4 June 2020

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The Right Hon George Eustice MP
Secretary of State, Department for Environment, Food and Rural Affairs
Seacole Building
2 Marsham Street
London
SW1P 4DF

Dear Secretary of State,

We are aware of the letters written to you by Julian Sturdy MP, Dr Tina Barsby and colleagues and Andrew Newby and colleagues requesting that you bring forward an amendment to the Agriculture Bill with the aim of changing the definition of GMOs in UK regulations.

Through our A Bigger Conversation initiative, we have for some time been facilitating dialogue about genome editing across the spectrum of scientific and stakeholder opinion. Consequently, we are familiar with the goals and perspectives that underpin this proposed change in UK regulations.

However, having considered the points made in the letters, we believe the proposal to be ill-judged, untimely and a hindrance rather than a help to government policy. We are, therefore, writing to draw your attention to why this is and to key errors in the case being presented to you.

In summary: firstly, the definition of GMOs in the Cartagena Protocol does not achieve what Sturdy and colleagues say it does. Secondly, the term "genome editing" covers a range of applications and even "simple" gene editing techniques are not "simple" either biologically or in terms of their impacts on trade and the market. Thirdly, other countries have not treated genome editing uniformly and, in fact, many acknowledge that the issue is far from straightforward and have sought to address its complexity in differentiated regulations.

Our key points are:

- The Cartagena Protocol definition of GMOs does not clearly exclude genome editing from its scope. Indeed, its definition of "modern biotechnology" encompasses both older transgenic and newer cisgenic technologies. Opinion amongst scientists and policy makers is divided on the matter, but there is little doubt that some forms of genome editing would be defined as GMO even if some others might not be. This is not, therefore, the simple and straightforward option your correspondents present it as. In our view, it would be unwise to build a new regulatory approach on such an unclear and disputed foundation.
- There are a number of different approaches in genome editing. Your correspondents refer to "simple" genome editing and to methods that have an impact similar to processes found in nature and/or "traditional" breeding. In reality, the matter is far from simple and the differences between approaches are far from clear cut. Again, scientific and stakeholder opinions vary as to the extent and degree of regulation (or deregulation) appropriate for this technology. However, in our dialogue we have found that many of those who are supportive of genome editing also recognise the benefit, and even necessity, of some form of regulation for some applications.

- This is arguably reflected in what is actually happening with genome editing regulation in a number of countries. The situation is far more variable than the statements made by your correspondents. Australia has deregulated the products of what is said to be "simple" genome editing, that is, the SDN-1 (site directed nuclease) technique. But products from SDN-2 and SDN-3 techniques are considered GMOs and remain regulated. Japan is currently proposing to take the same approach. New Zealand considers all gene-edited organisms to be GMOs and these are, therefore, regulated. The US has deregulated SDN-1 plant products but it is proposing much tougher regulations on gene-edited animals. Canada follows a regulatory approach which means some gene edited products may, and others may not, be regulated. Brazil, Argentina and Paraguay require no special regulations for the products of gene editing. However, Russia, the Ukraine, China, the whole of Europe and Mexico are regulating genome-edited plants – and, like the US, apply even stricter regulations on genome edited animals.

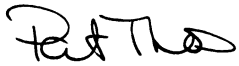
- These variations in regulatory approaches are not only a matter of politics and trade positioning. They also arise from a lack of scientific and policy consensus over the risks and benefits of the technology. The US FDA has taken the view that "both scientists and regulators need to be alert to the potential for [such] unintended alterations to take place." Earlier this year in a commentary in Nature Biotechnology it noted: "*At this early stage, as genome-editing technology is continuing to develop and the science is evolving, bringing products with unknown risks to market without adequate oversight to ensure they are safe and that they produce the promised effects will undermine consumer confidence and, ultimately, set back the progress of the entire field.*"

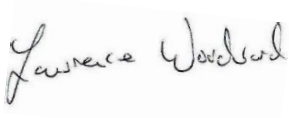
As research into CRISPR advances it become clear that precision (i.e. the ability to make a change at a predetermined place on the genome) is not the same as predictability or controllability. The technical issues are, therefore, far from straightforward, and the market, labelling and transparency issues are similarly challenging with public opinion in a state of flux. All the indications are that even consumers who are sympathetic to the technology believe it should be regulated to some degree and that the products arising from genome editing should be able to be traced and labelled. Many others, remain sceptical or opposed and certainly demand labelling. Likewise farmers that are sympathetic to the technology have legitimate concerns about co-existence and contamination.

We do not believe that these are matters which can – nor in our view should – be approached through a late stage amendment to a parliamentary bill that has not addressed either the principle or detail of the issues during its passage through the House of Commons.

Like Sturdy and colleagues, and the Government, we accept that genome editing is a powerful "game-changing" technology. It is therefore a matter of consequence to every UK citizen, as well as to our farmers, growers, plant and animal breeders. It follows that any regulatory change should be taken in a considered, open and transparent way and certainly not in the manner suggested by your correspondents.

Yours Sincerely,





Pat Thomas (Ms)
Director
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Lawrence Woodward
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cc: The Lord Gardiner of Kimble, Parliamentary Under-Secretary, Department for Environment, Food and Rural Affairs