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ARTICLE

The Protection of Selectively Bred and Gene Edited Farm Animals under EU Law

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Abstract

Since the eighteenth century, animal breeding has significantly evolved, culminating in the use of gene editing (GE) technologies like CRISPR-Cas9. These technologies offer unprecedented capabilities to modify animal genomes, potentially revolutionising breeding practices by achieving desired traits much faster compared to traditional selective breeding (SB). Because breeding programmes focussed on productivity traits have often compromised animal welfare, this article provides an analysis of the ethical issues underpinning the use of GE in animal breeding, and the current laws regulating such practices. In doing so, this article critically examines the European Union (EU)'s regulatory framework for SB and GE in farm animals, highlighting significant gaps and inconsistencies. Specifically, the use of GE animals is currently regulated under the EU's GMO legislation, while SB is more loosely regulated, posing substantial risks to animal welfare. The authors advocate for a regulatory framework that prioritises animal welfare goals and proposes reforms to enhance animal protection objectives by ensuring a more consistent and humane approach to farm animal breeding.

Keywords: animal welfare; gene editing; selective breeding

I. Introduction

Since the eighteenth century, when Robert Bakewell introduced controlled breeding strategies,[1] animal breeding has significantly evolved thanks to scientific advances, including artificial insemination, genomics[2], the first generation of genetic engineering tools,[3] and cloning. However, the advent of gene editing (GE) technologies in recent years, such as CRISPR-cas9 (CRISPR),[4] provide unprecedented power to modify animals' genomes,

[1] A Blasco, "Animal Breeding Methods and Sustainability" in ML Spangler (ed), *Animal Breeding and Genetics* (New York, Springer 2023) pp 5–25; W Wright et al., "Using Animal History to Inform Current Debates in Gene Editing Farm Animals: A Systematic Review" (2022) Frontiers in Sustainable Food Systems 1–18; B Schultz, et al. "Chapter 23, Genetic Improvement of Livestock, From Conventional Breeding to Biotechnological Approaches" in FW Bazer, GW Lamb, G Wu (eds), *Animal Agriculture* (Massachussets, Academic Press 2020) pp 393–405.

[2] TF Bishop and AL Van Eenennaam, Genome Editing Approaches to Augment Livestock Breeding Programs" (2020) 223 Journal of Experimental Biology 223.

[3] RE Hammer, et al., "Production of Transgenic Rabbits, Sheep and Pigs by Microinjection" (1985) 315(6021) Nature 680–3.

[4] JA Doudna and E Charpentier, "The New Frontier of Genome Engineering with CRISPR-Cas9" (2014) 346(6213) Science 1077.

potentially revolutionising breeding practices. CRISPR enables targeted cuts in the DNA, leading to precise modifications in animal genomes. At the same time, unlike previous generations of genetic modification technologies (GMOs), CRISPR does not necessarily require the insertion of foreign genes.[5] Compared to selective breeding (SB), defined as "the process of modifying the characteristics of living things especially to enhance one or more desirable traits by selection in breeding controlled by humans",[6] CRISPR allows for a faster achievement of desirable traits,[7] as well as the development of traits that are difficult to achieve through SB, such as disease resistance.[8]

While the discovery of GE represents a breakthrough, its use in farm animals raises significant ethical questions, particularly in the context of farm animal breeding and intensive animal agriculture. As farming has transitioned to large, industrialised operations known as concentrated animal feeding operations (CAFOs), especially in wealthier countries,[9] breeding choices have prioritised traits that increased productivity, often at the expense of animal welfare. This focus on yield has led to adverse effects like skeletal leg disorders, heart failure, footpad dermatitis, and sudden death syndrome in broiler chickens[10] and increased susceptibility to mastitis and lameness in dairy cows.[11]

While some applications of GE could benefit animal welfare, such as developing heat-resistant cattle,[12] this technology is also extensively used to increase productivity traits, like muscle mass[13]. Additionally, like SB, GE can be used for "disenhancement": the voluntary reduction of animals' physical functions or sensory capabilities, including their ability to suffer from pain,[14] and potentially even make them utterly insentient.[15] An example is chickens selectively bred to be born blind.[16] Animal disenhancement has sparked significant debate, primarily among ethicists and philosophers. Proponents view it as a way to reduce animal suffering, while opponents highlight concerns about its use in the context of industrial animal agriculture, the risk of perpetuating animal exploitation,

[5] Food and Agriculture Organization of the United Nations (FAO), Gene Editing and Agrifood Systems (Rome, 2022). https://doi.org/10.4060/cc3579en.

[6] Selective Breeding, In Merriam-Webster.com Dictionary, 2024, available at <https://www.merriam-webster.com/dictionary/selective%20breeding> (last accessed 18 December 2024).

[7] Desirable traits can be achieved in one generation compared to multiple required with SB. *See* Z Liu, et al., "Enhancing Animal Disease Resistance, Production Efficiency, and Welfare through Precise Genome Editing" (2022) 23 International Journal of Molecular Sciences 7331; Commissie Genetische Modificatie (COGEM), CRISPR & Animals. Implication of Genome Editing for Policy and Society. Policy Report CGM/180501-01, 2018, available at <https://cogem.net/en/publication/crispr-animals-implications-of-genome-editing-for-policy-and-society/>.

[8] Z Liu, et al., supra note 7.

[9] J McWilliams, "The Origins of Factory Farming in the United States, An Overview" in B Fischer (ed), *The Routledge Handbook of Animal Ethics* (New York, Routledge 2020) pp 117–27.

[10] M Gray, "Review of Literature and Publicly Available Data on the Longitudinal Effect of Balanced Breeding Strategies in Context of Historical Health and Welfare Outcomes", 2021, available at <https://www.nuffieldbioethics.org/publications/genome-editing-and-farmed-animals/evidence-gathering>.

[11] PA Oltenacu and B Algers, "Selection for Increased Production and the Welfare of Dairy Cows: Are New Breeding Goals Needed?" (2005) 34(4–5) Ambio 311–5.

[12] FDA, Risk Assessment Summary – V-006378 PRLR-SLICK cattle, 2022.

[13] AV Ledesma and AL Van Eenennaam, "Global Status of Gene Edited Animals for Agricultural Applications" (2024) 305 The Veterinary Journal 1–13; X Wang and B Petersen, "More Abundant and Healthier Meat: Will the MSTN Editing Epitome Empower the Commercialization of Gene Editing in Livestock? (2022) 65 Science China Life Sciences 448–50.

[14] A Shriver, "Knocking Out Pain in Livestock: Can Technology Succeed Where Morality Has Stalled?" (2009) 2 Neuroethics 115–24; K Devolder and M Eggel, "No Pain, No Gain? In Defence of Genetically Disenhancing (Most) Research Animals" (2019) 9(4) Animals (Basel) 154.

[15] A Shriver, "Prioritizing the Protection of Welfare in Gene-Edited Livestock" (2020) 10(1) Animal Frontiers 39–44.

[16] P Sandøe, et al., "The Blind Hens' Challenge: Does It Undermine the View that Only Welfare Matters in Our Dealings with Animals?" (2014) 23 Environmental Values 727–42.

and violations of animal integrity and dignity, among other issues[17]. Therefore, these potential applications raise fears that, without proper regulation and ethical considerations, GE could exacerbate existing welfare problems, prioritising the industry's interests over animals.

Currently, the EU loosely regulates SB, allowing the breeding of animals with genotypes and phenotypes detrimental to animal welfare.[18] At the same time, new genomic techniques (NGTs), including CRISPR, are subject to the stricter GMOs legislation, composed of several Directives and Regulations. These rules are based on the precautionary principle, whereby the EU and national competent authorities prohibit these technologies until they are proven safe for human and animal health and the environment.

Because of the power of GE and the adverse effects on animal welfare in pursuing productivity traits, it is essential to scrutinise how farm animal breeding is regulated, particularly in the EU, which has a large livestock industry and is currently debating the regulation of GE, starting with its applications on plants.[19] Additionally, this analysis is motivated by the growing public concern for animal welfare, as the latest Eurobarometer survey shows that 84 per cent of EU citizens demand higher farm animal welfare protection.[20]

Therefore, the primary objectives of this paper are to examine the EU's regulation of SB and GE in farm animals, highlighting their shortcomings; to propose reforms to ensure greater protection for animals under the law at the breeding stage; and present considerations for the potential development of specific rules for GE animals.

II. Selective breeding and gene editing technologies: risks and concerns over animal welfare

1. Welfare risks caused by the selection of high-yield traits in breeding programs

Animals selectively bred for high productivity are more at risk of experiencing poor welfare,[21] as they are more prone to behavioural, physiological and immunological problems.[22] Over the years, multiple studies and reports documented the negative correlation between high productivity and lower welfare,[23] with adverse effects on

[17] *See* N Thomas and A Langridge, "Gene Editing, Animal Disenhancement and Ethical Debates: A Conundrum for Business Ethics?" in N Thomas (ed), *Animals and Business Ethics. The Palgrave Macmillan Animal Ethics Series* (Cham, Switzerland, Palgrave Macmillan 2022) pp 203–25; *See* also PB Thompson, "The Opposite of Human Enhancement: Nanotechnology and the Blind Chicken Problem" (2008) 2 Nanoethics 305–16.

[18] European Commission, "Commission Staff Working Document Fitness Check of the EU Animal Welfare Legislation" (2022), available at <https://food.ec.europa.eu/system/files/2022-10/aw_eval_revision_swd_2022-329_en.pdf>.

[19] Topics European Parliament, "New Plant Breeding Techniques to Boost Resilience of Food System", available at <https://www.europarl.europa.eu/topics/en/article/20240125STO17062/new-plant-breeding-techniques-to-boost-resilience-of-food-system>.

[20] European Commission, "Special Eurobarometer 533, Attitudes of Europeans towards Animal Welfare" 2023, available at <https://europa.eu/eurobarometer/surveys/detail/2996>.

[21] M Gray, supra note 10.

[22] WM Rauw, et al, "Undesirable Side Effects of Selection for High Production Efficiency in Farm Animals: A Review" (1998) 56(1) Livestock Production Science 15–33.

[23] *See* eg, WM Rauw, et al, supra note 22; Farm Animal Welfare Council (FAWC), "Report on the Welfare Implications of Animal Breeding and Breeding Technologies in Commercial Agriculture" (2004), available at <https://www.gov.uk/government/publications/fawc-report-on-the-welfare-implications-of-breeding-and-breeding-technologies>; PA Oltenacu, et al, *supra* note 11; JA MacArthur Clark, M Potter and E Harding, "The Welfare Implications of Animal Breeding and Breeding Technologies in Commercial Agriculture" (2006) 103(3) Livestock Science 270–81; EFSA Panel on Animal Health and Welfare (AHAW), "Scientific Opinion on the Influence of Genetic Parameters on the Welfare and the Resistance to Stress of Commercial Broilers" (2010) 8(7) EFSA

animals' bodies and behaviour likely to aggravate if productivity traits remain the priority in breeding programs.[24] Additionally, selective breeding for productivity purposes has led to a drastic loss in genetic diversity of livestock, causing higher levels of inbreeding.[25]

For example, the broiler chicken industry's historical focus on fast-growth, breast yield, and feed efficiency[26] has led to welfare problems like skeletal disorders, contact dermatitis, ascites, sudden death syndrome,[27] and the inability to perform natural behaviours.[28] In contrast, slow-growth chickens have fewer welfare problems compared to fast-growth ones.[29]

Similarly, beef cattle breeds selected for extreme muscle mass, such as the Belgian Blue, suffer from reduced calf survival and increased risk of dystocia.[30] In dairy cows, pursuing ever-higher milk yields results in poor health and welfare,[31] with cows suffering from lameness, mastitis, fertility issues, and decreased longevity.[32] Lower-yielding breeds like Jersey cattle or Rendena cattle are less vulnerable to mastitis.[33]

The consequences of high yield also include an increased sensitivity to environmental stress like high temperature,[34] as well as the need for high management standards. As a result, high-yielding animals require specialised diets, disease control measures, a proper environment (eg, a specific temperature), and skilled keepers.[35]

While breeders seem to increasingly recognise the need to include fitness and welfare traits in breeding programs,[36] it is still unclear whether the current breeding choices are genuinely addressing or even reversing the welfare concerns caused by historically pursuing productivity traits or if they are just attempting to mitigate those adverse effects, making animals more robust without sacrificing yield.[37]

Journal 1666, [82 pp]; FAWC, "Opinion on the Welfare Implications of Breeding and Breeding Technologies in Commercial Livestock Agriculture" (2012), available at <https://www.gov.uk/government/publications/fawc-opinion-on-the-welfare-implications-of-breeding-and-breeding-technologies-in-commercial-livestock-agriculture>; E van Marle-Köster, et al, "Unintended Consequences of Selection for Increased Production on the Health and Welfare of Livestock" (2021) 64 Archives Animal Breeding 177–85.

[24] WM Rauw, et al, *supra* note 22.

[25] LF Brito, N Bedere, F Douhard, HR Oliveira, M Arnal, F Peñagaricano, AP Schinckel, CF Baes and F Miglior, "Review: Genetic Selection of High-Yielding Dairy Cattle Toward Sustainable Farming Systems in a Rapidly Changing World" (2021) 15(Supplement 1) Animal 100292.

[26] M Gray, *supra* note 10.

[27] EFSA AHAW, *supra* note 23.

[28] M Gray, *supra* note 10.

[29] LM Dixon, "Slow and Steady Wins the Race: The Behaviour and Welfare of Commercial Faster Growing Broiler Breeds Compared to a Commercial Slower Growing Breed (2020) 15 PLoS One e0231006.

[30] M Gray, *supra* note 10; COGEM *supra* note 7.

[31] EFSA, "Scientific Opinion of the Panel on Animal Health and Welfare on a Request From European Commission on the Overall Effects of Farming Systems on Dairy Cow Welfare and Disease" (2009) 1143 The EFSA Journal 1–38.

[32] PA Oltenacu, et al, *supra* note 11; JA MacArthur Clark, et al, *supra* note 23.

[33] WN Cheng and SG Han, "Bovine Mastitis: Risk Factors, Therapeutic Strategies, and Alternative Treatments – A Review" (2020) 33(11) Asian-Australasian Journal of Animal Sciences 1699–713.

[34] CA Becker, et al, "Invited Review: Physiological and Behavioral Effects of Heat Stress in Dairy Cows" (2019) 103 Journal of Dairy Science 6751–70.

[35] FAWC (2012) *supra* note 23.

[36] Nuffield Council on Bioethics, "Genome Editing and Farmed Animal Breeding: Social and Ethical Issues, (2021), available at <https://www.nuffieldbioethics.org/publications/genome-editing-and-farmed-animals>; *see* also eg, KD Gibson and CD Dechow, "Genetic Parameters for Yield, Fitness, and Type Traits in US Brown Swiss Dairy Cattle" (2018) 101 Journal of Dairy Science 1251–7; DNRG Kapell, et al, "Twenty-Five Years of Selection for Improved Leg Health in Purebred Broiler Lines and Underlying Genetic Parameters" (2012) 91 Poultry Science 3032–43.

[37] Nuffield Council on Bioethics *supra* note 36.

2. Off-target mutations and other risks related to gene editing

Beyond the welfare issues due to selecting for productivity, GE off-target mutations are often mentioned as a cause of concern as they have been associated with potential adverse effects on GE animals' welfare and health when they occur in coding sequences.[38] Although the frequency of off-target mutations is decreasing as the technology improves, there are still concerns that include the unintended integration of the repair template in the target site and ectopic insertions of the template,[39] the alteration of genomic segments at large distances from cutting sites,[40] and the ability to target multiple sites.[41] For example, many productivity traits are controlled by various genes, and editing a single gene may inadvertently alter other unrelated characteristics in ways that could impact welfare negatively.[42]

Additionally, the size of the mutation is not a good indicator of safety. Minor alterations like point mutations (ie, mutations "that occur in a genome when a single base pair is added, deleted or changed"[43]) may cause significant changes to a phenotype,[44] while alterations in long sequences of the genome may have no effect.[45] For this reason, the fact that some GE animals could be developed through traditional breeding is not a valid argument for supporting the safety of the GE product.[46] Instead, more information on the effects of a given alteration is required to assess its safety correctly.

3. Ethical concerns over animal breeding and disenhancement practices

The documented negative impacts on animal welfare due to increased productivity demand an ethical reconsideration of the current breeding choices, especially if animals are considered sentient beings with their own interests.[47] There is also an urgent need to address the ethical implications of new biotechnologies like GE as they expand humans' ability to modify animals' genomes. In intensive animal agriculture, there is a potential for this innovative technology to support a system detrimental to animal welfare.[48]

Within breeding, one of the core ethical concerns is that animals are bred for higher productivity to benefit the industry without benefits to the animals and often at the expense of their welfare, which depends on economic considerations.[49] For example, in breeds like Holstein and Brown Swiss, breeding polled cattle would remove the need to

[38] BK Redel, et al, "Novel Off-Targeting Events Identified after Genome Wide Analysis of CRISPR-Cas Edited Pigs" (2024) The CRISPR Journal. DOI: 10.1089/crispr.2024.0012; SL Hennig, et al, "Evaluation of Mutation Rates, Mosaicism and Off Target Mutations When Injecting Cas9 mRNA or Protein for Genome Editing of Bovine Embryos" (2020) 10 Scientific Reports 22309; Nuffield Council on Bioethics *supra* note 33.

[39] G Burgio and L Teboul, "Anticipating and Identifying Collateral Damage in Genome Editing" (2020) 36(12) Trends in Genetics 905–14.

[40] Ibid.

[41] Nuffield Council on Bioethics *supra* note 36.

[42] Ibid.

[43] *See* National Human Genome Research Institute, "Point Mutation Page" available at <https://www.genome.gov/genetics-glossary/Point-Mutation>.

[44] Roslin response to UK Government consultation on gene editing, available at <https://vet.ed.ac.uk/roslin/about/impact/roslin-response-uk-gov-consultation-gene-editing>.

[45] Nuffield Council on Bioethics *supra* note 36.

[46] Ibid.

[47] IAS Olsson, et al, "Taking Ethics into Account in Farm Animal Breeding: What Can the Breeding Companies Achieve?" (2006) 19 Journal of Agricultural and Environmental Ethics 37–46.

[48] Nuffield Council on Bioethics *supra* note 36.

[49] N Thomas, et al., *supra* note 17.

perform the painful procedure of dehorning.[50] Still, increased productivity has been prioritised over this welfare improvement.[51]

Similarly, attempting to adapt the animals to the industrial system with SB or GE rather than adjust the environment to accommodate the animals' needs better is ethically problematic. Because the industrial system is considered complex to dismantle, and animal welfare must be taken seriously[52], some scholars suggest replacing current farm animals with disenhanced animals (eg, animals unable to suffer[53]) to address "production diseases" (ie, "animal pathologies that occur as a result of or in association with livestock production practices"[54]). However, these proposals are considered controversial by other scholars as they fail to question the root cause of animal suffering, which is the production system itself, and simply provide a technological fix[55] that may potentially even lead to further animal instrumentalisation and a deeper consolidation of industrial farming by reducing the criticism of poor animal welfare.[56] With disenhancement, it is not the animal interests that are addressed but rather the industry ones, pushing further the idea that the current industrial conditions are taken as a given to which animals must be adapted.[57] However, given animal sentience, the focus on creating the opportunity for animals to have positive experiences despite being farmed further supports the idea that the environment should be changed rather than the animal.[58]

Consumers' preferences also reflect the animal ethics issues discussed by scholars. Studies have shown that GE animals tend to receive less public support compared to GE plants, and that the public tends to be more receptive to GE in animals for animal health and welfare purposes, as opposed to productivity goals. At the same time, other individuals may view GE animals as unnatural and an inappropriate replacement for traditional animal husbandry practices[59].

Ethical questions posed by the use of certain breeding techniques are also relevant from a legal perspective because the EU is one of the few jurisdictions in the world to recognise the sentience of animals in its constitution, and to mandate the legislature to take into account animals' welfare requirements. Specifically, Article 13 of the Treaty on the Functioning of the EU (TFEU) requires the Union and Member States "to pay full regard to the welfare requirements of animals" in the formulation and implementation of agricultural, fisheries, transport, internal market, research and technological

[50] It is important to note that dehorning as well is performed to fit the needs of the industry. But studies point to the fact that cattle horns play a role in socialisation. *See* eg, MF Bouissou, "Influence of Body Weight and Presence of Horns on Social Rank in Domestic Cattle" (1972) 20(3) Animal Behaviour 474–7.

[51] Nuffield Council on Bioethics *supra* note 36.

[52] PB Thompson, "The Vanishing Ethics of Husbandry" in B Bovenkerk and J Keulartz (eds), *Animals in Our Midst: The Challenges of Co-existing with Animals in the Anthropocene. The International Library of Environmental, Agricultural and Food Ethics*, vol 33 (Cham, Switzerland, Springer 2021) pp 203–21.

[53] A Shriver, "Knocking Out Pain in Livestock: Can Technology Succeed Where Morality Has Stalled?" (2009) 2(3) Neuroethics 115–24.

[54] PB Thompson, *supra* note 17.

[55] A Ferrari, "Animal Disenhancement for Animal Welfare: The Apparent Philosophical Conundrums and the Real Exploitation of Animals. A Response to Thompson and Palmer" (2012) 6 Nanoethics 65–76.

[56] A Henschke, "Making Sense of Animal Disenhancement" (2012) 6 Nanoethics 55–64; Nuffield Council on Bioethics *supra* note 36.

[57] S Monsó and S Hintze, "For Their Own Good? The Unseen Harms of Disenhancing Farmed Animals" in C Abbate and C Bobier (eds), *New Omnivorism and Strict Veganism: Critical Perspectives* (Routledge forthcoming).

[58] Ibid.

[59] *See* eg, AL Van Eenennaam and AE Young, "Public Perception of Animal Biotechnology" in H Niemann and C Wrenzycki (eds), *Animal Biotechnology*, vol 2 (Cham, Springer 2018) pp 275–303; MC Yunes, Z Osório-Santos, MAG von Keyserlingk and MJ Hötzel, "Gene Editing for Improved Animal Welfare and Production Traits in Cattle: Will This Technology Be Embraced or Rejected by the Public?" (2021) 13(9) Sustainability 4966; Nuffield Council on Bioethics, "Public Dialogue on Genome Editing in Farmed Animals" 2022, available at <https://www.nuffieldbioethics.org/publication/public-dialogue-on-genome-editing-and-farmed-animals/>.

development, and space policies.[60] However, since its adoption in 2007, Article 13 failed to produce tangible, regulatory effects changes in EU farm animal welfare legislation, including on the specific issue of animal breeding. Legal scholars have explained such a situation by the classification of live animals as "agricultural products" under the same Treaty,[61] the limited competence of the EU in regulating animal welfare,[62] as well as the enforcement gaps in competition policies and decision-making procedures biased in favour of private interests' groups[63].

III. The regulation of gene editing technologies and selective breeding in farm animals in the EU

1. Gene editing technologies

Organisms obtained through NGTs, like CRISPR, are regulated under GMO legislation,[64] as confirmed by the Court of Justice of the European Union (CJEU) in a 2016 ruling.[65] The GMO regulatory framework in the EU is composed of a series of regulations and directives[66] designed to protect human health and the environment, as well as harmonise rules about the commercialisation of GMOs on the EU market.[67]

None of these pieces of legislation is specifically designed to regulate genetically modified (GM) animals, as the EU legislature at the time primarily aimed at regulating plants and plant products. However, central among the different legislative acts regulating GMOs is Regulation 1829/2003 on Genetically Modified Food and Feed,[68] which requires producers of food and feed containing or consisting of GMOs, or food produced from or containing ingredients produced from GMOs,[69] to apply for a market authorisation to sell such products in the EU. In the case of GMOs or food containing or consisting of GMOs, the European Commission delivers a market authorisation on the basis of a risk assessment and a monitoring plan for environmental effects.[70] These rules apply to GM animals used for food to the extent that EU law defines food as "any substance or product, whether

[60] Art 13, Consolidated Version of the Treaty on the Functioning of the European Union, 2009 *OJ* C 326/54.

[61] Art 38, and Annex I, Consolidated Version of the Treaty on the Functioning of the European Union, 2009 *OJ* C 326.

[62] For instance, *see* K Sowery, "Sentient Beings and Tradable Products: The Curious Constitutional Status of Animals Under Union Law" (2018) 55 Common Market Law Review 55–99.

[63] A Di Concetto, *Le pouvoir des lobbies privés face au mouvement de protection animale. Les mutations contemporaines du droit de l'animal, édité par Olivier Le Bot* (Aix-en-Provence, DICE Éditions 2023).

[64] Commission Staff Working Document, Study on the Status of New Genomic Techniques Under Union Law and in Light of the Court of Justice Ruling in Case C-528/16, (2021) SWD 92 final.

[65] Case C-528/16, *Confédération paysanne and Others v Premier ministre and Ministre de l'agriculture, de l'agroalimentaire et de la forêt,* 25 July 2018, ECLI:EU:C:2018:583.

[66] Directive 2001/18/EC on the deliberate release of GMOs into the environment, Regulation 1829/2003 on Genetically Modified Food and Feed, Directive 2015/412 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory, Regulation 1830/2003 Concerning the Traceability and Labeling of Genetically Modified Organisms and the Traceability of Food and Feed Products Produced From Genetically Modified Organisms, Directive 2009/41/EC on Contained Use of Genetically Modified Micro-Organisms, and Regulation 1946/2003 on Transboundary Movements of GMOs. Those pieces of legislation are supplemented by additional implementing rules, recommendations and guidelines on more specific aspects. For further information, *see* "GMO Legislation" available at <https://food.ec.europa.eu/plants/genetically-modified-organisms/gmo-legislation_en>.

[67] Art 1, Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC – Commission Declaration, 2001 *OJ* L 106/5, 6.

[68] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, 2003 OJ L 268

[69] Art 3(1), Regulation 1829/2003 on Genetically Modified Food and Feed, 2003 OJ L 268/6.

[70] Art 5(5), Regulation 1829/2003 on Genetically Modified Food and Feed, 2003 OJ L 268 /8.

processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans,"[71] including live animals prepared for placing on the market for human consumption.[72]

Within the framework of this Regulation, the European Food and Safety Authority (EFSA) Panel on Animal Health and Welfare produced, on the request of the European Commission, a guidance document for the risk assessment of food and feed that contains or consists of GM animals.[73] This document also includes guidance on assessing the health and welfare of GM animals,[74] aiming to avoid the increase of harmful effects on animal welfare and promptly identify any adverse consequence before traits spread through further breeding. EFSA proposed a three-stage assessment of GM animals, starting with strict monitoring in a lab setting in stage A, moving to a second stage (stage B) of monitoring in experimental farms to conclude with observations in real farms (stage C). EFSA also produced a separate guidance document for the environmental risk assessment of GM animals within the framework of Regulation 1829/2003 and Directive 2001/18/EC.[75] These two documents outline the specific methodology, steps, and data required to submit an application. However, the EFSA guidance documents are not binding, and so the European Commission does not have to follow them when delivering market authorisations.

Directive 2001/18 on the Deliberate Release into the Environment of Genetically Modified Organisms[76] further regulates the commercialisation of GMOs on the EU market by providing a regulatory definition for GMOs, defined as organisms "in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination"[77] and where such genetic alteration resulted from the use of the techniques listed in Annex I(1)(1) of the Directive.[78] The list contained in the annex, although not exhaustive, includes techniques that can be used to create GM animals, such as recombinant nucleic acid techniques and micro-injection.[79]

To this date, the EU approved market authorisation for GM feed products only and never approved the commercialisation of GM animals used for food purposes as no application has been submitted.[80] However, a 2021 study by the European Commission indicated that the animal agriculture breeding industry was currently developing breeds of farmed animals for food purposes, using NGTs like CRISPR. This research concerns the development of new breeds of cattle, pigs, chickens and various fish species with desired traits such as resistance to bacteria, viruses and other pathogens, resistance to high or

[71] Art 2, Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety ("General Food Law Regulation"), 2002 OJ L 31/7.

[72] Art 2(b), General Food Law Regulation, 2002 OJ L 31/7.

[73] EFSA Panels on GMO and AHAW, "Scientific Opinion on the Guidance on the Risk Assessment of Food and Feed From Genetically Modified Animals and Animal Health and Welfare Aspects" (2012) 10(1) EFSA Journal 2501.

[74] Ibid.

[75] EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), "Guidance on the Environmental Risk Assessment of Genetically Modified Animals" (2013) 11(5) EFSA Journal 3200, 190 pp.

[76] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC – Commission Declaration, 2001 *OJ* L 106/1–39.

[77] Art 2(2), Directive 2001/18/EC on the deliberate release of GMOs into the environment 2001 *OJ* L 106/4.

[78] Art 2(2)(a), Directive 2001/18/EC on the deliberate release of GMOs into the environment 2001 *OJ* L 106/5.

[79] Annex I A, Part. 1, Directive 2001/18/EC on the deliberate release of GMOs into the environment, 2001 *OJ* L 106/17.

[80] For an overview, *see* "Genetically Modified Animals," available at <https://www.efsa.europa.eu/en/topics/topic/genetically-modified-animals>.

low temperature, hypoallergenic properties, higher and faster meat production or modification in meat quality.[81] Outside the EU, only a few GE animals have been approved for commercialisation for food use, including the AquAdvantage Salmon[82] and the SLICK-hair cattle in the United States[83] as well as GE red sea bream (*Pagrus major*) and tiger pufferfish (*Takifugu rubripes*) in Japan.[84] Given these rapid developments, the European Commission expects research on GE animals to grow in the future.[85] However, it is still unclear whether the use of NGTs on animals will follow the same regulatory fate as for plants produced from NGTs.

Recent developments in EU law suggest that some NGTs applications (such as those that do not require the insertion of foreign DNA) would not necessarily qualify as GMOs and would not be subject to the regulatory framework applicable to GMOs. Instead, NGTs would benefit from a specific, less burdensome regime. The CJEU Case C-528/16[86] first determined that the modification of plant organisms through the use of NGTs, such as CRISPR, qualified as GMOs under EU law, even though NGTs are not explicitly listed in Directive 2001/18.[87] In an attempt to counteract the CJEU's conservative approach to GE organisms, the European Commission subsequently proposed new legislation providing a specific regulatory framework for certain categories of GE plants such as those considered equivalent to conventional ones ("category 1 NGT"). The goal is thus to deregulate their use.[88] Notably, the European Commission did not propose to codify the precautionary principle in the Proposal.[89] Ultimately, under the Proposal, although plants originating from NGT do not qualify as GMOs for Directive 2001/18, the commercialisation of such plants remains subject to a market authorisation procedure with a risk assessment adapted to the lower risk profile of NGTs.[90]

Currently, the European Commission does not feel the need to anticipate the commercialisation of GE animal breeds originating from NGTs by providing a regulatory framework specific to these animal products. In the absence of specific rules, and considering the CJEU case law, the regulation of GE animals would, for now, likely fall under the GMO legislation.

[81] Commission Staff Working Document, Study on the Status of New Genomic Techniques Under Union Law and in Light of the Court of Justice Ruling in Case C-528/16, SWD(2021) 92 final, 16, 17 and 52.

[82] AV Ledesma and AL Van Eenennaam, *supra* note 13. However, AquaBounty, the company that produces the AquAdvantage salmon, recently announced its intention to stop the production of this GM salmon. Source: "AquaBounty Announces Plans to Cease Fish Farming Operations", Aquabounty.com, available at <https://investors.aquabounty.com/news-releases/news-release-details/aquabounty-announces-plans-cease-fish-farming-operations> (last accessed 24 December 2024).

[83] FDA, *supra* note 12.

[84] AV Ledesma and AL Van Eenennaam, *supra* note 13.

[85] Commission Staff Working Document *see supra* note 64.

[86] Case C-528/16, *Confédération paysanne and Others v Premier ministre and Ministre de l'agriculture, de l'agroalimentaire et de la forêt*, 25 July 2018, ECLI:EU:C:2018:583.

[87] The list contained in Annex I A, Part. 1, Directive 2001/18/EC is not exhaustive and does not include new genomic techniques as those did not exist when the Directive was adopted in 2001.

[88] Proposal for a Regulation of the European Parliament and of the Council on Plants Obtained by Certain New Genomic Techniques and Their Food and Feed, and Amending Regulation (EU) 2017/625, COM(2023) 411 final (July 2023).

[89] Although the European Commission did not propose to codify the precautionary principle into the Proposal for a Regulation on Plants Obtained by Certain New Genomic Techniques and Their Food and Feed, the Commission still refers to the precautionary principle in the Explanatory Memorandum. Proposal for a Regulation of the European Parliament and of the Council on Plants Obtained by Certain New Genomic Techniques and Their Food and Feed, and Amending Regulation (EU) 2017/625, COM(2023) 411 final (July 2023).

[90] IbidProposal for a Regulation of the European Parliament and of the Council on Plants Obtained by Certain New Genomic Techniques and Their Food and Feed, and Amending Regulation (EU) 2017/625, COM(2023) 411 final (July 2023), 10.

2. Selective breeding: uncertainties in the legality of selective breeding practices in EU law

a. The regulation of selective breeding techniques under the Breeding Regulation

Using highly selected breeds is common in EU animal agriculture, especially in the poultry, beef, dairy, egg and pork industries, because the SB of farm animals is allowed under EU law. Even though SB practices may produce similar effects on animals as GE techniques, SB techniques are excluded from the scope of the legislative acts regulating GE technologies and so do not qualify as genetic manipulation under EU law. Instead, the breeding of farm animals is regulated under Regulation 2016/1012 on Zootechnical and Genealogical Conditions for the Breeding, Trade in, and Entry Into the Union of Purebred Breeding Animals ("Breeding Regulation"), which provides rules related to the authorisations for breeding programs and animal breeds allowed to be traded within the EU.[91] The scope of the Breeding Regulation covers animals of the bovine, porcine, ovine, caprine and equine species, but it excludes poultry animals, whose breeding is mainly regulated under farm animal welfare legislation.

While the EU legislature recognised that SB has "in some cases, led to undesirable side effects, raising concerns in society about animal welfare"[92] in the preamble of the Breeding Regulation, the Legislature also considers that "the application of genomics and the use of advanced information technologies such as 'precision livestock farming' – which allows large data sets on alternative traits, directly or indirectly related to animal welfare and sustainability issues, to be recorded – hold considerable potential to address concerns in society."[93] The EU institutions, therefore, consider further genetic selection of animals as a solution to improve the welfare of animals. However, the Regulation does not require including welfare goals in breeding programs' objectives. Quite the opposite, "the improvement of the breed" is among the several alternative objectives breeders must achieve when seeking approval for a breeding program. Because the term "improvement" remains unspecified in the Breeding Regulation, breeders can easily interpret what constitutes an improvement for the breed in a way that undermines animal welfare goals.

Additionally, the Breeding Regulation does not contain provisions that would limit SB to protect animals from the effects that such a practice might entail on their welfare. Instead, the rules breeders must comply with when carrying out performance testing or genetic evaluation are exclusively based on a productivity criterion, leaving aside animal welfare and ethical considerations.[94]

b. Directive 98/58/EC concerning the protection of animals kept for farming purposes

While there is little doubt that SB is legal under the Breeding Regulation, there remains significant uncertainty regarding the legality of using highly selected breeds in light of EU farm animal welfare legislation, and specifically concerning selected poultry breeds. Such uncertainty is due to significant shortcomings in drafting EU farm animal welfare legislation.

The welfare of farm animals in the EU is primarily regulated under Directive 98/58/EC,[95] Concerning the Protection of Animals Kept for Farming Purposes, which applies to all vertebrate animals used for farming purposes in the EU[96] – and so including GE animals. Directive 98/58/EC includes a general prohibition on SB practices that would affect animal

[91] Regulation (EU) 2016/1012 of the European Parliament and of the Council of 8 June 2016 on Zootechnical and Genealogical Conditions for the Breeding, Trade in and Entry Into the Union of Purebred Breeding Animals, Hybrid Breeding Pigs and the Germinal Products Thereof ("Breeding Regulation"), 2016 *OJ* L171/66–143.

[92] Recital 11, Breeding Regulation, 2016 *OJ* L171/67.

[93] Ibid Recital 11, Breeding Regulation, 2016 OJ L171/67.

[94] Annex III, Breeding Regulation, 2016 OJ L171/126–7.

[95] Council Directive 98/58/EC of 20 July 1998 Concerning the Protection of Animals Kept for Farming Purposes, 1998 *OJ* L 221/23–27.

[96] Ibid Art 2, Directive98/58/EC, 1998 *OJ* L 221/23.

welfare. Specifically, Paragraphs 20 and 21 in the Annex of Directive 98/58/EC provide that "natural or artificial breeding or breeding procedures which cause or are likely to cause suffering or injury to any of the animals concerned must not be practised" and that "no animal shall be kept for farming purposes unless it can reasonably be expected, based on its genotype or phenotype, that it can be kept without detrimental effect on its health or welfare."[97]

However, the scope of the prohibition contained in Paragraphs 20 and 21 of Directive 98/58/EC is unclear, as the meaning of the term "breeding procedures" is not specified. The analysis of the text in the different linguistic versions adds to the confusion[98]: while the English version seems to refer to breeding procedures, as in both mating procedures and breeding practices using genetic selection; the French, Italian and Spanish versions refer to farming methods, as in production methods in general.[99]

Given the discrepancy in the different versions, it is necessary to turn to the legislative history of Directive 98/58/EC to decipher the Legislature's intent at the time of passing this prohibition. The language in paragraphs 20 and 21 of Directive 98/58/EC originates from the 1976 Council of Europe's Convention for the Protection of Animals Kept for Farming Purposes ("CoE Convention"),[100] as amended in 1992. The 1992 amendment aimed to extend the scope of the Convention to the "breeding" of animals and "to refer, next to animals produced by the normal breeding process, explicitly to animals produced as a result of modifications or novel combinations of general material,"[101] thereby pointing to an intent to regulate SB for animal protection reasons.

The legislative history of the 1992 amendment to the CoE Convention further documents the Council of Europe's intent. During the discussions leading up to the amendment of the CoE Convention, the Committee of Ministers that adopted the Protocol of Amendment interpreted this provision "as a requirement that breeding programmes must be designed to avoid foreseeable suffering or injury of the animals, such as difficult deliveries and lasting deformations." However, the Committee also "acknowledged that this provision does not prevent breeding which would cause minor or momentary suffering or injury (e.g. natural delivery, embryo transplantation) or which might necessitate interventions such as caesareans, which would not cause lasting harm" and further "agreed that the reasonable expectation in the second part of the sentence should be based on the phenotype or genotype of the animal concerned; this would exclude from the scope of this provision current practices of keeping animals in unfavourable husbandry systems until satisfactory alternatives have been developed."[102] The objective of this amendment was thus to regulate evolving technological practices, including biotechnologies, for animal welfare purposes, except for already-existing practices.[103]

The Standing Committee of the European Convention for the Protection of Animals Kept for Farming Purposes – an expert group composed of representatives from all

[97] Paragraphs 20 and 21, Annex, Directive 98/58/EC 1998, *OJ* L 221/27.

[98] In case of ambiguous language, traditional interpretation of EU law resorts to multilingualism, since all versions of the 23 EU official languages have equal legal value.

[99] Respectively: "*méthodes d'élevage;*" "*procedimenti di allevamento*;" "*procedimientos de cría*." The same discrepancies exist between the Czech and Slovak versions of the Directive, which respectively refer to "farming methods" and "breeding procedures." The authors thank Gabriela Kubíková for this legal and linguistic analysis.

[100] Council of Europe, European Convention for the Protection of Animals Kept for Farming Purposes, March 10, 1976, E.T.S. 87. Note that the Council of Europe is an international organization distinct from the EU.

[101] Council of Europe, Explanatory Report – ETS 145, p.1, para.7 and p.2, 6 February 1992, E.T.S. 145, available online: https://rm.coe.int/16800cb5e2

[102] Ibid, p.2

[103] The author would like to thank Edie Bowles at Advocates for Animals for kindly sharing her findings and analysis.

forty-seven Council of Europe member countries – has added further specifications to the general rules of the CoE Convention by way of "Recommendations." These recommendations have the same legal value as the Convention and are binding in any jurisdiction that ratifies them. The Standing Committee adopted a Recommendation Concerning Domestic Fowl (*Gallus gallus*)[104] among the twelve species-specific recommendations.[105] Article 20 of the Recommendation Concerning Domestic Fowl concerns breeding practices that change the animals' genotype or phenotype, and it provides that "(1) Breeding or breeding programs which cause or are likely to cause suffering or harm to any of the birds involved shall not be practised. In particular, birds whose genotype has been modified for production purposes shall not be kept under commercial farm conditions unless it has been demonstrated by scientific studies of animal welfare that the birds can be kept under such conditions without detriment to their health or welfare. (2) In breeding programs, particular attention should be paid to criteria conducive to improving birds' welfare and health, and to production criteria. Therefore, the conservation or development of breeds or strains of animals which would limit or reduce animal welfare problems connected with, for instance, aggressiveness or feather pecking should be encouraged."[106]

The EU subsequently codified the amended CoE Convention in 1998 by way of Directive 98/58/EC.[107] The wording found today in Paragraphs 20 and 21 was present in the legislative process as early as the publication of the European Commission's Proposal in its Article 6.[108] The version of the Directive adopted by the Council of the EU still contained the wording of Article 6 of the proposal, except that the provision was split into two paragraphs and placed at the end of the Annex.[109]

Despite the existence of an intent to regulate the SB of animals, the confusing drafting and inconsistent translations of Directive 98/58/EC allowed Member States to interpret Paragraphs 20 and 21 of the Annex liberally, to the extent that no Member States has ever prohibited the use of highly selected breed of farmed animals in national law.[110] Yet, considering the legislative history of this Directive, it is unlikely that this is what the legislators intended.

c. Species-specific standards: Directive 2007/43 laying down minimum rules for the protection of chickens kept for meat production

Of the four species-specific animal welfare directives, only Directive 2007/43 Laying Down Minimum Rules for the Protection of Chickens Kept for Meat Production (Chicken Directive) specifically provides animal welfare standards aiming to address the detrimental effects of selective breeding. In fact, the use of fast-growth chicken breeds provided the impetus for the EU to enact broiler welfare legislation specifically, given

[104] Council of Europe, Recommendation Concerning Domestic Fowl (*Gallus gallus*) adopted by the Standing Committee on 28 November 1995 at its thirtieth meeting (1995).

[105] A list of these recommendations is available online, available at <https://www.coe.int/t/e/legal_affairs/legal_co%2Doperation/biological_safety_and_use_of_animals/farming%20A_texts_documents.asp#TopOfPage>.

[106] IbidCouncil of Europe, Recommendation Concerning Domestic Fowl (Gallus gallus) adopted by the Standing Committee on 28 November 1995 at its thirtieth meeting (1995), Art 20.

[107] Directive 98/58/EC 1998 *OJ* L221/ 23–7.

[108] Art 6, Proposal for a Council Directive Concerning the Protection of Animals Kept for Farming Purposes, *OJ* C 156/6.

[109] Annex, Directive 98/58/EC 1998, *OJ* L 221/27.

[110] Austria transposed Paragraph 20 and 21 of Directive 98/58/EC in the most detailed and thorough way, by prohibiting "torture breeding," defined as "breeding which foreseeably associated with pain, suffering, harm, or fear for the animals or their offspring." However, both the legislative history of this legislation and the practice of using highly selected chickens breeds in the Austrian poultry industry suggest that this provision only applies to companion animals.

"that the fast growth rate of chicken strains currently used for [the purpose of producing meat] is not accompanied by a satisfactory level of animal welfare and health, and that the negative effects of high stocking rates are reduced in buildings where good indoor climatic conditions can be sustained."[111]

The welfare of broiler chickens as a result of their genetic traits is a significant issue because the EU broiler chicken meat industry almost exclusively relies on highly selected breeds. Examples of breeds include Ross 308, the most popular meat chicken in the world, which grows three times faster compared to 1950s breeds.[112] As evidence of the dominance of fast-growth breeds in the EU, the use of slow-growth breeds has become a defining feature of production segments the EU executive calls "alternative" (ie, alternative to non-industrial poultry production models), such as organic or quality chicken production.[113]

Yet, EU farm animal welfare law and policy has largely contributed to undermining the welfare of chickens in EU animal agriculture. First, the fact that the Breeding Regulation excludes poultry species from its scope facilitated the widespread use of genetically selected poultry breeds. Second, the effect of Paragraphs 20 and 21 of the Annex in Directive 98/58/EC – which apply to all vertebrate animals, including poultry – was furthermore undermined in 2007 with the enactment of the Chicken Directive,[114] which aimed to regulate the treatment of broiler chickens on industrial farms precisely,[115] with a focus on fast-growth chicken breeds.[116]

In adopting rules pertaining to the welfare of fast-growth chicken breeds, however, the EU Legislature may have inadvertently legalised the farming of animals whose genotype or phenotype is expected to have detrimental health and welfare effects, otherwise prohibited under Directive 98/58/EC.[117] Additionally, because the Chicken Directive does not exclude GE animals from its scope, the Chicken Directive could also have the effect of regulating the conditions in which GE chickens should be raised, thereby legalising the use of GE chickens. Lastly, the Chicken Directive is characterised by extremely lax provisions, which cannot reasonably be expected to meet the needs of fast-growing chickens. For instance, the Chicken Directive allows extreme density levels – up to 42 kg/square metres.[118] Although the Chicken Directive provides data collection regarding the on-farm mortality rate and the occurrence of foot dermatitis in animals, these indicators are deprived of any effects in the absence of notification rules and sanctions.[119]

[111] Recital 4, Council Directive 2007/43/EC of 28 June 2007 Laying Down Minimum Rules for the Protection of Chickens Kept for Meat Production ("Chicken Directive"), 2007 *OJ* L 182/19.

[112] J Ungoed-Thomas, "Frankenchicken' at the Centre of Fight for Animal Welfare" *The Guardian* 2022.

[113] Implementing Regulation 2020/464 on organic production (Commission Implementing Regulation (EU) 2020/464 of 26 March 2020 laying down certain rules for the application of Regulation (EU) 2018/848, *OJ* L 98/2–25) and the rules on consumer information regarding production methods for alternative, non-industrial systems set in Regulation 843/2008 as regards the marketing standards for poultry meat (Commission Regulation (EC) No 543/2008 of 16 June 2008 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 as regards the marketing standards for poultry meat, *OJ* 157/53, Art 11) do not allow the use of fast-growth breeds, thereby differentiating quality poultry meat from industrial broiler chicken meat.

[114] Chicken Directive, 2007 *OJ* L 182/19–28.

[115] Ibid.

[116] Recital 4, Chicken Directive, 2007 *OJ* L 182/19.

[117] In that sense, *see The Humane League UK v Secretary of State for Environment, Food and Rural Affairs* (2024) EWCA Civ 1560 (United Kingdom). In this ruling, the UK's Court of Appeal suggests that the use of fast-growth chickens is contrary to UK farm animal welfare laws, including the wording of paragraphs 20 and 21 of the Annex in Directive 98/58/EC, which was codified into UK law before the UK's withdrawal from the Union.

[118] Art 3, Chicken Directive, 2007 OJ L Ibid, 182/21–22.

[119] Annex III, 2007 *OJ* L 182/27.

IV. Reform proposals for a more humane and consistent regulatory framework

1. Limitations of the current regulatory framework in light of an ethical animal welfare approach

The current EU regulatory framework fails to regulate SB from an animal welfare perspective because of contradictory rules and often vague language. At the same time, Directive 98/58/EC includes a general prohibition on SB practices that would affect animal welfare, but the Chickens Directive implicitly allows the practice in a way that contradicts the general prohibition contained in Directive 98/58/EC. The European Commission itself highlighted such an inconsistency in its evaluation of the EU animal welfare legislation.[120] On the other hand, the Breeding Regulation entirely fails to regulate SB practices specifically enough to limit their effects on animal welfare in a way that also contradicts Directive 98/58/EC. Lastly, while GE animals are currently regulated under GMO legislation and thus subject to stricter rules than SB, the GMO regulatory framework lacks specific rules on GM animals. The EU Legislature should, therefore, revise these three pieces of legislation to provide more specific provisions that would regulate the SB of farmed animals. Additionally, the European Commission should strengthen the rules for GM and GE animals and align them with welfare and breeding regulations. The EU institutions should use the best available animal welfare science to carry out such a revision. More broadly, EU policy-makers should ground their approach to animal protection in a more ethical animal welfare framework, based on the animals' inherent interests, regardless of economic gains[121].

2. The revision of EU Directive 98/58/EC, Broiler Chicken Directive, Breeding Regulation and GM legislation

The following proposals are grounded in a realistic approach of the EU's competence in regulating the welfare of farmed animals[122]. These proposals are situated in the context of a possible revision of the EU farm animal welfare legislative framework, which the European Commission announced in 2020, "to align [such a framework] with the latest scientific evidence, broaden its scope, make it easier to enforce and ultimately ensure a higher level of animal welfare."[123]

[120] European Commission, "Commission Staff Working Document Fitness Check of the EU Animal Welfare Legislation", 2022, 44. available at <https://op.europa.eu/en/publication-detail/-/publication/c8d6998f-43d7-11ed-92ed-01aa75ed71a1/language-en>.

[121] M Michel, "Law and Animals: An Introduction to Current European Animal Protection Legislation" in A Peters, A Stucki and L Boscardin (eds), *Animal Law: Reform or Revolution? Schriften zum Tier in Recht* (Zurich, Basel, Schulthess Juristische Medien AG 2015) pp 87–116; G Bolliger, *Animal Dignity Protection in Swiss Law – Status Quo and Future Perspectives* (Zurich, Basel, Geneva, Schulthess 2016).

[122] The EU's competence in regulating animal welfare is strictly limited to the EU's competence in regulating the EU's agricultural market (Art 43, TFEU). However, the EU has also made an extensive use of its competence to adopt statutes whose primary objective is animal protection. *See* A Di Concetto, "The Double-Edge Sword: International Law and Its Effects on EU Farm Animal Welfare Legislation" (2022) 10 Global Journal of Animal Law 1–26.

[123] European Commission, Communication From the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, "A Farm to Fork Strategy for a Fair, Healthy and Environmentally-Friendly Food System," COM(2020) 381 (May 2020), p 8. Such a revision was eventually abandoned in 2023, but the possibility of the reelection of the European Commission's President, Ursula von der Leyen, potentially represents an opportunity that the next administration will carry out revision plans.

a. Amendment to Directive 98/58/EC, paragraph 21

By way of a tertiary law, the European Commission should amend paragraphs 20 and 21 in the Annex of Directive 98/58/EC to clarify the prohibition on the use of SB techniques. Such an amendment would increase the effectiveness and applicability of the provision and reduce legal uncertainty for EU operators. Specifically, the term "breeding procedures" must be clearly defined to differentiate between the *technologies and techniques* used for breeding animals, and the *breeding objectives*, indicating the traits to be achieved through SB. It is also essential to make all the linguistic versions consistent to reduce the discrepancies in the interpretation and transposition of this rule in national legislation.

Additionally, the Directive's annex should include an explicit prohibition on using SB and GE practices leading to expressing traits that may degrade animal welfare. The scope of such a prohibition should specifically cover breeding objectives that can cause pain, harm, suffering or behavioural disorders in animals.

b. Revision of the Broiler Chicken Directive

The EU Legislature should further amend the Chicken Directive to explicitly prohibit fast-growth chicken breeds. To avoid discrepancies in the interpretation and transposition of the Directive, the Directive would include a list of banned chicken breeds in the annex, which could be amended through tertiary law.

c. Revision of the Breeding Regulation

The EU Legislature should revise the Breeding Regulation to specify provisions regulating breeding programs from an animal welfare perspective, so as to remedy existing shortcomings in the Breeding Regulation and ensure consistency with Directive 98/58/EC.

First, the Breeding Regulation should provide a set of prohibitions, starting with a general ban on animal disenhancement, targeting specifically those disenhancements that may undermine animals' sentience or whole emotional spectrum, including by interfering with their ability to feel negative emotions. The prohibition should cover the use of technology to increase animals' tolerance to uncomfortable or unhealthy circumstances.

Another general ban should apply to the breeding of animals who, due to the breeding objectives, experience severe pain, adverse health, behavioural abnormalities, lose the ability to reproduce naturally and present invasive phenotypic alterations that severely alter their appearance. A more specific prohibition could include a ban on the breeding of animals with missing body parts whose absence may cause pain or suffering on the animal, as well as other malformations in other body parts, including the head, eyes, ears, skin, lack of feathers, the brain, or parts of the nervous system. The Breeding Regulation could further ban breeding animals that will experience difficulties in giving birth (dystocia) and animals whose species-specific behaviour would be altered in a way that may impact their welfare and their ability to live with members of the same species.

To ensure clarity, and by way of a delegated act, the EU Legislature should also mandate the European Commission to provide a regulatory list of prohibited species-specific traits that typically lead to animal diseases. For example, this delegated act could list fast-growing traits in broilers and turkeys, with specific thresholds in terms of body weight above which the animals are likely to suffer from premature death rates (eg, sudden death, heart failure syndrome), leg problems, ascites, lower immune response and difficulties in mating naturally. Similarly, for dairy cow breeds, prohibited traits could include thresholds in milk yields, above which occurrences of mastitis and lameness are higher in cows. In the same vein, the European Commission should specify, by way of a delegated act,

a regulatory list of allowed technologies and practices that have been scientifically proven not to cause prolonged pain to animals.

Breed societies, defined as "any breeders' association, breeding organisation or public body, other than competent authorities, which is recognised by the competent authority of a Member State [. . .] for the purpose of carrying out a breeding programme [. . .],"[124] should also be more closely regulated under EU law. The European Commission should amend Part I of Annex I, which relates to the requirements for recognising breeding societies and operations. More specifically, including welfare traits in their breeding programs should become a requirement to recognise those societies and operations. Similarly, Part 2 of Annex I, related to the requirements for the approval of breeding programs, should indicate expressly that a breeding program must include welfare traits to be approved.

Additionally, the Breeding Regulation should require breeding companies to collect and report data on the cumulative effects of breeding on animal genotypes and phenotypes. For this purpose, a centralised EU-level database should be created and managed by the European Commission's Directorate-General for Health and Food Safety (DG Sante), the administration responsible for animal welfare. Such a database would allow competent authorities to evaluate and monitor breeding programs' impact on animal welfare, as well as compliance with the law.[125]

Lastly, the expression "improvement of the breed" in the Breeding Regulation[126] should be more clearly defined to explain what type of change in the animals' phenotypes and genotypes breeders can consider an improvement.

d. Specific rules for GM and GE farm animals

The European Commission should strengthen the regulation of GM animals, including GE animals, to align with the ethical concerns and high animal welfare standards expected by EU citizens. One solution would be for the Commission to consider codifying the multi-step welfare assessment proposed by the EFSA into law,[127] thus mandating a thorough welfare assessment of GM/GE animals to prevent welfare harms. The Commission should further prohibit the development of GM/GE animals designed solely to increase productivity or enduring unfavourable conditions on farms. Additionally, the database proposed above could also include the data resulting from the EFSA GM animal welfare assessment to further integrate information about all animal breeds and traits. This proposed approach ensures coherence with EU legislation on animal welfare and breeding as well as Article 13 TFEU mandate to take into account animals' welfare requirements in the formulation and implementation of agricultural policies.[128]

V. Conclusion

Both SB and GE can lead to poor animal welfare when used to mainly pursue productivity traits. Additionally, the development of GE and its potential uses on animals reinforces the need to address several ethical questions on the overall genetic selection choices in

[124] Art 2(5), Breeding Regulation, 2016 *OJ* L171/67.

[125] This database could be inspired by the example of Scandinavian countries, which have established integrated databases to monitor dairy cattle traits, particularly those related to welfare and health, thereby facilitating the integration of such traits into dairy cattle. *See* M Gray, *supra* note 10 for further details.

[126] Art 8 (3)(a)(i) and (ii), Breeding Regulatuion, 2016 *OJ* L 171/66–143.

[127] EFSA Panels on GMO and AHAW *supra* note 73.

[128] Art 13, Consolidated Version of the Treaty on the Functioning of the European Union, 2009 *OJ* C 326/54.

breeding programs, especially considering the EU citizens' support for higher animal welfare standards in the EU.

The transition from using high-yield breeds is consistent with the broader idea of a just, sustainable transition in food and agriculture. Such a transition includes many aspects, such as environmental protection, animal welfare and social standards. High-yield breeds in animal agriculture are associated with industrial farm animal production, a significant source of greenhouse gas emissions. The use of high-yield breeds is also a marker of vertical integration practices, whereby family farms are under contract with breeders, growers and food processors and distributors – all of which often trace back to the same corporate entity – and in a way that undermines their bargaining power. These contracts often contain clauses with drastic requirements on how to raise the animals – starting with the type of breed farmers must use – and low remuneration levels in such a way that undermines the farmers' economic freedom.

In setting stricter standards on breeding practices, the reform proposals put forward in this paper are consistent with the idea of regulating industrial farm animal production to ensure consistent and just standards throughout the Union so that all farmers in the EU can compete fairly.

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