GMO POLICIES FOR ENVIRONMENTAL PROTECTION IN THE ERA OF GENOME EDITING

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Abstract In recent years, immediate human interference with nucleic acid sequences has resulted in what is popularly known as Genetically Modified Organisms (GMOs). The process, based on molecular technologies under the term genetic engineering, has added new information to the existing pool of genetic modifications produced from classical guided breeding or of spontaneous evolutionary occurrence under environmental pressure. On one hand, these products have been proposed as the future solution in food, medicine, health therapies including human genome modifications. On the other, they have also been accused that affect environmental stability and human health, especially in cases of DNA mix from distant species. Recent genetic engineering technologies, termed as genome editing, like clustered regularly interspaced short palindromic repeats (CRISPR), oligonucleotide-directed mutagenesis (ODM), zinc finger nucleases (ZFNs), transcription activator-like effector nucleases (TALENs) or directed evolution PCR, are also under examination, as they lead to GMOs. In comparison to their species of origin, GMOs produced with newer technologies contain genetic modifications closer to naturally existing nucleic sequences, being difficult their detection and evaluation. Present and future policies for GMOs are presented under an emerging technology revolution.

Keywords: GMO policies, genome editing, biodiversity

Introduction

Food and feed for thousands of years are mainly products of plant and animal origin. With time, plants and animals with the most desirable characteristics were selected by humans for the next generations of food and feed reproductive material.

Human interventions were guided from the need of increased productivities, affecting traits such as disease resistance, quality and quantity in ingredients (sugars, proteins) etc. Desirable traits resulted through natural selection of genetic modifications of these plants and animals caused by the increased human selective pressure. In recent years, with the advent in genetic engineering human selective pressure has advanced into direct modifications of nucleic acid sequences at the DNA level and has resulted of what is popularly known as Genetically Modified Organisms (GMOs). The process, based on molecular technologies under the term genetic engineering, has added new information to the existing pool of genetic modifications produced from classical guided breeding or of spontaneous evolutionary occurrence under environmental pressure. In an effort to regulate the presence of GMOs in the market and their economic and environmental impact, countries around the world are setting laws about the use of GMOs, with EU leading in the development of GMOs legal framework. This is an ongoing process and follows advances in nucleic manipulation, especially now with newer technologies like the interspaced short palindromic repeats (CRISPR), oligonucleotide-directed mutagenesis (ODM), zinc finger nucleases (ZFNs), transcription activator-like effector nucleases (TALENs) or directed evolution PCR. While in EU strict laws are applied for GMOs, in US law restrictions by governmental bodies such as FDA, APHIS & EPA are less severe, targeting mostly the labeling and not the ban of GMOs. The motive for those complex decisions for GMOs legislation, beyond protection of consumers and environment, is also stimulated from the desire to control food production and markets, setting patents for modified genomes and thus indirectly handling global food economics. In Table 1 is outlined the progression of laws for GMOs authorization and use in EU and USA, where differences of legislative approaches are reflected.

Table 1. Progression of GMOs laws in EU and USA

• **DIRECTIVE 2001/18 / EC** laying down conditions and rules for the release of any GMO into the environment. • **REGULATION (EC) 1829/2003** on the marketing of foods or feed consisting of or containing GMOs. According to him, labeling of products containing approved GMOs in a proportion higher than 0.9% is required • **REGULATION (EC) 1830/2003** amending DIRECTIVE 2001/18 / EC on the traceability and labeling of GMOs and foods containing material containing, consisting of, or produced from GMOs. • **COMMISSION REGULATION (EC) No 1946/2003** governing the intentional or accidental movement of GMOs between EU Member States or to third countries. • **Directive 2009/41 / EC** on the limited use of genetically modified micro-organisms. • **Directive (EU) 2015/412** amending Directive 2001/18 / EC as regards the possibility for Member States to restrict or prohibit the cultivation of GMOs in their territory. • **Publication of Commission Directive (EU) 2018/350** of 8 March 2018 amending Directive 2001/18/EC, concerning the environmental risk assessment (ERA) of GMOs. • **Regulation (EU) 2019/1381** on the transparency and sustainability of the EU risk assessment in the food chain (Transparency Regulation). The Transparency Regulation amended among others Regulation (EC) No 178/2002, Regulation (EC) 1829/2003 and Directive 2001/18/EC.	• **1982** FDA approves the first consumer GMO product developed through genetic engineering: human insulin to treat diabetes. • **1986** The federal government establishes the Coordinated Framework for the Regulation of Biotechnology. • **1992** FDA policy states that foods from GMO plants must meet the same requirements, including the same safety standards, as foods derived from traditionally bred plants. • **1994** The first GMO produce created through genetic engineering—a GMO tomato—becomes available for sale after studies evaluated by federal agencies proved it to be as safe as traditionally bred tomatoes. • **2005** GMO alfalfa and sugar beets are permitted for sale in the United States. • **2015** FDA approves an application for the first genetic modification in an animal for use as food, a genetically engineered salmon. • **2016** Congress passes a law requiring labeling for some foods produced through genetic engineering and uses the term "bioengineered," which will start to appear on some foods. • **2017** GMO apples are available for sale in the U.S. • **2019** FDA completes consultation on first food from a genome edited plant.

Future perspectives

For technologies like CRISPR in the forthcoming GM products the legal status in EU at this stage is absolutely restrictive and their future legislative status is unknown. On the other hand, in USA the decision is that products by newer technologies like CRISPR will be permitted after being evaluated in a case to case study before any authorization. One way or another, the tendency is that GMOs gradually will get their share in markets, especially if they are related to genetically engineered medical products or to human health applications.

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