

Progress with the global harmonization initiative[☆]

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The need for global harmonization of food safety regulations is growing with every new food safety incident. To be able to control food safety adequately, there must be a sound legal basis. Regrettably, often that basis has not been well developed or is not in existence. With regulation based on sound science, it is unlikely that incidents will be eliminated, but it will help to reduce the number and severity of food safety incidents. Regulations, however, will never stop incidents that have been created with criminal intent, although some legal measures may help. An example may be a global regulation for tamper-evident packaged food. Currently, as a direct result of the threat of bio terrorism, countries have been developing regulations on tamper-evidence for example for baby food and products sold at airports.

GHI association

To give GHI a legal existence, in October 2007, the GHI Association was registered in Vienna, Austria. The goal of GHI remains “Achieving consensus on the science of food regulations and legislation to ensure the global availability of safe and wholesome food products for all consumers”. This has been carefully incorporated in the constitution, which is entirely based on the Charter of GHI. To comply with the Austrian law, however, the Charter had to be translated into German and the text had to be adapted to meet legal requirements. The Executive Committee of GHI has painstakingly ensured that the translation and necessary changes did in no way alter the goal and objectives as described in the Charter. The German “Vereinsatzung” (constitution)^{*} can be found on the

^{*} Although in English the spelling is with an “s”, as a result on its inception during a meeting in the USA, in the official name the spelling is “Harmonization”, with a “z”.

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GHI website (<http://www.globalharmonization.org/constitution-german-2008.pdf>). An English translation will be posted on the website shortly. The Austrian law also required to have instead of “Co-Chairs” a President and a vice-president. The Founders of the Association are Huub Lelieveld (Netherlands), Larry Keener (USA), Gerhard Schleining (Austria), Sangsuk Oh (Korea), Vishweshwaraiah Prakash (India), Christine Boisrobert (USA) and Roland Poms (Austria). The Executive Committee consists of the same persons, with the exception of Roland Poms, who is the Chair of the Supervisory Board. Currently, Huub Lelieveld acts as President and Larry Keener as Vice-President.

Supervisory board

From the start, the founders of GHI stated that impartiality of the scientific consensus process would be an essential requirement to be able to cooperate with scientists from all over the world and therefore, this impartiality should be carefully maintained. This is the reason for the establishment of the Supervisory Board, which is also firmly embedded in the constitution of GHI. The intention is that the Supervisory Board will consist of representatives of independent scientific organisations from all over the world. Dr. Roland Poms, representing ICC, has accepted to chair this Board, with the first task to expand the Board to meet its objective. Any organisation fulfilling the above requirement of scientific independence, willing to share responsibility for supervising GHI, is invited to contact Roland Poms (see contact details).

Special interest groups

To support the activities of GHI, both EFFoST and IFT have formed Special Interest Groups (SIGs). The SIG Global Harmonization of EFFoST is chaired by Aleksandra Stjepanović (Serbia) and the similar SIG in IFT is lead by Christine Boisrobert, with support from Pablo Juliano (Uruguay) and Bala Balasubramaniam (USA).

Geographic responsibilities

To be able to cope with the increasing amount of correspondence about global harmonization, the responsibilities for communication have been divided geographically between members of the Executive Committee and members of the Special Interest Groups of EFFoST and IFT:

Asia	V. Prakash and Sangsuk Oh
North America	Larry Keener and Christine Boisrobert
Latin America	Pablo Juliano and Gisela Kopper (Costa Rica)
Europe	Gerhard Schleining and Huub Lelieveld
Africa	Roland Poms and Marcella Gross (Austria)

Meanwhile it is clear that more scientists are willing to assist with effective communication in the regional activities, such as in the Middle East, South Africa, Russia, former Yugoslavia, Lebanon and Iran.

Meetings

The interest in GHI is growing, which is evident from the many invitations to give presentations. In the past period, members of the Executive Committee and others have been giving presentations at meetings of

- the American Spice Trade Association (ASTA) in Laguna Niguel, California, USA
- Food Processing Machinery Europe (FPME) in Lisbon, Portugal
- GOAL (Global Outlook for Aquaculture Leadership) in Madrid, Spain
- the World Spice Congress in Goa, India
- the European Food Law Association (EFLA) in Bologna, Italy
- the Korean Food Safety Research Institute (KFSRI) in Seoul, Korea
- the Florida Public Health Association, Florida, USA
- food companies and equipment manufacturers.

Workshops and other meetings

In the past year, a number of workshops have taken place. The workshops are kept small, the target number of participants being 20, because they are set up to discuss food safety regulation issues. The intention always is to reach useful conclusions, aimed at making progress. During other meetings, strategies are developed about how best to move forward, having an impact, to meet GHI's goal and objectives. Workshops and meetings took place in:

- Lisbon, Portugal, in conjunction with the joint EFFoST – EHEDG Conference
- Cavtat, Croatia, in conjunction with CEFood 2008
- New Orleans, during the IFT Annual Meeting
- Shanghai, China, during the IUFoST World Food Congress
- Seoul, Korea, in conjunction with the symposium, organised by KFSRI (see above)
- Ljubljana, Slovenia, during EFFoST's First European Food Congress.

Future meetings

A workshop "Globalization – harmonization of food regulations" will be held during the conference EuroFood-Chem XV, 5–8 July 2009 in Copenhagen, Denmark, organised by the Food Chemistry Division of EuCheMS (the European Association of Chemical and Molecular Sciences), where the focus will be on toxicological issues.

A proposal had been submitted to IFT to organise a two-day **course** on global harmonization during the IFT annual meeting in Anaheim, USA, in July 2009, but regrettably, this proposal has not been accepted. It is being investigated as to whether this course can be converted to an on-line education programme.

GHI will also participate in the conference of EFFoST: "New challenges in food preservation – Processing, safety, sustainability", which will be held in Budapest, 11–13 November 2009.

Working groups

During the Workshop in Lisbon, four topics were chosen from a very long list of topics that was put together in earlier workshops. These four are intended as examples for obtaining global consensus. One of the topics is in the field of microbiological food safety. Another one is on toxicological safety, one is on food preservation and the fourth is on harmonization of test protocols.

Working group "Listeria monocytogenes in Ready-to-eat (RTE) meals"

There is a very large difference in requirements for *L. monocytogenes* in Ready-to-eat (RTE) meals. While, for instance, in Europe the maximum level is 100 per gram, in the USA it is absence in 25 g. In addition, the methods of determining *L. monocytogenes* in food differ between countries. Obviously, a scientific consensus on what is a safe maximum concentration and what test protocol should be used to establish that concentration, is essential for trade of RTE foods between countries. This Working Group is lead by Cindy Stewart (see Contacts).

Working group "Safe maximum residue levels of selected antibiotics in food"

In many countries there is a zero-tolerance for the presence of certain antibiotics in food. In 2006, the European Court of Justice ruled that all member states of the EU have the duty to seize and destroy food that contains more than nothing of these antibiotics, because that is the law. Such a requirement is scientifically not justifiable, because antibiotics are produced in nature, also by the microorganisms that are essential for sustainable life on our planet. This WG is lead by Jan Kwakman (see Contacts).

Working group "High-pressure processing of foods"

High-pressure (HP) processing has become a fairly mature food processing technology, but there are no legal

requirements and particularly the question of what process conditions will be adequate to ensure the safety of HP sterilised food products needs to be answered. This group has several members and we hope that soon we shall also have a Chair for this WG.

Working group “Toxicological test protocols”

Currently, toxicity is tested using animals and incompetent liver cells. In the past 10 years, evidence has been accumulated that these tests are often not relevant for humans. Substances showing toxicity using these tests may be nontoxic to man and substances that are shown to be safe may actually be toxic to man. There are new methods, using competent liver cells (i.e. almost completely functioning as liver cells in man), which are significantly more relevant and would eliminate the need for animal testing. The objective of this WG is to achieve a consensus on such a method. The WG is led by Firouz Darroudi (see Contacts). This subject is not only relevant for food producers, but also very relevant to manufacturers of food processing equipment, because materials in contact with food must not release unacceptable amounts of a toxic substance to the food being processed. The same applies to packaging materials in contact with food.

Other working groups

Currently, there is much interest in setting up WGs on “Nanotechnology and food”, “GRAS status”, the “Precautionary principle” and “Mycotoxins”. GHI was not to decide on Working Groups, in principle any group of stakeholders may start a WG. Once a WG has developed a scientifically founded consensus proposal, it may be submitted to GHI. That consensus document may then be sent by GHI to qualified experts on the subject, in as many countries as possible.

Cooperation with publishers

From the start in 2004, Elsevier Science and Food Safety Magazine (FSM) have been actively involved in GHI. The GHI logo has been developed by FSM and both Elsevier and FSM have been publishing articles on global harmonization.

Ensuring global food safety – exploring global harmonization

In 2008 Elsevier/Academic Press agreed to publish a book with the above title. The objective of the book is to make readers aware of the differences in regulations and their consequences, the possibilities to base regulations on sound science, ways to harmonise test methods and the advantages of using a risk/benefit based approach rather than a risk-avoidance approach in developing food safety regulations. The book is intended for the food industry, in particular those importing and exporting, including the multinationals, but also many food SMEs, food trade associations, professional organisations like EFFoST (European Federation of Food Science and Technology), IFT (Institute

of Food Technologists) and FPME (Food Processing Machinery Europe), universities and other educational institutions, and finally, lawyers that work for, e.g. growers of produce, the food trade and industry, manufacturers of equipment for the food industry and other suppliers of products and services to the food industry (e.g. detergents, packing material, transport). The book will also be valuable for students in the fields of food and feed, agriculture and law. The book will start with an introduction on the history of food regulations in the world. Since even with correct food regulations, problems may continue to occur, attention will also be paid to global food analysis capacity building. The need for science-based regulations will be illustrated by examples such as Sudan red, antibiotics, mycotoxins, monosodium glutamate and infants, acrylamide, furans, trans fatty acids and packaging materials.

Global harmonization initiative for food safety

CRC Press will publish a book on Food Safety Management, edited by Gisela Kopper, to be published in 2010. One of the chapters will be “Global Harmonization Initiative for Food Safety”, to be written by Huub Lelieveld and Bernd van der Meulen. The latter is professor of Law and Governance at Wageningen University, The Netherlands and director of the European Institute for Food Law. This chapter will discuss the function of food safety regulations, where the responsibilities are or should be, regulations as barriers to trade, zero-tolerance and of course, the role of science.

EC report

A report on the regulatory environment of the European food and dairy sector, written for the European Commission by Prof. Bernd van der Meulen, titled “Reconciling food law to competitiveness”, includes a discussion of GHI with special attention to the lack of scientific justification of zero-tolerance as a requirement for food safety. The report will be published by Wageningen Academic Publishers after consent of the EC, presumably early 2009.

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