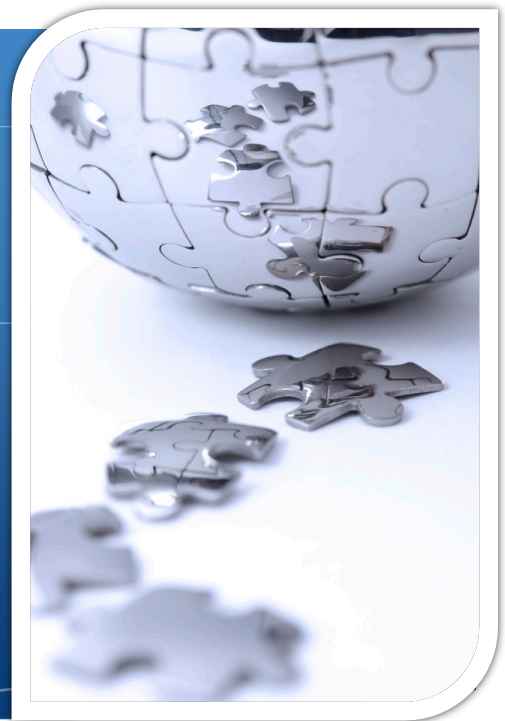


# GHI Matters

*The newsletter of the Global Harmonization Initiative*

September/October 2011



## Message from the President

Dear GHI Colleagues:

It's been a busy summer for GHI as we continue to build the infrastructure to support our association's consensus-building Working Groups format and educational outreach systems.

The GHI Executive Committee is pleased to announce that in June 2011 a non-profit organisation named GHI-Financials was established (pg. 4). The purpose of this foundation is to coordinate and collect funding from the food industry, governments and non-governmental organisations in an independent manner to support and facilitate GHI activities, particularly those of the GHI Working Groups. GHI-Financials, established under Dutch law, is an operating mechanism that will allow GHI to remain impartial in its oversight of the consensus-building process while at the same time, allow GHI to receive unencumbered funding to do its work.

Funding will help GHI support a number of efforts, such as facilitating opportunities for Working Groups to coordinate and hold meetings, communicate with each other, and prepare and publish findings. More details on the GHI-Financials mechanism will appear on the website soon!

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*Achieving consensus on the science of food regulations and legislation to ensure the global availability of safe and wholesome food products for all consumers.*

continued from page 1

A roundup of GHI Working Group (WG) activities and meetings is provided on pg. 6, and I would like to take this opportunity to officially welcome Prof. Naresh Magan of Cranfield University (UK) and Prof. Mark Shamtsyan of St. Petersburg State Institute of Technology, Russia, as co-chairs of the Mycotoxins in Food WG. Both have extensive expertise in the subject area, and Dr. Magan will serve as the WG's Science Leader and Dr. Shamtsyan will serve as WG Coordinator. I'd also like to welcome Isabella van Rijn of Agrispider in The Netherlands, who proposes to launch a new working group on harmonizing food safety regulations and religious dietary laws.

We also acknowledge a new Ambassador to the Ukraine, Prof. Yaroslav Zasyadko of the National University of Food Science and Technology (NUFT) in Kiev. Our Ambassador programme is beginning to grow, and GHI is actively preparing materials to provide our Ambassadors with the latest information possible in their efforts to increase membership.

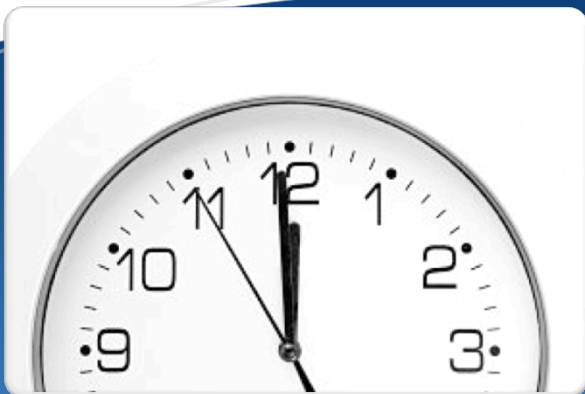
With kind regards and best wishes to you all, we look forward to your continued support.

—Huub Lelieveld, President, GHI



GHI meetings and workshops are where the consensus happens!

\*GHI has legal non-profit entity status and its charter and constitution are registered in Vienna, Austria as the GHI-Association (ZVR453446383).



Become a vital contributor to providing the world's regulators, policymakers and public health authorities with a foundation for sound, sensible, science-based food laws and regulations

## It costs only a few minutes to enroll

In order to build a truly global, impartial consensus on the current scientific knowledge that will inform objective regulatory decision-making on the world stage, GHI actively encourages scientists from industry, government and academia to join as individual members **at no cost**.

**Please visit our website and complete a GHI Membership Enrollment form. There is no fee to join GHI.**

[www.globalharmonization.net](http://www.globalharmonization.net)

## Trends in International Food Regulation

# US Food Safety Modernization Act (FSMA) Supports Harmonization Concept

The US Congress passed the Food Safety Modernization Act (FSMA) in December 2010. When President Obama signed the legislation into law on January 4, 2011, FSMA marked the most expansive changes to food safety regulation in the United States since 1938. The FSMA legislation comprises the following four main components:

- Improving capacity to prevent food safety problems
- Improving capacity to detect and respond to food safety problems
- Improving the safety of imported foods
- Enhanced partnership in food safety management with other agencies

The new law gives the US Food and Drug Administration (FDA) sweeping new enforcement authorities, institutes exacting new food import requirements, and introduces major new program activities for FDA. Many of the mandates of the law are required to be phased in in the next 18 to 36 months. Basic elements of FSMA include the following:

- Increases inspections of US and foreign food facilities
- Increases FDA's recall enforcement authority; the agency can now order recalls rather than negotiate with companies to issue voluntary recalls
- Specifies new food safety rules for produce industry
- Mandates food companies to develop food safety management plans to document all food safety steps throughout production and to share this information with FDA to improve traceability systems with regard to recalls

In August 2011, FDA published a general strategic plan outlining the agency's objectives for implementation as it moves forward in the new era of FSMA regulations. The

37-page document, "*Advancing Regulatory Science at FDA*," is especially interesting to our member scientists in the Global Harmonization Initiative (GHI). In the section

focusing on food science, the agency makes clear that harmonizing standards, regulations and validation methods to science-based guidelines is key to successful implementation of the new law.



For example, in a paragraph detailing how the agency plans to ensure that its government food pathogen testing laboratories will meet the highest standards of analytical performance, it states that FDA will "*harmonize* (emphasis mine) method validation guidelines for all methods developed and used in our testing laboratories" while also "actively collaborating with other government agencies, international partners, and multiple accrediting bodies to achieve a similar consensus on method performance standards and validation criteria." Ultimately, the document states that: "As collaborative global food safety surveillance programs increase, *harmonization of standards and validation criteria* will allow for greater data sharing and data acceptance between the US and our international trading partners."

It is encouraging that FDA's strategy paper reflects the long-standing, major tenet of GHI relative to harmonization of regulations to achieve food safety. It appears that as FDA begins the critical task of implementing the many new aspects of FSMA, the concept of regulatory harmonization at national and global levels will be at the forefront of the agency's actions. As a result, GHI will have an increasingly important role to play in providing science-based information that will bolster those efforts. "*Advancing Regulatory Science at FDA*" can be downloaded at [www.fda.gov/regulatoryscience](http://www.fda.gov/regulatoryscience).

—*Larry Keener is co-founder and a member of the GHI Executive Committee. He is the president of International Product Safety Consultants in Seattle, WA.*

## GHI Financials Officially Launched

In June 2011, individuals who read about the Global Harmonization Initiative (GHI) and began discussions about the organisation's progress with members of the GHI Executive Committee, established a separate non-profit entity called the GHI-Financials Foundation with the sole aim to raise funds for the work of the Global Harmonization Initiative (GHI) in an independent manner.

The GHI-Association, a not-for-profit association of scientists whose goal is to reach harmonisation of food safety regulations on a global scale by facilitating worldwide scientific consensus on food legislation and regulations based on sound science, is fully impartial. As such, the organisation does not accept funding from industry or governments. The only sources of funding are voluntary contributions from its members, scientifically independent scientific organisations, and charities.

GHI-Financials has an independent status with respect to its financial contributors in view of the status of the GHI-Association. Therefore, contributors from the food industry, NGOs, and governments that are interested in the activities of the GHI-Association and want to financially support these activities can now do so within certain parameters.

GHI-Financials is run by a three-member board who serve three-year terms (at minimum), and is supported by an advisory board in matters of networking with governments, NGOs, scientific organisations, and charities. The advisory board will aid the board of GHI-Financials with the development of scientific and regulatory programs to be executed by the GHI-Association.

Parties supporting the GHI-Association financially via GHI-Financials may suggest issues for consideration similarly to any other party. GHI-Financials, however, will not exert any pressure on the GHI-Association to adopt certain issues or give certain issues priority as to maintain the independent status of the GHI-Association.

The GHI-Financials legal charter is available in English at [www.globalharmonization.net](http://www.globalharmonization.net). The GHI Executive Committee is currently developing a campaign to raise funds from potential sponsors through this independent mechanism in order to provide financial support to GHI Working Groups meetings, activities and publications, as well as to assist with GHI's infrastructure development.



## Calendar

GHI holds or facilitates a number of general and working group meetings, symposia and workshops throughout the world. GHI members and ambassadors also make presentations at scientific meetings around the world. Here's a quick list of upcoming events:

### NOVEMBER 2011

9-10

**13th Annual Food Regulations & Labelling Standards Conference**, Sydney Harbour Marriott, Sydney, Australia ([www.informa.com.au/interestareas/food-beverage](http://www.informa.com.au/interestareas/food-beverage))

GHI's Australian Ambassador **Dr. Dilip Ghosh**, Executive Advisory Committee officer **Dr. V. Prakash**, and GHI members **Prof. Bernd van der Meulen** of Wageningen University and **Dr. Pablo Juliano** of CSIRO Australia will participate in this meeting. Prof. van der Meulen will give a presentation about GHI entitled, "Global harmonisation of food policies and labelling." Dr. Prakash will present the keynote address, "Travel of agriculture materials from farm to fork," in which he will discuss how to build food safety and security into the value chain. Dr. Ghosh will give a case study on personalised food and nutrition, and Dr. Juliano will discuss sustainability in the food and packaging industry and GHI's role.

9-11

**European Federation of Food Science and Technology (EFFoST) Annual Meeting**, Technical University of Berlin, Germany ([www.effost.org](http://www.effost.org))

Among the GHI-related activities planned, an initial meeting of the proposed Working Group on Harmonizing Food Safety Regulations and Religious Dietary Laws will be held from 13:30-16:30 on November 11 (location TBD) and chaired by GHI member **Isabella van Rijn**.

The time, date and location of the Mycotoxin in Food WG meeting, co-chaired by **Dr. Naresh Magan** and **Dr. Mark Shamtsyan**, will be announced soon.

## Working Group Spotlight

# Working Group on Religious Dietary Laws Proposed

**Editor's note: In this article, a GHI member proposes to establish a GHI Working Group on Harmonizing Food Safety Regulations and Religious Dietary Laws, citing the need for scientific consensus on the harmonization and integration of religious dietary laws within the framework of modern international food safety regulations and legislation. GHI members interested in participating in this WG may contact the author, Isabella van Rijn, via email, with a copy to GHI at [info@globalharmonization.net](mailto:info@globalharmonization.net).**

In many societies, religion plays a very important role in food choice. Many of the world's religions have their own religious dietary laws that forbid certain foods or closely regulate how allowed foods are produced, processed, handled, distributed and stored. For example, Judaism and Islam prohibit the consumption of pork altogether and of any meat that is not ritually slaughtered and processed in accordance with the respective religious mandates.

Due to migration and globalization, our food patterns have changed. Historically, religious practitioners emigrating to countries without religious dietary laws had to adjust their food consumption pattern to the local food pattern or to other religions' dietary laws similar to their own and available in that region. Today, consumers have access to a great range of food products prepared in accordance to various religious dietary laws. However, the producers of these religious foods often do not practice the same religion, or sometimes practice no religion at all, which may cause problems in the implementation of the religious dietary laws pertaining to the products they produce.

One example is halal ("permitted") meat. Halal is a term that is used to indicate whether a product can be used or consumed by a Muslim. Meat is the most strictly regulated of all foods in the Islam religion. With marked growth of the Muslim population throughout the world, there has been a shift from halal meat produced in the family kitchen or in small local factories to mass production by large companies at industrial level. The larger market for these foods inspired the food industry to turn halal into a

marketing tool and to increase the production of halal meat and meat products worldwide. (Similarly, kosher foods prescribed by Jewish dietary law have experienced a similar trajectory, as industrialization and transcontinental distribution have made it possible for foods to be produced, treated, processed, cooked and packaged thousands of miles away, making it more difficult to ascertain the kosher status of these products. In other words, even if the consumer can verify that a finished product has in fact been made with kosher ingredients, that product may have been processed on non-kosher equipment, rendering it non-kosher.)



Internationally, food safety laws and regulations regarding animal slaughtering can differ dramatically, which poses real challenges for halal meat producers. For example, legislation in the European Union for halal meat is lacking, while in Australia, all slaughter for halal meat is regulated by the government. In France, by contrast, there are over 50 certification bodies, all in competition with one another, while the Netherlands, Switzerland, Norway, Iceland and Sweden forbid ritual slaughtering outright. In addition, the certification bodies that do exist differ in their procedures to determine whether a product is halal or not.

For retailers and consumers the lack of consensus on regulation can cause confusion on what is actually meant by halal and whether a product that is halal-certified is truly halal (or kosher, as mentioned). This proposal to form a new GHI Working Group on Harmonizing Food Safety Regulations and Religious Dietary Laws will investigate the need for internationally harmonized regulations for religious dietary foods, determine how such standardized laws can be related to and harmonized with current food safety laws globally, and identify science-based approaches to ensuring that religious dietary foods are safe for consumption and meet religion-based allowance standards for production and handling.

—*Isabella van Rijn, MSc Public Health Nutrition, owner of Agrispider, an agricultural sector consulting firm. She can be reached at [isabella\\_vanrijn@yahoo.com](mailto:isabella_vanrijn@yahoo.com).*

## Working Groups in Brief

### MYCOTOXINS IN FOOD WORKING GROUP



Contamination of food by mycotoxins causes significant economic damage, and more importantly, starvation of millions of people. The moulds that produce mycotoxins often do damage while foods, in particular cereals, are still on the land, waiting to be

harvested, causing problems after harvesting and during transport/storage.

This is the focus of the Mycotoxins in Foods Working Group, which is collecting data and preparing a consensus document on the need for harmonized global regulations pertaining to discuss the size and distribution of problem and the conditions that will be effective in reducing post-harvest losses due to mycotoxins, all based on scientific evidence.

The WG will hold a meeting at the EFFoST Annual Meeting in Berlin on 9 November, time and location to be announced.

The Mycotoxins in Food WG is co-chaired by mycotoxin experts Professor Naresh Magan, Cranfield University, UK (WG Science Leader) and GHI Ambassador to Russia Mark Shamtsyan (WG Coordinator). GHI encourages interested scientists to join this effort by contacting WG co-chair Mark Shamtsyan via email at [shamtsyan@yahoo.com](mailto:shamtsyan@yahoo.com).

### CHEMICAL FOOD SAFETY & TOXICITY WORKING GROUP

The Working Group on Chemical Food Safety & Toxicity deals with topics involving naturally occurring toxins in the global food supply. Its aim is to investigate and formulate chemical issues in foods and non-food products to support the abatement of risks to human health through informed legislation.



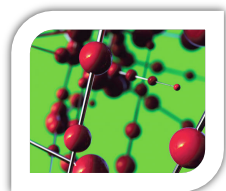
Group members met at a one-day symposium, "Food Safety versus Food Security: A Global Challenge," on 4 October to discuss legislative differences and scientific issues concerning the presence of low levels of pesticides, antibiotic residues and other chemical contaminants in foods. Look for a report from this meeting in the next issue of *GHI Matters*.

Those interested in joining this working group may contact WG Chair Jaap Hanekamp of HAN-Research, The

Netherlands, Chair of the GHI Working Group on Chemical Food Safety and Toxicology. He can be reached at [jaap.hanekamp@globalharmonization.net](mailto:jaap.hanekamp@globalharmonization.net).

### NANOTECHNOLOGY IN FOODS WORKING GROUP

The Working Group on Nanotechnologies in Food's mission is to objectively explore the global safety and regulatory issues associated with the application of nanotechnology to food systems, with a focus on identifying scientific knowledge gaps and toxicological information needed to perform risk assessments.



This working group is looking to build membership among interested scientists. Please email GHI at [info@globalharmonization.net](mailto:info@globalharmonization.net) to submit your name.

### LISTERIA MONOCYTOGENES IN READY-TO-EAT (RTE) MEALS WORKING GROUP

The focus of the *Listeria monocytogenes* in Ready-to-Eat (RTE) Meals Working Group is to build scientific consensus on what constitutes a safe maximum level and what test protocol should be used to determine that level in order to eliminate significant differences in global food safety requirements for *L. mono* in RTE meals—information essential for international trade of RTE foods.



Recently, a set of knowledge-building papers, "*Controlling Listeria monocytogenes in ready-to-eat foods: Working towards global scientific consensus and harmonization—Recommendations for improved prevention and control*," was published as the September 2011 edition of *Food Control*. The Elsevier-published papers will serve as the basis of the WG's basic consensus-building proposal in the GHI process. GHI is in the process of identifying expert reviewers for the WG draft proposal. (The publication is available on ScienceDirect for a fee at [www.sciencedirect.com/science/article/pii/S0956713511000260](http://www.sciencedirect.com/science/article/pii/S0956713511000260)).

If you would like to participate as an expert reviewer for this working group, please email GHI with a digital CV or qualifications at [info@globalharmonization.net](mailto:info@globalharmonization.net).

## Ensuring Global Food Safety: Exploring Global Harmonization

edited by C.E. Boisrobert, A. Stjepanovic, S. Oh, and H.L.M. Lelieveld

Reviewed by W.H. Sperber, PhD  
Global Ambassador for Food Protection, Cargill (retired)

Upon first seeing the title, *Ensuring Global Food Safety*, the reader might expect that this would be a book about traditional food safety, detailing the hazards and control measures involved in food production, processing, and distribution. In fact, this book is nothing like that. Rather, the book's content is better described by its subtitle, *Exploring Global Harmonization*.

Organized by several founders and principals of the Global Harmonization Initiative (GHI, [www.globalharmonization.net](http://www.globalharmonization.net)), the book extends an important GHI emphasis on food security and the economic and social "right to food" by developing a series of discussions about contemporary food safety issues and the feasibility and necessity of harmonizing a myriad of national food safety procedures and regulations with international standards. The need for such harmonization has been created by the growing global food trade and the increasing difficulty of identifying and controlling unexpected hazards.

Benefitting from the multi-disciplinary expertise of 58 contributors, the book is organized in 24 chapters. Major chapters cover regulations in many countries and procedures such as performance objectives, analytical methods, capacity building, and control of microbiological risks. The last, dealing with the harmonization of regulations for *Listeria monocytogenes* control, may be a useful model for the harmonization of regulations for additional foodborne microbial pathogens.

A wide range of specific issues is covered in additional chapters on antibiotics, mycotoxins, food additives such as monosodium glutamate, food packaging, nanotechnology, novel processes, carcinogens and other harmful chemicals, nutrition, and ethnic foods. Most of these chapters address topics that are not commonly encountered in traditional food safety texts, e.g., the analysis of the carcinogenic properties of foods and applied nutrition. These treatments of atypical issues are benefits for a profession in which most attention to food safety hazards is typically given to microbiological hazards.

This book should be a useful reference for those attempting to harmonize food safety regulations. It should also serve as a stimulus for the growing network of food safety professionals who are involved in emerging efforts to create or restructure national and international food safety organizations, thereby facilitating the harmonization of global food safety procedures and regulations.

*This review appeared on pg. 92 in the August 2010 issue of Food Technology magazine, a publication of the Institute of Food Technologists (IFT), Chicago, IL USA ([www.ift.org](http://www.ift.org)).*

### Ensuring Global Food Safety

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### DESCRIPTION

Based on the principles of the Global Harmonization Initiative (GHI), **Ensuring Global Food Safety** offers a rational and multi-faceted approach to current food safety issues, while arguing that a science-based global regulatory framework will enhance the safety, availability and quality of the food supply worldwide. GHI was specifically established to help build global consensus on the scientific evidence underpinning food safety policymaking. This book provides practical examples in key areas such as microbiology, toxicology and nutrition, as well as discusses possible improvements necessary to sustain the integrity of the global food supply in the 21st century.

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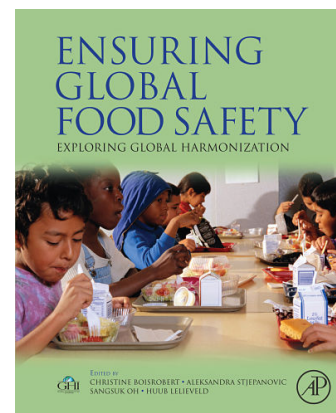
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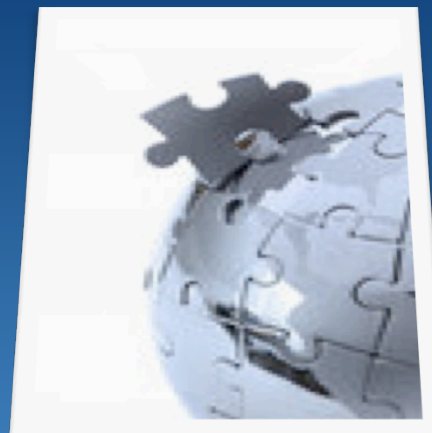
Dr. Yaroslav Zasyadko



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If you are interested in becoming a member of GHI, we invite you to take these simple steps:

1. Please visit [www.globalharmonization.net](http://www.globalharmonization.net) and complete the Individual Membership Enrollment form. You will be asked to provide full contact information, current professional affiliations and areas of scientific expertise. There is no fee to join GHI.
2. Once your application has been accepted, you will receive notification via email, along with information from GHI regarding upcoming meetings, working groups workshops, and more.
3. For further questions on GHI membership, please send your inquiry to the attention of the Honorary Membership Director via email at [membershipdirector@globalharmonization.net](mailto:membershipdirector@globalharmonization.net).



Gain an influential voice in consensus with other experts that will have a real impact on reducing world hunger, improving food safety and nutrition, and supporting new technology applications.



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