directive

However, organisms obtained by mutagenesis techniques which have conventionally been used in a number of applications and have a long safety record are exempt from those obligations, on the understanding that the Member States are free to subject them, in compliance with EU law, to the obligations laid down by the directive or to other obligations

<https://curia.europa.eu/jcms/upload/docs/application/pdf/2018-07/cp180111en.pdf>

<http://curia.europa.eu/juris/document/document.jsf?text=&docid=204387&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1&cid=686305>

ECJ Verdict: reaction

- “It is now likely that much of the potential of these innovative methods will be lost for Europe – with significant negative economic and environmental consequences. That strikes a serious blow to European agriculture and plant science,” European Seed Association Secretary General.
- “Public confidence and science-based decision-making are both important for ensuring that genome editing can deliver needed solutions. Looking forward, EuropaBio believes that the next step, for the EU and its Member States, is to engage citizens in an inclusive and fact-based dialogue on what genome editing is, and what it will or will not be used for. It will be important to build knowledge, develop understanding and deliver risk-proportionate policy approaches, allowing innovation, which is already taking place in other parts of the world, to also benefit the EU’s society, economy and the environment.”

Which way for the UK?



**UK plant genetics:
a regulatory environment to
maximise advantage to the UK
economy post Brexit**

Briefing paper

Graham Brookes
PG Economics Ltd
Dorchester, UK
September 2018

Post Brexit regulatory and trade arrangements scenarios examined

Scenario 1:

The status quo – continued alignment with the EU

Scenario 2:

improved implementation and some change; making the existing GMO system work 'as intended' and some NBTs not subject to GMO regulations

Scenario 3:

UK sets its own path -divergence from EU regulations on both GMOs and NBTs

Scenario 1: Status quo

- a. Uncertainty relating to the timing of approvals will continue, causing trading difficulties and additional cost for the user sectors of imported commodities;
- b. The current low level of GM crop-related research and development is unlikely to change, with only limited income opportunities arising from the existing licencing of UK-developed research to businesses located outside the EU. There is also a low probability of any GM crop technology ultimately being commercialised in the UK;
- c. With the regulatory position of many NBTs assumed to be the same as for GMOs, there is likely to be:-
 - A reduction in public and private investment
 - Potential for significant trade disruption, loss in competitiveness for UK and EU agriculture

Scenario 2: Improved Implementation

- Greater clarity, reduced cost, for approvals
- Greater flexibility for feed ingredients
- More positive environment for crop R&D
- Possible new private sector investment,
and more public/private collaboration

Scenario 3: Diverge from EU

- a. Reduced uncertainty, greater flexibility for traders and users of imported commodities.
- b. Move to science-based regulation on international norms will improve environment for commercialisation
- c. Greater possibility for novel products for UK farmers, benefit for UK economy

Michael Gove, the UK Secretary of State
the Department of Food and Rural Affairs,



to the annual conference of the British National
Farmers Union, Feb 2019:

“Precision application of pesticides and
fungicides, drones rather than ground
vehicles, **gene-edited crops which require
no additional chemical protection**, data
analytics which can refine and target
necessary interventions, sensors which
can alert us to animal disease and
maximise dairy yields, all of these and more
can both make food production more efficient
and lighten our environmental foot print.”

International dimension

26 European Business Organizations ask the EU for Pro-Innovation Rules For Plant Breeding: 23rd April 2019



“The introduction of targeted genetic variation in crops and other organisms can help to achieve important sustainable development goals and to contribute to a cleaner environment, to healthy diets, and the protection of biodiversity. It can also contribute to making crops more resilient and better withstand climate change.

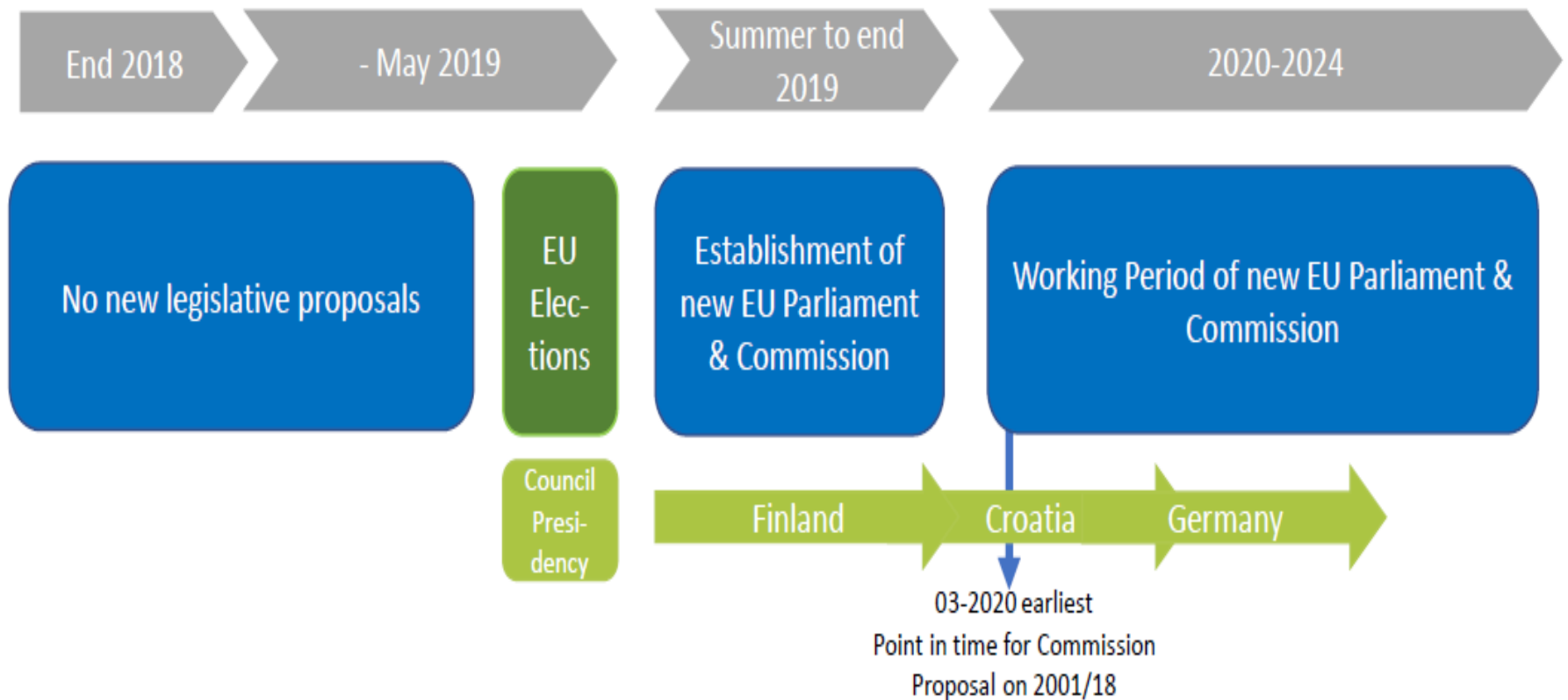
The costly and lengthy EU approval process for the products resulting from targeted mutagenesis, combined with potential national cultivation opt-outs under Directive 2001/18, will effectively deprive European farmers and consumers from the benefits of these products.”

ESA Advocacy on the way forward

Clarity must be achieved by a targeted amendment of the Directive that specifies that mutagenesis derived plants are not GMOs

- targeted amendment of Directive 2001/18 that **excludes products of old and new mutagenesis breeding from its definition;**
- alignment of the EU's policy and rules with those established and being developed in the rest of the world;
- create legal certainty for EU operators by avoiding that Member States adopt individual national rules for products resulting from conventional, random mutagenesis.

Relevant EU political Developments



ESA's basic principle for regulatory requirements

*Plant varieties developed through the latest breeding methods should **not be subject to different or additional regulations** if they **could also have been produced through earlier breeding methods** or by **natural processes** without human intervention.*

Latest from the EU AgriFish Council meeting: 14th May 2019

“The request of a common EU approach was supported by many delegations that generally asked for a consistent interpretation and an update of the current EU GMO legislation.”

<https://www.consilium.europa.eu/media/39365/st09271-en19.pdf>

Latest from the USA: 28th March 2018 (cont./)

This can include plant varieties with the following changes:

Deletions—the change to the plant is solely a genetic deletion of any size.

Single base pair substitutions—the change to the plant is a single base pair substitution.

Insertions from compatible plant relatives—the change to the plant solely introduces nucleic acid sequences from a compatible relative that could otherwise cross with the recipient organism and produce viable progeny through traditional breeding.

Complete Null Segregants—off-spring of a genetically engineered plant that does not retain the change of its parent.

Recent APHIS Letters of Enquiry



4/19/2019	Illinois State University	Genome Edited Penny Cress
2/25/2019	Max Planck Instit. Chem. Ecol.	Genome Edited <i>Nicotiana attenuata</i> with modified Nectar
2/18/2019	Intrexon	Genome Edited Lettuce
10/22/2018	Suntory Flowers Ltd.	Import of Cut Flowers of GE <i>Chrysanthemum</i>
9/27/2018	Yield10 Bioscience	Genome Edited <i>Camelina</i>
7/12/2018	Iowa State University	Genome Edited Maize
5/18/2018	University of Georgia	Soybean Engineered for Transposon Mutagenesis with siRNA
5/14/2018	University of Florida	Genome Edited Tomato

North America Genome Editing Market to 2025



- expected to reach US\$ 4,148.1 Mn in 2025 from US\$ 1,234.5 Mn in 2017.
- estimated to grow with a CAGR of 17.2% from 2018-2025.
- In 2017, the CRISPR segment held a largest market share of 53.6% of the genome editing market, by technology.
- In 2017, the biotechnology & pharmaceutical companies segment held a largest market share of 61.2% of the genome editing market, by end user.

Latest from Russia: 14th May 2019

Russia joins in global gene-editing bonanza

US\$1.7-billion programme aims to develop 30 gene-edited plant and animal varieties in the next decade.



Joint Statement of Western Hemisphere Agriculture Leaders: Niigata, Japan. May 12th 2019

Argentina, Brazil, Canada, Mexico, and the United States

“Together, we stand to work in partnership, and jointly with additional countries, to support regulatory approaches that are risk- and science-based, predictable, consistent, and transparent. Our five nations recognize that innovations in the agriculture sector contribute to improved productivity.....”

USDA 0069.19

Notably, the WTO stance in this area, which they describe as “precision biotechnology” supports the US position (available as [G/SPS/GEN/1658/Rev.3](https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?Query=(%40Symbol%3D%2B%2F%2Fsps%2Fgen%2F%2A%2B)%26Language%3DENGLISH%26Context%3DFomerScriptedSearch%26languageUIChanged%3Dtrue) from [https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?Query=\(%40Symbol%3D%2B%2F%2Fsps%2Fgen%2F%2A%2B\)%26Language%3DENGLISH%26Context%3DFomerScriptedSearch%26languageUIChanged%3Dtrue](https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?Query=(%40Symbol%3D%2B%2F%2Fsps%2Fgen%2F%2A%2B)%26Language%3DENGLISH%26Context%3DFomerScriptedSearch%26languageUIChanged%3Dtrue))

Overall Summary

- Significant differences in global attitudes especially EU vs. US
- Within Europe, ECJ verdict likely to reduce international competitiveness
- Lack of unified attitude in Europe also likely to deter commercial investment
- Brexit not likely to change situation in GB

Additional information

Nature Biotech. 2018. 36, 6-7. doi:10.1038/nbt0118-6b

<https://www.agri-pulse.com/articles/10564-will-new-regulations-stifle-innovation-in-plant-and-animal-breeding>

https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Advisory%20Legal%20Opinion%20Expected%20for%20New%20Plant%20Breeding%20Techniques%20_Brussels%20USEU_EU-28_1-16-2018.pdf

<https://curia.europa.eu/jcms/upload/docs/application/pdf/2018-01/cp180004en.pdf>

http://www.epsoweb.org/webfm_send/2362

Additional information

<http://european-seed.com/2018/07/a-bleak-view-for-agricultural-innovation-in-the-eu/>

http://blogs.royalsociety.org/in-verba/2018/07/26/when-is-genetic-modification-not-genetic-modification/?utm_campaign=6048&utm_source=adestra&utm_medium=email

<https://www.gov.uk/government/publications/developing-genetically-modified-organisms-gmos-if-theres-no-brexit-deal/developing-genetically-modified-organisms-gmos-if-theres-no-brexit-deal>

<https://geneticliteracyproject.org/2019/02/11/rebellion-against-europes-innovation-killing-crop-gene-editing-regulations-grows-among-scientists-frustrated-member-states/>