

Global harmonization of food regulations and legislation—the Global Harmonization Initiative

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It is generally assumed around the world that food is safe. Food must be safe, for its intended use for human consumption, but food safety and regulatory measures should not unnecessarily hamper the availability of human food or hamper the introduction of novel processing methods aimed at retaining the natural healthy properties of food.

The global availability of safe and wholesome food products

Food safety regulations have been devised to protect the consumer. Substances that had harmed humans were listed as toxic and therefore considered unacceptable in food. Absence of such substances merely meant undetectable by the methods available. At the time that most of the regulations were developed, however, analytical techniques were not well refined yet and absence usually meant less than a few milligrams per kg of product. Unintentionally, absence has got a different meaning with time as with time, the detection

limits went down and currently many substances may be detectable in nano- or even picograms per kg of product. In practice this means that where absence of substances is required, the concentration must be between a *million* or a *billion* times lower than at the time the regulations were established. Governments have a duty to ensure that the law is maintained and so must food safety inspectors. This may have fundamentally unacceptable consequences, such as consumers being denied essential nutrients and food needlessly being destroyed because it contains harmless concentrations of legally forbidden substances. This happens while it is known for 500 years that toxicity is a matter of concentration. Many compounds are essential for good health in certain concentrations while toxic in another higher concentration (“All substances are poisons: there is none which is not a poison. The right dose differentiates a poison and a remedy.” Paracelsus, 1493–1541).

Under-nutrition

A total of 1.25 billion people live on less than US\$1 per day, of whom 840 million suffer under-nutrition or hunger (Robert L. Thompson, chairman International Food & Agriculture Trade Policy Council, New Orleans, 19 July 2005).

Toxicity of an essential nutrient

Consumption of 200–250 mg iron/kg body weight is lethal. We get ill and eventually die if we do not consume enough iron.

Food preservation and desirable properties

Because safe food must be available around the year, food and food products must be preserved. Traditionally this is done by lowering the water activity (drying, addition of sugar and salt), increasing acidity (by addition of e.g. citric or lactic acid, or by fermentation), by the addition of preserving chemicals (such as sorbic acid) or by heat treatments. To limit damage to the food, combinations are used, for instance, with most jams (marmalades), where the addition of sugar and citric acid makes it possible to make the product safe for consumption for very long periods of time by giving

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it a pasteurisation treatment instead of a far more severe thermal sterilisation treatment. For many products, however, such treatments are still harmful, adversely affecting flavour, colour and nutrients. For over a 100 years, scientists have been looking for alternatives that would stabilise the product without losing its desirable properties. It is, however, only rather recently that such technologies reached a state that commercial application has become a realistic option, mainly as the result of a vast amount of—partly governmental or EU funded—research. It has been demonstrated that many food products may be preserved by novel methods with much less damage to the product than with the traditional methods, thus meeting consumer demands.

Health benefits

In the past two decennia, scientists became to understand the relation between food consumed and health. This led to the identification of food constituents that reduced health risks. For instance, the discovery that plant stanols and plant sterols, as well as certain types of husks, all of natural plant origin, may effectively reduce the concentration of low-density lipoprotein (LDL) cholesterol in blood led to the developments of a range of new products that fit in a healthy life style.

Global harmonization

Application of these insights, however, requires demonstration that the products developed are safe. This self-evidently is a fully justified requirement. The bad news, however, is that due to the differences in regulations between nations, demonstration of safety may have to be repeated over and over again, depending on where the products are produced, from where they or their ingredients originate or to where they are exported. The time and costs involved at least delay the availability of desirable products and in worse cases, products do not reach the market at all.

Having to prove safety only once, in a single country according to globally agreed protocols, would significantly reduce these hurdles and thereby also increase the interest in further research into novel methods and ingredients. This requires that food safety regulations and legislation have to be harmonised, *globally*. Food safety legislation often requires evidence produced by animal testing that is, mildly expressed, not popular. Apart from the debate about how relevant animal testing really is to establish safety requirements for humans, having to do such tests only once and the result being globally accepted would be a significant step in a highly desirable direction.

Food contact materials should not release toxic substances

Equipment manufacturers need to be certain about the composition of the materials used for constructions intended for contact with food.

Example

Conveyor belts may consist of stainless steel, polymer materials and require lubrication. Consequently, depending on conditions of use, food might come in contact with a whole range of potential contaminants:
Stainless steel: iron, chromium, nickel, molybdenum, titanium, ...
Polymer material: plasticisers, catalysts, stabilisers, fillers, pigments, ...
Lubricants: antimicrobials, antioxidants, rust inhibitors, anti-foaming agents, viscosity extenders...

Risk communication

Consequently, regulators and hence politicians, have to be convinced that changes are needed. This is not easy as scientists often have difficulty with communication. They like to use the scientifically correct wording and that may easily be misunderstood. As Dr. Coughlin expressed it at a recent food safety conference (Orlando, June 2006), “un-definable risk” is likely to be perceived as “unavoidable harm”. Because most people are not scientists, from an electoral point of view it’s easier to listen to the *vox populi*. One of the manifestations or consequences of this reality is adoption of the precautionary principle within the EU. In short, this principle requires the provision of objective scientific data for purposes of demonstrating food safety where the public health status of a substance has been called into question; whether or not there is a long history of the substance’s safe use as food.

Risk–benefit analysis

Reduction in the use of pesticides will not effectively prevent diet-related cancer. Diets high in fruits and vegetables, which are the source of most human exposures to pesticide residues, are associated with reduced risk of many types of cancer. Less use of synthetic pesticides would increase costs of fruits and vegetables and, thus, likely reduce consumption, especially among people with low incomes, who spend a higher percentage of their income on food (Lois Swirsky Gold, Thomas H. Slone, Neela B. Manley and Bruce N. Ames, The Fraser Institute—Centre for Studies in Risk, Regulation and Environment, Vancouver, British Columbia, Canada, 2002).

It is not our intention to advocate carelessness or poor science in risk assessment. To the contrary, it is our position that any and all potential adverse effects that may have resulted from a new process should be subjected to the most careful scientific scrutiny. It is our view, however, that it is a waste of time and resources to require approval in several countries, each demanding similar data produced by different protocols. What is needed are globally agreed protocols and a system to ensure that those protocols are

followed accurately. Once checked and perhaps double checked, the results should apply universally. Organisations or individuals, despite proven safety, who make statements calling into question the safety of a process, should be required to provide a sound scientific basis for their objection or in support of their position.

Similar questions and issues relating to food production and food safety are frequently raised about every aspect of the supply chain from farming to retail. For instance, does the use of hormones and antibiotics affect the safety of the meat? When is food kosher? Are all spices safe? Are microorganisms used to ferment food always safe? Pesticides may be essential to be able to produce enough food, when are they safe and when harmful? Microbicides (fungicides, bactericides), which are more harmful, microbicides or microbes? Pesticides or pests? On another front: what are food additives and what are processing aids? Regrettably, at this moment in time, it depends on where you live. In short, the question is... “what is the balance between benefit and safety risk?”

Chloramphenicol

In 2001, the EU decided to destroy a large amount of fish containing minute amounts of chloramphenicol. Chloramphenicol is an antibiotic produced by *Streptomyces venezuelae* that is frequently prescribed for humans and other mammals. On 28 September 2006, the European Court of Justice, considering that zero-tolerance applies to furazolidone and chloramphenicol, ruled that EU countries must seize and destroy meat containing such substances, even if containing just ppbs.

The Global Harmonization Initiative

It is for all those reasons discussed above that a few years ago, scientists involved in various scientific organisations, dealing with food science and technology, decided that it ought to be possible to harmonise food regulations and legislation, i.e. having the same rules and food laws everywhere on the globe. In 2004 the International Division of IFT and the European Federation of Food Science and Technology (EFFoST), in cooperation with Food Safety Magazine and Elsevier Science launched the Global Harmonization Initiative (GHI) to try to eliminate differences in regulations and legislation. Soon after this event, many other organisations have joined, including the International Union of Food Science and Technology (IUFoST), the Federation of European Microbiological Societies (FEMS), the Food Chemistry Division of the European Association for Chemical and Molecular Sciences (EuCheMS) and the European Hygienic Engineering and Design Group (EHEDG). In addition, scientific research organisations, such as the National Center for Food Safety & Technology (NCFST) in Chicago and food science & technology departments of universities all over the world have joined.

Scientific consensus

It is realised that GHI on its own will not be able to change regulations anywhere—let alone globally. GHI intends to establish whether global consensus is possible on issues that buttress such regulations. This requires the participation of responsible food scientists from all over the world and identification of experts. Publication of the results of the Global Harmonization Initiative will make it more difficult to abuse science. By obtaining global scientific consensus on food related issues, it will be hard for antis to find scientists who are willing to support unjustified statements. It will also be hard to counter or deny requests to governments for changes in regulations that are not based on sound scientific data.

The intention is not to promote a “no” or “yes” for particular cases, but to carefully review available evidence to see whether or not a consensus statement on safety can be made. There may be issues where the “yes” or “no” depend on circumstances, e.g. the method of use or the use by certain populations. For instance, lactose is a natural constituent of bovine milk. While for some populations lactose is a harmless energy source, for other populations it is a toxic substance. Likewise, peanuts are a staple in the diets of billions of people around the world, whereas for thousands of others they are a constant threat of anaphylaxis. In other cases there may be lack of evidence either way. In such cases research to obtain such evidence shall be proposed.

Harmonising organisations

It is realised that many organisations attempt to harmonise regulations and standards to which legislation refers. These organisations include Codex Alimentarius (a joint United Nations and World Health Organization commission), the World Trade Organisation (WTO), standardisation organisations such as ISO and organisations such as the European Food Safety Authority (EFSA). By far not all nations participate in these organisations and some may be politically biased or perceived to be biased. Nevertheless, the GHI will not repeat work done. To the contrary, where statements based on scientific evidence exist, they will be reviewed and most likely often be adopted as DRAFT consensus statements. Such statements may originate from organisations such as Codex Alimentarius, the International Commission for the Microbiological Specifications for Food (ICMSF), the European Food Safety Authority (EFSA), and the International Life Sciences Institute (ILSI). The GHI therefore is very pleased with participation of scientists involved in these and other organisations with similar goals.

Meanwhile, there has been a range of GHI meetings, including symposia and workshops, in places like Las Vegas, Warsaw, Lisle, New Orleans, Hamburg, Sofia, Orlando, Nantes, Cork and The Hague. Reports on these events and presentations can be found on the web site www.globalharmonization.org. This has resulted in a Charter (see below).

GHI membership

The process to identify relevant scientific organisations has been started. These organisations will be requested to inform their members about the GHI and to invite them to join GHI as scientific members. To avoid any financial hurdles, membership will be free, but to qualify, the following information must be provided:

- Names and titles
- Mail and email address
- Nationality (to ascertain that we shall have members in all nations)
- Education
- Membership(s) of scientific or professional organisations

- Current position
- Areas of expertise
- Years of experience in food science and technology
- CV
- Statement on why interested in GHI and scientific consensus

GHI experts

GHI is not after obtaining consensus between scientific organisations or any official bodies, but after consensus between individual scientists, regardless of their affiliations. This leads us to one of the most important but at the same time perhaps most difficult tasks for the GHI group: how to identify the real scientific experts and how to ensure that



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

CHARTER

The goal of the initiative is to ensure the global availability of safe and wholesome food products for all consumers.

To achieve this, undue barriers to free trade that masquerade as food safety protections must be vanquished. Such barriers include differences in regulations and legislation between countries globally. The international scientific community must, therefore, work towards achieving global consensus on the science underpinning food regulations and legislation. This will be achieved through attainment of the following objectives:

1. Identifying relevant scientific organizations
2. Inviting and encouraging the participation of these scientific societies in the global harmonization initiative and inviting their members to join in this activity in their field of expertise.
3. Identifying relevant non-scientific stakeholders
4. Establishing effective communication between non-scientific and scientific organizations.
5. Inviting all stakeholders (organizations and individuals) to identify and submit key issues requiring attention.
6. Prioritizing key issues with the subsequent formation of working groups to draft white papers or consensus statements regarding the scientific validity of these issues.
7. Steering working groups to assess the best available evidence and discuss their findings with the scientific community, working towards building consensus.
8. Publishing results on a per issue basis in journals, magazines and newspapers
9. Publishing collections of resulting consensus statements in book form
10. Presenting results and participating in appropriate conferences
11. Making results available to all stakeholders, particularly those responsible for developing or amending regulations and legislation, global communicators, risk managers and assessors.

All of these will be done in an open, transparent manner, to avoid bias or the appearance of bias, political or otherwise.

they will be able to participate in an independent way. Several discussions took place on the identification of experts. The initiative would fail if everybody could sign up as an expert on everything that he or she feels is something to be influenced. It is imperative that evidence of expertise is provided. To qualify as an expert, therefore, candidates need to provide:

- Name + contact details
- Education details
- Scientific expertise
- Experience
- Supporting letters of at least two peers with no business relation to the candidate
- List of peer-reviewed publications
- Any other information considered to be relevant

Operation procedure

Another activity that has been started is developing the consensus “operation procedure”. The first step will have to be identification of issues and then prioritising them. Proposed issues must be presented with justification and any opinion of an issue must be accompanied by evidence. In the follow-up of this process, we may depend on the availability of experts as working parties need to be set up to evaluate evidence provided. There will be a stage when a DRAFT consensus statement can be produced for circulation among all other experts on the subject and for publication on the GHI web site. The next phase may be quite effort intensive as replies need to be classified and evaluated and the process may have to be repeated several times.

Financing

So far, all the GHI work is done by volunteers who believe that the Initiative is worth the effort, but it is envisaged that

for success, funds are required as staff will be needed to deal with the necessary correspondence and archiving. Here, the GHI group faces a severe difficulty. Although stakeholders may play a role in providing issues and submitting evidence, the GHI group needs to be independent of stakeholders and therefore cannot and will not accept financial support from either industry or governments. How then to solve this problem? After considerable debate, it has been decided that support from scientific organisations is essential and need not affect impartiality. Recognising that scientific organisations are unlikely to have the funds to finance the entire operation, these organisations may decide to attempt to raise funds from, e.g. governments, industries, charities and individual members in any way, to secure resources required. Provided, however, that the organisations will in no way press the GHI to focus on specific issues on the behalf of any pressure group. The GHI should be kept unaware of the stakeholders that provide financial support to the scientific organisations. The reason that stakeholders would support the initiative despite not being recognised as such should lay in the fact that they *are* stakeholders, i.e. they will eventually benefit from global harmonization of food regulations and legislation. In line with the GHI Charter, any funding received by the GHI will be fully justified on the GHI web site and be open to inspection by participating scientific organisations.

GHI Foundation

To ensure that GHI will be able to operate professionally without losing impartiality, a GHI Foundation will be established in Vienna, Austria, with the Charter as the core of the constitution. Only employees will be paid. Of all others, only reasonable costs, such as for travelling, lodging and teleconferencing will be funded. The structure of the organisations is presented below:

