

## THE INTERNATIONAL AND EUROPEAN REGIME OF HEALTH PROTECTION AND FOOD SAFETY

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**ABSTRACT:** *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. This paper aims to present the main significant episodes in regulating food safety and health protection at international and European level.*

**KEY-WORDS:** *health, protection, food, safety*

**JEL CODE:** *K 32, K 33*

The increasing globalization of food trade and the harmonization of food standards and food safety measures have led to significant changes in the international and national regulatory frameworks for food. The World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) named the Codex Alimentarius as the source of international standards on food safety, which has had a profound impact on the status of Codex standards, guidelines and recommendations in international food trade, particularly among members of the WTO. In addition, there is an increasing recognition of the need to integrate and improve coordination of regulatory activities among national and international bodies to better protect human, animal and plant life and health, as well as the environment, without creating unnecessary barriers to trade. On the other hand, food policies are expanding to take account not only of food safety and food security but also nutrition and the human right to food.

Recent dramatic episodes of food-borne disease accidents and outbreaks have raised concerns about the effectiveness of current food control systems in protecting consumers and have sparked increased attention to the regulatory frameworks that govern food safety and food trade. Unease over microbiological and chemical contaminants of the food chain and the use of food additives, pesticides and veterinary drugs, as well as heightened consumer interest in diet-related health issues, have also raised the profile of

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food safety control systems. At the same time, population growth, urbanization and new technologies are influencing food production in unprecedented ways, thus requiring more vigilance by all those involved in the food chain – from primary producers to the consumer – to ensure food safety.

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).

These developments have given rise to new legislative needs. National regulatory frameworks have to be adjusted to meet international and regional obligations, while the distribution of responsibilities for the food sector at national level requires rigorous review. Traditionally, inspection and monitoring activities have often been dispersed among ministries of health, veterinary services, agriculture and fisheries, with the concomitant administrative burdens and inefficient resource use. Acknowledging the need to update and modernize their food regulatory frameworks, many countries have been reviewing their food legislation and related enactments to identify gaps and overlaps in responsibilities in the food control system and to foster collaboration among responsible ministries. There is a growing tendency to combat fragmentation and to improve the national legal and administrative framework by adopting a basic food law which establishes a primary authority to oversee the food system “from farm to fork”.

Dissatisfaction with the legislative framework for food control is often widespread at national level, but it is not always obvious what steps are required in order to comprehensively analyse the legislative scheme. This book aims to assist control authorities in addressing this specific need. It builds on the recent publication by FAO and WHO entitled “Assuring

Food Safety and Quality: Guidelines for Strengthening National Food Systems”, which provided comprehensive advice on the many considerations affecting the design of national food control systems. The present text draws on FAO’s experience in providing technical assistance to governments in developing new food laws and regulations, by setting out and examining the many elements of the national system which should be taken into account in a comprehensive review of national regulatory frameworks for food.

#### **REGULATORY REGIME OF HEALTH PROTECTION AND FOOD SAFETY AT INTERNATIONAL LEVEL**

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<sup>1</sup>. 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.

Significant regulatory activity has taken place in the international arena with regard to food over the last several years. The Uruguay Round of Multilateral Trade Negotiations in 1994 led to the establishment of the WTO in January 1995. Agriculture was included in the trade talks in a significant way for the first time and it was agreed to reduce tariff barriers for many agricultural products in order to encourage free trade. Two agreements relevant to food, the SPS Agreement and the Agreement on Technical Barriers to Trade (TBT Agreement), were concluded within the framework of the WTO. These agreements set important parameters governing the adoption and implementation of food quality and food safety measures.

The TBT Agreement, which had been in existence as a voluntary agreement (the “Standards Code”) since the Tokyo Round (1973–1979), was converted into a binding multilateral agreement through the Uruguay Round. It covers all technical requirements and standards (applied to all commodities), such as labelling, that are not covered under the SPS Agreement.

The SPS Agreement was drawn up to ensure that countries 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 aim is the establishment of a multilateral framework of guidelines and rules that will orient the development, adoption and enforcement of harmonized sanitary and phytosanitary measures and minimize their negative effects on trade. The use of international standards is intended to allow countries to prioritize the use of their often limited resources and to concentrate on risk analysis.

Codex Alimentarius is the main instrument for the harmonization of food standards, and constitutes a collection of internationally adopted food standards, codes of practice and maximum residue limits of pesticides and veterinary drugs in food. The objectives of Codex are to protect the health of consumers, to ensure fair practices in food trade and to promote the coordination of all food standards work undertaken by national governments. Under the SPS Agreement, Codex standards, guidelines and recommendations have been granted the status of a reference point for international harmonization. They also serve as the basic texts to guide the resolution of trade disputes. WTO members are called upon to base their national food safety measures on international standards, guidelines and other recommendations adopted by Codex where

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<sup>1</sup> General Assembly Resolution 39/248 of April 9, 1985 and Annex: Guidelines for Consumer Protection.

they exist, and so long as a country employs these standards, its measures are presumed to be consistent with the provisions of the SPS Agreement. (Countries may also apply stricter standards than the Codex standards, so long as those are based on science.) Thus, while Codex standards in and of themselves are not binding, they have become binding on WTO members through the SPS Agreement.

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). 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<sup>2</sup>. 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 Trade<sup>3</sup> 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<sup>4</sup>. 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<sup>5</sup>. 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”<sup>6</sup>. Therefore, the Agreement tries to balance two

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<sup>2</sup> See Snyder, F., “Toward an International Law for Adequate Food,” in Mahiou A., Snyder F., *Food Security and Food Safety*, Leiden/Boston: Martinus Nijhoff Publishers, 2006, pp.123-133; Shaw S., and Schwartz R., *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.

<sup>3</sup> 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.”

<sup>4</sup> Shaw S., and Schwartz R., *Trading Precaution: The Precautionary principle and the WTO*, United Nations University, Institute of Advanced Studies, November, 2005, p. 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)

<sup>5</sup> Button, C. *The Power to Protect: trade, health and uncertainty in WTO*, Hart Publishing, Oxford and Portland Oregon, 2004, p. 228.

<sup>6</sup> Shaw S. and Schwartz R., *op. cit.*, p 6

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<sup>7</sup>.

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*<sup>8</sup> and the *EC-Hormones*<sup>9</sup> 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<sup>10</sup>. 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*<sup>11</sup> 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

<sup>7</sup> See SPS Agreement, Preamble and Annex A, paragraph 3 (a).

<sup>8</sup> WTO Appellate Body, *European Communities – Trade Description of Sardines*, WT/DS231/AB/R, Report of the Appellate Body, September 26, 2002

<sup>9</sup> 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

<sup>10</sup> 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.”

<sup>11</sup> Helfer LR, *Intellectual property rights in plant varieties: an overview with options for national governments*. FAO Legal Papers Online No 31, July 2002. Food and Agriculture Organization of the United Nations, Rome, 2002, available on <http://www.fao.org/Legal/Prs-OL/lpo31.pdf>

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<sup>12</sup>. 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.”<sup>13</sup>

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<sup>14</sup>. 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.

The growth in the number of countries joining the WTO and therefore bound by its agreements has created a flurry of interest in revising legislation to meet international obligations and to capture the principles of these agreements, such as harmonization, equivalence and non-discrimination. Similarly, countries eager to join regional groupings such as the European Union (EU) have been faced with the task of conforming their national laws on a wide range of subjects to EU requirements. The Caribbean Community (CARICOM) and the North American Free Trade Agreement (NAFTA), among others, have also influenced the legislation of their members, especially although not exclusively on trade matters. Regional standard-setting organizations have been building on international models while tailoring standards and measures to regional interests. The creation of new regional economic groupings such as the African Union confirms the expectation that regional harmonization efforts will continue to grow.

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<sup>12</sup> For much deeper insights in the findings of the Appellate Body in these reports, refer mainly to Shaw S. and Schwartz R., *Trading Precaution*, p.7-8; Button, C., *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 en question: Dilemmes, constats et controverses*, Karhala, 2000, p.725-752

<sup>13</sup> Shaw S. and Schwartz R., *op. cit.*, p.11.

<sup>14</sup> Button, C. *op. cit.*, pp.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 Brosset, “Le commerce international des produits biotechnologiques,” in Maljean-Dubois, S. ed., *La société internationale et les enjeux bioéthiques*, Paris, Pédone, 2006, pp. 165-202; *Ibid.*, “Le cadre juridique international en matière de produits alimentaires génétiquement modifiés: entre pénurie et sur-alimentation,” in *La sécurité alimentaire*, pp. 265-321.

In the wake of a trend towards more efficient food safety policies, the 2007 Beijing Declaration on Food Safety<sup>15</sup> 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.

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."<sup>16</sup>

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<sup>17</sup>. 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

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<sup>15</sup> The 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](http://www.who.int/foodsafety/fs_management/meetings/forum07/en/index.html)

<sup>16</sup> Button, C., *op. cit.*, p.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

<sup>17</sup> See the famous declaration by U.S. President John F. Kennedy in his 1962 message to the Congress

or not with (the rather few) international obligations and (the many) international standards.

### REGULATORY REGIME OF HEALTH PROTECTION AND FOOD SAFETY AT EUROPEAN LEVEL

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)<sup>18</sup>. Of course, the reception of European consumer law and the many decisions of the Court of Justice have had substantial consequences on domestic legislation<sup>19</sup>.

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<sup>20</sup>. 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<sup>21</sup>. 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"<sup>22</sup>. It further regulates liability issues, making reference to the responsibility of both States and business operators<sup>23</sup>. In this latter

<sup>18</sup> 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>

<sup>19</sup> Micklitz H.S., Reich N., and Rott P., *Understanding EU Consumer Law*, Morsel, Intersentia, 2009

<sup>20</sup> 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>.

<sup>21</sup> Articles 5 to 10

<sup>22</sup> Article 14, para. 1.

<sup>23</sup> Articles 17 to 21

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)<sup>24</sup>.

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”<sup>25</sup>.

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

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<sup>24</sup> 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

<sup>25</sup> See article 5, para. 2 and article 7, para. 2

facts”<sup>26</sup>; 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”<sup>27</sup>; 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<sup>28</sup>. 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<sup>29</sup>. 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<sup>30</sup>. 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<sup>31</sup>.

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<sup>32</sup>. In this

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<sup>26</sup> 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

<sup>27</sup> See also, in the same direction, article 35 of the Charter of Fundamental Rights of the European Union

<sup>28</sup> ECJ, *Koinopraxia Enóseon Georgikon Synetairismon Diacheiriséos Enchorion Proíonton 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

<sup>29</sup> 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

<sup>30</sup> 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

<sup>31</sup> See Button C., *op. cit.*, 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).

<sup>32</sup> 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

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.

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