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Global regulatory policies for animal biotechnology: overview, opportunities and challenges

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Genome editing (GnEd) has the potential to provide many benefits to animal agriculture, offering a means for achieving rapid growth, disease resistance, and novel phenotypes. The technology has the potential to be useful for rapidly incorporating traits into existing selectively bred animals without the need for crossbreeding and backcrossing. Yet only four products from animals created via biotechnology, all growth-enhanced fishes, have reached commercialization and only on a limited scale. The past failure of genetically engineered (or GM) products to reach conventional producers can largely be attributed to the high cost of meeting GMO regulatory requirements. We review the history of GMO regulations internationally, noting the influence of Codex Alimentarius on the development of many existing regulatory frameworks. We highlight new regulatory approaches for GnEd organisms, first developed by Argentina, and the adoption of similar approaches by other countries. Such new regulatory approaches allow GnEd organisms that could have been developed by conventional means to be regulated under the same rules as conventional organisms and in the future is likely to enhance the opportunity for biotech animals to enter production. Treating certain GnEd products as conventional has had a large impact on the variety of biotechnological innovations successfully navigating regulatory processes. We suggest that for the full potential of GnEd technologies to be realized, enabling public policies are needed to facilitate use of GnEd as a breeding tool to incorporate new traits within existing animal breeding programs, rather than only a tool to create distinct new products.

KEYWORDS

gene transfer, genome editing, biotechnology policy, regulatory oversight, commercialization

1 Introduction

Today, farmers face unprecedented challenges globally. Animal agriculture needs to be better prepared to combat climate change and other emerging threats, while increasing agricultural production and reducing its environmental footprint. Animal agriculture researchers and breeders are committed to transforming the future of our food system, making it more resilient, while lowering the environmental impact. Traditional selective breeding has made great strides through incremental changes, but improvement can be slow, requiring many generations (often years, sometimes decades). Addressing the current challenges requires a step-change - i.e., a large, sudden improvement - and more rapid response. Scientific advances in genomics, assisted reproductive technologies, and genetic marker-assisted breeding are being utilized to improve the pace of genetic improvement, but more tools are

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