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Targeted genome modification applied to animals: in between controversies

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■ Debates about targeted genome modification techniques are currently numerous, but they often leave farm animals out of the picture. This article analyses the positions of the French stakeholders and draws up an overview of the directions that this controversial subject could take if these techniques were to be authorised in Europe for food production purposes.

Introduction

Until the early 2010's, there were very few genetically modified animals (GMAs), beyond a handful of laboratory animals, mostly mice, used primarily for research purposes and to produce high-value pharmaceutical molecules. The development of new targeted genome modification tools, particularly Crispr-Cas9, has boosted work on animals. The Crispr-Cas9 system comprises of palindromic repeats, short, regularly spaced DNA or RNA sequences[1] and an associated protein (Ducos *et al.*, 2017). As demonstrated by Jinek *et al.* (2012), Crispr-Cas9 can be used for targeted genome modifications. The Crispr-Cas9 system allows for targeted induction of DNA double-strand breaks using guide RNA, and subsequent introduction of new DNA sequences through DNA repair mechanisms. The use of Crispr-Cas9 in research laboratories has experienced exponential growth since 2012. The Nobel Prize in Chemistry was awarded on 7 October 2020 to the co-discoverers of the Crispr-Cas9 system, Emmanuelle Charpentier and Jenifer Doudna, reaffirming its significance and reigniting public interest in the field. We have grouped various techniques, including but not limited to Crispr-Cas9, under the term "New Genetic Technologies" (NGT). As the semantics chosen are often contentious, Box 1 clarifies several scientific concepts and commonly encountered expressions.

Beyond the medical field, the CRISPR method finds extensive use in agronomic research and promises numerous applications within the various agricultural sectors. There are growing numbers of plant-based projects that propose crops with increased resistance to drought, disease, or yields. Animal applications include "genetic forcing" to contain the spread of harmful species, such as mosquitoes, by subverting Mendelian heredity laws (Simard, 2018). Regarding farm animals, programmable nucleases have numerous potential applications (Ducos *et al.*, 2017; Maximiano *et al.*, 2021), such as providing resistance to diseases like porcine reproductive and respiratory syndrome (PRRS) (Ducos *et al.*, 2017; Maximiano *et al.*, 2021), nutritional benefits, such as hypoallergenic milk production, accelerated animal growth, a "welfare" alternative to cattle dehorning, etc. However, these applications are currently limited to laboratory settings and have not yet been introduced into food production circuits. At present, GMAs, whether produced using traditional or new methods of genome manipulation,

1 Crispr stands for Clustered Regularly Interspaced Short Palindromic Repeats. Cas9 is an endonuclease (protein that cuts the DNA molecule) associated with Crisp).

Box 1. ***Scientific concepts and vocabulary used in the field of new genetic technologies.***

1. Naming the products obtained: a legal definition

Genetically Modified Organism (GMO): "an organism, excluding human beings, in which the genetic material has been altered in a way that is not naturally occurring through mating and/or natural recombination" (Directive 2001/18/EC on the deliberate release into the environment of GMOs).

Genetically Modified Animal (GMA): the previous definition applying specifically to an animal.

2. Tool used

Targeted genome modification: a term used to describe genome modification methods developed from the 2000's onwards. These methods target the gene to be modified rather than simply inserting a foreign gene at random (transgenesis). Crispr-Cas9 belongs to the family of programmable nucleases, which also includes zinc finger nucleases (ZFNs) and transcription activator-like effector nucleases (Talens). These other nucleases, discovered earlier, can also be applied to achieve targeted modifications in genomes, but their application is more intricate and expensive compared to Crispr-Cas9. The name "molecular scissors" has been attributed to programmable nucleases owing to their targeted and precise modifications. These modifications enable inactivation, mutation, substitution or insertion of one or more DNA sequences.

New Breeding Techniques (NBT) or New Genetic/Genomic Techniques/Technologies) (NGT): general term used to describe genetic modification tools developed after 2001 and Directive 2001/18/EC. This term includes a wider range of techniques than the simpler tools known as targeted genetic modification.

Genome editing: refers to the techniques encompassed by the term NBT/NGT, which allow for modifications such as mutagenesis and transgenesis. The use of the French translation "Edition du génome" is a topic of ongoing debate, with some proponents advocating for the term "genome rewriting/correction" instead.

3. Potential applications

Cisgenesis: insertion of DNA elements found in other sexually compatible animals of the same or a closely related species, without rearranging or modifying them.

Intragenesis: insertion of DNA elements from sexually compatible animals of the same or a closely related species, but the elements have been rearranged or modified.

Transgenesis: introduction of genes or DNA elements from a species with which sexual reproduction is not possible.

The vocabulary employed when discussing various types of modified organisms is diverse and often up for semantic debate. Certain terms pertain to the product attained (1), while others refer to the methods utilised to obtain it (2), or even the type of modification induced (3).

are not present in the public domain in France and Europe. However, the topic is still under discussion within the scientific community, and stances are beginning to arise amongst experts in livestock breeding.

As animals are sentient and subject to various representations (cultural, scientific, political, economic, legal, etc.), they may be viewed as socio-technical objects (Barthe *et al.*, 2014). Nevertheless, differences between animals and plants suggest that the controversy surrounding genetically modified animals (GMAs) will not have the same dynamics or structure as that surrounding genetically modified plants (GMPs).

The aim of this article is to identify the specific features of the controversy surrounding GMAs, using published literature and official French stakeholder positions related to biotechnology and livestock farming. The aim is to examine the development of a new controversy, which currently remains within specialist circles, relating to NGTs in the livestock farming industry.

In the first part, we will show that all the elements are in place for the scientific controversy surrounding GMAs to emerge in the French public debate and we will review the existing legal framework in the primary relevant countries. We will then look at the concerns surrounding the GMA controversy and the controversy surrounding AquaBounty salmon, which for a long period of time was the only GMA offered[2] on the food market (in North America), to demonstrate that they do not inevitably foretell the shape of the controversy surrounding GMAs. We will then examine the positions taken by specialist circles in the French context, where GMAs are seldom visible in the public sphere and remains limited to the field of animal experimentation. Finally, we will explore some of the viewpoints taken by societal groups on the subject, which challenge established livestock farming models rather than biotechnologies themselves.

2 The situation is evolving rapidly and other GMAs are now approaching the market. A sea bream genetically modified to grow faster has been the subject of test sales in Japan in September 2021. In 2022, Genus-PIC's PRRS-resistant pigs are in a pre-market phase.

1. New genetic technologies: elements of an emerging controversy

This section outlines the uncertainties surrounding NGTs applied to farm animals, all of which contribute to the public controversy.

■ 1.1. Controversy analysis as a methodological approach

Controversy analysis (Callon, 2013; Lemieux, 2007) focuses on moments when everything is in the process of being done, is going to be done or, on the contrary, is not going to be done, or to express it in other terms: "openly constitute moments of potential reversal of relations and beliefs that were previously instituted" (ibid).

During such moments, the various parties involved attempt to persuade the public to take their side, and arguments are exchanged despite the inevitable uncertainties. The sociological definition of controversy is built around this concept of uncertainty. Sociotechnical controversy can therefore be described as a scenario in which a dispute/disagreement among multiple parties, each of whom possesses expert knowledge, but none of whom has the ability to establish unequivocal facts, is presented to a third party. A controversy is characterised by an entanglement of various issues, facts and values, and often involves contested definitions of both technology and society (Benvegnu and Laurent in Seurat and Tari, 2021).

This framework seems relevant for dealing with the possible emergence of NGTs in livestock breeding. GMAs have not yet become a matter of public controversy in France, and the debate is currently confined to scientific and livestock breeding circles. The potential development of biotechnologies in the livestock sector, while not new, has taken on a new dimension with the rapid progress made since the discovery of Crispr-Cas9 and, despite this progress, uncertainties remain regarding its use. The debates generated by this unstabilised knowledge raise questions that are not limited to the scientific community, but concern the livestock industry and the anthropozoological relationship in general (Delanoue *et al.*, 2018).

Using the prism of sociology of controversies allows us to witness the forces at work (who is speaking?), the range of perspectives presented (what worldviews are in conflict?), the behaviour of stakeholders (who is reacting to whom? who is collaborating with whom?), and their means of influencing the normative context. The examination of controversies makes it possible to "explore conceivable states of the world that are unknown due to uncertainties" (Barthe *et al.*, 2014).

■ 1.2. Genome modifications in an uncertain context: elements for the emergence of a public controversy

a. Tensions arising from the numerous scientific uncertainties

To start with, targeted genome modifications carry inherent uncertainties. Although they enable targeted, rather than random, modification, in contrast to previous methods, issues remain around tool control. This category encompasses the question of unintended effects, such as off-target effects (i.e. impacting non-targeted DNA sequences), or poor control during the modification process (Burgio and Teboul, 2020). The case of the Recombinetics bulls in the United States, which were modified by a Talen-type nuclease to be born without horns, offers a clear example of the potential impact of these uncertainties. In July 2019, the DNA sequences of two modified calves were analysed by the Food and Drug Administration (FDA). They discovered that, while both alleles did indeed contain the genetic sequence of the hornless variant, one of the alleles had also incorporated the DNA of the plasmid used for the targeted modification, as well as a second copy of the hornless variant. As a result, both calves were transgenic (Norris *et al.*, 2020).

Although this insertion does not pose a direct health risk, the developers did not identify it, and it was likely to confer antibiotic resistance to the animals. This event sparked lively debate within the scientific community, yet received limited coverage in the French media[3].

3 A Europress search using the keywords "bull*" or "calf*" or "cow*" and "Recombinetics" over the period 2019-2020, carried out on February 16, 2021, produced seven results. Of these, two did not deal with the event and were therefore off-topic. Of the remaining five, one "Sciences et Avenir" article was a repeat of the AFP news report on the issue. There were also three "Le Monde" articles on the topic and a duplicate from the "Le Monde".

While Crispr enables modifications without the need for bacteria, this example raises concerns about the ability of people concerned to identify undesired effects.

There are also uncertainties regarding the functioning of the genome, ranging from the impact of modifications on animals to interactions between genes in the case of multiple simultaneous introductions. The potential collateral effects stemming from these techniques are potentially numerous and remain to be assessed.

Beyond the purely scientific debate, broader uncertainties can partly be found in the academic literature, with multiple perspectives and a variety of arguments, including environmental, socio-economic, legal, or ethical questions (De Graeff *et al.*, 2019).

b. Environmental, socio-economic and ethical uncertainties

In their review, De Graeff *et al.* (2019) analyse 134 academic articles dealing with targeted genome modifications and list the arguments for and against their use on animals. They group them under seven topics: human health, efficiency, risks and uncertainties, animal welfare, animal dignity, environmental considerations and societal acceptability.

The latent environmental impact of NGTs, while not as widespread as in the plant industry, should not be overlooked. The potential risks are especially significant for aquaculture species, where the escape of animals can result in interbreeding between wild and domesticated fish. Currently, the possible consequences of introducing modified (trans)genes into wild populations (Okoli *et al.*, 2022) are hard to predict. Could such crossings upset the ecological balance or alter biodiversity? In addition, an assessment of the indirect environmental impact of these tools remains to be assessed. While some stakeholders consider NGTs to be a tool for reducing the environmental impact of livestock farming, for example by reducing phosphorus emissions from pigs (Golovan *et al.*, 2001) or by enhancing productivity, others, others, in contrast consider that the use of NGTs would lead to more intensive livestock farming, with negative effects on the environment.

The integration of NGTs into a socio-economic system raises several questions. The whole organization of livestock farming may get impacted. In particular, is there a danger of moving towards a monopolistic situation on genetic resources, through the patenting of living organisms? Won't breeders then lose their expertise and become dependent on companies developing GMOs? Will the diversity of legal frameworks or required scientific skills increase competitive imbalance between different world areas?

Furthermore, from an ethical viewpoint, the mere idea of modifying the genome, whether human, animal or plant, is a recurring debate. One of the most controversial use of Crispr was the announcement in China of the birth of genetically modified human twins in 2018. Using Crispr-Cas9, researcher He Jankui introduced a mutation into the CCR5 gene, hoping to confer the twins resistance to Human Immunodeficiency Virus (HIV). The scientific community has denounced this unjustified of a technology which is not fully controlled and has potential off-target effects, as well as the modification of germ cells that can be transmitted to offspring, These ethical concerns apply to animal modifications as well: is it ethical to modify animals for human gain, is there no risk of compromising their welfare? These questions, which can be traced back to the origins of domestication, are already present in the genetic selection process. The potential use of NGTs renews and exacerbates them, in so far they are not restricted to using the existing genetic variability, but make it possible to more rapidly and precisely alter the genetic heritage of a population, or even a species (Ducos, 2020).

In their previously cited review, de Graeff *et al.* (2019) highlight the shortcomings of the literature in addressing all these uncertainties. They lament the lack of disciplinary diversity, with the majority of authors belonging to the veterinary or biomedical sectors. They also note a lack of studies that systematically compare potential risks and benefits, which they believe could provide a better overall picture. Finally, their review highlights a discrepancy between the arguments put forward by experts and those used in the public debate. For example, issues such as the allocation of public funds to NGT research rather than other areas, equal access to these tools and the marketing of NGTs are under-represented in the expert discourse. These comments suggest that the debate should be broadened to include new actors.

Box 2. ***Overview of the different laws governing NGTs in different countries.***

Argentina

In 2015, Argentina became the first country to adapt its regulatory framework on GMOs to NGTs, thanks to Resolution No. 173/15. It adopted a "product-by-product" approach. Products that do not contain a "novel combination of genetic material" (i.e. a transgene) are excluded from GMO regulation and are subject to a simplified procedure (Whelan and Lema, 2015).

United Kingdom

To date, the UK has been subject to the European Directive 2001/18/EC on GMOs. In early 2021, the UK Department for Environment, Food & Rural Affairs (DEFRA) launched a public consultation proposing a review of the regulatory framework for GMOs and in particular NGTs: "DEFRA believes that organisms produced by genome editing or other genetic technologies should not be regulated as GMOs if they can also be produced by traditional breeding methods. Exiting the EU provides an opportunity to consult on the implications of this issue".

The United States

In contrast to the EU, which regulates according to the technique used to achieve a modification (Hermitte and Noille, 1993), the United States takes an approach based on the characteristics of the end product. Many plants modified with NGTs are not subject to GMO regulations, particularly in the case of "deletions, single base pair substitutions, introduction of sequences from related sexually compatible plants". The Food and Drug Administration (FDA) is responsible for evaluating GMOs used in agriculture. A bill to transfer jurisdiction to the United States Department of Agriculture (USDA), which is much more favourable to the use of genome editing than the FDA, is now open for public comment[4].

Norway

GMOs are regulated by the Norwegian Genetic Engineering Act of 2 April 1993. Similar to European legislation, the specificity of this act is to assess whether the proposed product will contribute to sustainable development and benefit society. "In deciding whether to accept or reject an application, special consideration must also be given to whether the deliberate release will benefit society and whether it is likely to promote sustainable development".

The Norwegian Biotechnology Advisory Board (2018), a body mandated by the government to deal with the social and ethical dimensions of biotechnology, has drafted a "Proposal for more flexibility in the EU regulation on the deliberate release of genetically modified organisms (GMOs)", which considers the type of modification being carried out. Depending on the type of modification, the assessment process may be simplified.

c. A look back at a debated legal framework

At present, the debate on the legal framework for NGTs focuses mainly on the plant sector and whether or not they should be classified as GMOs. In order to place the European debates in an international context, Box 2 outlines the legislation in place in different countries and the debates that have arisen.

Faced with legal uncertainty, the *Confédération paysanne* and ten other associations referred the matter to the

4 https://www.federalregister.gov/documents/2020/12/28/2020-28534/regulation-of-the-movement-of-animals-modified-or-developed-by-genetic-engineering

French Council of State in 2016, asking it to clarify whether products derived from NGTs should be considered as GMOs. The Council referred the matter to the Court of Justice of the European Union (CJEU), which ruled on 25 July 2018 that products derived from targeted mutagenesis, such as Crispr products, must be regulated as GMOs. This means that they are subject to the authorisation procedure laid down in Directive 2001/18/EC and that their cultivation is prohibited in certain Member States, including France. Despite this ruling, the French Minister of Agriculture declared[5] on 7 January 2021 that NGTs are not GMOs and that he hopes for a change in European legislation.

Following the CJEU's interpretation of Directive 2001/18/EC, the European Commission was asked to assess its suitability for regulating products derived from targeted genome modification. In a report published in April 2021, it concluded that: "there is every reason to believe that [Directive 2001/18/EC] is not adapted to certain NGTs and their products and that it needs to be adapted to scientific and technological progress" (European Commission, 2021). The European Commission therefore calls for further studies to decide what legal framework or adjustments would be appropriate. However, its conclusions do not apply to animals or micro-organisms, as the Commission considers that there is insufficient literature to reach a conclusion. To date, no application has been made to the European Union (EU) for authorisation to place a genetically modified animal (GMA) on the food market. Any such application will have to be assessed under Directive 2001/18/EC.

This legal framework, which is still under construction, is still being questioned and even contested by some actors. This period of uncertainty about the development of standard-setting mechanisms could help to open up the debate on the legal framework for GMAs.

5 Interview by Mathieu Robert (Agra presse), Nathalie Marchand (Les Marchés) and Vincent Motin (Réussir.fr); (2021, January 22). "NBTs are not GMOs". Agra Presse. https://www.agra.fr/agra-presse/les-nbt-ce-ne-sont-pas-des-ogm [accessed June 2021]

2. New genetic technologies in farm animals: a simple extension of the GMO controversy?

This section looks back at the earlier GMO controversy, to which the various stakeholders refer in order to relate to it or, on the contrary, to distinguish themselves from it. While the latter anticipated certain sets of arguments, the application of NGTs to animals seems to open up new questions and highlight potentially different issues.

2.1. The categorisation of NGTs in relation to GMOs: a strategic issue for those involved in the controversy

Some arguments can have a significant "impact" that becomes apparent during the controversy (Chateauraynaud, 2011) because of the consequences that will follow from them. The NGTs are the object of an argumentative strategy on the part of the actors in the controversy, which aims to associate or, on the contrary, to dissociate the new genome modification methods with those that preceded them.

Opponents to any kind of genome modification use the term "new GMOs" or "hidden GMOs" to associate NGTs with earlier methods of transgenesis. Some opponents to the use of NGTs are critical of the term "genome editing", which they see as an attempt to remove NGTs from the GMO debate and from Directive 2001/18/EC. By associating them with first generation GMOs, their opponents believe that there is nothing new and that the current balance (Directive 2001/18/EC and the safeguard clause prohibiting the cultivation of GMOs in France) should be maintained.

On the contrary, by distinguishing NGTs from GMOs, some of the actors are trying to facilitate their acceptance. By using a different name for NGTs, they have been spared two decades of arguments to which the following section returns.

2.2. The GMO Controversy as a Background to NGTs

Linking NGTs to GMOs allows the debate to continue in existing configurations.

Bernard De Raymond (2010) has shown that different configurations of the conflict over GMOs have followed one another, each with its own set of actors and specific sets of arguments. In 1996, as the first commercial approvals approached, around one hundred scientists signed a call for a moratorium on GM crops. This was an attempt to expose the divisions within the scientific community. Initially "confined", in the words of Lemieux (2007), to scientific expertise, the seed industry and government, the GMO controversy became public shortly afterwards when Greenpeace stopped a ship carrying large quantities of transgenic soya in Europe. Arguments began to emerge on environmental and health grounds, particularly around the issue of irreversibility: once GMOs are produced and marketed, there is no going back if there is a risk. Traceability and labelling became a key issue in the controversy. In 1998 and 1999, the GMO controversy became a testing ground for deliberative democracy, and a citizens' conference was organised. The arrival of the *Confédération paysanne* internationalised the debate and focused it on more economic issues such as the patentability of living organisms and the freedom to replant (Bernard De Raymond, 2010). With the emergence of the "junk food" arguments in the 2000s, GMOs became part of a broader challenge to the liberal system by the alter-globalisation movement (Chateauraynaud *et al.*, 2010).

These different periods also saw changes in the way people acted: the volunteer reaper movement gained visibility, and lawsuits for the destruction of other people's property became a forum for expressing opposition to GMOs. Collective actions are multiplying and "assuming their illegality" to encourage the government to change the rules (Bernard De Raymond, 2010). The controversy has shifted to a logic of conflict, making exchanges difficult (Chateauraynaud *et al.*, 2010).

The GMO controversy is a major issue in French society, although, like the NGT debate, it is mainly confined to GM crops. The debate on NGTs applied to livestock is part of this controversy, extending it and at the same time diverging from it, as the debate on regulatory issues clearly illustrates. The GMO controversy provides a framework for the NGT debate: first, a regulatory framework in which the cautionary principle is a key factor. Secondly, the actors have gained extensive experience of the controversy and can now draw on their knowledge of the risks and potential tensions to formulate their positions and develop their arguments. Although closely related to GMOs, NGTs are different techniques that raise different issues (e.g. mutation detection). Their use in animals also raises new questions that have rarely been addressed.

■ 2.3. The case of AquaBounty salmon

Until recently, the only GMA available on the food market was the AquAdvantage® salmon produced by the US company AquaBounty[6]. Although it was not produced using NGTs, this particular salmon is of interest to us as a GMA. Using first-generation transgenesis, a growth hormone gene and a cold-resistance gene were inserted into the fish's genome. The resulting salmon grows faster, taking half the time of conventional salmon to reach market weight (Lievens *et al.*, 2015).

AquaBounty stresses the sustainability of its salmon. On its website it describes its salmon as "local" because it is produced in the USA, "free of antibiotics and other contaminants" because it is farmed in a closed environment, and with a 25% improvement in feed efficiency that would reduce its environmental impact. By reversing the idea, often used in environmental arguments, that food produced in its own environment is more sustainable because it requires less external support (inputs, energy), the company is presenting its salmon as healthier and more sustainable precisely because it is farmed outside its natural environment. Biotechnology is becoming a solution to the problems of aquaculture.

Despite these arguments, it took the company 20 years to obtain marketing approval in the United States and then Canada. This approval, granted by the FDA in 2015, was suspended from 2016 to 2019 due to a lack of defined labelling standards. Despite the approval, many retailers have already stated that they will not sell this salmon in their stores[7]. Nevertheless, it remains difficult to know how this GMA is perceived by the general public in the absence of clear labelling[8].

The study of the salmon controversy showed that the arguments put forward by the various stakeholders were mainly environmental (overfishing on the one hand, risk of genetic pollution on the other), economic (interests of fish farmers threatened by the arrival of a new competitor on the market) and health (vulnerable populations and risk of developing food allergies). Barrey (2014) highlights the virtual lack of mobilisation of the animal welfare issue. This argument could be more influential today.

This case study invites us to question whether the same arguments would be used to debate the introduction of a GMA in France, bearing in mind that "cultural patterns of evaluation" vary from one country to another (Lamont and Thévenot, 2000). The fact that this first GMA is a fish also gives a particular focus to the debate because of its "intermediate" status between animals and plants (Bérard, 1998), with the general public often being more concerned about the welfare of mammals than fish. In addition, it faces issues that are closer to those of plants, such as the risk of escape into the natural environment and contamination of wild species. In view of all these considerations, the case of transgenic salmon does not necessarily prefigure the mobilisation of similar arguments for future GMAs, particularly for terrestrial animals.

3. Genetically modified animals in France: an issue with limited public visibility

For the time being, GM animals in France remain primarily a scientific issue: the GM animals on public exposure are experimental animals, and the actors expressing their views on the subject are those involved in research or breeding. The GMA should therefore be considered as an indicator of the relationship between science and society.

■ 3.1. An issue limited to scientific institutions…

Public statements on NGTs remain limited in France and are mainly confined to research institutes and their ethics committees. As far as French Breeding industry actors are concerned, we have identified only one public position.

An attempt to set up a multi-stakeholder consultation on the issue was launched in 2016 within the High Council for Biotechnology (HCB). However, the HCB, which is the reference committee on GMOs as its mission is to "provide independent advice to the government on […] GMOs or any other biotechnology"[9], has never issued an opinion or recommendation on GMAs, partly due to a lack of consensus within the committee itself and after a series of resignations (Huet, 2016).

The other multi-stakeholder entities that have managed to give an opinion on the issue recommend caution in the use of NGTs in animal breeding. The French Academy of Agriculture, for example, released an opinion in early 2020 (Vialle and Hervieu, 2020), rec-

6 AquaBounty, s.d. Our Salmon, AquaBounty.com, [online], accessed February 8, 2021, https://AquaBounty.com/our-salmon

7 Friend of the Earth, 2021. Company Commitments on GMO Salmon, foe.org, January 12, 2021, [online], accessed February 8, 2021, https://foe.org/company-commitments-on-gmo-salmon/

8 With the adoption of the National Bioengineered Food Disclosure Standard by 2022, GMO products will have to be labelled "bioengineered" or display a QR-code providing more information.

9 HCB website, accessed January 2021. https://www.hautconseildesbiotechnologies.fr

ommending that the general public should be involved in the decision-making process and that research into risk assessment[10] should continue. Of all the types of genetic modification enabled by NGTs, the Academy stresses that the rewriting of the genome must "preserve the identity of the species", meaning that the changes made should have been observed in species with a common ancestor. For example, a modification induced in a pig could be derived from alleles or genes in a closely related species such as the warthog.

The INRA-Cirad-Ifremer Ethics Committee also gave its opinion in December 2019[11]. It advises to proceed "with caution, in a spirit of prudence". Its recommendations call for questioning the potential applications of these techniques in the context of targeted research, considering animal welfare and informing society. For this Ethics Committee, productivity cannot be the only driving force behind the modification of animal genomes. It therefore calls for a certain deontology to be respected in the development of these techniques.

For now, the French Veterinary Academy seems to be the only entity that is enthusiastic about the use of NGTs in farm animals. In an opinion published in June 2019 (AVF, 2019), it supported the use of NGTs to develop disease-resistant traits in animals, improve prophylaxis and limit the use of antibiotics.

■ 3.2. …and a few French breeding industry players

The only official position taken by an actor in the breeding sector outside academic research is a communication from ALLICE, a consortium of French animal breeding and reproduction companies.

The organisation of the cattle industry is well suited to the introduction of these new tools, as reproductive biotechnologies are routinely used and the existing structures offer the possibility of monitoring "genome-edited animals". ALLICE expresses an interest in NGTs as part of basic research, to "optimise selection schemes" or to introduce new alleles (such as disease resistance alleles). However, the press release urges caution due to the lack of current knowledge about the functioning of the genome and the potential risks associated with its new mutations. ALLICE states that it is "working with INRAE to develop the technology in cattle for research and risk assessment purposes".

Furthermore, ALLICE supports a regulatory approach that combines a product-based approach (where the type of product obtained and its novelty trigger a specific legal framework) and a technology-based approach (where the legal framework is triggered according to the technique used to obtain a modification; in this specific case, ALLICE considers that transgenesis techniques should lead to a legal framework as GMOs). It expresses its concerns about the ability to control and detect animals and products derived from GMOs and therefore to enforce the current legal framework.

Finally, the press release concludes that: "In the current context of social controversy surrounding animal breeding, and given the risk to the industry's image, the French breeding companies within ALLICE have decided not to use these technologies to produce 'genome-edited' animals in France" (Schibler, 2020). Although it has not yet reached the general public, the controversy surrounding NGTs applied to animals is already having an impact on the practices of breeding actors, who are anticipating the reactions that these techniques could generate.

■ 3.3. The manipulation of living animals, a revealing aspect of the relationship between science and society

a. The GMA, an object of suspicion

The GMA is first and foremost a scientific object produced in a laboratory. It reveals the complexity of the relationship between science and society.

The only GMAs that have received media coverage in France have actually been experimental animals, which have been made public following incidents. In June 2015, Le Parisien[12] revealed that Rubis, a lamb carrying a fluorescent gene, had entered the food chain as a result of human error and ended up on the table of a private individual in the Ile-de-France [13]region. It was a classic case of risk management. A decade earlier, it was a fluorescent transgenic rabbit from an INRA laboratory that hit the headlines after becoming the focus of the artist Edouard Kac's project "Tales of a Rabbit Gone Viral" in 2000[14]. Created for research purposes, this rabbit was perceived as the product of scientific madness.

While it may seem simplistic to analyse individual attitudes to GMOs solely in terms of collective myths, this approach is often used in relation to genetically modified products and more broadly to the relationship between science and society. Wagner and Kronberger (2002) have shown that collective myths influence people's perceptions of biotechnology. The myth of the "sorcerer's apprentice" is part of this imaginary and refers to the idea that man, and also science, creates its own problems (Beck, 2001).

In fact, these two examples relate to a wider issue of trust in research and food safety authorities[15]. In the specific

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10 A minority of the Academicians take a different view and are more favourable to the use of NGTs, as indicated by their title: 'Biotechnologies, necessary and essential tools for our future' (French Academy of Agriculture, 2020b).

11 Web link: https://www.inrae.fr/en/news/genome-editing-technologies-animals

12 *Le Parisien* Newspaper. 2015. The crazy case of the sheep-medusa that ended up on a plate [in Franch]. *leparisien.fr*, 23 juin 2015, [online], accessed February 8, 2021, www.leparisien.fr/faits-divers/la-folle-histoire-du-mouton-ogm-23-06-2015-4885599.php

13 From a public health perspective, the ewe lamb was considered safe, as it carried the gene but did not express the green fluorescent protein.

14 Kac E., s.d. Rabbit Remix, ekac.org, accessed 10 January 2021, https://www.ekac.org/gfpbunny.html

15 The GMO controversy started in the 1990s and developed in conjunction with the Bovine Spongiform Encephalopathy (BSE) crisis. Both controversies are part of a wider controversy about the agricultural model. The BSE crisis, which began in 1996, marked a crisis of trust between science and society. It was the first socio-technical controversy to concern food and farming methods, challenging the relationship between agriculture and society. This crisis has often been depicted through the lens of madness, featuring the sorcerer's apprentice who violated the laws of nature by turning cows into cannibals (Lévi-Strauss, 2001).

case of food, scientific and technical management no longer seems to reassure consumers. The health crises of recent decades (contaminated blood, mad cow disease, horsemeat, etc.) have damaged relations between the agri-food industry, the scientific community and civil society. Trust in technological developers is one of the factors influencing people's perception of risk (Chevassus-au-Louis, 2002), especially at a time when consumers are moving further away from food production sites and facilities (Poulain, 2013).

b. Scientific innovation challenged by society

Even if NGT-derived products were to reach the market, it is by no means certain that they would be accepted by industry or consumers.

Indeed, scientific and technological innovations are sometimes rejected by their intended users (Weary *et al.*, 2016). This can sometimes be explained by scientists' misunderstanding of the expectations of other stakeholders, both professionals and representatives of civil society. Weary *et al.* (2016) examined the barriers to adoption of solutions developed by scientists to change agricultural practices such as dehorning in North America: pain management solutions have been developed, but some farmers have not adopted them. They found that fear of additional costs and extra work were among the factors holding back change. The authors also found that some farmers believe that dehorning causes only temporary pain limited to the calves, so they see no point in pain management.

The sociology of innovation has also focused attention on the adoption or non-adoption of an innovation by a society. Akrich *et al.* (1988) have shown that the diffusion model, which assumes that an innovation is recognised for its own qualities once it has been developed, is rarely valid. The authors conceptualise a "whirlwind" model in which the innovative object is developed and constructed at the same time as the society that will adopt it: "the environment is shaped at the same time as the innovation it evaluates". There is therefore no guarantee that NGT application projects will meet the expectations of all stakeholders.

4. Modified animals for more sustainable livestock farming?

This final section looks back at the promises made about NGTs and, on the basis of the few positions that have been expressed within civil society, questions their ability to gain the support of civil society actors.

4.1 Biotechnology for sustainability and animal welfare

First-generation GMOs are often associated with an intensive, industrial model of agriculture, particularly because of the applications developed (transgenic plant varieties resistant to herbicides) and their inclusion in a monopolistic model that privatises living organisms. Some stakeholders are now trying to refocus the debate by presenting NGTs as genetic tools for more sustainable systems. For example, in June 2020, a number of representatives of the German Green Party expressed their support for the use of NGTs in agriculture. They argued that there is no technology that can be ruled out to meet the challenges facing agriculture in the face of the urgent environmental situation. However, they regret that other members of the Green Party judge the technology on the basis of its principle rather than its applications[16]. They therefore call for a revision of European legislation, as they believe that Directive 2001/18/EC does not reflect current knowledge and encourages a monopolistic situation by large companies. This position contrasts with that of the Greens and most European ecological parties.

NBTs applied to animals can also be presented as a solution to a number of problems in livestock farming. The issue of GMAs is part of a growing debate on livestock farming (Delanoue *et al.*, 2018; Legendre *et al.*, 2018). It is criticised on several fronts: its impact on health, the environment and the conditions in which animals are reared (Delanoue *et al.*, 2018). These three dimensions lead to uncertainties about the "right" way to farm and, more generally, about the place of farming in society. For example, projects propose to end the controversial practice of crushing male chicks in laying hen farming by introducing a gene that prevents the development of males in ovo (Lee *et al.*, 2019), or to end the dehorning of cows by removing their horns using NGTs. These hornless cows, mentioned above, promise to reduce the time needed to introduce the hornless allele compared to conventional breeding and to eliminate dehorning, a controversial practice both in terms of animal welfare and the additional workload and costs for farmers. The argument for speeding up genetic progress is still controversial, as it varies greatly depending on the species, the genetic determinism of the trait (mono- or polygenic) and the organisation of the industry concerned (Mueller and Van Eenennaam, 2022).

4.2 Promises that remain elusive

Despite the above commitments, the few positions taken by civil society actors suggest that the debate on NGTs may focus more generally on the choice of livestock models to be developed.

The other actors involved in agricultural issues have mainly expressed their views on crops. This section presents the few mentions by civil society actors of NGTs applied to farm animals that have been identified.

The *Comité Consultatif National d'Éthique* (CCNE), which brings together various stakeholders representing civil society, issued an opinion on targeted genome modification in September 2019 that foreshadows possible points of disagreement between proponents and opponents of NGTs. It opposes: "the deletion of bovine horns by targeted genetic modification, with the aim of increasing the density of stables by limiting the risk of injury between ani-

16 The Greens (German Green party) (2020), "New times, new answers: Regulating genetic engineering law in line with the times [German]". *Alliance 90/The Greens*, June 10, 2020, [online], accessed January 30, 2021, https://www.gruene.de/artikel/neue-zeiten-neue-antworten-gentechnikrecht-zeitgemaess-regulieren

mals, or the mutation of the myostatin gene to increase their muscle mass for commercial profitability, while neglecting the issue of farm animal welfare" (CCNE, 2019). Similarly, the GMO monitoring website Inf'OGM (infogm.org) has published a number of articles on NGTs applied to animals. One article, on hornless cows obtained by targeted genome[17] modification, questions the justification for genetically modifying animals when the farming system can be changed. Some authors are also concerned about the potential use of NGTs as palliatives that would prevent farming systems from moving towards more sustainable systems (Ducos, 2020).[18]

Furthermore, although NGTs are described as a tool to improve animal welfare, animal welfare organisations have not (yet) taken up the issue. There is only one mention of the issue on the website of Compassion in World Farming, published in 2013[19]. The organisation expresses strong concerns about the impact of genetic modification on animal welfare: "There may be exceptional circumstances in which the use of genetic engineering could lead to animal welfare benefits […]. In the meantime, we should be sceptical about any attempt to present genetic engineering as a benign approach to improving animal welfare".

Thus, even if civil society representatives are not very active on the issue of NGTs, the few opinions expressed show that the farming system as a whole is being questioned rather than specific practices. The incentive process (i.e. "the set of actions designed to attract the interest and support of influential stakeholders") through animal welfare does not seem to work here (Barthe *et al.*, 2014).

The example of hornless cows is often cited when discussing the improvement of farming conditions through NGTs. However, advances in research and the development of new projects focusing on traits that are more difficult to modify may help to change the above views. For example, many studies are being carried out on disease resistance, some of which address problems for which there are currently few or no alternatives.

Conclusion

The arguments mobilised in relation to NGTs are numerous: conventional arguments about GMOs and arguments used in the livestock controversy. In a context of mistrust of science, it is doubtful that presenting NGTs as the solution to livestock problems is an effective way of avoiding controversy. Underlying the criticisms of animal agriculture are wider issues that challenge our relationship with the living world, with science and with food. The use of biotechnology is likely to raise many more questions than it answers.

By contributing to research on NGTs, the social sciences can provide a better understanding between the various stakeholders involved in the debate. Such research can help to overcome the conflicting positions that have emerged in the GMO debate (Chateauraynaud *et al.*, 2010). Some authors recommend the use of "responsible innovation" tools for more democratic decision-making (Macnaghten and Habets, 2020).

However, the international context is moving fast. In December 2020, a genetically modified pig engineered not to produce the alpha-gal sugar molecule that can cause allergic reactions was approved by the FDA for the food and therapeutic markets. The inclusion of this new GMA in both the food and medical sectors could generate new arguments and provide a clearer picture of the specific nature of consumers' relationship with animal food and animal medicines. In September 2021, a genetically modified sea bream was the focus of test sales in Japan. More recently, in March 2022, the FDA in the United States granted food approval to a cow from Recombinetics whose hide had been genetically modified to make it more tolerant to heat. The launch of several GM crops based on targeted genome modification could bring the debate into the mainstream.

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Abstract

The tools for genome modification are numerous and lead to a variety of uses: inactivation, mutation, deletion or insertion of a DNA element or a gene in an organism. Some methods induce a random modification, while others, which are of interest to us, are carried out in a targeted manner. Regardless of the tools chosen, the types of modification executed or the purpose of these modifications, the subject is a controversial one. This article looks at the debates that arise from the potential application of these genetic tools to farm animals and seeks to show that this subject, currently the preserve of specialists, has all the criteria to become a public controversy. The paper first reviews the main uncertainties raised by the subject and examines the debates around the legal framework. It then explores the possible ways in which the subject could be thematized, recollecting the GMO controversy and the case of the salmon produced by AquaBounty in the US, until recently the only Genetically Modified Animal (GMA) authorized on the food market. A third part offers a quick overview of the actors who express themselves on the subject and the rare evocations of GMA in France. These confirm that the subject remains confined to the scientific and professional environment, where the GMA becomes a revealer of the relational dynamics between science and society. Although civil society actors have not yet taken up the subject, the few positions observed in the last part suggest that interest through the prism of animal welfare does not work.

Résumé

Les modifications ciblées du génome appliquées aux animaux d'élevage : à la croisée des controverses

Les outils de modification du génome sont nombreux et peuvent conduire à des utilisations variées : inactivation, mutation, suppression ou insertion d'un élément d'ADN ou d'un gène dans un organisme. Certaines méthodes induisent une modification aléatoire, tandis que d'autres, qui nous intéressent plus particulièrement, s'effectuent de manière ciblée. Quels que soit les outils choisis, les types de modification réalisés ou la finalité de ces modifications, il s'agit d'un sujet controversé. Cet article s'intéresse aux débats qu'engendre la potentielle application aux animaux d'élevage de ces outils génétiques et cherche à montrer que ce sujet, pour l'instant l'apanage de spécialistes, réunit toutes les conditions pour se transformer en controverse publique. Une première partie revient sur les principales incertitudes que soulève le sujet et s'arrête sur les débats entourant le cadre juridique. Nous explorons ensuite les approches thématiques possibles du sujet, en revenant sur la controverse autour des OGM et le cas du saumon produit par la société AquaBounty aux états-Unis, jusqu'à récemment l'unique Animal Génétiquement Modifié (GMA) autorisé sur le marché alimentaire. Une troisième partie présente les acteurs qui s'expriment sur le sujet et les rares évocations des GMA en France confirment que le sujet reste confiné au milieu scientifique et professionnel, l'GMA devenant alors un révélateur de dynamiques relationnelles qu'entretiennent sciences et société. Enfin, nous montrons que, bien que les acteurs de la société civile ne se sont pas encore emparés du sujet, les rares prises de position observées laissent penser que l'intéressement par le prisme du bien-être animal ne fonctionne pas.

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