About A Bigger Conversation
www.abiggerconversation.org
A Bigger Conversation is an initiative of Beyond GM in the UK. While the Beyond GM campaign reaches out to citizen stakeholders, the A Bigger Conversation aims to bring together experts and forward thinkers – including scientists, academics, farmers, breeders and grassroots leaders – from all sides of the debate to establish a more in-depth dialogue around key issues around genetic engineering, food and farming.

About Compassion in World Farming
www.ciwf.org
Compassion in World Farming was founded 50 years ago in 1967 by a British farmer who became horrified by the development of modern, intensive factory farming. Today we campaign peacefully to end all factory farming practices. We believe that the biggest cause of cruelty on the planet deserves a focused, specialised approach - so we are relentlessly focused on ending factory farming.
BACKGROUND

Gene editing technology in agriculture is now extending beyond plant species into a variety of different farm animals.

Biotechnologists argue that it can help improve animal welfare and increase yield and that altering the genome via gene editing should be viewed as an extension of normal animal breeding. Animal welfare and some civil society groups are unconvinced by this argument. In addition, the July 2018 European Court of Justice ruling means that new breeding techniques such as gene editing are, by law, genetic engineering and therefore must be regulated – and labelled – as such.

While gene editing in humans has attracted a great deal of media, and therefore public, attention around the science and ethical issues it raises, gene-edited animals, especially those intended for the human food chain, have yet to become a topic of widespread public or consumer concern.

More often than not, discussions about gene-edited animals focus on claims made about what the technology can achieve, how it will be regulated and, in some corners, what can be done to remove regulatory restrictions and hasten these products to the market. But there are equally important discussions; about ethics, risks vs benefits, alternative approaches, consumer preference and the larger agricultural system of which gene-edited animals are also a part.

The UK government has made it clear that it expects the products of biotechnology – including gene-edited animals – to be a major driver of agriculture in the future. In the US and Canada the first genetically engineered farm animal, the AquAdvantage salmon – produced using older style genetic engineering techniques – can now be sold, unlabelled, until 2022 when new USDA labelling requirements for the products of biotechnology come into force.

Worldwide regulatory agencies are struggling to keep pace with advances in biotechnology. For the general public, the idea of gene-edited animals intended for the food chain may barely beon the radar, but it is coming our way and we need to begin talking about it.

COMING TOGETHER

On June 18, 2019, an unusually diverse group of stakeholders gathered to discuss a rapidly developing issue in animal agriculture – gene-edited livestock. The day-long roundtable meeting, which was co-hosted by A Bigger Conversation and Compassion in World Farming, saw a mix of leading animal biotechnology scientists, ethicists, veterinarians, academics, theologists, policy makers, civil society groups and others gather together for a robust discussion on what the technology means for the animals and for the livestock sector.

The discussion was conducted under the Chatham House Rule and the day was structured into themed sessions: Do We Need Gene-Edited Animals?; Ethical And Philosophical Dimensions; Alternatives To Gene-Editing; and Assessing Risk, Monitoring Outcomes.

Participants noted that it has taken decades to refine the questions around genetic engineering as applied to plants and crops. While the discussion about livestock is more complex, this historical context was helpful in that it allowed the group to get to the nub of some issues more quickly.
Within a complex and deeply connected system like agriculture, the development and application of any technology cannot easily be viewed in isolation. Perhaps inevitably during the course of the day, discussions in one theme area overlapped with other theme areas. This report attempts to capture the discussion as it happened, overlaps and all. As far as possible, we have endeavoured to remain true to the conversation as it happened in order to give readers a sense of ‘being there’. Our hope is that the issues raised will serve to inform other emerging discussions around this issue.

AGREEMENT TO DISAGREE

Among the attendees were those who were strongly for and strongly opposed to gene editing technology in farm animals and while there was much agreement to disagree, there were also surprising points of accord around the table that might be built upon in future discussions.

FOOD SYSTEM CHANGE

There was, for instance, a general agreement that, in a variety of ways, our food system is no longer functioning optimally, that it needs to change and is, in fact, changing. The direction of that change and who or what the main drivers of it will be, however, was a subject of debate. It was clear from the discussion that there were different views about the application of incremental change versus systemic change and the degree and desirability of whole system management compared to a more pragmatic ‘single-problem-single-solution’ approach – although, in reality many farmers operate in an area somewhere between the two.

SELECTIVE USE OF GENE-EDITING

There was acknowledgement that certain diseases in farm animals, some of which can be devastating to entire herds, need to be addressed. Increased use of antibiotics and vaccines has drawbacks and may be inappropriate, ineffective or have knock on consequences for human health. In these instances, the case was made that gene editing may prove to be a useful tool. Many participants seemed willing to accept this – or at least did not dismiss it out of hand. However, some stressed that gene editing should not be used to address diseases that primarily result from keeping animals in stressful, crowded conditions. Such diseases should be tackled by improving housing, husbandry and hygiene.

RECOGNISING ‘ANIMALNESS’

There was agreement that we have a duty of care to our farm animals. Yet several participants said they found it difficult to introduce some ethical and welfare aspects into the discussion around the table. Some felt that concepts of ‘animalness’, or the essential nature of animals, as well as questions around what animals are for, and what we use them for, are under-represented in discourse on gene-edited livestock, although they are of importance to large numbers of people. Their view was that intensive livestock operations make it difficult for animals to express their “animalness” and that gene-editing could be used to further entrench factory farming systems to a degree that it will make it more difficult to recognise and manage farm animals as sentient beings with their own intrinsic value.

THE NEED FOR REGULATION

The value of gene editing in terms of precision, efficiency and accessibility was also set out, but the notion that being more precise, at least in some aspects, equated with being safer or more predictable was challenged. For the most part, participants seemed willing to accept that there is sufficient uncertainty about gene editing, on a variety of levels, to preclude deregulation. It was also acknowledged that the goals and nature of regulations, as well as the need for greater stakeholder involvement, need to be explored and more clearly articulated.
CHALLENGE THE NEED FOR SPEED
A perceived advantage of gene editing is that it allows breeders to create new breeds more quickly – potentially avoiding 15 years of backcrossing in order to produce desirable traits in farm animals. This, it was agreed, had some advantages. But questions were also raised about the need for speed and whether it is genuine or ‘manufactured’ and whether speeding-up the processes around gene editing made it more difficult to study and understand its impacts and to regulate it sensibly.

NEXT STEPS
Although the roundtable was not intended to be a discussion about policy, during the course of the day some implications for policy and regulation did arise and these are discussed in the Assessing Risk, Monitoring Outcomes and Commentary sections of this report.

Following the meeting, participants were encouraged to continue the dialogue with the organisers and each other and to submit any further thoughts they may have had. Those additional thoughts, some further suggested reading, next steps or policy priorities that they felt were important have also been incorporated into this report.

The overall conclusion of the day was that gene editing is a powerful and potentially transformative technology. Applied to animals, under well-defined circumstances it may have some benefits. But hype suggesting that this technology is a magic bullet for the challenges of livestock production and for sustainable livestock farming is unhelpful and misleading.

Gene-edited livestock requires a much more nuanced understanding of current problems and science and civil society has really only arrived at the beginning of this discussion.

We are grateful to those individuals who agreed to participate so fully in this roundtable and we look forward to keeping the conversation going.
DO WE NEED GENE-EDITED ANIMALS?

Do we need gene-edited farm animals?

In beginning the day with this question, it quickly became apparent that context is everything.

The question was met with more questions – “Who is ‘we’?”, “What is ‘it’?”, “Define ‘need’?” – before the discussion eventually refocused itself on the current challenges and needs of the livestock industry and the animals within that system and how gene editing technology proposes to meet those needs.

The legitimacy or validity of the question “do we need gene-edited farm animals?” was raised. It was pointed out that over the course of time many technologies, with different types of benefits and costs associated with them, have offered themselves up as alternatives to the ones we have without being asked to justify society's “need”.

This is undoubtedly true. However, as was also pointed out, support for gene-edited farm animals, from research institutions and, as a result, in the media, is without exception based on the technology's ability to meet specific needs. It was therefore appropriate to ask the question: do we need gene-edited animals?

THE TOOL IN THE TOOLBOX

The phrase “we need every tool in the toolbox” was prominent throughout this session, and indeed the entire day. It is a phrase that has become something of a mantra in response to the complex problems we face in food and farming.

There was resistance to using this phrase amongst a number of participants. Why?

On the one hand, it is a simple shorthand for the notion that gene editing is not a panacea for all problems and goals; that it needs to be seen as one component of a range of approaches. On the other hand, it describes a distinct set of options but does not capture the whole systems management of living landscapes that many regard as critical.

The difference may be more to do with ways of thinking than science or ideology.

Those working with gene-edited animals appeared to take a more linear approach, looking for specific solutions to specific problems, tending to see the technology itself as neutral and believing that it is up to us, as a society, to decide how we use it.

In contrast, several people around the table viewed agriculture as a connected system where seeds, soil, animals and environment, as well as the machinery and chemicals used are in constant interaction. Changes to one aspect can trigger changes throughout the system and these changes can ripple out beyond the farm environment to the wider environment, to public health and even economic stability.

Within the perspective of a single problem/single solution dynamic, gene-edited animals appear to
hold great promise for the livestock industry, providing both short- and longer-term answers to intractable welfare problems. Within the perspective of an interconnected system, however, some questioned the direction in which gene editing will take animal agriculture and argued that, whether short-term or longer-term, the definition of solutions and measures of success need to be broader and more focused on sustainability and accessibility.

**SOME HISTORICAL CONTEXT**

Gene editing – the deliberate alteration of the genome to produce a specific character or trait in a living organism – is a new form of genetic engineering. The use of genetic engineering technology in food and farming has historically been framed as meeting the needs of – and therefore delivering benefits to – a wide range of stakeholders including consumers, farmers, industry and the wider environment. Over the decades these needs have been identified as:

- The need to improve yields in order to feed the world
- The need to reduce pesticide use as the toxicity of the agrochemicals – for both humans and the wider environment – has become apparent
- The need to produce more nutritious food – in response to accelerating declines in food nutrient levels
- The need to give farmers in developing nations a helping hand – in order to grow the cash crops on which the world's food supply depends
- The need to create novel foods – something which the food industry depends on in order to continue to stimulate the marketplace.

It was suggested by several around the table that older style genetic engineering has largely failed to meet these needs.

With the advent of new genetic engineering technologies – of which CRISPR is the most well known example – it is claimed that new and wider possibilities have opened up. It is a technology that is said to be quicker and easier to use and more precise and closer to the process of natural breeding than older style genetic engineering. It is developing rapidly and most recently has been proposed as a way of meeting a variety of needs within the livestock sector such as:

- Protecting animals from disease by altering their immune response
- Creating animals with desirable commercial attributes
- Adapting animals to their environments

There are other possibilities being explored but, according to the experts at the table, at least half of the R&D focus in gene-edited farm animals is on viral resistance. This research, in turn, is focused on those animals with the highest value in the marketplace (see *Alternatives to Gene Editing*, for more on this).

During the session these goals were considered more closely.

**PROTECTING ANIMALS FROM DISEASE**

Among the world's livestock certain diseases – e.g. PRRS (Porcine Reproductive and Respiratory Syndrome) and ASFv (African Swine Fever) and, in farmed salmon, ISA (Infectious Salmon Anaemia, or ‘salmon flu’) – have not only become commonplace, they have become difficult to eradicate.
Other long-standing diseases in farm animals, such as scrapie in sheep, TB and foot and mouth disease in cattle also continue to be problematical.

This is a tragedy for the animals and can represent a significant loss of income for farmers. Some of these animal diseases and the medications used to treat them may also be a threat to human health.

It was proposed, therefore, that from a technological perspective, gene editing was a fairly simple way to produce animals that were resistant to devastating diseases.

Just over 70 billion farm animals are reared globally each year for food. Two thirds of these are reared in intensive systems. While numbers vary from country to country, it is estimated that in the UK alone millions of farm animals (approximately one in five) die each year due to disease, as well as other causes such as exposure, poor management and accidents on the farm.

The desire to protect animals from suffering and disease was expressed by all around the table. The point was made that gene editing might be welcome if the disease being addressed is, for example, the result of external environmental pressures (e.g. those prevalent in the hot, humid climates) which are nothing to do with the way in which the animal is kept or the requirements of global trade (e.g. slaughter polices for Foot and Mouth Disease).

However, it was felt that if a disease primarily stems from keeping animals in crowded, stressful conditions that undermine their immune system, this was a different matter. Several around the table expressed the view that the reasons why disease arise and are spread need to be carefully considered and that they would not support gene-edited disease resistance if it perpetuated what they saw as the inhumane conditions of industrial farming and global trade.

“For me need comes down to animal health and animal welfare. I would argue that we need to explore all the tools in the toolbox. At the minute there a series of diseases which are having significant impact on animal health and animal welfare and we don't have the tools to deal with those effectively”

Creating Animals with Desirable Commercial Attributes

Genetically engineered animals may meet other needs too. Many of the identified needs of the livestock sector are urgent and it was proposed that gene editing can achieve in two years what might otherwise take 15 years, via normal breeding, to achieve.

As the global population grows, for instance, it prompts the question of how we will continue to meet the world’s requirements for animal-based foods. Gene editing has been proposed as a way to do this by developing animals with the ability to produce more muscle mass (meat) while consuming less feed. This, it is argued, reduces input costs for the farmer and, on a global scale, helps reduce the landprint of livestock farming and may also help to reduce its climate impacts.

Via gender skewing, gene editing could be used to produce more female dairy cows (thus more milk) or more female chickens (more eggs). This gender preselection, say biotechnologists, has the added bonus of lowering the number of male cows and chickens culled shortly after birth.

But some at the table suggested that these attributes also have a profit motive – and that this may be a
powerful but unspoken driver for these kinds of gene edits. Many participants did not accept this ‘need’ as a reasonable justification for applying gene editing.

Some also challenged the notion that large amounts of additional food are needed to feed the growing world population. The point was made that we already produce sufficient food to feed well over 10 billion people. But over half of this is lost through post-harvest losses, consumer and food business waste, being used to feed increasing numbers of farm animals or, as biofuels, to feed cars and machinery. Wouldn’t a simpler solution be to use the food we produce more wisely?

ADAPTING ANIMALS TO THEIR ENVIRONMENTS

The livestock industry needs animals that are able to thrive in both extensive and intensive systems. As livestock production spreads to tropical countries, whose climates are not necessarily well suited to large-scale livestock farming, animals need protection from heat as well as other weather- and climate-related threats to their health.

Gene editing has, thus, been proposed as a way of making animals more heat tolerant. This is an important consideration in tropical countries where more and more animals for the global market are being raised. But, as local average yearly temperatures rise, this is also an evolving problem associated with climate change in traditionally livestock-rich countries.

For animals raised in intensive systems where stress and overcrowding can lead to activities such as tail biting in pigs, or injury or bruising in horned cattle herds, gene editing may be able to offer tail-less pigs, or cows without horns. However, some argued that hornless cattle breeds already exist and tail docking in pigs could more simply be prevented by keeping pigs in good conditions and, in particular, by providing enrichment materials such as straw.

At the extreme end of the technology, it has also been proposed that it could be used to produce animals who don’t feel pain or stress. There was opposition to this from those around the table who felt strongly that this crossed a line – essentially turning animals into ‘machines’ for human use.

WHAT ARE THE ANIMALS’ NEEDS?

Although there was some resistance to the idea, most around the table expressed the view that the way the food system is organised at the moment shapes, to a large extent, both the experience and the needs of the animals that are part of it.

For this reason some felt that the question of ‘need’ should not be seen just as an issue relating to individual animals or individual breeds, nor did it arise solely as a result of genetic deficits within those animals or breeds.

The animal, for instance, needs to be healthy and protected from disease. But does it, in and of itself, need to be more productive? Does it need to make more meat, milk and eggs?

These are human needs imposed on the animal. Recognition of this, of course, brings up the question of what animals are for and whether their ‘animalness’ should be subjugated to human needs (this is discussed in greater detail in Ethical and Philosophical Dimensions).
These considerations speak to the “who is ‘we’? and “what is ‘it?’” discussion that characterised the early part of the session and also to the difficulty, perhaps especially for policy-makers, of trying to align and prioritise a variety of different needs.

DEMONSTRATING BENEFITS IN ORDER TO ASSESS RISK

Even though benefits are the main ‘selling point’ for genetic engineering technologies, it was suggested that claims around benefits are often not rigorously addressed.

Countries all over the world have developed, however narrowly, frameworks for risk assessment around environmental impact or for health impacts of genetically engineered agricultural products. Few have developed a framework for assessing benefits and, without a proper framework for such an assessment, benefit cannot be taken or weighted as a countermeasure to risk.

Norway was presented as an example of the first country to include broader issues of societal utility (public good) and sustainable development in its GMO regulations.

“Maybe the question we need to be asking is whether we need to better define when we think gene editing could make a contribution which hasn't got any significant downsides rather than trying to answer yes or no to the whole question”

Societal utility is a complex concept closely linked to basic human needs, distribution between generations, between rich and poor countries and economic growth. But it also encompasses whether the technology is beneficial to small or large farms, whether it is likely to have any effect on employment, food security, landscape aesthetics or human and animal health and welfare, as well as an assessment of who will benefit from the technology.1

These are questions that most regulators find difficult to incorporate in assessment frameworks. The UN Cartagena Protocol on Biosafety, for example, calls for an assessment of “socio-economic considerations of genetic engineering technologies” – though in reality the 156 countries that are party to the protocol struggle with this.

Based on presumed benefits, many biotechnology companies are calling on the EU and, post-Brexit, the UK, to rewrite existing regulations in order to exclude or deregulate the products of gene editing. It was remarked, however, that re-writing existing regulations would also elicit a strong demand from civil society to tackle the question of both need and benefit in a more rigorous way and that a failure to do so will be a massive failure of regulation that risks the (further) loss of public confidence in the regulatory system.

THE VOICES OF ‘OTHERS’

The question of how we define need inevitably leads to the question of who gets to define it and whose needs – business, government, farmers, animals or consumers – matter most and whether these needs are more or less aligned or whether they are mutually exclusive.

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Some felt that, in upholding the need for gene-edited animals, government policy supports the needs of UK PLC to be competitive within the international marketplace and to be seen as an innovator. It was pointed out that this is a legitimate need and, whether it is recognised within civil society or not, the research establishment and biotech companies have ‘needs’ too.

Nevertheless, a concern identified in this and other sessions during the day, was a tendency for the needs of business and the proposed benefits of technology for business, to take priority over all other stakeholders’ needs, including those of the animals themselves.

Some felt that one reason why the needs of other groups are ignored, deprioritised or overlooked altogether is that policymakers and regulators historically rely on a narrow selection of ‘experts’ to advise them. Regulators need to be made aware of the full range of informed opinions in order to regulate effectively. But ‘others’ – citizens, ethicists, faith groups, civil society organisations of all kinds – are rarely involved in policymaking or regulatory decisions.

Acknowledging that different groups have legitimate but different needs and concerns raises the issue of how we involve a wider group of stakeholders in the discussion around gene-edited animals.

The fact is that gene editing is a powerful technology that is becoming the flagship for food and farming policy in the UK, Europe and the rest of the world. Something so powerful and so potentially transformative, which will affect the lives and perceptions of citizens, requires greater citizen involvement in determining how the technology – the tool in whose toolbox – should be used (see further discussion in Regulating Risks, Monitoring Outcomes).

### Public Priorities

In grappling with understanding new technologies, consumers inevitably ask: “Is there a need for it?” Gene-edited animals are no exception.

In the days before the roundtable, A Bigger Conversation posed a simple question on twitter: “When it comes to gene-edited (genetically engineered) farm animals, intended for the human food chain, which question do you most want to know the answer to?”

- Is there a genuine need? 55%
- Will they be safe to eat? 18%
- Do the animals benefit? 12%
- How do we regulate them? 15%

190 people answered and while this small number makes it hard to draw definitive conclusions, the findings are broadly in line with public attitude surveys of the past.

These consistently show that, depending on what's being discussed, people are less concerned about the risks and ethics, than they are about questions like “Why are we even doing this at all?” “What are the alternatives?” and “Are there other ways of achieving the same end?”

### SUMMARY

So, do we ‘need’ gene-edited farm animals?

During the course of this session a complex dynamic emerged; one which suggests that the needs of farming in general, and livestock farming in particular, are not singular nor isolated but instead are context specific.

Individual starting positions of “Yes, of course...” or ‘No not at all...’ or ‘No, unless...’ or ‘Yes, if...’ – did not tend to shift during the discussion nor during the course of the day. Even so, there were points of agreement. It was generally acknowledged, for example, that some applications of gene editing, like
those used for devastating viral diseases that can be difficult to solve in other ways, should not be automatically discounted.

Within the bigger context of agriculture, gene editing may be a partial or incremental solution to such problems and may even bring some animal welfare benefits. The use of gene editing to increase production or grow profits, however, was considered by most participants to be inappropriate and they strongly argued that this route would likely entrench the industrial livestock system.

Rather than being a universal panacea, gene editing may be a technology with useful but limited applications. This does not negate the technology, but it does suggest that its use comes with important caveats and the need to acknowledge limitations. In order to identify these limitations more information is needed. In promoting gene-edited livestock, the research establishment has been quick to outline its promise and possibilities, but information on the limits and unknowns of the technology itself are less well articulated.

"If the scientists, researchers or research institutions claiming that we need to feed 15 billion people – and that this technology is essential to that – were forced to acknowledge that we already produce enough calories and enough food to feed all these people, but the people are not getting fed because of access to land, access to food, waste and the global food system – which is the truth – then you would have a different response to the need for their technology"

There is also room to question the ‘tool in the toolbox’ metaphor – and whether it obscures more than it clarifies. There was awareness at the table that the dominant model drives decision making around policy. Thus, if biotechnology can be likened to a tool, the dominant model could be likened to a toolbox. It is the framing of the question, the points of reference, and how we organise our thoughts.

In the UK, as elsewhere, the toolbox is sustainable intensification – an extension of an industrial system that nearly every major authority has concluded is no longer viable. If, for instance, agroecology were the dominant system, decisions around gene editing, about when it is needed, when it is not, and an understanding of its natural limits and scope might look very different.

Overall, the conclusion of this opening session was that the response to the question, "Do we need gene-edited animals?" is not necessarily a simple ‘yes’ or ‘no’ but needs to be based on an understanding of what the problem is, how it arises and what the overall goal is. Understanding the place which gene editing could occupy within in the livestock sector, then, would seem to require clearer criteria than currently exists, including:

- A comprehensive assessment of risk to show it does not cause health and welfare problems for humans, animals or the environment
- An equally comprehensive assessment of benefits – are these assumed or they proven?
- A comparison with other methods in order to assess whether the same outcome can be achieved in another way that could, on balance, be even better for the animals and the food system
- An understanding of trajectory – and assurances that it does not entrench the current intensive farming model that is, increasingly, seen as doing more harm than good.
ETHICAL AND PHILOSOPHICAL DIMENSIONS

The discussion about ethics is really a discussion about consequences; about the ability to look further down the line at the potential results, good or bad, of our actions. It is also about what we owe to each other, to our animals and to our living environment and how much we are willing to invest in a transaction that we, as individuals, might not live to see the outcome of.

As the discussion progressed, and as recognised in the ‘needs’ session, gene editing was presented as a powerful tool with the potential to ‘do good’ – which begged the question: Is it ethical not to develop it or to put unreasonable barriers in the way of developing it?

But that question can also be extended to ask whether, in developing the potential of this powerful ‘tool’, we also have an ethical duty to understand its consequences.

While we hoped to avoid a narrow discussion about animal welfare within the session, ethical questions around deliberate changes to the genome of farm animals invariably involve discussion about welfare. As with most technological interventions, the issues raised are not singular nor isolated but arise and exist within a wider context.

For this discussion we put aside what some people believe is an important ethical question, which is whether we should eat animals for food. However, it was noted that one of the premises of better welfare for livestock is the need de-intensify the system, and for people to reduce and replace some of their consumption of animal foods. Therefore the act of de-intensification potentially has an impact on the discussion since the number and type of ‘tools in the toolbox’ that might be needed or used to address welfare issues in livestock would change with fewer airmass in the system.

OLD PROBLEMS IN A NEW LIGHT

One of the early questions in the session was whether gene editing brought with it new ethical questions. Overall, there was agreement that many of the ethical questions posed by gene-edited farm animals are very similar to those around other forms of animal breeding.

In terms of animal breeding, the question was posed: what was exceptional about modifying the animal genome using genetic engineering technology, as distinct from other measures one might take to address some of the needs within the system (such as vaccines or antibiotics)?

It was also put forward that focusing or framing the question around new ethical issues suggests that the status quo was acceptable and problem-free up to this point. This is clearly not the case and the same sort of skewing can arise when the conversation subtly frames gene-edited farm animals as being a simple extension of selective breeding.

It was suggested that discussions, questions and criticisms around new technological innovations are often deliberately framed as new, and therefore unanswerable, because we have no experience of them. This is an advantage for developers but not for other stakeholders.

However, because we do have experience of the longer-term consequences of conventional animal breeding we come to the subject forearmed with an understanding of potential consequences. Similar
to the discussion about need, because we have a long experience with genetic engineering (at least in plants), we also come forearmed with a series of basic questions that may also be applicable to the genetic engineering of livestock.

It was acknowledged that selective breeding also has an ethical dimension in this regard, and that its negative impacts on farm animal welfare may not have been given adequate consideration by early pioneers. Indeed poor welfare or worsening health of farm animals (notably skeletal and metabolic diseases, lameness and mastitis) was a concern expressed by several around the table.

These impacts can be magnified or minimised depending on the systems in which farm animals are kept. Thus there was also some (inconclusive) discussion about scale and about intensive farming versus extensive farming.

**THE INTRINSIC NATURE OF ANIMALS**

What creates the dynamic in this particular discussion is the notion of animals as sentient beings, with needs and intrinsic value beyond their value in a commercial livestock system.

It was proposed that there is something essential about the nature of animals – their ‘animalness’ (see opposite) – and about different kinds of breeds of animals, that could be changed by directly modifying their genomes.

It is, of course, uncertain that changing the genome would change the intrinsic qualities of the animal; but it is also uncertain that it won’t. Therefore, for those who respect the essential nature of the animal, the possibility that interfering with the genome changes its nature in some fundamental way – often described as playing God – is real and important.

Coming back to the issue of welfare, and knowing what we know about selective breeding, the question persists about whether gene editing should be accepted from the start as a purely positive development.

Even in trying to untangle this question, there are ethical issues to explore. It was proposed that, as humans, we have an epistemological problem with understanding the needs of animals and the quality of their day-to-day experience and that there is an element of anthropomorphism and thinking of animals in human terms.

In response it was pointed out that what we understand about animal sentience is not based entirely on anthropomorphism. There is a large body of ongoing research that looks at how animals respond
emotionally to their environment and this research uses the same tools that we would use to examine human emotions – in other words measuring activity in portions of the brain that we know are involved in the processing of emotions.

WHOSE ETHICS?

It was agreed also that the question of ethics can appear different depending on where you are standing and who you are.

Circling back to the idea of the tool in the toolbox – raised in the session, Do We Need Gene-edited Animals? – it was suggested that the toolbox, as it is widely conceived, fits a particular understanding of ethics or goals that will function differently according to an individual's or group's goals and priorities. What one person understands about ethics and well-being does not necessarily reflect a universal understanding of those things.

“So if I speak specifically about what Christian ethics thinks about animals and what our relationship to animals and to gene editing is, that's going to reflect a particular people's understanding of where animals come from and what they're for and what our relationship with them is. That might be different from an industrial plan for how others are going to achieve their goals”

In the same vein, it was suggested that there is, potentially, a difference between academic ethical discussions and what the average 'person on the street' might think of as ethical issues and that there was far too little information on what average citizens think in this regard.

However, it was observed that, in early consumer research around GMOs in the 1990s, being uncomfortable with the idea of “playing God” was a consistent factor.

This was not always a religious idea but was instead focussed around the extent to which we can predict the impacts of genetic engineering and the agency of putative or claimed control. For this reason, a process that took place in a controlled environment was seen as different from, for example, a pest-resistant crop that might be growing in an open environment. These were observed to be important ethical distinctions in the public discourse.

It was also noted that many of these ethical questions are being discussed in the context of human gene editing and that a caution exists around applying this technology to humans that does not seem to exist around its application in farm animals.

WIDER IMPACTS

In addition to the impact on the animals, the question was also raised about whether there was an impact on humans and on the environment. These impacts were not so much focused on safety as they were on the questions of social justice, fairness and access to technology. It was acknowledged that these questions are also not new and have been applied to plant genetic engineering in agriculture for several decades.

Genetically engineered cotton was the example raised. This cotton was introduced into the system
with the idea of helping improve yields and profits for cotton farmers generally but primarily for those who lived and farmed in some very impoverished parts of the world. It was proposed that non-ethical business practices played a significant part in pushing the technology onto these farmers leading to some very poor outcomes in terms of social justice.

Using the example of gene-edited animals, one assumption might be that the farmer who would most benefit would likely be a subsistence farmer in the Global South for whom having their entire herd eradicated by disease would be devastating to their livelihoods, and by extension their families and their communities.

The ethical question, then, is how to address that need in a way that protects the farmer from future harm. How does a subsistence farmer in Zimbabwe, for example, get access to a technology that, in theory, would be beneficial to him and his family without having to be connected to and locked-in to a global agribusiness supply chain model, which, as previously acknowledged, is also problematic and likely coming to the end of its useful life?

“"I'm not attracted to the equation of animal genome/animal nature at all. I worry a lot, as I think probably everyone around the table would, about the quality of life that animals experience and I am also perplexed by how we get to an understanding of what that means and give it effect in the way in which we behave towards animals and things we do to them”

WHO OWNS THE PIG?

Connected to this issue was some discussion about intellectual property – something that has often been shown to limit the use of the processes of genetic engineering to those who can afford them. Most of these processes are protected by intellectual property. As has been seen with genetically engineered crops, some companies are quite aggressive in enforcing this protection, others less so.

The reasons for relying on intellectual property were explained as wanting to stop somebody from using your process or product, wanting to sell it to somebody in order to make money or using it to raise the overall economic value of a company.

“"Genetic companies don’t want to own the pigs; we want to own the genetics”

One participant explained, however, that these uses were not the reason why patents were invented in the first place. The original intention of parenting was to share technology rather to block others or raise money or share value.

It was also noted that universities and other institutions looking to develop gene editing viewed intellectual property as a way of encouraging partnerships in the commercial sector and as revenue streams to the institutions. Often it is left to the commercial partner to protect and enforce intellectual property rights.

Based on the experiences of some farmers who have been prosecuted for growing genetically modified crops that did not belong to them, the question was raised about who owns the products – the animals – that result from gene editing. Is it the farmer or the company?

Since there are no commercial gene-edited animals on farms right now, the answer to that is based, in part, on how the business of ‘genetic improvement’ in farm animals is already being conducted.
Using the example of pigs, we were told that today's breeding companies do not sell the pig, they sell ‘genetic improvement’. So the farmer owns the pig, but the breeding company owns the intellectual property (i.e. the genetic code) behind the pig. Investment is recouped via a royalty on the sale of that pig’s offspring. As a business model this can only generate profit if there are a lot of offspring circulating within the marketplace. In this respect, the business model for gene-edited animals is not that different from older style genetically engineered crops.

By way of a metaphor, the comparison was made between a farm animal and a car. The vehicles we drive are, for example, covered by all sorts of design patents but, just like the pig, when you buy the car, you own the car. The counter argument to this was that this was true unless something went catastrophically wrong with the car, at which point the liability would revert to the seller and manufacturer. Would that be the same with gene-edited animals created by patented processes?

PLAYING GOD

The need to make decisions based on longer-term goals and visions also arose. It was proposed that very often technology and ‘innovation’ are applied in a very short-term context to meet an immediate need in an immediate way when, in fact, it might more clearly be seen as part of the larger system and a larger suite of problems which we are trying to address within the agricultural system.

Uncertainty around the longer-term effects of applying gene editing, it was proposed, also has an ethical dimension. It was observed that we have learned vast amounts about the genomes of plants and animals; but while we think we have complete knowledge about certain traits or genes, or how an organism evolves or functions within an ecosystem, we can very often and very quickly be proven wrong. In other words, we should honour the unknowns.

In response to the idea that animals may have evolved in ways that we do not yet understand the issue of gene drives – which can force evolution quickly through entire populations – was also raised. This kind of ‘in the field’ process, it was proposed, needs careful examination.

It was noted that Kevin Esvelt, one of the inventors of the gene drive technology, took exception to the idea that evolution was amoral and has stated that, in relation to this technology, we need to work to make it moral. What ‘moral’ means might, of course, be open to broad interpretation.

Nevertheless, it was argued that the speed with which CRISPR can be applied and the theoretical speed with which gene drives can force evolution in one direction or another necessitates a need to slow down and ask some of these ethical questions of ourselves. These questions – e.g. How much do we know? Where did we get that information from? and Who has a say in crafting our future and deciding which direction we take? – should be examined within the larger context of food and farming.

It was also acknowledged that involving multiple stakeholders in the process of doing anything is problematical and that stakeholders in the developed world may have a different ethical perspective and framework from those elsewhere in the world. Thus, while it may be a priority for us in the West to define a technology in terms of boosting markets or better adapting animals to the conditions in which we currently raise them, that might not be the priority in another part of the world.

**ISLAND ECONOMICS**

In the UK, the economic perspective is a live issue with the advent of Brexit. As part of Europe we are already experiencing a trade disconnect between, for instance, more liberal US regulations on the products of gene editing and the more precautionary approach traditionally taken by European regulators.

It is uncertain which direction Britain will take post-Brexit but is likely to be closer to the US regulatory approach than the European one. If this is the case, do we risk cutting ourselves off from our largest trading partner, the European Union, in order to foster technology which currently is not accepted in that market, but which might be in other markets either as livestock products or as intellectual property? A factor here is that the Precautionary Principle – which has an ethical dimension – is being reviewed in the EU in the context of the need for an “innovation principle” which, it is argued, brings with it different ethical questions.

“I think back to the Animal Welfare Bill and selecting sheep for scrapie resistance, they found that when they used scrapie-resistant sheep they lost the milking ability and their mothering abilities and that wasn't anything to do with gene editing”

Economic questions are, ultimately, also ethical questions because the economic decisions we make affect the greater well-being and prosperity of the human population in any given country.

This discussion hinted at some of the regulatory issues and conflicts to come, for instance, other countries used gene editing in a way that meets their needs and ethics but which does not meet ours. Would global regulation solve this dilemma or should innovators be given the opportunity to use the technology in any and every way? If the latter, would individual countries in effect become economic islands, potentially unable to sell their products elsewhere because they do not comply with ethical or regulatory norms in other countries. We pick this discussion up again in *Assessing Risk, Monitoring Outcomes*.

**SUMMARY**

Although this was initially a topic that attendees had reservations about and were worried was rather complex, the session on ethics was one of the fastest moving and liveliest of the day. The questions around the ethics of gene editing were left deliberately, and some might have felt frustratingly, open in order to ascertain how far participants had thought about the various ethical dimensions of using this technology on farm animals.

Those dimensions are vast, but for anyone with knowledge of the historical debates around genetic
modification and industrial food production, they are also familiar. They extend well beyond just the
effects on the animals to issues of social and political justice, to our obligations to future generations
and to human health and welfare and the environment.

As noted in the previous section on need, gene editing is energetically, and as some argued
disproportionately, promoted as a benefit. We (the public as well as regulators and policymakers) are
perhaps rather too slow to challenge or explore the ethics of this promotion. In addition, discussion
of ethics allows for the possibility of unanswerable questions and uncertainty – attributes which
policymakers, in particular, find vexing.

The technology for gene-edited animals is rapidly developing and coming to market and this makes
the question of ethics more urgent and less academic and abstract. Yet, in comparison to the vigorous
ethical debate around gene-edited humans, the debate around gene-edited animals is not very
well advanced.

The line between disease treatment and enhancement, which seems clear in human bioethics, seems
more blurred in discussions around farm animals. Yet editing which confers disease resistance in
animals is heritable and therefore passed on to offspring – and so, potentially, are any off-target effects
arising from that change.

The question of ethics is a discussion that is crucial to things like assessment, monitoring and
regulation. The UK’s Farm Animal Welfare Committee, for example, includes an ethicist in order to
bring this perspective. But, as discussed during the day, there is a difference between the academic
perception of ethics and the everyday human perception of ethics. Therefore involving consumer
stakeholders, and accurately studying and interpreting their understanding of ethics, how they express
this and what is important to them also needs to be part of the regulatory mix. At the moment there is
no framework for how this might be achieved.

The argument for using gene editing as one of the tools in the toolbox, to relieve suffering and possibly
even promote extensive systems, seemed compelling and fairly straightforward until the notion of
ethics and animal sentence was raised – at which point the conversation can become more complex
and more divided.

Currently the sentence of animals and their ability to experience
pain and stress is enshrined in UK and European law. Whether
this will remain the case in the UK post-Brexit is uncertain.
It was interesting to note that the ethical questions engaged
many people around the table.

Some participants, however, took a pragmatic view that the
practical and arguably more measurable welfare of large
numbers of animals likely trumped some of the less accessible
and difficult to answer questions about ethics and individual “animalness”.

For those concerned with animalness it was felt that the current system fails to provide an accurate
assessment of the direct and indirect impacts on the animal and its environment. If such a framework
were available it might help to address some of the ethical questions being raised.

It was observed, as well, that even within this wide-ranging discussion there was a presumption,

“The first word that came to my mind was ‘knowledge’. We need to have knowledge to be able to make ethical decisions – or any other kind of decisions”
without asking, that farm animals do exist primarily for human use and that this presumption does not give space or provide answers to a larger ethical question of whether there are potentials for animal lives outside that presumption.

It was clear that the issue of gene-editing did not necessarily open up new ethical questions but rather resurrected and revisited questions which have existed for some time around animals in the farming system and the way we treat them. As with the needs discussion, there was a strong insistence from some participants that ethics should be looked at in the wider context both in the short-term but also in terms of longer-term goals and outcomes.
The question of whether there are alternatives to gene editing seemed straightforward enough. As with all the session themes, it was envisaged that there would be inevitable overlap with discussions and issues raised in the earlier sessions, for instance on benefits, limits and boundaries. Primarily, however, the aim was to address whether there are situations where gene editing in livestock is an appropriate, even positive use of technology, as well as identifying whether there are situations where – because viable and effective alternatives exist – it is not.

In order to discuss alternatives it is important to have a baseline understanding of how the technology is being used. We therefore invited those involved in gene editing farm animals to give a brief resume of current development and utilisation in livestock systems as well as the status of regulation.

The group was told that, currently, most gene editing in farmed livestock is focussing on disease resistance – at least half on viral disease resistance. Gene editing is especially important here as viruses operate within the cell and damage the host through that mechanism. For this reason they can be much harder to deal with than, for example, a bacterial infection of the gut.

There are now a significant number of production-focussed initiatives in use or in development. These include:

- Using gene editing to prevent a virus, such as Porcine Reproductive and Respiratory Syndrome virus (PRRS, or Blue Ear) entering or replicating the host animals’ cells. This research focusses on altering the immune response of the animal to the pathogen and also on helping the immune system directly attack the pathogen.

- Gender skewing is a way of predetermining the sex of offspring. Farmers in the dairy and the egg-laying sector of the poultry industries prefer female calves and chicks, so males are often slaughtered soon after birth. Gender selection is also becoming important in the swine industry. Selection for gender or for a more favourable gender ratio in litters could mitigate some of this waste of life.

- Producing animals that are sterile is another research area. This has, for instance, been a focus in farmed Atlantic salmon, in order to avoid escaped fish interbreeding with wild stocks. Sterile animals can also act like a living genetic ‘bank’ for species where semen storage is difficult (e.g. poultry). Stem cells from these animals can, in theory, be injected into breeding animals to spread genes for desirable traits such as disease resistance or heat tolerance, through a population of animals in fewer generations than is possible with conventional breeding.

“Where we say ‘alternatives to gene editing’ do we mean that we want to deal with diseases in our livestock e.g. selective breeding, old style genetics, better biohazard management, etc. Or do we want an alternative food system?”
• There are projects aimed at increasing muscle mass in order to produce more meat. Most of these are happening outside the UK and Europe. Originally focussed on regulating growth hormones, newer research on hypermuscularisation targets the myostatin gene (MSTN). To date, the farmed animals in which the myostatin gene has been edited include pigs, cattle, sheep, goats and Channel Catfish.

• There are specific projects around scrapie in sheep and the gene that makes PrP (prion protein), which many believe triggers the disease.

• There is a great interest in trying to improve feed conversion – in other words creating animals that require less food, but still produce high amounts of meat, milk and eggs. Although this is a high priority within the industry it is not clear that there are any current projects in this area.

• A number of initiatives are being pursued around “animal welfare” but it is a moot point as to whether or not they are primarily production focussed; they are certainly specific to various production systems. An example of this would be producing a mutation in cattle to ensure they are born without horns.

• Adapting animals to their environments also has some touchpoints with welfare. For example, the Roslin Institute has a large DFID funded initiative, called Centre for Tropical Genetic Livestock and Genetics and Health (a collaboration between the Scottish Rural College and CGRI College, Nairobi) which is looking at heat adaption traits. These ‘Slick Cattle’ have a slick coat which helps them tolerate heat in tropical environments. The US-based company RecombineGenetics Inc is similarly working on re-engineering Angus beef so that it will thrive in hotter countries like Brazil.

• There is also interest in selection and improvement of commercial breeding animals by altering or replacing their genetic lineage with cells derived from elite animals (e.g. animals with known desirable characteristics). Companies will select animals through traits, for which there may be tens of thousands of genetic markers, and use these to improve breeds, but also to edit desirable traits across to another line.

It was explained that once an animal has been gene-edited the genetic changes will be passed on to offspring. However, the process is not fool proof. While every animal is a genetic mix of half mother and half father, all animals carry some mutations which are uniquely ‘theirs’. These de novo mutations are the basis for evolution.

Using genomic sequencing, scientists can identify what came from the mother and what came from the father. Any differences are assumed to be de novo mutations. These mutations, we were told,
could be caused by the gene editing process, but equally they could have arisen by chance. For this reason, researchers believe that there is little difference between gene-edited animals and those which are the products of conventional breeding.

WITHIN SYSTEM MODIFICATION OR RADICAL FOOD CHANGE?

As in previous sessions, several participants referred to “context” and there was an ongoing sense that the acceptability or need for gene editing, and the viability of alternatives, would be different if we had different goals for our food system and different structures for agricultural production.

This underlying theme was captured by one of the participants who asked whether, when referring to alternatives to gene editing, we were talking about treating diseases in farm animals within existing production systems or whether we were considering an alternative farming and food system entirely.

“Intensive agriculture is not just a welfare problem. It’s also is leading to problems in soil quality and biodiversity loss and health problems in humans. There are many organisations, and not just NGOs, that say we need to have a fundamental rethink about how we are producing food”

This prompted further questions, such as whether gene editing is a technology of ‘intensive’ and ‘industrial’ agriculture or whether it would be valid/valuable in a less intensive system and/or one that has ‘better food’ at heart.

It was clear that many participants felt that we are at a crossroads with agriculture and farming and that they related this to issues such as climate change, biodiversity loss, environmental degradation and what one termed “massive health problems” in humans and animals. For them the pursuit of ‘cheap food’ and intensive/industrialised food production was seen as leading and contributing to these problems.

Some participants viewed gene editing technology as neutral and felt, because of this, it could potentially be used in any type of production system – whether extensive, intensive or something between. Others indicated that, in reality, the application of a technology – and with it the assessment of need, risk and regulation, as well as issues of investment – could not be separated from a consideration of the desirability and goals of different farming systems. From this perspective, gene editing would most likely reinforce intensive/industrialised food systems at a time when, many agree, greater priority should be given to less intensive production.

It was said that, given there are significantly differing views within society about the desirability and sustainability of different food systems, we should also acknowledge that regulatory and policy decisions by governments and agencies are not value neutral. They have a very significant effect in moving food production and its impacts in a particular direction.

POLARISATION OR A SPECTRUM OF PRODUCTION SYSTEMS?

Some participants suggested that food and farming systems are developing in arguably two distinct strands which might be described as ‘intensive/industrial’ and ‘extensive/agroecological’ albeit with some grey areas between. It was argued that within intensified industrialised agriculture, such as pigs, poultry and intensive dairy production, gene editing probably has a role to play in mitigating problems as well as increasing productivity.
Other participants felt that, in the livestock sector at least, systems are not necessarily polarised between intensive and extensive. It was explained that the poultry sector in the UK and elsewhere in the world operates a spectrum of farming production practices from standard intensive, to free range, to organic; all of which have their merits and problems. While the farming system used is generally thought of as a key determinant of welfare, how well any particular system works is often due to the quality of “human intervention”; in other words, “management”.

The poultry sector in the UK, we were told, has reduced its use of antibiotics by 82% in the last 7 years by modifying existing systems and management practices and the view was expressed that gene editing technology might have a role in those kind of modification approaches.

However, it was noted by others that – as with the reduction in antibiotic use – modification and improvements can be achieved by making system changes within the production process and/or the processing and retail system without recourse to ‘high tech’ applications. The example of making pigs more resilient to disease was given, where later weaning and allowing greater space and altering production patterns has significant benefits.

Even so, it was pointed out, such simple system modifications are often not introduced because of the economics of the supply chain and retail pressures. In theory, premium pricing at the retail end should incentivise these changes, but in reality there is a disconnection between theory and practice due to the complex (and often hidden) nature of the supply and retail chain involving things like price resistance, loss leaders, retailer control on suppliers and market positioning.

One participant accepted “with caution” and “misgivings” that from an animal welfare perspective there are potentially some uses of gene editing that could be useful and helpful, and cited hornless cattle and in pigs (outside of the UK) developing alternatives to using castration without anaesthetic.

This acceptance however, was accompanied by concern that it might also be taken too far and used to modify innate behaviour to fit in with production systems that conflict with the animals’ essential characteristics or “animalness”.

**THE REALITY OF GENE EDITING USE**

One of the most notable themes of the day was that participants who are currently involved in developing gene editing technology within conventional production systems repeatedly pointed to its limited use. It is, we were reminded, just one tool and it is not – and will not necessarily become – the most used one.

There was widespread agreement that for various reasons it is a mistake to consider gene editing a panacea and that the challenges of production and health are often multi-faceted and involve more than simple gene or trait changes.

“Does innovation always have to be high tech? No. What does non-high tech innovation look like? It depends on what you mean by high tech? With intensification and industrialisation of pigs, poultry and dairy production, genome editing is probably as good a way as any of dealing with any of the problems. The idea that the range of problems that arise within those systems of production can be addressed without high tech inputs, without breaking that system, is fantasy”
“I think absolutely there are good alternatives to gene editing and we should use them when available. What we are really targeting in a number of these gene-editing approaches are diseases where we are grasping at straws for anything else to work”

Wasting Disease) where a successful vaccine had been developed and there was no need to use gene editing.

A number of participants reinforced this perspective and argued that gene editing should be seen as the alternative to all the “other things that are not effective” - in the same way that vaccines should not be seen as a universal cure-all. These are all “tools” and ought not to be given undue prominence compared to things such as good management, building design, feeding, bio-security measures and production patterns.

INTENSIVE AND EXTENSIVE PRODUCTION SYSTEMS

The point was made several times during the discussion that the value of gene editing does not need to be limited to intensive/industrialised production and that in some areas where it is being focussed, such as viral diseases, challenges are found across systems.

In Asia, for example, PRRS is as endemic in backyard pig production as it is in commercial systems. In this case – and possibly in others – it is the intensive nature of production patterns, inadequate buildings and poor bio-security which is the issue rather than the commercial model. It highlights, as one participant said, the need to think about the animal within the production system rather than the animal per se.

Various contributions highlighted the complexity of this: one view was that the 'genetic disposition' of species and breeds might be more resilient or more vulnerable depending on the intensity or structure of the production system. This is why commercial breeding focusses on “elite lines” which select for traits desirable within particular production patterns.

Another participant pointed out that the ability of the producer to make management changes which might be more animal-friendly was limited by the economic strictures of the production system and the supply chain. This led some to conclude that gene editing and other high-tech innovations will always focus on and be part of the intensive/industrialised system.

“This can be seen in the fact that standard breeding techniques – according to those involved with the sector – constitute almost all of the methods used by leading pig breeders and genetic suppliers. For example, despite the publicity given to the potential of gene editing to deal with PRRS (Porcine Reproductive and Repertory Syndrome), even if this edit works, 95% of pig genetics will likely still be the result of standard breeding.

In the case of PRRS breeders have turned to gene editing after decades of work on other approaches which have not worked well. This was in contrast to PMWS (Porcine Multisystemic Wasting Disease) where a successful vaccine had been developed and there was no need to use gene editing.

“Let's say intensive farming has gone and we have extensive farming and the number of pigs in the UK is one fifth of what it is today, but PRRS is still rife. If I knock on your door and say I have a genetic animal that is resistant to PRRS. Would you would still want to know about it?”
Others disagreed and reiterated that gene editing could have a role in less extensive systems. A hypothetical scenario was presented where UK livestock production was non-intensive but would still be vulnerable to diseases such as the PRRS virus which cannot be isolated in a world of global travel and trade.

**GENE EDITING AND THE IPR BUSINESS MODEL**

The question about intellectual property rights (IPR) was not answered directly, but it was suggested that if we had extensive livestock production with a vastly reduced number of pigs, companies might not be interested in funding R&D into high tech innovation because their business model needs large numbers of animals in conditions that are conducive to standardised global products.

A view was expressed that whilst gene editing technology might theoretically have a role in small scale and extensive farming systems, the reality is that how it has been developed and focussed, how it is being rolled out and who owns and operates it is entirely based on an intensive, industrialised model of production. As a solution, it is geared towards the challenges of that type of production and the high volume, low cost livestock products that come out of it. The business model of the developers relies on owning the intellectual property and participating in roll out systems that make a financial return solely from this model of food production. In this way, the technology is not value neutral.

Not all participants agreed with this view and others felt that it left open the question as to why gene editing – and genetic engineering technology in general – was seen as unacceptable when other IPR-based high tech approaches were not. Some of the points made, e.g. that system modifications were preferable to IPR technological interventions, could also be made, for example, in reference to vaccines. Why, one participant asked, are we happy to pay private companies “vast amounts” for a vaccine but have concerns if a breeding company uses IPR-based genetic technology?

**SUMMARY**

It was envisaged that this session would pick up on some of the themes outlined in the earlier sessions but that primarily it would address whether or not there are situations where gene editing is appropriate and those where it is not; and where it might be the most positive use.

The session revealed and aired differences in views and probably values between participants, but also differences in how they viewed the farming system and what an optimal system looks like.

There was, potentially, some common ground. Firstly, that the public promotion of gene editing technology as some kind of panacea was misleading and misplaced; and secondly, there was a reiterated acknowledgement that this technology could have a value and role as a tool directed at specific problems.

There was no agreement about how and when (or where) that tool is best employed and the extent to which it was feasible and/or desirable, given current economic and structural conditions in farming and food to put systemic changes in place before turning to gene editing technology. To make progress in this area requires greater understanding of the degree to which various stakeholders accept, reject or seek to change the current food production system. That is a longer conversation.
ASSESSING RISK, MONITORING OUTCOMES

Whether discussing gene-edited plants or gene-edited animals, the single most pressing issue of the moment is how – and for some, if – they should be regulated.

The 2018 decision by the European Court of Justice (ECJ) ruled that organisms that arise from a newer technique called directed mutagenesis are genetically modified organisms (GMOs) as defined by the EU GMO Directive. As such they should be regulated in the same way as GMOs produced using older techniques. Many new gene editing techniques – including those used on animals – are de facto directed mutagenesis methods and, therefore, fall under current regulations. The ECJ ruling was made after considerable deliberation and consultation with experts in the field, and was fully in line with strict EU regulations on genetically engineered organisms as well as the current status of the science for this technology.

Much of civil society applauded the judgement, which was made with the Precautionary Principle – which is enshrined in EU law – in mind. However, the biotechnology research establishment has, for the most part, been vocal in its objections and active in its efforts to overturn the judgement or have it invalidated, because it sees the ruling is a threat to progress and innovation.

With this in the background the discussion of regulation picked up on a theme from earlier in the day, namely risks versus benefits.

The nature of any deliberation of risk assessment and monitoring is necessarily one of trade-offs. There is no agreed metric against which we can compare risk with benefit, especially – as was pointed out – when the group that might benefit from the technology isn't necessarily the one that carries the burden of risk. Therefore the key to ensuring that no single group is overly disadvantaged, it was generally agreed, is to be clear about what we are trying to achieve and to ensure a wider group of stakeholders is involved in presenting and assessing the totality of the evidence.

DECISION-MAKING IN A VOID

Decisions around the assessment, regulation, monitoring and labelling of the products of genetic engineering – both the old and new technologies – are informed not just by the science (some around the table argued not even by the science) but by the narratives that spring up to support and drive science and the development of new technologies along a particular track.

As touched upon in the session on ‘needs’, these narratives can be framed as business cases, and as altruistic contributions to health, welfare and public good. But once the narrative – good or bad – is set, it can be very difficult to alter the its course.

From some at the table there came a strong condemnation of the way popular narratives stop us from looking at the totality of the evidence – and therefore make the process of risk assessment less thorough than it should be.
It was noted, for example, that what is deemed to constitute a risk to be assessed scientifically, is not itself a scientific judgement but a value and policy judgment about what the scope of that risk assessment should be. This is not just a problem of the food system but one which exists around several other complex systems such as social media and other uses of technology such as driverless cars. The way in which official risk assessments are framed is typically left to a group of scientists who confine their attention to those things about which they have expertise and ignore everything else.

Some felt that politicians often hide behind science because it is easier than being seen to be taking responsibility for controversial judgements. This failure in responsibility has consequences.

While we often talk about risk in terms of health, welfare and environment, subcontracting the responsibility for deciding what is a risk and what is a benefit and what trade-offs are acceptable, to a small group of scientists, as noted by several around the table, is a dangerous, though rarely acknowledged, risk that has been quietly built in to the regulatory assessment process.

THE NEED FOR LONG-TERM STUDIES

Calls for a more 'light-touch' regulation of gene-edited plants and animals are driven by the belief that, because the changes in the genome are precise and often (though not always) small, they are unlikely to cause any adverse effects for the animal or for those who consume the food products of that animal. But it was noted, by one of the scientists in attendance, that if we ‘follow the science’ – as many politicians and regulators urge – that claim is largely without foundation.

The size of the change made to the genome has no predictable relation to the size or scope of possible off-target effects. It may cause no problems, but equally it may cause profound problems.

This technology is in its infancy, and while our scientists know a great deal, there is equally a great deal they don't know. Where research has followed gene-edited animals over the medium- to longer-term the science shows health and welfare problems can and do arise.

In the papers circulated prior to the meeting, and afterwards, reviews detailed problems such as lameness, gastric problems, lethargy, extra vertebrae, enlarged tongues, increased resistance to antibiotics and reduced ability to deal with stress.

It was proposed by some participants that to understand the effects on the animals we need to be studying them over the full course of their lifetimes. We also need to be studying the same animals that we are proposing to put into the farming system. Guestimates made using laboratory mice or rats, generally killed after a few weeks, may not yield reliable information.

Similarly, it was argued, that to understand the effects that consuming gene-edited animals may have on human health, we need to be studying their consumption over the longer-term. To understand the effects that gene-edited farm animals may have on the environment, and their interaction with the environment, long-term studies are needed.

“I think it's fairly easy to underestimate how little time most political decision makers feel that they have to devote to overall objective setting like this – and the reason we don't get that engagement by the people who we think ought to be doing it is that they don't feel any clear pressure from civil society”
“I’m just curious – what are we labelling here? Is it the animal or the product of the animal that has been genome edited? How are we going to trace that labelling through all the products that are made from it, whether it’s in this country or other countries? Are we going to trace the percentage? It could be 1% or 100%. How are we going to capture all that information on a tin or a box or a packet in a way that is readable? Or are we going to ask people to use their smartphones and download an app?”

Yet it is not at all clear that gene-edited animals provide easy answers – or indeed any answers – to any or all of these challenges, whilst the research, as it stands, does raise questions of risk that we should take time to investigate.

THE THINGS WE CAN’T SEE

As noted in previous sessions, the 25-plus years of historical context with genetically engineered plants can provide an indication of the kinds of questions that may be useful and relevant when monitoring and assessing gene-edited animals.

It was proposed that while gene-edited animals (and plants) can look the same as conventionally bred ones – and are therefore considered ‘substantially equivalent’ – they may not be the same under the ground, or under the skin. Any differences, especially in a connected system like agriculture, can sometimes take years to become apparent.

The example was given of plants that work synergistically with the mycorrhiza, the underground network of fungi in the soil that helps to deliver food and nutrients to the plant, and which are symbiotically rewarded with a little carbohydrate which helps to feed them. It has been shown that some genetically modified plants have a lowered capacity for this interaction – and both the soil and the plant suffer as a result.

The question was then posed: how might this play out in a farm animal context? Could gene editing affect the way animals assimilated nutrients, for example. It was suggested that alongside other stakeholders, veterinarians, who have a day-to-day relationship with animals will have unique insights and an active role to play in understanding and advising scientists and regulators on what they should be looking out for as the technology develops.
TRACEABILITY AND LABELLING

The difficulty of differentiating gene-edited and non-gene-edited animals through analytical methods was touched upon. Although it was pointed out that methods are being, and will continue to be, developed that could make detection easier and cheaper, it was also argued that supply chain audits and monitoring can be used to great effect.

The sheer size and complexity of the food chain undoubtedly makes monitoring the origin, spread and final destination of food products a challenge. Some around the table felt it was impractical and unnecessary to have to ‘keep tabs’ on gene-edited animals. Others remarked that we have already made great strides in this area with conventionally reared and organic animals.

The cattle ‘passports’ which accompany all cows in the UK show date of birth, breed, genetic origins and information on dams and sires. Other forms of registration apply for other farm animals. Online records of medical treatments given to farm animals are also, increasingly, being required.

In organic agriculture there is now a highly developed and sophisticated system of production system audits – description of the production system, details of changes in the supply chain and development of product sampling when that is appropriate. These audits protect the integrity of the system.

Audits and declarations are also used as the basis of collecting royalty payments for plant breeders, and similar systems are set up around the collection of royalties for animal breeders. As discussed in *Ethical and Philosophical Dimensions*, money from gene-edited animals is made via royalties on offspring. So traceability will be essential in this sphere too.

Traceability and labelling is now a ‘must have’ for food marketing and consumer choice. Several participants pointed out that it is inconceivable that we might have gene-edited livestock products being produced on the farm and sold into the foodchain without some form of labelling and transparent traceability.

Moreover, given the unknowns that accompany this new technology, labelling and traceability work like an insurance policy, enabling epidemiological scientists to understand who was eating what. This means that if there are any long-term consequences from the wide-scale consumption of gene-edited animal products, the source can be more easily identified.

For this reason, some said, labelling and monitoring must also be viewed as connected risk issues. For them to work properly, funding, structures and mechanisms need to be put into place to support them.

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**The question of spontaneous mutations**

Traceability is not without its challenges. Breeders around the table posed a hypothetical that drove this point home.

Company A produces a gene edited animal that is resistant to foot and mouth disease and releases this animal onto the market. At the same time, animals bred by Company B spontaneously develop a mutation that also confers resistance to the disease.

What is the difference between the two animals and will one be regulated differently from the other?

The answer from other scientists at the table was that the spontaneous mutation may produce the same result – resistance to foot and mouth disease – but at a genetic level there are likely to be obvious differences which allow one animal to be differentiated from the other.

However, this is by no means a given and it highlights a need for clarity about what we are monitoring and how we are going to monitor it.
SUMMARY

Just as there is no ‘global’ approach to regulation of plant GMOs, there is no consensus between the countries of the world on how to regulate the products of gene-editing. Regulation will always be a complex issue and it becomes more so when complex life forms, such as animals, are involved.

In this session, as with the ‘alternatives’ session, there was very little to agree upon. That some level of regulation is required was accepted, but what form that should take was an area of dispute. Some of the scientists at the table felt that it would be impossible to tell a gene-edited animal from a conventionally bred one and that trying to do so would be a waste of time and resources. But others felt that, with a new technology and one which potentially crosses several regulatory borders, such as welfare, health and environment, regulation and monitoring was justified and necessary.

It was also pointed out that the development of gene editing technologies goes hand in hand with the development of detection technology. Scientists need this for their work and it can also be employed to assist the post-marketing surveillance of gene-edited animal products – and it is a necessity for the collection of royalties from offspring.

There is no way, at this point in time, to say for certain if gene-edited animals are safe to consume or not. Some believe that they are, others think they may not be – and the science is not definitive for either perspective.

All over the world regulators are struggling with the question of how to regulate gene-edited animals. No global approach has yet come to the fore. Different stakeholder groups are calling for regulation for different reasons and yet when it comes to regulation only a very narrow selection of needs is being considered.

An underlying theme throughout the discussion was consternation at the mixed messages coming from policymakers and government. For example, it was noted that although the UK government had recently issued a 25-year plan for the environment and has begun work on future farming reform, gene editing has not been a core consideration – in terms of welfare, productivity of the sector or environmental objectives – in those proposals.

This is at odds with the public face of policy. Former Environment Secretary Michael Gove repeatedly said gene editing was a centrepiece of farming development; recently installed Prime Minister Boris Johnson has likewise made the deregulation of the UK biotechnology sector a policy priority. Food entrepreneur Henry Dimbleby, recently appointed by Defra to produce a National Food Strategy, has been quoted as saying he is keen to explore new ways of feeding the UK post-Brexit including lab grown meats and genetically engineered foods.

Depending on how deeply concrete they are, these positions effectively shut-down stakeholder discussion or debate. Many participants felt that a powerful and potentially transformative technology deserved more serious, consistent and in-depth consideration than this.
COMMENTARY

We did not attempt to reach a defined agreement at the end of the meeting, nor to produce a statement outlining consensus or disagreement. Instead, this report has tried to set out key points raised in an accurate and impartial way so readers can draw their own conclusions. However, we think it is fair to say that there was a broad measure of agreement around the table on the following points:

- Gene editing is a powerful and potentially transformative tool.
- Gene editing is not a silver bullet that can or should be aimed at all the problems of animal agriculture in the expectation that it is a cure-all.
- It is important to consider, and to be transparent about, the context and goals in which all technological interventions – and especially potentially transformative ones like gene editing – are being applied.
- For some limited applications – like those used for devastating viral diseases or entrenched animal welfare issues that are difficult to solve in other ways – gene editing may represent a more societally acceptable approach than some existing methods and should not be arbitrarily discounted.
- Complete deregulation is not realistic. Views on regulation around the table differed, but there was a consensus on the need for some form of regulation.
- We all need to be speaking the same language. If there is to be a meaningful public discussion then agreement needs to be reached on the use of terms and phrases such as ‘natural’, ‘intensive’, ‘extensive’, ‘industrial’, ‘bioengineering’, ‘animal welfare’ et.

In convening this Roundtable the question was posed: “Do we need gene-edited farm animals?” and if the Roundtable provided an answer it was that context matters and that the question cannot be adequately addressed with a simplistic a ‘yes’ or ‘no’. This logically leads to a consideration of what would form the agreed criteria or conditions on which “need” could be assessed either generally or on an individual basis.

That, in turn, depends on who the ‘we’ is and, as was acknowledged, there are many ‘we’s’ – direct stakeholders but also people who are not direct stakeholders but who nevertheless have a concern or interest in the application of this technology.

Because of this, any criteria (e.g. risk and benefit assessments) will vary according to the goals and concerns of those different “we’s”. At present, development of gene editing is being driven and powered by a narrative which excludes the views and inputs of many (if not most) of these stakeholders and concerned citizens.

There was general acceptance around the table that there could and should be more transparency and broader engagement in the narrative-building and the drive, direction and speed of the development as well as the application of gene editing technology in livestock. However, the difficulty of doing that was recognised.
In this respect, it was notable that some of the most difficult discussions around the table were not between those who are either ‘for’ or ‘against’ gene-edited animals – and indeed this was not the spirit in which attendees came to the discussion. Instead they were between those who look at farming and its problems and challenges in a systemic context and those who see these problems and challenges in a more linear way and who tend to contextualise gene editing as simply a ‘tool in the toolbox’.

There was also disagreement about the relative importance of intensive versus extensive livestock farming and whether one was inherently and consistently better for animal welfare than the other. In the end, there was acknowledgement that some intensive operations could achieve higher welfare than some extensive operations – but in the context of animal agriculture as a whole, this was more likely to be an exception than a rule.

Given the extent of the gaps between these ‘baseline’ views, the broad areas of agreement that were identified are a testament to the willingness of the participants to engage with each other. After the meeting one participant offered up the insight that working on the character of conversation seemed to be of the highest priority:

“I believe that people are most open to persuasion when they feel heard and understood. And, it can be helpful to model the discourse pattern as: ‘I prioritise this concern, so I do that thing’. This might help people locate similarities and differences for further discussion. Others may think, ‘Wow, I didn’t know anyone had that priority’, or ‘I share the priority, but that action has dangerous ramifications’, or ‘The thing you prioritise means something different to me’.”

The challenge with seeking and teasing out that level of understanding in order to find consensus is that it takes resources and time. It is clear that neither government nor industry is willing to invest in either. On the contrary, the dominant narrative is predicated on the declared – but not proven – need to create and disseminate gene-edited animals as quickly as possible.

A range of policy, research, socio-economic and regulatory recommendations fall of out of these kinds of Roundtable discussions and these should be given the time and space to be explored. To this end, it seems to us that – as a minimum – government, research and policy agencies and industry bodies should work with the civil society bodies in the following ways:

- Government should give more careful consideration to how we assess the creation and introduction of new genetic engineering technologies for breeding animals (and plants). This process requires a much more rigorous and nuanced evaluation of evidence and should include (among others) scientific, social, environmental, welfare and ethical concerns.

- Citizens must be involved. This involvement could take the form of an independent expert group and ideally a citizen-centred process to explore the issues as well as hold key players (including government) to account.

- Market development pathways should also be regulated to ensure that all of the above considerations are taken into account.

It has been stated several times in this report that gene editing is a profoundly transformative technology. It, therefore, requires a correspondingly profound level of discussion, scrutiny and understanding. We believe context and depth of understanding are to everyone’s benefit and strongly encourage all stakeholders to make it a priority.
PARTICIPANTS

- **Prof Bruce Whitelaw** – Deputy Director of Partnerships at The Roslin Institute and Professor of Animal Biotechnology at the Royal (Dick) School of Veterinary Studies
- **Máire Burnett** – Technical Director, British Poultry Council
- **Simon Doherty** – President, British Veterinary Association
- **Marc Casale** – Deputy Director Animal Welfare, DEFRA
- **Serena Cook** – Farm Animal Welfare and Future Farming Team, DEFRA
- **Dr Peter Mills** – Assistant Director, Nuffield Council on Bioethics
- **Anna Wilkinson** – Programme Officer, Nuffield Council on Bioethics
- **Dr Ricarda Steinbrecher** – Co-director of EcoNexus, biologist and molecular geneticist
- **Craig Lewis** – Genetic Services Manager for PIC Europe; Chair EFFAB
- **Dr Sarah Ison** – Global Farm Animal Advisor, World Animal Protection
- **Erik Millstone** – Joint Leader, STEPS Centre Agriculture and Food Policy; Professor of Science Policy, University of Sussex; Director of Studies, SPRU MSc in Science and Technology Policy
- **Dr Claire Marris** – Reader, Centre for Food Policy, City University of London
- **Honor Eldridge** – Head of Policy, Sustainable Food Trust
- **Margaret Mar** – Independent Crossbench Member of the House of Lords; Officer of the All Party Parliamentary Group on Agroecology (APPGA).
- **Margaret B Adam** – Postdoctoral Researcher, Christian Ethics of Farmed Animal Welfare, University of Chester
- **Dan Crossley** – Executive Director, Food Ethics Council
- **Peter Stevenson** – Chief Policy Advisor, Compassion in World Farming UK
- **Nick Palmer** – Head of Compassion in World Farming UK
- **Lawrence Woodward** – Director, Beyond GM

CHAIR

- **Pat Thomas** – Director, Beyond GM
SUGGESTED READING

THIS READING LIST WAS CIRCULATED TO ALL PARTICIPANTS PRIOR TO THE MEETING

REPORT
The ethics of genome editing in non-human animals: A systematic review of reasons reported in the academic literature
Nienke de Graeff, Karin R. Jongmsa, Josephine Johnston, Sarah Hartley, and Annelien L. Bredenoord
Philosophical Transactions B: Biological Sciences, 2019,
https://doi.org/10.1098/rstb.2018.0106

PAPER
Livestock 2.0 – genome editing for fitter, healthier, and more productive farmed animals
Christine Tait-Burkard, Andrea Doeschl-Wilson, Mike J. McGrew, Alan L. Archibald, Helen M. Sang, Ross D. Houston, C. Bruce Whitelaw, and Mick Watson
Genome Biology, 2018
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6258497/pdf/13059_2018_Article_1583.pdf

POLICY BRIEF
Addressing socio-economic and ethical considerations in biotechnology governance: The potential of a new politics of care
Fern Wickson, Christopher Preston, Rosa Binimelis, Amaranta Herrero, Sarah Hartley, Rachel Wynberg, Brian Wynne
Food Ethics, 2017
https://link.springer.com/content/pdf/10.1007%2Fs41055-017-0014-4.pdf

REPORT
Who’s talking about non-human genome editing? Mapping public discussion in the UK
Robert D.J. Smith & Gabrielle Samuel
Department for Business, Energy & Industrial Strategy, May 2018

REPORT
Genome editing – An ethical view
Nuffield Council on Bioethics, 2016

POLICY BRIEF
Sowing fresh seeds – Food, farming and animal welfare post-Brexit
Compassion in World Farming, 2017

POLICY BRIEF
Nuffield Council on Bioethics call for evidence on gene-editing
Submission by Compassion in World Farming, 2016

POLICY BRIEF
Post Note – Genome editing
Parliamentary Office of Science & Technology, November 2016
file:///C:/Users/Patricia/Downloads/POST-PN-0541.pdf

PAPER
The three main monotheistic religions and gm food technology: an overview of perspectives
Emmanuel B Omobowale, Peter A Singer, and Abdallah S Daar
BMC International Health and Human Rights, 2009

REPORT
Welfare of genetically modified and cloned animals used for food
Dr R. D. Kirkden and Professor D. M. Broom, 2012
https://www.ciwf.org.uk/media/4237869/welfare_of_genetically_modified_and_cloned_animals_used_in_food.pdf
REPORT
Options for future discussions on genetically modified and cloned animals
Pew Initiative on Food and Biotechnology and Michigan State University, 2007

ARTICLE
Why the future of gene-edited foods is in the balance
Clive Cookson
Financial Times, 11 March 2019
https://www.ft.com/content/12b978aa-0544-11e9-bf0f-53b8511afdf3

ARTICLE
Genetically edited pigs could be bred after Brexit to help stop costly disease
Sarah Knipston
Daily Telegraph, 20 June 2018

ARTICLE
Gene editing providing hope as hog industry battles PRRS
Corryn La Ru,
AgriPulse, 8 August 2018

ARTICLE
Scientists make gene-edited chickens in bid to halt next pandemic
Kate Kelland
Reuters, 22 January 2019

POST-MEETING ADDITIONAL PAPERS WERE SUBMITTED TO THE ORGANISERS FOR CONSIDERATION

POLICY BRIEF
Statement on gene editing
Note: EGE is preparing an opinion on gene editing which will be completed by summer 2019. The request for this opinion was made in a letter from Commissioner for Research, Innovation and Science, Carlos Moedas, in July 2018.

PAPER
Ethical frameworks and farmer participation in controversial farming practices
SP Cardoso and HS James Jr.
Journal of Agricultural and Environmental Ethics, 2010

REPORT
Meeting report of the OECD conference on “Genome Editing: Applications in Agriculture—Implications for Health, Environment and Regulation”
Friedrichs S, et al
Transgenic Research, 2019

ARTICLE
Big tongues and extra vertebrae: the unintended consequences of animal gene editing
Preetika Rana and Lucy Craymer
Wall Street Journal, 14 December 2018