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GHI Matters

The newsletter of the Global Harmonization Initiative



Message from the President

Although it is February when you see this, the 8th issue of our Newsletter "GHI matters", I wish all of you a successful (continuation of) 2013 and I hope you started the year successfully. Stay healthy and connected!

Our Ambassadors are very active as you may conclude from the many articles on a variety of subjects in this issue. Some of them get the help of others, see the report by Esmeralda Paz Lemus about a successful conference in Mexico, presided by the GHI Ambassador there and in which GHI was involved. Also, the number of Ambassadors continues to grow and stands at 35 now. There are important messages and you are invited to respond to assist Ambassadors in their endeavours.

There are articles from the leaders of the Working Groups "Food contact materials", "Nanotechnology" and "Food safety regulations in relation to religious dietary laws", who all would appreciate your responses. They address important issues.

The preparation of issue 9 of the Newsletter has started and will be published in April. If you would like to raise issues or comment on the contents of this or previous Newsletter, do not hesitate to send a message to <u>newsletter@globalharmonization.net</u>.

Enjoy reading!

Huub Lelieveld, 31 January 2013.

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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.

Nanotechnology applications in food

With the advancement of nanotechnology, several commercial products have reached the market and found favored with most of consumers in Taiwan. The regulatory agency, Taiwan's Food and Drug Administration (TFDA), has tried to adapt existing regulations for market, but there is no accepted worldwide definition of nano-food.

The 'International symposium on nano-science and nanotechnology in food and related regulatory aspects' was held in Taipei (TW), with the support of TFDS. Dr Shyu (Dean of College of Bioresources and Agriculture, NTU, TW) defined nanotechnology as a technology able to promote innovations in agriculture and food but in need of globally harmonized regulations for future development. Subsequent presentation explored a range of topics and issues including Dr Hongda Chen (USDA), who presented "Advances in implication research of nanoparticles on environment, health and safety issues relevant to food and agriculture".

Dr Chen was not able to join the symposium in Taipei, but gave his speech via audio conference, and emphasized the importance of responsible development of nanotechnology and explained nanosystem (nano2), the next phase of the development of nanotechnology up to 2020. Two local speakers (Dr Hsiao-Wei Wen and Dr Ke Liang Bruce Chang) shared their experiences of developing systems for detecting microbes and self-assembled nanoparticles for food applications, respectively. Whilst Professor Hyun Jin Park described how safety management of nanotechnology has been an important issue in Korea.

Classification of nano-materials is based on type of material and manufacturing method, and Dr Qasim Chaudhry explained the challenges in risk assessment of nanomaterials applied in food and the regulatory development in Europe. In addition to the symposium, there were three workshops for the industry and general public with the purpose of make nanotechnology be more apparent, protecting nanotechnology-based innovation by the food industry and realize benefits for consumers. Thus, TFDA may establish a global-harmonized regulation for nano-foods.



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).

The participants, about 180 representing organisations globally, appreciated the speakers, and learnt much about important challenges in risk assessment for nano-materials in food. Furthermore, the TFDA regulatory agencies reported the symposium had been helpful in preparing draft guidance on use and application of nanotechnologies in food, and would like to have a similar symposium for more general audience. Hopefully, the guidance will be transparent and acceptable to both industry and consumer.

Professor An-I Yeh, Graduate Institute of Food Science and Technology at the National Taiwan University and co-chair of the GHI Working Group Nanotechnology

Points to ponder: food regulatory issues and nutrition security Need for nutritional information for all RTE foods: Please may I know what I am eating?

Despite the presence of global and national food regulatory bodies, sometimes, the food trade does not help the consumer make the right/ desirable informed choice regarding selection of foods. One of the important issues related to this, is missing nutrition information on catered foods.

Dietary and nutrition transition are key factors affecting the health of people. During the last 50 years, populations across the world have witnessed a major change in eating patterns, aptly termed as dietary transition. Prior to that, the most significant change was hunter- gatherer society converting to settled civilizations with planned agriculture. Though major, this change was spread across hundreds of years. In comparison, the changes brought about over last 50 years, due to advances in food processing, are remarkable and worthy of scientific debate because of their impact on human health.

Traditional home cooked meals are increasingly replaced with processed, packaged, convenience and ready-to-eat (RTE) foods or episodes of eating out. This particular facet of dietary transition is altering nutrient intakes (nutrition transition), which for the most part are undesirable. The quest for convenience has become the foremost driver for decision making rather than health or taste, which is recognized as a prominent determinant for all food selection. People have more disposable income with which to purchase RTE catered foods encouraging wrong and unhealthy eating habits. This is more common in urban populations in both young and old alike, with younger populations subscribing more and more to such food choices. As a rule, these foods are high in fat and energy as well as sugar and salt. Often the fat is saturated or from trans-fat source. These foods may also include additives that are not allowed, raising food safety issues.

In a survey of urban children from Bangalore (IN), nearly 75% of urban children consumed a snack outside home everyday, only 25% of which were a healthy selection, and indicated a high level of fat consumption in the whole population. The story would be similar in any other urban population.

While buying processed and packaged food, consumers have the option of making an informed choice, thanks to nutrition labelling being made mandatory under food regulations of many countries. However, RTE foods sold in hotels, restaurants and other eating-places have no label/ declaration of nutritional value, be it small street vendors and bakers or large multinationals. These foods have become a major source of extra calories, fats, sugar and salt. With the increasing frequency of eating out, efforts must be made to provide consumers with information about the foods they are eating and their nutritional values. Under food regulation acts, all caterers can be asked to make the nutrition information available to consumers to help them make better choices.

Ways of disseminating the information include:

- Printing of nutrition information on the hotel restaurant menu card
- Display of nutrition information on boards in the eating-place
- Printing of small hand-outs for the customer to pick up

The consumer will only benefit from information about nutritional value of a portion, as served (energy, protein, fat, sugar, salt/ sodium, type of oil/ fat, dietary fibre etc.), the source (e.g. whether fresh or processed from canned or preprepared ingredients such as concentrates etc.) and time of preparation. This can be achieved with access to numerous online databases describing food composition and training. It is easy to calculate the nutritional value of prepared dishes per serving portion with the ingredients and online tools. This can assist the consumer in making healthy choices and better selection of foods while buying RTE products. Because today many people move around the world, for business and holidays, this is a global issue, and the information displayed should be harmonized and provided in all places in such a way that it is easily understood everywhere.

The key issue: Need for nutritional information for all RTE foods, delivered everywhere by any means, to provide information for consumer and promote selection of healthy foods -

Prof. Jamuna Prakash, Department of Food Science and Nutrition, University of Mysore (India) and GHI Ambassador for India, jampr55@hotmail.com

Agenda Meetings with GHI involvement

26 February – 1 March 2013

4th MoniQA International Conference, Budapest, Hungary. The topioc of the conference is "Food Safety under Global Pressure by Climate Change, Food Security and Economic Crises", see <u>http://budapest2013.moniqa.org/</u>. Dr. Vishweshwaraiah Prakash, GHI Board Member and Distinguished Scientist of CSIR – INDIA, will present a keynote on "Food and Nutrition Security in the Context of Climate Change and Resilient Agricultural Produce". In addition, there will be a GHI Board meeting (27 February, 14:00 - 15:30), a GHI general meeting (27 February, 16:00 -17:30) and a GHI Work Group Mycotoxin meeting (28 February, 14:00 - 16:00.



13-16 March 2013

The 8th edition of the Nutra India Summit, Mumbai, India (<u>http://www.nutraindiasummit.in/nutra 2013/</u>index.php). Nutra India is India's flagship event for the Nutraceuticals, Nutrition ,Functional Foods, Dietary Supplements and Ingredients. The event is chaired by Dr. Vishweshwaraiah Prakash. More details in the next GHI Newsletter.

GHI

7-10 May 2013

EuroFoodChem XVII, Istanbul, Turkey (<u>http://</u><u>www.arber.com.tr/eurofoodchemxvii.org</u>). During this event there will be several GHI activities, including a general meeting, to give participants an opportunity to raise issues and ask questions about what GHI is doing and trying to achieve; a meeting of the Working Group "Food Safety in relation to religious dietary laws"; a GHI Ambassadors meeting and possibly also again a course on genotoxicity testing. The events are coordinated by Isabella van Rijn, who is the Chair of the above WG. Anybody wanting to contribute to any of these events or having other questions may contact Isabella at <u>religiousdietary-laws@globalharmonization.net</u>.



13-16 July 2013

As usual, GHI will be present again during the IFT annual meeting, this time held again in Chicago, Illinois, see <u>http://www.am-fe.ift.org/cms/</u>. GHI will have a, by now traditional, general meeting to which everybody with an interest in global harmonization of food regulations is invited. More details will follow in the Newsletter of April.



15-20 September 2013

The IUNS 20th International Congress of Nutrition will take place in Granada, Spain (<u>http://www.icn2013.com</u>) and there will be a GHI presence, with presentations from various GHI members, details to follow later.

GHI

My Journey as a GHI Ambassador

I came across the GHI by chance during the IUFoST Congress in August 2012 in Foz do Iguaco (Brazil). I happened to bump into Huub who introduced the objectives and rationale behind the establishment of the GHI. Following his description, I was able to visualize accomplishing many of my personal and professional goals in the aspect of food technology as a GHI Ambassador for Sri Lanka. I have always been passionate about legal and regulatory perspectives of food, and I saw GHI as the perfect organization to promote, accomplish and publicize knowledge vital for informed decisions on the behalf of the general public.

My current involvement, in terms of regulatory or rather assessment activities of food, is via accreditation. As a (external) lead assessor for the Singapore Accreditation Council of Singapore, I have the opportunity to go around Singapore evaluating laboratories in the field of chemical, biological and environmental analysis, most of them engaged in testing of food and water. For these laboratories, I see accreditation as recognition of their competence and compliance towards international standards.

Accreditation is not yet sufficiently emphasized in Sri Lanka. As a GHI ambassador, I want to endorse accreditation to all laboratories in Sri Lanka, as well as the region of South Asia, involved in food and water testing. Accreditation builds customer confidence, minimizes risk, increases credibility and reduces cost. It also enhances service and quality by providing continuous improvement opportunities. In short, the pros of laboratory accreditation outweigh the cons.

In conclusion, as a member of the GHI, I wish to learn from my peers, update my knowledge and stay relevant in the area of food technology. There are numerous areas in the realm of food science and technology for which the GHI could render its assistance and perspectives. In addition to being excited about the accomplishments to come, I also want to mention that my unwavering support will be rendered to the GHI for its future endeavours.

Viduranga Waisundara Lecturer – Temasek Polytechnic, Singapore (for a little while yet)

"Sobre Inocuidad, Calidad y Funcionalidad de los Alimentos en la Industria y Servicios de Alimentación" Hacia una Cultura de Calidad en el Consumo de Alimentos (CUCCAL) The 5th International Congress on Food Safety, Quality and Functionality of Food Industry and Food Services Towards a Culture of Quality in the Food Consumption (CUCCAL)

With the support of the United Nations Organization for Food and Agriculture, FAO. From October 29 to November 2, 2012, Mazatlan Sinaloa, Mexico

Many thanks to the Committee and speakers who helped the 5th International Congress to be such a success! This Congress, the first of which took place in 2005, has been strengthening by the support of public and private institutions and companies, which have found the opportunity to disseminate their research and present up-to-date and relevant information from the Academy, and the National and international food industry. The 5th Congress, held in the beautiful port of Mazatlan (MX), was hosted by the Instituto Tecnológico de Mazatlan and sponsored National (CONACYT) and international institutions such as EHEDG (European Hygienic Engineering & Design Group), SBCTA (Sociedade Brasileira de ciencia y tecnologia de alimentos), GHI (Global Harmonization Initiative), IUFoST (International Union of Food Science & Technology), EFFoST (European Federation of Food Science & Technology) and IFT (Institute of Food Technologist) with the support of FAO (United Nations Food and Agricultural Organization) and was attended by 332 people including:

- 45 at the pre-congress course
- 175 delegates amongst which were students, academics and industrialists
- 70 children in the CUCCAL Kids Forum
- 42 national and international speakers
- 11 teams of undergraduate students in the competition "INOCUITON"

International speakers included Huub Lelieveld, Piet Steenaard, Juliane Días Gonçalves, Roger Clemens, Alejandro Echeverry, Amy Parks and Adriana Quintanar Guzmán. Their support ensures information presented at the Congress will reach Mexican Society, and safeguard the culture of quality in the consumption of food (CUCCAL).



Inaugural ceremony: Dr Juan Antonio Cortés Ruíz (Presidium, ITMAZ), Huub Lelieveld (GHI), Dr PH Roger Clemens (IFT), Marco Antonio León Félix (SOMEICCA), Juliane Días Gonçalves (sbCTA), Piet Steenaard (EHEDG), Dr Evaristo Méndez Gómez (ITMAZ) y M. en C. Manuel José Correa Pérez (ITMAZ), Presenting: I.B.Q. José Abel Ortega (ITMAZ)

Esmeralda Paz Lemus

Kosher Food Safety Initiative: Harmonizing religious and food safety requirements

A message about harmonizing religious and food safety requirements in Canada from Albert Chambers, President of Monachus Consulting, and a member of the GHI WG: Food Safety in relation to religious dietary laws.

The primary driver for the Canadian Kosher Food Safety Initiative (CKFSI, www.ckfsi.ca) was recognition that micro, small and medium-sized (MSMEs) kosher food manufacturers were facing demands for food safety management system (FSMS) certification. These came from Canadian retail customers and from US importers responding to the Food Safety Modernization Act of 2011, and there was an expectation that Canada should modernise its food safety legislation, which in did in November 2012 with the Safe Food for Canadians Act.

In Canada, the kosher market has been growing at 15-19% annually, roughly the same rate as the global market. This demand has been fuelled by the market perception that "Kosher = safe". Although some manufacturers' products undergo Federal or Provincial inspections, many others have traditionally limited government oversight. A CKFSI survey found kosher food businesses in Canada are much less likely to have documented HACCP plans (only 40%) or be subject to third party audits (only 33%). CKFSI also found kosher manufacturers were apprehensive about modifying traditional practices to meet changing requirements based on food safety management systems.

Canadian kosher food manufacturers service all segments of the supply chain. Following discussions with the Canadian Food Inspection Agency (CFIA) and Canadian Ministry of Agriculture and Agrifood (AAFC), it was agreed CKFSI would initially focus on bakeries, and confectionary and oil manufacturers.

But, CKFSI's objectives are to assist all manufacturers by:

- Creating user-friendly food safety standards that are harmonized with Kosher requirements
- Facilitating transfer of information between kosher certifying agencies and food safety certification bodies
- Developing audit methods designed to inform, correct and improve food safety compliance by Kosher manufacturers
- Establishing a sustainable programme recognized by Government(s), and/or benchmarking by private sector schemes 6

CKFSI has been established in five (5) phases

- Research and Development a survey of kosher food manufacturers, analysis of regulatory requirements in Canada and the United States (major export market), and a review of food industry and science expectations for the selected industries.
- Analysis Phase comparison of industry food safety best practice with kosher requirements to identify commonalities and limitations.
- Toolkit Development for each industry, harmonized standards based on ISO 22000:2005, ISO 22002 Part 1 (pre-requisites for food manufacturers) and CFIA's Food Safety Enhancement Program (FSEP) were developed, e.g. produced to date:
 - Food processing safety pre-requisite programmes: Standards and interpretations guidelines
 - Audit process manual
 - Kosher audit manuals and kosher audit checklists for bakers, and oils and confectionary manufacturers
 - Guidance for Mashgiachs (supervisors)
 - Audit report template
 - Corrective action plan report template
 - Food provider questionnaire
- Pilot Project Phase currently in this phase, CKFSI is testing harmonised standards with companies from the three sectors as well as the harmonised audit methods (i.e. kosher inspectors include some of the new food safety requirements in their regular inspections): the fully implemented system will provide regular updates to the electronic registry and supplement annual audits by food safety certification bodies.
- Final Phase: Sustaining CKFSI Canadian Government funding ends on 31st March 2013. Business plans and options for government recognition or private sector benchmarking are being developed. CFIA recognises HACCP-based, industry-led food safety schemes (bit.ly/10EuXgc⁾ through a rigorous review process; this is one option for CKFSI, which has been trademarked under Canada Kosher 22000[™]. Another is benchmarking through the Global Food Safety Initiative (GFSI).

It is hoped the pilot phase will demonstrate the feasibility of this approach in assisting kosher MSMEs to implement FSMS certification, which meets customer expectations and the requirements of authorities in Canada and abroad. Ensuring access to userfriendly standards, which harmonise kosher requirements and food safety best practices, will enable kosher food businesses to take advantage of increased demand and preserve consumers' perception that kosher means safe.

The Canadian Kosher Food Safety Initiative (CKFSI, www.ckfsi.ca), launched in November 2011, is a partnership amongst Canada's Kashruth certification agencies (British Columbia Kosher, Badatz Toronto, Ottawa Vaad HaKashrut and Montreal-Kosher Certification Agency), Canadian Ministry of Agriculture and Agrifood (AAFC, bit.ly/13LFsgv), the Canadian Food Inspection Agency (CFIA) and two companies with extensive experience in food safety and quality assurance, Food with Conscience а (www.foodwithaconscience.com) and Medina Quality (www.medinaguality.com).

Albert Chambers gave a presentation on behalf of CKFSI at the second meeting of the GHI Working Group: Food safety in relation to religious dietary laws in Montpellier (FR) 23rd November 2012. He is also working with CKFSI as it reviews its options for a sustainable future. He joined GHI in May 2010.



Working Group Food Contact Materials

GHI's new Working Group on 'Food Contact Materials' held its inaugural meeting in Valencia on Friday, 9th November 2012, after the EHEDG 2012 World Congress. Its objective is to identify differences in legislation that applies to Food Contact Materials around the world. Where conflicts between countries or regions arise from apparent differences in scientific opinion, these will be addressed with the objective that all parties move to adopt what can be agreed as best practice.

The 12 participants represented not only Europe but also Mexico and the USA, and representatives from Argentina, Japan, Russia, Thailand and Turkey offered comments and advice prior to the meeting. The meeting recognised the magnitude of the task and each participant undertook to examine the European Regulations (circulated with the Minutes) and compare them with their country's equivalent legislation. In the meantime, we will draw on the experience of major global companies, which inevitably encounter discrepancies in standards (e.g. permissible constituent limits) required by different customers or jurisdictions, as this will highlight inconsistencies in global legislation.

Eric Partington, Chair

Journal of Hygienic Engineering and Design

JHED is a platform for publication of evidencebased research on hygienic engineering and design including hygienic principles, equipment and components, processing, utilities, services, cleaning, sanitation, food production and processing, food quality and safety, and education as well as industry and consumer needs. It is a self-sustaining, peerreviewed, international journal with open access offering new approaches, innovation and expert opinions of the highest possible global scientific standards. The current readership is in excess of 15,000 people, worldwide.



The journal was first issued in 2011 in time for the 'World Congress in Hygienic Engineering and Design', which took place in Ohrid (MK, 22-25th September). This issue included 75 high quality practical science papers from 19 countries (NL, UK, DE, FR



DK, FI, BE, ES, PL, BG, EI, SE, MK, RS, HR, RU, AM, US and Montenegro). Reviewed by the 32 Congress Scientific Committee members, these papers covered hygienic engineering and design, food quality and safety, and food produc-

tion and processing.

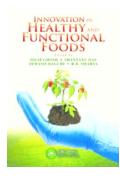
Articles are available online at <u>http://www.jhed.mk/</u> <u>categories/naslovna/</u> or in hard copy. Updates on new developments, technologies and innovations within the food and beverage industries worldwide are also available online, making JHED essential reading for anyone working in this sector and a valued source of information for key decision makers globally.

GHI members are invited to submit papers for the second volume. More information about topics can be found at <u>www.jhed.mk/categories/view/408</u>. The deadline for the next isue is 31st March 2013 – visit <u>www.jhed.mk/categories/view/411</u> for more information.

Vladimir Kakurinov, Editor-in-Chief and GHI Ambassador for Macedonia

New Book

It is a pleasure to know that recently, in September



2012, a new book has been published on "Innovation in Healthy and Functional Foods", the lead editor is the GHI Ambassador in Australia, Dr. Dilip Ghosh, Director, Nutriconnect, Sydney. Coeditors are Shantanu Das, Product Development Manager, Riddet Institute, Palmerston North, New Zealand; Debasis Bagchi, Univer-

sity of Houston College of Pharmacy, Texas, USA and R.B. Smarta, Managing Director, Interlink Marketing Consultancy Pvt. Ltd., Mumbai, India. Publisher: CRC Press.

I intend to write a review on the book in the next GHI Matters'.

Halal Science and Innovation

On the 8th and 9th of January 2013 I was invited by Dr. Quamrul Hasan, GHI Ambassador in Japan, as a speaker on Halal in Europe at the International seminar on Halal Science and Innovative product development in Brunei Darussalam. Next to the guests of honour from the Ministry of Industry and Primary resources of Brunei Darussalam, Dr. Quamrul Hasan managed to invite 25 speakers from different countries (Brunei Darussalam, Japan, Thailand, Australia, Malaysia, Indonesia, France, Korea and Cambodia) presenting on Halal food from a different background and expertise, however leading to the same outcome, namely guaranteeing the authenticity of halal food and the development of new halal products and innovative analytical methods for the identification of haram substances.

During the seminar it became clear that there is an increasing number of analytically methods to guarantee the authenticity of halal food and scientists are succeeding in developing quicker and easier methods for the analysis of haram substances in halal food.

The main message of the seminar is that Halal should not only be seen as a credence quality attribute on food or as a marketing tool used my non -Muslims and Muslims, but as a way of life. Anyone involved in producing or manufacturing halal food and/or halal ingredients should therefore have access to the requirements for halal to be able to meet the requirements of the consumers.

The next meeting of the Global Harmonization Initiative on Food Safety in relation to religious dietary laws will therefore focus on the halal guidelines from this point of view.

The next meeting of the GHI working group "Food safety in relation to religious dietary laws will be on 28 February 2013.

If you are interested in becoming a member of this working group please send your interest to: religiousdietarylaws@globalharmonization.net under the reference of member RDL

Ir. Isabella van Rijn Chair GHI Working Group Food safety in relation to religious dietary laws

Huub Lelieveld.

Setting new standards for glazing and chemical additives limits

Egypt's local sources of seafood are not sufficient to satisfy demand, primarily because of overfishing in Mediterranean and higher local consumption by an increasing population. The gap between production and consumption (ca. 380 000 metric tons) is met through imports from various sources including the European Union, Morocco and South-East Asia. The most successful import is frozen fillets of *Pengasius hypothalamus*, also known as Basa (white, red and pink) or Asian Catfish.

In the last three years, imported Basa has successfully substituted all types of 'white fish' fillets including cod (*Gadus* spp.), haddock (*Melanogrammus aeglefinus*), Saith (*Pollachius virens*) and Nile perch (*Lates niloticus*) in the HORECA sector and subsequently in superand hypermarkets entering homes throughout Egypt. With an import price that starts at 2-3 USD/ Kg it is difficult to compete with Basa even with local *Tilapia* spp. and Nile perch, which are tastier than the neutral Basa but cost more. However, a glaze makes the net weight of flesh less than 80% of frozen weight after thawing.

Egyptian standards for frozen fish, in their current form, do not stipulate glazing limits nor do they places limits on water retaining chemical additives. This leads to purchase of low cost fillets with higher water/ glaze content and increasing consumer complaints.

Efforts to alert the Egyptian Organization for Standards (EOS) to this problem are currently in progress and will, hopefully, result in the formation of a technical committee to improve current standards or draft new regulations in line with other standards globally (e.g. EU or US) limiting on additives and stressing labeling for net weight after thawing with penalties for violators.

Readers are invited to share their views on this and similar fraudulent practice globally, and whether establishing a GHI Working Group to address this issue would be advantageous. Morad S. Ahmed, GHI Ambassador- Egypt

US Food Safety Modernization Act and the Need for Harmonization of Food Safety Legislation

The burden of foodborne illness in the US is substantial. One in six Americans experiences a foodborne illness every year (Source: Center for Disease Control). Of those, nearly 130 000 are hospitalized and 3000 die. Preventing foodborne illnesses, according to CDC and FDA officials, will improve public health, reduce medical costs, and avoid costly disruptions of the food system caused by outbreaks and large-scale product recalls.

Implementation of the United States Food and Drug Administration 'Food Safety Modernization Act' (FSMA) is currently underway. FSMA is the most sweeping reform of US food safety laws in more than 70 years, and was signed into law by President Obama on January 4, 2011. It aims to ensure the US food supply is safe by shifting the focus from response to prevention.

The FDA issued two major FSMA rules on January 4, 2013: 'Preventive controls for human food' and 'Standards for produce safety'. Consistent with US official government procedures, the proposed rules are available for public comment for the next 120 days; the consultation ends on or about May 16, 2013. These rules are part of an integrated reform effort that focuses on prevention, and addresses the safety of foods, domestic and imported; additional rules are to be published shortly.

'Preventive controls for human food' as proposed requires processors and manufacturers of human food, to be sold in the US, whether foreign or domestic in manufacturing or processing, to develop a formal plan to prevent food products from causing foodborne illness. The rule would also require food processors to have plans for correcting any problems that arise. The legislation, as written, is based ostensibly on Hazard Analysis and Critical Control Points (HACCP) for food safety assurance. HACCP has been adopted by the USFDA for juice products (Juice HACCP Rule, 2001) and seafood (Seafood HACCP, 1995). The USDA Food Safety Inspection Service (USDA FSIS, 1996) has also adopted this approach in implementing pathogen reduction programs for the production and processing of meat products.

'Preventive controls for human food' has two major features. Firstly, it includes new provisions requiring hazard analysis and risk-based preventive controls and, secondly, it would revise existing Good Manufacturing Practice (CGMP) requirements codified in 21 CFR 110.

The proposed rule would apply to facilities that manufacture, process, pack or store human food. In general, with some exceptions, the new rules would apply to facilities that are required to register with the FDA under current food facility registration regulations.

Such facilities include manufacturers, processors, warehouses, storage tanks and grain elevators. Of late, the USFDA has taken the approach that food safety assurance encompasses the entirety of production and manufacturing supply chains. It is interesting to contemplate the scope of the proposed FDA HACCP initiative and precisely what food safety elements will be mandatory for inclusion in the HACCP plan.

At present, food processors operating under existing Federally mandated plans have some latitude as to which of its "pre-requisite" food safety elements to include in HACCP plan. The USDA FSIS HACCP system includes or allows meat processors to establish sanitation standard operating procedures (sSOPs), which fundamentally are the equivalent of food safety pre-requisites. The sSOPs, however, are not an integral part of the HACCP plan. It is noteworthy that Preventive Control is lacking critical limits; an essential and fundamental element of the HACCP food safety assurance strategy. In addition, the proposed rule is largely mute on the subject of Transportation Food Safety. It is speculated that the USFDA will rely on language in the updated cGMPs for oversight of this highly vulnerable element of the supply chain.

Under proposed FSMA rules, the USFDA is proposing most food manufacturers be in compliance with the new controls one year after the final rules are published in the Federal Register, but small and very small businesses would be given additional time.

The USFDA is also proposing to establish 'Standards for produce safety'. The proposed rules call for the promulgation of enforceable safety standards for the production and harvesting of produce on farms.

'Standards for produce safety' proposes science and risk-based standards for the safe production and harvesting of fruits and vegetables. But, this legislation is unprecedented in the annals of US food safety law. The proposal had first to provide acceptable definitions for "a farm" and "farming activities" before it could reasonably proceed with drafting the proposed rules and regulations. Likewise, in this proposal, the USFDA had to provide clear differentiation between certain on-farm (e.g., crating, boxing, washing and sorting produces) and food processing activities.

Without this differentiation, many farms would be required to register with USFDA as food processors and, therefore, comply with 'Preventive controls for human food', as previously discussed.

'Standards for produce safety' as it is written would require larger farms to comply with the new onfarm standards for produce safety no later than 26 months after the final rule is issued. According to USFDA proposals, small and very small farms would have additional time to comply, and all farms would have additional time to comply with certain requirements related to water quality and safety. Like 'Preventive controls for human food', 'Standards for produce safety' would apply to all foreign and domestic farming operations that intend to sell produce into US markets.

There are rules still to come: 'Foreign supplier verification for importers' will require importers to verify that foreign suppliers are following procedures that provide the "same" level of health protection as that required of domestic food producers. About 15% of foods consumed in the US are imported including almost half (49%) of fresh fruit and 21% of vegetables. While 'Accredited third party certification' should help ensure food producers in other countries comply with US food safety laws, and 'Preventive controls for animal food' will implement preventive controls at animal food facilities, similar to those proposed for human food.

To date the USFDA has issued two of the five rules that underpin President Obama's Food Safety Modernization Act. The proposed regulations, 'Preventive controls for human food' and 'Standards for produce safety' have global reach, and will impact food processors and growers, domestic and foreign.

The USFDA is seeking aggressively to develop new laws and regulation for control of most operations involved in the production, processing and storage of foods and food products, which are intended for human consumption. The proposed regulations extend beyond the boundaries of the US, and are anticipated to impact greatly on foreign food producers. FSMA regulations are seeking assurance that foreign producers adhere to the "same" level of health protection, as that required of domestic food producers. Here, we have the challenge: are proposed FSMA rules asking for "equivalence" or are they mandating "identical" health protection strategies? This raises, again, the need for harmonization of food safety regulations and legislation, globally.

President Obama is to be applauded for his efforts to reduce the public health impact of foodborne disease. But, the fallout from implementing the Food Safety Modernization Act will not only be local. The perturbations will be forceful and long standing, and it is expected that supply chain partners will derive public health and economic benefit from the implementation of science-based preventive control strategies. Because FSMA rules will transcend national boundary considerations, it is important that all stakeholders have a voice in the process.

GHI Ambassadors and other members are encouraged to submit comments to the Executive Committee, which can be submitted to US regulatory officials by GHI representatives with US citizenship before the end of the consultation period (May 16, 2013).

A summary of the proposed rules as discussed above can be found at: <u>http://1.usa.gov/Z3NVGQ</u>

Larry Keener

Plastics and Paper 2012: GHI activities and issues of interest

Plastics and Paper Conference 2012 was held in Vienna (AT) on 11-14th December 2012, with high levels



of participation from government agencies, academia and the industry. The agenda included topics from evaluation of nonintentionally added substances (NIAS) to food contact materials (FCMs) using TTC (threshold of toxicological concern) for safety assessment as well as a detailed update on regulatory aspects glob-

ally, and enforcement control in Europe. Non-globally regulated substances were discussed; regulated at the national level, these include printing inks, nanomaterials, mineral oils in paper and board, and polymeric coatings (e.g. for metallic cans) and demonstrate the need for global harmonization.

There was a presentation from the European Food Safety Authority (EFSA) about future guidelines for FCMs, post-consumer recycled polypropylene, and product recalls in Europe, and presentation by Dr Roland Franz (IVV Fraunhofer Institute, Freising, DE), which discussed in detail experimental results and migration modelling for nanoparticles migration from FCMs. However, three jurisdictions appear to be dominating, namely the USFDA, the European Union, and Japan, which increasingly are taken as international points of references for new regulations.

'General situation of FCMs regulations in Latin America and an update of the MERCOSUR advancement' I provided an updated on the regulatory situation in Latin America; described GHI, its objectives and the book 'Ensuring Global Food Safety – Exploring Global Harmonization'; explained activities of the GHI FCMs Working Group (led by Eric Partington, UK) including its first meeting at AINIA in Valencia (ES) on 9th November 2012). I also described the role and activities of Universität für Bodenkultur (BOKU, Vienna, AT), the seat of the GHI; some attendants from industry were very pleased as they studied at BOKU.

On Thursday, 13th December, I visited Dr Gerhard Schleining, a member of the GHI Board, in Department of Food Science and Technology (DLWT) at BOKU. I was very impressed by the facilities on offer, particularly the research and sensory laboratories, and the pilot plant as well as some of their recent achievements. For example, a PC- programme recording and processing facial responses of sensory panellists. I was also interested to know that last year an Austrian beer manufactured at the pilot plant, by the students, was awarded the first prize at a German beer contest!

Plastics and Paper (P&P) is organized annually by Smithers Pira

(Surrey, UK - www.smitherspira.com).

Prof. Alejandro Ariosti, GHI Ambassador for Argentina

Correction

In issue 7 of the Newsletter, in the article by Huub Lelieveld and Hans Steinhart about the Global Harmonization Symposium "The need for global harmonization", that took place during the 16th IUFoST World Congress of Food Science and Technology in Foz do Iguaçu, Brazil, 5-9 August 2012, there was a mistake, corrected by the GHI Ambassador in Costa Rica:

The article mentioned that "Offices have been established in Brazil, China and India, and there is little doubt this initiative will impact global standards and regulations." The FDA, however, does **not** have an office in Brazil. The Latin American Regional Office is in San José, Costa Rica, which covers the whole region. Besides, FDA has an office in Mexico City and in Santiago, Chile.

Meeting data template

We are keen to announce relevant meetings in the GHI Newsletter and on the GHI website. To be able to do so in a useful way, appropriate information is needed. To make it easy, the following template may be copied and pasted in an email to Dr. Aleksandra Martinovic (aleksandram74@gmail.com), GHI Meetings Coordinator and GHI Ambassador for Montenegro.

Full name of the event: Details of location: Name venue: Street and number: Town: Province or state: Country: Web page: Start and time: End date and time: Website of the event Titles of GHI actvity*: Start date and time of GHI activity End date and time of GHI activity GHI officers or members involved: Names: Email addresses: Phone numbers:

*e.g. presentations, posters, working group meeting

GHI is an initiative of the European Federation of Food Science and Technology (**EFFoST**), which is the European part of the International Union of Food Science and Technology (**IUFoST**) and the International Division of the Institute of Food Technologists (**IFT**). GHI is supported by many other scientific organsations and receives support from the European Hygienic Engineering and Design Group (**EHEDG**).



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Chemical food safety Food contact materials Genetic toxicology High-pressure processing Listeria in RTE food Mycotoxins Nanotechnology Nutrition Regulatory aspects of reducing post harvest losses Food safety in relation to religious dietary laws

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- Mr. Eric Partington, UK
- Dr. Firouz Darroudi, The Netherlands
- Dr. Hosahalli S. Ramaswamy, Canada
- Dr. Cynthia Stewart, USA
- Dr. Naresh Magan, UK and Dr. Mark Shamtsyan, Russia
- Dr. Frans Kampers, Netherlands and Dr. An-I Yeh, Taiwan
- Dr. Vishweshwaraiah Prakash, India

Dr. Kenneth Marsh, USA

Ms. Isabella van Rijn, MSc, Netherlands and Mr. Ismail Odetokun, Nigeria



GHI Ambassadors

www.globalharmonization.net

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Become a GHI Member

If you are interested in becoming a member of GHI, we invite you

to take these simple steps:

- 1. Please visit 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.



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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