March 2021

The UK Government's Department for Food and Rural Affairs (Defra) has published a proposal to weaken regulations so that some types of unlabelled genetically modified (GM) plants, animals and foods can be produced in England and enter the environment and the food chain without proper risk assessments or any public information about their whereabouts.¹ The focus of the first part of the consultation is on GMOs created using a set of newer genetic engineering techniques known as gene editing. GeneWatch UK's submission in response to the first (gene editing) part of Defra's consultation has already been submitted and published.² The second part of the consultation, which is addressed here, covers potential further deregulation of other GMOs.

Section 3 – Part 2: Questions on broad reform of legislation governing organisms produced using genetic technologies

Q1.

There are a number of existing, non-GM regulations that control the use of organisms and/or products derived from them. The GMO legislation applies additional controls when the organism or product has been developed using particular technologies.

Do you think existing, non-GM legislation is sufficient to deal with all organisms irrespective of the way that they were produced or is additional legislation needed? Please indicate in the table whether, yes, the existing non-GMO legislation is sufficient, or no, existing non- GMO legislation is insufficient and additional governance measures (regulatory or nonregulatory) are needed.

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

Please answer Y/N for each of the following sectors/activities:

Please provide evidence to support your response [open response]

A system of risk assessments, risk management, monitoring, traceability and labelling is necessary for all open releases of GMOs in order to protect human health and the environment. Impacts on animal welfare should also be considered. Evidence is provided below.

2.

Where you have answered no (existing, non-GMO legislation is insufficient to deal with organisms produced by genetic technologies), please describe what additional regulatory or non-regulatory measures you think are required to address this insufficiency, including any changes you think need to be made to existing non-GMO legislation. Please explain how any additional measures you identify should be triggered (for example: novelty, risk, other factors).

Please provide evidence to support your response

GMOs exist not only as ingredients in food and feed but as novel organisms which may spread and reproduce in the environment, potentially posing risks to biodiversity. The production process for GM foods does not begin in factories but in living organisms (animals and plants) which also interact with their environment. These GMOs are patented because they are 'novel', i.e. they possess new properties and traits that are not present in the plant, animal or micro-organism before it has been genetically engineered. The GMOs themselves are novel: novelty does not apply only to any food that might be produced from them. The process of genetically modifying plants and animals can also have unintended effects, which may impact human health or the environment.³ Further, GM animals suffer serious adverse effects on their welfare.⁴

GMOs are living organisms. Thus, when they are released into the environment, environmental conditions can change their properties in ways that may pose risks to human health: for example, GM plants which have been genetically engineered to increase the uptake of iron from the soil may also increase the uptake of toxic heavy metals if planted in contaminated soil.⁵ The dose of an altered nutrient or protein in a GM plant or animal can also change in different environmental conditions. A particular transgene can have large effects on the entire phenotype of a plant and these effects can sometimes be reversed when plants are moved from the glasshouse to the field.⁶ Thus, risk assessment, risk management, traceability and labelling cannot take place only at the level of the ingredient or food product (as with some novel foods, for example), but must encompass the whole process of environmental release, from farm to fork.

Regulation of GMOs should respect the requirements of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, to which the UK is a Party. This is an international agreement which aims to ensure the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health.⁷ For example, this agreement requires that:

- relevant national authorities should be equipped and trained to sample, detect and identify LMOs in shipments;
- the Biosafety Clearing-House (BCH) is utilised as a mechanism to facilitate the international exchange of information on Living Modified Organisms (LMOs);
- Parties make decisions on import of LMOs for intentional introduction into the environment in accordance with scientifically sound risk assessments;
- Parties adopt measures and strategies for preventing adverse effects and for managing and controlling risks identified by risk assessments; take measures to prevent unintentional transboundary movements; ensure that LMOs undergo appropriate periods of observation prior to use; and cooperate in identifying LMOs and their traits that may pose risks, and in taking appropriate management measures.

Existing non-GMO legislation is insufficient to fulfil these requirements: a system of risk assessments, risk management, monitoring, traceability and labelling is necessary. These measures are triggered by the definition of an LMO included in the Protocol. Currently, these requirements are met in the UK by GMO regulations.

Examples of relevant risks have been identified by the Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management to the Cartagena Protocol, which has published guidance in relation to LMOs in general, with specific examples for plants, trees and insects that are vectors of diseases.⁸ Other examples of potential risks of GMOs that need to be assessed, monitored and managed, for the protection of human health and the environment, are provided in Guidance published by the European Food Safety Authority for GM plants and animals.^{9,10} Without a regulatory system which includes risk assessments, risk management, monitoring, traceability and labelling, it is not possible to prevent potential harm to human health or the environment. Risk assessment of long-lived or highly mobile GMOs (trees, insects, fish) is particularly challenging.

Risk assessment alone is insufficient, as traceability is essential to enable products to be recalled if anything goes wrong, and labelling is essential to provide consumer choice. There are many reasons why consumers may choose not to eat GM foods, including:

- Documented harm to biodiversity in countries where GM crops are grown (for example, adverse impacts on Monarch butterflies^{11,12}, or frogs¹³), or the adverse impacts identified by the Farm Scale Evaluations of GM crops in the UK^{14,15,16,17};
- Increased herbicide residues on herbicide-tolerant GM crops¹⁸;
- The adverse impacts of resistant pests, weeds and viruses, which have arisen in response to the commercial cultivation of GM crops^{19,20,21,22,23,24,25,26,27,28,29,30,31,32}:
- Concerns for animal welfare associated with the use of cloning in production of GM farm animals, and/or the introduction of traits which are harmful to the animals, and/or the release of such animals into the environment³³;
- The existence of patents on GM crops and the associated impacts on farmers (preventing seed saving) and consolidation of the agrochemical/seed industry.

Thus, the existing system of GMO regulation is necessary to protect human health and the environment and facilitate consumer choice.

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