EXPLANATORY MEMORANDUM FOR EUROPEAN UNION LEGISLATION/DOCUMENTS WITHIN THE SCOPE OF THE UK/EU WITHDRAWAL AGREEMENT AND THE WINDSOR FRAMEWORK

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PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON PLANTS OBTAINED BY CERTAIN NEW GENOMIC TECHNIQUES AND THEIR FOOD AND FEED, AND AMENDING REGULATION (EU) 2017/625

REGULATORY SCRUTINY BOARD OPINION

SUBSIDIARITY GRID

IMPACT ASSESSMENT REPORT

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT

Submitted by the Department for Environment, Food and Rural Affairs

18 August 2023

SUBJECT MATTER

1. The EU has proposed a new regulation to create a new regulatory framework for plants, and derived food and feed, developed through new genomic techniques (NGT), such as gene editing (known in England as Precision Breeding and as targeted mutagenesis in the EU). This framework includes new requirements for NGT plants obtained by targeted mutagenesis and cisgenesis and food and feed containing, consisting or produced from these plants. NGT plants currently fall under the scope of the Union legislation on GMOs (Directive 2001/18/EC, Regulation (EC) No 1829/2003, Regulation (EC) No 1830/2003.

2. These existing EU GMO regulations are largely regarded as being too burdensome, disproportionate, and a barrier to developing improved varieties of crops, particularly for techniques such as gene editing, which can introduce genetic changes that could also have occurred through traditional breeding. Currently,

breeding of organisms that fall under EU GMO legislation need to follow a lengthy authorisation process to be sold as food or feed. On average, it takes about 6 years from submission of an application to import a GMO and an EU decision on whether to authorise it (including the risk assessment). It can take SMEs an extra 15 months to pass the completeness check, which happens before the application is accepted.

3. In 2018, the European Court of Justice (ECJ) ruled that the definition of a GMO covers all organisms developed through NGT such as gene editing, including those that could have been produced by traditional breeding methods[1]. The Netherlands and Estonia led a coalition of 14 EU Member States calling for the EU to update their GMO laws to accommodate 'new plant breeding techniques' following the ECJ's ruling. The other supporting members states included Belgium, Cyprus, Finland, France, Germany, Greece, Italy, Portugal, Slovenia, Spain, Sweden, and the UK. Spain have been a keen advocate of this policy area and now they have taken over the presidency, we expect progress to be made during their tenure.

4. The European Commission's recent 'Study on the status of NGTs' acknowledges limitations in the capacity of the current EU GMO legislation to keep pace with scientific developments, concluding that current regulations are not fit for purpose. Following this study, the EU Commission ran a public consultation in 2022 on a proposal to develop new legislation for plants produced by NGTs. 80% of participants agreed that the existing provisions of the EU GMO legislation are not adequate for plants produced by NGTs.

5. Therefore, the EU's proposal is to remove qualifying NGTs from current GMO regulatory requirements and to introduce a simpler and less onerous regulatory process. The proposal includes the creation of two NGT categories with different regulatory requirements for each category. In brief, category 1 NGTs (NGT1) will require notification prior to marketing, but will not require any further authorisations or risk assessments. Category 2 NGTs (NGT2) will require adapted risk assessments and mandatory labelling and traceability requirements. The EU definition of a NGT1 is broadly aligned with the definition in the Genetic Technology (Precision Breeding) Act 2023 (The Precision Breeding Act), which focuses on substantive equivalence to traditionally bred counterparts and the same rationale has been applied by the EU for the deregulation of NGT1 plants. However, the definition of NGT2 includes organisms produced by targeted mutagenesis (gene editing) and cisgenesis, which do not meet the criteria for NGT1. NGT2s will require a more in-depth risk assessment and mandatory labelling and traceability requirements. In the proposal, there are incentives for NGT2 applications that improve nutrition, sustainability and food security, which may be granted reduced statutory time limits. There is also support for SMEs through a pre-submission

[1] Organisms obtained by mutagenesis are GMOs and are, in principle, subject to the obligations laid down by the GMO Directive (europa.eu)

advice service to advise on any plausible hypothetical risks identified by the applicant, and exemption of fees for traceability measures.

6. If this proposed regulation is adopted, it would apply in Northern Ireland, as the existing GMO regulations and EU Regulation 2017/625 on controls are part of the limited number of EU laws that apply directly in Northern Ireland under the Windsor Framework

SCRUTINY HISTORY

7. There is no Parliamentary scrutiny history relevant to the Explanatory Memorandum.

MINISTERIAL RESPONSIBILITY

8. Responsibility lies with the Secretary of State for Environment, Food and Rural Affairs.

INTEREST OF THE DEVOLVED GOVERNMENTS (DGs)

9. The Department of Agriculture, Environment and Rural Affairs (DAERA) in the Northern Ireland Executive will have a particular interest in this proposal.

10. Scottish Government and Welsh Government will have an interest as this policy area is subject to the [Provisional] Common Frameworks on Plant Varieties and Seeds, Food and Feed Safety and Hygiene, Animal Health and Welfare and Food Compositional Standards and Labelling.

11. Policy and regulation of GMOs is a devolved area in the UK. The Devolved Administrations were consulted during the preparation of this EM. Their comments, mainly regarding their intentions not to amend their respective GM regulatory regime, were accepted. The Scottish Government does not presently intend to amend the GM regulatory regime in Scotland to remove categories of products which are currently regulated as GMOs, and take careful note of the European Commission's ongoing consideration of the issues involved. The Welsh Government holds a similar position and does not presently intend to amend the GM regulatory regime in Wales. UKG is continuing to engage with Devolved Governments following publication of the EU's proposal.

LEGAL AND PROCEDURAL ISSUES

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i. Legal Base:

The proposal is based on Articles 43, 114 and 168(4)(b) of the Treaty on the Functioning of the European Union (TFEU). These articles provide the legal basis for the Union to adopt measures which have as their objective to implement the

common agricultural policy (Article 43), and to ensure the good functioning of the internal market (Article 114) and a high level of human health protection in the veterinary and phytosanitary fields (Article 168(4)(b)).

ii. Voting Procedure:
Ordinary Legislative Procedure

iii. Timetable for adoption and implementation:
Expected to be implemented from 2025 onwards.

POLICY AND LEGAL IMPLICATIONS

13. This proposal has arisen following determination by the EU Commission that the existing EU GMO authorisation procedure and risk assessment requirements are not proportionate or well adapted to the variety of potential plant products that can be obtained through NGTs. This follows the trend internationally, where many countries such as Argentina, Canada, USA, Japan have developed more proportionate regulations for products of NGTs.

14. England is ahead of the EU in this process. In April 2022, through the Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2022, England established a more proportionate regulatory process to make it easier to conduct research field trials. Under this regulation, researchers are allowed to conduct field trials on qualifying higher plants[2] without the burden of going through the GMO approval process. Instead, researchers are required to notify Defra before conducting the field trials.

15. In March 2023, the Precision Breeding Act passed into law in England, providing a framework from which to create a new science-based and proportionate regulatory regime for precision bred plants, animals, food and feed.

16. The proposed EU regulatory framework is very similar to the regulatory framework outlined in the Precision Breeding Act in England, both of which seek to develop a more proportionate and simpler system for NGTs/Precision breeding. As in the Precision Breeding Act, the EU also considers NGTs to be substantially equivalent to traditionally bred counterparts. However, while the definition of NGT is essentially the same as precision breeding, what the EU consider falling under the umbrella of equivalence to traditionally bred counterparts may differ. This refers to the aforementioned 2 categories of NGT (NGT1 and NGT2). Understanding the criteria for these categories is important for understanding the extent of divergence. The EU's proposal only covers plants, whilst the Precision Breeding Act covers plants and animals. The EU proposal is also in alignment with a number of other

[2] plants produced using biotechnologies where the genetic changes could have arisen through traditional breeding,

elements including no legal requirement to label food and feed products as NGTs. However, labelling is proposed for seeds produced using NGTs in order to allow choice at the beginning of the supply chain to support maintaining organic production that is free from NGTs.

17. As it stands, NGTs are in the research and development stage. It will be several years until we see the commercial cultivation or manufacturing of NGTs within the EU.

18. Until the EU introduces this proposal any precision bred products from England would be considered a GMO under current EU legislation and would need to be authorised and labelled as such before being placed on the EU market. The same would be the case in Northern Ireland under the Windsor Framework. Under the Windsor Framework, however, future PBO food products authorised as safe for use in food in England can move under the Northern Ireland Retail Movement Scheme for sale in Northern Ireland. UKG will continue to engage and work together with the EU and other countries to understand and minimise, as much as possible, any implications for trade.

CONSULTATION

19. The proposal does not identify cost implications for business importing and as such no separate consultation or an impact assessment is required. The EU have previously publicly consulted ahead of this proposal.

FINANCIAL IMPLICATIONS

20. There are no known financial implications anticipated.

THE RT. HON. MARK SPENCER M.P.

MINISTER OF STATE FOR FOOD, FARMING AND FISHERIES

DEPARTMENT FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS