HOUSE OF LORDS

Secondary Legislation Scrutiny Committee

29th Report of Session 2021–22

Instruments under the European Union (Withdrawal) Act 2018: Published Draft Instrument

Drawn to the special attention of the house:

Draft Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2022

Includes information paragraphs on:

2 instruments relating to COVID-19

Draft Civil Enforcement of Road Traffic Contraventions (Representations and Appeals) (England) Regulations 2022 and one related instrument

Draft Cumbria (Structural Changes) Order 2022 and two related instruments

Draft Early Legal Advice Pilot Scheme Order 2022

Draft Flood Reinsurance (Amendment) Regulations 2022

Draft Goods Vehicles (Licensing of Operators) (Amendment) Regulations 2022

Road Vehicles (Construction and Use) (Amendment) Regulations 2022

Statement of Changes in Immigration Rules

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Secondary Legislation Scrutiny Committee

The Committee's terms of reference, as amended on 13 May 2021, are set out on the website but are, broadly:

To report on draft instruments published under paragraph 14 of Schedule 8 to the European Union (Withdrawal) Act 2018; to report on draft instruments and memoranda laid before Parliament under sections 8 and 23(1) of the European Union (Withdrawal) Act 2018 and section 31 of the European Union (Future Relationship) Act 2020.

And, to scrutinise –

> (a) every instrument (whether or not a statutory instrument), or draft of an instrument, which is laid before each House of Parliament and upon which proceedings may be, or might have been, taken in either House of Parliament under an Act of Parliament;
>
> (b) every proposal which is in the form of a draft of such an instrument and is laid before each House of Parliament under an Act of Parliament,

with a view to determining whether or not the special attention of the House should be drawn to it on any of the grounds specified in the terms of reference.

The Committee may also consider such other general matters relating to the effective scrutiny of secondary legislation as the Committee considers appropriate, except matters within the orders of reference of the Joint Committee on Statutory Instruments.

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Registered interests

Information about interests of Committee Members can be found in the last Appendix to this report.

Publications

The Committee's Reports are published on the internet at https://committees.parliament.uk/committee/255/secondary-legislation-scrutiny-committee/publications/

Committee Staff

The staff of the Committee are Christine Salmon Percival (Clerk), Philipp Mende (Adviser), Jane White (Adviser) and Emily Pughe (Committee Operations Officer).

Further Information

Further information about the Committee is available at https://committees.parliament.uk/committee/255/secondary-legislation-scrutiny-committee/

The progress of statutory instruments can be followed at https://statutoryinstruments.parliament.uk/

The National Archives publish statutory instruments with a plain English explanatory memorandum on the internet at http://www.legislation.gov.uk/uksi

Contacts

Any query about the Committee or its work, or opinions on any new item of secondary legislation, should be directed to the Clerk to the Secondary Legislation Scrutiny Committee, Legislation Office, House of Lords, London SW1A 0PW. The telephone number is 020 7219 8821 and the email address is hlseclegscrutiny@parliament.uk.

Twenty Ninth Report

INSTRUMENTS UNDER THE EUROPEAN UNION (WITHDRAWAL) ACT 2018

Consideration of published draft instruments under Schedule 8 to the European Union (Withdrawal) Act 2018

Published draft on which the Committee makes no recommendations

- Air Navigation (Amendment) Order 2022

INSTRUMENTS DRAWN TO THE SPECIAL ATTENTION OF THE HOUSE

Draft Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2022

Date laid: 20 January 2022

Parliamentary procedure: affirmative

This instrument proposes to remove the current legal requirement in England to submit a risk assessment and seek consent from the Secretary of State before releasing plants with genetic modifications, which could have occurred naturally or been produced by traditional breeding, for non-marketing purposes. Under the proposed new arrangements, a notice will have to be given to the Secretary of State and published before the seed/other propagating plant material is placed into the ground for germination/onward growth. The Department for Environment, Food and Rural Affairs says that this policy change is to be a first step of a wider reform programme in the area of genetic technologies and gene editing which is to "unleash the potential of these technologies" and drive innovation. The proposals are of significant public interest, as indicated by a large number of responses to the Government's consultation and three submissions we have received which raise a range of concerns. This report looks at some of these concerns, including how relevant plants will be assessed as qualifying for release and whether there will be safeguards and containment measures. The House may wish to explore these issues further with the Minister.

The draft Regulations are drawn to the special attention of the House on the ground that they are politically or legally important and give rise to issues of public policy likely to be of interest to the House.

1. These draft Regulations have been laid by the Department for Environment, Food and Rural Affairs (Defra) with an Explanatory Memorandum (EM) and an Impact Assessment (IA). The instrument proposes to remove current requirements in England to submit a risk assessment and seek consent from the Secretary of State before releasing genetically modified (GM) plants, which could have occurred naturally or been produced by traditional breeding methods, for non-marketing purposes. According to Defra, this is to remove a regulatory burden for research and development trials involving such plants, as a first step of a wider reform programme in this area.

2. We have received submissions from Beyond GM, GM Freeze and Organic Farmer & Growers (OF&G) which raise a range of concerns about the proposals. We are publishing the submissions in full on our website.[1] We are also publishing at Appendix 1 the Department's response to our questions which were informed by the submissions.

Background

3. Defra explains that a case before the Court of Justice of the European Union (CJEU)[2] confirmed in July 2018 that in EU law all organisms produced by biotechnology are Genetically Modified Organisms (GMOs), and that

1 https://committees.parliament.uk/committee/255/secondary-legislation-scrutiny-committee/publications/8/scrutiny-evidence/.

2 Court of Justice of the European Union, Confédération paysanne and Others v Premier ministre and Ministre de l'agriculture, de l'agroalimentaire et de la forêt, Case C-528/16, (25 July 2018).

they need to be regulated as such, even if they cannot be distinguished from organisms occurring naturally or produced by traditional breeding methods. According to Defra, the Government disagreed with this view and intervened in the case at the time "to present a different view based on scientific evidence and to argue that the regulatory regime should be proportionate to risk".

4. Defra explains that in the Government's view, where genetic alterations and combinations are of the type that are selected for in traditional breeding, the environmental release of these plants should not be regulated in the same way as the environmental release of GMOs. According to Defra, this is "because it is the characteristics of the end-product that determines its risk to human health and the environment–not how they were made". Following Brexit, the Government now intend to change the law in England to allow GM plants that could have occurred naturally or through traditional breeding methods for release for non-marketing purposes. This is to enable the bioscience sector to test the benefits and safety of relevant new products "without the burden of unnecessary regulatory processes".

5. Defra states in the IA that the changes will "send a signal that the UK Government wants to unleash the potential of these technologies and that this is the initial step of a wider reform programme", adding that it "will have a positive impact on investment to drive innovation and generate wider spill over benefits into the UK economy from this increased investment". **Regrettably, the EM does not provide any further information on the Government's plans for wider reform**.

6. The Department says that the Advisory Committee on Releases to the Environment (ACRE)[3] has advised on the safety aspects of the changes, concluding that where genetic alterations and combinations are of the type that are selected in traditional breeding, any associated health and environmental risks would be comparable, so the environmental release of these organisms should not be regulated in the same way as the environmental release of GMOs. According to Defra, this view is supported by the Royal Society.

Changes proposed by this instrument

7. Under current law, each GMO has to be assessed and authorised on a case-by-case basis before it can be used and released into the environment. This involves a risk assessment, a public consultation, and the publication of details of when and where its research trial will take place. In addition, consent must be sought from the Secretary of State.

8. Under the proposed new arrangements, any individual or organisation intending to release a "qualifying higher plant" into the environment will have to notify the Secretary of State. The draft regulations define "qualifying higher plant" as a higher plant which is a GMO, but which has not been genetically modified other than to make modifications that could have occurred naturally or could have been made using traditional breeding methods.[4] The notice will need to be submitted to Defra before the seed or

3 ACRE is an advisory non-departmental public body, sponsored by Defra, which provides statutory advice to ministers on the risks to human health and the environment from the release of GMOs. Advisory Committee on Releases to the Environment, 'About Us', https://www.gov.uk/government/organisations/advisory-committee-on-releases-to-the-environment/about [accessed 8 February 2022].

4 As set out in regulation 5(2) of the Genetically Modified Organisms (Deliberate Release) Regulations 2002 (SI 2002/2443).

other propagating plant material is placed into the ground for germination or onward growth. The notice can be given by email and will be published on the gov.uk website/public register. These changes will apply only to relevant plants and not to animals.

Further use of qualifying higher plants

9. Asked whether qualifying higher plants could be used for food or animal feed and whether the labelling of such products would have to state their GM nature, Defra explained that:

> "The instrument deals with plants released for non-marketing purposes, meaning developers are able to carry out research and development of such plants. However, the marketing of these plants will not be possible without consent from the Secretary of State, as they would still be GMOs. For this to be possible, developers would need to follow the GMO regulations and therefore would need to be labelled under the GMO Food and Feed Regulations."

Criteria to be used to assess whether a plant qualifies as a qualifying higher plant

10. While the draft Regulations provide a definition of the term "qualifying higher plant", they do not include criteria to assess whether the modifications of a relevant plant could have occurred naturally or could have been produced by traditional breeding methods. This is an issue that Beyond GM, GM Freeze and OF&G raised in their submissions.

11. Beyond GM stated that "neither the Instrument nor its Explanatory Memorandum provides a basis on which to justify creating a new subclass of exempted organisms. In addition, this subclass of genetically modified organisms is not defined or recognised in current scientific literature, in UK regulations [Environmental Protection Acts 1990 and 2002 and 2019 amendments], in international definitions (e.g., Cartagena Protocol) or the regulations of many other countries. The definition of a GMO is not minor theoretical point but a foundational concept in the regulation of agricultural genetic technologies and we therefore believe that the regulatory change presented in this Instrument is problematic".

12. GM Freeze argued that the consultation suggested "significant uncertainty about such criteria" and that there is "clearly a high level of uncertainty about how and by whom the new category of 'qualifying higher plant' will be determined". OF&G questioned the term "to occur naturally", suggesting that it is not one they would "recognise in any way that would align with the techniques involved in altering genetic material by the invasive practice […] in what is often referred to as 'genetic editing'".

13. We asked the Department about the scientific and regulatory criteria that will be used to determine whether a genetic change could have occurred naturally or through traditional breeding methods, and when these would be published. The Department told us that:

> "ACRE is in the process of developing guidance for developers to determine if the genetic change could have occurred naturally or by using one of the techniques in the Genetically Modified Organisms (Deliberate Release) Regulations 2002 5(2). The guidance will be available shortly."

14. **We regret that the guidance has not yet been published, especially as the Department would have been aware of the concerns which were raised during consultation. The House may wish to press the Minister for an explanation why the guidance has not been made available in time for it to be taken into account by Parliament in its consideration of these draft Regulations. We urge the Department to ensure that the guidance is published in good time before the new rules come into effect and that this guidance is communicated effectively, in order to provide clarity to researchers and those who have concerns about the new policy.**

Safeguards and containment measures

15. Under the current rules, an individual risk assessment and consent by the Secretary of State are required before any GMOs may be released. The instrument removes these requirements for qualifying higher plants. The submissions we received raised concerns about the safeguards that will apply to the release of such plants into the environment.

16. Beyond GM argued that the new approach in effect relies on "GMO developers to self-declare whether their product is a GMO or not […] which is not appropriate for the deliberate environmental release of any kind of GMO". OF&G suggested that "Risk assessments must have been in place and checks properly made in all situations with plant breeding especially in the field where escape does pose a significant risk." GM Freeze raised concerns that "Non-marketing releases of experimental GMOs have, in many instances, led to the escape of pollen, seed and other plant material capable of reproduction", and that "With no mandatory containment measures, farmers, food producers and distributers will be vulnerable to significant business disruption and potentially catastrophic costs in the event that 'qualifying higher plants' contaminate conventional or organic crops of the same, or a closely related species. Such contamination could lead to lost business, the loss of organic status (where relevant) and legal action."

17. Asked about these concerns, Defra explained that:

> "For GM plant research and development, where the changes could have been produced by traditional breeding methods, we will be moving to a self-declaration system. This approach is informed by advice from ACRE our independent scientific advisers and is more in step with approaches developed using traditional breeding methods. ACRE's view is that an organism produced by gene-editing, or another genetic technology would not pose a greater safety risk than a traditionally bred or naturally occurring version of that organism, as a result of how it was produced. Researchers will still be required to notify Defra of these trials and commercial cultivation of these plants, food and animal feed derived from them will still need to be authorised in accordance with existing GM rules.
>
> This SI will allow plants produced using genetic technologies that produce changes that could have occurred through traditional breeding, to be treated in the same way as their traditionally bred counterparts at the field trial stage. Underpinning this approach is the key principle that it is the final characteristics of an organism which determine whether it presents any safety risks, regardless of the method used to produce

> that organism. ACRE's view is that where [Genome Editing] introduces genetic alterations and combinations that are of the type that are selected for in traditional breeding, the environmental release of these organisms should not be regulated in the same way as the environmental release of [GMOs]."

18. While the instrument establishes a notification requirement for the release of the qualifying higher plants, the information that must be notified to the Secretary of State for each release does not include the location or scale of any release, or details of the containment measures that will be employed to ensure that the GMOs do not affect either commercial crops or the wider environment. This is a particular concern for organic farmers. We asked how the Department could be sure that adequate containment measures have been put in place. Defra said that:

> "[A]s GM plant material cannot be marketed without being authorised, researchers carrying out field trials that could lead to the marketing of the plant material (either directly or indirectly) may need to put measures in place to minimise gene flow to any sexually compatible commercial crops in the vicinity and/or minimise persistence of reproductive material at the site if there is the possibility of material entering the human food or animal feed chain. Any measures will depend on the plant species involved and on the characteristics of the trial site. Defra will not be specifying these measures; it will be the responsibility of researchers to abide by the law and gain authorisation for GM plants that are grown, or if material from them is present, in commercial products."

19. Defra also highlighted that:

> "The qualifying GM plants, covered by this SI do not pose a greater risk to human health or to the environment than their traditionally bred counterparts. We have more than thirty years of experience of GM field trials in England and none of these have affected commercial crops or the wider environment."

20. Asked about who would be liable for any potential environmental or economic damage following the release of qualifying higher plants, Defra told us that:

> "On the basis of the scientific advice provided to us by ACRE we do not believe that field trials involving these qualifying higher plants will lead to any more risk of environmental or economic damage than traditionally bred plants would. ACRE's view is that an organism produced by gene-editing, or another genetic technology would not pose a greater safety risk than a traditionally bred or naturally occurring version of that organism, as a result of how it was produced."

21. Defra added that:

> "[R]esponsibility to follow all regulations is on the developer or whoever is releasing a GMO/GE. If they do not and there is subsequent economic or environmental impact it is likely that they would bear responsibility for it, but obviously this would have to be proven by the claimant."

22. We also asked whether, in the context of public concerns about GMOs, a lack of clarity as to what constitutes qualifying higher plants and the lack

of safeguards risk undermining trust in the research community in this sensitive area, a concern raised by Beyond GM. Defra responded that:

> "ACRE is in the process of developing non-statutory guidance for developers […]. Additionally, established Safeguards already exist based on the risk posed by these plants at the development stage in laboratory glasshouses, where they will be fully assessed under contained use rules. This includes approval of the safe working systems within the laboratory by the competent authority (jointly HSE/Defra). Therefore, we do not think this will affect the trust in the research community."

23. Defra says that it will "monitor and review the impact of the instrument as part of its standard policymaking procedures and ensure that the provisions are adhered to". **Given the public interest in the new rules and that they rely on self-declaration, the Department should consider conducting and publishing an evaluation of the practical application of the new rules and of any environmental or economic damage, to inform the wider reforms that the Government intend to take forward in this area.**

Devolution

24. The new rules only apply to England. We asked the Department about the views of the Devolved Administrations (DAs) and whether it was concerned about a different regulatory approach in different parts of the UK, an issue raised by OF&G. Defra responded that:

> "We have engaged with the DAs to establish whether there was appetite to make corresponding changes in respect to Scotland and Wales. This included ministerial engagement at the Inter-Ministerial Group [Environment, Food and Rural Affairs] meetings in June and September. Our [Secretary of State] also wrote to DA ministers after the release of the Government Response clearly stating our intention to bring forward [a statutory instrument] on GE plant research and development. Welsh Government and Scottish Government have made clear that they do not currently wish to pursue equivalent changes in Scotland and Wales. […] this regulatory divergence should not cause any issues for researchers, developers or the public."

25. **We note the Department's response but remain concerned about what the new rules in England will mean for collaboration between researchers in different parts of the UK**.

Consultation

26. Defra conducted a public consultation from 7 January to 17 March 2021 to seek views on whether the products of genetic technologies should continue to be regulated as GMOs if they could have been produced by traditional breeding methods, and on longer-term reform of legislation governing GMOs. The consultation received 6,440 responses,[5] of which the Department attributed 3,904 to a coordinated campaign. While 55% of public sector bodies and 58% of academic institutions supported the Government's approach, most

5 Defra, 'Genetic technologies regulation: government response': https://www.gov.uk/government/consultations/genetic-technologies-regulation/outcome/genetic-technologies-regulation-government-response [accessed 8 February 2022].

individuals (88%) and businesses (64%) who responded were opposed. Non-governmental organisations (NGOs) were evenly split (50%).

27. The Department concludes that the consultation did not receive any scientific evidence indicating that GE organisms should be regulated as GMOs; and that a number of responses expressed the view that GMOs are demonstrably different to the products of gene editing. In its submission, Beyond GM criticised this conclusion, arguing that "Responses from all sides of the spectrum gave scientific perspectives–backed up by evidence–that gene edited organisms should continue to be regulated as GMOs", adding that the EM "fails to reveal […] the extent to which scientific opinion on all sides of the spectrum questioned and criticised the scientific basis of Defra's proposals".

28. Asked about this criticism, Defra responded that:

> "The consultation, which included views from scientific experts including ACRE and the Royal Society, received no new scientific evidence indicating that gene edited organisms should be regulated as GMOs. The ACRE advice on the consultation[6] was supported by the Royal Society which stated that "genome editing is likely to involve fewer such changes than traditional breeding techniques" and that "these are no more likely to pose a risk to human health or the environment than non-editing derived mutations, which occur spontaneously in each new generation".[7]
>
> Defra did receive responses which questioned the scientific basis of some aspects of our proposal. For example, concerns were expressed that Defra had failed to define or scientifically document what was meant by the term "could have been produced by traditional breeding". The independent Advisory Committee on Releases to the Environment (ACRE) addressed this question in their advice on the consultation. They said: "Traditional breeding relies on the dynamic nature of genetic material and makes use of a range of genetic changes, including major structural variations which occur naturally within species and their close relatives that are used in breeding programmes. Examples of these are exchanges, rearrangements and duplications of extensive stretches of DNA containing potentially hundreds of genes that have taken place during breeding for disease resistance in tomato and wheat and during the domestication of peach varieties."[8]
>
> Some respondents also questioned the assertion that gene editing techniques can be targeted more precisely, countering that, like GM, the process can involve random events potentially leading to unanticipated or off-target effects. In response to the question regarding unanticipated

6 ACRE, 'ACRE advice concerning Defra's consultation on the regulation of genetic technologies': https://www.gov.uk/government/publications/acre-advice-the-regulation-of-genetic-technologies/acre-advice-concerning-defras-consultation-on-the-regulation-of-genetic-technologies [accessed 8 February 2022].

7 Defra, 'Genetic technologies regulation: government response': https://www.gov.uk/government/publications/acre-advice-the-regulation-of-genetic-technologies/acre-advice-concerning-defras-consultation-on-the-regulation-of-genetic-technologies [accessed 8 February 2022].

8 ACRE, 'ACRE advice concerning Defra's consultation on the regulation of genetic technologies': https://www.gov.uk/government/publications/acre-advice-the-regulation-of-genetic-technologies/acre-advice-concerning-defras-consultation-on-the-regulation-of-genetic-technologies [accessed 8 February 2022].

or off-target effects, ACRE has stated that where gene editing introduces genetic alterations and combinations that are of the type that are selected for in traditional breeding, any associated health and environmental risks would be comparable.

All concerns that were raised have been considered as part of Defra's step by step policy development process to develop a science-based proportionate approach to the regulation of gene edited organisms."

29. Defra added that consumer research published by the Food Standards Agency in July 2021[9] found that "after being informed about GE [Genome Editing], 57% of participants were 'not at all' or 'not very concerned' about GE. Consumers tended to find genome edited food more acceptable than GM food, typically because they perceived it as safer and more natural."

Use of secondary legislation

30. This instrument proposes a change in policy and regulation away from the current approach in retained EU law. Beyond GM argued that the "fundamental and far-reaching redefinition" of GMOs should have been taken forward through primary, rather than secondary legislation. The critical submissions we received, and the number of consultation responses indicate a significant interest amongst producers, consumers and the wider public in the issues. We therefore asked the Department whether it would have been more appropriate to take forward the policy changes through primary, rather than secondary legislation, thereby allowing for greater transparency and more robust scrutiny. Defra responded that:

"The public consultation on genetic technologies enabled Defra officials to capture the views of a wide range of individuals and organisations. We received a total of 6,440 responses (including ~3,900 campaign responses) with contributions from individuals, businesses, NGOs, academia, scientific community and public sector bodies. Respondents shared a wide variety of views with varying degrees of support for gene editing technologies. We considered all these views in establishing our approach.

After considering the wide range of views captured in the consultation, we outlined in the Government Response to the Consultation that we will be taking a cautious step-by-step approach.

The SI is our first step, which will focus on freeing up research on plants to enable scientists to develop our knowledge base and drive innovation in farming. Research scientists will be able to carry out field trials more easily for plants produced by genetic technologies where the resulting genetic changes could have been developed using traditional breeding methods.

We want to make changes carefully. Research scientists will continue to be required to notify Defra of these plant research trials. The commercial cultivation of these plants, and any food products derived from them, will still need to be authorised in accordance with existing GMO rules.

9 Food Standards Agency, 'Consumer perceptions of genome edited food': https://www.food.gov.uk/research/research-projects/consumer-perceptions-of-genome-edited-food [accessed 8 February 2022].

> Our next step will be to review the regulatory definitions of a GMO to exclude organisms produced by gene editing and other genetic technologies if they could have been developed by traditional breeding. We will also consider the appropriate measures needed to enable gene edited products to be brought to market. This will be followed by a review of our approach to GMO regulation more broadly."

31. In our recent report, *Government by Diktat: A call to return power to Parliament*, we expressed our concern about the use of secondary legislation to make significant policy change.[10] We said: "It cannot be emphasised strongly enough that the critical problem about relegating significant policy change to secondary legislation is that parliamentary scrutiny of secondary legislation is far less robust than that afforded to primary legislation" (paragraph 18). And we set out the three ways in which it is less robust: it cannot be amended so the Houses have only an "all or nothing" choice; it is not subject to line-by-line scrutiny, with hours and days of consideration in each House; and, rejection of secondary legislation is very rare, with the legacy of the Strathclyde Review still casting a shadow.

32. We share the view of the Delegated Powers and Regulatory Reform Committee, set out in its report, *Democracy Denied? The urgent need to rebalance power between Parliament and the Executive*,[11] in its revised Guidance to Departments, that "[t]he appropriate threshold between primary and secondary legislation should … be founded on the overarching principle that the principal aspects of policy should be on the face of a bill and only its detailed implementation left to delegated legislation" (page 57). **Given the interest in, and concerns about, policy relating to GMOs, including in the House during the passage of the Agriculture Bill, and the number of issues that this instrument in particular has raised, in part caused by the absence of the associated guidance, we see strength in the argument that primary, rather than secondary, legislation would have been more appropriate in this case**.

Conclusion

33. The intention is for the changes proposed by this instrument to be a first step of a wider reform programme. The proposals are of significant public interest, as indicated by critical submissions we have received and the large number of consultation responses. With guidance on the new rules still under development, the draft Regulations raise questions about the practical implementation of the policy, including how qualifying higher plants will be assessed, the reliance of self-declaration and the absence of prescribed safeguards and containment measures. These are issues which the House may wish to explore further with the Minister. **The draft Regulations are drawn to the special attention of the House on the ground that they are politically or legally important and give rise to issues of public policy likely to be of interest to the House.**

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10 SLSC, 20th Report (Session 2021–22, HL Paper 105).

11 Delegated Powers and Regulatory Reform Committee, 12th Report (Session 2021–22, HL Paper 106).

INSTRUMENTS RELATING TO COVID-19

Restrictions on businesses and public gatherings

Health Protection (Coronavirus, Restrictions) (Self-Isolation) (England) (Amendment) Regulations 2022 (SI 2022/72)

34. The changes made by this instrument are intended to provide a consistent definition of "fully vaccinated" across the Self-Isolation Regulations[12] and the International Travel Regulations.[13] They mean that in England a person who has been vaccinated outside the UK will be exempt from the requirement to self-isolate if identified as a close contact of a positive COVID-19 case if their vaccine status satisfies the International Travel Rules.

35. The changes also update the Self-Isolation Regulations to specify the evidence required for a person to demonstrate that they are medically unable to be vaccinated and therefore exempt from self-isolation requirements.

36. These Regulations reinstate the position set out in the No 5 Regulations[14] which came into effect on 9 December 2021 but lapsed, due to an error, on 25 January 2022. These replacement Regulations took effect on 27 January: during the brief interruption those who failed to self-isolate were at risk of being treated as having committed an offence. **This is not good practice, and we trust it will not recur.**

Changes to business practice and regulations

Draft Airports Slot Allocation (Alleviation of Usage Requirements) Regulations 2022

37. An airport 'slot' is permission to use all necessary airport infrastructure to operate an aircraft at a specified date and time for take-off or landing. Normally, an airline has to use at least 80% of its slots in the preceding season (either winter or summer) to be entitled to the same slots in the next equivalent season. To address the persistent reduction in air traffic during the COVID-19 pandemic, these provisions have been waived or reduced.

38. The usage rate is now being increased incrementally as the sector recovers. This instrument amends the airport slot usage rule to 70% for the summer 2022 season (which will affect reallocation of the same slots for summer 2023.) It also adds certain government-imposed measures related to COVID-19 (which severely reduce the viability of or demand for travel on the route in question) to the list of reasons under which under-usage can be justified. The Explanatory Memorandum (EM) states that these relief measures are designed to assist airlines which might otherwise have to bear the costs of operating near-empty aircraft in order to retain their slots. We note that, in response to the consultation, airlines preferred a 60% usage rule whereas most airports preferred the 70% rate. The rationale given in the EM for choosing the higher figure was rather abstract and the House may wish to press the Minister for a clearer explanation of why the higher threshold was chosen, which treats the airlines less favourably.

12 Health Protection (Coronavirus, Restrictions) (Self-Isolation) (England) Regulations 2020 (S.I. 2020/1045).

13 Health Protection (Coronavirus, International Travel and Operator Liability) (England) Regulations 2021 (S.I. 2021/582).

14 Health Protection (Coronavirus, Restrictions) (Self-Isolation) (England) (Amendment) (No. 5) Regulations 2021 (S.I. 2021/1382).

INSTRUMENTS OF INTEREST

Draft Civil Enforcement of Road Traffic Contraventions (Representations and Appeals) (England) Regulations 2022

Civil Enforcement of Road Traffic Contraventions (Approved Devices, Charging Guidelines and General Provisions) (England) Regulations 2022 (SI 2022/71)

39. These Regulations provide for the civil enforcement of:

- parking contraventions throughout England, and
- bus lane contraventions, and moving traffic contraventions, in England but outside Greater London (which has been operating this system since 2003).

40. To free up police officers' time, these Regulations extend the range of offences that can be dealt with by civil enforcement officers acting on behalf of local authorities, or in some cases traffic cameras. From 31 May 2022, as well as parking offences, civil enforcement officers will be able to deal with moving traffic offences, such as ignoring no entry signs, performing banned turns, waiting on box junctions and driving in mandatory cycle lanes. The legislation also adds penalties for buses driving in prohibited areas, and sets out a uniform regime for all these offences of differential penalty charges, with certain discount and surcharge periods. The draft affirmative instrument similarly makes the appeal system consistent, strengthening the appeal rights for moving traffic offences, so motorists may now appeal penalties issued for any of these offences on the grounds of procedural impropriety or "compelling reasons".

Draft Cumbria (Structural Changes) Order 2022

Draft North Yorkshire (Structural Changes) Order 2022

Draft Somerset (Structural Changes) Order 2022

41. These three sets of draft Orders give effect, from 1 April 2023, to the creation of single tiers of local government for Cumbria, where there will be two new unitary councils, called Cumberland, and Westmorland and Furness, and North Yorkshire and Somerset, which will become single principal authorities for the whole of North Yorkshire and Somerset respectively. The draft Orders propose arrangements for preparing the transition to the new councils, including with regard to elections. The Department for Levelling Up, Housing and Communities (DLUHC) says that for Cumbria, further secondary legislation will be brought forward once a decision has been made on the future arrangements for the Cumbria Fire and Rescue Service which, without further legislation, would have to be divided between the two new unitary authorities. The Government intend to maintain a fire service on a county-wide basis, subject to local consultation on the available options.

42. The Explanatory Memoranda (EMs) set out the feedback received during consultation on the different unitarisation proposals. **We note that while unitarisation should, according to the Government, be "locally led" and "command a good deal of local support", the EMs show that not all chosen proposals received majority support from local residents during consultation. In Cumbria, for example, the only proposal**

("The Bay") to receive support from a majority of local respondents was not taken forward. Asked about this consultation feedback, DLUHC explained that:

> "The support criterion, that a proposal should have a good deal of support, is not a criterion about which proposal has the majority support of a particular group of stakeholders. First, it is about the views from all stakeholders–residents, local businesses, the voluntary sector, other public service providers. Second, it is quite possible, as in the case of Cumbria, that more than one proposal can have good deal of support. As explained in paragraph 7.5 of the Explanatory Memorandum to the Cumbria Order, the Secretary of State considered that the proposal for an East-West unitary met all three assessment criteria; The Bay proposal […] did not meet the criteria on 'improving local government and service delivery' and 'being a credible geography'".

43. Similarly, the Department said that in relation to Somerset "the Secretary of State considered that the proposal for a single unitary met all three criteria and the proposal for two unitaries met the criterion for a good deal of support, but it did not meet the criteria on 'improving local government' and 'being a credible geography'".

44. **We note the three criteria. Given the Government's commitment to unitarisation being "locally-led", however, it is not clear whether or how the three criteria are prioritised. The House may wish to ask the Minister to explain how the criteria are applied and, in particular, on what basis unitarisation is permitted to go ahead even if public consultation suggests that a proposal may not enjoy genuine widespread support from local residents.**

Draft Early Legal Advice Pilot Scheme Order 2022

45. The post-implementation review of the Legal Aid, Sentencing and Punishment of Offenders Act 2012 found that, while the changes had succeeded in reducing legal aid spend generally, clients with housing issues might have resolved their issues prior to formal proceedings if they had received legal advice at an earlier stage. This Order is to enable a pilot scheme to test this theory further and to inform future policy. The outcome will be published in due course.

46. The proposal is at a very early stage, following a feasibility study, the Ministry of Justice intends to run the pilot scheme from 1 April 2022 to 31 March 2024 involving 1,600 individuals living or habitually resident in the area of Manchester City Council or of Middlesbrough Council. Half the individuals selected to take part in the pilot scheme will receive up to three hours early advice on housing, debt, and welfare benefits issues, the other half will form a control group. (The advice does not include representation.) The Order also establishes a fee for legal advisers, which is comparable to existing fees but includes an uplift to account for the additional reporting that providers will be asked to undertake. Further details on the proposed structure of the pilot are published in Appendix 2.

Draft Flood Reinsurance (Amendment) Regulations 2022

47. These draft Regulations propose changes to the Flood Reinsurance Scheme ("the FR Scheme") to improve its efficiency and effectiveness and to promote

the uptake of property flood resilience measures in households. The current FR Scheme was launched in 2016 to provide reinsurance to insurers for risks to household properties arising from a flood and to promote the availability and affordability of flood insurance for UK households. The FR Scheme is time-limited until 2039. Its liability limit was set in April 2016 at £2.1 billion (with increases in line with the Consumer Price Index) for an initial period of five years; future liability limits will be set every three years.

48. Under the new arrangements, claims can be paid so that they include an amount of resilient repair up to a value of £10,000 over and above the cost of like-for-like reinstatement of actual flood damage. According to the Department for Environment, Food and Rural Affairs (Defra), this is to enable homeowners to return to their homes more quickly following a flood and reduce the cost of future claims. The draft Regulations also propose to reduce the levy from £180 million to £135 million. The levy is the FR Scheme's primary income and is raised from UK household insurers based on their market share. Asked why it was possible to reduce the levy at this stage, Defra explained that:

> "Flood Re [the FR Scheme] have met their initial liquidity and capital requirements and have a high solvency ratio, meaning that the Scheme is financially secure. Government and Flood Re consider it important that the levy setting cycle is now made more flexible so that it can better reflect the true income needs of the Scheme, as well as ensuring it can adapt more quickly to changing risk levels. This will also allow Flood Re to obtain better value for money in purchasing reinsurance, to be more dynamic to their needs and potentially changing risk profile and ensure the total levy (a form of tax) is not higher than it needs to be. […] We have consulted the Government Actuary Department (GAD) who agree that £135m is suitable and well within the risk appetite of Flood Re. […] Careful consideration has been given to assure ourselves that Flood Re has enough funds to cover any losses as a result of a major flood event. […] The new levy amount will result in lower levy payment for relevant insurers."

Draft Goods Vehicles (Licensing of Operators) (Amendment) Regulations 2022

49. From 21 May 2022, new EU Regulations[15] require the licensing of operators who carry goods for hire or reward using a Light Goods Vehicle (a goods vehicle exceeding 2.5 tonnes in mass when laden). Currently such licensing only applies to Heavy Goods Vehicles (HGVs - which exceed 3.5 tonnes in mass when laden). The UK-EU Trade and Cooperation Agreement obliges the UK to implement these requirements for UK vehicles taking goods to the EU. These Regulations therefore set out the revised licensing arrangements which will apply to around 4,200 Light Goods Vehicle operators in the UK. For convenience and with the consent of the relevant Minister, these Regulations also implement the legislation in Northern Ireland.

50. Operators may apply to have one or more Light Goods Vehicles added to a pre-existing HGVs licence, but a separate licence will be required for those who only operate Light Goods Vehicles (at an initial cost of £658 for five years). All licensed operators must appoint at least one Transport Manager to organise work scheduling, driver rest and vehicle maintenance. A three-

15 Regulation (EU) 2020/1055.

year transitional exemption is allowed for Transport Managers who do not already hold a certificate of professional competence, so that they can keep working while studying to qualify. This transitional exemption will apply to anyone who can demonstrate that they have been managing fleets of Light Goods Vehicles for at least 10 years prior to 20 August 2020. The EU Regulations also limit an international Transport Manager to working for no more than four operators and with no more than 50 specified vehicles (although this figure does not include any vehicles that they manage which operate solely within the UK).

Road Vehicles (Construction and Use) (Amendment) Regulations 2022 (SI 2022/59)

51. This instrument allows the fitment and use of elongated cabs and aerodynamic devices on heavy goods vehicles (HGVs) on the roads in Great Britain. Improved aerodynamic performance can reduce HGVs' CO_2 emissions and fuel consumption. In addition, the elongated cabs are designed to improve driver visibility, making their use safer for other road users. EU legislation to permit this change was passed in 2015[16] but only came into effect from 6 December 2019. The Department for Transport (DfT) says that due to the pressure on parliamentary time, it was not possible to implement the change before Brexit. DfT will publish good practice guidance on the use of rear aerodynamic devices in urban areas on the gov.uk website on 14 February 2022 which will recommend that such devices are folded away in built up areas. Although the overall length of HGVs may be increased by extending the cab, the loading length may not be altered, and these vehicles will still need to meet the turning circle rules.

Statement of Changes in Immigration Rules (HC1019)

52. This instrument amends the Immigration Rules, to add care workers to the Shortage Occupation List, and make the role eligible for the Skilled Worker route. The Skilled Worker route is for applicants with a specific job offer from an approved sponsoring employer, and the salary offered must be at least £20,480 per year or £10.10 per hour whichever is the higher. The changes do not, however, include home carers employed by private individuals, who will be seeking to recruit carers from the same labour market, and may be disadvantaged by the change.

53. These changes also disapply the usual requirement that a role must be skilled to at least Regulated Qualification Framework (RQF) level 3 (approximately A level). Applicants do not need to hold a formal qualification; it is the skill level of the job they will be doing which determines whether the threshold is met. The Home Office states that these changes are aimed at helping to alleviate current pressures on the health and social care system as a result of COVID-19; there is no quota set for the number of these applicants to be admitted. The Home Office explains that no Impact Assessment (IA) has been provided because the legislation responds to an interim recommendation of the Migration Advisory Committee, which will not publish its final recommendations until the end of April 2022. **We are concerned that these measures may be premature because without an IA the precise effects on the labour market will not have been fully identified.**

16 Directive (EU) 2015/719(4).

INSTRUMENTS NOT DRAWN TO THE SPECIAL ATTENTION OF THE HOUSE

Draft instruments subject to affirmative approval

Draft	Airports Slot Allocation (Alleviation of Usage Requirements) Regulations 2022
Draft	Civil Enforcement of Road Traffic Contraventions (Representations and Appeals) (England) Regulations 2022
Draft	Cumbria (Structural Changes) Order 2022
Draft	Early Legal Advice Pilot Scheme Order 2022
Draft	Flood Reinsurance (Amendment) Regulations 2022
Draft	Goods Vehicles (Licensing of Operators) (Amendment) Regulations 2022
Draft	Scotland Act 2016 (Social Security) Adult Disability Payment and Child Disability Payment Amendment) Regulations 2022
Draft	Somerset (Structural Changes) Order 2022
Draft	North Yorkshire (Structural Changes) Order 2022

Made instruments subject to affirmative approval

SI 2022/72	Health Protection (Coronavirus, Restrictions) (Self-Isolation) (England) (Amendment) Regulations 2022

Instruments subject to annulment

SI 2022/57	Education (Student Fees, Awards and Support) (Amendment) Regulations 2022
SI 2022/59	Road Vehicles (Construction and Use) (Amendment) Regulations 2022
SI 2022/60	Universal Credit and Employment and Support Allowance (Claimant Commitment Exceptions) (Amendment) Regulations 2022
SI 2022/62	Carbon Accounting (Provision for 2020) Regulations 2022
SI 2022/65	Afghanistan (Sanctions) (EU Exit) (Amendment) Regulations 2022
SI 2022/71	Civil Enforcement of Road Traffic Contraventions (Approved Devices, Charging Guidelines and General Provisions) (England) Regulations 2022
SI 2022/82	European Qualifications (Health and Social Care Professions) (Amendment etc.) (EU Exit) Regulations 2022
HC1019	Statement of Changes in Immigration Rules

APPENDIX 1: ADDITIONAL INFORMATION FROM THE DEPARTMENT FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS ON THE DRAFT GENETICALLY MODIFIED ORGANISMS (DELIBERATE RELEASE) (AMENDMENT) (ENGLAND) REGULATIONS 2022

Lack of clarity and definition

The Department's summary of responses to the consultation indicates significant uncertainty about the criteria that should be used to determine which genetic changes could have occurred naturally or by any of the techniques used in traditional breeding as listed in 5(2) of the Genetically Modified Organisms (Deliberate Release) Regulations 2002.

Q1: Is there an established scientific view on what constitutes genetic changes that could have occurred naturally and how such changes can be assessed?

A1: Defra has sought expert scientific advice from its independent Advisory Committee on Releases to the Environment (ACRE). An established evidence-based scientific view, supported by ACRE is that the composition of genetic material between individual organisms of the same species is subject to high levels of natural variation and selection. Genetic changes, which can occur in nature, arise from a variety of biological factors such as natural recombination during sexual fertilisation and spontaneous mutations. Naturally occurring genetic changes include point mutations affecting a single nucleic acid base pair and insertions, deletions and rearrangements of different sized fragments of DNA. These naturally occurring mutations can also include larger changes such as the movement of whole segments of chromosome to a different part of the genome. Transposable elements (or jumping genes) are also responsible for a significant proportion of naturally occurring genetic variation

The assessment of genetic changes that have been made to an organism, for example by gene-editing, is carried out by researchers using a variety of well-established approaches. Whole genome sequencing is perhaps the most comprehensive method since it has the potential to document the entire genetic make-up of the edited genome. Other methods of analysis include quantitative PCR and Southern blotting which are used to confirm that the intended genetic changes have been introduced and are stable.

Q2: Will there be scientific and regulatory criteria to determine whether a genetic change could have occurred naturally? When will these be published?

A2: ACRE is in the process of developing guidance for developers to determine if the genetic change could have occurred naturally or by using one of the techniques in the Genetically Modified Organisms (Deliberate Release) Regulations 2002 5(2). The guidance will be available shortly.

Q3: If there are no such criteria, how will determinations be made whether a genetic change could have occurred naturally?

A3: As referenced in Q2 guidance on the regulatory criteria will be made available.

Q4: In the absence of such criteria, how can the new system be managed in a consistent way? How can the Department ensure that the same standards are applied when qualifying higher plans are released by different organisations?

A4: As referenced above guidance on the regulatory criteria will be made available.

Safeguards

Under the current rules, a risk assessment and consent by the Secretary of State are required before any GMOs may be released. The instrument removes these requirements for qualifying higher plants.

Q5: With the system moving to notification of the Secretary of State–will the Department simply rely on organisations self-declaring any releases? Is this a sufficiently robust approach given the potential risk of environmental or economic damage?

A5: For GM plant research and development, where the changes could have been produced by traditional breeding methods, we will be moving to a self-declaration system. This approach is informed by advice from ACRE our independent scientific advisers and is more in step with approaches developed using traditional breeding methods. ACRE's view is that an organism produced by gene-editing, or another genetic technology would not pose a greater safety risk than a traditionally bred or naturally occurring version of that organism, as a result of how it was produced. Researchers will still be required to notify Defra of these trials and commercial cultivation of these plants, food and animal feed derived from them will still need to be authorised in accordance with existing GM rules.

Q6: What safeguards and containment measures will there be to ensure that the non-marketing release of qualifying higher plans does not lead to the escape of pollen, seed and other plant material capable of reproduction, potentially leading to the contamination of conventional or organic crops of the same, or a closely related species? Such contamination could lead to lost business, the loss of organic status and legal action and therefore to significant environmental and economic damage.

A6: This SI will allow plants produced using genetic technologies that produce changes that could have occurred through traditional breeding, to be treated in the same way as their traditionally bred counterparts at the field trial stage. Underpinning this approach is the key principle that it is the final characteristics of an organism which determine whether it presents any safety risks, regardless of the method used to produce that organism. ACRE's view is that where GE introduces genetic alterations and combinations that are of the type that are selected for in traditional breeding, the environmental release of these organisms should not be regulated in the same way as the environmental release of genetically modified organisms (GMOs).

However, as GM plant material cannot be marketed without being authorised, researchers carrying out field trials that could lead to the marketing of the plant material (either directly or indirectly) may need to put measures in place to minimise gene flow to any sexually compatible commercial crops in the vicinity and/or minimise persistence of reproductive material at the site if there is the possibility of material entering the human food or animal feed chain. Any measures will depend on the plant species involved and on the characteristics of the trial site. Defra will not be specifying these measures; it will be the responsibility of researchers to abide by the law and gain authorisation for GM plants that are grown, or if material from them is present, in commercial products.

Q7: Who would be liable for any potential environmental or economic damage following the release of qualifying higher plants?

A7: On the basis of the scientific advice provided to us by ACRE[17] we do not believe that field trials involving these qualifying higher plants will lead to any more risk of environmental or economic damage than traditionally bred plants would. ACRE's view is that an organism produced by gene-editing, or another genetic technology would not pose a greater safety risk than a traditionally bred or naturally occurring version of that organism, as a result of how it was produced.

[T]he responsibility to follow all regulations is on the developer or whoever is releasing a GMO/GE. If they do not and there is subsequent economic or environmental impact it is likely that they would bear responsibility for it, but obviously this would have to be proven by the claimant.

Q8: The instrument establishes a notification requirement for the release of the qualifying higher plants, but the information that must be notified to the Secretary of State for each release (set out in a new Schedule 3A) does not include the location or scale of any release, or details of the containment measures that will be employed to ensure that the GMOs do not affect either commercial crops or the wider environment. How can the Department be sure that adequate containment measures have been put in place?

A8: The qualifying GM plants, covered by this SI do not pose a greater risk to human health or to the environment than their traditionally bred counterparts. We have more than thirty years of experience of GM field trials in England and none of these have affected commercial crops or the wider environment.

Q9: The instrument removes restrictions in "all cases and circumstances in which a person intends to release a qualifying higher plant, other than those in relation to the marketing of such qualifying higher plants". What does "all cases and circumstances" mean in practice, and does such an open provision present a risk that the provision will be abused?

A9: As per the Environmental Protection Act 1990, anyone wanting to import, acquire, release or market any GMOs has to be granted consent from the Secretary of State. In practice, this Statutory Instrument removes the need for consent if they want to release such plants (or import/acquire them for the purposes of such release) for research and development purposes, providing such plants could have been produced by traditional breeding methods. This provision ensures research and development can happen more easily. Anyone wanting to market these plants will need to abide by the established GMO regulations, including obtaining consent from the Secretary of State, therefore we think there is no more risk of abuse with these provisions than currently exists.

Q10: Given public concerns about GMOs, does the lack of clarity as to what constitutes qualifying higher plants and the lack of safeguards risk undermining trust in the research community in this sensitive area?

A10: As stated above, ACRE is in the process of developing non-statutory guidance for developers to determine if the genetic change could have occurred naturally or by using one of the techniques listed in the Genetically Modified Organisms (Deliberate Release) Regulations 2002 regulation 5(2).

17 ACRE, 'ACRE advice concerning Defra's consultation on the regulation of genetic technologies'; https://www.gov.uk/government/publications/acre-advice-the-regulation-of-genetic-technologies/acre-advice-concerning-defras-consultation-on-the-regulation-of-genetic-technologies [accessed 8 February 2022].

Additionally, established Safeguards already exist based on the risk posed by these plants at the development stage in laboratory glasshouses, where they will be fully assessed under contained use rules. This includes approval of the safe working systems within the laboratory by the competent authority (jointly HSE/Defra). Therefore, we do not think this will affect the trust in the research community.

Use of secondary legislation

Q11: This instrument proposes a significant shift in policy and regulation away from the current approach in domestic and EU law. The number of consultation responses indicates a significant interest amongst producers, consumers and the wider public in the issues. In the interest of transparency and robust scrutiny, would it have been more appropriate to take forward such a shift in policy through primary, rather than secondary legislation?

A11: The public consultation on genetic technologies enabled Defra officials to capture the views of a wide range of individuals and organisations. We received a total of 6,440 responses (including ~3,900 campaign responses) with contributions from individuals, businesses, NGOs, academia, scientific community and public sector bodies. Respondents shared a wide variety of views with varying degrees of support for gene editing technologies. We considered all these views in establishing our approach.

After considering the wide range of views captured in the consultation, we outlined in the Government Response to the Consultation[18] that we will be taking a cautious step-by-step approach.

The SI is our first step, which will focus on freeing up research on plants to enable scientists to develop our knowledge base and drive innovation in farming. Research scientists will be able to carry out field trials more easily for plants produced by genetic technologies where the resulting genetic changes could have been developed using traditional breeding methods.

We want to make changes carefully. Research scientists will continue to be required to notify Defra of these plant research trials. The commercial cultivation of these plants, and any food products derived from them, will still need to be authorised in accordance with existing GMO rules.

Our next step will be to review the regulatory definitions of a GMO to exclude organisms produced by gene editing and other genetic technologies if they could have been developed by traditional breeding. We will also consider the appropriate measures needed to enable gene edited products to be brought to market. This will be followed by a review of our approach to GMO regulation more broadly.

Devolved Administrations

Q12: The EM states that the changes apply to England only. Were the Devolved Administration consulted and if so, what is the position of the Devolved Administrations in Scotland and Wales to these changes?

A12: The Scottish Government and Welsh Government have both expressed their desire to make no changes to the current GMO regulations.

Q13: Were the Devolved Administration consulted?

18 Defra, 'Genetic technologies regulation: government response': https://www.gov.uk/government/consultations/genetic-technologies-regulation/outcome/genetic-technologies-regulation-government-response [accessed 8 February 2022].

A13: We have engaged with the DAs to establish whether there was appetite to make corresponding changes in respect to Scotland and Wales. This included ministerial engagement at the Inter-Ministerial Group (IMG) Efra meetings in June and September. Our SoS also wrote to DA ministers after the release of the Government Response clearly stating our intention to bring forward an SI on GE plant research and development.

Welsh Government and Scottish Government have made clear that they do not currently wish to pursue equivalent changes in Scotland and Wales. Consequently, the territorial application of this SI is England only.

Q14: Will they make equivalent changes and, if not, does the Department have concerns about a different regulatory approach in different parts of the UK?

A14: the DAs will not be making an equivalent regulatory change in their jurisdictions, this regulatory divergence should not cause any issues for researchers, developers or the public.

Relationship with the EU

Q15: Will the changes put the renegotiation of the current organic equivalency agreement embedded in the UK/EU TCA by December 2023 at risk due to the regulatory divergence?

A15: These products would still have to undergo a full GMO authorisation process under the EU regime before being placed on the EU market, therefore we do not anticipate these changes on research and development will have any implications in negotiating any new trade agreements, nor in renegotiations. In our government response we indicated that we will be considering the impacts and opportunities for trade. We will continue to monitor EU policy in this area and any impacts where these arise.

Q16: Is it correct that EU law on this issue is currently being reviewed?

A16: The European Commission's recent 'Study on the status of new genomic techniques (NGTs)' can be accessed following this link[19]. It 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 has now committed to run a public consultation on the legislation for plants produced by new genetic technologies in Q2 2022, with the aim to develop a new legal framework for Q2 2023.[20]

Impact

Q17: Could you provide a copy of the Regulatory Triage Assessment?

A17: The Impact Assessment has been published on the legislation.gov website and can be accessed through the following link: https://www.legislation.gov.uk/ukia/2021/94 .

Q18: The EM states that there is no, or no significant, impact on business, charities, or voluntary bodies and that the instrument will reduce overall cost to business.

19 European Commission, 'EC study on new genomic techniques': https://ec.europa.eu/food/plants/genetically-modified-organisms/new-techniques-biotechnology/ec-study-new-genomic-techniques_en [accessed 8 February 2022].

20 World Trade Organisation, *The European Commission Study on the Status of New Genomic Techniques in the European Union* (12 July 2021): https://ec.europa.eu/food/system/files/2021–07/wto-sps_20210715_eu-statement_ngt.pdf [accessed 8 February 2022].

Which business sectors were considered or consulted to reach this conclusion? For example, was the organic sector included in the assessment?

A18: In January 2021, Defra held a public consultation to gather views on the regulation of genetic technologies in England. The public consultation enabled Defra officials to capture the views of a wide range of individuals and organisations. Following on from the consultation, Defra has continued to engage with interested parties including developers, farmers, environmental NGOs, organics and agri-businesses. These conversations have and will continue to feed into our policy narrative, to provide the best possible assessments of business impact.

The SI reduces the regulatory burden imposed on field trials for the purposes of research and development. The commercial cultivation of these plants and any food or animal feed products derived from them will still need to be authorised in accordance with existing GMO rules. As a result, implementation of the SI was assessed as having no additional impact on businesses other than those directly participating in plant development trials.

Consultation

Q19: The EM states that: "The consultation received no scientific evidence indicating that gene edited organisms should be regulated as GMOs". Does this fail to reveal the extent to which the scientific basis of Defra's proposals was questioned and criticised during consultation?

A19: The consultation, which included views from scientific experts including ACRE and the Royal Society, received no new scientific evidence indicating that gene edited organisms should be regulated as GMOs. The ACRE advice on the consultation[21] was supported by the Royal Society which stated that "genome editing is likely to involve fewer such changes than traditional breeding techniques" and that "these are no more likely to pose a risk to human health or the environment than non-editing derived mutations, which occur spontaneously in each new generation"[22].

Defra did receive responses which questioned the scientific basis of some aspects of our proposal. For example, concerns were expressed that Defra had failed to define or scientifically document what was meant by the term "could have been produced by traditional breeding". The independent Advisory Committee on Releases to the Environment (ACRE) addressed this question in their advice on the consultation. They said: "Traditional breeding relies on the dynamic nature of genetic material and makes use of a range of genetic changes, including major structural variations which occur naturally within species and their close relatives that are used in breeding programmes. Examples of these are exchanges, rearrangements and duplications of extensive stretches of DNA containing potentially hundreds of genes that have taken place during breeding for disease resistance in tomato and wheat and during the domestication of peach varieties."[23]

21 ACRE, 'ACRE advice concerning Defra's consultation on the regulation of genetic technologies': https://www.gov.uk/government/publications/acre-advice-the-regulation-of-genetic-technologies/acre-advice-concerning-defras-consultation-on-the-regulation-of-genetic-technologies [accessed 8 February 2022].

22 Defra, 'Genetic technologies regulation: government response': https://www.gov.uk/government/consultations/genetic-technologies-regulation/outcome/genetic-technologies-regulation-government-response [accessed 8 February 2022].

23 ACRE, ' ACRE advice concerning Defra's consultation on the regulation of genetic technologies': https://www.gov.uk/government/publications/acre-advice-the-regulation-of-genetic-technologies/acre-advice-concerning-defras-consultation-on-the-regulation-of-genetic-technologies [accessed 8 February 2022].

Some respondents also questioned the assertion that gene editing techniques can be targeted more precisely, countering that, like GM, the process can involve random events potentially leading to unanticipated or off-target effects. In response to the question regarding unanticipated or off-target effects, ACRE has stated that where gene editing introduces genetic alterations and combinations that are of the type that are selected for in traditional breeding, any associated health and environmental risks would be comparable.

All concerns that were raised have been considered as part of Defra's step by step policy development process to develop a science-based proportionate approach to the regulation of gene edited organisms.

Q20: The EM sets out in percentages the support amongst different groups of stakeholders for the changes proposed by this instrument. Given that the majority of responses, even excluding campaign responses, was from individuals, does this approach fail to adequately reflect the degree of wider public concern about the changes?

A20: Our social scientists undertook a detailed analysis according to established approaches which considered all responses and generated a Summary of Response document which is an overview of all submissions. This approach to the detailed analysis was undertaken in a similar way to that for other Defra consultations in line with best practice. The analysis was not undertaken to support a particular viewpoint or conclusion and aimed to transparently report the findings from the consultation.

The Summary of Responses[24], which was published along with the Government response stated that the majority of individuals (88%) and businesses (64%) supported continuing the regulation of GEOs as GMOs; NGOs were evenly split (50%); while a slightly higher proportion of public sector bodies (55%) and academics (58%) did not support continuing to regulate such organisms as GMOs compared to those in support.

In addition, we have noted the public views expressed in the FSA consumer research published in July 2021[25] that found that after being informed about GE, 57% of participants were 'not at all' or 'not very concerned' about GE. Consumers tended to find genome edited food more acceptable than GM food, typically because they perceived it as safer and more natural.

Q21: What was the total number and percentage of responses (irrespective of type of respondent) which supported continuing the regulation of GEOs as GMOs?

A21: Our team of social scientists undertook a detailed analysis according to established approaches which considered all responses and generated a Summary of Response document which is an overview of all submissions. The approach for the detailed analysis was undertaken in a similar way to that for other Defra consultations in line with best practice. Two types of questions asked in the consultation–open and closed. Open questions are where respondents provide text in their own words. All responses to these questions were included in the analysis (i.e., Citizen Space, email and postal responses). Closed responses are where

24 Defra, *Summary of responses to a consultation on the regulation of genetic technologies* (29 September 2021): https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1021309/genetic-technologies-regulation-summary-of-responses.pdf *[accessed 8 February 2022].*

25 Food Standards Agency, 'Consumer perceptions of genome edited food': https://www.food.gov.uk/research/research-projects/consumer-perceptions-of-genome-edited-food [accessed 8 February 2022].

respondents select from pre-defined options e.g., multiple choice. For analysis of closed questions, as indicated in the Summary of Responses, the analysis was based on Citizen Space responses only.

The reason for this was a lack of standardised responses amongst email and postal submissions. Specifically, whilst some emails did clearly answer the closed questions, for others it was not clear. We therefore only reported Citizen Space responses for the closed questions (as done in another Defra consultation, Health and Harmony).

Of the 3,083 Citizen Space responses which were factored into the calculation the numbers and percentages supporting - and opposing - continuing to regulate GEOs as GMOs were as follows:

Option	Total (n=3083)	%
Yes–they should continue to be regulated as a GMO	2596	84.2
No–they should not continue to be regulated a GMO	459	14.9
Not Answered	28	0.9

Q22: Is it correct that the instrument only deals with plants/seeds/propagating material that is released for non-marketing purposes, such as putting the plants into the ground for onward growth or germination, or could such plants be used for human consumption/food or animal feed later on? If so, would the labelling of any products have to provide information about the genetically modified nature of the plants?

A22: The instrument deals with plants released for non-marketing purposes, meaning developers are able to carry out research and development of such plants.

However, the marketing of these plants will not be possible without consent from the Secretary of State, as they would still be GMOs. For this to be possible, developers would need to follow the GMO regulations and therefore would need to be labelled under the GMO Food and Feed Regulations.

21 January, 4 and 8 February 2022

APPENDIX 2: FURTHER INFORMATION FROM THE MINISTRY OF JUSTICE ON THE DRAFT EARLY LEGAL ADVICE PILOT SCHEME ORDER 2022

Policy questions:

Q1: In running the scheme what will be the criteria for selection?

A1: Our selection criteria will seek to identify individuals with early stages of legal need, experiencing problems that if left unaddressed might escalate to crisis point. The appointed independent evaluator will be expected to identify a suitable proxy indicator for this legal need as part of the feasibility study.

Q1a: It says that people will be chosen by reference to criteria contained in guidance published by the Lord Chancellor, - is that yet available?

A1a: The specific guidance determining selection criteria will be published following a feasibility study, undertaken by the independent evaluator. We would be happy to notify you when it is published.

Q1b: And by a person appointed by the Lord Chancellor, - is that likely to be an academic or a local authority official?

A1b: It is possible that the person appointed by the Lord Chancellor may be an individual or individuals employed by the local authority, or an independent evaluator. The feasibility study will test options in relation to whom will or action the selection criteria.

Q1c: The wording of the SI indicates that those who are selected but receive no advice will also be informed that they are part of the pilot–will that control group also be required to fill in any evaluation or description of their experience? Otherwise, they will be just like any other Housing benefit claimant–what marks them out?

A1c: The pilot is seeking to develop robust quantitative impact evidence, and so how to best collect control or comparison group evidence is a priority issue to be examined. The specific criteria and process for identifying and engaging the control or comparison group is to be determined based on feasibility work to be undertaken by the independent evaluator.

Q2: The EM says that the pilot will last for two years and a report will be published. What is the timetable? When is the evaluation report expected to be published?

A2: It is anticipated that the delivery of advice will be focused in 2022, to allow outcomes and issues to be subsequently tracked over time. The specific process is to be determined based on feasibility work to be undertaken by independent, professional researchers. While we may make a decision to stop selecting participants into the pilot scheme, we currently do not intend to set a fixed period during the pilot in which participants will be expected to access advice provision.

We intend to publish the evaluation report following the conclusion of the pilot scheme.

Q3: What is the fee structure for the legal advisers?

A3: Legal aid providers will be paid a standard fee, with no escape fee, for the work they undertake under this pilot scheme.

Q4a: Can you tell us what the baseline fee is that you are using and how much the enhancement is to arrive at the total of £200.70?

A4a: We have used the non-London hourly rates for Housing and Family matters to generate the baseline fee for the work that will be carried out as part of the pilot scheme. The fees for this work are: £45.95p/hr for preparation, attendance and advocacy; £25.74p/h for travel and waiting time, and £3.65 per item for routine letters out and telephone calls.

Taking the existing fees as a starting point, we have included an addition 25% uplift to meet the costs of the evaluation requirements which will be placed on providers for the purposes of the pilot as a condition of their contract, but which wouldn't usually be required in the delivery of civil legal aid. This will include, for example, the reporting of extra data for evaluation purposes which wouldn't ordinarily be required for the administration of legal aid. The hourly rates for the pilot work, as show in Table 7(da): Early Legal Advice Pilot, are: £57.43p/h for preparation, attendance and advocacy; £32.17p/h for travel and waiting time, and £4.56 per item for routine letters out and telephone calls.

Providers will not be expected to carry out advocacy work, attend court or travel to specific sites, however we do envisage that they will be required to complete tasks under the banner of 'preparation', i.e., work with the client to understand their legal matters and complete necessary documentation. They are also likely to engage in phone calls with relevant organisations and agencies (e.g., local authority or government departments) to resolve a client's matters.

Our final standard fee is therefore just under 3.5 hours of the hourly rate of preparation, attendance and advocacy work to account for work relating to advice provision and any additional letters or telephone calls.

Q4b: Is that a flat fee for the 3 hours or is it per hour?

A4b: This is a flat fee for the three hours of work. Legal aid providers will still be paid the full fee even if they do not deliver work for the total three hours allocated.

Q4c: How long will the additional paperwork take to complete?

A4c: We will test this with legal aid providers; however, our intention is to make this additional reporting a minimal burden on providers, prioritising the most critical details to understand delivery and produce a process evaluation.

Q4d: The Committee is concerned that if the fee is too low you won't get many lawyers volunteering–have you tested the views of the local legal practices to see if a) they are willing to participate and b) willing to do so at that fee?

A4d: While the proposed scheme differs from the current legal aid regime, our intention is to ensure that the pilot scheme reflects real world conditions including remuneration currently offered for similar legal aid work (i.e. the standard fee for housing and debt matters).

We have met legal aid providers currently delivering Housing and Debt legal aid services in the pilot locations as well as representative bodies such as the Law Centres Network and the Law Society to discuss the pilot, including the remuneration

rates. A number of practitioners have expressed interest in participating in the pilot scheme at the fee that is set.

Evaluation questions:

Q5: Can a project plan be provided?

A5: The invitation to tender specification contains a project plan; however, this document is part of a live tender and so cannot be shared with the committee at this time.

Q6: Since this pilot is designed to inform future policy on a sensitive subject–how rigorous will the running of it be?

A6: As a central part of the pilot, the Ministry of Justice is commissioning a process, impact, and value for money evaluation to support the effective delivery of the project, and the generation of robust impact evidence. An initial phase ahead of pilot delivery will be an in-depth feasibility study to fully assess and recommend a robust, practical research pilot and evaluation design.

Where the focus of the evaluation is on the development of robust quantitative impact evidence and to evaluate what works, the feasibility study will include exploring the possibility of undertaking a Randomised Control Trial approach. This is considered the gold-standard approach to assessing impact, highly novel in the Access to Justice policy area.

Q6a: Are professional researchers being used?

A6a: The evaluation of the pilot will be undertaken by external professional researchers to ensure its independence and rigour. The evaluation is currently in the process of being commissioned through the Crown Commercial Services Research & Insights Dynamic Purchasing System.

Q6b: Will the project and the evaluation be overseen by a university?

A6b: The professional researchers undertaking the pilot evaluation are yet to be appointed but might include academic expertise.

However, Sector and academic experts from the Ministry of Justice's Legal Support Advisory Group, and its evaluation sub-group made up primarily of academics and researchers, have overseen the development of the pilot and will continue to advise on the project. Academics in the Legal Support Advisory Group include Professor Dame Hazel Genn (UCL) and Dr. Natalie Byrom (Legal Education Foundation) while the members of the evaluation-subgroup include Dr. Naomi Creutzfeldt (University of Westminster), Dr. Mavis Maclean CBE (University of Oxford) and Dr. Robert Thomas (University of Manchester).

Q6c: How will it be monitored to ensure that the individuals chosen do conform with the criteria.

A6c: Understanding and monitoring the characteristics (demographic and protected) of users and the demand for the service has been identified as a key issue for the pilot's research. The most effective way to sample, monitor and analyse this will be established as part of the feasibility study work, ahead of pilot delivery. It is intended that the findings and recommendations from the feasibility study will be published, and trial protocols be made transparent.

We have conducted an initial equalities assessment of the pilot proposal which suggests that the individuals from a diverse range of groups are likely to benefit from the scheme, such as women, people from younger age groups (i.e., those between 25-34 and 35-44), people from Black, Asian and Minority Ethnic Backgrounds, and disabled people.

We intend to use the findings of the feasibility study as well as the pilot scheme, including whether different participants experience different outcomes based on their characteristics, to undertake a full equalities assessment when considering whether the pilot should be expanded nationally.

4 February 2022

APPENDIX 3: INTERESTS AND ATTENDANCE

Committee Members' registered interests may be examined in the online Register of Lords' Interests at http://www.parliament.uk/mps-lords-and-offices/standards-and-interests/register-of-lords-interests. The Register may also be inspected in the Parliamentary Archives.

For the business taken at the meeting on 8 February 2022, Members declared the following interests.

Draft Somerset (Structural Changes) Order 2022

Baroness Bakewell of Hardington Mandeville
Former leader of Somerset County Council

Draft Flood Reinsurance (Amendment) Regulations 2022

Lord Powell of Bayswater
Director of Insurance Company

Attendance:

The meeting was attended by Baroness Bakewell of Hardington Mandeville, Lord De Mauley, Lord German, Viscount Hanworth, Lord Hodgson of Astley Abbotts, Lord Hutton, the Earl of Lindsay, Lord Lisvane, Lord Powell of Bayswater and Lord Rowlands.