

# Making the Case for Regulatory Science in Agriculture

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## ■ FEEDING A GROWING GLOBAL POPULATION

The United Nations predicts that the world population is expected to reach 9.7 billion by 2050.<sup>1</sup> In this time, China, India, Indonesia, Nigeria, Pakistan, and the United States are each expected to exceed populations of 300 million people. Food and Agriculture Organization (FAO) projections show that feeding this growing world population will require raising overall food production by ~70% between now and 2050.<sup>2</sup> The bulk of this would need to come from developing countries where agricultural production will need to almost double. This implies significant increases in the production of food to feed a growing global population. Additional challenges to agricultural production include a declining rural labor force and the demand for more feedstocks for a growing bioenergy market. These demands, coupled with overall urban population growth in agriculturally dependent developing countries, mean that countries must adopt more efficient and sustainable production methods.

Implementation of biotechnology can be used in many ways to achieve global food production goals, including higher agricultural yields, increased food and worker safety, and the reduction of reliance on agrochemicals. In the long term, advanced technologies can help to increase production of the most valuable components of specific crops, such as modifying the amino acid composition of plant proteins to increase the nutritional value of staple crops. However, despite the consistent safety and efficacy record of biotechnology, regulatory policies remain almost as restrictive as when, for example, genetically modified (GM) crops were first introduced. As a result, there are still only a few GM crops widely grown, and public acceptance of foodstuffs made from GM crops is very low. There is a critical need to go beyond popular biases against the use of agricultural biotechnology and develop progressive regulatory frameworks based on scientific evidence rather than misinformation and fear.

Products of agricultural biotechnology that are regulated must undergo rigorous testing and then must be granted approvals by a competent authority before they can be used freely. Partially in response to this requirement, a relatively new field has been born, regulatory science in agriculture. Regulatory science in agriculture seeks to aid decision making by predicting the likelihood of harmful effects. This is critical to the responsible advancement of agricultural-use technologies from concept, through research and development, to commercialization and then throughout a technology's life. "Regulatory science" is a broad term that addresses the following: regulatory affairs, the direct interaction of the

institution with a regulatory body; regulatory compliance, institutional enforcement of the regulatory requirements placed on permits to operate or quality parameters of safety assessments; regulatory policy, where principles of stakeholders are brought together to guide decisions and develop cohesive and sustainable regulatory frameworks for technologies; risk science, where scientific data are assembled and utilized in an assessment to evaluate risk or safety, providing a scientific basis for policy and risk–benefit management decisions and subsequent communication of risk to the general public to create acceptance of management decisions; and stewardship, which develops principles and programs to oversee the responsible and sustainable introduction and use of technologies and products in agriculture.

## ■ GROWING NEED FOR TRAINED SCIENTIFIC PROFESSIONALS

The increasing pace of bioscience product development and services means compliance with federal and state regulations is critical to the success of biotechnology products and the companies that develop and make them.<sup>3</sup> Companies and federal regulators alike report an increasing need for trained professionals educated in agriculturally focused regulatory sciences. In a country in which 11.1% (14.3 million) of U.S. households were food insecure at some time during 2018,<sup>4</sup> and an estimated 821 million people around the world suffered from hunger last year,<sup>5</sup> it is critical that we ensure that "boots-on-the-ground" science is well represented to ensure agriculturally focused regulatory policy decisions are informed through the best available science available at all levels (consumer, producer, industry, federal government, state governments, and beyond). Only then will we be able to reduce global food insecurity and ensure a safer more productive food supply.

Many programs train regulatory science professionals to work in the pharmaceutical field, whereby regulatory science is defined as the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products. However, there is a dearth

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of university programs in regulatory science specifically related to agriculture. There is an obvious need for a unified program that can provide undergraduate, graduate, and continuing education opportunities in agriculturally focused regulatory science. Any program should place a strong emphasis on course work based on up-to-date scientific research that includes (but is not limited to) environmental and human health risk science, toxicology, and pesticide fate. For students to be prepared to step into an agriculturally focused regulatory science career, become better stewards of our environment, and make difficult decisions that will impact our most vulnerable populations, they must understand the state of the best available science, how it is incorporated into regulatory and policy decisions at the state, national, and international levels, and finally how to best communicate such information to create public acceptance of science-based policy decisions.

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### Notes

The authors declare no competing financial interest.

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