

# THE GLOBAL ARENA OF FOOD LAW: EMERGING CONTOURS OF A META-FRAMEWORK

*Bernd van der Meulen\**

## Abstract

Food is one of the most regulated social and economic sectors. At the global level several organisations such as the UN, FAO, WHO, the Codex Alimentarius Commission and the WTO play a role in food governance through formulating and enforcing rules regarding production, manufacturing, trade and distribution. These rules are based on a variety of motives such as protecting human rights, promoting health, ensuring food security, ensuring food safety, promoting fair or free trade, dealing with incidents and promoting economic development. Despite the variety in sources and motives generally these rules seem to reinforce rather than contradict each other. In this sense a global system of food law seems to be emerging. Among other things, this system puts emphasis on the role of science through the risk analysis methodology. At closer inspection the global system of food law appears not to address stakeholders' behaviour regarding food, but rather the national regulatory frameworks addressing such behaviour. In this way global food law is a meta-framework for the food sector.

## 1 Introduction

### 1.1 Global Food Governance

The global governance infrastructure for food is far advanced in comparison to many other areas. This should not come as a surprise.

Without exception, all people in the world are consumers of food, the vast majority, several times a day. They need food to sustain their health and energy, and food plays a large social role as well. Food shortages immediately lead to acute problems, not to mention chronic hunger and undernourishment. But, even if food is available, it may present risks. Unfortunately, food does not only sustain life and health. It has been chosen by many natural enemies as pathway into the human body. And many hazards not as such designed by nature to attack man may still cause collateral damage to people. As if all this were not enough, additional risks stem from ignorance, fraud and carelessness of people handling food in production, trade and preparation. The human body's capacity to store surplus nutrients is an additional source of health problems in situations where supply is continuously generous. The need for regulation is apparent.

All countries in the world are food producers; all participate in the international trade in food, both as importers and as exporters.

All trade-related questions apply to food: how to ensure free and fair trade and how to ensure the life and health of people. At the global level, different institutions and their member states deal with these questions, and from their efforts emerge the contours of a truly global system of food governance.

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\* B.M.J. van der Meulen is Professor of Law and Governance at Wageningen University, the Netherlands <<http://www.law.wur.nl/uk>>; Chairman of the Dutch Food Law Association <<http://www.nvlr.nl>>; Director of the European Institute for Food Law <<http://www.food-law.nl>>; member of the Board of Directors of the European Food Law Association <<http://www.efla-aeda.org>>; and member of the Editorial Board of the European Food and Feed Law Review <<http://www.lexxion.eu/effl>>. This contribution elaborates on previous publications, such as: Bernd van der Meulen and Menno van der Velde, *European Food Law Handbook* (2008), available at: <<http://www.wageningenacademic.com/foodlaw>>; Irene Scholten-Verheijen, Bernd van der Meulen and Theo Appelhof, *Landkaart levensmiddelenrecht* (2009); and Bernd van der Meulen, Harry Bremmers, Leon Geyer, Nidhi Gupta and Hans Bouwmeester, *Nano Food Regulation: Towards an Adaptive Regulatory Infrastructure for Nanotechnology Applications in the Food Sector* (forthcoming). Many thanks to Prof. Margaret Rosso Grossman, Anna Szajkowska and Irene Scholten-Verheijen for their valuable comments and suggestions. Comments are welcome at <[Bernd.vanderMeulen@wur.nl](mailto:Bernd.vanderMeulen@wur.nl)>.

In this contribution I will sketch these contours. This contribution will show that, generally speaking, food law at the global level does not directly regulate stakeholders' behaviour regarding food but imposes requirements on national and regional regulatory frameworks that in turn apply to stakeholders. In this sense, global food law is not a framework for practices but a framework for frameworks, or a meta-framework.<sup>1</sup> The impact of global food law on the regional and national level of food governance will be illustrated with the example of the European Union.

## 1.2 What's on the Menu?

This article is structured as follows. Following this general introduction, it introduces the most relevant players in section 2. Next, section 3 discusses the human rights dimension. Section 4 describes the role of the WTO in regulating trade and providing dispute resolution. Section 5 discusses sanitary measures as justifiable barriers to trade. They must be science-based (the topic of section 6) or based on international standards such as the Codex Alimentarius (discussed in section 7). Section 8 introduces global instruments for crisis management. Finally, the conclusions of this contribution appear in section 9.

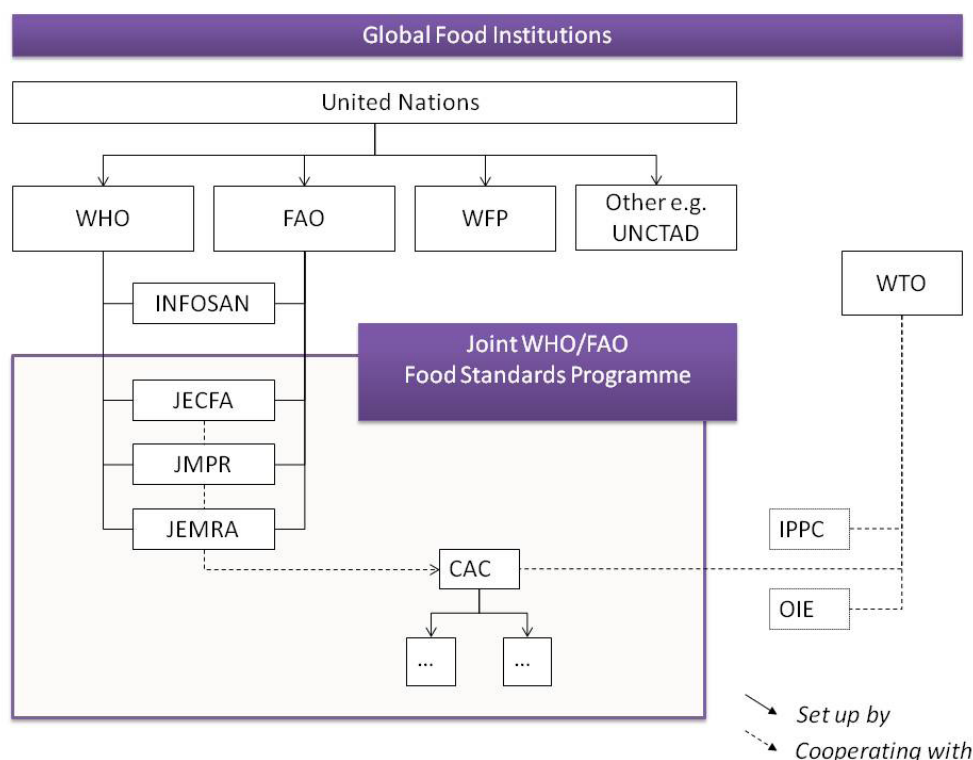
## 2 Players in the Global Arena

### 2.1 Introduction

At the global level, food law is embedded in the general international law structures dominated by the United Nations and the World Trade Organization. Some other organisations specifically address food and food-related issues. This section introduces the most important organisations.<sup>2</sup> Most of them also feature later in this contribution. Frame 1 provides a graphic presentation of their interrelationships.

<sup>1</sup> This seems to have been overlooked by Robert Wolfe in his article 'See You in Geneva? Legal (Mis) Representations of the Trading System', (2005) 11(3) *European Journal of International Relations* 339-365 (an earlier version is available on the Internet with a slightly different title: 'See you in Geneva? Pluralism and centralism in legal representations of the trading system'). His central argument is that, in order to understand the rules of trade, one should not look at the WTO but at trading practices: 'The WTO in a familiar phrase may be "rule-based", but officials do not "make" the rules; participants in the trading system make the rules.'

<sup>2</sup> For a different selection, see D. John Shaw, *Global Food and Agricultural Institutions* (2009), analysing the FAO, the WFP, the ARD (Agricultural and Rural Development Department of the World Bank), IFAD (International Fund for Agricultural Development) and the CGIAR (Consultative Group on International Agricultural Research).

**Frame 1: Global Food Institutions**

\* Many thanks to Geronda Klop for designing this frame.

**2.2 United Nations**

The United Nations (UN)<sup>3</sup> is the largest international organisation. Virtually all states in the world are members (192). The main tasks of the UN are to ensure international peace, security and respect for human rights. Its headquarters are in New York and Geneva. The UN employs some 40,000 staff.

The UN's 'Bill of Rights' consists of the Universal Declaration of Human Rights and two covenants that lay down the rights mentioned in this declaration in binding treaties: the International Covenant on Civil and Political Rights (ICCPR) and the International Covenant on Economic, Social and Cultural Rights (ICESCR).

This Bill of Rights is complemented by treaties that guarantee respect for the rights of specific groups (such as the UN Convention on the Elimination of All Forms of Discrimination against Women and the UN Convention on the Rights of the Child) or elaborate certain rights (such as the Convention on the Prevention and Punishment of the Crime of Genocide). Several of these treaties (Article 11 ICESCR in particular) recognise the right to adequate food as human right (see section 3).

Specialised daughter organisations of the UN have the mandate to deal with specific themes. These include the World Food Programme (WFP), the UN Food and Agricultural Organization (FAO), the World Health Organization (WHO) and others like the United Nations Conference on Trade and Development (UNCTAD).<sup>4</sup> The World Trade Organization (WTO) is not a daughter organisation of the UN, but it does cooperate closely with the UN.

<sup>3</sup> See generally: <<http://www.un.org>>.

<sup>4</sup> See generally: <<http://www.unctad.org>>. UNCTAD is not discussed in this contribution.

### 2.3 Food and Agricultural Organization

The FAO was set up on 16 October 1945,<sup>5</sup> a date commemorated every year as ‘World Food Day’. The FAO’s objective is to eradicate hunger and to make high quality food accessible to all. Its focuses on both developed and developing countries. The FAO supports the elaboration of agreements and policies by providing a neutral platform for negotiation and information. It aims to improve nutrition, raise agricultural production and contribute to the world economy.

The FAO is governed by a Conference of the member states that meets every second year to evaluate the work done and approve the budget. Forty-nine member states are chosen from the Conference to act as temporary Council. The FAO consists of eight departments that focus on specific topics such as Agriculture and Consumer Protection, Economic and Social Development and Technical Cooperation.

The FAO’s headquarters are in Rome. It has a considerable number of regional, sub-regional and national offices around the world, with total staff of about 3,600.

### 2.4 World Health Organization

The UN established the WHO in 1948<sup>6</sup> to monitor global health trends, coordinate health care activities and promote health of the world’s population.

The WHO has 193 member states, Its secretariat employs 8,000 people, working at the organisation’s headquarters in Geneva and in regional and country offices. Its most important institution is the ‘World Health Assembly’, which meets once a year in Geneva to determine the policy and the programme budget of the organisation. The Executive Board, which consists of 34 members, implements WHO policy.

The WHO plays a central role in the case of global crises threatening public health, such as large-scale food safety incidents like the melamine crisis. The WHO derives powers vis-à-vis the member states from the International Health Regulation 2005 (IHR).<sup>7</sup>

The WHO has set up a global information network for the rapid exchange of information in food safety crises, namely the International Food Safety Authorities Network (INFOSAN) (see section 8).

### 2.5 Joint FAO/WHO Food Standards Programme

To promote fair trade in food that makes a positive contribution to consumers’ life and health, the FAO and the WHO have joined forces in a common food standards programme. In the context of this programme, three risk assessment bodies provide a scientific basis for international standards formulated by the Codex Alimentarius Commission. Sections 6 and 7 discuss the Joint FAO/WHO Food Standards Programme in more detail.

### 2.6 World Food Programme

The WFP<sup>8</sup> is the food aid arm of the United Nations. It is a UN organisation that provides food to refugees, in long-term development projects in the Third World and in situations where people are without adequate food due to natural or man-made disasters.

The WFP’s objective is to save lives and to protect livelihoods in situations of emergency, to be prepared for such situations and to re-establish food security

<sup>5</sup> See generally: <<http://www.fao.org>>.

<sup>6</sup> See generally: <<http://www.who.int>>.

<sup>7</sup> See: <[http://whqlibdoc.who.int/publications/2008/9789241580410\\_eng.pdf](http://whqlibdoc.who.int/publications/2008/9789241580410_eng.pdf)>.

<sup>8</sup> See generally: <<http://www.wfp.org>>.

when emergencies have passed. Furthermore, the WFP works to reduce hunger and malnutrition anywhere in the world and to reinforce the capacity of countries to reduce hunger.

The WFP is governed by its Executive Board, consisting of 36 member states of the UN or the FAO. The Board meets four times a year to formulate the WFP's short- and long-term policies on food supply. The organisation's headquarters are in Rome.

### 3 The Human Rights Dimension

The recognition of food as a human right by the UN and its member states is the most fundamental dimension of international food law. Article 11 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) explicitly mentions the right to adequate food as part of the right to an adequate standard of living.

#### Frame 2: Article 11 of the ICESCR

##### Article 11

- (1) The States Parties to the present Covenant recognize the right of everyone to an adequate standard of living for himself and his family, *including adequate food*, clothing and housing, and to the continuous improvement of living conditions. The States Parties will take appropriate steps to ensure the realization of this right, recognizing to this effect the essential importance of international co-operation based on free consent.
- (2) The States Parties to the present Covenant, recognizing the fundamental *right of everyone to be free from hunger*, shall take, individually and through international co-operation, the measures, including specific programmes, which are needed:
  - (a) To improve methods of production, conservation and distribution of food by making full use of technical and scientific knowledge, by disseminating knowledge of the principles of nutrition and by developing or reforming agrarian systems in such a way as to achieve the most efficient development and utilization of natural resources;
  - (b) Taking into account the problems of both food-importing and food-exporting countries, to ensure an equitable distribution of world food supplies in relation to need.\*

\* Emphasis added.

The Committee on Economic, Social and Cultural Rights has elaborated the meaning of this article in a General Comment. According to General Comment No. 12,<sup>9</sup> food is considered adequate if it is accessible 'in a quantity and quality sufficient to satisfy the dietary needs of individuals, free from adverse substances, and acceptable within a given culture'. In other words, adequacy encompasses nutritional quality, availability, acceptability and safety.

With regard to the realisation of the human right to food, or *food security*, member states have three types of obligations: an obligation to respect – this is an obligation not to interfere with people's means to feed themselves; an obligation to protect – from interference by third parties; and an obligation to fulfil – provide food in situations like natural disasters where people are unable to take care of themselves.

These state obligations can be seen as the human rights foundation of food law and agricultural law. Food law aims to ensure the safety ('free from adverse substances') of available food as well as, to a certain extent, its cultural acceptability (through labelling requirements with regard to ethical subjects like genetic modification and irradiation). The availability of food is a subject of agricultural policy and development cooperation.

In 2005, the FAO published 'Voluntary Guidelines to Support the Progressive Realization of the Right to Adequate Food in the Context of National Food Security'.<sup>10</sup>

<sup>9</sup> Available at: <<http://www.unhchr.ch/tbs/doc.nsf/0/3d02758c707031d58025677f003b73b9?Opendocument>> and <[http://www.fao.org/righttofood/common/ecg/51635\\_en\\_General\\_Comment\\_No.12.pdf](http://www.fao.org/righttofood/common/ecg/51635_en_General_Comment_No.12.pdf)>.

<sup>10</sup> Available at: <<http://www.fao.org/docrep/meeting/009/y9825e/y9825e00.htm>>.



So far, FAO member states have been unwilling to accept obligations under the right to food beyond the obligations of the state towards its own population. If, however, the world is serious about the Millennium Development Goals (in particular about halving world hunger by 2015) such reluctance cannot continue.<sup>11</sup>

Of the institutions introduced above, the World Food Programme, in particular, helps to ensure the availability of food in emergency situations (obligation to provide). The FAO focuses on ensuring sustainable production in the long run. However, the topic most addressed in international food law is food safety, in combination with the state obligation to protect against food safety risks through regulatory systems.

Despite all the efforts at UN level, many countries refuse to recognise social, economic and cultural human rights like the right to food as justiciable rights, that is to say, rights that can be invoked in a court of law.<sup>12</sup> Notable exceptions are India,<sup>13</sup> South-Africa<sup>14</sup> and Switzerland.<sup>15</sup> Generally speaking, human rights are the area of international law that addresses individuals most directly. For all practical purposes, the consequence of the reluctance of states to recognise the justiciability of the right to food is that, even with regard to human rights, the international framework functions only as a framework for state regulation, not as a framework for business practices.

## 4 Trade and Dispute Settlement

### 4.1 The World Trade Organization

As a successor to the General Agreement on Tariffs and Trade (GATT) of 1947, the World Trade Organization (WTO) started its operations on 1 January 1995. The WTO performs various roles at the same time.<sup>16</sup> It is a platform for negotiations on world trade,

<sup>11</sup> For further reading on the right to food, see B.M.J. van der Meulen, *The Right to Adequate Food: Food Law between the Market and Human Rights* (2004); Bernd van der Meulen, 'The Freedom to Feed Oneself: Food in the Struggle for Paradigms in Human Rights Law' in Otto Hospes and Irene Hadiprayitno, *Governing Food Security* (2010), available at: <<http://www.wageningenacademic.com/eifl>>; Wenche Barth Eide and Uwe Kracht (eds.), *Food and Human Rights in Development, Vol. I: Legal and Institutional Dimensions and Selected Topics* (2005); Wenche Barth Eide and Uwe Kracht (eds.), *Food and Human Rights in Development, Vol. II Evolving Issues and Emerging Applications* (2007); George Kent, *Freedom from Want: The Human Right to Adequate Food* (2005), available at: <<http://press.georgetown.edu/pdfs/9781589010550.pdf>>.

<sup>12</sup> See generally Margret Vidar, 'State Recognition of the Right to Food at the National Level', UNU-WIDER Research Paper No. 2006/61, available at: <<http://www.rlc.fao.org/iniciativa/pdf/DAMundo.pdf>>. For an analysis of the situation in the Netherlands, see Bernd van der Meulen and Otto Hospes (eds.), *Fed up with the right to food? The Netherlands' policies and practices regarding the human right to adequate food* (2009), available at: <<http://www.wageningenacademic.com/righttofood>>. In the case of the Netherlands, there appeared to be light at the end of the tunnel of disregard for economic, social and cultural rights when a justice of the peace (kantonrechter) in Heerlen mustered the courage to decide a case concerning the right to water (as part of the right to food and the right to health and sanitation) (District Court of Maastricht, section Heerlen, 25 June 2008, LJN BD5759, available (in Dutch) at: <<http://www.rechtspraak.nl>>). However, the Dutch magistrate's courage was short-lived. The Court of Appeals in Den Bosch (Gerechtshof 's-Hertogenbosch, 2 March 2010, LJN BL6583, available (in Dutch) at: <<http://www.rechtspraak.nl>>) made short work of it, overturning the verdict and returning to the political mainstream.

<sup>13</sup> See Human Rights Law Network, *Right to Food* (2009, 4th ed.); and Pooja Ahluwalia, 'The Implementation of the Right to Food at the National Level: A Critical Examination of the Indian Campaign on the Right to Food as an Effective Operationalization of Article 11 of ICESCR', Center for Human Rights and Global Justice Working Paper, Economic, Social And Cultural Rights Series, No. 8 (2004).

<sup>14</sup> See Constitutional Court of South Africa, 4 October 2000, *Grootboom et al. v. Grootboom et al.*, case CCT 11/00, available at: <[http://www.law-lib.utoronto.ca/Diana/TAC\\_case\\_study/Grootboom.pdf](http://www.law-lib.utoronto.ca/Diana/TAC_case_study/Grootboom.pdf)>. See also Article 27 of the South African Constitution. On the right to food in South Africa, see: <<http://www.fao.org/righttofood/kc/downloads/vl/docs/AH256.pdf>> and S. Kozah, 'Realising the Right to Food in South Africa: Not by Policy Alone – A Need for Framework Legislation', (2002) 20 *South African Journal on Human Rights* 664-683.

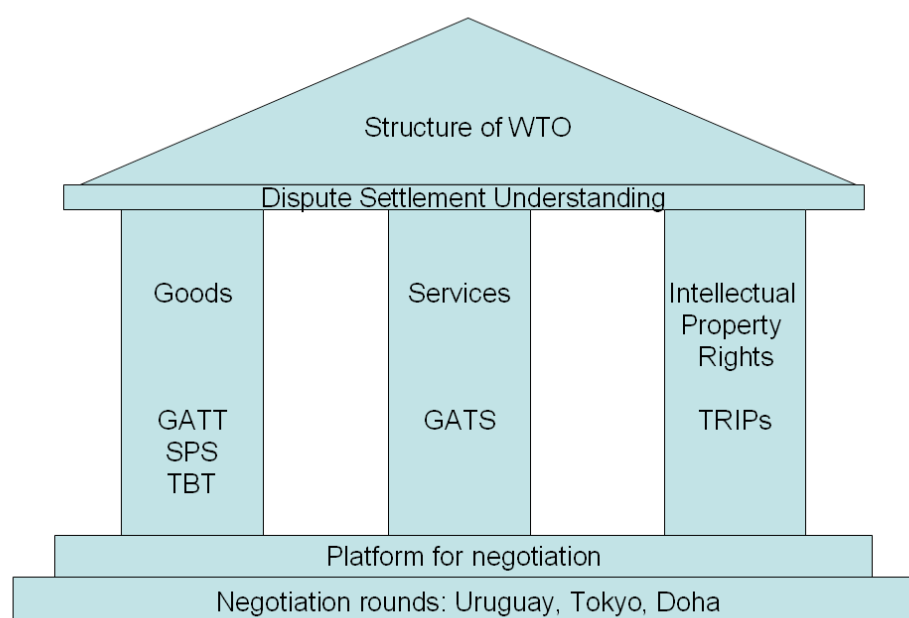
<sup>15</sup> See Urteil der II. öffentlich-rechtlichen Abteilung vom 27. Oktober 1995, *i.S. V. gegen Einwohnergemeinde X. und Regierungsrat des Kantons Bern (staatsrechtliche Beschwerde)*, BGE 121 I 367. For an abstract, see: <<http://www.servat.unibe.ch/dfr/c1121367.html>>.

<sup>16</sup> See generally: <<http://www.wto.org>>.

but it is also a system of law. This system of law is a so-called ‘single undertaking’. This means that once accord has been reached on certain agreements, states have to accept the whole package or nothing at all. They cannot pick and choose. There are three major domains: trade in goods, governed by GATT 1994 (which incorporates GATT 1947 into the WTO structure), trade in services, governed by the General Agreement on Trade in Services (GATS),<sup>17</sup> and intellectual property rights, governed by the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs).<sup>18</sup> The most important domain for food is the trade in goods. The relevant provisions are discussed in section 4.3 and section 5.

Treaties concluded between the WTO members are legally binding. The Dispute Settlement Understanding provides an adjudication procedure to resolve conflicts.<sup>19</sup> Frame 3 presents the structure of the WTO. The WTO is not a large international organisation with institutions like, for example, the EU. It only has a permanent secretariat in Geneva.

**Frame 3: Structure of the WTO**



## 4.2 Negotiation Platform

The WTO is a platform for international negotiations on the liberalisation of world trade. These negotiations take place in rounds named after the location of the kick-off meeting. The WTO itself resulted from the so-called Uruguay round. Since 2001, the WTO has been involved in the Doha round.

<sup>17</sup> As this topic is only remotely – or not at all – related to food, it will not be discussed in this contribution.

<sup>18</sup> The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) provides a minimum framework for the protection of intellectual property in international trade. The agreement lays down requirements for the protection of rights such as copyrights, patents, trademarks, designs and – most importantly for food – geographic indications. See in great detail on this topic Bernard O'Connor, *The Law of Geographical Indications* (2004; reprinted 2007). The present contribution does not discuss this subject.

<sup>19</sup> See the Understanding on Rules and Procedures Governing the Settlement of Disputes, available at: [http://www.wto.org/english/docs\\_e/legal\\_e/28-dsu\\_e.htm#3\\_11](http://www.wto.org/english/docs_e/legal_e/28-dsu_e.htm#3_11).

### 4.3 WTO Law on Trade in Goods

As indicated above, WTO law is binding in character. As regards food, the GATT, SPS and TBT agreements are most important. This section discusses the GATT and the TBT Agreement. The SPS Agreement is the topic of section 5.<sup>20</sup>

#### 4.3.1 GATT

The GATT, which predates the WTO, entered into force in 1947. By means of GATT 1994, GATT 1947 was included as an annex to the WTO Agreement.<sup>21</sup> The GATT aims to liberalise international trade by setting equal treatment of all trading partners as the norm.<sup>22</sup> However, it also recognises the need to make exceptions. The most important exceptions can be found in Article XX (general exceptions) and Article XXI (security exceptions). As food law aims to protect consumer health, the most important exception to international free trade from the point of view of food law is the protection of health, an exception found in Article XX(b) of the GATT. The exception given for the protection of human, animal or plant life or health has been further elaborated and expanded in the SPS Agreement.

#### 4.3.2 SPS Agreement

A core document in international food law is the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). For this reason, this contribution devotes a separate section to it (see section 5).

#### 4.3.3 TBT Agreement

The WTO Agreement on Technical Barriers to Trade (TBT Agreement) addresses technical regulations, standards and conformity assessment procedures. As far as the food sector is concerned, it touches upon standardisation of requirements for issues like packaging and labelling. Measures aiming at protecting health from food- or feed-borne risks fall under the SPS Agreement. The TBT Agreement complements the SPS Agreement. It ensures the right of member states to take measures to protect legitimate interests, such as people, flora, fauna, the environment and consumers, but in a way that avoids unnecessary trade barriers. For this reason, measures must be transparent and non-discriminatory. The TBT Agreement applies a notification procedure requiring WTO members to report proposed technical standards and conformity requirements. This provides an important source of information. In this way, the TBT Agreement contributes to the international harmonisation of standards and promotes mutual recognition of technical standards and conformity requirements.

### 4.4 Dispute Settlement and Enforcement

WTO law has more impact than many other branches of international law, because it is endowed with a potent conflict resolution mechanism. WTO members who find themselves confronted with infringements (e.g. unjustified trade barriers) by other members can present a dispute to the WTO if negotiations do not solve the issue. In such cases, the Dispute Settlement Body (DSB) forms a panel to adjudicate on the basis of WTO law. If a party does not agree with the decision of the panel, it can take the case to the Appellate Body (AB).

<sup>20</sup> On the role of the WTO, see also Marsha A. Echols, *Food Safety and the WTO: The Interplay of Culture, Science and Technology* (2001).

<sup>21</sup> WTO Agreement, Annex 1A: Multilateral Agreements on Trade in Goods.

<sup>22</sup> The most-favoured-nation clause (Article I GATT).



The WTO does not have powers to enforce decisions taken in this procedure. However, if the decision reached is not implemented by the party found at fault,<sup>23</sup> it can condone the implementation of sanctions by the winning party. These sanctions usually take the form of punitive import levies on goods from the state found at fault. If the levies are condoned by the DSB, imposing them does not constitute an infringement of WTO obligations.

## 4.5 Businesses and International Trade Disputes

### 4.5.1 Introduction

The WTO dispute settlement procedure is accessible only to members of the WTO. Only states and organisations of states such as custom territories and the EU are members. The procedure is therefore not directly available to businesses. However, some WTO members like the EU and the United States provide some relief to their national industries.

### 4.5.2 EU: The Trade Barriers Regulation

In the EU, on 1 January 1995 (the starting date of the WTO), the so-called Trade Barriers Regulation (TBR) came into force.<sup>24</sup> This regulation gives businesses,<sup>25</sup> business associations and EU member states the right to lodge a complaint with the European Commission against barriers to trade adopted or maintained by third countries. The complaint must demonstrate the existence of the measure and prove that it is contrary to international obligations and that it has adverse effects. If warranted by EU interest, the Commission will investigate the case and – if the Commission agrees that an infringement of international (WTO) law has taken place – try to come to a solution either through negotiations or, if necessary, a dispute settlement procedure. The Commission's decision on the complaint can be appealed before the European Court of Justice.

### 4.5.3 United States: Section 301 of the 1974 Trade Act

In the United States, Section 301 of the 1974 Trade Act<sup>26</sup> addresses situations in which other countries maintain acts, policies and practices that violate or deny US rights or benefits under trade agreements or are unjustifiable, unreasonable or discriminatory and burden or restrict US commerce.<sup>27</sup>

An interested party may file a petition with the US Trade Representative (USTR) requesting an investigation of a particular practice of a foreign country. The USTR decides if an investigation is appropriate. If it is and if the investigation shows that the

<sup>23</sup> An important case involving the EU is the so-called *EU Biotech* case. The de facto moratorium on GM food in several EU member states was found to constitute an infringement, see: <[http://www.wto.org/english/news\\_e/news06\\_e/291r\\_e.htm](http://www.wto.org/english/news_e/news06_e/291r_e.htm)>. On this case, see Dario Bevilacqua, 'The EC-Biotech Case', (2006) 6 *European Food and Feed Law Review (EFFL)* 331-347.

<sup>24</sup> Council Regulation (EC) No. 3286/94 of 22 December 1994 laying down Community procedures in the field of the common commercial policy in order to ensure the exercise of the Community's rights under international trade rules, in particular those established under the auspices of the World Trade Organization (OJ 1994 L 349/71) See generally: <<http://ec.europa.eu/trade/tackling-unfair-trade/trade-barriers>>. A brochure about the TBR is available at: <[http://trade.ec.europa.eu/doclib/docs/2005/april/tradoc\\_122567.pdf](http://trade.ec.europa.eu/doclib/docs/2005/april/tradoc_122567.pdf)>.

<sup>25</sup> Called 'Community enterprise' if they complain about barriers to export and 'Community industry' if they complain about barriers to import.

<sup>26</sup> As amended (19 USC § 2411).

<sup>27</sup> For an overview, see Jean Heilman Grier, 'Section 301 of the 1974 Trade Act' (2001), available at: <<http://www.osec.doc.gov/occic/301.html>>.

practice complained of is actionable under Section 301, this may imply – as far as is relevant in this context – that the USTR must follow the dispute settlement provisions set out in the WTO agreement.

## 4.6 WTO Framework

The WTO is a member-driven organisation. Only public law entities can be members. WTO law embodies limits, which the members have agreed upon, to their liberty to set barriers to international trade. The rights of WTO members can be upheld in the dispute settlement procedure. The extent to which businesses engaged in international trade can benefit from the norms and procedures of the WTO depends entirely on the actions of the relevant member state.

## 5 Sanitary Measures

### 5.1 Introduction

In the food trade, differences in technical standards like packaging requirements may cause problems, but more often it is concerns about food safety, human health and animal and plant health that induce national authorities to take measures that may frustrate the free flow of trade. Two WTO agreements address these concerns: the TBT Agreement, which is discussed above, and the SPS Agreement.

The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) ensures that countries only apply measures to protect human and animal health (sanitary measures) and plant health (phytosanitary measures) based on an assessment of risk or, in other words, based on science. The SPS Agreement therefore covers various safety aspects of foods in trade. It elaborates on Article XX(b) of the GATT and expands its scope. The emphasis in the GATT is on non-discrimination, whereas the emphasis in the SPS Agreement is on harmonisation.<sup>28</sup>

#### Frame 4: Article XX(b) of the GATT on (Phyto)sanitary Measures

##### Article XX: General Exceptions

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;

...

### 5.2 SPS Agreement

The SPS Agreement recognises and further elaborates on the right of the parties to this agreement to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent

<sup>28</sup> Veijo Heiskanen, 'The Regulatory Philosophy of International Trade Law', (2004) 38(1) *Journal of World Trade* 1-36; Alessandra Arcuri, 'The post-discriminatory era of the WTO: Toward world-wide harmonization of risk law?', Working Paper presented at the 22nd Annual Conference of the European Association of Law and Economics, Ljubljana, 15-17 September 2005, available at: <[http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=974981](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=974981)>.

with the provisions of the agreement. Measures must be scientifically justified, and they may neither discriminate nor constitute disguised barriers to international trade (see frame 5).<sup>29</sup>

### Frame 5: Article 2 of the SPS Agreement on Science

#### **Agreement on the Application of Sanitary and Phytosanitary Measures**

*Reaffirming* that no Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health, subject to the requirement that these measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail or a disguised restriction on international trade;

...

#### **Article 2: Basic Rights and Obligations**

1. Members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement.
2. Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.

...

If measures conform to international standards, no scientific substantiation of their necessity is required. These measures are by definition considered necessary (Frame 6).

### Frame 6: Article 3 of the SPS Agreement on International Standards

#### **Article 3: Harmonization**

1. To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement....
2. Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994.

...

The most important international standards regarding SPS measures are set by the so-called three sisters of the SPS Agreement (see frame 7). The Codex Alimentarius Commission (CAC), the International Office of Epizootics (OIE)<sup>30</sup> and the Secretariat of the International Plant Protection Convention (IPPC). Standards on food and on food safety are mainly to be found in the so-called Codex Alimentarius.<sup>31</sup> This contribution will not discuss the other two sisters.

<sup>29</sup> On the SPS Agreement and its formal and informal applications, see Joan Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures: A Commentary* (2007).

<sup>30</sup> The abbreviation follows the French spelling.

<sup>31</sup> The Agreement on Technical Barriers to Trade has similar articles. Article 2 on 'Preparation, Adoption and Application of Technical Regulations by Central Government Bodies' states:

With respect to their central government bodies:

2.1 Members shall ensure that in respect of technical regulations, products imported from the territory of any Member shall be accorded treatment no less favourable than that accorded to like products of national origin and to like products originating in any other country.

2.2 Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade ...

### Frame 7: The SPS's 'Three Sisters'

#### SPS Agreement – Annex A: Definitions

##### 3. *International standards, guidelines and recommendations*

- (a) for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice;
- (b) for animal health and zoonoses, the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics;
- (c) for plant health, the international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with regional organizations operating within the framework of the International Plant Protection Convention; and
- (d) for matters not covered by the above organizations, appropriate standards, guidelines and recommendations promulgated by other relevant international organizations open for membership to all Members, as identified by the Committee.

If no international standards apply or if measures are stricter than the applicable international standards, the authority taking the measures is required to substantiate their necessity on the basis of scientific evidence.

The EU faced this requirement in a dispute about meat from US cattle that had been treated with growth-promoting hormones. The EU refused to admit this meat to its market. The United States filed a complaint under the WTO and was found to be in the right.<sup>32</sup> The Codex Alimentarius allows the use of a limited number of hormones in cattle (with certain restrictions). The EU could not prove that their concern was science-based.

In making the choice to join the WTO, members restrict their own discretion to take trade-restricting measures for purely political reasons, that is to say, on the basis of democratic deliberation. They commit themselves to taking into consideration the lead of science in deciding what is necessary to protect health. The extension of members' remaining political discretion is uncertain. The Appellate Body currently seems to be showing greater deference than it did in the past.<sup>33</sup>

## 5.3 Sanitary Measures

The SPS Agreement strongly encourages harmonisation of sanitary measures taken by WTO members and brings deviating approaches within the ambit of the methodology of scientific risk analysis.

...

2.6 With a view to harmonizing technical regulations on as wide a basis as possible, Members shall play a full part, within the limits of their resources, in the preparation by appropriate international standardizing bodies of international standards for products for which they either have adopted, or expect to adopt, technical regulations.

<sup>32</sup> The WTO's Appellate Body ruled on 16 January 1998 (WT/DS48/AB/R). On this case, see Dario Bevilacqua, 'The Codex Alimentarius Commission and its Influence on European and National Food Policy', (2006) 6 *EFFL* 3-16. The EU revised its legislation but maintained the ban. The case has been reopened. This time it is the EU complaining against the retaliations. The EU believes that it has now provided sufficient scientific substantiation to justify its measures. See US/Canada – Continued Suspension, cases DS320 and 321, available at: <[http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds320\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds320_e.htm)>.

<sup>33</sup> See AB, 14 November 2008, United States – Continued Suspension of Obligations in the EC – Hormones Dispute, WT/DS320/AB/R; and AB, 16 October 2008, Canada – Continued Suspension of Obligations in the EC – Hormones Dispute, WT/DS321/AB/R.

## 6 Standard-setting

### 6.1 Introduction: Joint FAO/WHO Food Standards Programme

Measures necessary to protect public health are accepted as justified barriers to trade. A measure is necessary if it is based on scientific principles, that is to say, on risk analysis, or if it conforms to international standards such as those set by the Codex Alimentarius Commission. This presumption that international standards conform to SPS requirements makes it advantageous for WTO members to follow international examples. The logic behind the presumption of the conformity of the Codex standards to the GATT/SPS requirements is twofold. On the one hand, the SPS Agreement encourages international harmonisation. If measures conform to each other, there is no barrier to trade. On the other hand, the Codex standards are themselves science-based through the application of the risk analysis methodology.

### 6.2 Risk Analysis Methodology

The Codex Alimentarius Procedural Manual elaborates the concept of risk analysis.<sup>34</sup> Risk analysis should follow a structured approach with three distinct but closely linked components: risk assessment, risk management and risk communication.<sup>35</sup>

The methodology of risk analysis is what makes the food regulatory framework science-based. Depending on the context in which risk analysis is applied, science is confronted with two different tasks: (1) to identify risks or (2) to exclude risks.<sup>36</sup> Each task has an impact on the burden of proof and the consequences of inconclusive risk assessment.

The SPS Agreement seems to regard risk analysis as the responsibility of the authority that wishes to impose a measure that may impede international trade (i.e. a trade barrier). In such situations, science is required to positively identify a risk that is then taken care of by the protective measure. Under premarket approval schemes, the task faced by science is not to *identify* risks but to *exclude* them. Only if proof of safety is provided will the product at issue be allowed to enter the market. The Codex applies such a scheme to food additives. These are substances added to food for technological reasons.

### 6.3 Risk Assessment

The Codex Alimentarius Procedural Manual defines risk assessment as a science-based process consisting of four steps: (i) hazard identification; (ii) hazard characterisation; (iii) exposure assessment; and (iv) risk characterisation.<sup>37</sup>

Risk assessment for international standard setting is undertaken in three joint FAO and WHO committees: the Joint FAO/WHO Committee on Food Additives (JECFA), the Joint FAO/WHO Meetings on Pesticide Residues (JMPR) and the Joint FAO/WHO Meetings on Microbiological Risk Assessment (JEMRA). They advise on maximum limits for food additives, pesticide residues and pathogens and on other scientific issues regarding food safety.

These three risk assessors are independent from risk managers. The Codex Principles for Risk Analysis for Application by Governments calls for the separation of risk assessment and risk management functions to the extent practicable.

<sup>34</sup> Codex Alimentarius Commission, *Procedural Manual* (2010, 19th ed.).

<sup>35</sup> Codex Alimentarius Commission, 'Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius', *Procedural Manual* (2010, 19th ed.) 84-91.

<sup>36</sup> On this topic, see Bernd M.J. van der Meulen, 'Science-based Food Law', (2009) 1 *EFFL* 58-71.

<sup>37</sup> Codex Alimentarius Commission, 'Definitions of Risk Analysis Terms Related to Food Safety', *Procedural Manual* (2010, 19th ed.) at 91.



In the EU, such independence is considered a principle.<sup>38</sup> The European Food Safety Authority (EFSA) is charged with risk assessment. Risk management is the responsibility of the European Commission, the Council, the European Parliament and the member states. The EFSA is independent from these authorities but has no risk management powers of its own. In the United States, by contrast, both scientific risk assessment and (administrative and regulatory) risk management are the responsibility of the Food and Drug Administration (FDA) or – for certain types of foods of animal origin – the Department of Agriculture (USDA).

Apparently, the need for independent risk assessment is open to debate. A modified FDA model is applied in Australia/New Zealand,<sup>39</sup> Canada<sup>40</sup> and Japan.

## 6.4 Precaution: Three Different Meanings

A concept that sometimes confuses discussions regarding the regulation of food safety and its scientific base is ‘precaution’. Confusion results from use of the term to indicate at least three different notions. As explained in the following subsections, precaution is used: (1) to attribute responsibility for providing scientific data needed for risk assessment; (2) to choose the risk management option after risk assessment has shown the existence of a risk; and (3) as a basis for risk management in cases where risk assessment is inconclusive.

### 6.4.1 Collection of Data

In some situations, the burden of carrying out scientific research to acquire the data needed for risk assessment is shifted from public authorities to private parties.<sup>41</sup> In premarket approval schemes, in particular, businesses that wish to bring potentially hazardous products to the market are required to provide scientific substantiation of the safety of these products before market access can be granted.<sup>42</sup>

### 6.4.2 Level of Protection

Public authorities regulating food safety need to choose a level of protection. If risk assessment identifies a certain food safety risk, the authorities must decide whether this risk is acceptable or to what extent it should be eliminated. Extremely low limits and zero tolerance levels for certain contaminants are sometimes labelled ‘precautionary’.<sup>43</sup>

### 6.4.3 Scientific Uncertainty

How should risk managers proceed if the outcome of risk assessment is inconclusive?

Often, the ‘precautionary principle’<sup>44</sup> implies a justification for risk managers to work from a worst case scenario when scientific risk assessment indicates that health risks may exist but causality remains uncertain (suspicion but not proof).

The Codex Alimentarius explicitly chooses as its foundation the fact that Codex standards are based on scientific risk analysis, in particular as regards their health

<sup>38</sup> Article 6 of Regulation (EC) No. 178/2002.

<sup>39</sup> Food Standards Australia New Zealand. See: <<http://www.foodstandards.gov.au>>.

<sup>40</sup> Health Canada, see: <<http://www.hc-sc.gc.ca/index-eng.php>>.

<sup>41</sup> See, for example, European Commission, Communication on the precautionary principle, COM (2000) 1. See also Helle Tegner Anker and Margaret Rosso Grossman, ‘Authorization of Genetically Modified Organisms: Precaution in US and EC Law’, (2009) *EFFL* 3-22.

<sup>42</sup> On this topic, see Bernd van der Meulen, ‘Structural Precaution’, paper presented at WiCaNem 2010, available at: <<http://www.wicanem2010.nl>>.

<sup>43</sup> Tsunehiro Otsuki, John S. Wilson and Mirvat Sewadeh, ‘Saving Two in a Billion: Quantifying the Trade Effect of European Food Safety Standards on African Exports’, (2001) 26 *Food Policy* 495-514.

<sup>44</sup> Article 7 of Regulation (EC) No. 178/2002.

and safety aspects. Precaution is recognised as an inherent element of risk analysis. However, in situations of scientific uncertainty, as a rule, no Codex standards should be adopted (see frame 8.).

Here we find a significant difference between the Codex Alimentarius and an actual regulatory system. The Codex is a *model* for national legislation. It is not in itself a set of rules with which stakeholders must comply. While the regulatory system needs to cover all eventualities, the Codex can limit itself to presenting a model on the topics where consensus has been reached and leave other issues open for future consideration. Alternatively, the CAC can take an intermediate step by proposing softer approaches rather than standards.

### Frame 8: The Codex Alimentarius on Scientific Uncertainty<sup>45</sup>

#### Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius

10. When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Codex Alimentarius Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code of practice, provided that such a text would be supported by the available scientific evidence.
11. Precaution is an inherent element of risk analysis. Many sources of uncertainty exist in the process of risk assessment and risk management of food related hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis. Where there is sufficient scientific evidence to allow Codex to proceed to elaborate a standard or related text, the assumptions used for the risk assessment and the risk management options selected should reflect the degree of uncertainty and the characteristics of the hazard.

At the national level, the food regulatory framework has to encompass the entire area. National legislators do not enjoy the luxury of leaving scientifically unresolved issues unregulated. Usually, if a topic is not regulated, the consequence is that businesses enjoy liberty to do as they please.

The SPS Agreement acknowledges this dilemma. In Article 5(7) the SPS Agreement states:

In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.<sup>46</sup>

Obviously, this approach to precaution mainly plays a role in a context where restrictive measures (i.e. barriers to trade) need scientific justification. In cases where proof of safety is required (market access requirements) it will play a less important role or none at all. As long as risk assessment is inconclusive, the required proof of safety has not been provided and access will not be granted.

## 6.5 Risk Management: Sanitary Measures

The procedure of risk analysis is designed to result in risk management measures. This concept largely overlaps with 'sanitary measures' as defined in the SPS Agreement.

According to paragraph 1 of Annex A to the SPS Agreement:

[s]anitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing,

<sup>45</sup> Codex Alimentarius Commission, above n. 34.

<sup>46</sup> This provision probably served as a model for the wording of the precautionary principle in Article 7 of Regulation (EC) No. 178/2002.

inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.

In other words, sanitary measures encompass both the setting of the regulatory system through general rules (regulation) and the application of the system through individual decisions.

## 6.6 Risk Analysis

Based on the above, risk analysis emerges as a methodology that is designed to be used in standard setting both at national and international level. It does not in itself apply to private parties.

## 7 The Codex Alimentarius

### 7.1 Introduction

The sections above refer repeatedly to the Codex Alimentarius. What is this Codex Alimentarius that provides such important standards for international trade in food?<sup>47</sup> In 1961, the Food and Agricultural Organization (FAO) and the World Health Organization (WHO) established the Codex Alimentarius Commission (CAC). Over the years, the CAC established specialised committees hosted by member states all over the world. Some 175 countries, representing about 98% of the world's population, participate in the work of Codex Alimentarius.<sup>48</sup> A number of NGOs and organisations representing private sector interests have observer status.

Food standards are established through an elaborate procedure of international negotiations. This procedure currently comprises eight steps, but a proposal is in the pipeline to reduce the number of steps to five (the first five steps indicated in frame 9).

**Frame 9: Codex Procedure for Adopting Standards and Codes<sup>49</sup>**

Step	Action
Step 1	Member government proposal submitted to a Codex committee
Step 2	Draft elaborated by a member government within the committee
Step 3	Draft circulated to members and international organisations for comments
Step 4	Draft with comments back to the committee
Step 5	Draft revised and submitted to the CAC for consideration
Step 6	Revised draft circulated to members and international organisations for comments
Step 7	Draft with comments considered by committee: CAC either adopts the code or sends it back to committee for revision
Step 8	CAC adopts the standard or code of practice, which is circulated to member countries and international organisations

All standards and codes taken together are referred to as the Codex Alimentarius (Latin for 'food code'). It can be regarded as a virtual book filled with food standards.

<sup>47</sup> In recent years, some media interest was sparked by a hate campaign against the Codex. See for example: <<http://video.google.com/videoplay?docid=-5266884912495233634#>>.

<sup>48</sup> See generally: <<http://www.CodexAlimentarius.net>>. The CAC invests in capacity-building but actual participation by third world Countries is a matter of concern.

<sup>49</sup> Codex Alimentarius Commission, above n. 34.

Besides the food standards, the Codex Alimentarius includes advisory provisions called codes of practice or guidelines that mainly address food businesses but can also be used by national regulators.

At present the Codex comprises more than 200 standards for specific foods (so-called vertical standards), close to 50 food hygiene and technological codes of practice, some 60 guidelines, over 1,000 food additives and contaminants evaluations and over 3,200 maximum residue limits for pesticides and veterinary drugs. Finally, the Codex Alimentarius includes requirements of a horizontal nature on labelling and presentation and on methods of analysis and sampling.<sup>50</sup>

## 7.2 Procedural Manual

The 'constitution' of the Codex Alimentarius is the Procedural Manual. The Procedural Manual not only specifies the procedures and format for setting Codex standards and guidelines but also presents some general principles and definitions (see frame 10). The principles relate, among other things, to the scientific substantiation of the work of the Codex Alimentarius and the use of risk analysis for food safety (see frame 11).

### Frame 10: Some Definitions in the Codex Alimentarius Procedural Manual<sup>51</sup>

<b>Food</b>	Means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of 'food' but does not include cosmetics or tobacco or substances used only as drugs.
<b>Food hygiene</b>	Comprises conditions and measures necessary for the production, processing, storage and distribution of food designed to ensure a safe, sound, wholesome product fit for human consumption.
<b>Food additive</b>	Means any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result, (directly or indirectly) in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods. The term does not include 'contaminants' or substances added to food for maintaining or improving nutritional qualities.

<sup>50</sup> Susana Navarro and Richard Wood, *Codex Deciphered* (2001) at 1. On the Codex Alimentarius, see also FAO, *Understanding The Codex Alimentarius* (2006, 3rd ed.), available at: <[http://www.who.int/foodsafety/publications/codex/understanding\\_codex/en/index.html](http://www.who.int/foodsafety/publications/codex/understanding_codex/en/index.html)> and <[ftp://ftp.fao.org/codex/Publications/understanding/Understanding\\_EN.pdf](ftp://ftp.fao.org/codex/Publications/understanding/Understanding_EN.pdf)>; Eddie Kimbrell, 'What is Codex Alimentarius', (2000) 3(4) *AgBioForum* 197-202; FAO/WHO, *Report of the Evaluation of the Codex Alimentarius and Other FAO and WHO Food Standards Work* (2002), available at: <[http://www.who.int/foodsafety/codex/eval\\_report/en/index.html](http://www.who.int/foodsafety/codex/eval_report/en/index.html)> and <[http://www.codexalimentarius.net/web/evaluation\\_en.jsp](http://www.codexalimentarius.net/web/evaluation_en.jsp)>. The most important book on the Codex Alimentarius is probably the dissertation of Marielle D. Masson-Matthee, *The Codex Alimentarius Commission and Its Standards: An Examination of the Legal Aspects of the Codex Alimentarius Commission* (2007).

<sup>51</sup> Codex Alimentarius Commission, *Procedural Manual* (Rome 2010, 19th ed.).

**Frame 11: Some Principles in the Codex Alimentarius Procedural Manual<sup>52</sup>****Statements of Principle concerning the role of science in the Codex decision-making process and the extent to which other factors are taken into account**

1. The food standards, guidelines and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of the food supply.
2. When elaborating and deciding upon food standards Codex Alimentarius will have regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade.
3. In this regard it is noted that food labelling plays an important role in furthering both of these objectives.
4. When the situation arises that members of Codex agree on the necessary level of protection of public health but hold differing views about other considerations, members may abstain from acceptance of the relevant standard without necessarily preventing the decision by Codex.

**7.3 Standards**

The work of the CAC has resulted in a vast collection of internationally agreed food standards that are presented in a uniform format. Most of these standards are of a vertical nature. They address all principal foods, whether processed, semi-processed or raw. Standards of a horizontal nature are often called ‘general standards’, like the General Standard for the Labelling of Prepackaged Foods.<sup>53</sup>

According to this general standard, the following information shall appear on the labelling of prepackaged foods: the name of the food (which shall indicate the true nature of the food); a list of ingredients (in particular whether one of a list of eight allergens is present); the net contents; the name and address of the business; the country of origin where omission could mislead the consumer; lot identification; date marking and storage instructions; and instructions for use.

**7.4 Codes**

In addition to formally accepted standards, the Codex includes recommended provisions called codes of practice or guidelines. These include, for example, a Code of Ethics for International Trade in Food,<sup>54</sup> and a set of hygiene codes like the Recommended International Code of Practice – General Principles of Food Hygiene and the Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application (see frame 12).

**Frame 12: The Principles of HACCP according to the Codex Alimentarius**

Principle 1	Conduct a hazard analysis.
Principle 2	Determine the Critical Control Points (CCPs).
Principle 3	Establish critical limit(s).
Principle 4	Establish a system to monitor control of the CCP.
Principle 5	Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.

<sup>52</sup> Id.

<sup>53</sup> CODEX STAN 1-1985 (Rev. 1-1991).

<sup>54</sup> CAC/RCP 20-1979 (Rev. 1-1985).



Principle 6	Establish procedures for verification to confirm that the HACCP system is working effectively.
Principle 7	Establish documentation concerning all procedures and records appropriate to these principles and their application.

## 7.5 Legal Force

The Codex standards are not legally binding norms. They do slightly resemble directives in European law in the sense that they present models for national legislation, but without an obligation to implement them. Member states undertake to transform the Codex standards into national legislation. No sanctions apply, however, if they do not honour this undertaking.

What is the purpose of such non-binding standards? The answer comprises different elements. Generally speaking, nation states are reluctant to enter into internationally binding agreements because they limit their sovereignty. For this reason, it turns out to be easier to agree to non-binding ‘soft law’ standards than to binding ‘hard law’ ones. By agreeing to non-binding standards, participating states develop a common nomenclature: a ‘language of food law’. All states and other subjects of international law will mean the same thing when they meet to negotiate about food – ‘food’ as defined in the Codex. The same holds true for ‘milk’ and ‘honey’ and all the standards that have been agreed upon. The notion of HACCP has been developed – and is understood – within the framework of the Codex Alimentarius.<sup>55</sup> In this way, the Codex Alimentarius provides a common frame of reference, but there is more.

The mere fact that national specialists on food law enter into discussions on these standards will influence their work at home. A civil servant drafting a piece of legislation will always look for examples. In the case of food, he will find examples in abundance in the Codex. In these subtle ways, the Codex Alimentarius is likely to have a major impact on the development of food law in many countries, even without a strict legal obligation to implement.<sup>56</sup>

It turns out that soft law has a tendency to solidify. Once agreements are reached, parties tend to attach more weight to them than was initially intended or explicitly agreed. The following subsections show that this is true for Codex standards as well. Due to several developments, they are well on their way to acquiring at least quasi-binding force.

## 7.6 WTO/SPS Agreement

As we have seen above, the inclusion of the Codex Alimentarius as benchmark in the SPS Agreement greatly enhances its significance. WTO members that follow Codex standards need not prove the necessity of the sanitary and phytosanitary measures they take. If they cannot base their measures on the Codex, they have to show that their measures are science-based.

In the food sector, the practical result is that companies have access to the majority of the world’s markets if their products are up to Codex standard. It is much easier to apply the Codex than to study and apply a whole range of different national standards. The catch is that companies depend on their national governments to take action within the WTO if they face trade barriers that do not comply with the Codex.<sup>57</sup>

<sup>55</sup> Recommended International Code of Practice – General Principles of Food Hygiene CAC/RCP 1-1969, Rev. 3-1997, Amd. (1999).

<sup>56</sup> Some examples of how this worked out in the EU appear below.

<sup>57</sup> As discussed in section 4.5, some WTO member like the EU and the United States grant businesses some rights as regards obliging their governments to take action in this respect.

## 7.7 The Codex and the European Union

### 7.7.1 The Codex in Case Law

In the context of European food law, the Codex is also having an increasing legal impact. In its case law, the European Court of Justice uses Codex standards as an interpretation aid for open standards in European law. In the so-called *Emmenthal cheese* case, for example, the Court was called upon to judge whether the definition of Emmenthal cheese in French legislation constituted a barrier to trade as prohibited in the EC Treaty.<sup>58</sup> The case concerned a French cheese trader who was prosecuted for attempting to sell a product as Emmenthal cheese that did not have a brown rind as required under the French standard for Emmenthal cheese. The Court decided that the French law indeed breached the ban on quantitative trade barriers in the EC Treaty (now Article 34 TFEU). In its reasoning, the Court considered that the definition of Emmenthal in the Codex does not in all situations require a rind (see frame 13). In other words, in cases like this, the Codex standard helps to define the limits that European law imposes on national legislators.

**Frame 13: Use of the Codex Alimentarius by the European Court of Justice to define Emmenthal cheese, Judgment of 5 December 2000, Case C-448/98**

32. In the case at issue in the main proceedings it should be noted that according to the Codex alimentarius referred to in paragraph 10 of this judgment which provides indications allowing the characteristics of the product concerned to be defined, a cheese manufactured without rind may be given the name Emmenthal since it is made from ingredients and in accordance with a method of manufacture identical to those used for Emmenthal with rind, save for a difference in treatment at the maturing stage. Moreover, it is undisputed that such an Emmenthal cheese variant is lawfully manufactured and marketed in Member States other than the French Republic.
33. Therefore, even if the difference in the maturing method between Emmenthal with rind and Emmenthal without rind were capable of constituting a factor likely to mislead consumers, it would be sufficient, whilst maintaining the designation Emmenthal, for that designation to be accompanied by appropriate information concerning that difference.
34. In those circumstances, the absence of rind cannot be regarded as a characteristic justifying refusal of the use of the Emmenthal designation for goods from other Member States where they are lawfully manufactured and marketed under that designation.
35. The answer to the question referred for a preliminary ruling must therefore be that Article 30 of the Treaty precludes a Member State from applying to products imported from another Member State, where they are lawfully produced and marketed, a national rule prohibiting the marketing of a cheese without rind under the designation Emmenthal in that Member State.

### 7.7.2 The Codex in Legislation

The EU's basic regulation on food law, Regulation (EC) No. 178/2002 (also known as the General Food Law), recognises the significance of the Codex Alimentarius. Article 13 the General Food Law emphasises the importance of the development of international standards. More important, however, is Article 5(3) of the Regulation (see

<sup>58</sup> At the time Article 30 (later Article 28) of the EC Treaty, now Article 34 of the Treaty on the Functioning of the European Union.

frame 14). Although this provision leaves a wide margin of appreciation for the national and EU legislators, it introduces an obligation to take international standards like the Codex into account.

**Frame 14: International Food Law Standards:  
Article 5(3) of the General Food Law**

**Article 5(3) of Regulation (EC) No. 178/2002**

Where international standards exist or their completion is imminent, they shall be taken into consideration in the development or adaptation of food law, except where such standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives of food law or where there is a scientific justification, or where they would result in a different level of protection from the one determined as appropriate in the Community.

This comes close to an obligation under European law for both the EU and the member states to include standards like the Codex in national and Community food legislation. If this provision is indeed interpreted and applied in this way, this will boost the legal position of Codex standards in Europe. The General Food Law itself gives the proper example. The definition of food, which forms the foundation of the Regulation, is based on the Codex Alimentarius (see frame 15).

**Frame 15: Comparison of Definitions of ‘Food’ in the Codex Alimentarius  
Procedural Manual and Article 2 of the General Food Law**

**Codex Alimentarius Procedural Manual, Definitions for the Purposes of the Codex Alimentarius, p. 49:**

For the Purposes of the Codex Alimentarius:

Food means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of ‘food’ but does not include cosmetics or tobacco or substances used only as drugs.

**Article 2 of Regulation (EC) No. 178/2002**

*Definition of ‘food’*

For the purposes of this Regulation, ‘food’ (or ‘foodstuff’) means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

‘Food’ includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.

‘Food’ shall not include:

- (a) feed;
- (b) live animals unless they are prepared for placing on the market for human consumption;
- (c) plants prior to harvesting;
- (d) medicinal products within the meaning of Council Directives 65/65/EEC and 92/73/EEC;
- (e) cosmetics within the meaning of Council Directive 76/768/EEC;
- (f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC;
- (g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971;
- (h) residues and contaminants.

Later food legislation also follows this example. The General Hygiene Regulation (EC) No. 853/2004, for example, states in its fifteenth recital: 'The HACCP requirements should take account of the principles contained in the Codex Alimentarius.' Indeed, the definition of HACCP in Article 5 of the Regulation closely resembles the text presented in frame 12.

An obligation to include Codex maximum residue limits (MRLs) in EU legislation is included in Regulation (EC) No. 470/2009. The General Labelling Directive (2000/13/EC) does not make explicit reference to the Codex, but its list of mandatory requirements in Article 3 includes all requirements from the Codex General Standard for the Labelling of Prepackaged Foods listed above in section 7.3.

The principle laid down in Article 6 of the General Food Law to the effect that food law should be based on risk analysis can be understood in this context. If requirements of European food safety law are not in conformity with the Codex Alimentarius, sooner or later they will be contested under the SPS Agreement as barriers to international trade. They will only stand up to scrutiny in the WTO forum if they are science-based, that is, based on risk analysis.

### 7.7.3 The EU Joins the Codex

For over 40 years, the EU was not a member of the Codex Alimentarius Commission. Instead, it exercised its influence through its member states who were in the CAC. On 17 November 2003,<sup>59</sup> the EU took the logical next step in the process of increasing recognition of the Codex. The Council, acting on behalf of the European Communities, applied for membership of the Codex Alimentarius Commission, and the EU is now a full member.

## 7.8 The Codex in International Food Law

It follows from the above that the Codex Alimentarius standards are designed as models for national food law. The Codex codes of practice include businesses among their addressees but are of a strictly voluntary nature. In the EU, Codex norms are applied via European law, either by adoption in EU legislation or as an aid to the interpretation of open concepts in EU law. The Codex Alimentarius is not used as such to judge the behaviour of private parties.

## 8 Crisis Management

### 8.1 Introduction

Given the scale of the international food trade, it comes as no surprise that food safety incidents may also take on a global dimension. The latest and most telling example is the melamine crisis. If the problem is global, the instruments used to deal with it must be global as well.

### 8.2 The International Health Regulations

The World Health Organization performs global outbreak warning and management functions. These operate under a legal framework known as the International Health Regulations (IHR), which were last revised in 2005. The IHR is a legally binding international agreement to prevent the international spread of disease, which is open to all the member states of the WHO as well as to third countries. First developed in 1969,

<sup>59</sup> Council Decision 2003/822/EC, OJ 2003 L 309/14. Point 83 of the Action Plan on Food Safety has been implemented in this way (Annex to the 2000 White Paper on Food Safety, COM (1999) 719 final).

it applied mostly to only three infectious diseases: cholera, plague and yellow fever. The current IHR (2005) has a much broader scope and applies to all diseases, including food-borne illnesses and diseases from new and unknown causes, irrespective of origin or source, that could present significant harm to humans.<sup>60</sup>

The IHR is a global legal framework for detecting and responding to international public health risks and potential public health emergencies of international concern.<sup>61</sup> Under these regulations, every country is obliged to prevent and control the spread of disease inside and outside its borders and to report potential public health emergencies of international concern to the WHO. As states parties, the countries benefit from WHO's surveillance activities and from reports from other countries on critical health risks.

Member states should designate a national IHR focal point, which must be accessible at all times, 24 hours a day. They must communicate with the WHO and notify it of all events that may constitute a public health emergency of international concern within 24 hours of assessment using the decision tool – a flow chart that goes through the criteria for assessment and notification. Countries also need to be able to respond to the WHO's requests for verification of information. Countries should assess their public health systems and strengthen and maintain their capacity to detect, report and respond rapidly to public health risks and emergencies of international concern.<sup>62</sup> They should implement appropriate measures recommended by the WHO.

The WHO, in turn, will coordinate global surveillance and assessment and disseminate public health information to states.

### 8.3 INFOSAN

In response to recommendations from several international conferences, resolutions from the World Health Assembly and guidelines from the Codex Alimentarius Commission, the World Health Organization, in collaboration with the Food and Agriculture Organization, developed the International Food Safety Authorities Network (INFOSAN) to promote the exchange of food safety information and to improve collaboration among food safety authorities at the national and international level. The INFOSAN network provides a mechanism for the exchange of information on both routine and emerging food safety issues.

INFOSAN Emergency is designed to provide rapid access to information during food safety emergencies. As of October 2006, 151 countries were members of INFOSAN. Each member country has designated one or several INFOSAN focal points. Each country also has one dedicated INFOSAN emergency contact point that will be activated specifically during major international emergencies involving disease from or contamination in food.<sup>63</sup>

The European Rapid Alert System for Food and Feed (RASFF) was established on 18 March 2005 as an INFOSAN emergency contact point for the transmission of INFOSAN food safety information. At a meeting of the Standing Committee for the Safety of the Food Chain and Animal Health on 20 September 2005,<sup>64</sup> all the member states of the EU and the European Free Trade Association (EFTA) agreed that the RASFF would be their single point of information exchange for INFOSAN.

Closer cooperation and clearer procedures should be established between both systems to avoid overlap and misunderstanding, particularly in relation to the information transmitted to third countries.<sup>65</sup>

<sup>60</sup> International Health Regulations: Guidance for National Policy-Makers and Partners, available at: <<http://www.who.int/csr/IHR%20Guidance%20for%20national%20policy%20makers%20and%20partners.pdf>>.

<sup>61</sup> Article 2 of the IHR.

<sup>62</sup> International Health Regulations, Annex I at 51.

<sup>63</sup> World Health Organization, in cooperation with the Food and Agricultural Organization of the United Nations, *The International Food Safety Authorities Network (INFOSAN) Users Guide*, October 2006, available at: <[http://www.who.int/foodsafety/fs\\_management/infosan/en](http://www.who.int/foodsafety/fs_management/infosan/en)>.

<sup>64</sup> Article 58 of Regulation (EC) No. 178/2002.

<sup>65</sup> European Commission, Health and Consumer Protection Directorate-General, *The Rapid Alert System*



## 8.4 Crisis Management

Instruments for managing international food safety crises focus on enabling member states and harmonising their reactions. No international agency has the power to impose obligations directly on people and businesses.

## 9 Conclusion

International food law is a meta-framework: a framework of frameworks. It does not in itself regulate stakeholders dealings with food, but rather sets requirements that such regulation must meet at national level.

The International Covenant on Economic, Social and Cultural Rights establishes *objectives* to respect, protect and ensure access to adequate food, understood in terms of nutrition, availability, acceptability and safety. The WTO adds to this the objective of free trade. Together, these objectives place an emphasis on protection against unsafe food.

The *methodology* to be applied is risk analysis. Measures aimed at protecting the health of consumers must be based on science either directly, through the application of the risk analysis methodology, or indirectly, by conforming to international standards such as the Codex Alimentarius (which in turn are based on risk analysis). These standards are not binding upon citizens and businesses but provide models for national and regional food law.

In this way, the Codex Alimentarius provides a model for the *content* of national food legislation,<sup>66</sup> encompassing vertical standards for a wide range of products, lists of synthetic additives that may be used in food for a technological function and maximum limits for pesticide residues and contaminations with micro-organisms or chemical substances. It also provides codes of practice for food hygiene and general standards on food labelling.

Finally, the WHO supports its members through a system for rapid information exchanges when dealing with large-scale food safety incidents.

All in all, these elements result in a global system of food safety governance. Even though this system is created by different, more-or-less independent players, it shows a certain coherence in that the elements mutually reinforce rather than contradict each other. The risk analysis methodology has been adopted in the WTO's policies to liberalise trade and in its procedures for dispute settlement. Applying the Codex Alimentarius is recognised as a harmonised way for member states to fulfil their commitment to base sanitary measures on risk analysis. The common understanding of what food safety means also underlies the emerging structure of crisis management made available by the WHO.

The food safety framework that applies to citizens/consumers and businesses and the actions taken in response to the information made available by the WHO remain the exclusive domain of national and regional authorities.

for Food and Feed (RASFF) Annual Report (2006) at 51, available at: <[http://ec.europa.eu/food/food/rapidalert/report2006\\_en.pdf](http://ec.europa.eu/food/food/rapidalert/report2006_en.pdf)>.

<sup>66</sup> Spencer Henson and John Humphrey, 'Codex Alimentarius and Private Standards' in B.M.J. van der Meulen (ed.), *Private Food Law* (forthcoming 2011), pointing out that private standard-setting organisations are also among the Codex's clients.