Scientific Bulletin. Series F. Biotechnologies, Vol. XXI, 2017
ISSN 2285-1364, CD-ROM ISSN 2285-5521, ISSN Online 2285-1372, ISSN-L 2285-1364

WHY HARMONIZE FOOD REGULATIONS AND WHAT IS NEEDED TO MAKE IT WORK?

Huub LELIEVELD

University of Bodenkultur, GHI-Association; c/o Department of Food Science & Technology, 18 Muthgasse, 1190, Vienna, Austria

Corresponding author email: huub.lelieveld@globalharmonization.net

Abstract

Regrettably after decades of negotiations between countries and supranational organizations, there are still too many differences that hamper movement of safe food across borders and hamper innovations and it does not look like the differences will disappear soon. Therefore, where possible, serious scientists should continue to work together to provide scientifically correct evidence that may be used as tools by stakeholders to try influence negotiations and to try convince local authorities that harmonization is in the interest of everybody. To make it work in practice requires that those who need to know and that means most people, at all levels, understand the scientific evidence. Not only large companies are affected by unjustified differences in regulations, but also small companies and street vendors and ultimately all consumers, who in many countries have a democratic vote and thus are influential. In turn this makes it necessary that the science is translated in a language that those who need to know understand. The Global Harmonization Initiative therefore not only tries to find consensus on scientific issues, but also seeks means to make the findings understood by everybody, requiring simplification, but without losing the true scientific facts, and translation into local languages. Then having the results published in scientific journals, popular scientific magazines, newspapers and magazines aimed at the general public. Another crucial aspect is that those who do the negotiations understand what they are talking about, because expressions used in regulations and during negotiations tend to have – often vastly - different meanings in different countries or regions.

Key words: *food safety regulations, food security, harmonization, science-based, toxicity.*

INTRODUCTION

The fact that every year an estimated 600 million (almost 1 in 10 people in the world) fall ill after eating contaminated food and that 420,000 of them die (WHO, 2015), indicates that effective regulations are needed to protect consumers from safety hazards and misleading information. Regrettably, however, food regulations often differ between countries, often even between neighbouring countries, despite declarations by many countries and international organisations that harmonization is necessary. Moreover, the regulations often have no scientific basis and are factually wrong. The processes of harmonizing, however, seem to be extremely difficult and very slow, requiring persistence and willingness to accept changes in existing regulations. Many meetings between representatives of participating countries are needed to make progress and meetings often take place just once annually. It therefore looks like the differences will persist for a long time – if not forever. That these differences exist is the reason for many food safety and food security problems in the world, especially in low-income countries. The differences hamper trade, because of difficulties at the border between countries. In particular small trading companies often are unaware of the differences and discover them when their food products reach the border. Much food and many food products are perishable and delays at the border for inspection and negotiation with authorities are costly. A selection of examples will be discussed that illustrates the consequence of the regulatory differences. In the worst case authorities seize and destroy food and food products that are in reality healthy, only because the law requires so and challenging the correctness of the law is virtually impossible under such circumstances.

TOXICITY AND CARCINOGENICITY

Differences in regulations may be used to hide protectionism as seems to be the case with the maximum residual level (MRL) of carbendazim in orange juice in the USA. Carbendazim is one of the few pesticides that are allowed to protect oranges (and other produce) from spoilage by moulds. Because carbendazim is safe in the concentrations needed, it is allowed in most countries. The maximum residual level (MRL) allowed in the European Union is between 100 and 700 parts per billion (ppb; parts per 10^9) and in Canada between 500 and 6000 ppb. The MRL in the USA is 10 ppb

and the FDA decided that “to ensure the continued safety of orange juice FDA is also sampling import shipments of orange juice and will deny entry to shipments that test positive for carbendazim.” (FDA, 2012a). Interestingly the US Environmental Protection Agency stated “There is no public health concern from drinking orange juice containing carbendazim at reported levels” (FDA, 2012b).

In 2005 the UK government ordered the destruction of £100,000,000 worth of food products because these products contained trace amounts of Sudan Red 1, originating from chilli powder used as an ingredient. At the time, Dr. Julie Sharp representing Cancer Research UK declared "The risk of cancer in humans from Sudan Red I has not been proven and any risk from these foods is likely to be very small indeed." And indeed, a person who drinks 800 litres per day of contaminated Worchester sauce for the rest of his life has a chance to suffer damage from the chemical; based on animal testing. Be aware that there are no known cases of cancer caused by Sudan Red 1 in humans.

Nature is a producer of chemicals that are suspected to be only man made (exogenous chemicals). Chemicals that are not allowed but nevertheless present in food, however, are not necessarily additives. Most man-made chemicals also occur in nature in concentrations that due to much better techniques can be detected now, but not previously. They are produced by animals, microbes (bacteria, fungi, parasites), plants and geochemical processes (e.g. volcanoes). They include e.g., chlorinated organic compounds. More than 5000 different natural organic halogens have been identified in nature (Gribble, 2003; Gribble, 2011).

All food and food products originate from nature, being exposed to soil and air. Soil is produced by microbes and microbes produce antibiotics, causing the presence of low concentrations of antibiotics in soil. Consequently produce growing on or in the soil, will contain low concentrations of antibiotics and so does meat, because the feed cattle consume grows on the soil. In 2006 the European Court of Justice ruled that food containing trace amounts of antibiotics, no matter how minute the amount, must be seized and destroyed (Court of Justice, 2006). In this particular case the antibiotics were furazolidone and chloramphenicol in meat. These antibiotics have frequently been administered in million times higher quantities than found in the food for several successive days to treat infections in babies in developed countries. In the case reference is made to a similar dispute in 2002 about frozen duck breasts and rabbit meat from China, consignments that were accompanied by health and export certificates issued by the Chinese authorities for dispatch purposes. In these products residues of chloramphenicol (1.4 ppb) and furazolidone (49 ppb) were detected in the duck breast and residues of furazolidone (2.7 ppb) in the rabbit meat. Regulations about the use of antibiotics in animal husbandry and fishery differ between countries. This applies to what antibiotics are allowed and to the concentrations considered acceptable in the product (Collignon and Voss, 2015). The EU law requires absence, “zero tolerance”. The meaning of “absence” and thus the meaning of the law have become dependent on sensitivity of analytical techniques and often have little to do with safety of the product. In China, the concentrations reported are considered safe. Developing countries often export the best quality of their products to developed countries, leaving lower quality for the local population. The EU position is that the food must be destroyed and is not allowed to be returned to the country of origin. It is distressing that the best food from a country is destroyed for scientifically unjustifiable reasons, leaving a population suffering from poorer quality of food.

In June 2014 in The Netherlands furazolidone was found in meat making the government order the destruction of 2474 calves to protect consumers, despite the statement of the Netherlands Food and Consumer Product Safety Authority that the meat was safe to eat. The average exposure to humans eating meat would be only 1.2 µg per meal (and worst case 8 µg per meal). The internationally recognized amount to cause potential harm is 3 µg per day during a life time (i.e. 50 or 70 years). There are no reports of harmful effects of therapeutic doses of 200 mg per day during 21 days (WHO, 1993), which is 25,000 times more than the worst case amount.

One of the reasons why the general public is concerned about chemicals is the conviction that chemicals are carcinogenic. This is because anytime a chemical is mentioned in the press as being carcinogenic, only the chemical is mentioned and not the amount needed to make the chemical carcinogenic. While for some chemicals like aflatoxin, very small amounts may cause cancer, other chemicals must be present for a long time in a high concentration. Moreover, it depends on whether the chemical is administered as a pure chemical or in a food matrix, the way it usually enters the body. Our body consists for more than 0.3 % of sodium chloride (NaCl). Nevertheless, even NaCl is carcinogenic (WCRF/AICR, 2007). Globally many people drink coffee every day.

Coffee contains many confirmed carcinogens, including acetaldehyde, benzaldehyde, benzene, benzofuran, benzo(a)pyrene, caffeic acid, catechol, 1,2,5,6-dibenzanthracene, formaldehyde, etc. These compounds are present in relevant concentrations. Nevertheless, a thorough review of 1277 studies done in the period 1970-2015 shows that the consumption of moderate amounts of coffee does not increase the risk of developing cancer (Pourshahidi, 2016). It is time that publicists will publish in such a way that also the general public understands the meaning of studies of carcinogenicity. It should be made perfectly clear that the research is done using animals and giving these animals high doses in a short time to approach small doses over a long period of time. Moreover, the chemicals tested are not administered in a natural food matrix as in the normal way of consumption. Finally, it ought to be mentioned that if animals develop cancer from a chemical this does not prove that humans would do so too. There is a vast amount of evidence that this often is not the case (Bracken, 2008). There are in-vitro methods that are more accurate, fully relevant to humans, cheaper, and provide results in a single day. These in-vitro methods are 100% relevant to humans because they make use of competent human liver cells (Darroudi, 2010).

Lessons

Firstly, there is an almost complete lack of understanding by politicians, the general public and authorities that toxicity is **never** a matter of a substance alone but always a matter of a certain amount of a substance. For every substance there is an amount where it does not do harm and there is an amount that is deadly. In between, the substance can be healthy, mildly unhealthy or sickening. Absence may also be unhealthy and may also cause death. Laws or regulations that require total absence are absurd, because virtually nothing is totally absent in the environment and hence also in food. By requiring absence, the methods of analysis determine what is considered safe. A few decades ago "absence" meant for many products less than a few milligrams (mg,
10^{-3} g), because of the detection limits of the methods of analysis that were available. Since then methods of analysis have improved tremendously and most substances can be measured in quantities of picograms (10^{-12} g), femtograms (10^{-15}g) or even less. The presence of chemicals in such small amounts is often natural and hence, unavoidable. The presence of picograms or femtograms of substances in food, however, means that the substance is not absent and legally such food is not in compliance with regulations that require absence.

The second issue is that regrettably there are (pseudo)scientists who make money by scaring people and publishing about food safety what since the presidential election in the USA in 2017 have become known as "alternative facts". If something has a chemical name, it probably is toxic or carcinogenic and will harm your health. If in the European Union it has an E-number, it is because they want to hide that it is something with a chemical name. Thirdly, regulations that are based on "alternative facts" leave no room for common sense and judges who in most cases are not food scientists or toxicologists, have no freedom to reach sensible conclusions. Fourthly, there are companies that are led by greedy people who care about shareholder value and bonuses, not about the health of people.

MICROBIOLOGICAL FOOD SAFETY

Although the general public tend to be much more interested in chemical food safety, most food safety incidents are caused by microbes. Contrary to chemicals, microbes can multiply and that usually is the reason for safety incidents. Healthy people rarely get ill from eating food that has a low number of microbes, but if the number increases the situation changes. There can be two main reasons for illness, firstly the microorganisms themselves may cause illness by destroying the cells that constitute human organs (e.g., Salmonella and Listeria strains) others produce toxic substances (e.g., Staphylococci and Bacillus strains). To present a serious risk, a certain number is required, the "infectious dose". For a few types of microbes the infectious dose can be just a few while for others it may be several millions. It depends on the individual's health and also the type of food. Some food effectively neutralize the acidity in the stomach and thereby makes an important barrier ineffective. To produce enough toxin to make a healthy person ill, in most cases many millions of bacteria are needed and therefore, the cause usually is the growth of toxigenic bacteria in the food before it is consumed. In most instances food poisoning happens during preparation when not enough attention is paid to hygiene. The number of people per incident is then relatively low, although in cases where restaurants are the source of the incident, still hundreds of people may be affected. Matters, however, can be very bad when a food processing company is ignoring hygiene or is fumbling with the processing conditions (such as pasteurization, cooking at the required temperature or drying) that are intended to make the food products safe. In such cases thousands or more people may be affected.

In 1985 a Mexican company produced Queso Fresco, a Mexican-style soft cheese, from unpasteurized milk that contained *Listeria monocytogenes.* This resulted in 62 deaths (CDC, 1985). It took authorities a month to find the source of this outbreak of listeriosis. In 1993 there was an outbreak of *Escherichia coli* O157:H7 in Jack in the Box restaurants in the USA. The outbreak was traced back to undercooked meat contaminated with faecal matter. The company had ten months earlier been warned about using undercooked burgers and contaminated beef, but went on with their practices. It caused 4 deaths and up to 700 people getting ill (CDC, 1993). In 2011 there was an outbreak of a foodborne disease in Germany caused by *Escherichia coli* O104:H4 (EHEC) causing Haemolytic Uremic Syndrome (HUS). Because it was very difficult to find the source, this became one of the world's most widespread outbreaks of foodborne illnesses with 3950 people getting ill and 53 died. First cucumbers from Spain and the Netherlands were suspected as source of infection. Follow up studies failed to confirm that cucumber was the source. Finally the European Food and Safety Authority (EFSA) found the source to be fenugreek seeds imported from Egypt. The distributor had sold the seeds to 70 companies, 50 of them in Germany who used them to grow sprouts. (CDC, 2011). In 2008-2009 there was an outbreak of foodborne illness in the US, where more than 700 people got ill and 9 people died. The source was found to be products with ingredients from the Peanut Corporation America (PCA) that were contaminated with *Salmonella thyphimurium*. Albeit being aware of the contamination of their ingredients, they still sold them leading to an enormous foodborne infection scandal involving 46 states, 360 companies and 3,900 infected products with PCA product ingredients. The owner of the Peanut Company America received the largest criminal sentence of all food safety cases; 28 years of prison (CDC, 2009).

Lessons

There are three major causes of incidents that cause severe damage to the health of many people and even deaths. Firstly there are professionals in the companies who know but do not want or dare to speak out. If they report to their superiors, they are put under pressure to deny and hide the facts and go on with their job or lose it. Secondly, companies do not have the knowledge, expertise and/or capacity to ensure that the food or food products they make are safe. If this is the case, the company should not be allowed to produce food before they meet these requirements. Thirdly, of course there can be a new, unknown cause that could not be predicted or in any case had not been predicted. For everything there is a first case. As soon as the incident has been reported and the incident is serious, i.e. may lead to severe health problems, information available should carefully but also quickly be checked for correctness and then be shared with authorities and made public in an understandable way.

MYCOTOXINS

As mentioned earlier, all food and food products originate from nature, and thus have been exposed to soil and air. Under certain but in many countries often prevailing circumstances nature supports the growth of moulds that produce harmful substances that are toxic in very low concentrations: mycotoxins. In some countries this problem causes half of the harvest of staple food to become unfit for consumption. Because of the scarcity of food, in many cases people still consume such food with devastating consequences – no time for developing tumours, but acute poisoning leading to a very painful process of dying. Much is known about controlling the growth of the harmful moulds, during the growth phase (e.g., methods to keep the top of the soil dry), during transport (by better protection of the products, avoiding moulds passing the skin of the products) and during storage (e.g., controlling the humidity by thermal insulation of silos) (Aldred *et al*., 2004; Shapira and Paster, 2004). Where the soil is contaminated with too high concentrations of mycotoxins the roots of the crop will absorb the toxin (Hariprasad, 2013). Growing crops on such soil should not be allowed. Methods to abate these problems, however, are applied only in some regions, regrettably not everywhere. This is partly because they are not known everywhere and partly because they require investments.

GENETICALLY MODIFIED ORGANISMS

Crops can be enhanced and losses be limited by using genetically modified crops. The use of GMO crops is an important method to alleviate hunger on the southern hemisphere (Herrera-Estrella and Alvarez-Morales, 2001). In the developed world, it is easy to find support for abandoning genetically modified food. There is no shortage of food and is very lucrative to be against it as a (pseudo)scientist. Writing books that are negative about GMOs may make them bestsellers. Many NGOs have been founded to fight against GMOs, researchers received and receive horrible threats. People are encouraged to destroy GMO test crops by these anti-GMO NGOs, such as happened in the Philippines in 2013 (Alberts *et al*., 2013). Fake

scientists get attention on television and in the press. In some cases they even become professors (be it extra-ordinary, paid by NGOs who easily collect money to fight against the technology). Personally, I am convinced that these "scientists" know better, but fame is easier to obtain in the negative way than by doing decent research. It is also much easier to make money as an anti. Serious, decent scientists are accused of being corrupt and paid by industry. Industry-supporting governments are accused of being ruthless and against nature. Everything is twisted such that it looks like decent genetic research cannot be right. That populations starve and many die because of anti-GMO activities, such as e.g., in 2001, when during the massive famine in Southern Africa several governments in the region objected to genetically modified (GM) grain, citing health and environmental concerns, Zimbabwe blocked the GM food aid from entering the country. In Zambia, where some GM grain had already arrived, the government placed it under lock and key, banned its distribution and then blocked another 40,000 tonnes that were on the way (Africa Renewal, 2003). This is the result of overwhelming activities of antis, in particular in Europe, who claim with no evidence that GM food is dangerous. The local governments choose to let their citizens starve to death rather than giving them GM food. The reality is that, because of the negativism by antis, both in the USA and in Europe very thorough research has been done to find out about negative aspects or any harmful incidents resulting from the use of GM crops. The EU alone spent more than € 300 million on the safety of GMOs. The main conclusion to be drawn from the efforts of more than 130 research projects, covering a period of more than 25 years of research, and involving more than 500 independent research groups, is that biotechnology, and in particular GMOs, are not per se more risky than e.g. conventional plant breeding technologies (European Commission, 2010). Another reality is that hundreds of millions of people consume GM food daily and there is not a single report of a health incident related to GM food.

Lessons

That genetically modified (GM) crops have been proven to be as safe as non-modified crops is not sufficient to use GM crops to fight against hunger. Reasons are that since the development of GM technology there have been antis, people who feel that GM products are dangerous, supported by scientists at the time that not much research on the safety of GMOs had been done. To maintain this opinion after decades of research is only understandable because some scientists do not understand the research of do not want to know for other reasons. Antis always get attention and therefore have much influence on the public opinion and equally on politicians and law makers, regulators. It is easy to mislead the general public because the technology is new and therefore not familiar. What is lacking is scientifically correct but nevertheless clearly understandable explanations, what GM means, how it is done and why it is safe. That may not be easy, but it is essential to overcome the problems and thereby not missing an important way to beat hunger in the world. Instead of scientists talking to each other, they need to find a language that non-scientists understand.

FOOD FRAUD

Food fraud is the illegal tampering with food for economic gain. There are many examples of food fraud, such as the addition of substances to enhance the colour or products. In Hungary, in 1994, lead oxide was added to dried paprika to enhance the colour and that way made low-quality product look better (Williams, 1994). This caused 46 people hospitalised and 59 people arrested. Similarly in China the non-food colorant Sudan Red 1 was added to chilli powder. The chilli powder had been used in many products all over the world but in this case resulted only in financial consequences because some governments demanded the destruction of food containing trace amounts of the colorant. Also in China, in 2008, and again for financial gain, irresponsible and greedy companies had diluted milk and masked this by adding melamine, making the protein content looking the same as in unadulterated milk, because the melamine enhanced the nitrogen value in the Kjeldahl analysis that at the time was still used. This was a case with severe health consequences because of infant formula made with the melamine-adulterated milk. According to a report from the Chinese Ministry of Health,

294 000 infants had been affected by melamine-contaminated infant formula by the end of November 2008. More than 50 000 infants have been hospitalized, and six deaths had been confirmed (FAO/WHO, 2009). Although China had by far the most victims, contaminated products found their way to all continents. These are just a few examples of the many cases of adulteration of food and food products. From scientists who have been involved in the investigation of the incidents we know that the magnitude of the consequences of these cases of food fraud could have been limited. In some companies employees who knew about a food safety issue were instructed not to make the issue known to anyone, to avoid damage to the

reputation of the company. Being scared to lose their jobs – having families to support – they indeed did not report to the authorities (e.g., Motarjemi, 2014).

Lessons

By adding unauthorised additives to food, the food may become unhealthy to consume and may lead to severe damage to consumers and even death. In some cases unauthorised substances may be added out of ignorance. Regrettably, however, there are scrupulous people and organisations with as sole objective to earn money for themselves and/or their shareholders. In both cases, employees who know about such issues and report it to their superiors usually do not dare to raise their concerns to authorities. Their jobs are at stake. Thus there is a need for a way to make it possible to report such malpractices anonymously and from everywhere, so that measures can be taken to limit the damage, while at the same time having a possibility to rapidly check if such reports are honest and not a way of revenge of an unhappy employee.

INNOVATION

National regulations require evidence of safety for every new product, ingredient or process. The objective, to ensure that food put on the market is safe, self-evidently is correct. However, there are many differences in requirements between countries, firstly in what substances are allowed and in what concentrations and secondly in the methods to be used to provide the evidence of safety. For international trade this means that for every country to which a company wants to export and for every country from which a company wants to import high costs are involved in finding out what the differences are and then in doing the additional work to be able to provide the data required. Not only is this costly, it also takes considerable time and hence will cause delays in marketing of new products. To justify investments in research and development of new products and processes, the target market must be large enough. With so much uncertainty about national approvals, justification becomes hard, it makes companies to refrain from investments in innovations. Globally harmonized requirements and test methods would make innovations more attractive.

ORGANISATIONS THAT ATTEMPT TO HARMONIZE REGULATIONS

That harmonization of laws and regulations for food and food products are highly desirable has been recognised for a very long time. Several organisations are active, be it to various degrees, with such harmonization. The Codex Alimentarius Commission (CAC), established by the FAO in 1961 and supported by the World Health Organisation (WHO) a year later, is trying to harmonize food safety requirements since its first meeting in 1963. CAC is recognised by the World Trade Organisation (WTO) as the international authority on food safety. The commission, however, suffers from a number of drawback. Firstly, as an intergovernmental organisation, representatives are inclined or probably often instructed to protect the interest of their country. Many times the representatives are not scientists but non-scientific governmental officials. Moreover, by far not all countries are represented in all committees (meetings usually are attended by representatives of 50-60 countries) and the frequency of meetings of these committees is low, usually once yearly, causing progress to be slow, despite the work done between these meetings. Lastly, there are many countries for which harmonization is extremely important, that simply cannot afford to participate in all meetings. Nevertheless, CAC standards are important because of their recognition by the WTO.

The Global Food Safety initiative (GFSI) was founded in 2000 by food retailers and manufacturers with the objective to make the supply chain safer, through the harmonization of food safety standards. It is a non-profit organisation that is managed by the Consumer Goods Forum (http://www.theconsumergoodsforum.com/about-the-forum/our-mission). GFSI is charged with providing continuous improvement in food safety management systems to ensure confidence in the delivery of safe food to consumers worldwide (Global Food Safety Initiative, 2011).

The Global Harmonization Initiative (GHI) is the single international organisation that is impartial: non-governmental and non-industrial. Its membership consists of individual food scientists from all over the world and thus members are not representing a country or company. The goal of the organisation is to promote harmonization of global food safety regulations and legislation, based on solid scientific evidence. Since its inception in 2004, it gradually became clear that the differences in regulations between countries are not related to the lack of consensus between scientific experts. Rather scientists fail to communicate with non-scientists: the general public, politicians, and editors of magazines, newspapers and other mass communication media. GHI is addressing a number of crucial issues to resolve the issues discussed.

Firstly, before countries may usefully discuss food safety, they need to understand the terminology used, they need to realise that words often have different meanings between countries. This is the case even if countries use the same language, like the UK and the USA. There is reason why there are dictionaries UK-English/USA-English. The differences can be dramatic as for instance in discussing concentrations, as discussed above: A billion in the USA is thousand times less than a billion in the UK; in the case of a trillion the difference is a million (fortunately million means the same in both countries). Countries disagree what many relevant words mean, e.g. in the case of a very important subject: The definitions of Food Additives differ between e.g., Canada, Japan, USA and the EU and they all differ from the Codex Alimentarius definition. That is the reason why GHI has a Working Group Nomenclature on Food Safety and Quality. The mission of this WG is to harmonise definitions in these areas. The WG has started with Russian and English, and will then move to Spanish, French and Italian. These "basic" languages could then be used for translations into other languages.

Secondly, it is imperative that those who decide on regulations, politicians, understand at least the basics of food safety. Because politicians are strongly influenced by the electorate, it is also important that the general public understands the basics of food safety. Regrettably, with possibly few exceptions, they do not. Understanding the consequences of lack of hygiene and hygienic measures is essential to reduce food safety incidents as well as premature spoilage of food. By far most of the hygiene related food safety incidents are due to handling of food by housewives or -men, caterers and street vendors. In addition, regrettably there are not enough capable food inspectors, they often have not had sufficient education and training to recognise wrongdoings related to food safety and hygiene. To reduce the number of demands for absurd regulations, a large enough part of the population needs to understand that any chemical is only harmful if there is too much of it and that often not enough of the same chemical may cause illness. Similarly, it must be understood that to become ill from microbes too requires a certain number and also many microbes are essential for people's health. The WG Education of GHI therefore is working on the production of material for the education and training at all levels, suitable for translation in local languages but also using a pictorial language because according to the United Nations almost 800 million people in the world cannot read (D'Ameida, 2015); in developing countries the illiteracy often is >60% but even in the USA it is >14% (Statistic Brain, 2014). Further GHI is cooperating with IUFoST and the World bank in the Global Food Safety Curriculum Initiative (GFSCI). The aim of the initiative is to provide food safety students globally with a science-based education in food safety so that, as professionals, they can fulfil expressed needs by governments, industry and academia in their countries and regions (http://foodsafety.iufost.org/global-food-safety-curricula-initiative).

Thirdly, in is unacceptable that reporting of the contamination of food that may seriously affect people's health are suppressed by e.g., the management of companies, to avoid financial consequences or by authorities, to avoid damage to the reputation of a country. Governments should protect those who - for good reasons and after not being heard by their management - in good faith warn authorities to prevent harm to consumers. This requires harmonized regulations based on ethics, self-evidently taking into account that there could be false reports. Incidents reported must be checked and undue harm to companies and countries should be avoided. The WG Ethics of GHI is developing proposals for such global regulations. In addition GHI is developing a global incident alert network for unauthorized food additives (GIANUFA). Anytime it is found that an unauthorised (illegal) substance is added to food, wherever on the globe, that may harm consumers, the individual who made the discovery should alert a dedicated committee. If needed, this may be done anonymously and such that the individual cannot be traced or identified. A committee then should have the means and a protocol to verify the issue in a very short time, using a global network. In the same time, experts should decide the potential harm that may be caused. Depending on the severity, an alert should be spread globally by a press release, initially in English. Then the essential information should be sent to all relevant authorities. The press release should then also be translated – as soon as possible, but carefully because correct translation is also essential - into local languages, this should be done by local food scientists, if needed supported by professional translators. That way the entire world could be alarmed in just a few hours, preventing undue damage (sickness, death) of consumers.

CONCLUSIONS

By far not everything that is relevant has been discussed in this article. Harmonization of test methods, viruses and prions for instance have not got the attention these topics deserve, but more

information on these topics can be found in the recommended literature. The intention of this article is to demonstrate that there is a need for regulations, but also that prevailing regulations often are flawed and there are many unjustifiable differences in regulations between countries. To remove barriers to trade and to avoid undue destruction of healthy food, regulations must be based on sound science and be globally harmonized. To make it work, education, training and communication related to food safety must be improved so that the general public is armed against misinformation. Then of course, governments must be made to want to improve laws and regulations for which an impartial global group of food scientists is willing to deliver the tools.

ACKNOWLEDGEMENT

The author is grateful to Dr. Veslemøy Andersen for patiently reading subsequent draft versions of the article and providing comments that significantly improved the quality.

REFERENCES

Manda, O., 2003. Controversy rages over 'GM' food aid - Zambia, citing health concerns, bars genetically modified grain. Africa Renewal, 16 (4), 5

Alberts, B., Beachy, R., Baulcombe, D., Blobel, G., Datta, S., Fedoroff, N., Kennedy, D., Khush, G.S., Peacock, J., Rees, M. and Sharp, P., 2013. Standing Up for GMOs. Science 341, 1320

Aldred, D., Magan, N. and Olsen, M., 2004. The use of HACCP in the control of mycotoxins: the case of cereals. In: Mycotoxins in Food – Detection and Control. Edited by N. Magan and M. Olsen. Woodhead Publishing Limited/CRC Press, 139-173

Bracken M.B., 2008. Why animal studies are often poor predictors of human reactions to exposure. JLL Bulletin: Commentaries on the history of treatment evaluation
(http://www.jameslindlibrary.org/articles/why-animal-studies-are-often-poor-predictors-of-human-reactions-to-exposure/) Accessed 31 March 2017

CDC, 1985. Epidemic Notes and Reports Listeriosis Outbreak Associated with Mexican-Style Cheese-California. MMWR, 1985/34, 357-9

CDC, 1993. Preliminary report: foodborne outbreak of Escherichia coli O157:H7 infections from hamburgers -- Western United States, 1993. MMWR 1993, 42: 85-86

CDC, 2009. Multistate Outbreak of Salmonella Infections Associated with Peanut Butter and Peanut Butter--Containing Products --United States. MMWR, 2009/58 (Early release), 1-6

CDC, 2011. Questions about the 2011 E. Coli Outbreak in Germany

Collignon, P. and Voss, A., 2015. China, what antibiotics and what volumes are used in food production animals? Antimicrobial Resistance and Infection Control 4, 16

Court of Justice, 2006. Joined Cases C-129/05 and C-130/05: Judgment of the Court (Second Chamber) of 28 September 2006 (reference for a preliminary ruling from the College van Beroep voor het bedrijfsleven — the Netherlands) — NV Raverco (C-129/05), Coxon & Chatterton Ltd (C-130/05) v Minister van Landbouw, Natuur en

Voedselkwaliteit (Directive 97/78/EC — Regulation (EEC) No 2377/90 — Veterinary checks — Products entering the Community from third countries — Redispatch of products that do not satisfy the import conditions — Seizure and destruction). (Joined Cases C-129/05 and C-130/05)

D'Ameida, K., 2015. 781 Million People Can't Read this Story. Inter Press Service. http://www.ipsnews.net/2015/04/781-million-people-cant-read-this-story/. Accessed 30 March 2017

Darroudi, F., Ehrlich, V., Wuillot, A., Dubois, T., Knasmüller, S. and Mersch-Sundermann, V., 2010. Testing for food safety using competent human liver cells. In: Ensuring global food safety – exploring global harmonization. Edited by Christine E. Boisrobert, Aleksandra Stjepanovic, Sangsuk Oh and Huub L.M. Lelieveld. Elsevier/Academic Press, London, 125-138

European Commission, Directorate-General for Research and Innovation Biotechnologies, Agriculture, Food, 2010. A decade of EU-funded GMO research. Luxembourg: Publications Office of the European Union. ISBN 978-92-79-16344-9

FAO/WHO, 2009. Toxicological and health aspects of melamine and cyanuric acid. Report of a WHO Expert Meeting in collaboration with FAO supported by Health Canada, Rome

FDA, 2012a. Orange Juice Products and Carbendazim: Addendum to FDA Letter to the Juice Products Association (January 9, 2012) https://www.fda.gov/Food/FoodborneIllnessContaminants/Pesticides/ucm287783.htm. Accessed 31 March 2017

FDA, 2012b. Carbendazim in Orange Juice (updated 28 February 2017) https://www.fda.gov/Food/FoodborneIllnessContaminants/Pesticides/ucm288004.htm. Accessed 17 March 2017

Global Food Safety Initiative, 2011. What is the GFSI Guidance Document Sixth Edition? http://globalfoodsafetyresource.com/wp-content/uploads/2014/07/pdf_What_is_the_GFSI_Guidance_Document_Sixth_Edition.pdf

Gribble G.W., 2003. The diversity of naturally produced organohalogens. Chemosphere 52, 289-297

Gribble G.W., 2011. Recently discovered naturally occurring heterocyclic organohalogen compounds. Heterocycles, 84 (1), 157-207

Hariprasad, P., Durivadivel, P., Snigdha, M. and G. Venkateswaran, G., 2013. Natural occurrence of aflatoxin in green leafy vegetables. Food Chemistry 138, (2–3), 1908–1913

Herrera-Estrella, L. and Alvarez-Morales, A., 2001. Genetically modified crops: hope for developing countries? EMBO reports 2 (4), 256-258

Bielaszewska, M., Mellmann, A., Zhang, W., Köck, R., Fruth, A., Bauwens, A., Peters, G., Karch, H., 2011. Characterisation of the *Escherichia coli* strain associated with an outbreak of haemolytic uraemic syndrome in Germany, 2011: a microbiological study. Lancet Infect Dis. 11(9), 671-676

Motarjemi, Y., 2014. Whistleblowing: Food Safety and Fraud. Food Safety Magazine 20(3), 58–66

Motarjemi, Y., Moy, G.G., Jooste, P.J. and Anelich, L.E., 2013. Milk and Dairy Products. In: Food safety management: a practical guide for the food industry, Edited by Yasmine Motarjemi and Huub Lelieveld. Academic Press/Elsevier, Amsterdam

Pourshahidi, L.K., Navarini, L., Petracco, M. and Strain, J.J., 2016. A Comprehensive Overview of the Risks and Benefits of Coffee Consumption. Comprehensive Reviews in Food Science and Food Safety 15 (4), 671–684

Shapira, R. and Paster, N., 2004. Control of mycotoxins in storage and techniques for their decontamination. In: Mycotoxins in Food – Detection and Control. Edited by N. Magan and M. Olsen. Woodhead Publishing Limited/CRC Press, 190-223

Statistic Brain, 2014. Illiteracy Statistics. http://www.statisticbrain.com/number-of-american-adults-who-cant-read/. Accessed 30 March 2017

Van der Meulen, B. and Van der Velde, M., 2008. European Food Law Handbook. Wageningen Academic Publishers, Wageningen, p. 327

WCRF/AICR (World Cancer Research Fund/American Institute for Cancer Research), 2007. Sugar and salt. In: Food, nutrition, physical activity and the prevention of cancer: a global perspective, 141-147. Washington DC: AICR

WHO, 1993. Toxicological evaluation of certain veterinary drug residues in food, 40th JECFA, WHO Food Additives Series 31, Geneva. Cited by Antoon Opperhuizen, Advies over furazolidon in kalveren. Nederlandse Voedsel- en Warenautoriteit, 26 juni 2014

WHO, 2015. Fact sheet N°399, December 2015 http://www.who.int/mediacentre/factsheets/fs399/en/ Accessed 31 March 2017.

Williams, C. J., 1994. Market Focus : Tainted Paprika Poisons Hungary's Culinary Pride : The health of the industry is also at stake. Los Angeles Times, 11 October 1994.

RECOMMENDED BOOKS

Ensuring Global Food Safety – Exploring Global Harmonization, 2010. Edited by Christine E. Boisrobert, Aleksandra Stjepanovic, Sangsuk Oh and Huub L.M. Lelieveld. Elsevier/Academic Press.

Regulating Safety of Traditional and Ethnic Foods, 2016. Edited by Vishweshwaraiah Prakash, Olga Martín Belloso, Larry Keener, Siân Astley, Susanne Braun, Helena McMahon and Huub Lelieveld. Elsevier/Academic Press.

Food safety management: A practical guide for the food industry, 2014. Edited by Yasmine Motarjemi and Huub Lelieveld. Elsevier/Academic Press.

Handbook of Hygiene Control in the Food Industry, 2nd edition, 2016. Edited by Huub Lelieveld, John Holah and Domagoj Gabrić. Elsevier/Academic Press.

Global Food Legislation: An Overview – Edited by Evelyn Kirchsteiger-Meier and Tobias Baumgartner. ISBN: 978-3-527-33555-8; Wiley, 2014

EU Food Law Handbook – Edited by Bernd van der Meulen. ISBN: 978-90-8686-246-7; , Wageningen University Press, 2014

Genetic Modification and Food Quality: A Down to Earth Analysis. Robert Blair and Joe M. Regenstein. ISBN: 978-1-118-75641-6; Wiley, 2015