

17 March 2021

Response to Defra consultation on ‘The regulation of genetic technologies’

Institute of Food Science and Technology represents the UK’s leading food science and technology professionals, supporting advancement of food science and technology for public benefit.

IFST is positively supportive of the application of new technology for the benefit, safety and health of the public and the wider environment, providing it can be assured as safe using sound evidence-based science.

It is our considered view that a fundamental review of the current approach and attitude to regulation of food should be undertaken to develop a framework model able to address risk assessment and risk management of all types of technological modification of food, feed, food and feed improvement agents, food supplements and food contact materials, irrespective of their type of intervention, to determine whether each case presented was safe for its intended use and what, if any specific risk management considerations needs to be developed and applied.

It is imperative for the global food system that definitions and subsequent safety assessments for any new technology are applied consistently and based upon sound science across jurisdictions to avoid disruption and ensure new technologies, providing they are proven safe, are not impeded from reaching their potential to benefit consumers and the environment.

The IFST engagement of its members for this Defra call for evidence has identified that there are issues other than safety that need to be considered if changes to the current regulations are to be made. There are differences of opinion amongst the informed scientists and food technologists who make up the IFST’s membership, and this reflects the differences of opinion amongst the UK population.

Our further specific responses to the consultation questions are attached.

Your sincerely,



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Chief Executive

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Part 1

Question 1

Should Gene Edited Organisms (GEOs) be regulated as a GMO even if their genetic change(s) could have been produced through traditional breeding?

Yes – they should continue to be regulated as a GMO

No – they should not continue to be regulated as a GMO

✓

Please explain your answer

IFST is positively supportive of the application of new technology for the benefit, safety and health of the public and the wider environment, providing it can be assured as safe using sound evidence-based science.

The confusion and misunderstanding associated with the application of genetic technologies in our food system has created many problems regarding supply chain and consumer assurance which is at the heart of any food supply system. The issue of GEOs being regulated as GMOs will compound these issues that are associated with the misunderstanding of how genetic technologies are used.

A fundamentally new approach and attitude is required for regulation addressing risk assessment and risk management, designed to address all technologies and methods of modification of food, feed, food and feed improvement agents, food supplements and food contact materials – irrespective of their type of intervention – where it modifies or changes the nature, properties or characteristics of the plant, fungi and algal varieties, animal breeds and the subsequent foodstuffs placed in the market for consumption. This could then be applied to any GMO, GEO or novel food, as currently defined, to determine whether it was safe for its intended use and what, if any specific risk management considerations would need to be applied.

In the specific case of GEO and GMO, robust definitions are needed in risk analysis and in communication with all supply chain partners and consumers. Not addressing these definitions robustly in risk assessment, risk management, overall governance, and specifically in regulations themselves, will risk the rejection of GEOs and any other new potential beneficial technology by consumers and a loss of confidence in our food supplies.

Any new legislation relating to GEO's or to any foods produced using novel technologies should be functional and proportionate so that they do not restrict the access to the benefits of investing in new varieties and breeds so that only large multinational companies see the benefits. A distributed system of innovation and subsequent implementation across the agri-food sector is required if net-zero targets and alignment to the UN Sustainable Development Goals is to be realised. A convergent observation of IFST members is there is a requirement for clarity between GEO and GMO and all other mechanics for accelerated development of varieties and breeds to help support effective and successful innovation and implementation. In particular, the difference between GEO and GMO needs to be better understood across all stakeholders; regulators, industry and consumers. Clarity in the regulations would assist this.

Different regulatory approaches to GEO are being applied in various different national regulatory jurisdictions and even within jurisdictions. GEOs are already regulated for approvals, labelling and traceability through the supply chain and to recognise the different

forms of GE in Japan for example (see, doi: 10.3389/fbioe.2019.00387 and <https://www.fas.usda.gov/data/japan-maff-guidance-handling-genome-edited-organisms-under-cartagena-act>). In the EU guidance from EFSA proposes that GE plants that do not contain exogenous DNA should not be treated the same as GMO (see, <https://www.efsa.europa.eu/en/efsajournal/pub/6299>) but a European Court of Justice ruling in 2018 confirmed that all genome-edited plants should be treated legally as genetically-modified organisms (GMOs), using definitions dating from 2001.

It is imperative for the global food system that definitions and subsequent safety assessments for any new technology are applied consistently and based upon sound science across jurisdictions to avoid disruption and ensure new technologies, providing they are proven safe, are not impeded from reaching their potential to benefit consumers and the environment.

Question 2

Do organisms produced by GE or other genetic technologies pose a similar, lesser, or greater risk of harm to human health or the environment compared with their traditionally bred counterparts as a result of how they were produced?

Similar	Lesser	Greater

Please provide evidence to support your response- details of the genetic technology, the specific risks and why they do or do not differ. Which applications/areas your answer relates to (cultivation, breeding, human food, animal feed, human and veterinary medicines, other). Please explain your answer.

This is an overly simplistic approach to a very complex situation. The issues of potential toxicity, including allergenicity, and potential unintended environmental consequences must be assessed on a case-by-case basis, as for any other novel foods. Risk analysis for GEOs and GMOs should be similar to new varieties produced by other breeding methods.

A fundamental review of the current approach and attitude should be undertaken to develop a framework model which is able to address risk assessment and risk management of all types of technological modification of food, feed, food and feed improvement agents, food supplements and food contact materials, irrespective of their type of intervention, to determine whether each case presented was safe for its intended use and what, if any specific risk management considerations needs to be developed and applied.

A robust and comprehensive risk assessment and risk management regulatory framework would therefore be able to address all scenarios, including those as yet not developed, and apply a consistent approach to preventing risks to the environment, to animal welfare, to food safety, whilst ensuring new technological benefits are leveraged for society, health, and the environment without affecting consumer acceptability.

Any new governance must address the following:

1. Provision of definitions for GEOs and GMOs that can be used by all food chain and business operators. This will enable transparency in communicating the role GEOs

can have in a supply chain and provide definition where GEOs are developed without transgenics.

2. Opportunity for transparency of the use and safety status of GEOs and any other novel technology being applied to feed and food to support trust. This has not been fully achieved with GMOs and it has resulted in a lack of trust in defining the role of genetic technology
3. Options for transparency of the use of GEOs and any other novel technology being applied to feed and food – the current model is inconsistent and flawed e.g. if GMO feed is used for the production of livestock products then food products do not have to state GMOs are used in production of the end food product; similarly, if an enzyme, processing aid or ingredient is produced with the assistance of a genetically modified microorganisms then the food product does not have to declare this.
4. The practicalities of enforcement, for example the current inability to distinguish a GEO from a traditionally bred product based on analytical testing.

Question 3

Are there any non-safety issues to consider (e.g. impacts on trade, consumer choice, intellectual property, regulatory, animal welfare or others), if organisms produced by GE or other genetic technologies, which could have been produced naturally or through traditional breeding methods, were not regulated as GMOs? Please explain your answer.

The IFST engagement of its members for this Defra call for evidence has identified that there are issues other than safety that need to be considered if changes to the current regulations are to be made. There are differences of opinion amongst the informed scientists and food technologists who make up the IFST's membership, and this reflects the differences of opinion amongst the UK population.

The role of genetic technologies in feed and food supply chains have often not engaged the processors and manufacturers of foods and beverages. This lack of engagement also includes programmes of food product development regarding the extent and expectations of genetic technologies.

If this situation occurs with GEOs it will limit the market development of new products that can provide a range of benefits e.g., improved processing and nutrition, that can result in increased productivity and sustainability. Communication of the role of new technology and benefits of it must be maintained across all supply chain partners and consumers.

Communication of GMO benefits have often focused on agricultural stakeholders and quantifiable outcomes (e.g. increased yield with effective weed control through the use of herbicide resistant crops), whereas qualitative outcomes are of exceptional impact in the case of GEOs (e.g. enhanced colour and polyphenol content of soft fruits; improved sugar content of tomatoes; reduced cold sweetening in potatoes).

An effective regulatory regime which addresses GEO as well as any future new technological developments, must be capable of ensuring that the hurdles to market entry including costs, are comparable to conventional approaches, so that innovators large and small can predict a return on investment and a realistic route to market.

Question 4

What criteria should be used to determine whether an organism produced by gene editing or another genetic technology, could have been produced by traditional breeding or not? Please explain your answer (100 words max).

IFST members noted that expert review is required to identify appropriate criteria. To avoid the raising of non-tariff barriers and creation of global food system disruption, international agreement will be needed on the metrics to be used to assess whether GEOs could have been derived using traditional breeding strategies.

Part 2**Question 5**

Is non-GM legislation sufficient to deal with all organisms irrespective of the way that they were produced or is additional legislation needed? Please indicate on governance (regulatory or non-regulatory).

Sector / activity	Yes (sufficient GMO governance)	No (insufficient GMO governance)
a) cultivation of crop plants		
b) breeding farmed animals		
c) human food		
d) animal feed		
e) human and veterinary medicines		
f) other sectors/activities		

Please provide evidence to support your response (100 words max).

IFST is positively supportive of the application of new technology for the benefit, safety and health of the public and the wider environment, providing it can be assured as safe using sound evidence-based science.

A fundamental review of the current approach and attitude should be undertaken to develop a framework model which is able to address risk assessment and risk management of all types of technological modification of food, feed, food and feed improvement agents, food supplements and food contact materials, irrespective of their type of intervention, to determine whether each case presented was safe for its intended use and what, if any specific risk management considerations needs to be developed and applied.

A robust and comprehensive risk assessment and risk management regulatory framework would therefore be able to address all scenarios, including those as yet not developed, and apply a consistent approach to preventing risks to the environment, to animal welfare, to food safety, whilst ensuring new technological benefits are leveraged for society, health, and the environment without affecting consumer acceptability.

Any new governance must address the following.

1. Provision of definitions, in this case for GEOs and GMOs that can be used by all food chain and business operators. This will enable transparency in communicating the role this new technology can have in a supply chain and provide clarity.
2. Opportunity for transparency of the use and safety status of any novel technology being applied to feed and food to support trust. This has not been fully achieved with GMOs and it has resulted in a lack of trust in defining the role of genetic technology.
3. Options for transparency of the use any novel technology being applied to feed and food – the current model is inconsistent and flawed e.g. if GMO feed is used for the production of livestock products then food products do not have to state GMOs are used in production of the end food product; similarly, if an enzyme, processing aid or ingredient is produced with the assistance of a genetically modified microorganism then there is no requirement to declare this.
4. The practicalities of enforcement, for example the current inability to distinguish a GEO from a traditionally bred product based on analytical testing.

This fundamental review of approach and attitudes for regulation would replace the current siloed approach for GMO and novel foods etc.

Any constructive way forward should engage manufacturers involved in developing food and beverage products. This is very much the 'missing middle' between agricultural production and retail/consumers. Without engaging this missing middle any attempt to engage new technologies for food, including GEO, will often be limited in application.

Question 6

Where you have answered no (existing, non-GMO legislation is insufficient), please describe what additional regulatory or non-regulatory measures you think are required to address this insufficiency. Please explain how any additional measures you identify should be triggered (for example: novelty, risk, other factors). (200 words max).

A newly devised framework model able to address risk assessment and risk management of all types of technological modification of food, feed, food and feed improvement agents, food supplements and food contact materials, irrespective of their type of intervention, to determine whether each case presented was safe for its intended use and what, if any specific risk management considerations needs to be developed and applied.