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Genetic Engineering in Agriculture

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GENETIC ENGINEERING IN AGRICULTURE

1 INTRODUCTION

Since its inception, agriculture has depended on the modification of the genetic makeup of plants and animals. Through selective breeding, countless generations of crops and livestock animals have been selected for traits considered beneficial to humans. Starting in the early 20th century, scientific discoveries resulted in numerous technologies that accelerated innovation in agriculture, with genetically modified organisms (GMOs) and genetically modified (GM) foods being the most notable and frequently discussed.[1]

This paper describes the use of GMOs in agriculture and the potential of new gene-editing technologies. In addition, the paper provides a comparative overview of the regulatory system for GMOs in Canada, the United States (U.S.) and the European Union (EU).

2 BIOTECHNOLOGY IN AGRICULTURE

Broadly, biotechnology can be defined as "the application of science and engineering in the direct or indirect use of living organisms, or parts or products of living organisms, in their natural or modified forms."[2] In most cases, this term is used to refer to modern technologies developed through various life sciences such as molecular biology, biochemistry and genetics.

Bodies such as the Food and Agriculture Organization of the United Nations (FAO) have stated that biotechnologies can facilitate faster agricultural innovation.[3] Some can be used to simply amplify certain natural events – mutation breeding, for example, generates random mutations to increase the likelihood of finding a new beneficial trait in a crop. Others, like recombinant DNA and GMOs, can be used as shortcuts to conventional breeding and can enable the development of crops and livestock animals that would not be possible otherwise.

2.1 DEFINING GENETICALLY MODIFIED ORGANISMS

According to the World Health Organization (WHO),

> [g]enetically modified organisms (GMOs) can be defined as organisms (i.e. plants, animals or microorganisms) in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating and/or natural recombination. The technology is often called "modern biotechnology" or "gene technology," sometimes also "recombinant DNA technology" or "genetic engineering."[4]

Although the terms "genetically modified" and "genetically engineered" are used interchangeably in public discourse, they have different connotations that are relevant to the debate on the use of GMOs in agriculture. In Canada, GM foods are regulated as "novel foods" under section B.28.001 of the *Food and Drug Regulations* pursuant

to the *Food and Drugs Act*.[5] The regulations define "genetically modify" as "chang[ing] the heritable traits of a plant, animal or microorganism by means of intentional manipulation."[6] This definition is broader than the one above, as it includes old and new approaches to manipulating the genetic makeup of living organisms and does not list specific technologies.

Genetic engineering is a type of modern biotechnology used to modify the genome – or genetic material – of living organisms. This method introduces specific novel traits into a plant or animal by direct manipulation of its genome. Genetic engineering has typically relied on the use of recombinant DNA, which is produced by joining multiple DNA fragments, usually for genetic manipulation.[7] Recombinant DNA technology can be used to introduce foreign DNA – either from the same species or from a different one – into the genome of a living organism. This technology thus enables the introduction of individual genes into an already established commercial crop variety.[8]

Gene-editing technology is a more recent form of genetic engineering. Gene editing refers to cutting out, replacing or inserting a specific DNA sequence from an organism's genetic material. Like recombinant DNA, this technology can insert genetic material into the genome, but it can also make edits without using foreign DNA. These alterations to an organism's own genetic material can be used to add, amplify, remove or diminish a specific trait. Gene editing has been widely used in research but, until recently, has remained prohibitively expensive. A more affordable form of gene-editing technology, referred to as CRISPR, is now allowing more and more researchers to use gene editing in agriculture.[9] The term CRISPR stands for "clustered regularly interspaced short palindromic repeats," a description of how this bacterial immune system is organized in the genome.

2.2 CRISPR – A New Tool in Genetic Engineering

CRISPR is a biotechnology that has been developed to accurately modify the genes of living organisms. Initially discovered as a bacterial immune system against viruses, this discovery's potential to be used as a genetic engineering tool has been discussed in the scientific literature since 2012.[10] It has since been used in a myriad of organisms, from plants to mice, and been cited in many research papers.

The CRISPR system has three advantages over previous biotechnologies used in agriculture. First, unlike mutation breeding, it can introduce precise changes into an organism's genome, making specific changes instead of generating mutations that may or may not be beneficial. Second, unlike recombinant DNA, it can work without introducing any foreign DNA, alleviating some ethical concerns. Third, CRISPR is more economical than other gene-editing technologies to date because it can be customized for each purpose relatively easily. Because of these three improvements, CRISPR has galvanized the scientific community and has the potential to revolutionize the agricultural biotechnology sector.[11]

CRISPR technology offers many possibilities for innovation in agriculture. For example, researchers have used CRISPR to develop fungus-resistant wheat, drought-resistant corn and tomato plants with a larger fruit size.[12]

2.3 Genetically Modified Organisms in Canadian Agriculture

Since 1994, Health Canada has approved close to 100 GM foods for sale in Canada, including apples, canola, corn, potatoes, rice, soybeans, squash and tomatoes.[13] While some are imported, several of these GM foods are produced domestically.

Canola, soybeans and corn constitute 99.5% of the GM crops grown in Canada. Cultivation of these crops occupied an area of 14 million hectares in 2017, of which 13.2 million hectares were for the GM varieties, meaning that GM varieties accounted for between 85% and 100% of production for these crops.[14] These GM crops are all engineered to be herbicide-tolerant. GM corn is also engineered to be insect resistant.

Although most GM foods that have been approved by Health Canada are plants, a GM salmon was approved for sale in Canada in May 2016, with the fish being raised in facilities in Panama. This farmed salmon was engineered to produce a Chinook salmon growth hormone, enabling it to grow to market size in half the time of non-GM farmed salmon. In August 2017, the company marketing this variety stated that it had sold about 4.5 tonnes of the GM salmon in Canada.[15]

To date, all approved GM foods have been developed through some form of recombinant DNA technology. Although CRISPR crops such as the ones mentioned above have been developed, none has been commercialized yet.

2.4 Advantages and Criticisms of Genetic Modification in Agriculture

Genetic engineering, including gene editing, can have numerous benefits: faster and more precise breeding, higher crop yields, development of more nutritious food, and decreased need for herbicides and pesticides.[16] Moreover, this technology has also enabled the development of disease-resistant crops, such as a virus-resistant papaya in Hawaii[17] and an eggplant engineered to produce a natural bacterium-derived pesticide in Bangladesh.[18] In both cases, the GM varieties were developed in response to a crop disease that could have devastated local food production.

In Canada, GM crops have enabled various environmental gains. According to a 2018 study, the use of herbicide-tolerant crops is estimated to have lowered herbicide use by 8%–20% compared with alternative growing methods. These GM crops allow farmers to reduce greenhouse gas emissions: since less herbicide is applied and the crops can be grown using low- or no-till farming, farmers use less fuel during cultivation. Additionally, these reduced tillage practices increase soil carbon sequestration by leaving soils undisturbed and allowing them to retain more water and organic matter.[19]

However, the use of GMOs in agriculture also has its share of critics: some are concerned that intellectual property control of GM seeds puts poorer farmers at a disadvantage, some have ethical concerns about the use of biotechnology on living beings, and some argue that alternative methods (e.g., conventional breeding) are sufficient to achieve similar goals. Although the safety of GM foods is also often cited as a concern,[20] scientific consensus is that GMOs currently on the market are just as

safe as their non-GMO counterparts.[21] Most GM crops have been on the market for over two decades without adverse effects for human or animal health. Moreover, many resources have been devoted to assessing the safety of GMOs, including international standards for the safety and risk assessment of biotechnology-derived foods developed by the FAO and the WHO.[22]

3 REGULATIONS AND LABELLING

3.1 REGULATIONS AND LABELLING OF GENETICALLY MODIFIED FOODS

3.1.1 CANADA

In Canada, GMOs are regulated mainly by Health Canada, the Canadian Food Inspection Agency (CFIA), and Environment and Climate Change Canada (ECCC). GMOs do not have a separate regulatory framework in Canada. Rather, each department or agency administers existing laws and regulations, as follows:

- Health Canada: safety standards for GM foods under the *Food and Drugs Act* and safety-related labelling;
- CFIA: feed derived from GMOs under the *Feeds Act*, plants with novel traits under the *Seeds Act* and non-safety-related voluntary labelling of products; and
- ECCC: fish products of biotechnology under the *Canadian Environmental Protection Act, 1999*, jointly with Health Canada and with Fisheries and Oceans Canada.[23]

More specifically, GM foods and other biotechnology-derived foods are regulated as "novel foods" under the *Food and Drug Regulations*.[24] For safety assessments, producers or importers who wish to commercialize GM foods can find detailed guidance about the information and data required in Health Canada's *Guidelines for the Safety Assessment of Novel Foods*.[25]

There is no mandatory labelling policy for GM foods in Canada. As with other foods, Health Canada requires labelling of GM foods for health or safety concerns (e.g., the presence of an allergen), or when there are compositional or nutritional changes to the product.[26]

A 2018 survey offered some evidence that the Canadian public might prefer mandatory GM food labelling, although it also highlighted confusion about the technology and about how it is regulated.[27] On the other hand, agricultural and agri-food industry associations, such as the Canadian Federation of Agriculture, generally prefer voluntary labelling. This association points out that claims regarding health, safety and nutrition are covered by existing labelling regulations.[28]

3.1.2 UNITED STATES

The U.S. regulatory framework for GMOs is similar to Canada's. The U.S. Food and Drug Administration, the U.S. Department of Agriculture (USDA), and the U.S. Environmental Protection Agency carry out functions similar to those of their

Canadian counterparts. Most importantly, the approval and regulatory processes in the U.S. and Canada focus on the safety of the final product and on how it compares with a non-GM food, not on the process used to develop it.[29]

In 2016, the U.S. Congress enacted a law requiring the USDA to establish a federal framework for mandatory labelling of GM foods. This law prohibits individual states from enacting mandatory labelling standards different from the national framework.[30] The *National Bioengineered Food Disclosure Standard* was published in December 2018 and is scheduled to enter into force on 1 January 2020.[31]

3.1.3 European Union

The GMO regulations of the EU have been characterized by some researchers as some of the most stringent in the world.[32] In contrast with the product-based regulatory approach taken by both Canada and the U.S., the EU's approach is process-based, subjecting products to different regulations based on how they were developed, not on their final characteristics.

There are three directives and two regulations that form the basis of GMO legislation in the EU. Each member state is responsible for implementing legislation and enforcement frameworks that meet the goals of the directives and regulations, which are: protecting human and animal health and the environment via safety assessments; ensuring harmonized procedures for risk assessment and approval; ensuring clear labelling of GMOs to enable the public to make an informed choice; and ensuring the traceability of GMOs.[33]

Under the EU framework, all food, food products or feed produced from GMOs must be labelled, even when the final product contains no GM material, as may be the case with refined products like oil, flour and syrups. However, food produced from animals fed GM feed and foods produced using a GM enzyme (e.g., cheese) do not need to be labelled.[34]

3.2 CRISPR-Specific Regulations

In Canada, the federal government has not made an explicit pronouncement over the regulatory regime for CRISPR and other gene-editing technologies. However, any product developed through gene editing would be considered a novel food and therefore subject to regulation and testing under section B.28.001 of the *Food and Drug Regulations*.[35]

In the U.S., the USDA clarified its stance on gene-editing technologies, including CRISPR, in early 2018. The department stated that it would not regulate plants produced through gene editing as long as the changes introduced could have been developed via conventional breeding. It also noted that techniques like gene editing "expand traditional plant breeding tools because they can introduce new plant traits more quickly and precisely, potentially saving years or even decades in bringing needed new varieties to farmers."[36]

In contrast, the European Court of Justice ruled in July 2018 that organisms produced by means of gene-editing techniques are considered GMOs under Directive 2001/18/EC, which pertains to the deliberate release of GMOs into the environment.[37] In other words, gene-editing techniques like CRISPR are subject to the same regulatory regime as GMOs produced via recombinant DNA, even in cases in which no foreign DNA is introduced.

The European Court of Justice ruling was criticized by many in the scientific community. These critics noted that the directive in question was designed for techniques that insert foreign DNA into an organism, not for precise gene-editing techniques. In their view, equating a precise tool like CRISPR with the introduction of transgenic DNA misrepresents the science behind these technologies. They also noted that this ruling would hinder agricultural innovation in Europe that takes advantage of these new developments.[38]

4 CONCLUSION

More GMOs are expected to be developed and go through the regulatory and approval pipeline in the coming years. With CRISPR technology lowering development costs for researchers around the world, there will also likely be an increase in the number of crops and livestock engineered through gene editing, many of which would not have any traces of foreign DNA.

Although GM crops are widely used in Canada and have brought many benefits to farmers and the environment, consumer reticence remains. This is reflected in polls showing that Canadians expect more transparent labelling. Moreover, Canadian agricultural products that rely heavily on biotechnological innovation could be affected by international factors, including the forthcoming U.S. labelling regulations, as well as the EU regulations on GMOs, which have implications for the *Comprehensive Economic Trade Agreement* that Canada has signed with the EU.

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