Stakeholder questionnaire on new genomic techniques to contribute to a Commission study requested by the Council

Fields marked with * are mandatory.

Questionnaire on new genomic techniques to contribute to the study requested by the Council

Discussed and finalised in the Ad-hoc Stakeholder meeting on 10 February 2020

B a c k g r o u n d

The Council has requested [1] the Commission to submit, by 30 April 2021, "a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law" (*i. e.* Directive 2001/18/EC, Regulation (EC) 1829/2003, Regulation (EC) 1830/2003 and Directive 2009/41 / E C) .

To respond to this Council's request, the Commission is collecting contributions from the stakeholders through the questionnaire below. The study covers all new genomic techniques that have been developed a f t e r 2 0 0 1 .

I n s t r u c t i o n s

For the purpose of the study, the following definition for new genomic techniques (NGTs) is used: techniques that are capable of altering the genetic material of an organism and which have emerged or h a v e b e e n d e v e l o p e d s i n c e 2 0 0 1 [2] .

Unless specified otherwise, the term "NGT-products" used in the questionnaire covers plants, animals, micro-organisms and derived food and feed products obtained by NGTs for agri-food, medicinal and i n d u s t r i a l a p p l i c a t i o n s a n d f o r r e s e a r c h .

Please substantiate your replies with explanations, data and source of information as well as with practical examples, whenever possible. If a reply to a specific question only applies to specific NGTs/organisms, p l e a s e i n d i c a t e t h i s i n t h e r e p l y .

Please indicate which information should be treated as confidential in order to protect the commercial

interests of a natural or legal person. Personal data, if any, will be protected pursuant to Regulation (EU) 2018/1725 [3].

[1] Council Decision (EU) 2019/1904, OJ L 293 14.11.2019, p. 103-104, https://eur-lex.europa.eu/eli/dec/2019/1904/oj
[2] Examples of techniques include: 1) Genome editing techniques such as CRISPR, TALEN, Zinc-finger nucleases, mega nucleases techniques, prime editing etc. These techniques can lead to mutagenesis and some of them also to cisgenesis, intragenesis or transgenesis. 2) Mutagenesis techniques such as oligonucleotide directed mutagenesis (ODM). 3) Epigenetic techniques such RdDM. Conversely, techniques already in use prior to 2001, such as Agrobacterium mediated techniques or gene gun, are not considered NGTs.
[3] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, OJ L 295, 21.11.2018, p. 39–98

Guidelines

Please note that the survey accepts a maximum of 5000 characters (with spaces) per reply field. You might be able to type more than 5000 characters, but then the text will not be accepted when you submit the questionnaire. You will also receive a warning message in red colour below the affected field.

You have the option to upload supporting documentation in the end of each section. You can upload multiple files, up to the size of 1 MB. However, note that any uploaded document cannot substitute your replies, which must still be given in a complete manner within the reply fields allocated for each question.

You can share the link from the invitation email with another colleague if you want to split the filling-out process or contribute from different locations; however, remember that all contributions feed into the same single questionnaire.

You can save the draft questionnaire and edit it before the final submission.

You can find additional information and help here: https://ec.europa.eu/eusurvey/home/helpparticipants

Participants have until 15 May 2020 (close of business) to submit the questionnaire via EUsurvey.

QUESTIONNAIRE

Please provide the full name and acronym of the EU-level association that you are representing, as well as your Transparency Registry number (if you are registered)

If the name of the association is not in English, please provide an English translation in a parenthesis

Eurogroup for Animals

Please mention the sectors of activity/fields of interest of your association

> Animal advocacy (NGO)

If applicable, please indicate which member associations (national or EU-level), or individual companies /other entities have contributed to this questionnaire

If applicable, indicate if all the replies refer to a specific technique or a specific organism

A - Implementation and enforcement of the GMO legislation with regard to new genomic techniques (NGTs)

* 1. Are your members developing, using, or planning to use NGTs/NGT-products?

- ○ Yes
- ⦿ No
- ○ Not applicable

*   Please explain why not

> No. New genetic techniques are currently dominated by gene editing using molecular tools such as CRISPR-Cas. 'Editing' an animal's genome involves procedures that cause pain, suffering, distress and lasting harm. It is an inefficient process, using large numbers of animals to produce a single individual with the desired edit. These considerations are valid for both terrestrial and aquatic animals. The unintended effects of NGTs on the animal genome may cause pathogenic outcomes with detrimental effects on animal welfare and human health.

* 2. Have your members taken or planned to take measures to protect themselves from unintentional use of NGT-products?

- ○ Yes
- ⦿ No
- ○ Not applicable

*   Please explain why not

> We are aware of, and fully agree with, the ruling of the European Court of Justice, which defines NGT as GMOs, therefore establishing that NGTs fall under the same rules that are applicable to GMOs. Concerning the animal sector, we are disseminating relevant information to all of our member organisations and call for a moratorium on the genetic editing of animals at least until (a) the risks have been rigorously characterised and assessed and (b) there has been a fully informed public consultation, including risks, harms, ethical issues and alternative approaches.

*   2 bis. Have you encountered any challenges?

- ○ Yes

◉ No

* 3. Are you aware of initiatives in your sector to develop, use, or of plans to use NGTs/NGT-products?

○ Yes

○ No

◉ Not applicable

* 4. Do you know of any initiatives in your sector to guard against unintentional use of NGT-products?

○ Yes

○ No

◉ Not applicable

* 5. Are your members taking specific measures to comply with the GMO legislation as regards organisms obtained by NGTs?

Please also see question 8 specifically on labelling

○ Yes

○ No

◉ Not applicable

* 6. Has your organisation/your members been adequately supported by national and European authorities to conform to the legislation?

○ Yes

○ No

◉ Not applicable

* 7. Does your sector have experience or knowledge on traceability strategies, which could be used for tracing NGT-products?

○ Yes

○ No

◉ Not applicable

* 8. Are your members taking specific measures for NGT-products to ensure the compliance with the labelling requirements of the GMO legislation?

○ Yes

○ No

◉ Not applicable

* 9. Do you have other experience or knowledge that you can share on the application of the GMO legislation, including experimental releases (such as field trials or clinical trials), concerning NGTs/NGT-products ?

○ Yes

○ No

◉ Not applicable

Please upload any supporting documentation for this section here. For each document, please indicate which question it is complementing

The maximum file size is 1 MB

B - Information on research on NGTs/NGT-products

* 10. Are your members carrying out NGT-related research in your sector?

- ○ Yes
- ○ No
- ● Not applicable

* 11. Are you aware of other NGT-related research in your sector?

- ○ Yes
- ○ No
- ● Not applicable

* 12. Has there been any immediate impact on NGT-related research in your sector following the Court of Justice of the EU ruling on mutagenesis?

Court of Justice ruling: Case C-528/16 http://curia.europa.eu/juris/documents.jsf?num=C-528/16

- ○ Yes
- ● No
- ○ Not applicable

*   Please explain why not

> We are concerned about the detrimental impacts on animal welfare of the application of NGTs. Gene editing enables rapid, instant, substantial and multiple changes to the genome, in a wider variety of species, thereby removing a number of technical barriers to modifying genomes. This raises some significant animal welfare concerns as well as ethical concerns. There have been many claims that the newer gene editing techniques are much more precise, and have few (if any) unintended effects. However, there is increasing evidence that off-target and unintended alterations have been under-reported.

* 13. Could NGT-related research bring benefits/opportunities to your sector/field of interest?

- ○ Yes
- ● No
- ○ Not applicable

*   Please explain why not

The added value of using NGTs in the food and farming sector cannot be demonstrated as there is no available evidence of positive effects in terms of environmental, economic and social impacts, not to mention animal welfare.

There is currently no evidence that this research can bring advantages, and most of all there is no assessment model to review suggestions to use NGTs in farmed animals.

Farmed animal breeders hope to exploit new technologies to boost the already excessive production performances of farmed animals, with a view to further industrialising and intensifying an unsustainable sector and to "fight diseases" that have been largely created by the industrial animal agriculture model itself. The intensification of animal agriculture drives global deforestation, environmental degradation, loss of biodiversity, and the rapid spread of infectious diseases among animals (due to the genetically homogeneous animal populations) as well as occurrence of zoonotic pandemics. Additionally, it is the principal component of compromised animal welfare. Additionally, the unintended release of gene edited organisms into the wild, may negatively impact the health and welfare of wild populations.

* 14. Is NGT-related research facing challenges in your sector/field of interest?

- ○ Yes
- ○ No
- ◉ Not applicable

* 15. Have you identified any NGT-related research needs/gaps?

- ◉ Yes
- ○ No
- ○ Not applicable

* Please specify which needs/gaps, explain the reasoning and how these needs/gaps could be addressed

Yes, we need research on detection methods for NGTs and other GMOs to provide correct and transparent information to consumers and at the same time protect human and animal health.

Developments and applications of GE in animals for human consumption and for research purposes:

- ● involve procedures that may cause animals pain, suffering or distress;
- ● use very large numbers of animals;
- ● enable a greater number of species to be manipulated;
- ● encourage a wider variety of applications, leading to increased animal use and suffering;
- ● increase the perception of animals as 'commodities' for human benefit, e.g. as research tools or units of production;
- ● are progressing at a rate that is outstripping ethical debate and public understanding.

Research funding would be far better invested in driving a radical and rapid shift away from industrial animal agriculture and non-animal research models.

Please upload any supporting documentation for this section here. For each document, please indicate which question it is complementing

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C - Information on potential opportunities and benefits of NGTs/NGT-products

* 16. Could NGTs/NGT-products bring benefits/opportunities to your sector/field of interest?

- ○ Yes
- ◉ No

*   Please explain why not

> We do not currently see a role for NGT/NGT products in our sector. For other sectors, any potential opportunities are currently unverified and need to be carefully assessed. In regards to the food and farming sector and animals used in research, we need to challenge any claims for benefits until we have data available and a long-term assessment of the impact of such technologies on human, animal, plant health as well as on society and the economy.

* 17. Could NGTs/NGT-products bring benefits/opportunities to society in general such as for the environment, human, animal and plant health, consumers, animal welfare, as well as social and economic benefits?

- ○ Yes
- ◉ No

*   Please explain why not

> No. Any such opportunities have not so far been clearly demonstrated and demands for further research are based on assumptions.
> In terms of animal welfare, the use of these technologies raises some significant concerns:
> •   the techniques are 'inefficient' and require procedures that cause suffering and waste animals' lives
> •   the impact of each genetic change on the animal's wellbeing is often not known before the edit is made, and effects can also be unpredictable
> As a consequence, we are calling for a moratorium on the genetic editing of animals at least until (a) the risks have been rigorously characterised and assessed and (b) there has been a fully informed public consultation, including risks, harms, ethical issues and alternative approaches.

* 18. Do you see particular opportunities for SMEs/small scale operators to access markets with their NGTs/NGT-products?

- ○ Yes
- ◉ No

*   Please explain why not

> No. NGTs will probably lead to a further consolidation of the food industry and SMEs will most likely not be in a position to compete.

* 19. Do you see benefits/opportunities from patenting or accessing patented NGTs/NGT-products?

- ○ Yes
- ◉ No

*   Please explain why not

Since NGT research involves patents and licences that are costly, SMEs will encounter additional obstacles in competing in such a market.

Please upload any supporting documentation for this section here. For each document, please indicate which question it is complementing

The maximum file size is 1 MB

D - Information on potential challenges and concerns on NGTs/NGT-products

* 20. Could NGTs/NGT-products raise challenges/concerns for your sector/field of interest?

- ⦿ Yes
- ○ No

*   Please describe and provide concrete examples/data

Yes, the development of NGTs/NGT-products raises enormous concerns for animal welfare, ethical uses of animals and for those concerned with these important issues.

Developments and applications of GE in animals for human consumption:

● involve procedures that may cause animals pain, suffering or distress;
● use very large numbers of animals;
● enable a greater number of species to be manipulated;
● encourage a wider variety of applications, leading to increased animal use and suffering;
● increase the perception of animals as 'commodities' for human benefit, e.g. as research tools or units of production;
● are progressing at a rate that is outstripping ethical debate and public understanding.

New genome techniques, such as genome editing using mechanisms such as CRISPR-Cas, make changes within the DNA of organisms with relative ease and efficiency in comparison to previous genetic modification technology. These GE techniques remove a number of technical barriers to modifying the genetic makeup of plants, animals and humans. This has created a new momentum in animal biotechnology which is generating a broad range of potential applications not just in farm animals, but also in companion animals, laboratory animals as well as in human medicine (such as somatic cell editing), and also the control of 'undesirable' animal populations in the wild.

The use of this technology raises some significant animal welfare concerns:
● the techniques are 'inefficient' and require procedures that cause suffering and waste animals' lives
● the impact of each genetic change on the animal's wellbeing is often not known before the edit is made, and effects can also be unpredictable

These concerns, and the ethical issues discussed in section F, apply not only to farm animals, but also to animals used in many other contexts. Examples include: in research and testing (e.g. as disease 'models'); as 'bioreactors' to produce biologically active compounds; as sources of cells, tissues and organs in xenotransplantation; in the creation of 'pets', sports animals and 'living art'; in the 'de-extinction' of extinct or endangered animals; and in the population control of 'undesirable' species (e.g. disease vectors, parasites and invasive species and the associated impacts on wildlife through the use of 'gene drives'.

* Are these challenges/concerns specific to NGTs/NGT-products?
◉ Yes
○ No

* Please explain

New genome techniques, such as genome editing using mechanisms such as CRISPR-Cas, make changes within the DNA of organisms with relative ease and efficiency in comparison to previous genetic modification technology. These GE techniques remove a number of technical barriers to modifying the genetic makeup of plants, animals and humans. This has created a new momentum in animal biotechnology which is generating a broad range of potential applications not just in farm animals, but also in companion animals, laboratory animals as well as in human medicine (such as somatic cell editing), and also the control of 'undesirable' animal populations in the wild.

*

21. Could NGTs/NGT-products raise challenges/concerns for society in general such as for the environment, human, animal and plant health, consumers, animal welfare, as well as social and economic challenges?

◉ Yes

◯ No

*   Please describe and provide concrete examples/data

> There is economic pressure for farm animal breeders to exploit new technologies that help breed healthy and productive animals, and many see this potential in the new GE techniques. The Farm Animal Breeding and Reproduction Technology Platform (a European industry-led platform for breeding and reproduction organisations and knowledge institutes) states that "genome editing could help [them] to achieve some of these aims faster and more efficiently, sparing years of classical breeding and selection." They have called for 'modernisation of the regulations', which is a serious concern despite their acknowledgement that "this technology should only be applied with the greatest care and after a significant period of testing". Compared with previous technology, genome editing raises additional societal concerns because:
>
> ●   it can be more difficult to predict the nature and/or level of harms, new phenotypes with multiple mutations can be created, either through 'multiplexing' the desired changes and/or introducing unintended changes elsewhere in the genome;
>
> ●   if manipulation via genome editing attempts to recreate a trait that naturally occurs in other populations, it will leave no trace that the new variant was artificially 'created'. This creates serious concerns around traceability, product labelling and consumer choice
>
> ●   convergence of gene drive with gene editing means whole populations may be altered in a few generations
>
> ●   these techniques may be applied to a much wider range of species than previous genetic modification methods, and live, edited animals are generated more rapidly;
>
> ●   the accessibility of these new tools enable use of 'Biohacking' & DIY kits in garage 'labs';
>
> ●   many people hold beliefs that make them especially concerned about the application of genome editing
>
> There are also legitimate and fundamental public concerns about 'naturalness' and interfering with animals' integrity; and the application of new techniques simply because they are available, without proper consensus as to whether it is 'right' to manipulate animals in this way or whether people would find the subsequent uses of these animals acceptable. These concerns should be properly explored and given due respect.
> The potential release of genetically edited animals into the wild (even if unintentional) can negatively impact wild animal populations. Therefore, it is necessary to apply the precautionary principle.

*   Under which conditions do you consider this would be the case?

> Developments and applications of GE in animals for human consumption:
>
> ●   involve procedures that may cause animals pain, suffering or distress;
>
> ●   use very large numbers of animals;
>
> ●   enable a greater number of species to be manipulated;
>
> ●   encourage a wider variety of applications, leading to increased animal use and suffering;
>
> ●   increase the perception of animals as 'commodities' for human benefit, e.g. as research tools or units of production;
>
> ●   are progressing at a rate that is outstripping ethical debate and public understanding.
>
> The use of this technology raises some significant animal welfare concerns:

- the techniques are 'inefficient' and require procedures that cause suffering and waste animals' lives
- the impact of each genetic change on the animal's wellbeing is often not known before the edit is made, and effects can also be unpredictable

* Are these challenges/concerns specific to NGTs/products obtained by NGTs?

- ◉ Yes
- ○ No

* Please explain

New genome techniques, such as genome editing using mechanisms such as CRISPR-Cas, make changes within the DNA of organisms with relative ease and efficiency in comparison to previous genetic modification technology. These GE techniques remove a number of technical barriers to modifying the genetic makeup of plants, animals and humans.

* **22. Do you see particular challenges for SMEs/small scale operators to access markets with their NGTs /NGT-products?**

- ◉ Yes
- ○ No

* Please explain and provide concrete examples and data

In general, SMEs have limited access to technology, and the patenting and licensing would be difficult in their case.
The consolidation of the industry works against SMEs. Most patents are controlled by few large corporations.

* **23. Do you see challenges/concerns from patenting or accessing patented NGTs/NGT-products?**

- ◉ Yes
- ○ No

* Please describe and provide concrete examples/data

Patenting will accelerate industry consolidation and will reduce diversity while at the same time it may failed to deliver on promised results, including increased yields.

Please upload any supporting documentation for this section here. For each document, please indicate which question it is complementing

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E - Safety of NGTs/NGT-products

* **24. What is your view on the safety of NGTs/NGT-products? Please substantiate your reply**

We believe the precautionary principle should be applied.

* 25. Do you have specific safety considerations on NGTs/NGT-products?

◉ Yes

◯ No

*   Please explain

This response focuses on the safety of the organism being edited.

GE can give rise to adverse outcomes due to the consequences of the desired edit (intended effects) and unintended changes that may arise around the cleavage site ('on target' effects). Adverse outcomes can also be engendered by alterations elsewhere in the genome, due to sequence homology or from the nature of the cell's DNA repair systems that are exploited by the technology ('off target' effects).

There have been many claims that the newer gene editing techniques are much more precise, and have few (if any) unintended effects. However, there is increasing evidence that off-target and unintended alterations have been under-reported. The GE 'polled' calves have been revealed to carry multiple antibiotic resistance genes from bacterial plasmid vector within their genomes despite the researchers originally reporting no unexpected alterations.

Even more concerning is the presence of 'stray DNA' within edited genomes. The DNA repair process appears to be somewhat random, with the cell taking DNA from whatever source is available to it, including that present in the culture medium. Both goat and bovine DNA (from sera present in culture medium) have been reported in edited mouse genomes, with retrotransposons and retrovirus DNA also incorporated.

This demonstrates that GE is a potential mechanism for horizontal gene transfer of pathogens, including, but not limited to viruses. The mechanisms that repair double-stranded breaks in DNA from GE can also result in increased risk of cancer, and there are increasing reports of widespread deletions and rearrangements.

Even simple single base editing methods create previously undetected regions of 'accidental' editing. In addition, non-coding regions of DNA are increasingly being found to have important roles in gene function and regulation, so inserting genetic material may disrupt gene expression and negatively affect animal health and welfare. These inadvertent genetic changes caused by GE systems are known to be hampering the technology's uptake in human medicine.

There is still much to learn about the way cells repair breaks in their DNA, and the undesired effects that gene editing tools can have, which is unsurprising as they have only been in use for a few years.

In some cases, the phenotype of some GE animals may be indistinguishable from their wild-type counterparts, indeed there is a drive to use GE to increase the spread of naturally occurring mutations throughout herds (so called 'precision breeding'). This is a risky approach, because adverse effects may not become apparent unless animals are maintained in a less controlled environment than that of the laboratory or experimental farm, or bred in sufficient generations, or in sufficient numbers to indicate trends and significance.

Due to the above risks and uncertainties, it is essential to screen the genome, for each line and for a number of generations and report any unintended effects, in both genotype and phenotype.

Many in science are now calling for a comprehensive and stringent examination of DNA cleavage sites, but this is neither currently common practice nor perceived to be as innovative and attractive a direction to pursue compared to other lines of GE research.

Please upload any supporting documentation for this section here. For each document, please indicate which question it is complementing

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F - Ethical aspects of NGTs/NGT-products

* 26. What is your view on ethical aspects related to NGTs/NGT-products? Please substantiate your reply

Humans have been modifying animals for millennia, through selective breeding, surgical mutilations and administering drugs and hormones. Many of these modifications raise animal welfare and ethical issues. What is different about gene editing is that it enables rapid, instant, substantial and multiple changes to the genome, in a wider variety of species, thereby removing a number of technical barriers to modifying genomes. This raises some significant animal welfare concerns as well as ethical concerns. See answer to Q27 for further explanation of these concerns and the drivers for gene editing, which some view as a panacea for issues as diverse as food security, disease resistance and raising extinct animals.

* 27. Do you have specific ethical considerations on NGTs/NGT-products?

🔘 Yes
⚪ No

* Please explain

New genetic techniques are currently dominated by gene editing using molecular tools such as CRISPR-Cas. 'Editing' an animal's genome involves procedures that cause pain, suffering, distress and lasting harm. It is an inefficient process, using large numbers of animals to produce a single individual with the desired edit. Despite claims that these newer GE techniques are much more precise than previous methods, they still cause unpredictable and unintended changes to the genome, which are only just starting to be reported.

Gene editing (GE) has been positioned as a viable tool to address challenges such as increasing human demands for: animal protein, meats of specific qualities and animals resistant or resilient to infectious disease. It has also been suggested to help respond to animal welfare concerns and to global heating (e.g. by creating 'hornless cattle' and heat tolerant animals). However, there are alternative approaches to addressing all of these challenges, including improving animal husbandry and reducing food waste - one third of the food produced in the world for human consumption every year is lost or wasted.

In the UK and across the EU there is currently no market for products made from genetically modified animals, but regardless of the lack of public acceptance, GE has been used in recent years to generate hundreds of edited pigs, cattle, sheep and goats. These will potentially be used to create genetic lines with disease resistance and resilience traits, or enhanced productivity. If the majority of people are not willing to accept GE animal products, then there is still no market for them, and research efforts - and animal lives - are wasted. This raises the question of why research into generating GE animals is being funded by the taxpayer, and how the public might feel about being unwittingly complicit in this research.

Editing the genomes of animals is regulated by legislation controlling animal research and testing such as the UK Animals (Scientific Procedures) Act 1986, EU Directive 2010/63, and legislation controlling GMOs such as Genetically Modified Organisms (Contained Use) Regulations 2014. Gene editing is subject to strict rules on authorisation, release, use in feed and food and labelling. These rules were set up to ensure a high

level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, whilst ensuring a high level of protection of animal health and welfare8. We believe that products of new genetic modification techniques should remain strictly regulated as GMOs.

Please upload any supporting documentation for this section here

The maximum file size is 1 MB

83bd1c35-610d-411a-a895-f2cf6311f64c /Eurogroup_presentation_on_genome_editing_October_2019__2_.pdf
6c230283-7dcf-47bf-b7a5-9ebadb8cfee5 /References_for_Erogroup_for_Animals__response_to_NGT_consultation.pdf

G - Consumers' right for information/freedom of choice

* 28. What is your view on the labelling of NGT-products? Please substantiate your reply

There are several important issues relating to consumer choice. It is worth restating that the public generally does not accept genetically modified animals in food. However, with regulations being inconsistent across international borders and the technical difficulties in distinguishing between naturally occurring and 'engineered' mutations, there is a risk that GE food products will find their way onto supermarket shelves here. Recent consultations show that the public was "not convinced of the need" to use GE to develop faster growing animals for human consumption and that gene editing farm animals to increase efficiency /profitability was seen as less acceptable use of the technology. There are legitimate public concerns around animal integrity and 'naturalness', but the use of GE is escalating without public consensus on whether it is right to manipulate animal genomes in this way, and for what purposes. It is imperative to ensure public trust and enable informed purchasing choices in any GE application in farmed livestock. Any future developments must be transparent, accessible to, and acceptable to the public, with clear product labelling that does not use misleading euphemisms such as 'precision breeding' or 'smart breeding'.

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H - Final question

* 29. Do you have other comments you would like to make?

◉ Yes
○ No

Please provide your comments here

We are deeply concerned that the drive to use GE is outstripping the public debate regarding acceptable innovations. The technology is unproven and causes unintended changes to the genome that may well have a pathogenic outcome. Alternatives to genome editing farmed animals are neither properly explored nor

implemented. The drivers to alter farmed animals do not account for legitimate animal welfare, ethical and public concerns.

Gene editing animals for all applied purposes should stop until (a) the risks have been rigorously characterised and assessed and (b) there has been a fully informed public consultation, including risks, harms, ethical issues and alternative approaches.

At a time when human impacts on other animals and the environment are under unprecedented scrutiny, we would like to see a watershed for farmed animals. Rather than obtaining ever more productivity and profit from individual animals, who are sentient and have intrinsic worth, it is time for human behaviour change to drive sustainable agriculture that respects farmed animals and their welfare needs.

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Contact

SANTE-NGT-STUDY@ec.europa.eu
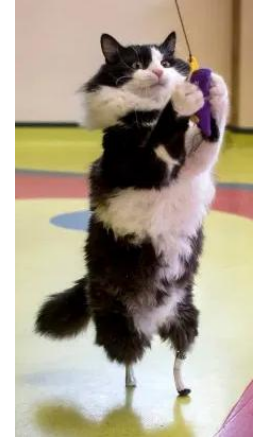
Gene editing in animals

Dr Penny Hawkins
Research Animals Department, RSPCA, UK

EGE Round Table on Gene Editing, Brussels, 16 October 2019

Humans have been 'modifying' animals for millennia

- Training

- Selective breeding

- Surgical mutilations

- Administering drugs and hormones

- Therapeutic modification

- Mutagens

- Genetic technologies

EUROGROUP FOR ANIMALS

Does the use of gene editing raise specific ethical issues?

What is different about genome editing (GE)?

- Outcomes are **unpredictable**, even with 'more precise' techniques such as CRISPR

- Enables **instant, substantial and multiple changes** to the genome

- Genes from **different species** can be inserted, which would not be possible using conventional techniques

- It is being used in increasing **numbers of species**

- There are genuine and legitimate public concerns about **'naturalness'** and **animal integrity**

- These concerns are **not taken into account**

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A researcher who helped to develop CRISPR says …

I had been **astounded at how quickly** labs around the world had adopted the technology for applications across biology, from modifying plants to altering butterfly-wing patterns to fine-tuning rat models of human disease.

At the same time, I'd **avoided thinking too much** about the philosophical and ethical ramifications of widely accessible tools for altering genomes.

Like everyone else, **I wanted to get on with the science** made possible by the technology.

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Time to reflect and reassess

- 'Polled' calves who had been edited using TALENS

- Recombinetics, Inc: the calves are 'precision bred'

- US Food & Drug Administration: they carry multiple antibiotic-resistance genes from bacterial plasmid vector and have widespread deletions and rearrangements

- **Multiple sources of stray DNA – plasmid vectors; culture media (e.g. bovine DNA in GE mice, from fetal bovine serum); pathogens**

- **It is unethical to continue using this technology without understanding these effects**

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Does the purpose of the genome editing make a difference?

Some purposes cannot be justified

- Genome editing companion animals, for appearance, behaviour or to address health issues

- Genome editing animals for food production

  - These animals are already pushed towards – or beyond – their biological limits, so GE to increase production is unacceptable

  - GE to 'improve' product quality, or improve disease resistance, are also unacceptable – **there are better approaches to achieving these goals, including 'animal welfare'**

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GE in animal research

- Directive 2010/63/EU permits harms to animals

- GE is a harm, even if the phenotype is below threshold

- GE has resulted in an explosion in animal numbers, due to the drive to create new lines and the inherent wastage involved

- Companies promote new animal 'models' (e.g. Surrogen's 'humanised swine')

- This treats animals as commodities and lessens the value of animal life

We use pigs as "oinkcubators" to grow human cells and tissues and

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Societal concerns are important

- The public pays for GE research, directly or indirectly

- The drive to use GE technology is outstripping the public debate

- Many people are deeply concerned about the impact of GE on 'naturalness' and the integrity of the animal

- UK Royal Society survey (2017): participants 'not convinced of the need' for GE to increase yield and said it was a 'less acceptable' use of the technology

(un)natural

NUFFIELD COUNCIL on BIOETHICS   Ideas about **naturalness** in public and political debates about **science, technology** and **medicine**

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Public attitudes should not be manipulated

- Recombinetics: 'precision breeding', AgResearch: 'smart' cattle
- Roslin Institute/Abacus Bio survey on attitudes to GE food products
  - Gene-edited plants and animals were considered together
  - No opportunity to express concerns about animal welfare or ethics
  - Participants expected to accept that GE will always improve animal health
  - Respondents who did not buy meat products were excluded

Proper consultation is essential

- Public dialogue on Animals Containing Human Materials – concerns about potential impact on animal cognition

- **involve.org.uk** - *Rethink public engagement for gene editing*

  - A model for engaging 'publics' and stakeholders

  - nature.com/articles/d41586-018-03269-3

Fully informed public consultation, including risks, harms, ethical issues and alternative approaches

A moratorium

Gene editing animals for all applied purposes should **stop** until the **risks have been rigorously characterised and assessed**, and the public has been properly **informed and consulted**

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