# GeneWatch UK's response to Defra's consultation on deregulation of gene edited organisms

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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. This response is to the first (gene editing) part of Defra's consultation. The second part of the consultation, which is not addressed here, covers potential further deregulation of other GMOs.

Defra has launched the consultation online during a pandemic, when many people who do not have internet connections cannot take part and other people, such as key workers and those who are home schooling, will not have the time. Thus, the Government is proposing major changes to the food that people eat in England, and to their environment, at a time when many people cannot have a say. The proposals have major implications for businesses in the food and farming sector, but also many other sectors where gene edited organisms could be released, in contravention of most countries' regulatory standards, such as forestry and horse racing.

The Government's proposal (which covers England only) has not been properly thought through and poses numerous important questions that need to be addressed. The following questions are highlighted below:

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## 1. The Government proposal

The UK Government's consultation covers only England and not Scotland, Wales or Northern Ireland.

Although Defra claims it is conducting a consultation, it has already stated that it wants to deregulate at least some genetically modified organisms (GMOs) developed using newer gene editing techniques (part 1 of the consultation). At the same time, deregulation of all GMOs would be considered on a longer timescale (part 2 of the consultation). The consultation document is very thin, and includes very little detail and no evidence.[2]

In the first part of the consultation, the Government's aim is to deregulate some GMOs produced using a set of techniques known as 'gene editing'. Unless the government recognises the huge complexities and serious implications of this proposal, and listens to the very wide and diverse groups affected, rather than just a narrow group of researchers with vested interests, new legislation could be introduced that would have manifest negative consequences. The Government's plan is to change the definition of GMOs, so that at least some GMOs produced using gene editing techniques are no longer treated as GMOs. The consultation states, "*organisms produced by GE (gene editing) or by other genetic technologies should not be regulated as GMOs if they could have been produced by traditional breeding methods*". This would remove them completely from the existing regulations covering releases of GMOs into the environment and the human food chain.

These regulations cover the need for health and environmental risk assessments, public information, monitoring, traceability and labelling.

The consultation makes clear that its proposal does not apply to organisms which introduce genetic material from other species (known as 'transgenics'). However, what is meant by "*could have been produced by traditional breeding*" is not defined and is instead included as a question in the consultation. There are many arguments why gene-edited GMOs are not the same as traditionally bred plants or animals. Gene edited crops are created in laboratories and patented on the basis that they are significantly different from organisms that exist in nature. They are the result of human decisions, including commercial interests, which may have adverse consequences. For example: (i) the gene editing process introduces unintended mutations as well as the intended ones; (ii) foreign DNA is used in the process of gene editing and can be left in the organism; (iii) a small change (even a single mutation) in an organism's DNA can have major consequences, including unintended consequences (for example, a change in nutritional content can damage plant growth or make it more attractive to pests) (iv) gene editing creates traits in plants, animals or micro-organisms that do not exist in nature (even if they "could" have done so), and these can have unintended effects in the environment and/or on human and animal health.[3,4]

Evolution is especially important to consider as both the organism and its environment will evolve in response to the change in DNA that has been introduced: for example, pests will evolve resistance to gene edited pest-resistant trees, weeds will evolve resistance to the blanket spraying of herbicide tolerant gene edited plants, and pathogens will evolve resistance to gene edited disease-resistant animals. This can exacerbate problems with pests, weeds or pathogens in ways that are hard to predict (for example, a virus could evolve to become more virulent). Even a small, 'precise' change in DNA (if that were possible) can have these kinds of consequences and thus potentially pose major hazards to human or animal health or to the environment. These issues are discussed in more detail below.

Because gene-edited organisms are classed as genetically modified organisms (GMOs) in most countries in the world, exempting any gene edited organisms from GMO regulations would mean that labelling, traceability, information and risk assessment requirements would differ from most of the world, including other parts of the UK. This would have major implications for global trade and for the UK's internal market.

The focus of the consultation is on GM crops and GM animals for use in agriculture (such as pigs, cows and chickens). But the proposed changes to the law would apply to any organism that is gene edited. In laboratories, researchers have been working on a wide range of gene edited GMOs, including gene edited trees, fish, insects, pets, horses, various wild animals, and micro-organisms (such as viruses and bacteria). The proposal means that any of these gene edited organisms could be released into the environment without proper risk assessment or traceability, despite the fact it would be illegal to release them in this way in most countries in the world. This could happen when these organisms are commercialised, or during open air experiments and field trials. Similarly, those gene edited organisms that are exempted from regulation could be imported from anywhere in the world without any risk assessments, labelling or traceability.

## 2. Risks to the environment and human health

The Government's proposal would exempt (at least some) gene edited GM organisms from the current requirements for health and environmental risk assessments and ongoing monitoring. This exemption would apply to imports as well as to gene edited GMOs produced, tested and/or marketed in England. There would be no means to track where these gene edited GMOs ended up, or to contain their spread. Questions regarding a few of the potential risks to the environment and human and animal health are considered further below.

### *2.1 How would harm to the environment and farming caused by herbicide-tolerant gene edited GM crops be avoided?*

Herbicide tolerant (transgenic) GM crops dominate the market today, with 88% of the area planted with GM crops in 2018 containing one or more herbicide tolerant traits, according to industry figures.[5] This is because multinational agrochemical companies can sell both the patented seed and the associated herbicide. These crops are mainly planted in North and South America and their main use is in animal feed (including animal feed, mainly soya, imported to the UK). They include GM soy, maize, oil seed rape, cotton, alfalfa and sugar beet. Cultivation of GM herbicide-tolerant crops is limited outside North and South America and does not occur in the EU. This is mainly due to significant concerns about negative impacts on farming and the environment. However, if gene edited GM crops were to be deregulated in England, herbicide-tolerant gene edited crops, with similar adverse impacts, could be planted experimentally in field trials or grown commercially without any regulatory oversight.

Only two gene edited crops are currently on the market, both in the USA, and one is an herbicide-tolerant oil seed rape (canola) which is tolerant to sulfonylurea (SU) herbicides (including the weedkiller Draft), marketed by Cibus under the trade name Falco.[6] Cibus also states it is developing herbicide tolerant gene edited rice and flax. Another company using gene editing to develop herbicide-tolerant GM crops is Bioheuris (based in Argentina).[7] Transgenic GM herbicide tolerant crops usually include genes from bacteria that produce enzymes that inactivate or degrade herbicides. To generate genome edited herbicide tolerant crops, the strategy used instead is to mutate enzymes inside the plant to make them insensitive to the corresponding herbicides. These enzymes include EPSPS, the enzyme targeted by glyphosate-based herbicides such as RoundUp, HPPD that is inhibited by herbicides such as isoxaflutole and mesotrione and ALS (also known as AHAS) that is inhibited by five families of herbicides including sulfonylureas (SU), imidazolinone (IMI), triazolopyrimidine, pyrimidinyl-benzoate and sufonyl-aminocabonyl-triazolinone[8,9]. Thus, there is an expectation that a number of different herbicide tolerant gene edited plants will be developed in the future.

Herbicide tolerant GM crops are genetically engineered so they can be blanket sprayed with the associated herbicide (weedkiller) without killing the crop. The first such transgenic GM crops on the market were 'RoundUp Ready' crops created by Monsanto (now Bayer), which are blanket sprayed with the weedkiller Roundup (active ingredient, glyphosate). There has

been significant environmental harm associated with these crops. This includes the loss of biodiversity and habitats associated with blanket spraying of crop fields with weedkiller: for example, a significant decline in Monarch butterfly populations in North America, driven by the loss of the milkweed habitat where they lay their eggs.[10,11] Other negative impacts include the spread of weedkillers in the environment, including in soils and watercourses, with multiple adverse effects: for example, the adverse effects of RoundUp on amphibians, including frogs.[12]

The potential for such negative impacts on biodiversity, including insect and birdlife, were one reason that GM crops were never commercialised in the UK, following the results of the Farm Scale Evaluations (FSEs) of such GM crops, published in the 2003.[13,14,15,16] Now that there is a lot more evidence of environmental harm, from growing herbicide-tolerant GM crops in North and South America, it is hard to understand how deregulating gene edited GM herbicide-tolerant crops would be consistent with the UK Government's stated aim of maintaining high environmental standards.

Over time, blanket spraying of RoundUp Ready crops with RoundUp has led to the weeds that are sprayed developing resistance to this weedkiller.[17] Such weeds are sometimes known as 'superweeds'. This has led to more spraying, often with multiple herbicides, and more resistant weeds.[18,19] This has negative consequences for the environment, but also for farmers, who face increased costs and greater difficulties in tackling weeds. Other herbicide tolerant traits in existing transgenic GM crops include tolerance to glufosinate, HPPD inhibitors such as mesotrione and isoxaflutole, and ALS inhibitors such as sulfonylurea and imazamox. In response to the problem of glyphosate resistant weeds, the industry has developed new transgenic GM herbicide tolerant crops which are resistant to additional weedkillers, such as 2,4-D and dicamba, as well as glyphosate. Such crops exacerbate concerns about adverse environmental impacts, pesticide residues in the food chain, and the future evolution of weeds which will become resistant to multiple herbicides.[20] In the case of dicamba, there is also concern about the impacts of drift from GM crop field to neighbouring crops, which can be damaged or killed as a result. The commercialisation of dicamba-resistant transgenic GM crops has led to numerous lawsuits in the USA.[21]

There are also concerns about human health, associated with the blanket spraying of weedkillers on herbicide tolerant GM crops. Such concerns would also apply to gene edited GM crops. Over time, farmers have doubled their glyphosate applications on RoundUp Ready transgenic GM soya per season from two to four, and the late season spraying of glyphosate results in much higher residues in the harvested plants and products.[22] In 2015, the World Health Organisation's (WHO) cancer agency, the International Agency for Research on Cancer (IARC), classified glyphosate as "probably carcinogenic to humans".[23] This has led to ongoing controversy about its safety, including lawsuits in the United States.[24]

If gene edited GM crops are deregulated, this would include herbicide-tolerant gene edited crops such as Cibus' sulfonylurea-tolerant oil seed rape. Significant harm to biodiversity could result without any prior risk assessment. Further, since oil seed rape spreads easily in the environment and can establish as weeds, there would be no control over where these plants ended up, and any herbicide-tolerant traits could transfer from oil seed rape to wild

relatives. In addition, the risk to human health of increased pesticide residues, due to blanket spraying, would not be assessed. Over the longer-term, weeds would become resistant to sulfonylurea herbicides, leading to more use of weedkillers. Other gene edited herbicide tolerant crops could also be introduced (in different crop plants, and/or with tolerance to other weedkillers).

This problem could be introduced (and re-introduced) into English farmland multiple times, since deregulated gene edited herbicide-tolerant GM crops could be introduced through multiple sources, within England or as imports (which would also be deregulated). Further, gene edited crops or resistant weeds could also spread elsewhere (for example into Scotland or Wales). As well as causing environmental damage and problems for farmers, this could contaminate food supply chains and damage the food and agriculture sectors (see Sections 4.2 and 4.3).

### *2.2 How would environmental harm and the evolution of resistant pests, weeds and pathogens be monitored?*

As noted in Section 2.1, the widespread planting of herbicide-tolerant GM crops in North and South America has led to harm to biodiversity and the spread of herbicide-tolerant weeds, with negative impacts on the environment and farming. Similar problems can be expected to occur with gene edited herbicide-tolerant crops.

Similarly, the planting of pest resistant GM crops has led to the spread of resistant pests and surges in secondary pests.[25] Pest-resistant gene edited crops are not currently a major area of research: however, if they were developed, similar problems would be expected to occur. Disease resistant gene edited crops are a major area of research and are considered in Section 2.3 below: again, problems can be expected, such as the evolution of pathogens. These problems should ideally be avoided but at minimum they require adequate surveillance and monitoring, so that actions to mitigate harms can be undertaken if this is possible.

Current regulatory requirements for GMOs require a monitoring plan to be submitted to regulators, but if gene edited GM crops are deregulated there will be no monitoring to identify or address environmental harms.

This lack of monitoring is not only a concern for plants but for all gene edited organisms that would be exempted from regulation as GMOs, including highly mobile wild animals such as insects and fish, long-lived species such as trees, and micro-organisms (including potential pathogens).

### *2.3 How would silent reservoirs of pathogens and dangerous evolution of pathogens be avoided if disease-resistant gene edited GM plants and animals are deregulated?*

Disease-resistance in animals and plants, including farmed and wild animals and trees, is a major area of gene editing research. A major area of concern includes the potential for pathogens, including viruses, bacteria and fungi, to evolve in response to genetically engineered resistance in the plant or animal, so that the plant or animal is no longer

resistant to disease. Apart from reducing the effectiveness of genetically engineered resistance, this can potentially lead to the pathogen evolving to become more virulent or more transmissible, with potentially devastating consequences. A related concern is that a GM disease-resistant animal may be infected but not sick, perhaps benefitting the individual animals but putting other animals at risk of infection. These risks are required to be considered in current risk assessments for GM disease resistant animals.[26] However, if disease-resistant gene edited plants and animals are no longer regulated as GMOs, there will no longer be any requirement for such risks to be assessed before they are released into the environment, either in experiments or on a commercial scale.

These risks are not purely theoretical. Despite much research, disease resistant GM crops have proved very difficult to deliver. The only exception is a small quantity of GM papaya with resistance to the Papaya ringspot virus (PRSV). GM papaya is grown commercially in the USA (Hawaii) and has also been grown in China. However, GM papaya is now losing PRSV-resistance in China and Taiwan, where a new variant of PRSV appears to have evolved.[27]

Many of the technical problems encountered by researchers working on transgenic GM plants are likely to be the same for gene edited GM plants: these include a tendency for genetically engineered disease resistance to compromise the yield or quality of the crop; resistance to one type of pathogen to confer susceptibility to another type; potential negative side effects on beneficial microbes (for example, fungi interacting with the plant or microbes in the gut of feeding animals); and a loss of disease resistance, due to pathogens evolving over time.[28] Conventional breeding, in some cases using Market Assisted Selection (MAS), is a more effective way to achieve durable and broad-spectrum resistance, while employment of a single resistance gene and adaption of the pathogen often leads to resistance breakdown in a short period.[29] Disease resistance is therefore an example where a small change in a single gene can be more risky than the multiple mechanisms of resistance in conventionally bred plants: the argument that such changes "could have' occurred naturally is therefore spurious.

The same concerns apply to GM trees (See Section 2.6), whether created using transgenics or gene editing: disease-resistant trees can lead to pathogens evolving to become resistant and disease-tolerant trees (which do not necessarily negatively affect pest or pathogen populations, but are intended to survive attack) could become reservoirs for pests and pathogens, with consequences for neighbouring susceptible trees.[30] None of these risks would be assessed if gene edited trees were exempt from regulation.

### *2.4 How would food safety be guaranteed?*

Food sold in England has to meet general food safety requirements and some new foods and ingredients are specifically assessed. However, this is not sufficient to assess the safety of GM foods, including those produced through gene editing.

For example, several attempts are underway to create gene edited GM crops with altered nutrient content, including altered oil content or increases in specific nutrients.[31] If nutrient levels are altered in GM plants (including gene edited plants) the effect on humans and

animals may depend on the concentration or dose received when eating it and other complex factors, such as what else is in their diet. This concentration can vary depending on environmental conditions, such as the amount of sunlight or the type of soil. Many vitamins and minerals, for example, are necessary in small quantities, but harmful in large ones, and may be harmful to particular groups of people. Other problems can arise because GM plants are not 'ingredients' but living organisms that interact with their environment. For example, one problem with attempts to genetically engineer enhanced iron and zinc content in plants is that such plants may also accumulate toxic metals such as cadmium if they are planted in contaminated soils.[32] For this reason, risk assessments for GM crops under current GMO regulations require samples of the plants to be grown in several different locations. In addition, scientific evidence of benefits and harms associated with different nutrients often changes over time. Conventional ingredients can be added or removed, but altered nutritional properties in gene edited plants will spread in the environment and these changes may not be reversible. This could affect whole foods that are eaten without processing, such as apples or tomatoes, or commodity crops such as wheat or maize, that are used in bread or processed foods.

Gene edited meat, milk, eggs and fish may also be produced and, if deregulated, could enter the market without any traceability or labelling. This would make it very difficult to recall products if anything goes wrong. Other sectors that could be affected include the drinks industry: for example, if gene edited barley, hops, cider apples or grape vines were introduced.

### *2.5 How would reproductive material (such as seeds or animal sperm) from gene edited GM organisms be controlled?*

If gene edited organisms are deregulated, there will be no labelling or traceability for seeds or other plant or animal reproductive material (rootstocks, nuts, fruits, bull sperm etc.). This means that it would be extremely difficult to track the whereabouts of gene edited organisms and their impacts on health or the environment.

### 2.6 *How would the risks of releasing gene edited GM insects, fish and trees be addressed?*

Due to their highly mobile or long-lived nature, the impacts of GM insects, fish and trees are particularly difficult to predict, monitor and track. If gene edited organisms are deregulated, they could spread in the environment without any prior risk assessment or knowledge of their whereabouts.

Genome editing has been attempted in diverse flies, bees, beetles, butterflies, moths, and grasshoppers.[33] Reportedly, researchers are even studying whether it is possible to genetically engineer bees to be resistant to pesticides.[34] Currently, only GM mosquitoes, and a few GM agricultural pests, produced by the UK company Oxitec (now owned by US venture capital firm Third Security, LLC) have been considered for open release into the environment, and some experimental releases have of these GM insects have taken place (mainly experimental releases of GM mosquitoes in Brazil). No open release trials of GM insects have taken place in the UK or the EU. If gene edited organisms were deregulated,

gene edited insects could be released in experimental trials or on a commercial scale in England, with no prior risk assessment or public consultation and without any requirements for monitoring or traceability. Gene edited agricultural pests could contaminate the food chain (see Section 4.3), and disease-resistant gene edited insects could lead to the same problems with the evolution of pathogens discussed in Section 2.3.

If gene edited organisms were deregulated, gene edited fish could be released in experimental trials or on a commercial scale in England, with no prior risk assessment or public consultation and without any requirements for containment, monitoring or traceability. Transgenic GM fluorescent aquarium fish are currently marketed as pets in the USA (tradename GloFish), but are banned in the EU and elsewhere. In addition, some transgenic GM salmon from experimental production of GM salmon by US company AquaBounty has been sold (unlabelled) as food in Canada. Although there are still major concerns about adverse impacts on wild salmon should these fish escape (especially the effects of enhanced growth leading to GM salmon outcompeting wild salmon for resources), this GM salmon is required ty US and Canadian regulators to be produced in contained on-land facilities. Studies to date on gene edited fish and seafood have focused on proof-of-principle of gene editing techniques in a number of different species (Atlantic salmon; rainbow trout; Rohu, grass, and common carp; channel and southern catfish; Pacific oyster; Nile tilapia and gilthead sea bream). Studied traits include sterility, enhanced growth, and disease resistance (see Section 2.3 for a discussion of the risks of disease resistance).[35] If gene edited fish were to be deregulated in England there would be no means for regulators to assess the risks or to restrict their production to contained on-land facilities.

If gene edited organisms were deregulated, gene edited trees could be released in experimental trials or on a commercial scale in England, with no prior risk assessment or public consultation and without any requirements for monitoring or traceability. Insect resistant transgenic GM poplar trees have been planted in China in the past, but they performed poorly and no new varieties have been approved.[36] There is currently a proposal to release blight-tolerant transgenic GM American Chestnut trees in forests in the USA: however, this has yet to be approved. Numerous concerns include the possibility that these GM trees (which are still infected but survive) may act as a reservoir for blight (see Section 2.3). Gene editing has been applied to trees since 2014, with a focus on poplar, citrus and apple trees.[37,38,39] Trees are long-lived and produce large amounts of seed and pollen that can disperse over long distances and support large diverse communities and food webs: therefore, risk assessment is considered essential before releasing GM trees within the EU and internationally.[40,41]

## *2.7 How would the risks of releasing gene edited GM wild animals be addressed?*

To date no GM wild animals have been released into the environment, with the exception of GM insects (see Section 2.6). However, the use of gene editing has considerably expanded the species that are being altered in laboratories, and some scientists have called for the release of gene edited wild animals into the environment. These include proposals for the "genetic rescue" of endangered species (including mammals such as the black-footed ferret, and birds such as the passenger pigeon and hen harrier, in the USA), the "de-extinction" of animals such as the woolly mammoth, and the release of genetically engineered wild

species in attempts to wipe out invasive species or introduce disease-resistance in endangered species.[42] However, editing the genomes of wild animals has raised concerns that this research has the potential to rapidly alter ecosystems in irreversible and damaging ways.[43] Criticisms include the continued high risk of failure due to the difficulties of cloning (and failure of alternatives in birds), technical risks inherent in re-introductions of species, loss of culture in resurrected animal species, lack of remaining habitat for some species, potential negative consequences for extant species (including diverting funding and resources, and providing reduced incentives for traditional conservation), ecological impacts of introducing long-absent or genetically-modified species, and potential negative impacts on human populations.[44,45]

There is potentially no limit to the wild species that might be gene edited in future, including, for example, bats, birds, lizards, squirrels and frogs. As with farm animals, there could be potentially serious negative impacts from attempts to create disease resistant wild animals and release them into the environment (see Section 2.3).

If gene edited organisms are deregulated there would be no risk assessment before they are released into the environment, no monitoring, no public information, and no traceability. Gene edited wild organisms could be imported and released without any records of what they are, or where they are in the environment. Any adverse consequences could be irreversible.

### *2.8 How would the risks of releasing gene edited GM micro-organisms, such as bacteria and viruses, be considered or controlled?*

Most research using genetically engineered viruses and bacteria takes place in "contained use" facilities, such as laboratories, which are not covered by the current consultation.

However, a number of open releases of transgenic GM micro-organisms have taken place. For example, in the European Union (EU), consent was given for a genetically engineered virus (Citrus leaf blotch virus) to be released in field trials in Spain in 2015, with the aim of using this GM virus to delay citrus flowering.[46] Similarly, consent was given for the open release of genetically engineered bacteria (from the species *Pseudomonas fluorescens*) in Sweden in 2005, with the aim of controlling fungal pathogens in wheat.[47] We know about these open releases because there is a register of applications established under current GMO regulations. Applicants are required to state what genetic changes have been made and answer a series of questions, such as whether the micro-organism is a known pathogen or not.

If (some) gene edited GM organisms are deregulated in England there would be no record of where they are released (for experimental or commercial purposes), no risk assessments and no monitoring. This would be of particular concern for human, animal or plant pathogens which cause disease or illness. Small mutations in micro-organisms can dramatically alter the properties of pathogens, thus the risks of gene editing include creating or enhancing the virulence of human, animal or plant pathogens. Any adverse consequences could be irreversible. More subtle problems could include a broad range environmental risks, such as changing the behaviour of the plants or pests to which gene

edited micro-organisms are applied, in ways that have adverse consequences for ecosystems.

### 3. Harm to animals

Consideration of animal welfare is part of the risk assessment process for GMOs. Exempting gene edited animals from risk assessment is likely to lead to harm to animals.

## *3.1 How would the harm to animals associated with cloning and other reproductive technologies be avoided?*

There are two major approaches to editing the genomes of mammals. The first is a two-step approach where gene editing is used to generate targeted mutations in somatic cells (non-reproductive cells), followed by cloning animals using somatic cell nuclear transfer (SCNT). Cloning involves implanting a donor nucleus (containing DNA) from the somatic cell into an egg cell. The second method is a one-step approach involving direct injection (called "cytoplasmic injection") of fertilized egg cells (zygotes) with editor mRNA (messenger RNA). mRNA is a chemical which carries genetic information from DNA into the cell. In both cases, the egg must be implanted into the mother animal, in the hope of producing live offspring with the intended changes to their DNA.

Most applications of gene editing in mammals still rely on the use of cloning (SCNT) to reproduce gene edited animals, resulting in serious negative welfare impacts, including effects on health, on a significant proportion of the clones and surrogate dams involved in the cloning process.[48] This includes large numbers of failed pregnancies, still births, deformities and early deaths. Alternatives such as cytoplasmic injection (CPI) have somewhat lower failure rates, but still raise animal welfare issues regarding failure rates, and cause additional problems because the desired trait is not successfully expressed in all offspring or all cells of offspring (known as mosaicism). A single gene edited animal typically requires hundreds (or sometimes thousands) of embryo transfers (with CPI or SCNT respectively).[49] For the animals, the impacts of the following should be considered:

- Egg harvesting procedures, including superovulation, typically involving hormones, and/or surgery, in female egg donors (except where these eggs can be obtained from slaughterhouse carcasses);
- Pregnancy in surrogate mothers, typically also involving hormone injections and surgery;
- Miscarriages, stillbirths, deformities and deaths associated with the numerous unsuccessful pregnancies;
- Slaughter of live animals which do not carry the required genome edits;
- Any adverse effects in the surviving ('successfully edited') animals.

For example:

- The University of Minnesota and the company Recombinetics have edited the genomes of dairy cows to make them hornless, using CRISPR-Cas9: 295 nuclear transfers resulted in 26 implanted embryos and only 5 live births (from 14 pregnancies at day 40). Of these, three were non-viable and only two calves survived to 90 days.[50] These researchers predict that repeated re-editing and cloning would

be required over a period of 15 to 20 years to create a population of hornless cows big enough for the commercial market, assuming that the top 1% of bulls would be gene edited and cloned in each generation.[51]

- The Roslin Institute at the University of Edinburgh has used genome-editing tools to attempt to make European domestic pigs resistant to a deadly viral disease called African swine fever.[52] 502 embryos transferred to 14 recipients led to 8 pregnancies (one subsequent abortion at 15 weeks) and finally 55 piglets being born. Of those, 9 piglets (16%) were edited, 5 (9%) had one copy of the desired genetic change and 2 (3.6%) had two copies (both of these were accidentally killed by their mother within 24 hours after birth). Of the 9 edited piglets, two were stillborn.

If gene edited animals were deregulated in England, as the Government proposes, there would be no assessment of the risks to animal welfare caused by the repeated use of cloning or other methods to create the founder animals. Cloning could also be used on an industrial scale to attempt to create commercially viable flocks or herds of animals.

### 3.2 *How would the introduction of harmful traits in farm animals (such as excessive muscle growth) be avoided?*

Genome editing techniques have been used to create animals with increased muscle growth. These include pigs, cows, sheep and goats. In these animals, genome editing is used to knock out the myostatin gene (MSTN) that inhibits the growth of muscle cells. However, problems observed with increased muscle growth can include birthing difficulties due to large offspring size, enlarged tongues and severe health problems, including lameness. In these examples, the use of new genome editing techniques does not address or resolve many of the problems of animal suffering caused by the use of older genetic engineering techniques.

### 3.3 ***How would the broader implications for animals in food production be considered?***

Most potential agricultural applications of genome editing in farm animals aim to produce more meat, faster, using less space and thus support a highly industrial form of agriculture that causes a lot of animal suffering (instead of changing/adapting the system so that there is less animal suffering). This is the case even for supposedly beneficial traits such as disease-resistance, which could lead to animals being packed more tightly into industrial-scale farms.

In addition, gene editing narrows the gene pool, which reduces diversity and puts animals at increased risk of health problems. A narrower gene pool plus greater intensification could also increase the risk of spreading disease to non-resistant animals.

Gene edited pesticide-resistant bees (see Section 2.6) could lead to increased use of pesticides, with harmful effects on other organisms and the wider environment. Similar problems would arise in other sectors (e.g. aquaculture) if other gene-edited pesticide-resistant animals were to be developed.

These broader implications will not be considered if gene edited animals are deregulated.

### *3.2 How would the implications for the welfare of horses, working animals and pets be considered?*

If gene edited animals are deregulated, this would include horses, working animals and pets. However, any suffering to the animals during their production and/or lifetimes would not be considered if there is no approvals process. Gene edited animals could also be imported from other countries, where controls over the welfare of gene edited animals might be limited.

The first gene edited dogs were reported in China in 2015, where researchers created beagles with double the amount of body mass, by micro-injecting dog embryos.[53,54] Of 65 embryos they edited, 27 puppies were born, but only two had disruptions in both copies of the myostatin gene, and disruption of myostatin was complete in only one of these. One of the researchers told MIT Technology that the dogs are expected to have stronger running ability for hunting and police (military) applications. However, apart from the use of multiple dog embryos in the production of these gene edited dogs, double-muscle growth might also be expected to cause suffering to the animals. These concerns apply to both working animals and pets. The same gene has been edited in rabbits and could be edited in other pets.[55]

In Argentina, researchers have used gene editing to target the same gene in horses, creating a number of gene edited embryos using cloning.[56] Again, there could be serious implications for the welfare of these animals where these embryos to be implanted and gene edited horses born.

### *3.3 How would the implications for the welfare of wild animals be considered?*

Gene edited wild animals are also likely to be created and released if gene edited organisms are deregulated (see Section 2.7). The animal welfare issues discussed above will also apply to these wild animals.

## 4 Impacts on trade and consumer choice

Gene-edited organisms are classed as genetically modified organisms (GMOs) in most countries in the world, including the EU, the devolved administrations (Wales, Scotland and Northern Ireland) and Parties to the Cartagena Protocol on Biosafety.[57] The proposals therefore have major implications for consumer choice and for trade within the UK's internal market, with the EU, and more globally. Since the whereabouts of gene edited organisms, in the food chain or the environment, will be unknown if they are deregulated, it would be impossible to comply with other countries' labelling, traceability and monitoring requirements for GMOs. Businesses in the food, farming, aquaculture and fishing sectors will undoubtably be impacted, but there are also many other sectors where gene edited organisms could be released, such as forestry and horse racing.

### *4.1 How would consumer choice and trust in food retailers be maintained?*

If (some) gene edited GMOs are not regulated as GM foods, they will not be labelled as GM. This means that consumers that do not want to eat them will not be able to avoid them, even if they wish to do so (this might be due to animal welfare or environmental or other concerns, not just food safety issues). Although the EU has approved some GM crops for use in 'food and feed' in England and elsewhere, these are only used in animal feed and a small amount of cooking oil. This is because supermarkets prefer not to stock GM foods because customers don't buy them. Currently, only a few species of GM crops enter the UK (mainly soya and maize for use in animal feed), but if gene edited organisms are deregulated, this could expand in future to include a wider range of foods, including gene edited fish, for example, and meat, milk and eggs from gene edited farm animals. Drinks could also be affected: for example, if gene edited barley, hops, cider apples or grape vines were introduced. Under the UK Government's proposal, such products would not be traced, monitored or labelled on the English market, so it would be difficult for retailers to maintain public trust in the integrity of food supplies or offer customers the choice of avoiding any of these foods or drinks.

This problem would be exacerbated by the risks of contamination (see Sections 4.2 and 4.3).

### *4.2 How would contamination of non-GM food and drink supplies with gene edited GM crops, meat or fish be avoided?*

There are numerous examples of contamination incidents in the countries where GM crops are grown today, in which crops and food supplies have become contaminated with GM crops or foods. These have resulted in costly product recalls and damage to export markets. GM contamination incidents have often resulted from experimental releases, not only from commercial products, and have often spread worldwide.[58]

For example, in 1998, Aventis's GM StarLink maize (corn) contaminated maize supplies and many food manufacturers had to recall whole product lines. Aventis had to pay more than U.S. $1 billion to withdraw StarLink and compensate producers.[59,60] The Starlink contamination incident had a large negative effect on U.S. maize (corn) prices.[61] In 1999, the EU detected pollen from a GM canola not yet approved for consumption in the EU in a honey shipment from Canada. As a result, honey shipments to the EU dropped by 55% between 1998 and 2000, with a monetary loss of $4.8 million, to the lowest level in over ten years.[62] When Canadian flax exports were contaminated with an experimental transgenic GM variety called Triffid, which had been thought to have been destroyed, the total costs for quarantine, testing, segregation etc. in the first 1-2 years alone were estimated to be 29 million Canadian dollars. This does not include costs to the EU flax industry. In the long term, Canada lost some shares to Russia and Ukraine, who increased flax production to service short supplies in the EU flax market.[63] Similar problems occurred with GM RoundUp Ready wheat not approved for cultivation, which was found on an Oregon farm in May 2013, causing Japan and South Korea to temporarily reject some U.S. wheat imports and the EU to call for tougher testing of shipments from the EU. This led to a class action law suit which was settled by Monsanto paying $ 350,000.[64] The same wheat was again found in Montana in 2014 and Washington State in 2016 and this led Japan and South Korea to announce that they would defer new purchases of U.S. wheat until they could implement a new test for this GM wheat.[65] Glufosinate resistant GM rice, which escaped into the supply

chain from field trials conducted from 1999 to 2001 in Louisiana State University, was detected in a rice shipment to the EU in 2006. As a result, the EU greatly reduced imports from the U.S., costing U.S. rice farmers at least U.S.$ 1.2 billion.[66] In 2014, China, which has not approved GM alfalfa, rejected all shipments containing GM material upon testing of hay imports from the U.S. This resulted in a drop in U.S. hay prices.[67] Starting in November 2013, China rejected more than 850,000 metric tons of U.S. maize (corn) containing GM MIR162 maize (corn) produced by Syngenta, which was not approved for import to China. According to analysis by the U.S. National Grain and Feed Association (NGFA), this trade disruption cost between $1 billion and $2.9 billion in economic losses.[68] This contamination incident led to Syngenta being sued by Cargill and by U.S. farmers for financial damages.

The proposal to deregulate gene edited GM organisms could also lead to contamination of non-GM supplies, but this could occur much more broadly, including meat and dairy products, fish, the drinks sector, and many non-agricultural products. Contamination would also have major adverse effects on organic farmers (see Section 4.5). There would be particular problems for Scotland and Wales, due to land borders with England and the existence of the internal market in Great Britain.

### *4.3 How would contamination of non-GM food and drink supplies with gene edited GM insects be avoided?*

Transgenic GM agricultural pests have been developed by the UK company Oxitec (now owned by US venture capital firm Third Security, LLC). A small open release trial of Oxitec's GM diamondback moths has been conducted in the USA, but no further trials are planned, and proposals to release GM diamondback moths in the UK, GM olive flies in Spain and GM fruit flies in Brazil and Australia never went ahead. A major concern of farmers, especially of organic farmers, was that their crops would become contaminated with GM insects, since these were genetically engineered so that the female larvae of these GM insects would die within the crop. Similarly, in future, gene edited insects, released experimentally or on a commercial scale, could contaminate crops, including organic crops and other certified GM-free supplies. If gene edited insects are deregulated there would be no way to prevent such contamination and the damage to markets that could result.

### *4.4 How would agricultural and horticultural exports to the EU and elsewhere be protected?*

Gene edited products are required to be labelled as GM in most countries in the world and most consumers do not want to eat them. Thus, gene-edited foods produced in England would have to be labelled as GM foods before export to most countries in the world. There are also a number of 'GM free' markets, where products must be certified as GM free to obtain the relevant status and labelling. For example, these include organic foods and the growing 'non-GMO' market in the USA.[69]

The Government's proposal would remove the legal requirement to trace and label at least some gene edited foods in England, under the laws covering GMOs. Thus, gene edited ingredients would not be traceable through the food chain and could not be labelled in the way that most countries require.

This would likely have major implications for exports of food, drinks, animals, plants and seeds from England, since in many cases exporters would not be able to comply with the legal requirements of other countries, since they would not know whether or not their supplies contained gene edited GMOs. The whole agriculture sector could be affected, including everything from sugar to bread, meat and milk, fruit and vegetables, beer, wine and cider, live animals, bull sperm, seeds and other plant reproductive material.

Some research is now taking place using gene editing in turf grass.[70] UK turf grass sales could therefore also be affected.

The consequences could be worldwide, but it should be noted that the EU has particular powers to restrict imports from England, or the whole UK, under the UK-EU trade agreement, to increase inspections at borders, or to withhold third country listing from some or all agricultural products.

### *4.5 How would the organic sector be protected?*

Regulations for organic farming worldwide prohibit the use of GMOs and products produced by or from GMOs. Within the EU, this ban is included in EU Council Regulation 834/2007. Since gene edited organisms are regarded as GMOs in most countries in the world, and this definition is supported by organic farming organisations and their customers, gene edited organisms and products produced by or from them cannot be labelled or sold as organic products.

A 2015 USDA Organic Survey revealed that 92 U.S. organic farms suffered combined monetary losses of over $6 million between 2011 and 2014 due to transgenic GMO contamination.[71] Others have estimated that contamination of the total organic maize crop could costs U.S. organic farmers $90 million annually and report that, in Brazil, farmers lost higher premiums for organic products because of transgenic GM contamination of organic soybeans.[72]

As part of the recent UK-EU trade agreement (Annex TBT-4, p.515), the EU has recognised the laws and regulations of the UK regarding organic products as equivalent to EU laws and regulations, so organic foods can be exported from the UK to the EU, with an organic label. However, the EU can object to any change in UK law that changes the status of organic products and withdraw the equivalence agreement.

Similarly, exports of organic foods, drinks or seeds from the UK could also be banned internationally, if they could not be guaranteed to be free of gene edited GM organisms, or products derived from such organisms, as required by organic certification schemes worldwide.

### *4.6 Where would gene-edited GM products be sold?*

Although the risks to markets for GM-free products are manifold, the existence of significant markets for gene edited products is unclear. Only two gene edited crops are on the market

to date, in the USA, and the companies involved (Cibus and Calyxt) are far from commercially successful. Cibus withdrew from a planned IPO in without explanation in 2019 (likely due to large operating losses).

### *4.7 How would imports of gene edited GM products be controlled*?

If gene edited GM organisms are deregulated in England, they will not be traceable as there will be no record of where they are in the environment or the food chain. Similarly, imports would not be controlled, so that gene edited crops, foods, drinks, trees, fish, insects, pets, race horses, farm animals and bacteria (for example) could all enter England without any risk assessments, monitoring, labelling or traceability. These gene edited GM organisms could end up anywhere in the environment or food chain, including in products intended for export to countries which require gene edited organisms to be regulated as GMOs. This could include numerous products that might be rejected by consumers and/or could be banned from export overseas. Imports could include gene edited organisms that developers might be hesitant to produce in England, for example due to animal welfare or environmental concerns (see Sections 2 and 3), but which the UK Government would be powerless to control. Examples of some of the business sectors that might be affected are considered below.

### *4.8 How would the forestry sector be protected?*

If gene editing were deregulated in England, with no labelling or traceability, there could be no guarantee that wood, nuts, or other products from gene edited trees, or saplings, rootstock, or grafts from the trees themselves, were not present in exports from the English forestry sector. Thus, it could become impossible to meet the traceability and labelling requirements of other countries, leading to onerous controls or even total bans on any exports. It is unclear how any testing for gene edited trees could be conducted if these organisms are not registered in a database, together with the required testing methods, prior to release.

### *4.9 How would the fish and seafood sectors be protected?*

If gene editing were deregulated in England, with no labelling or traceability, there could be no guarantee that gene edited fish or seafood was not present in exports from the fishing or aquaculture sectors in England. Thus, it could become impossible for these sectors to meet the traceability and labelling requirements of other countries, leading to onerous controls or even total bans on any exports. It is unclear how any testing for gene edited organisms could be conducted if these organisms are not registered in a database, together with the required testing methods, prior to release.

### *4.10 How would the horse racing, greyhound and pigeon racing sectors be protected?*

In October 2020, the Horse and Hound reported that "*Genetically modified horse embryo tech could be used to enhance performanc*e", following reports of production of the first genetically edited horse embryos in Argentina, with the aim of enhancing muscle growth

(see Section 3.2). This research involves researchers based at the Argentinian company Kheiron Biotech, which states that it aims to improve muscle growth, endurance and speed in horses, using gene editing.[73]

The International Federation for Equestrian Sports (FEI) lifted a ban on cloned horses in 2013, arguing that 'fair play' was protected. However, a similar decision has not been taken with regard to GM horses, including gene edited horses.[74]

If gene editing were deregulated in England, with no labelling or traceability, there could be no guarantee that gene edited horses were not present in English horse racing, show jumping, polo or other competitions. Under the Government's proposal, gene edited horses could be produced in England or imported without any regulatory control. This would likely lead to a ban on horses from England taking part in internationally recognised competitions.

Horse breeding registries might also be affected, since British studbooks could no longer guarantee the status of English horses, which could have been gene edited without any system of labelling or traceability, if they are exempted from regulation. This could result in a significant drop in the value of English-registered horses, or even a ban on exports.

Similar concerns would apply to the greyhound and pigeon racing sectors.

### *4.11 How would rare breeds be protected?*

Farming of rare breeds of farm animal is based on registered pedigrees.[75] However, if gene editing is deregulated, it could be applied to rare breeds without the relevant breed society being fully informed about what has taken place. This would lead to uncertainty about the status of rare breeds, which could affect their trade within the UK and overseas. For example, rare breed certificates obtained in England might be regarded as invalid elsewhere. Export of rare breeds from England could even be banned, including into the EU, or to Scotland, Wales and Northern Ireland, and perhaps internationally.

### *4.12 How would the pet breeding sector, including pedigree dogs or cats, be protected?*

GM pets could be created using gene editing techniques, which have already been applied to enhance muscle growth in dogs and rabbits (see Section 3.2). Gene editing might be applied to pedigree breeds in future.

If gene editing is deregulated, it could be applied to pedigree animals, including dogs, without the relevant breed society (such as the Kennel Club or the Governing Council of the Cat Fancy) being fully informed about what has taken place. This would lead to uncertainty about the status of pedigrees, which could affect their trade within the UK and overseas. For example, pedigree kennel club registrations obtained in England might be regarded as invalid elsewhere, significantly reducing the value of all England-registered pedigree animals. Export of pedigree animals from England could even be banned: into the EU, or to Scotland, Wales and Northern Ireland, or internationally.

### *4.13 How would the UK internal market be protected?*

Wales, Scotland and Northern Ireland have devolved powers for decision-making in relation to food safety and the environment, including GMOs. As a result of the Northern Ireland Protocol, Northern Ireland will effectively remain in the EU single market for goods, whilst the rest of the UK (Great Britain) will not. Trade between England, Wales, Scotland and Northern Ireland is covered by the Internal Market Act, and Common Frameworks are being written, to manage decision-making by civil servants and ministers, including dispute resolution. A draft Food and Feed Safety Hygiene Common Framework has been published which states (para 5.18), that, "*Where one or more nation wishes to diverge from a four nations approach to food & feed safety and hygiene, before divergence can happen, nations must first see if they can agree a common approach that accommodates the desired outcomes of individual nations*". [76] However, it is clear that a common approach has not been agreed in the context of this consultation, which applies to England only.

The Government's proposal to deregulate gene edited organisms will reinforce internal UK borders and make a mockery of the internal market, potentially impeding the free flow of a wide range of goods, including foods, agricultural products, forestry products, horses, pets etc., as outlined above. Further, devolved nations will have to deal with the risks of contamination which could be devastating to exports, as discussed in Sections 4.2 and 4.3.

### *4.14 Who would be liable if anything if anything goes wrong?*

Without traceability, monitoring and labelling, it would be difficult to determine who was liable for harm caused by gene edited GM organisms if anything went wrong, or for lost or damaged markets. The costs of harm and lost or damaged markets might be borne by taxpayers, consumers, retailers, farmers and other business sectors, rather than the producers who should be responsible for the safety of their products.

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