

Food Safety and Global Health: An International Law Perspective

Stefania Negri

Following the recurrence of serious events of food contamination across the globe, food safety has become a matter of ever increasing international concern and the World Health Organization has defined foodborne diseases as a global public health challenge. Protecting global health from foodborne hazards is a compelling duty and a primary interest of both States and non-State actors; it calls for enhanced proactive cooperation between national and international institutions. Unfortunately, the present state of international law on food safety regulation and governance is still unsatisfactory and reforms are desirable in many respects. This paper suggests that improvements and progresses could be achieved in three major areas of intervention: a) the human rights framework, where the profile of the emerged right to safe food should be raised by way of express recognition in international human rights law, backed up by authoritative interpretation by the UN Committee on Economic, Social and Cultural Rights and strengthening of accountability and remedial measures; b) the regulatory framework, where trade and health issues related to food safety should be addressed in a way that contributes to easing tensions between trading parties while prioritizing consumer protection over freedom of trade; c) the sanitary framework, where international preparedness and response to public health hazards posed by foodborne diseases should benefit, where appropriate, from the extended application of the International Health Regulations and the possible devise of enforcement measures aimed at ensuring international health security.

INTRODUCTION

Recent events concerning food contamination in China,¹ the United States,² Canada,³ Italy,⁴ and Ireland⁵ have contributed to bringing food safety issues back in the spotlight of public opinion. Some of these events, which have found a wide echo in international media, have triggered a worldwide alert that evoked the concerns raised by the high profile “food scares” of the near past (mainly bovine spongiform encephalopathy and avian influenza). As a result, global governance of public health challenges posed by foodborne hazards has been put high again on the international agenda of governmental agencies and international organizations.

Awareness of the significance of food safety has been greatly enhanced in the last two decades, and its impact on health, marketing, and foreign trade are now recognized at different levels. Food safety issues have thus been at the core of extensive scientific and legal literature, with a focus on the most critical aspects of the subject and its intersection with other key legal issues (e.g. consumer protection, biotechnology and safety of genetically modified organisms, application of the precautionary principle, traceability of products, quality standards setting, responses to bioterrorist threats, freedom of trade

and legitimacy of restrictions, international cooperation and governance of public health risks).⁶

Scientists and legal scholars have paid special attention to the management of foodborne diseases, which are indeed a source of major concern for the whole international community.⁷ These diseases encompass a broad spectrum of illnesses⁸ causing morbidity and mortality worldwide and their real overall health impact on the world population is yet unknown. Moreover, globalization of trade has led to the rapid and widespread international marketing of food products, demanding that the most careful controls be carried out along the entire food-chain from “farm to fork”.⁹ Whenever such controls fail – and food production and distribution fall short of complying with regulations and standards set either at national or international level – the potential likelihood of transboundary incidents involving tainted food increases, and global health is hence seriously put at risk.

For the reasons stated above, international food safety is perceived as a global challenge. In the wake of a trend towards more efficient food safety policies, the 2007 Beijing Declaration on Food Safety¹⁰ gives voice to the global community’s concern that a comprehensive and integrated approach be adopted, prompting all stakeholders to take cooperative and concerted actions and strengthening links between the different sectors involved. The Declaration, in fact, recognizes that “integrated food safety systems are best suited to address potential risks across the entire food-chain from production to consumption” and that “oversight of food safety is an essential public health function that protects consumers from health risks”. In this perspective, it mainly urges States to develop transparent regulation to guarantee safety standards; to ensure adequate and effective enforcement of food safety legislation using risk-based methods; to establish procedures, including tracing and recall systems in conjunction with industry; to rapidly identify, investigate and control food safety incidents and to alert the World Health Organization (WHO) of those events falling under the revised International Health Regulations. In short, the Declaration expresses the need to understand food safety as both a national and an international responsibility.

Moving from the consideration that food safety issues and the enhancement of health security are of growing international concern, it is interesting to inquire whether the international community is provided with the appropriate legal instruments to face foodborne hazards globally. To this end, this paper will first adopt a human rights-based approach to food safety to make the case for a human right to safe food and to suggest that such a right has progressively emerged as a “derivative” right and could further evolve into a self-standing right; second, it will explore the present state of international law with regard to food safety regulation and harmonisation in light of the overarching need to prioritize consumer protection over “free trade at all costs”; and third, it will focus on the available means of global management of food safety risks for global public health protection.

Albeit crucial for understanding the multiple facets of food safety governance, all political, economic, social and ethical considerations fall beyond the scope of the present investigation, which is meant to remain faithful to the legal perspective. Therefore, by focusing only on international law norms and obligations, this paper aims to offer a contribution to the current debate on food safety, with the awareness that it represents only a

starting point for further analysis and more in-depth reflections on the innovations and developments needed in food safety regulation to achieve the compelling objective of protecting world health.

A RIGHTS-BASED APPROACH TO FOOD SAFETY: THE “RIGHT TO SAFE FOOD” IN INTERNATIONAL HUMAN RIGHTS LAW

Although emphasis is increasingly being placed on the concept of food safety,¹¹ legal literature has seldom expanded on the status of a “human right to safe food” in international law.¹² The right to safe food in human rights law is encompassed by both the right to health¹³ and the right to food.¹⁴ It is so closely interrelated with these fundamental human rights – being at the same time one of their integral components and an element upon which their realization is dependent – that it fits perfectly with the generally accepted idea that all human rights are universal, indivisible, interrelated, interdependent and mutually reinforcing.¹⁵

The International Bill of Human Rights provides the basic legal framework for construing a human right to safe food, and the general comments elaborated by the United Nations Committee on Economic, Social and Cultural Rights (“the Committee”) offer authoritative guidance for interpretation.

Article 25, paragraph 1, of the Universal Declaration of Human Rights affirms that “[e]veryone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care and necessary social services”,¹⁶ while article 12, paragraph 1, of the International Covenant on Economic, Social and Cultural Rights enunciates the right to health as “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health”.¹⁷ In its General Comment No. 14 on the domestic implementation of article 12, the Committee “interprets the right to health, as defined in article 12.1, as an inclusive right extending not only to timely and appropriate health care but also to the underlying determinants of health, such as access to safe and potable water and ... an adequate supply of safe food.”¹⁸ As far as legal obligations are concerned, the Committee makes it clear that States Parties are under the obligation to adopt domestic laws aimed to ensure “the underlying determinants of health, such as nutritiously safe food and potable drinking water” and to provide for implementation of such legislation.¹⁹ The Committee further draws attention to the obligation to safeguard all individuals under the States Parties’ jurisdiction from health hazards deriving from the activities of third parties (especially private actors such as individuals, groups or corporations), including the expressly mentioned duty to protect consumers from dangerous practices by food manufacturers.²⁰

Moreover, the Committee reiterates the view expressed in General Comment No. 12²¹ that guaranteeing “access to the minimum essential food which is nutritionally adequate and safe, to ensure freedom from hunger to everyone”²² is one of the core obligations incumbent upon States Parties to grant satisfaction of minimum essential levels of the right to health. The Committee’s approach is particularly meaningful in this latter respect, since inclusion of the entitlement to safe food in the minimum core content of the right to health demands that States Parties commit themselves to comply with

non-derogable obligations of immediate effect (i.e. those which are not dependent upon resource availability, such as respect of the principle of non-discrimination and of the duty to adopt expeditious and effective measures for the progressive realization of the right), and to refrain from invoking unavailability of adequate resources to justify inaction and lack of progress. In this context, obligations of immediate effect would encompass the duty to guarantee that all individuals under the jurisdiction of the State have equal access to safe and nutritious food; the duty to enact food safety and consumer protection legislation, including accountability measures; the duty to take all necessary steps to implement international regulations and standards.

Notwithstanding the Committee's approach implicitly acknowledges the crucial role played by food quality and safety in protecting health, and ultimately life, most of human rights relevant documents, backed up by legal scholarship, deal with the right to safe food in the context of the food security discourse. Therefore, although it would be a misconception to equate the right to adequate food with the right to safe food, food safety and food security are considered the two sides of the same coin.²³

In normative terms, the human right to adequate food is rooted in the above-mentioned article 25, paragraph 1 of the Universal Declaration and further elaborated in article 11, paragraph 2, of the Covenant, which recognizes the fundamental right of every person to be free from hunger, and the duty of States to take, individually and through international cooperation, the measures needed to implement this right by improving the methods of production, conservation and distribution of food. In its general comment on the right to adequate food, the Committee underlines that "the right ... is indivisibly linked to the inherent dignity of the human person and is indispensable for the fulfilment of other human rights enshrined in the International Bill of Human Rights".²⁴ While recognizing that the right to adequate food is crucial for the enjoyment of all rights, the Committee considers that the core content of this right implies "the availability of food in a quantity and quality sufficient to satisfy the dietary needs of individuals, free from adverse substances".²⁵ The latter formula is explained as setting "requirements for food safety and for a range of protective measures by both public and private means to prevent contamination of foodstuffs through adulteration and/or through bad environmental hygiene or inappropriate handling at different stages throughout the food chain; care must also be taken to identify and avoid or destroy naturally occurring toxins".²⁶

Moreover, the relevance of food safety to the realization of the right to food both at national and international level is further emphasized by the Committee when it stresses that domestic policies of implementation of article 11 "should address critical issues and measures in regard to all aspects of the food system, including the production, processing, distribution, marketing and consumption of safe food", and that States and international organizations have a joint and individual responsibility to ensure that "products included in international food trade or aid programmes ... be safe".²⁷

Within the United Nations, the General Assembly has long adopted the same approach as the Committee: in resolution 63/187 of 18 December 2008 on the right to food, just as it has been doing since 2001, the Assembly "reaffirms the right of everyone to have access to safe, sufficient and nutritious food, consistent with the right to adequate food and the fundamental right of

everyone to be free from hunger”.²⁸ The Human Rights Council has repeated the same formula in its resolution on the right to food of 27 March 2008, the first adopted by the Council so far.²⁹

In different contexts, several international declarations and other soft law instruments have reaffirmed the individual right to *adequate and safe food*. The World Declaration on Nutrition, adopted by the FAO International Conference on Nutrition in December 1992, asserts that “access to nutritionally adequate and safe food is a right of each individual” (para. 1); the 1996 Rome Declaration on World Food Security includes the States’ commitment to “implement policies aimed at eradicating poverty and inequality and improving physical and economic access by all, at all times, to sufficient, nutritionally adequate and safe food and its effective utilization” and the related Plan of Action provides that States “[a]pply measures, in conformity with the Agreement on the Application of Sanitary and Phytosanitary Measures and other relevant international agreements, that ensure the quality and safety of food supply, particularly by strengthening normative and control activities in the areas of human, animal and plant health and safety”;³⁰ the Draft Principles on Human Rights and the Environment of 16 May 1994 state that “all persons have the right to safe and healthy food and water adequate to their well-being” (para. 8); the Declaration adopted at the FAO World Food Summit Five Years Later in June 2002 confirms “the right of everyone to have access to safe and nutritious food” (preamble); and the 2007 Beijing Declaration on Food Safety reiterates the statement of the 1992 Declaration on Nutrition. Moreover, the view that “[f]ood safety and food security are inseparable” has been at the basis of the PAHO/WHO Plan of Action for Technical Cooperation in Food Safety, that acknowledges that food safety and security “jointly contribute to progress toward the attainment of the Millennium Development Goals, particularly the reduction of hunger and poverty.”³¹ Likewise, the FAO report on Ethical Issues in Food and Agriculture states that “[a]chieving food security requires: i) an abundance of food; ii) access to that food by everyone; iii) nutritional adequacy; and iv) food safety”.³²

From this legal framework it can be inferred that in the human rights perspective it is generally recognized that every individual is entitled to food that is safe and of good quality, since safe food is functional to achieving freedom from hunger and enjoyment of the best attainable state of health; hence it is crucial for protecting life and human dignity. Clarifying whether this entitlement shapes an autonomous right, separate and distinguishable from the rights to adequate food and to health, and whether it can be considered a fundamental human right, will probably be the subject of further insights by future legal scholarship. It is worth considering, however, that food safety has been already defined “an inalienable right of each individual” by FAO Director-General, Jacques Diouf,³³ and that the World Health Organization has clearly acknowledged that “[t]he availability of safe food improves the health of people and is a basic human right”.³⁴

At the moment – drawing on the wealth of human rights instruments that approach food safety halfway between enshrining an express legal entitlement to safe food and considering it as an implicit attribute of the rights to adequate food and to health – the argument could be made that a “human right to safe food” has progressively taken shape as a “derivative” right and might be on its way to becoming a self-standing right. In this perspective, the

evolution of the right to safe food might be compared to the one undergone by the right to safe drinking water, another underlying determinant of the right to health which has achieved over time the status of an autonomous fundamental right.

Making the case for a human right to safe food through a rights-based approach to food safety may offer some advantages in terms of effectiveness and accountability. Of course, recognizing such a right calls for a better definition of the specific legal obligations it imposes, as well as for availability and accessibility of adequate remedies. To meet these needs the Committee could play a fundamental role, either interpreting the right by way of adoption of a general comment, or by way of exercise of its new functions under the Optional Protocol to the Covenant.³⁵ In fact, once it enters into force, the Protocol will empower the Committee to receive and examine communications by individuals claiming to be the victims of violations by a State Party of any of the rights set forth in the Covenant. It will thus fill a gap in the present state of international law in matter of justiciability of economic, social and cultural rights, whose effective implementation and full realization have been hampered by lack or scarcity of judicial remedies at the universal level (for inexistence so far of a specifically competent forum), at the regional level (considering, for example, the incompetence *ratione materiae* of both the European Court of Human Rights³⁶ and the Inter-American Commission of Human Rights³⁷ on core rights, like the right to health), and at the national level as well.³⁸

Looked at from this angle, the Optional Protocol and the future interpretive activity of the Committee reveal all their importance for a better comprehension of the human right to safe food. It is thus to be expected that the Committee's future case law will shed light on the nature and scope of this right and contribute to its interpretation and implementation in accordance with the Covenant.

PRIORITIZING CONSUMER PROTECTION OVER FREEDOM OF TRADE IN THE GLOBAL MARKET: THE RELEVANCE OF FOOD SAFETY REGULATIONS, INTERNATIONAL STANDARDS AND PRECAUTION

Global food trade has dramatically increased the risk that contaminated food may pose serious health hazards and spread foodborne diseases worldwide. Consequently, achieving food safety in the global market calls for prioritization of public health interests over freedom of trade. While the realization of the right to safe food beyond the framework of human rights law requires that consumer protection be given precedence over "free trade at all costs", "the challenge is to work out how the difficult interface between [trade and health] can be managed."³⁹

The protection of consumers has received ample coverage first and foremost in domestic law. When major environmental and food-related disasters have shifted the attention from the local to the transnational dimension of food safety, consumer protection has also been dealt with in the regional and international context.

Within national legal orders consumer protection is an important part of private law, which is founded on the four basic consumer rights: the right to safety, the right to be informed, the right to choose and the right to be heard.⁴⁰ Many States have created national public authorities entrusted with the task

of protecting and promoting health, with specific focus on food safety and consumer protection: the U.S. Food and Drug Administration is the most prominent example, although similar agencies have been created all over the world. The national dimension of consumer law and food safety regulation is relevant to the international law viewpoint depending on whether it complies or not with (the rather few) international obligations and (the many) international standards.

In the European Union, consumer law has progressively gained recognition and importance after the introduction of article 129a by the 1992 Maastricht Treaty (now article 153 of the EC Treaty).⁴¹ Of course, the reception of European consumer law and the many decisions of the Court of Justice have had substantial consequences on domestic legislation.⁴²

In the specific domain of consumers' protection from food-related risks, EC Regulation No. 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety is of the greatest importance, since it represents the main source of European food safety legislation binding on all Member States.⁴³ The crucial general principles enunciated in the Regulation concern: *a*) the general objectives to be pursued by food law, that is a high level of protection of human life and health and the protection of consumers' interests, including fair practices in food trade; *b*) resort to risk analysis in food law, with risk assessment being based on the available scientific evidence and undertaken in an independent, objective and transparent manner; *c*) application of the precautionary principle where the possibility of harmful effects on health have been identified but scientific uncertainty persists; *d*) protection of the interests of consumers and prevention of fraudulent or deceptive practices, the adulteration of food, and any other misleading practices; *e*) transparency through public consultation and information.⁴⁴ The Regulation also sets forth the obligations of EU Member States with regard to food trade, general safety requirements of food law and traceability, stating the basic rule that "food shall not be placed on the market if it is unsafe".⁴⁵ It further regulates liability issues, making reference to the responsibility of both States and business operators.⁴⁶ In this latter respect, it is important to take due consideration of the direct effect of the Regulation, which enables European citizens to enforce consumer rights both against Member States before Community Courts (vertical direct effect), and against other individuals and companies in actions before national judges (horizontal direct effect).⁴⁷

Some provisions of the Regulation also point to another crucial aspect of food safety regulation: the need to strike a fair balance between consumer protection and freedom of trade within the Union and with third countries. In this respect, the Regulation first notes the paramount importance of safety and confidence of consumers, the Community being a major global trader in food and, in this context, a major supporter of the principles of free trade in safe food and of fair and ethical trading practices. It also notes that some Member States have adopted horizontal legislation on food safety imposing a general obligation on economic operators to market only food that is safe; nonetheless, it stresses that due to the adoption of different national criteria, and to the lack of legislation in other Member States, barriers to trade in foods are liable to arise, so that it is necessary to establish general requirements to ensure that the internal market functions effectively. The Regulation finally

considers that in trade relations with third countries it is necessary to ensure that food exported or re-exported from the Community complies with Community law and that, even where there is agreement of the importing country, food injurious to health is not exported or re-exported. On the basis of these considerations the Regulation states that “[f]ood law shall aim to achieve the free movement in the Community of food and feed manufactured or marketed according to the general principles and requirements” set in the Regulation itself; it adds that risk management measures adopted in application of the precautionary principle should “be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community” and should “be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment”.⁴⁸

Food safety regulation and health and trade-related issues in Community law should also be read through the lens of the combined provision of the relevant EC Treaty rules, namely: article 30 allowing “prohibitions or restrictions on imports, exports or goods in transit justified on grounds of ... the protection of health and life of humans”, provided that such prohibitions or restrictions do not “constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States”; article 95, paragraph 3, stating that in matters of approximation of laws the Commission’s proposals, aimed to the adoption of a harmonisation measure “concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts”;⁴⁹ article 152 on public health, requiring at paragraph 1 that “[a] high level of human health protection ... be ensured in the definition and implementation of all Community policies and activities” and that “Community action ... be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health”;⁵⁰ article 174 stating that Community policy on the environment must enhance the protection of human health.

The case law of the European Court of Justice has greatly contributed to the interpretation of these provisions while enunciating some important principles of law. The Court has in fact stated that the application of the precautionary principle extends from environmental issues to the common agricultural policy whenever the European institutions deem it necessary to adopt measures for public health protection, this latter objective being an integral part of any Community policy.⁵¹ The Court has thus concluded that the Community can legitimately adopt a restrictive measure any time it foresees a risk for public health and even before the seriousness and gravity of the risk are proved, provided that such a risk is not merely hypothetical but is supported by adequate scientific evidence.⁵² The Court has however affirmed that in case of uncertainty as to the existence and extent of the health risk it is necessary that a scientific evaluation be made, in order to guarantee the objectivity and correctness of the decisional process within the Community.⁵³ This approach, which focuses on the procedural aspects of regulation-making, is considered an alternative for implementing the precautionary principle at EU level, and is supposed to guarantee a less intrusive review of national decisions.⁵⁴

Moreover, measures of trade restriction adopted under article 30 EC Treaty within the internal market are subject to the scrutiny of the Court, that pronounces on their legitimacy under Community law and according to its settled case law.⁵⁵ In this perspective, the trend is distinctively oriented towards recognition of the primacy of the general interest of public health protection over any right of economic operators and other stakeholders.

At the universal level, a major step was taken by the United Nations in the field of consumer protection and food safety regulation when the General Assembly unanimously adopted in 1985 a set of general guidelines that represent an internationally recognized set of minimum objectives, potentially being of particular assistance to developing countries.⁵⁶ First and foremost, the *Guidelines for Consumer Protection* intend to meet the need for the protection of consumers from hazards to their health and safety; this objective is pursued through information and education programmes on foodborne diseases and food adulteration, as well as through promotion of national policies prioritizing areas of essential concern for the health of the consumer (food, water and pharmaceuticals) and maintaining, developing or improving food safety measures (product quality control, adequate and secure distribution facilities, standardized international labelling and information, etc.). Although they are not binding on States, the importance of the Guidelines cannot be sidelined, since their adoption reinforces the increasing recognition in recent years that consumer policy issues can no longer be seen as being of purely local concern, but must be considered and faced in an international context.

Further developments in this direction were registered a few years ago, when the FAO Committee on World Food Security elaborated the *Voluntary Guidelines to Support the Progressive Realization of the Right to Adequate Food in the Context of National Food Security*.⁵⁷ Some of these guidelines are indicative of the trend towards progressive integration, both at the national and international level, among the multiple dimensions of food safety regulation and management. Guideline 4, for example, provides that States should guarantee adequate protection to consumers against fraudulent market practices, misinformation and unsafe food. It adds that national measures of consumers' protection should not constitute unjustified barriers to international trade and should be in conformity with the WTO agreements. Guideline 9, specifically devoted to food safety and consumer protection, urges or encourages States to: 1) take measures to ensure that all food, whether locally produced or imported, freely available or sold on markets, is safe and consistent with national food safety standards; 2) establish comprehensive and rational food-control systems that reduce risk of foodborne disease using risk analysis and supervisory mechanisms to ensure food safety in the entire food chain including animal feed; 3) adopt scientifically based food safety standards, including standards for additives, contaminants, residues of veterinary drugs and pesticides, and microbiological hazards, and to establish standards for the packaging, labelling and advertising of food, taking into consideration internationally accepted food standards (Codex Alimentarius) in accordance with the WTO Agreement on the Application of Sanitary and Phytosanitary Measures; 4) adopt measures to protect consumers from deception and misrepresentation in the packaging, labelling, advertising and sale of food and facilitate consumers' choice by ensuring appropriate information on marketed food,

and provide recourse for any harm caused by unsafe or adulterated food, including food offered by street sellers, in conformity with the WTO agreements; 5) cooperate with all stakeholders, including regional and international consumer organizations, in addressing food safety issues, and consider their participation in national and international fora where policies with impact on food production, processing, distribution, storage and marketing are discussed.

As in these Guidelines, reference to the Codex Alimentarius and WTO agreements when discussing of consumer protection and relevant trade implications at the universal level is a must. As a matter of fact, international cooperation in the field of food safety regulation is steadily institutionalized in the Codex Alimentarius Commission (CAC)⁵⁸ and its specialised subsidiary bodies since the 1960s, with the World Trade Organization later offering both the normative framework and the judicial forum to settle trade disputes.

The Codex Alimentarius is an ensemble of standards and guidelines regarding food safety and quality, including food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice. Although standards and guidelines developed by internationally recognized bodies – such as the CAC or the World Organization for Animal Health (OIE) – are not binding *per se*, they are generally recognized and have thus become the accepted norms in international trade, which means that where there is no national legislation, these standards can be used directly, in order to ensure the safety of international food and food related aid. In fact, Codex standards are referred to as fundamental reference points in the area of food safety. Albeit voluntary, their application is strongly incentivized because food production that meets these standards is generally viewed as facilitating trade and improving export rates.

The advantages of having universally agreed food standards for the protection of consumers, with a view to facilitating trade, are acknowledged by two important WTO Agreements: the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement on Technical Barriers to Trade (TBT Agreement).⁵⁹ These Agreements recognize that international standards and technical regulations bring benefits to both producers and consumers; their objective is to facilitate secure and predictable access to markets ensuring that health regulations do not create unnecessary obstacles to trade.⁶⁰ In particular, the SPS Agreement provides a multilateral framework of rules applying to all measures which may affect negatively the freedom of international trade, in particular to any trade-related measure taken to protect human life or health from risks arising from additives, contaminants, toxins, veterinary drug and pesticide residues, or other disease-causing organisms in foods or beverages. Building on the provision of Article XX(b) of the General Agreement on Tariffs and Trade⁶¹ and the terms of its *chapeau* – which predated the first reference to the precautionary principle by almost 40 years – the SPS Agreement incorporates elements of precaution, setting out the right of Governments to restrict trade to pursue health objectives, provided that the measures adopted be based on scientific evidence or on an appropriate risk assessment and according to the principles of non-discrimination and proportionality.⁶² Scientific justification (as provided in Article 2.2 and as backed up by the risk assessment discipline under Article 5) is, in point of fact, the pivot of the Agreement's management

of the health-trade interface.⁶³ Hence, while in Article XX of GATT restrictive measures are an exception, in the SPS Agreement “there is a right [under article 5.7], albeit a conditional right, to take provisional measures subject to the requirements for risk assessment laid out in Article 5.1, 5.5 and 5.6”.⁶⁴ Therefore, the Agreement tries to balance two conflicting interests: the sovereign right of Members to determine the level of health protection they deem appropriate, on the one hand, and the need to ensure that a sanitary or phytosanitary requirement does not represent an unnecessary, arbitrary, discriminatory, scientifically unjustifiable or disguised restriction on international trade, on the other. In order to achieve this goal, the SPS Agreement encourages Members to use existing international standards, guidelines and recommendations; it acknowledges the authority of Codex standards by making express reference to them as a privileged basis for internationally harmonised regulation.⁶⁵

The relevance of Codex standards is further confirmed by the case law of the WTO Appellate Body, which considers them as the international benchmarks against which national food measures and regulations are evaluated within the legal parameters of the WTO Agreements. Most important of all, in the disputes concerning the *EC–Sardines*⁶⁶ and the *EC–Hormones*⁶⁷ cases, the Appellate Body Reports pointed to the recognition of Codex standards as “relevant international standards” to be used by States as a basis for their technical regulations, and hinted to the possibility that such standards might be adopted without consensus.⁶⁸ In admitting such possibility the Appellate Body is said to have sensibly contributed to a greater politicisation of Codex decision processes and standard setting procedures, since adoption of standards without consensus approval implies the possibility that Member States be required to conform to standards they have not supported with their vote.

Moreover, the Codex Alimentarius is backed up by the trade sanctions of the WTO, since any non Codex-compliant nation would automatically lose in any food-trade dispute with a Codex compliant country, unless it were in a position to justify a possible ban on food products on the basis of a risk assessment rigorously supported by adequate scientific evidence. This approach was laid out in both the *EC–Asbestos*⁶⁹ and *EC–Hormones* cases, where the Appellate Body established some basic principles in matter of trade restrictions on products that are likely to pose a health hazard: first and foremost it recognized that public health interests must always take precedence, unless unilateral precautionary measures, not supported by the protection afforded by international standards or risk assessment, disguise protectionist interests; second, it established that the right to fix a higher level of national protection be justified through available, pertinent scientific information, which implies that there exists a rational relationship between the measure and the risk assessment; third, it stressed that States putting in place a measure based on the precautionary principle must continue their scientific research and perform serious reviews of the precautionary measure to show evidence of their good faith.⁷⁰ Through this approach, the Appellate Body showed that “the WTO cannot and does not stand for free trade at any cost”; it rather emphasised the importance of international standards for “uphold[ing] a rules-based multilateral trading system that ensures secure and predictable market access, while respecting health and [safety] concerns.”⁷¹

Be that as it may, it is necessary to highlight the fact that many global food safety issues still lie beyond the reach of international trade agreements.⁷² Actually, it has been observed that, depending on their focus and characteristics, health regulations may fall under the SPS Agreement, the TBT Agreement or the GATT alone, and that this fragmentary approach is really disadvantageous, especially in view of the need to manage the challenges posed by “the latest frontier[s] of the contested trade-health relationship.” This is one of the main reasons why the most important international organizations involved (mainly WHO, WTO and FAO) are steadily improving coordination of their activities and complementing each other’s work in the field of health and trade issues. Together with national governments they are also furthering efforts to protect consumers across the globe from threats to food safety due to the most diverse causes.

This international health-trade cooperation is best explained by the WHO and WTO Secretariat: “[t]he usefulness of this link lies in the clarity it bestows on the distinct roles of the two organizations: on the one hand the evidence based nature of WHO’s scientific work and, on the other, the more legal trade-related obligations under the WTO. ... Moreover, the link between the standard-setting work of the Codex and the scientific input from the WHO is important in that it lends some dynamics to the trade rules. While countries negotiate trade rules in the WTO, the WTO is not a scientific body and it does not develop standards. The WHO’s active presence at SPS meetings has allowed WHO staff to provide advice on health matters relevant to trade. Examples are WHO’s input on the risks of mad cow disease (BSE) to human health, and on the health effects of genetically-modified organisms in food. WHO representatives have also provided expert testimony to WTO dispute settlement panels, for example in the EC-Hormones case.”⁷³

MANAGING GLOBAL FOOD SAFETY RISKS IN THE WHO NETWORK: THE INTERNATIONAL HEALTH REGULATIONS (2005) AND BEYOND

According to the WHO, foodborne diseases are a global public health challenge.⁷⁴ Public health emergencies like HIV/AIDS, SARS, avian influenza and the latest pandemic influenza A(H1N1) have marked a watershed in global health governance. The international community has become fully aware that the most challenging health crises need to be fought through effective measures of prevention, control and early response to the outbreak of diseases that can pose a serious threat to human health worldwide.⁷⁵ Foodborne diseases, be they caused by bacterial⁷⁶ or chemical contamination,⁷⁷ have the potential to impact adversely on the health of wide segments of the world population.

Faced with the menace of new human pandemics, zoonoses and foodborne hazards, the World Health Organization has responded to the general demand for global health security working out a strategy inspired to the principles of timeliness and effectiveness of surveillance, alert and reaction. This strategy is based on updated rules and procedures that can easily adapt to the transmission dynamics of new or emerging diseases (human-to-human or animal-to-human transmission, and transmission via food) and it mainly operates through the sharing of information and of the

necessary technical and operational support. Its basic normative source are the International Health Regulations (2005), in force from 15 June 2007.⁷⁸

Being the product of WHO's exercise of the quasi-legislative powers conferred on its Assembly, the revised Regulations actually represent an international legal instrument binding on virtually all States of the international community.⁷⁹ As professor Lawrence Gostin stresses, WHO's normative powers are impressive and far-reaching "as states can be bound by health regulations without the requirement to affirmatively sign and ratify".⁸⁰ In fact, according to articles 21 and 22 of the Constitution of WHO, regulations produce compulsory effects for all Member States that do not expressly "opt out" or make reservations to them within a limited deadline. In this specific case, the IHR 2005 can be said to have been substantially agreed by consensus among all WHO member states.

In order to provide the global community with adequate instruments to face acute public health risks that threaten people worldwide, the Regulations try to strike a balance between sovereign rights, human rights, freedom of traffic and trade and shared commitment to protect global health.⁸¹ To this end, they contain a range of innovations including: a broader scope of application which is not limited to specific diseases; States Parties' obligations to develop certain minimum core public health capacities; obligations to notify WHO of events that may constitute a public health emergency of international concern according to defined criteria; provisions authorizing WHO to take into consideration unofficial reports of public health events and ask States for verification; procedures for the determination by the Director-General of a "public health emergency of international concern" and issuance of corresponding temporary recommendations; protection and full respect for the dignity, human rights and fundamental freedoms of persons;⁸² the establishment of National IHR Focal Points and WHO IHR Contact Points for urgent communications between States Parties and WHO.⁸³ In this perspective, the IHR 2005 define the rights and obligations of States Parties and indicate the proper procedures in order to create a governance system which places at the heart of decision-making and operative activities the interaction among national and international health authorities, thus of State and non-State actors, with a view to sharing responsibilities and fulfilling the duty to cooperate.⁸⁴

As said before, one of the most important innovations introduced by the revised Regulations is their application to a much broader spectrum of infectious diseases,⁸⁵ which require continuous epidemiologic surveillance and compulsory notification to WHO when unusual and unforeseen events of international relevance occur. Widening their field of action also to "emerging" diseases, the Regulations are meant to guarantee an effective response to the new health challenges of a globalized world. As pointed out by professor David Fidler in his early commentaries on the draft Regulations, this innovative approach – which provides for an "open category" encompassing any disease that may seriously and generally put public health at risk – represents the real revolutionary element characterizing the IHR 2005, since they allow a more flexible application with a better management of new health hazards.⁸⁶ It is indeed in this new perspective that the Regulations have become an essential tool for global health protection and a true pillar of international health law.

Within the described wider scope of the IHR 2005 fall certain food safety events with international implications – especially bacterial food contamination and foodborne diseases of microbiological origin⁸⁷ – that may require action under the legal provisions of the Regulations. In such cases, States Parties are under the obligation to notify to WHO the events detected at national level which meet the conditions laid down in Annex 2: unusualness of the event, emergence of a new disease with significant zoonotic potential, high rate of mortality or morbidity, potential transboundary diffusion, and potential interference with international travel or trade.⁸⁸

Together with the innovations introduced by the IHR 2005, other new initiatives were launched within WHO's network of food safety governance in order to strengthen the surveillance, early warning and reaction system framed by the Regulations.

In the first place, WHO established in 2004, and further developed in cooperation with the Food and Agriculture Organization, the *International Food Safety Authorities Network* (INFOSAN),⁸⁹ a joint network whose task is to promote the exchange of food safety information and to improve collaboration among food safety authorities at national and international levels, in particular among WHO and INFOSAN National Focal Points (i.e. national authorities involved across the farm-to-fork chain in food legislation, risk assessment, food control and management, food inspection services, etc.). INFOSAN Emergency – a food safety emergency network which is an integral part of INFOSAN – facilitates the identification, assessment and management of food safety events under the IHR 2005, complementing and supporting the existing WHO *Global Outbreak Alert and Response Network* (GOARN).⁹⁰

Secondly, being aware that thorough investigation of foodborne risks is important in order to control ongoing outbreaks and transmission of disease, to detect and remove implicated foods and to prevent future events, WHO has recently developed the *Guidelines for the Investigation and Control of Foodborne Diseases*.⁹¹ The Guidelines are meant to overcome the problem that sometimes these outbreaks go unrecognized, unreported or are not properly investigated, their effects becoming evident only when major health or economic damage has already occurred. In fact, the Guidelines draw on the basic idea that successful identification, investigation and control of foodborne diseases depend on good communication among the most relevant actors and professional groups involved in outbreaks management (governmental health authorities, sanitary and veterinary officials, laboratories, food scientists and consumers), on recourse to validated procedures and protocols, on timely and effective response.

In the third place, WHO has also turned its attention to early warning of outbreaks and early reaction for prevention of spread, which are basic prerequisites for containment and control of zoonotic diseases that can be transmitted indirectly via contaminated food. In this direction, an initiative involving WHO, FAO and OIE gave birth in 2006 to the *Global Early Warning System for Major Animal Diseases, including Zoonoses* (GLEWS), a joint early warning system built on the combination and coordination among the alert mechanisms of the three organizations. GLEWS's task is to detect, analyse and assess each event for its potential international importance according to the risk assessment criteria set forth in the IHR 2005. Together with INFOSAN, GLEWS guarantees extension of international surveillance and response to the entire farm-to-table chain. The two emergency networks

share information on events related to food of animal origin, or to contamination of non-animal food products. GLEWS informs INFOSAN Emergency of events where transmission via food is likely and relevant events are in turn notified to WHO's IHR system.

Fourthly, further innovations concern WHO's attempts to face the problem of under-reporting of data on foodborne diseases, which hinders both accurate determination of the proportion of diseases attributable to contaminated food and realistic estimate of its global burden on health, development and trade. To fill this data gap WHO launched in 2006 an *Initiative to Estimate the Global Burden of Foodborne Diseases*, again in collaboration with its usual partner organizations, FAO and OIE. The Initiative benefits from the support and expertise of the *Foodborne Disease Burden Epidemiology Reference Group* (FERG), an advisory board which assembles, analyses and reports data on foodborne diseases, develops models for estimation and appraisal of the overall burden of such diseases and puts such models at the disposal of states for studies at country level.⁹²

Giving birth to these initiatives, WHO has created a network of institutions, programmes and procedures which endeavour to foster international cooperation at the highest degree of quality and effectiveness under the general umbrella of the International Health Regulations. Nonetheless, the IHR 2005 do not include any enforcement mechanism for States which fail to comply with their provisions and do not apply to private entities.⁹³ IHR implementation is thus primarily the responsibility of health ministries and the other States authorities involved, and WHO only offers some guidance to Member States indicating preferred areas of work and expected results.⁹⁴ In this respect, the Organization suggests that the process of legislative implementation at national level should start with the general consideration of how the IHR 2005 are to be implemented in the legal and governance contexts of the State Party concerned; it is then expected to continue with the assessment of existing legislation, regulations and other instruments to determine whether their revision, or adoption of new ones, is appropriate to facilitate the full and efficient implementation of the Regulations. However, failure to comply with the obligations imposed by the IHR 2005 is not complemented by any sanctions regime, and the few relevant reference points on their implementation can be found in Article 3, stating that implementation "shall be guided by the Charter of the United Nations and the Constitution of the World Health Organization". The preamble of the WHO Constitution in turn recalls the United Nations Charter, declaring that in conformity with it the principle that "[t]he health of all peoples is fundamental to the attainment of peace and security and is dependent upon the fullest co-operation of individuals and States" is one the fundamental principles which are "basic to the happiness, harmonious relations and security of all peoples". Translating principles into practice, it could be argued that violations of the obligations to cooperate imposed by the IHR 2005 – which result in hampering a timely and adequate management of health risks of international concern, hence leading to serious challenges to global health – could be reported or denounced to the United Nations Security Council as being a menace to international peace and security, with a call for action under Article 41 of the Charter. This approach may find support in modern thinking and theories on global health security, especially in professor Ilona Kickbusch's argument that health is a key component of global security.⁹⁵

THE NEED TO MOVE FORWARD

It is generally acknowledged that due to their transboundary dimension and their potential widespread impact on human health, food safety challenges demand close international cooperation and global governance. Following in the wake of a clear trend in international law and practice, we are now witnessing the emergence of a general principle on food safety, underpinned by the progressive affirmation of a human right to safe food, which requires that international standards and guidelines be voluntarily complied with, legal obligations be fulfilled in good faith and all stakeholders at different levels play their proactive role in enhancing the international community's preparedness and capacity of response to food safety threats. It is in fact common view that protecting world health from foodborne illnesses and similar hazards is to be seen as a compelling duty and a primary interest of both States and non-State actors. This is in tune with the idea that food safety contributes to the realization of public health in its global dimension, that is to say public health conceived and theorized in the seminal studies of prominent academics and experts as a global public good.⁹⁶

While food safety governance at the global level calls for multi-sectoral approaches and multi-level cooperation to minimize the effects of food safety-related public health events, international law can still count on a limited set of legal instruments. This paper has tried to give evidence for this assertion showing that, from the viewpoint of both human rights law and international law, there is a strong need to move forward in order to enhance effectiveness of the right to safe food, strict compliance with generally accepted international standards and guidelines, agreement on more stringent and clear international obligations in matter of food safety regulation at the universal level, and last, but not least, creation of enforcement mechanisms. In fact, the present state of international law on food safety regulation still has faults and drawbacks, as authoritatively confirmed by professor Francis Snyder: "Food supply insecurity and unsafe food are tolerated, encouraged or even positively promoted by many aspects of current international law. Serious reform is essential if we want to create an international law for (and not just 'of') adequate food".⁹⁷ The legal framework explored by professor Snyder and his call for reform also lend further support to professor Gostin's general reflections on global health law governance, and especially to his argument that "[i]nternational law has serious structural problems of application, definition and enforcement" and that "[e]xisting legal solutions have deep structural faults".⁹⁸

Therefore, it is to be hoped that the joint efforts of the major international organizations involved at both the universal and the regional level (WHO, FAO, WTO, UE) – which point towards the prospective enhancement of the degree of cooperation among international actors, State authorities and private stakeholders – will succeed in shaping an improved legal framework for food safety governance, which may benefit from the commitment of both international and national institutions.

In such an evolving and interdependent scenario, national initiatives concerning targeted domestic legislation can indeed be welcomed as positive steps forward whenever they substantially contribute to realizing the right to safe food, enhance consumer protection, adopt Codex standards, introduce

accountability measures, and strengthen foodborne disease monitoring and surveillance systems. As cases in point, special mention should be made of the recently adopted *Chinese Food Safety Law* of 28 February 2009⁹⁹ and of the bills introduced to the United States Congress in 2009, namely the *Food Safety Rapid Response Act* and the *FDA Food Safety Modernization Act*,¹⁰⁰ which may undoubtedly contribute to safeguarding the health of consumers of large sections of the world population (especially in consideration of the fact that these initiatives concern two of the most populated countries in the world), and hence protect global health.

Stefania Negri is associate professor of International Law at the Faculty of Law of the University of Salerno (Italy), where she teaches International Human Rights Law and International Procedural Law. She has recently been visiting research fellow at the Graduate Institute of International and Development Studies in Geneva, where she has carried out a research project on the evolving relationship between global health and human rights with the co-direction of Professors Andrew Clapham and Ilona Kickbusch.

¹ In July 2008, due to an increase in the incidence of kidney ailments among Chinese babies, some dairy products were analyzed and found contaminated by melamine. Complaints about kidney problems traced back to a brand of infant formula, while contamination traces were also detected in liquid milk and exported powdered milk of processed food products from the Sanlu Group. This food safety crisis affected more than 54.000 children and caused at least six fatalities. Many countries banned Chinese dairy food and the World Health Organization defined this crisis as one of the largest food safety events that it had had to deal with in recent years. See http://www.who.int/foodsafety/fs_management/infosan_events/en/index.html.

² According to the US Food and Drug Administration (FDA) and the Centre for Disease Control and Prevention (CDC), the sources of the massive outbreak of illnesses of *Salmonella Typhimurium* in the United States in September 2008 were peanut butter and peanut paste produced by Peanut Corporation of America's processing plant in Georgia. As a precautionary measure, the producers recalled all peanut products from that plant and secondary and tertiary consumers were advised to check the origin of their purchases in order to avoid the potentially contaminated products. The Salmonella food poisoning made more than 650 people sick in 44 States and probably contributed to 9 deaths. See <http://www.fda.gov/oc/opacom/hottopics/Salmonellatyph.html>.

³ In August 2008, the Canadian Food Inspection Agency reported a widespread outbreak of *Lysteria Monocytogenes* in deli meat linked to a Maple Leaf Foods plant in Toronto. The producers recalled all products from the market but the food contamination illness caused 20 deaths. See <http://www.inspection.gc.ca/english/corpaffr/recarapp/recal2e.shtml>.

⁴ In March 2008, following the detection of dioxin-positive milk and buffalo mozzarella samples in some areas of the Campania Region, the Italian Ministry of Health identified the 83 agricultural companies which supplied the 25 cheese factories where the contamination was detected and promptly took measures to seize and isolate them. The Italian Government recalled from sale the mozzarella cheese linked to dioxin contamination although it made clear that the level of dioxin detected could not pose any serious risk to health. The Report by the U.S. Department of Agriculture is available at <http://www.fas.usda.gov/gainfiles/200804/146294161.pdf>.

⁵ In August 2008, a food poisoning outbreak of *Salmonella Agona* affected the UK and Ireland, and a number of chicken, beef and bacon products from Dawn Farm Foods were withdrawn from sale as a precautionary measure. At the beginning of December 2008, the Irish Government announced that laboratory results of animal feed and pork fat samples obtained by the Food Safety Authority of Ireland (FSAI) confirmed that dioxins were present at levels which were found to be in breach of Commission Regulation (EC) No. 1881/2006 (setting maximum levels for certain contaminants in foodstuffs). Since this problem called for

action, the FSAI required the food industry to recall from the market all Irish pork products produced from pigs slaughtered in Ireland from September 1, 2008. The alert was subsequently lifted on January 23, 2009. See <http://www.fsai.ie/alerts/fa/index.asp>.

⁶ Legal literature on food safety and related issues has flourished especially from the mid-1980s onward. See, e.g., WHO, *The Role of Food Safety in Health and Development* (Geneva: WHO Technical Report Series 1984); WHO-FAO, *Biotechnology and Food Safety* (Rome: FAO Food and Nutrition Papers 1996); WHO-FAO, *Risk Management and Food Safety* (Rome: FAO Food and Nutrition Papers 1997); Jan MacDonald, "Big Beef Up or Consumer Health Threat? The WTO Food Safety Agreement, Bovine Growth Hormone and the Precautionary Principle," *Environmental and Planning Law Journal* 15, no. 2 (1998): 115-126; Shirley A. Coffield, "Biotechnology, Food, and Agriculture Disputes or Food Safety and International Trade," *Canada United States Law Journal* 26, (2000): 233-251; Serge Frechette, "Biotechnology, Food, and Agriculture Disputes or Food Safety and International Trade," *ibid.*, 253-260; Gaëlle Bossis, "La notion de sécurité alimentaire selon l'OMC: entre minoration et tolérance timide," *Revue générale de droit international public* 105, no. 2 (2001): 331-359; Barry Kellman, "The Smart Border: Food Safety and Bioterrorism," *Canada United States Law Journal* 29 (2003): 197-204; John McNamara, "The Smart Border: Food Safety and Bioterrorism," *ibid.*, 205-214; Luca Marini, *Il principio di precauzione nel diritto internazionale e comunitario. Disciplina del commercio di organismi geneticamente modificati e profili di sicurezza alimentare* (Padova: Cedam 2004); Afifi Abdelrahman, "Sources et normes de sécurité alimentaire en droit international," *Revue égyptienne de droit international* 61 (2005): 1-54; Donna Roberts and Laurian Unnevehr, "Resolving Trade Disputes Arising From Trends in Food Safety Regulation. The Role of the Multilateral Governance Framework," *World Trade Review* 4, no. 3 (2005): 469-497; Ahmed Mahiou and Francis Snyder, ed., *La sécurité alimentaire/Food Security and Food Safety* (Leiden-Boston: Martinus Nijhoff Publishers 2006) and the impressive bibliography at 823-868; Obijiofor Aginam, "Food Safety, South-North Asymmetries, and the Clash of Regulatory Regimes," *Vanderbilt Journal of Transnational Law* 40, no. 4 (2006/07): 1099-1126; Meredith T. Mariani, *The Intersection of International Law, Agricultural Biotechnology, and Infectious Disease* (Leiden-Boston: Martinus Nijhoff Publishers 2007); Mai-Anh Ngo, "La conciliation entre les impératifs de sécurité alimentaire et la liberté du commerce dans l'accord SPS," *Revue internationale de droit économique* 21, no. 1 (2007): 27-42; Margherita Poto, "Regulations on Food Safety and the Role of African Actors in the Global Arena," *Journal of African and International Law* 1, no. 1 (2008): 107-130.

Some authors focused on regional regimes, with particular reference to the European Union. See, e.g., José-Luis Valverde, Augusto J. Piqueras García and Maria Dolores Cabezas López, "La 'nouvelle approche' en matière de santé des consommateurs et sécurité alimentaire: la nécessité d'une agence européenne de sécurité des aliments," *Revue du marché unique européen* 7, no. 4 (1997): 31-58; Franklin Dehousse, Ken Engelstad and Benjamin Gevers, "La sécurité alimentaire et le principe de précaution: quelle nouvelle réglementation alimentaire pour l'Europe?" *Studia Diplomatica* 53, no. 1/2 (2000): 95-112; Grace Skogstad, "The WTO and Food Safety Regulatory Policy Innovation in the European Union," *Journal of Common Market Studies* 39, no. 3 (2001): 485-505; Yves Petit, "L'autorité européenne de sécurité des aliments (A.E.S.A.) et la nouvelle approche alimentaire communautaire," *Journal des tribunaux* 10, no. 93 (2002): 209-214; Naomi Salmon, "A European Perspective on the Precautionary Principle, Food Safety and the Free Trade Imperative of the WTO," *European Law Review* 27, no. 2 (2002): 138-155; Jacques Bourrinet and Francis Snyder, ed., *La sécurité alimentaire dans l'Union européenne* (Brussels: Bruylant 2003); Manuel Diez de Velasco Vallejo and José Manuel Sobrino Heredia, "Vers une politique communautaire de sécurité alimentaire," in Georges Vanderaendern, ed., *Mélanges en hommage à Jean-Victor Louis* 1 (2003): 119-138; Julien Cazala, "Food Safety and the Precautionary Principle: the Legitimate Moderation of Community Courts," *European Law Journal* 10, no. 5 (2004): 539-554; Ellen Vos and Frank Wendler, ed., *Food Safety Regulation in Europe. A Comparative Institutional Analysis* (Antwerpen: Intersentia 2006); Emilie H. Leibovitch, "Food Safety Regulation in the European Union: Toward an Unavoidable Centralization of Regulatory Powers," *Texas International Law Journal* 43, no. 3 (2008): 429-452.

⁷ For full coverage of food safety issues see the relevant web pages at http://www.who.int/topics/food_safety/en/.

⁸ According to the WHO, "foodborne illnesses are defined as diseases, usually either infectious or toxic in nature, caused by agents that enter the body through the ingestion of food" (see

WHO Fact Sheet No. 237, Reviewed March 2007). Major foodborne diseases of bacterial origin are brucellosis, salmonellosis, listeriosis, escherichiosis, campylobacteriosis, cholera, botulism; other agents causing serious health problems are naturally occurring toxins (such as mycotoxins and marine biotoxins), and agents which may contaminate food through pollution of air, water and soil, like the so-called Persistent Organic Pollutants (e.g., dioxins) and metals (especially lead, mercury and cadmium). Other unconventional agents embrace anthrax and the agent causing Bovine Spongiform Encephalopathy, which is associated with the variant Creutzfeldt-Jakob disease.

⁹The “farm to fork” approach implies that food hygiene legislation issued both at the national and at the international level apply at every stage of the food chain, including primary production (e.g., farming, fishing and aquaculture), and that official and effective controls under the responsibility of national authorities be carried out from the input level to the front end retail. The “farm to fork” approach to food safety was the subject of extensive debate at the Pan-European Conference on Food Safety and Quality, held in Budapest on February 25-28, 2002 (see especially the FAO conference document on *FAO Veterinary Public Health and Food and Feed Safety Programme: the Safety of Animal Products from Farm to Fork*, available at <http://www.fao.org/docrep/MEETING/004/AB500E.HTM>), and at the Second FAO/WHO Global Forum of Food Safety Regulators, held in Bangkok on October 12-14, 2004 (see http://www.foodsafetyforum.org/global2/index_en.asp). For further information on this approach as adopted in the context of the activities of the European Commission’s Directorate-General for Health and Consumers, see http://ec.europa.eu/food/index_en.htm; see also the Commission’s explanatory booklet *From farm to fork – Safe food for Europe’s consumers* (2005), available at http://ec.europa.eu/food/resources/publications_en.htm.

¹⁰The Declaration was adopted by consensus by the High-level International Food Safety Forum, “Enhancing Food Safety in a Global Community,” held in Beijing on November 26 and 27, 2007, with the participation of senior officials and well-known experts from relevant international organizations and various government authorities as well as representatives of food industry and consumers. Available at:

http://www.who.int/foodsafety/fs_management/meetings/forum07/en/index.html.

¹¹ On the evolving concept of food safety, see especially Francis Snyder, “Toward an International Law for Adequate Food,” in *La sécurité alimentaire*, 79-163, at 117-121. Professor Snyder asserts that “[t]he idea of risk, the technique of risk analysis and the precautionary principle form the core of the contemporary concept of food safety and how to put it in practice through law” (119).

¹² *Ibid.*, 148-159; see also: Zhao Rongguang and George Kent, “Human Rights and the Governance of Food Quality and Safety in China,” *Asia Pacific Journal of Clinical Nutrition* 13, no. 2 (2004): 178-183, especially 180-181.

¹³ See mainly René-Jean Dupuy, ed., *The Right to Health as a Human Right* (Alphen aan den Rijn: The Hague Academy of International Law and the United Nations University 1979); Virginia A. Leary, “The Right to Health in International Human Rights Law,” *Health and Human Rights: An International Journal* 1, no. 1 (1994): 24-56; Brigit C.A. Toebes, *The Right to Health as a Human Right in International Law* (Antwerpen: Intersentia 1999); Eibe Riedel, “The International Protection of the Right to Health,” in Rüdiger Wolfrum et al., ed., *Encyclopedia of Public International Law* (Heidelberg: Max Planck Institut 2008); Andrew Clapham and Mary Robinson, ed., *Realizing the Right to Health* (Zurich: Rüffer & Rub, 2009).

¹⁴ See mainly Philip Alston, ed., *The Right to Food* (The Hague: Martinus Nijhoff Publishers 1984); Ian Brownlie, *The Human Right to Food* (London: Commonwealth Secretariat, 1987); Kerstin Mechlem, “Food Security and the Right to Food in the Discourse of the United Nations,” *European Law Journal* 10, no. 5 (2004): 631-648; Jean Ziegler, Christophe Golay, Claire Mahon and Sally-Anne Way, *The Fight for the Right to Food: Lessons Learned* (Basingstoke: Palgrave Mcmillan, forthcoming 2010).

¹⁵ Building on the idea which underpins the formulation of the Universal Declaration of Human Rights, and after its enunciation in the *Vienna Declaration and Programme of Action* (World Conference on Human Rights, Vienna, 25 June 1993, para. 5), the concept has been reiterated by the General Assembly of the United Nations and other human rights bodies. For the most recent example, see General Assembly Resolution 63/116 of December 10, 2008, adopting the *Declaration on the sixtieth anniversary of the Universal Declaration of Human Rights*.

¹⁶ Universal Declaration of Human Rights, adopted and proclaimed by General Assembly Resolution 217 A (III) of December 10, 1948.

¹⁷ International Covenant on Economic, Social and Cultural Rights, adopted and opened for signature, ratification and accession by General Assembly Resolution 2200 A (XXI) of December 16, 1966, in force from January 3, 1976. The definition adopted by the Covenant reproduces almost *verbatim* the terms used in the preamble of the WHO Constitution to first enunciate the right to health at the international level: “[t]he enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition” (Constitution of the World Health Organization as adopted by the International Health Conference, New York, June 19-22, 1946).

¹⁸ Committee on Economic, Social and Cultural Rights, General Comment No. 14, The right to the highest attainable standard of health, UN Doc. E/C.12/2000/4, August 11, 2000, para. 11.

¹⁹ *Ibid.*, para. 36.

²⁰ *Ibid.*, para. 51.

²¹ Committee on Economic, Social and Cultural Rights, General Comment No. 12, The right to adequate food, UN Doc. E/C.12/1999/5, May 12, 1999, para. 14.

²² *Ibid.*, General Comment No. 14, para. 43 (b); see also General Comment No. 3, The nature of States parties obligations, UN Doc. E/1991/23, December 14, 1990, para. 10.

²³ It would be interesting to further reflect on the question posed by one of the speakers at the latest Dubai Food Safety Conference: “When food is in shortage, can policy makers accept lower food safety standards to protect food security?” (see “Balancing Food Safety and Food Security – FAO Perspective,” presentation by Ezzedine Boutrif at Dubai Food Safety Conference, held in February 2009, available at <http://www.dubaifoodsafety.com>).

²⁴ Committee on Economic, Social and Cultural Rights, General Comment No. 12, para. 4.

²⁵ *Ibid.*, para. 8.

²⁶ *Ibid.*, para. 10.

²⁷ *Ibid.*, paras. 25 and 39, respectively.

²⁸ The draft resolution was adopted by 184 votes to 1 (United States): see General Assembly Official Records, Sixty-third Session, 70th Plenary Meeting, December 18, 2008, U.N. Doc. A/63/PV.70, at 24. See also General Assembly Resolutions 62/164 of December 18, 2007, 61/163 of December 19, 2006, 60/165 of December 16, 2005, 59/202 of December 20, 2004, 58/186 of December 22, 2003, 57/226 of December 18, 2002, and 56/155 of December 19, 2001.

²⁹ Human Rights Council Resolution 7/14, adopted by consensus.

³⁰ FAO, World Food Summit (Rome, November 13-17, 1996), Rome Declaration on World Food Security, November 13, 1996, and World Food Summit Plan of Action, para. 21 (b).

³¹ FAO/WHO Regional Conference on Food Safety for the Americas and the Caribbean (San José, December 6-9, 2005).

³² Available at: <http://www.fao.org/docrep/003/X9601E/x9601e00.HTM>.

³³ FAO/WHO Global Forum of Food Safety Regulators (Marrakesh, January 28-30, 2002), Inaugural Statement by Dr. Jacques Diouf, Director-General Food and Agriculture Organization of the United Nations, available at <http://www.fao.org/docrep/MEETING/004/Y3680E/Y3680E04.htm>.

³⁴ WHO, *WHO Global Strategy for Food Safety: Safer Food for Better Health* (Geneva: WHO 2002), 5.

³⁵ The Optional Protocol has recently been adopted by both the United Nations Human Rights Council and the General Assembly: see Human Rights Council Resolution 8/2 of June 18, 2008 and General Assembly Resolution 63/117, adopted by consensus on December 10, 2008. In literature, see especially Claire Mahon, “Progress at the Front: The Draft Optional Protocol to the International Covenant on Economic, Social and Cultural Rights,” *Human Rights Law Review* 8, no. 4 (2008): 617-646.

³⁶ In the absence of any express protection of the right to health by the European Convention on Human Rights, the Strasbourg Court has declared its incompetence with regard to alleged violations of the right, thus declaring some individual applications inadmissible *ratione materiae*, *Fiorenza v. Italy* (dec.), No. 44393/98, November 28, 2000; *Pastorino and Others v. Italy* (dec.), No. 17640/02, July 11, 2006). Strasbourg case law shows that the Court has only dealt with some aspects of the right to health where it has been able to establish a link to the violation of a right expressly guaranteed by the Convention. The Court has thus drawn upon the interconnected nature of all rights to address health issues through the lens of civil

rights, namely the right to security of the person, and first and foremost the right to private and family life. According to the Court's settled jurisprudence, in fact, specific issues concerning the health of applicants are mainly encompassed by article 8 of the Convention: *Herczegfalvy v. Austria*, No. 10533/83, September 24, 1992, Series A No. 244, para. 86; *Raninen v. Finland*, No. 20972/92, December 16, 1997, *Reports* 1997-VIII, para. 63; *Guerra and Others v. Italy*, No. 14967/89, February 19, 1998, *Reports* 1998-I, para. 60; *Botta v. Italy*, No. 21439/93, February 24, 1998, *Reports* 1998-I, para. 32; *Pretty v. United Kingdom*, No. 2346/02, April 29, 2002, *Reports* 2002-III, para. 63; *Y.F. v. Turkey*, No. 24209/94, July 22, 2003, *Reports* 2003-IX, para. 33; *M.C. v. Bulgaria*, No. 39272/98, December 4, 2003, *Reports* 2003-XII, para. 152; *Okyay and Others v. Turkey*, No. 36220/97, July 12, 2005, *Reports* 2005-VII, paras. 67-68; *Roche v. United Kingdom* [GC], No. 32555/96, October 19, 2005, *Reports* 2005-X, para. 155; *Marie-Thérèse Trocellier v. France* (dec.), No. 75725/01, October 5, 2006; *Ledyayeva, Dobrokhotova, Zolotareva and Romashina v. Russia*, Nos. 53157/99, 53247/99, 53695/00 and 56850/00, October 26, 2006. Seldom has the Court affirmed a direct link between the right to health and the right to life: *Öneryildiz v. Turkey*, No. 48939/99, November 30, 2004, *Reports* 2004-XII, para. 65; *Tarariyeva v. Russia*, No. 4353/03, December 14, 2006, paras. 73-74.

³⁷ The right to health is set forth in article 10 of the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights of 17 November 1988, O.A.S. Treaty Series No. 69 (1988), but article 19, paragraph 6, of the same Protocol restricts the applicability of the system of individual petitions only to violations of articles 8.a (rights of workers) and 13 (right to education). In its decision on the admissibility of the application in the case of *Miranda Cortez et al.*, the Inter-American Commission declared its incompetence *ratione materiae* with regard to article 10 of the Protocol and stated that it would examine health-related issues in the merits phase in accordance with articles 26 and 29 of the American Convention (*Jorge Odir Miranda Cortez et al. v. El Salvador*, Case 12.249, Report No. 29/01, March 7, 2001, para. 47).

³⁸ See mainly Alphonsus P.M. Coomans, ed., *Justiciability of Economic and Social Rights. Experiences from Domestic Systems* (Antwerpen-Oxford: Intersentia 2006).

³⁹ Catherine Button, *The Power to Protect: Trade, Health and Uncertainty in the WTO* (Oxford-Portland: Hart Publishing 2004), 227. The author expands on the health and trade interface providing an insightful and detailed analysis of both WTO Agreements and the relevant jurisprudence of the Dispute Settlement Body.

⁴⁰ See the famous declaration by U.S. President John F. Kennedy in his 1962 message to the Congress.

⁴¹ Article 153, paragraph 1 of the EC Treaty states that "in order to promote the interests of consumers and to ensure a high level of consumer protection, the Community shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information, education and to organise themselves in order to safeguard their interests." The texts of Community acts on consumer protection, health and safety are available at <http://eur-lex.europa.eu/en/legis/20090301/chap152030.htm>.

⁴² See especially the latest book by Hans-W. Micklitz, Norbert Reich and Peter Rott, *Understanding EU Consumer Law* (Mortsel: Intersentia 2009).

⁴³ Regulation (EC) No. 178/2002 of the European Parliament and of the Council of January 28, 2002 (OJ L 31/1, 1.2.2002) as amended by Regulation (EC) No. 1642/2003 of the European Parliament and of the Council of July 22, 2003 (OJ L 245/4, 29.9.2003), Commission Regulation (EC) No. 575/2006 of April 7, 2006 (OJ L 100/3, 8.4.2006), and Commission Regulation (EC) No. 202/2008 of March 4, 2008 (OJ L 60/17, 5.3.2008). See also Commission Regulation (EC) No 2230/2004 of December 23, 2004 laying down detailed rules for the implementation of European Parliament and Council Regulation (EC) No. 178/2002 with regard to the network of organizations operating in the fields within the European Food Safety Authority's mission (OJ L 379/64, 24.12.2004). Prior to Regulation No. 178/2002 the European Commission had adopted "The General Principles on Food Law in the European Union – Commission Green Paper," COM(97) 176 final, April 30, 1997, and then the "White Paper on Food Safety," COM(99) 719 final, January 12, 2000. Further information of the EU food safety policy and legislation is available at <http://europa.eu/scadplus/leg/en/s80000.htm>. See also Snyder, "Toward an International Law for Adequate Food," 134-138, and the author's cited *supra* at note 6.

⁴⁴ Articles 5 to 10.

⁴⁵ Article 14, para. 1.

⁴⁶ Articles 17 to 21.

⁴⁷ Direct effect is a basic principle of Community case law. The concept of direct effect and its further distinction into vertical and horizontal direct effect was mainly elaborated by the Court of Justice in the following landmark cases: *NV Algemene Transporten Expeditie Onderneming van Gend en Loos v. Nederlandse Administratie der Belastingen*, Case 26/62, Judgment of February 5, 1963, *Reports* 1963, 1; *Defrenne v. Sabena*, Case 43/75, Judgment of April 8, 1976, *Reports* 1976, 455.

⁴⁸ See article 5, para. 2 and article 7, para. 2, respectively.

⁴⁹ On the application of articles 30 and 95, see especially ECJ, *The Queen, on the application of Alliance for Natural Health and Nutri-Link Ltd v. Secretary of State for Health and The Queen, on the application of National Association of Health Stores and Health Food Manufacturers Ltd v. Secretary of State for Health and National Assembly for Wales*, Joined cases C-154/04 and C-155/04, Judgment of July 12, 2005, *Reports* 2005, I-06451; *Commission of the European Communities v. Kingdom of Spain*, Case C-88/07, Judgment of March 5, 2009, *Reports* 2009.

⁵⁰ See also, in the same direction, article 35 of the Charter of Fundamental Rights of the European Union.

⁵¹ ECJ, *Koinopraxia Enóseon Georgikon Synetairismon Diacheiriséos Enchorion Proïonton Syn. PE (KYDEP) v. Council of the European Union and Commission of the European Communities*, Case C-146/91, Judgment of September 15, 1994, *Reports* 1994, I-4199, para. 61; *United Kingdom of Great Britain and Northern Ireland v. Commission of the European Communities*, Case C-180/96, Judgment of May 5, 1998, *Report* 1998, I-2265, para. 100; *The Queen v. Ministry of Agriculture, Fisheries and Food, Commissioners of Customs & Excise, ex parte National Farmers' Union*, Case C-157/96, Judgment of May 5, 1998, *Report* 1998, I-2211 ss., para. 63.

⁵² ECJ, *National Farmers' Union*, para. 63; *Agrarproduktion Staebelow GmbH v. Landrat des Landkreises Bad Doberan*, Case C-504/04, Judgment of January 12, 2006, *Reports* 2006, I-679, para. 39.

⁵³ CFI, *Pfizer Animal Health SA v. Council of the European Union*, Case T-13/99, Judgment of September 11, 2002, *Reports* 2002, II-3305, paras. 146-172; *Alpharma Inc. v. the Council of the European Union*, Case T-70/99, Judgment of September 11, 2002, *Reports* 2002, II-3495, paras. 159-183.

⁵⁴ See Button, *The Power to Protect*, 232-233. The author, however, criticizes the possibility to apply the procedural review model within the WTO context: "it is by no means clear that, in the WTO setting, the validity of process is a sufficient reason to respect national regulatory decisions. By focusing on the democratic legitimacy of regulatory trade-offs, the frame of reference is necessarily national. Accordingly, the interests of other WTO Members are likely to be excluded." (233).

⁵⁵ ECJ, *NV United Foods E Pvbv Aug. Van den Abeele v. Belgian State*, Case 132/80, Judgment of April 7, 1981, *Reports* 1981, 995, para. 22; *Verband Sozialer Wettbewerb Ev v. Clinique Laboratoires SNC and Estée Lauder Cosmetics GmbH*, Case C-315/92, Judgment of February 2, 1994, *Reports* 1994, I-317, para. 15.

⁵⁶ General Assembly Resolution 39/248 of April 9, 1985 and Annex: Guidelines for Consumer Protection.

⁵⁷ See Report of the 30th Session of the Committee on World Food Security (CFS), Rome, September 20-23, 2004, Annex 1: *Voluntary Guidelines to Support the Progressive Realization of the Right to Adequate Food in the Context of National Food Security* - September 23, 2004.

⁵⁸ CAC is a joint intergovernmental body created by WHO and FAO in 1963 to set and harmonize standards for consumers' protection and for fairer practices in food trade. CAC has reached the number of 179 Member States plus the European Community. The Commission has also published a voluntary *Code of Ethics for International Trade in Food*, which provides some guidance to stop exporting countries and exporters from dumping poor-quality or unsafe food on to international markets. The Code is currently under revision and the discussion of the proposed revised draft has been on the agenda of the Codex Committee on General Principles, held in Paris from March 30 to April 3, 2009.

⁵⁹ Both available at http://www.wto.org/english/docs_e/legal_e/legal_e.htm.

⁶⁰ See Snyder, "Toward an International Law for Adequate Food," 123-133; Sabrina Shaw and Risa Schwartz, *Trading Precaution: The Precautionary Principle and the WTO*, UNU-IAS

Report (2005), available at

<http://www.ias.unu.edu/binaries2/Precautionary%20Principle%20and%20WTO.pdf>, at 7.

⁶¹ General Agreement on Tariffs and Trade (GATT), Geneva, October 30, 1947 (incorporated into GATT 1994), Article XX: "Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures: ... (b) necessary to protect human, animal or plant life or health."

⁶² Shaw and Schwartz, *Trading Precaution*, at 6: "As stated in the Preamble, the SPS Agreement is an elaboration of Article XX (b). However, while the SPS Agreement permits Members to enact SPS measures if specific obligations are met, Article XX (b) sets out general exceptions for violations to the GATT. The 'necessity test' is a much higher threshold, which does not seem to allow for preventative action when there is a lack of scientific evidence. The term 'necessary' places the burden of proof squarely on the Member taking the action, and, until recently in *EC-Asbestos*, no WTO Member has been able to pass the 'necessary' hurdle" (footnotes omitted).

⁶³ Button, *The Power to Protect*, 228.

⁶⁴ Shaw and Schwartz, *Trading Precaution*, at 6.

⁶⁵ See SPS Agreement, Preamble and Annex A, paragraph 3 (a).

⁶⁶ WTO Appellate Body, *European Communities – Trade Description of Sardines*, WT/DS231/AB/R, Report of the Appellate Body, September 26, 2002.

⁶⁷ WTO Appellate Body, *European Communities – Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R - WT/DS48/AB/R, Report of the Appellate Body, January 16, 1998. In the *EC-Hormones* dispute between the United States, Canada and the European Union, the issue relevant to human health, trade and food safety has gone through the entire dispute settlement process. Like the cholera case, the beef hormone case underscores the importance of basing food safety regulations on scientific evidence and international food safety standards.

⁶⁸ See *EC-Hormones*, para. 166; *EC-Sardines*, para. 227: "we uphold the Panel's conclusion, in paragraph 7.90 of the Panel Report, that the definition of a 'standard' in Annex 1.2 to the *TBT Agreement* does not require approval by consensus for standards adopted by a 'recognized body' of the international standardization community. We emphasize, however, that this conclusion is relevant only for purposes of the *TBT Agreement*. It is not intended to affect, in any way, the internal requirements that international standard-setting bodies may establish for themselves for the adoption of standards within their respective operations. In other words, the fact that we find that the *TBT Agreement* does not require approval by consensus for standards adopted by the international standardization community should not be interpreted to mean that we believe an international standardization body should not require consensus for the adoption of its standards."

⁶⁹ WTO Appellate Body, *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*, WT/DS135/AB/R, Report of the Appellate Body, March 12, 2001.

⁷⁰ For much deeper insights in the findings of the Appellate Body in these reports, refer mainly to Shaw and Schwartz, *Trading Precaution*, 7-8; Button, *The Power to Protect*, and further bibliographic references indicated by these authors. In WTO-EC comparative perspective, see mainly Chen Weidong, "Food Safety and Trade: How to Decide the Appropriate Level of Food Safety? A Comparative Study of Trade Dispute Settlement about Food Safety in the WTO and the EC," in *La sécurité alimentaire*, 725-752.

⁷¹ Shaw and Schwartz, *Trading Precaution*, 11.

⁷² Button, *The Power to Protect*, 228-229, with special reference to the contested trade of genetically modified organisms. On questions concerning trade of GMOs, see also 107, 230-232; also Estelle Brossset, "Le commerce international des produits biotechnologiques," in Sandrine Maljean-Dubois, ed., *La société internationale et les enjeux bioéthiques* (Paris: Pédone 2006): 165-202; *Ibid.*, "Le cadre juridique international en matière de produits alimentaires génétiquement modifiés: entre pénurie et sur-alimentation," in *La sécurité alimentaire*, 265-321.

⁷³ WHO/WTO, *WTO Agreements and Public Health. A joint study by the WHO and the WTO Secretariat* (Geneva: WHO/WTO 2002), 142-143, paras. 296-297, available at http://www.wto.org/english/res_e/booksp_e/who_wto_e.pdf.

⁷⁴ WHO, *Foodborne disease outbreaks: Guidelines for investigation and control* (2008), v.

⁷⁵ The United Nations General Assembly expressed its serious concern about the new public health emergencies that threaten global health, underscoring the need for closer international cooperation, even beyond emergency, and towards a strengthened capacity of response. See, e.g. General Assembly Resolutions 58/3 of October 27, 2003, 59/27 of November 23, 2004, 60/35 of November 30, 2005, entitled *Enhancing capacity-building in global public health*. See also General Assembly Resolution 63/33 of November 26, 2008, *Global health and foreign policy*.

⁷⁶ According to WHO, the most virulent pathogens causing foodborne diseases are BSE (bovine spongiform encephalopathy), Campylobacter, *Escherichia coli*, *Salmonella*, *Shigella*.

⁷⁷ "The contamination of food by chemical hazards is a worldwide public health concern and is a leading cause of trade problems internationally. Contamination may occur through environmental pollution of the air, water and soil, such as the case with toxic metals, PCBs and dioxins, or through the intentional use of various chemicals, such as pesticides, animal drugs and other agrochemicals" (<http://www.who.int/foodsafety/chem/en/index.html>).

⁷⁸ World Health Assembly, Fifty-Eighth plenary meeting, May 23, 2005, Resolution WHA58.3, *Revision of the International Health Regulations*.

⁷⁹ At present the IHR 2005 are binding on 194 States, including all WHO Members, of which only two (India and the United States of America) submitted reservations under Article 62 of the Regulations.

⁸⁰ Lawrence O. Gostin, "Global Health Law: Health in a Global Community," in Lawrence O. Gostin, *Public Health Law: Power, Duty, Restraint* (Berkeley: University of California Press 2008), available at <http://lsr.nellco.org/georgetown/ois/papers/15>. See also David P. Fidler, "From International Sanitary Conventions to Global Health Security: The New International Health Regulations," *Chinese Journal of International Law* 4, no. 2 (2005): 325-392; David P. Fidler and Lawrence O. Gostin, "The New International Health Regulations: An Historic Development for International Law and Public Health," *Journal of Law, Medicine & Ethics* 34, no. 1 (2006): 85-94; Michael G. Baker and David P. Fidler, "Global Public Health Surveillance under New International Health Regulations," *Emerging Infectious Diseases* 12, no. 7 (2006): 1058-1065; Erik Mack, "The World Health Organization's New International Health Regulations: Incursion on State Sovereignty and Ill-Fated Response to Global Health Issues," *Chicago Journal of International Law* 7, no. 1 (2006): 365-377.

⁸¹ According to Article 2 of the IHR 2005, "The purpose and scope of these Regulations are to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade."

⁸² Article 3 (1) of the IHR 2005 provides: "The implementation of these Regulations shall be with full respect for the dignity, human rights and fundamental freedoms of persons." For further considerations on this issue, see Stefania Negri, "Emergenze sanitarie e diritto internazionale: il paradigma salute–diritti umani e la strategia globale di lotta alle pandemie ed al bioterrorismo" (Public health emergencies and international law: the health–human rights paradigm and the global fight against pandemic diseases and bioterrorism), in *Scritti in onore di Vincenzo Starace* 1 (Napoli: Editoriale Scientifica 2008): 571-605.

⁸³ See in particular Articles 2 to 12 of the Regulations.

⁸⁴ Professor Fidler lays special stress on this specific aspect of the revised Regulations, which he deems to be the most relevant: "the new IHR create a strategy and framework for integrated, flexible and forward-looking governance for addressing serious threats to public health. The new IHR engage State and non-State actors, address numerous public health threats and draw together objectives found in multiple international legal regimes – specifically those concerning infectious disease control, human rights, trade, environmental protection and security – and configure them in a way that has no precedent in international law on public health." (Fidler, "From International Sanitary Conventions," 326).

⁸⁵ The IHR 1969 only concerned more serious illnesses such as cholera, plague, yellow fever, smallpox, typhus. In addition to these illnesses, the revised Regulations also apply to new and "emerging" infectious diseases, such as SARS, human influenza caused by new virus subtypes, viral haemorrhagic and other fevers known as Ebola, Lassa, Marburg, West Nile, Dengue and Rift Valley fevers, and to any other disease which may spread rapidly internationally and

represent a serious risk to public health. They apply as well to any event of potential international public health concern, including those of unknown causes or sources.

⁸⁶ David P. Fidler, "Comments on WHO's Interim Draft of the Revised International Health Regulations," in Lawrence O. Gostin, ed., *Public Health Law and Ethics: A Reader* (Berkeley: University of California Press 2002); *Ibid.*, "Revision of the World Health Organization's International Health Regulations," *ASIL Insights* (April 2004), available at <http://www.asil.org/insights/insigh132.htm>. Professor Fidler's commentaries referred to the document *International Health Regulations: Working Paper for Regional Consultations*, IGWG/IHR/Working Paper/12.2003, January 12, 2004.

⁸⁷ For chemical food contamination the WHO launched in 1976 the Global Environment Monitoring System - Food Contamination Monitoring and Assessment Programme (GEMS/Food) (see <http://www.who.int/foodsafety/chem/gems/en/index.html>).

⁸⁸ IHR 2005, Annex 2: "Decision instrument for the assessment and notification of events that may constitute a public health emergency of international concern."

⁸⁹ Further information available at:

http://www.who.int/foodsafety/fs_management/infosan/en/index.html.

⁹⁰ GOARN is a global network launched in 2000 with the aim of combating the international spread of outbreaks, ensuring that appropriate technical assistance reaches affected states rapidly and contributing to long-term epidemic preparedness and capacity building. For further information, see <http://www.who.int/csr/outbreaknetwork/en/>.

⁹¹ WHO, *Foodborne Disease Outbreaks: Guidelines for Investigation and Control* (2008), available at

http://www.who.int/foodsafety/publications/foodborne_disease/fdbmanual/en/.

⁹² The task and activities of the Initiative and FERG, together with more detailed information on cooperation with states, are thoroughly described at

http://www.who.int/foodsafety/foodborne_disease/ferg/en/index.html.

⁹³ It is indicative that the United States submitted an understanding that the provisions of IHR 2005 do not create judicially enforceable private rights: see the Diplomatic Note of 13 December 2006, available at http://www.who.int/csr/ihr/states_parties/en/index.html.

⁹⁴ WHO, *International Health Regulations (2005): Areas of work for implementation* (2007), WHO/CDS/EPR/IHR/2007.1, available at

http://www.who.int/ihr/area_of_work/en/index.html. See also the "Toolkit for implementation in national legislation" at

http://www.who.int/ihr/legal_issues/legislation/en/index.html and especially *International Health Regulations (2005): A brief introduction to implementation in national legislation* of January 2009.

⁹⁵ For detailed information on professor Kickbusch's theories and publications see at <http://www.ilonakickbusch.com/home/index.shtml>.

⁹⁶ See, e.g., Lincoln C. Chen, Tim G. Evans, Richard A. Cash, "Health as a Global Public Good," in Inge Kaul, Isabelle Grunberg, Marc A. Stern, ed., *Global Public Goods: International Cooperation in the 21st Century* (New York: Oxford University Press 1999); Inge Kaul (co-edited with Pedro Conceição et al.), *Providing Global Public Goods: Managing Globalization* (New York: Oxford University Press 2003); Ilona Kickbusch, Lea Payne, "Constructing Global Public Health in the 21st Century," Meeting on Global Health Governance and Accountability, June 2-3, 2004, Harvard University, Cambridge, available at <http://www.ilonakickbusch.com/global-health-governance/index.shtml>; Christopher L. R. Bartlett, Ilona Kickbusch, Denis Coulombier, "Infectious Diseases: preparing for the future," *ibid.*; Ilona Kickbusch, Graham Lister, ed., *European Perspectives on Global Health. A Policy Glossary* (Brussels: European Foundation Centre 2006).

⁹⁷ Snyder, "Toward an International Law for Adequate Food," 162.

⁹⁸ Lawrence O. Gostin, "Global Health Law Governance," *Emory International Law Review* 22 (2008): 35-47, at 36-37.

⁹⁹ The Chinese law passed by the National People's Congress Standing Committee, in force as of June 1, 2009, creates a national food safety commission, sets new and stricter standards and aims to tighten supervision and increase penalties for offenders. Under the new legislation, consumers can get financial compensation of up to 10 times the price of the product, in addition to compensation for any harm caused by tainted food. On earlier Chinese food safety law, see Bian Yongmin, "Current Chinese Law on Food Safety: An Overview," in *La sécurité alimentaire*, 167-186; Drew Thompson and Hu Ying, "Food Safety in China: New Strategies," *Global Health Governance* 1, no. 2 (Fall 2007), available at <http://www.ghgj.org>;

for documentary materials and relevant commentaries, see Francis Snyder, *The European Union and China, 1949-2008: Basic Documents and Commentary* (Oxford: Hart Publishing 2008). In general, on China's health governance see especially Yanzhong Huang, *Governing Health in Contemporary China: Political and Policy Dynamics* (New York: Routledge forthcoming March 2010).

¹⁰⁰ *The Food Safety Rapid Response Act of 2009* [S.1269.IS] was introduced on June 16, 2009, by U.S. Senators Klobuchar and Chambliss and has three main provisions: first, it directs the CDC to enhance the nation's foodborne disease surveillance system by improving the collection, analysis, reporting and usefulness of data among local, state and federal agencies as well as the food industry; second, it directs the CDC to provide support and expertise to state health agencies and laboratories for their investigations of foodborne disease; and third, it establishes regional "Food Safety Centers of Excellence" based on collaborations between selected higher education institutions and state public health agencies, which would assist state and local agencies. This bill complements the *Food Safety Modernization Act of 2009* [S.510.IS], introduced in March, which aims at strengthening the Food and Drug Administration's authority and resources to ensure a safe food supply. With regard to previous analogous initiatives, on July 29, 2008, the then Senator Barak Obama had introduced in the U.S. Senate the bill *Improving Food-borne Illness Surveillance and Response Act of 2008* (available at <http://www.govtrack.us/congress/bill.xpd?bill=s110-3358>), which never became law. The Obama bill was meant to enhance the identification and investigation of foodborne illness outbreaks; improve the collection, analysis, reporting, and usefulness of data on foodborne diseases; establish a diverse working group of food safety experts and stakeholders to develop an annual public report and strategic plan to address deficiencies in foodborne illness surveillance; enhance the food safety capacity and roles of state and local agencies, and integrate their efforts as fully as possible into national food safety initiatives.