From the Chair, Ruth Hussey

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The Rt Hon George Eustice MP
Secretary of State for Environment, Food and Rural Affairs
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16 March 2021

Dear George,

Defra consultation on the regulation of New Genetic Technologies

My predecessor, Heather Hancock, previously provided views to you through Rt Hon Matt Hancock in response to the write round ahead of the consultation launch, and I am writing now to offer some further thoughts as the consultation comes to a close. Depending on your decision, the consultation outcome may have a significant impact on the FSA and its responsibilities, and I am keen to ensure that these impacts are well-understood and to offer some further views on future GMO regulation and suggestions for future joint working.

Whilst Defra holds the central policy responsibility for GMOs and new genetic technologies, the FSA, as the food safety regulator, holds responsibility for the safety and assessment of GM material used in food and feed. We therefore have a strong interest in ensuring that, depending on the consultation outcome, the future

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regulatory framework is fit for purpose and will meet broader government objectives of protecting consumers, encouraging innovation and supporting international trade and the UK internal market.

As my predecessor has set out, there is a clear case for updating regulatory frameworks to reflect new scientific and technological advances in gene editing. I have set out below in more detail the implications for the FSA's existing regulatory frameworks and any new framework that may be needed, as well as considerations around detection and enforcement, and wider consumer interests.

Implications for FSA regulatory frameworks

With the absence of data, it is not currently possible to give a comprehensive safety statement on these technologies in food and feed, and therefore some form of safety assurance will be needed through oversight and appropriate regulation. Removed from the GMO umbrella, products would be regulated under existing legislation, which may not be suited for the characteristics of these products. For example, changing the definition of a GMO to exclude new genetic technologies will see some genome edited foods captured instead by the Novel Foods framework which, in the view of the FSA, is fairly onerous and potentially disproportionate to the likely risk from genome edited products.

In the case of genome edited feed, this would fall under the Animal Feed framework, which does not require a pre-market safety assessment. GMO definition changes would therefore result in safety assurance gaps and different regulatory approaches for edited food and feed. FSA officials are engaging with Defra colleagues on this and have recommended the impact of differential regulation for food and feed be considered as part of Defra's impact assessment.

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Safety assurance through a new, tailored framework

To avoid disruption to two legislative frameworks, a possible solution might be provided by devising a new specialised authorisation process provided for in legislation. This might, for example, require producers to notify the FSA of their genome edited product and submit production and safety data, with regulators confirming an edit is safe and not a GMO, which could allow its swift placement on the market. This approach would support the recent view given by the FSA's scientific Advisory Committee on Novel Foods and Processes (ACNFP) that simple genome editing (which could have been produced through traditional breeding) should not be assessed in the same way as GMOs, although ACNFP recognised there may need to be some elements of assessment and oversight because genome editing allows changes to be introduced more quickly than traditional breeding. Regardless of the process, some form of oversight will be particularly important in providing consumer trust and confidence in these technologies.

Detection and enforcement

One of the greatest challenges for food or feed products using these technologies is detection and enforcement to assure consumers that products have met appropriate regulatory standards. With genome edited products it is often impossible to detect the edit unless there is prior knowledge of the edit made and one can intentionally look for it in the product. It is important that the future regulatory framework is designed so that it supports industry to adhere to achievable regulatory standards whilst building in appropriate safeguards against the risk of evasion. We look forward to discussing further with your officials.

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Consumer interests

The FSA has a statutory duty to represent the interests of consumers in relation to food, with aspects such as consumer choice and labelling integral to this. As well as our regular consumer surveys, the FSA has recently commissioned research to look at consumer views of genome edited foods; the final report is due in early April and will be made publicly available. These consumer insights will form part of the wider evidence base that the FSA will draw on as any new regulatory approach is discussed.

As you are aware, consumer confidence in our food system is underpinned by reliable information about the provenance and composition of food. This can be achieved in different ways, but food labelling is an obvious area of focus and it is likely that there will be strong consumer demand for clear information about the use of genetic technology in food production. This highlights the need for a joined-up approach on food labelling. The FSA works closely with Defra officials on food labelling policy, for which we have responsibility for some aspects in Wales and Northern Ireland. Drawing on our expertise and evidence base, we have offered the FSA's help and support to ensure that future labelling policy is well-integrated across the various government departments with an interest, underpinned by the best science and evidence about what works to build consumer confidence and encourage safe, healthy and sustainable choices.

Devolved Administrations

Whilst we understand the rationale for the consultation only applying to England, any possible future changes to the definition of a GMO will impact Scotland, Wales, and Northern Ireland. If genome edited products are still regulated as GMOs in Wales and Scotland, this would lead to them being assessed under two different regimes.

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In the future, the UK Internal Market Act 2020 could require Scotland and Wales to allow genome edited food and feed to be legally placed on their markets, irrespective their own regulatory requirements. Under the terms of the Northern Ireland Protocol, EU rules relating to GMO's, including definitions, will remain applicable in Northern Ireland. As such, impacts on the UK's integrated supply chain across the nations will need consideration.

I trust these comments will be helpful and look forward to continuing collaborative working on this matter. Because of the high public interest in GMOs and the FSA's important role in future regulation of these products, the FSA Board will be discussing the progress and outcome of the consultation and any resulting policy change at our upcoming meetings. We have encouraged consumers and stakeholders to respond to the consultation, and I look forward to continued close and constructive working with Defra colleagues on these important issues.

I have copied this letter to the Secretary of State for Health and Social Care.

Yours sincerely,

Dr Ruth Hussey CB, OBE, DL

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