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Editorial

A Special Issue of the Journal of Regulatory Science on Genetically Modified Organisms

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Ever since Herbert Boyer and Stanley Cohen [1] developed the first genetically modified organism (GMO) in 1973, advances in biotechnology – or genetic engineering as the science of gene manipulation has come to be known throughout the world – have made it possible to develop numerous plant crops, microorganisms, and more recently animals, whose genetic makeup has been modified to include one or more genes that confer desirable traits belonging to other organisms. After extensive research in the 1980s, the 1982 approval of the first GMO product developed commercially through genetic engineering: human insulin synthesized in genetically engineered bacteria [2], and the publication of the Coordinated Framework for the Regulation of Biotechnology, which involves the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA), by the White House Office of Science and Technology Policy (OSTP) in 1986 [3], the world saw the introduction of the first commercial GMOs in the 1990s. The OSTP updated the Coordinated Framework in 1992 and again in 2017. Excellent short and extensive reviews of the history of genetic engineering can be found in a blog by Gabriel Rangel [4] and Colwell [5], respectively.

More than 25 years later, GMO corn is approved for planting in 38 countries and GM soybeans are the most widely planted crop in the whole world. Many other GM plants are being grown today, including alfalfa, papaya pineapple, apples, potatoes, sugar cane, eggplant, etc. After years of mishandling, approval for raising GM salmon was granted by the FDA in 2015, but a court recently ordered the FDA to conduct an environmental risk assessment of the salmon [6], which is not yet available to consumers.

The development and expansion of approvals for growing GM crops has been the subject of stringent regulations in many countries. Many of these regulations are openly or surreptitiously based on the precautionary principle, and there is no global agreement on the requirements GM organisms must comply with to be approved for planting, growing, raising or importation. Some

countries rely on "substantial equivalence" in their regulations on genetic engineering, whereas others use a "case-by-case" approach. Because of the enormous implications of biotechnology on human and animal health, nutrition, and the environment, it would seem timely to pursue a standardization and globalization of such regulations. In 2000, the Cartagena Protocol on Biosafety – an international accord on regulating the transfer, use and handling of GMOs – was adopted by 172 countries (now 173) and went into effect in 2003 [7], and in 2003 the Joint Food and Agriculture Organization of the United Nations (FAO)/World Health Organization (WHO) Food Standards Program, through its Codex Alimentarius Commission, published a set of Principles and Guidelines on Foods Derived from Biotechnology [8]. Therefore, the basis for international harmonization of regulations on GMOs does exist, but many regulatory agencies around the world, for political or technical reasons, fail to update their requirements and corresponding methodologies, with the resulting delays and unnecessary costs associated with various elements of GMO regulations.

The Journal of Regulatory Science, now in the first year in continuous publication mode, is proud to publish its first Special Issue, which examines some proposals from industry to facilitate the structuring of a more widely accepted, science based, standardized future international regulatory framework for approval of genetically modified organisms.

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