

ASTA 2007
Annual Meeting &
100th Anniversary
Celebration

Larry Keener

The Global Harmonization Initiative



Dana Point, California - April 19, 2007



The Global Harmonization Initiative



Seattle – Rotterdam – Vienna

Progress Report

Order of Discussion



- **Background information**
- **Drivers for harmonization**
- **GHI activities and actions**

GLOBAL HARMONIZATION



2004

LAUNCH OF GLOBAL HARMONIZATION INITIATIVE
TO PROMOTE THE ELIMINATION OF
DIFFERENCES IN REGULATIONS AND LEGISLATION



International Division



FoodSafety
magazine





GOAL

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



Strategy

1. Providing the foundation for sound, sensible, science-based regulation
2. Creating a forum for scientists and technologists to interact with regulatory authorities, globally
3. Providing industry and regulators an independent, authoritative information resource



Will Not

1. GHI **WILL NOT** DIRECTLY CHANGE REGULATIONS, BUT INTENDS TO PROVIDE TOOLS FOR PROMOTING HARMONIZATION
2. GHI **WILL NOT** REPEAT WORK THAT HAS BEEN DONE, BUT WILL COLLECT AND EVALUATE AVAILABLE DATA, TO PRODUCE DRAFT STATEMENTS RELATED TO CONTRAVERSEY IN SCIENCE AND REGULATION OF FOODS





Impetus



Food Supply Chain Globalization

Benefits of Harmonization

Harmonization Improves Health Risk Assessment



Harmonization establishes: common principles; transparency in risk understanding and assessment; facilitating use for regulatory purposes. Harmonization promotes best practice science, and enhances the availability of scientific information globally, thereby reducing costs.



Harmonization delivers sound science for development of sustainable regulations and promotes healthy populations



Drivers for Harmonization

Global Realities

- **Global disparity in food safety standards, and legislation**
- **Globally trade disputes and disruption in commerce due to food safety issues**
- **Globally billions of tons of food at risk of destruction due to food safety concerns**
- **Globally *840 million people suffer from lack of access to proper nutrition**

Supply Chain Partners of Tomorrow?

Growth Potential from Poverty Reduction

Country	Pop'n (000)	% < \$1/day	% < \$2/day
China	1299	16.6	46.7
India	1065	34.7	79.9
Indonesia	239	7.5	52.4
Brazil	184	8.2	22.4
Pakistan	159	13.4	65.6
Russia	144	6.1	23.8
Bangladesh	141	36.0	82.8
Nigeria	126	70.2	90.8
Mexico	105	9.9	26.3

Source: World Bank. [World Development Indicators](#) database (Bob Thompson, UI)

Source: CIA -World 6,536,473,538 Aug. 2006

Regulatory Trends

Among Industrialized Nations

1. Single agency focused on food safety
2. Use of risk analysis to design regulations (FSOs)
3. Recognition of the importance of the supply chain in addressing food safety hazards (ISO22000)
4. HACCP system as basis for new regulations for microbial pathogens in food (Juice HACCP)
5. More stringent standards for many food safety hazards
6. New and more extensive standards for novel processing and preservation techniques
7. Improving market performance in food safety through providing information (China)

EU Court Decision

9/28/06

Decision: *Animal derived foods introduced in the EU which fail mandatory testing must be seized and destroyed. The foods cannot be redirected back to the country of origin.*

Case: Involved frozen duck breast and rabbit imported from China.

The imported food was shown to contain residues of Furazolidone and Chloramphenicol; 49ppb and 1.4ppb respectively.

Note: Case sets new precedence for EU and mentions “Zero Tolerance”.

Role of National Governments

- Protect public health (**Food Safety**)
- Ensure adequacy of its food supply (**Security**)
- Promote trade and commerce (**Prosperity**)

Food Safety ?

Food safety is the biological, chemical or physical status of a food that will permit its consumption without incurring excessive risk of injury, morbidity or mortality.

“Judging food safety, is judging acceptability of risks - a normative, qualitative, or frequently a political activity”.

Global Food Safety Concerns

Biological hazards

- Bacteria
- Prions
- Viruses
- Protozoa

Chemical hazards

- Allergens
- Pesticides /agricultural
- Veterinary compounds
- Hormones

Novel technologies

- Genetic modification
- Novel preservation
- Novel foods
- Naïve populations

Building regulatory capacity

- Lack of oversight
- Lack of regulations and standards
- Extended supply chains

Global Regulatory Situation

1. Countries with *elaborate regulatory and science infrastructure* for evaluating food safety
2. Countries with *developing* regulatory and scientific capability
3. Countries *without* regulatory approvals process or scientific capability



Assessment of Food Safety Systems in the Americas

35* member nations of the PAHO/WHO

Cluster	N° of countries
1	3
2	14
3	5
4	4
5	3
6	3
7	1

Cluster 7 : only 1 country (Chile)
Cluster 1: best conditions in their food safety systems. (96% and 100%) (USA, Canada, Brazil)

Clusters 2 and 4: countries with lower development level in their food safety systems 25 to 60%, with average of 44% and 48% (do not even reach, on average, 50% of the conditions for the ideal system)

Clusters 3, 5, 6 and 7: with global average in their development level from 58% to 81% (Arg, Mx, Ven, etc.)

*Cuba and Haiti excluded due to insufficiency of information on their Food Safety Systems

Main weaknesses detected in 29 countries:

1. Absence or scarcity of provisions establishing **punishing mechanisms** and even control mechanisms
2. Absence or scarcity of **transparency** in the drafting of food regulations (no integration of entities related to the food area, provisions drafted by the government without consulting the remaining sectors)
3. **Insufficient harmonization with international standards** and lack of provisions referred to follow-up and confiscation of food in case of problems
4. Insufficient definition and delimitation of functions of governmental authorities (**overlapping of functions or loopholes in the appointment of competent authorities for the control of certain activities**)

Food Scares

Bisphenol A (BPA)

Salmonella

0157H7

Semicarbazide
(azodicarbonamides)

“Man-Made Chemicals in Food Products”

Sudan Red

Botulism

Benzene

Melamine

Acrylamide

Ochratoxin

Bisphenol A (BPA)

Scientists say evidence mounting that chemical in plastic is dangerous

BY MARLA CONE
Los Angeles Times

Evidence is mounting that a chemical in plastic may be risky in the small amounts that seep from bottles and food packaging, according to a report to be published this week in a scientific journal.

Authors of the report, who reviewed

“You can’t open a scientific journal related to sex hormones and not read an article that would just floor you about this chemical.”

FREDERICK VOM SAAL
Co-author of report

potent chemical as a sex hormone.”

In their study, vom Saal and Hughes suggest an explanation for conflicting results of studies: 100 percent of the 11 funded by chemical companies found no risk, while 90 percent of the 104 government-funded, nonindustry studies reported harmful effects.

Steven Hentges, executive director of the polycarbonate business unit of

Common plastic may not be safe; Bisphenol A used in food containers

April 14, 2005-The Toronto Star A2

Rita Daly

heated, cleaned with harsh detergents or exposed to acidic foods or drinks.

The plastics chemical is the focus of one of the most-contentious debates involving industrial compounds that can mimic sex hormones. Toxicologists say exposure to man-made hormones skews the developing reproductive systems and brains of newborn animals, and could be having the same effects on human fetuses

or the chemical, and 94 found harmful effects.

In an interview yesterday, vom Saal, a reproductive biologist at University of Missouri, Columbia, said there is now an “overwhelming weight of evidence” that the plastics compound is harmful.

“This is a snowball running down a hill, where the evidence is accumulating at a faster and faster rate,” vom

conclusion. It has an opinion, not a scientific conclusion.”

There has been an escalating battle between vom Saal and the chemical industry since 1997, the first to reveal mice exposed to triggered a rash of deaths by industry and

The chemical, i



Semicarbazide

(azodicarbonamides)

- **Plastisol liners for jar lids**
- **Seaweed and seaweed derived food ingredients**
- **Pesticide formulations**

Acrylamide

- **Traditional food preparation methods involving heating, i.e., deep fat frying, baking, brewed coffee**
- **Conventional methods heat preservation, i.e., hot fill and retort processing**

Sudan Red

- **Prohibited substance for addition to human food**
- **Found as contaminant in number of food items**
- **Massive recalls, Europe, Canada, Asia**

The Other Sudan Crisis

April 11, 2005

American Council on Science and Health (ACSH)

Elizabeth M. Whelan, Sc.D., M.P.H.

<http://www.acsh.org/>





Benzene

Hard Times for Soft Drinks

By [Michael Blanding](#), [AlterNet](#). Posted [March 13, 2006](#)



Soda has already been linked with weight gain and cavities; now the **FDA** admits that some popular soft drinks could contain a carcinogen. Will the fizz finally go flat?

Benzene in soft drinks

Wednesday 01 March 2006

Following reports of benzene in some soft drinks in the US, the **Food Standards Agency** asked the soft drinks industry to measure levels in the **UK**.

Benzene in Soft Drinks

Health Canada is aware of recent reports of benzene in soft drinks sold in the United States and is investigating the situation in Canada. Based on the limited information currently available, Health Canada is not recommending that consumers change their consumption habits.

US: Benzene talk not a concern – FDA

30 March 2006| **Source: just-drinks.com editorial team**

The Food and Drug Administration has played down rising concern over the presence of benzene in soft drinks.

“Man-Made Chemicals in Food Products”

27 food product assayed

- **Organochlorine pesticides**
- **Phthalates**
- **Alkylphenols**
- **PCBs**
- **Flame retardants (brominated)**
- **Organotin compounds**

Findings: Residues reported in all foods studied at 0.1 – 10ng/g

New York Times

April 3, 2007

Drugs Are in the Water. Does It Matter?

By CORNELIA DEAN

Residues of birth control pills, anti-depressants, painkillers, shampoos and a host of other compounds are finding their way into the nation's waterways, and they have public health and environmental officials in a regulatory quandary.

On the one hand, there is no evidence the traces of the chemicals found so far are harmful to human beings. On the other hand, it would seem cavalier to ignore them.

The pharmaceutical and personal care products, or P.P.C.P.'s, are being flushed into the nation's rivers from sewage treatment plants or leaching into groundwater from septic systems. According to the Environmental Protection Agency, researchers have found these substances, called "emerging contaminants," almost everywhere they have looked for them.

Most experts say their discovery reflects better sensing technology as much as anything else. Still, as Hal Zenick of the agency's office of research and development put it in an e-mail message, "there is uncertainty as to the risk to humans."

In part, that is because the extent and consequences of human exposure to these compounds, especially in combination, are "unknown," the Food and Drug Administration said in a review issued in 2005. And aging and increasingly medicated Americans are using more of these products than ever.



William Duke

So officials who deal with these compounds have the complex task of balancing reassurance that they take the situation seriously with reassurance that there is probably nothing to worry about. As a result, scientists in several government and private agencies are devising new ways to measure and analyze the compounds, determine their prevalence in the environment, figure out where they come from, how they move, where they end up and if they have any effects.

In many cases, the compounds enter the

water when people excrete them or wash them away in the shower. But some are flushed or washed down the drain when people discard outdated or unused drugs. So a number of states and localities around the country have started discouraging pharmacies, hospitals, nursing homes and residents from disposing of drugs this way. Some are setting up "pharmaceutical take-back locations" in drugstores or even police stations. Others are adding pharmaceuticals to the list of hazardous household waste, like left-

Continued on Page 8

Food Scares

(Fact, Fiction, Otherwise)

Consequences

**Destruction of
food products**

**Political Sanctions,
Tariffs, and Hysteria**

Legislation/Regulations



GOAL

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



Scientific Consensus

GH

**GLOBAL HARMONIZATION INITIATIVE
WORKING GROUP**



**ALL COMMENTS AND OPINIONS RECEIVED BY GHI
WILL CONSIDERED (ITERATIVE PROCESS)**

**GHI COLLABORATING EXPERTS WILL SEEK
CONSENSUS ON AN AGREED CONCLUSIONS**

**THIS CONCLUSIONS WILL BE PUBLISHED AS THE
CONSENSUS DOCUMENT ON THE PARTICULAR
CASE.**

SCIENTIFIC CONSENSUS BUILDING

GLOBAL HARMONIZATION



2004

**LAUNCH OF GLOBAL HARMONIZATION INITIATIVE
TO TRY TO ELIMINATE
DIFFERENCES IN REGULATIONS AND LEGISLATION**



International Division



FoodSafety
magazine





International Division



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Univerza v Ljubljani



Supporting Organizations

GHI MEETINGS

2004 – JULY	IFT SYMPOSIUM AND USA INAUGURAL MEETING LAS VEGAS
2004 - OCTOBER	EFFoST CONFERENCE AND EUROPEAN INAUGURAL MEETING WARSAW
2005 - APRIL	WORKSHOP CHICAGO, II, USA
2005 – JULY	IFT SYMPOSIUM AND PLANNING MEETING NEW ORLEANS
2005 - SEPTEMBER	EuCheMS CONFERENCE AND WORKSHOP HAMBURG, GERMANY
2005 - NOVEMBER	Fi CONFERENCE - SEMINAR PARIS, FRANCE
2006 - MARCH	FOOD SAFETY WORLD - WORKSHOP WASHINGTON DC, USA
2006 - MAY	EFFoST - EuCheMS - WORKSHOP SOFIA, BULGARIA
2006 - JUNE	IFT ANNUAL MEETING ORLANDO, FL, USA
2006 -SEPTEMBER	IUFoST CONFERENCE NANNTES, FRANCE
2006 SEPTEMBER	IFT/EFFoST NONTHERMAL DIV. WORKSHOP CORK, IRELAND
2007 – JULY	IFT ANNUAL MEETING CHICAGO, IL , USA
2007 AUGUST	EXECUTIVE COMMITTEE MEETING, VIENNA, AUSTRIA
2007 NOVEMBER	WORKSHOP LISBON, PORTUGAL

OTHER PRESENTATIONS



2005 SEPTEMBER	MUNICH DRINKTEC MÜNCHEN
2005 OCTOBER CONGRESS	WARSAW EASTERN EUROPEAN FOODtech
2006 SEPTEMBER WORKSHOP	CORK, IRELAND IFT/EFFoST NONTHERMAL DIV.
2006 SEPTEMBER	NANNTES, FRANCE IUFOST CONFERENCE
2006 SEPTEMBER	TUSKEGEE, UNIVERSITY - IFNC CONFERENCE
2006 OCTOBER CENTER CONFERENCE	MELBOURNE, AUSTRALIA 3RD INNOVATIVE FOOD
2006 OCTOBER	CANBERRA, AUSTRALIA - FOOD STANDARDS
AUSTRALIA /NEW ZEALAND	



PUBLICATIONS



2004 SEP:  GUEST COLUMN: REMOVE THE DIFFERENCE

2004 SEP: TIFS - GLOBAL HARMONISATION OF FOOD LEGISLATION

2004 NOV:  THE WAY FORWARD

2005 APR:  EDITORIAL

2005 SEP: INTERNATIONAL FOOD INGREDIENTS

2005 AUG: NEWS BITES IN 

2005 AUG:  NEWSLINE - GLOBAL HARMONISATION OF FOOD
REGULATIONS AND LEGISLATION

2005 SEP:  - WEBSITE: GHI'S PLANS

2005 OCT:  GREEN LIGHT ON HARMONIZED FS

2005 DEC:  PUTTING SCIENCE FIRST

2005 DEC: FOOD SAFETY EUROPE: ALL FOR ONE AND ONE FOR ALL

2006 JAN:  INTERNATIONAL REVIEW OF FOOD SCIENCE - CAN GLOBAL
HARMONIZATION OF FOOD LEGISLATION BE ACHIEVED?



SUPERVISORY BOARD

CONSISTING OF REPRESENTATIVES OF SCIENTIFIC ORGANIZATIONS AND STAKEHOLDERS

- TO GUARD THE IMPARTIALITY AND INTEGRITY OF THE CONSENSUS PROCESS
- TO ELECT MEMBERS OF THE EXECUTIVE COMMITTEE

EXECUTIVE COMMITTEE

ELECTED BY THE BOARD OF SUPERVISORS

- TO MANAGE THE EXECUTION OF ACTIVITIES ACCORDING TO THE CHARTER
- TO ELECT CO-CHAIR

SECRETARIAT

PUBLIC RELATIONS OFFICER

CO-CHAIRS

ELECTED BY THE EXECUTIVE COMMITTEE

- TO CHAIR THE EXECUTIVE COMMITTEE
- TO ACT AS PRIMARY CONTACTS FOR WORKING GROUPS

Unpaid

Paid when possible

WORKING GROUPS



Current Activities

- 1. Identifying additional scientific organizations to be invited to join the Initiative as member organizations**
- 2. Identifying individual food scientists, technologists and engineers, working in academia, food companies, institutes and scientific organizations, to be invited to join as individual scientific members**
- 3. Creating a position paper identifying and explaining the relevant issues affecting the global food industry**
- 4. Developing a strategy to find the shortest route to achieving global harmonization in concert with international standard-setting bodies such as the Codex Alimentarius Commission and the International Organization for Standardization (ISO) that are working on similar efforts.**
- 5. Developing a constitution and by laws**
- 6. Registering GHI as a legal entity**



GHI Registers as Legal Entity- Vienna, Austria 2007



University of Vienna



WEBSITE: WWW.GLOBALHARMONIZATION.ORG



GLOBAL HARMONIZATION INITIATIVE
WORKING GROUP

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Search this site

info@globalharmonization.org

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What is the Global Harmonization Initiative?

There's no question that as the avenues of global trade widen, the higher the probability of "traffic" jams in worldwide commerce. Barriers to trade in the form of differing—and sometimes, conflicting—country-by-country import/export rules and requirements, can and do make it difficult for food businesses to get traction in overseas markets. In an attempt to eliminate these hurdles, a network of scientific organizations has launched a global initiative to facilitate harmonization of food safety regulations and legislation. The objective is to discuss, globally, the scientific issues that buttress the decisions made by individual governments and international regulatory bodies in order to achieve global scientific consensus on such issues. The Global Harmonization Initiative (GHI) Working Group anticipates that elimination of the regulatory differences will make it more attractive for the private sector to invest in food safety R&D, consequently strengthening the competitiveness of each nation's food industry and of the industries supplying the food sector. [>> More](#)

News

28 November 2005:

"You are invited to comment on the [draft Charter](#)."

"You are also invited to comment on the [GHI definitions on membership and experts](#)."

Please send in your comments to info@globalharmonization.org

Calender

**8 March 2006 Food Safety
World Conference [Workshop](#)
[GHI: International
Developments in Risk
Management](#):**

**June 24-28 2006 Orlando, FL
[Symposium IFT Annual
Meeting + FOOD EXPO](#)**

How to Join!

Interested organizations and individual industry scientists and professionals are encouraged to participate in this worldwide effort.

Please contact us at:

info@globalharmonization.org

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Thank You!