



Editorial

A new journal for the emerging field of Regulatory Science

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The growing popularity of the term “Regulatory Science” and accompanying effort to advance this discipline among regulators and academicians necessitates an accompanying scientific journal, accessible to all and free to authors and readers alike. Toward this end, the International Journal of Regulatory Science (IJRS) editors endeavor to elevate the discourse involving the application of science to the regulatory process. We hope this journal will provide momentum to this emerging discipline, appropriately named regulatory science, and provide a written forum to help define this field.

Much of the current emphasis on regulatory science within the Food and Drug Administration (FDA) focuses on drugs and medical devices, as depicted in their Framework for FDA’s Regulatory Science Initiative (2010) and strategic plan for Advance Regulatory Science at FDA (2011). FDA is seeking to augment their efforts through the formation of Centers of Excellence in Regulatory Science and Innovation. At the date of this publication, two such centers have been established and FDA is reviewing proposals to fund more centers.

The National Academies report *Enhancing Food Safety, The Role of the Food and Drug Administration* (2007) highlights the paucity of training in the field of regulatory science. They state, “The committee recognizes the difficulty of finding individuals trained in the breadth and depth of food safety problems who are also proficient in epidemiology, mathematical modeling, economics, or other disciplines necessary to support a risk-based approach. Academic institutions do not typically configure their programs with the necessary training to prepare students to be a part of a risk management team.” Since this report, regulatory science curriculums have been established at five universities in the United States, one of which focuses on food systems.

In many ways, the intersection between academia and regulators with respect to regulatory science in food systems involves Hazard Analysis and Critical Control Point principles. This focus is re-enforced

through the FDA's Food Safety Modernization Act. At the publication of the first IJRS issue, five rules stemming from the Food Safety Modernization Act are open for public comment including Produce Safety, Preventive Controls for Human Food, Preventive Controls for Animal Food, Accreditation of Third-Party Auditors, and Foreign Supplier Verification Programs. However, regulatory science encompasses more broadly defined disciplines than those currently used within preventive risk-based systems, or what FDA calls the science of developing new tools, standards and approaches to assess the safety, efficacy, quality and performance of FDA-regulated products. The purpose of this journal is to provide an opportunity to publish in this field and combine multiple disciplines to help define regulatory science.

Presently, much of the communication between the regulatory and regulated community within the United States (US) occurs during public hearing and comments to notices within the Federal Register involving proposed rules. We hope this journal will provide a vehicle for continued discourse about the science behind these and other regulations and how they may or may not contribute to the public goods including public health, environment, security, and safety.

This journal should attract articles that delve into the interconnectedness of multiple agencies, jurisdiction, practices and their complementarity, or lack there in, throughout the world. IJRS will accept a range of articles related to the regulation of food and feed, the environment, drugs, transportation, communications, and other related fields that focus on legislation and rules, risk assessment, risk management, risk communication, inspection services, laboratory services, analytical techniques, surveillance, monitoring, response, education, policy, cost-benefits, and economic development.

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Sincerely,

Tim Herrman, William Slikker, Samuel Godefroy, and Christian Nansen

Editors-in-chief

IJRS