

**TRANSNATIONAL CORPORATIONS AND  
INTERNATIONAL FOOD SAFETY GOVERNANCE**  
with special reference to interventionist food

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# TRANSNATIONAL CORPORATIONS AND INTERNATIONAL FOOD SAFETY GOVERNANCE

with special reference to interventionist food

Carmen Otero García-Castrillón\*

## I. INTRODUCTION

Food industry comprises a large number of strongly interdependent operators whose activities are developed all over the world. For the sake of simplification the food business can be classified in downstream (manufacturers: agriculture and transformation) and upstream (retailers). Food companies are largely integrated (horizontally and vertically) and, therefore, get involved in both business areas. Perhaps only half a dozen of food clusters control the passage of food from soil to supper<sup>1</sup>. Hence, a low number of Transnational corporations (TNCs) - that is, companies with establishments scattered over the territories of several States that have acquired a level of autonomy in their relations with each other - control the food business<sup>2</sup>.

TNCs pursue their corporate strategies in the light of the law framework and these strategies are elaborated through the use of law<sup>3</sup>. The national laws fragmentation of the international market pose difficulties and opportunities for business, who face the patchwork of varying national laws searching for the most efficient solution in the particular competitive situation. TNCs in different sectors have benefited from the states' jurisdictional fragmentation leading to abuses which could hardly be judicially controlled<sup>4</sup>. Critics against this situation are abundant particularly when human rights

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<sup>1</sup> "Survey of Agriculture and Technology", *The Economist*, 2000, 25 March. To illustrate the situation, Cargill's experience can be enlightening. After creating joint ventures horizontally, it started to establish partnerships with farmers' cooperatives. In every case, what might have looked like a good marketing opportunity for a small farmer-owned cooperative was an arrangement that assured Cargill a reliable supplier without increased investment. Farmers became captive suppliers to Cargill, and, therefore, effectively absorbed. This practice resembles the colonial creation of dependency, serving the interests of the colonizers at the expense of the colonized. It can also be described as the recreation of feudalism. Kneen, *Invisible Gigant. Gargill and its Transnational Strategies*. Pluto Press. 2002, 194-195 and 198. The most significant agri-food TNCs are Cargill, Pepsicola, Coca Cola, Conagra, RJB Nabisco, Anheuser Bush (USA); Nestlé (Switzerland); Unilever (Netherlands); and Danone (France). Agrochemical corporations, like Monsanto and Dupont (USA); Novartis (Switzerland); Zeneca (United Kingdom) and Agroevo (Germany), do also act in the food business. On the effects of firms over agriculture see J. Chen and E.S. Adams, "Feudalism Unmodified: Discourses of Farms and Firms". Anglo-American Agricultural Law Symposium: Part 2: Theme III: Agribusiness: The way ahead. *Drake Law Review*. Vol. 45, 1997, 361-433.

<sup>2</sup> Though widely used, the term Multinational Companies (MNC) is to a certain extent disputed. F. Rigaux, "Transnational Corporations", in M. Bedjaoui Ed. *International Law: Achievements and Prospects*. Martinus Nijhoff and UNESCO. 1991, 121-122, P. Fisher, "Transnational enterprises". *Encyclopedia of Public International Law*. Vol. 8. North Holland. 1985, 515-519; R.A. Higgot, G.R.D. Underhill and A. Bieler, Eds. "Introduction". *Non State Actors and Authority in the Global System*. Routledge. London-NY. 2000, 1.

<sup>3</sup> F. Snyder, "Global Economic Networks and Legal Pluralism", in G.A. Bernamm, M. Hedeger and P.L. Lindseth Eds. *Transatlantic regulatory cooperation. Legal problems and Political Prospects*. Oxford University Press. 2000, 113; and "Governing globalisation", in M. Likosky Ed. *Transnational Legal Process*. Butterworths. 2002, 93.

<sup>4</sup> F. Rigaux, *op. cit.* 129 says "(T)ransnational corporations have traditionally taken advantage of the fragmentation of the states' jurisdiction to built up a private transnational power-structure which has managed to keep itself beyond the reach of concurrent competing states' jurisdiction".

are at stake<sup>5</sup>. It has to be acknowledged that the human right to adequate food encompasses food safety<sup>6</sup>. Beyond the possibility of prosecuting human rights violations in national and certain international *fora*, initiatives for a new paradigm in the international regulation and prosecution of TNCs behaviours are in process<sup>7</sup>. Up to this day, however, there are no cases of TNCs violations of the human right to food related to food safety<sup>8</sup>.

Though the food industry requires an harmonized food safety environment for their economic transactions, they also benefit from the regulatory differences among states. Industries may have common interest in working together to solve common problems, but they are also in competition. Therefore, collective action is a solution at the level of shared structures (macro level) while individual action is pursued in particular circumstances (micro level). Individual solutions often disseminate to become standard practice leading to the birth of the *lex mercatoria*, which is construed from below, bottom-up<sup>9</sup>. The coincidence of cooperation and competition among major private actors in the same sector at the same time is referred to as the “new competition”<sup>10</sup>. Business collective action has always looked for its involvement in international rule making, particularly in trade related instruments. TNCs have never been shy to tell governments at any and every level, privately and publicly, what they should do. Sometimes it is dressed up in economic development terms, sometimes in humanitarian terms and often just as naked self-interest<sup>11</sup>. Business interests are often assumed by the states and defended as national interests in international forums<sup>12</sup>, and this has evolved

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<sup>5</sup> Among many others, F. Rigaux, *op. cit.* 127-129.

<sup>6</sup> The right to food is recognised by article 25 of the Universal Declaration of Human Rights and Article 11 of the International Covenant of Economic, Social and Cultural Rights (ICESC). States that have ratified the ICESCR are under an obligation to regulate the conduct of third parties in order to protect individuals under their jurisdiction against human rights abuses. International law puts the responsibility on the individual states to ensure that TNCs do not violate human rights through their operations in their country. USA has not ratified ICESCR. Paragraph 1 of the 1996 FAO World Food Summit, <http://www.fao.org/wfs/final/rd-e.htm>, defined food security as the situation where “all people, at all times, have physical and economic access to sufficient, *safe* and nutritious food to meet their dietary needs and food preferences for an active and healthy life”.

<sup>7</sup> See *infra*.

<sup>8</sup> They have dealt with jeopardizing access to food due to environmental destruction. For example, in the Ogoni region of Nigeria, by 1995 oil had been exploited for about three decades resulting in environmental degradation to the degree that population experienced difficulties in growing sufficient food for their own consumption. *Bowoto et al. V. Chevron Corp. et al.* n° C 99 2056 (N.D. Cal. 2000); *Wiwa v. Royal Dutch Petroleum Co.* 226 F.3d 88 (2d Cir. 2000); 532 U.S. 941 (S.Ct. 2001); 2002 U.S. Dis. LEXIS 3293 (S.D.N.Y. 2002). Still pending before the U.S. courts is a class action brought by 10.000 Ecuatorian Indians against the U.S. DynCorporation for fumigating cocaine and heroine believed to be growing in the area where they live. Among other things, the fumigation caused the destruction of the crops which were their means of livelihood (*Arias v. DynCorp*, n° 1:01CV01908 (D.D.C., filed September 11, 2001).

<sup>9</sup> D. McBarnet, “Transnational transactions: legal work, cross-border commerce and global regulation”, in M. Likosky Ed. *Transnational Legal Process*. Butterworths. 2002, 100-101.

<sup>10</sup> B. Portnoy, “Alliance capitalism as industrial order; exploring new forms of interfirm competition in the globalising economy”, in R.A. Higgot, G.R.D. Underhill and A. Bieler, Eds. *Non State Actors and Authority in the Global System*. Routledge. London-NY. 2000, 157.

<sup>11</sup> B. Kneen, *op. cit.* 9. As applied to Cargill.

<sup>12</sup> S.K. Sell, “Structures, agents and institutions: Private corporate power and the globalisation of intellectual property rights”, in R.A. Higgot, G.R.D. Underhill and A. Bieler, Eds. *Non State Actors and Authority in the Global System*. Routledge. London-NY. 2000, analyses the exemplary case of WTO TRIPs Agreement, pursued by US national industry and negotiated by the US government. It is apparent that representatives of corporations concerns are directly associated with international negotiators and that they actively defend the interest of the corporations seated in their countries. F. Rigaux, *op. cit.* 127,

to what has been called the “triangular diplomacy”: a nexus of bargaining relationships between states, between states and firms and between firms<sup>13</sup>.

Nowadays, the economic activity of the food industry is based on demand<sup>14</sup>; and demand has adopted a comprehensive health approach. In this scenario two different and paradoxical trends have come to the forefront of the food business. On the one hand, the intervention in the food process through technology has led to genetically modified<sup>15</sup> (GMs) and functional (also named nutraceuticals)<sup>16</sup> foods, which may come within the concept of “novel foods”<sup>17</sup>. On the other, the “non-interventionist” organic food<sup>18</sup> has gained adepts. Both trends are focussed on the food process from agriculture to the final product. Both do also present challenges to international food safety governance<sup>19</sup>. However, interventionist food is in the spot light because, on the one hand, biotechnology has the greatest effect on the most heavily traded agri-food

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points that representatives of those countries should be accused of duplicity when at the political level they support the demand of TNCs while at the same time claiming that they have no power to control them and refusing to take any responsibility for their actions on the grounds that such corporations belong to a private economic sector which is independent of the State. E.M. Fox, “Global markets, national law and the regulation of business – a view from the top”, in M. Likosky Ed. *Transnational Legal Process*. Butterworth, 2002, 143, points that it is often conceived that companies interests are good for national economy. But, nations should neither enforce nor withhold enforcement in the interest of a national champion.

<sup>13</sup> B. Portnoy, *op. cit.* 168.

<sup>14</sup> A different and controversial issue is the extent to which demand is truly created by consumers and corporations just try to satisfy it. D. Mayer, “Community, Business Ethics and Global Capitalism”, *American Business Law Journal*, 2001, 215-260. Confirming the “demand” oriented approach of food business, it is interesting to note that in 1994 Cargill created a Specialty Plants Products department for costumers who have a particular requirements, such as what are now being referred to as IP crops that have special characteristics specified by the end user. Some of these speciality crops are being created through genetic engineering. B. Kneen, *op. cit.* 25-26

<sup>15</sup> Genetically modified organisms are the result of modern biotechnology, also referred as genetic engineering or genetic manipulation, which involves the transfer of hereditary material (DNA, RNA) from one organism to another in a way that cannot be achieved naturally. GM crops are particularly designed to resist insect damage, viral infections and to tolerate certain herbicides. An extremely controversial issue is the percentage of GM components a product has to have in order to be qualified as GM food.

<sup>16</sup> These are products that provide a health benefit beyond the nutrients traditionally contained in the particular product (dietary supplements). The expression food fortification is also used for products aimed at preventing or correcting a nutritional deficiency of a population. In the US and the EC there is no legal definition for functional foods. They are in a grey regulatory area between food and drugs. However, through the labelling regulations it is determined what can and cannot be said about the health benefits of a particular food or ingredient.

<sup>17</sup> Novel foods are understood as foods and foods ingredients that have not been used to a significant degree for human consumption (in the CE before 15 May 1997 – Regulation 258/97 concerning novel foods and novel foods ingredients, *JOEC* (1997) L 43/1; in the US the 1994 Dietary Supplement Health and Education Act qualifies as a new dietary ingredient those that were not marketed in the US before 1994).

<sup>18</sup> Food may be labelled as organic when it is obtained through an organic production method described in the particular regulations. It tends to include the use of renewable resources and the conservation of soil and water to enhance environmental quality. In the EC, Regulation 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs, as modified, -consolidated text is available CONSLEG 1991R2092-23/03/2002-. In the US, the Organic Foods Production Act of 1990 as amended in 2000, and implemented by the National Organic Programme, <http://www.ams.usda.gov/nop>.

<sup>19</sup> As to organic food, in United Kingdom, for example, the Food Standards Agency maintains that there are no real health advantages to organic food while the Soil Association claims that additives and chemical inputs in non-organic produce real health risks. J. Mason, “Threats to integrity pose obstacles to growth”, *Financial Times*, 10 July 2002.

commodities in the global trading system<sup>20</sup> and, on the other, trade in nutraceuticals is progressively increasing. Therefore, interventionist food deserves special attention.

As opposed to food<sup>21</sup>, there is not an authorised definition of food safety. However, it is well understood that the concept refers to the standards<sup>22</sup> food has to satisfy not to harm human health<sup>23</sup>. It is not generally understood to comprise its nutritional aspects and should not be confused with food quality<sup>24</sup>. Strictly speaking, neither does it encompass consumers' information, which is reached through labelling<sup>25</sup>. Together, both aspects would provide for consumer trust and satisfaction; a more complete view of consumers' food safety. As such, food safety is clearly an issue of consumer protection and an essential national public health function<sup>26</sup>. Consumers' protection is within the field of market regulation, not of market access. Nevertheless, it has been the openness of markets and the application of new technologies to the food production and processing what has brought the subject to the international arena. Although traditionally importers tended to accept the food safety judgements of regulators from the exporting countries leading to a reciprocal adjustment, international trade on new food products has revealed the problems caused by the differences between national food safety regulatory approaches<sup>27</sup>.

Food safety is the common interest of states, international organisations, food industries and, of course, consumers. At least in principle, industries and consumers formally intervene in the making of food safety regulations at national level. In addition, disregarding their respective "weight", both have their means to influence politics

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<sup>20</sup> In particular, maize (Argentina, Canada, EC, South Africa, USA), soybean (Argentina, Canada, EC -for processing only-, South Africa, USA), oilseed rape (Canada, United States), chicory (EC for breeding purposes only), squash (Canada, USA), potato (Canada, USA).

<sup>21</sup> 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. *Codex Alimentarius Procedural Manual*, Definitions, section I.

<sup>22</sup> Document approved by a recognised body that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method. Adapted from Annex 1TBT.

<sup>23</sup> FAO and WHO subscribe that food safety refers to all those hazards, whether chronic or acute, that may make food injurious to the health of the consumer. FAO and WHO, *Assuring Food Safety and Quality: Guidelines for the Strengthening National Food Control Systems*. 2003, 3.

<sup>24</sup> For FAO and WHO, food quality includes other attributes that influence a product's value to the consumer. *Assuring Food Safety and Quality*, *op. cit.*, 3. Though food quality might include safety, the close relationship of food safety with public health and, therefore, with public intervention, recommends separating food safety from more general quality issues.

<sup>25</sup> As a matter of fact, certain products whose risks for human health are known are allowed to enter in the market (fat food). Once the consumer is informed, it is up to him whether to consume the product or not. This does not obscure the fact that consumers information may be essential to protect their health by alerting persons with allergies or reactions to certain foods or food ingredients.

<sup>26</sup> The close relationship of food safety with public health calls for public intervention since national constitutions establish states' responsibility for the life and physical integrity of human beings.

<sup>27</sup> With J. Braithwaite and P. Drahos, *Global Business Regulation*. Cambridge University Press. 2000, 415, it is possible to speak of a "renationalization" of agri-food safety regulation. For the purpose of this study, and despite the absence of a total unification of community law in the field of food safety, European community regulation can be included within the "national" law category since it is deemed to be applied in a territory which is taken as a unit.

internationally through different *vias*: while industries have the finance and the technology, consumers have what has been called “civil regulation”<sup>28</sup>.

It is not the aim of this project to enter into the socio-political debate about the TNCs power and its implications for sovereignty or the shrinking state phenomenon<sup>29</sup> in the food safety field. Nevertheless, from a “constitutional” perspective, it might be worth noting that those debates do not impinge on global governance approaches based on international democratisation<sup>30</sup> and the so-called “new multilateralism”<sup>31</sup>. As Petersmann says, the focus on “positive integration law” requires promoting participatory politics<sup>32</sup>. This paper aims to address, from a legal perspective, the involvement of TNCs in international food safety harmonization governance and the efforts to increase their international accountability considering interventionist food. Therefore, both the development of legal norms and the structures to enforce them should be taken into consideration. However, the necessary departing point must be that TNCs are not full subjects of international law<sup>33</sup>. To be so the concerted volition of states would have to concur and, at this point, that can hardly be envisaged. For the time being, they are legal agents subject to the prescribing and enforcing jurisdiction of states and, beyond the controversial issue of the self executing nature of certain treaty obligations, they are legally bound by the rules of international law only when these are mediated by a state legal order.

This paper is structured in two major parts dealing respectively with the regulation and the implementation of food safety standards. The first part presents food safety regulatory framework (part II). Although this framework can be qualified as legally pluralist (II.A), it is possible to identify common features (II.B) in the variety of participants, structures and instruments involved. The case is illustrated through a review of particular regulations with special attention to interventionist food (II.C). The

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<sup>28</sup> P. Newell and D. Glover, “Business and Biotechnology: Regulation and the Politics of Influence”. *Institute of Development Studies*. Globalisation and Poverty, 26, use the term to denote actions taken by civil society actors that have the intention or effect of restraining, regulating or resisting the actions of private actors that are thought to be beyond the state control. These include public resistance, confronting public regulation, acting as watchdogs for effective monitoring and enforcement of regulations, and litigation.

<sup>29</sup> L. Peral Fernández, *Paradojas de la no-globalización*. Lengua de trapo, Madrid, 2003, 44, points that “(T)he reality is that there where the State exists, it is emptying its content while developing de-regulation, thus no-one appears as the guarantor of the rights and no-one is economically responsible of its continuous violations”.

<sup>30</sup> E.U. Petersmann, “Constitutionalism and WTO Law: From a State Centered Approach towards a Human Rights Approach in International Economic Law”, in D.L.M. Kennedy and J.D. Southwick Eds. *The Political Economy of International Trade Law: Essays in honour of Robert E. Hudec*. Cambridge University Press, 2002, 67, “WTO guarantees of freedom and non-discrimination should be interpreted as constituting rights and obligations not only for governments, but also for their citizens”.

<sup>31</sup> R.A Higgot, *op. cit.* 4. Instead of the mere interaction of states, attempt to a socio-political reconstitution on a global scale building a system of global governance from the bottom up.

<sup>32</sup> E.U. Petersmann, *op. cit.* 68.

<sup>33</sup> TNCs have some international rights (mainly in the foreign investment field); their international duties may be deduced from instruments directed at States (horizontal effects) and certain international instruments give companies standing before dispute settlement institutions (Iran-USA Claims Tribunal; the European Court of Human Rights). In any case, the “formal” issue of international legal personality of TNC is under discussion. For some, the concept of legal personality becomes an intellectual prison, and the whole notion of subjects and objects has no credible reality and no functional purpose in present international law. N. Jägers, “The Legal Status of the Multinational Corporation Under International Law”, in M.K. Addo, Ed. *Human Rights Standards and the Responsibility of Transnational Corporations*. Kluwer, 1999, 264-267.

second part reflects on the different mechanisms for controlling food safety standards implementation (part III). In this regard, attention is drawn to the absence of international control (III.A), national public action (III.B), self-enforcement (III.C) and private dispute resolution (III.D). The paper closes with summary final conclusions.

## **II. INTERNATIONAL REGULATION OF SAFETY STANDARDS AND CERTIFICATION SCHEMES**

Food safety rules are based on the determination of the standard levels food products have to satisfy in order to enter the market. The determination of those standards imply dealing with risks and its causes; that is, hazards. In a general meaning, risk is defined as future possible negative consequences of present choices and events<sup>34</sup>. As applied to food, hazard is understood as a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect<sup>35</sup>. Together with the standards, food safety rules incorporate certification schemes to verify and guarantee that the products satisfy the required standards. Regarding nutraceuticals and, particularly, GM foods, the potential negative health effects are related to allergic reactions and antibiotic resistance.

For TNCs, food safety regulation serves the purpose of creating predictability. It provides with a legal playing field which determines the scope of their responsibilities. Not only are food safety issues growing in complexity, but the increased international food trade reveals the problems posed by normative fragmentation. International regulation brings order to commercial interaction and lowers transaction costs by reducing barriers to trade. Since international standards will simplify and expand world trade, TNCs search for certain level of harmonisation in an international environment of open markets. Establishing international standards rises the issue of the degree of harmonisation. In the case of food, the fact that the human body is essentially equal in all parts of the world cannot obscure the important food-cultural differences among populations<sup>36</sup>. TNCs themselves are well aware of the different impact that various cultures may have in their business. This impact is not only unavoidable, but also convenient for stimulating competition. Therefore, it is necessary to reconcile demands for unrestricted international trade with increasing national and local demands for more autonomy in assessing and regulating the risks of this trade.

International harmonization of food safety has been in the states, international organisations and business agendas for quite some time, and interventionist food is taking much of their efforts lately. Parallel to the multiple initiatives of different international governmental organizations (IGOs), the industry has also developed self regulatory strategies collectively, through their own non governmental organizations (INGOs), as well as individually. Many times governments promote these private regulatory strategies. In addition, states are encouraged to negotiate in order to reach mutual recognition agreements which would facilitate international trade. In the international food safety field, the existence and activities of IGOs, business INGOs,

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<sup>34</sup> For the purposes of the Codex Alimentarius, risk is defined as a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food. *Codex Alimentarius Procedural Manual*, Definitions.

<sup>35</sup> *Codex Alimentarius Procedural Manual*, Definitions.

<sup>36</sup> M.A. Echols, *Food Safety and the WTO. The interplay of culture, science and technology*. Kluwer. 2001, 17.

TNCs on their own and of governments looking for mutual recognition agreements, through public and private, hard and soft, law may well respond to a legally pluralist framework. However, this varied international action enjoys salient common features. The particular regulations on interventionist food provide a clear example. The involvement of TNCs in food safety regulation governance can be followed along the way.

## A. LEGAL PLURALISM

The concept of legal pluralism refers to a variety of institutions, norms and dispute resolution processes, and the relationships established among them. The rules include public and private international and national regulation; hard and soft law<sup>37</sup>, and even what has been called micro-law; that is, the way individuals in the liberal state provide order in their lives<sup>38</sup>. Presently, food safety regulation responds to a plural methodological framework, and can be qualified as legally pluralist.

In the food safety field, an area where there are fundamental policy issues that should be decided by public authorities, “national deregulation” is definitively not an option<sup>39</sup>. In this regard, international trade has not in any way stimulated a regulatory race to the bottom. On the contrary, it has contributed to harmonize national food safety standards up more than down<sup>40</sup>. Nevertheless, the so-called “California effect”<sup>41</sup> has not been achieved in the most controversial food safety issues<sup>42</sup>.

Traditionally, most systems for regulating food safety were based on clear and predictable legal definitions of unsafe food, enforcement programmes to remove such food from the market, and the application of sanctions. This national and public centered regulatory approach was reactive, unable to anticipate and, therefore, lacked the flexibility required particularly by the rapid changes in technologies applied to food. The international harmonization of food safety regulation needs to be clear and predictable but also flexible. Moreover, it has to realize that food safety cannot be fully achieved without the cooperation and active participation of all stakeholders; farmers, industry and consumers. Therefore, supported by private and international initiatives,

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<sup>37</sup> F. Snyder, *op. cit.* (2000) 105-107; *op. cit.* (2002) 71-72. The concept of legal pluralism refers to a distinct regime for governing legal economic networks. They are less a structure of multilevel governance than a conjunction of distinctive institutional and normative sites for the production, implementation and sanctioning of rules.

<sup>38</sup> M.W. Reisman, *Law in Brief Encounters*. Yale University Press. 1999, 17-18. Although micro-law takes place in the private sphere, it has to be acknowledged that the boundary between the public and the private sphere in liberal systems is moveable; it shifts according to the objectives and policies of the community.

<sup>39</sup> Deregulation can be understood as the removal of government regulation and control. However, as B. Kneen, *op. cit.* x, points, TNCs have and will continue to shape the agricultural policy in as many countries and regions as they can while the public’s role in this policy is confined to that of passive consumer.

<sup>40</sup> J. Braithwaite and P. Drahos, *op. cit.* 411.

<sup>41</sup> A “California effect” takes place when a country (or coalition of countries) exports its own more stringent standards to, or imposes them upon, one or more of its trading partners through the use of market access. For example, a country may ban or threaten to ban imports of products that do not conform to certain standards. If, in reaction, that country’s trading partners raise their regulatory standards in order to remain able to export their products, a California effect has taken place. S. Princen, *EU Regulation and Transatlantic Trade*. Kluwer. 2002, 2.

<sup>42</sup> S. Princen, *op. cit.* 183-185; regarding the growth hormones in meat production, and 256-259; regarding GMOs.



the introduction of national preventive regulatory approaches have resulted in industry taking greater responsibility for, and control of, food safety risks. The Hazard Analysis Critical Control Point System (HACCP) is paradigmatic in this regard. The HACCP consists in establishing control along the food chain at different Critical Control Points (CCP) – a step in the process at which control is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level -. It emphasises in-process diagnosis, control and documentation rather than end-product testing<sup>43</sup>.

International public and self-regulation should assume their respective roles and interact with each other. A mandatory regulatory approach has to be integrated with the promotion of voluntary compliance. The balance could well be found in an adequate combination of rules which are formal and informal, imposed and negotiated, prescriptive and discretionary in their mode of implementation, evolving over time and rigorously specified from the beginning, they may be interpreted and developed through case law, they may depend on the efforts and actions of professional bodies or standard setting bodies and national regulatory agencies for their implementation. This implies a complex international regulatory strategy which combine the available instruments in the most adequate way to reach food safety objectives<sup>44</sup>. Moreover, the consequences of consumers' micro-law cannot be disregarded. However, it cannot be forgotten that, ultimately, the primary means for the implementation and enforcement of food safety regulation resides in national systems<sup>45</sup>.

Then, the issues are, firstly, establishing at what levels public and private international regulation should take place; and, secondly, providing for their coordination, which calls for some kind of subsidiarity<sup>46</sup>. The coordination of regulation and sites requires good governance. Food safety good governance may well be related to the legal philosophy movement of law proceduralization (“procéduralisation du Droit”). This involves the law stepping back from creating formal substantive norms and concentrating instead on providing the framework for decision making by ensuring that the best possible forum of interested parties can be convened to arrive at the eventual substantive norm<sup>47</sup>. This perfectly corresponds to a holistic approach towards food safety.

## 1. International Governmental Organizations

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<sup>43</sup> The HACCP model in food regulation was originally developed by NASA hazard analysis to ensure the safety of food for their astronauts. The US firm Pillsbury took the model into the food industry in the 1960s. J. Braithwaite and P. Drahos, *op. cit.* 415. Its principles have been formalised by the CAC Committee on Food Hygiene, see *infra*, and provide a systematic structure to the identification and control of foodborne hazards. It is appealing to governments who want to cut their inspection function to simply audit documentation of in-process controls. Of course, the role of consumers cannot be denied.

<sup>44</sup> D. Matthews and J.F. Pickering, “Business Strategy and Evolving Rules in the Single European Market”; in R.A. Higgot, G.R.D. Underhill and A. Bieler, Eds. *Non State Actors and Authority in the Global System*. Routledge. London-NY. 2000, 107.

<sup>45</sup> See *infra*.

<sup>46</sup> In this sense, E.M. Fox, *op. cit.* 134, uses the expression “world economic federalism” in view of the objectives to promote efficiency of regulation for the broader community and to serve the values and choices of the local community.

<sup>47</sup> This is in line with the theory of “reflexive law” (which relies on procedural norms that regulate processes, organisation and the distribution of rights and competences, and contains both normative evaluations and strategic considerations) developed by the sociologist G. Teubner, which, in addition, must consider the value of public participation in the regulatory process. S.E. Gaines and C. Kimber, “Redirecting self-regulation”. *Journal of Environmental Law*. Vol. 13 n° 2, 2001, 158.

Relevant IGOs involved in food safety issues include the World Health Organization (WHO)<sup>48</sup>, the Food and Agriculture Organization (FAO)<sup>49</sup>, and the Organization for Economic Cooperation and Development (OECD)<sup>50</sup>. These IGOs contribute to harmonizing international food safety regulatory requirements, standards and policies. The OECD has also intervened in the regulation of TNCs behaviour.

Regarding the establishment of common standards and certification schemes the FAO/WHO Codex Alimentarius Commission (CAC)<sup>51</sup> for food, the International Office for Epizootics (IOE)<sup>52</sup> for animals, and the FAO's International Plant Protection Convention (IPPC)<sup>53</sup> for plants, are the most significant institutions<sup>54</sup>. Beyond the aim of setting food safety standards, these institutions intend to facilitate international trade.

Among the standards' setting organizations, the CAC predominance is undeniable. The CAC is a United Nations (UN) food standards body run jointly by the FAO and WHO. It was established in 1963. CAC work is organised through committees, where specific issues are discussed, and regional committees with coordinating functions<sup>55</sup>. *Ad Hoc* committees can also be appointed. Regarding interventionist food, there is a committee on Food Additives and Contaminants, and *Ad Hoc* committee on Biotechnology. The committees depend on expert technical bodies, convened by the FAO and the WHO to

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<sup>48</sup> WHO is the United Nations (UN) agency with a specific mandate for the protection of public health. Article 2.u of its Constitution gives a mandate to develop, establish and promote international food standards.

<sup>49</sup> FAO is the UN agency with a specific mandate to raise levels of nutrition and standards of living, to improve agricultural productivity, and to better the condition of rural populations (article 1 of its constitution). Several FAO's initiatives have led to the development of agencies or groups, such as FAO/International Atomic Energy Agency (IAEA), International Consultative Group on Food Irradiation, whose tasks include food safety issues. In addition, FAO's Global System for the Conservation and Utilization of Genetic Resources for Food and Agriculture constitutes a complex regime comprising codes of conduct (the International Code of Conduct for Farm Germplasm Collecting and Transfer, 1993), principles (Farmers rights) model agreements, and monitoring and reporting of the world's plant genetic resources.

<sup>50</sup> OECD is an International Organization whose Members share a commitment to democratic government and the market economy. The OECD produces internationally agreed instruments, decisions and recommendations to promote rules of the game in areas where multilateral agreement is necessary for individual countries to make progress in a globalised economy, including TNCs behaviour and food safety concerns.

<sup>51</sup> FAO's governing bodies, at global and regional levels, have given high priority to the work of CAC and to FAO's programmes and activities in the field of food quality, safety and consumers' protection.

<sup>52</sup> IOE is an international agreement which includes among its objectives protecting plants and animals from the spread of pathogens through international trade. It was created in 1924. To this end, it accords health and safety standards. It has produced an Aquatic Animal Health Code and a Terrestrial Animal Health Code. OIE expanded its scientific standard setting activities into "animal production food-safety" through the establishment of a Permanent Working Group on Food Safety in 2002 (XV Resolution of the OIE International Committee, 70th General Session, 2002), whose initial focus has been the safety measures applicable at the farm level.

<sup>53</sup> IPPC is a multilateral treaty deposited with FAO's Director General and administered through the IPPC Secretariat located in FAO's Plant Protection Service. IPPC is in force since April 1952. Its purpose is to secure common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote measures for their control. To this end, it provides a framework and a forum for international cooperation, harmonization and technical exchange in collaboration with regional and national plant protection organizations.

<sup>54</sup> UN Economic Commission for Europe has also played a role in standard setting, largely for quality, on perishable products, mainly fruits and vegetables.

<sup>55</sup> Article IX of the CAC Regulation. *Codex Alimentarius Procedural Manual*.

advise and provide technical and scientific reports on risk analysis<sup>56</sup>. All government delegations have full membership, authority to participate in decision making and equal voting rights<sup>57</sup>, and many times industry representatives have been part of national delegations<sup>58</sup>. Decisions are normally adopted by consensus<sup>59</sup>.

The legal impact of CAC, IOE and IPPC works have been substantially strengthened through the World Trade Organization (WTO) Agreement on Sanitary and Phytosanitary Measures (SPS). As a matter of fact, the very existence of the SPS is linked to the drawbacks that the CAC had to go through during the long running disagreement between the United States (US) and the European Community (EC) over growth promoting hormones in meat<sup>60</sup>. In regulating international trade obstacles, the SPS applies to sanitary and phytosanitary measures; that is, any measure aimed at protecting health— and this includes food safety measures<sup>61</sup> - within Member states boundaries<sup>62</sup>. In other words, it applies to all the measures designed to avoid that imports prejudice health. The SPS Agreement does not itself establish standards or standards setting mechanisms, but strongly relies on the work of CAC, IOE and IPPC to set the inertial position for sanitary requirements for food, animals and plants respectively<sup>63</sup>. This reliance on “international standards, guidelines and recommendations”, has reinforced the principle of “international treatment”, above the most favoured national and national treatment principles, within the food safety field<sup>64</sup>. The SPS linkage to CAC, IPPC and OIE turns these standards setting organizations more into a political battlefield.

It is important to note that the WTO Agreement on Technical Barriers to Trade (TBT), which does establish a standard setting mechanism<sup>65</sup>, is not applicable to sanitary and

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<sup>56</sup> These are respectively the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Joint Expert Meeting on Pesticide Residues (JMPPR). These committees are closed to observers since in the view of FAO and WHO the presence of observers could establish an atmosphere of influence. However, participation of industry members could be possible if they attend in the capacity of individual experts.

<sup>57</sup> It is important to note that developing country delegations lack the resources and the expertise to fully participate in the Codex. D. McCrea, “A view from Consumers”, in N. Rees and D. Watson Eds. *International Standards for Food Safety*. AN ASPEN Publication. Maryland. 2000, 155.

<sup>58</sup> See *infra*.

<sup>59</sup> However, CAC procedures also allow for decisions to be made by voting and even by a secret ballot (simple majority of members present) when consensus fails to be reached; Articles VI and X of the CAC Regulation., *Codex Alimentarius Procedural Manual*.

<sup>60</sup> In this regard it is interesting to recall that when negotiations started on the Uruguay Round of GATT, the most powerful trading blocks were soon equipped with proposals to “increase efforts to harmonise national health safety standards” (US) and to “lessen the impact of health regulations on trade (EC)”. D. McCrea, *op. cit.* 155-157; J. Braithwaite and P. Drahos, *op. cit.* 403.

<sup>61</sup> Labelling requirements may also fall under this scope. See *supra* note 16.

<sup>62</sup> A sanitary or phytosanitary measure is any measure applied a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms; b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs; c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or d) to prevent or limit other damage within the territory of the Member from the entry, establishment of spread of pests. Annex A of the SPS.

<sup>63</sup> Articles 3, 12.3 and Annex A.3 SPS.

<sup>64</sup> J. Braithwaite and P. Drahos, *op. cit.* 412.

<sup>65</sup> Annex 3 includes the so called “Code of Good Practice”, which is open for acceptance to all standardizing bodies within the territories of the member States, whether a central government body, a local government body or a non-governmental body. In this respect is interesting to note that the TBT

phytosanitary measures<sup>66</sup> and does not expressly refer to CAC, IPPC nor OIE<sup>67</sup>. Therefore, in principle, this standard setting mechanism would not be applied in the food safety field. However, in the hypothetical case that food safety measures were not exclusively aimed at protecting health within a Member national boundaries but also abroad, TBT would have to be applied cumulatively with the SPS<sup>68</sup>. In any case, it has to be pointed that, despite their legally confusing relation, the special SPS and TBT rules apply prior to the more general regulation of the WTO GATT-94<sup>69</sup>.

Finally, within the international trade regulation of food, the recently entered into force Cartagena Protocol on Biosafety<sup>70</sup>, which tackles transboundary movements of living modified organisms (LMOs), takes into consideration the protection of human health<sup>71</sup>. A LMO is any living organism having a novel genetic combination obtained through modern biotechnology<sup>72</sup>. Certain LMO are used for food, feed and processing purposes (LMO-FFP) and, as a matter of fact, they represent the 90% of LMO's international trade<sup>73</sup>. To the extent that interventionist GMO food contains LMOs-FFP, they are within the scope of the Cartagena Protocol. The cornerstone of the Cartagena Protocol resides in a scheme permitting importing states to require an authorisation prior to importation and in providing a procedure leading to obtain it<sup>74</sup>. However, this scheme expressly excludes LMOs-FFP, and therefore the corresponding GM foods. For them, the Protocol only establishes an information system between countries in order facilitate transparency regarding national authorizations of LMOs and the corresponding national regulations<sup>75</sup>.

Although the commitments and/or recommendations of all these IGOs aim both to the protection of food safety and the facilitation of international trade, their incidence in one

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requires to notify the acceptance of the Code of Good Practice to the ISO/IEC Information Centre. It is difficult to insert CAC within one of those three categories of standardizing bodies. In any case, CAC, whose secretariat is definitively seated within the territory of a member state (Italy), has not notified its acceptance of the Code of Good Practices to the ISO. However, it is "in liason" with ISO; see <http://www.iso.ch>.

<sup>66</sup> Article 1.5 TBT.

<sup>67</sup> It could only be said that article 2.6 TBT indirectly refers to them when it says "... with a view to harmonising technical regulations ... Members shall play a full part in the preparation by appropriate standardizing bodies ...".

<sup>68</sup> G.E. Isaac and W.A. Kerr, "Genetically Modified Organisms and Trade Rules: Identifying Important Challenges for the WTO". *World Economy*, 2003, 29-42

<sup>69</sup> G. Marceau and J.P. Trachtman, "The Technical Barriers to Trade Agreement, the Sanitary and Phytosanitary Measures Agreement and the General Agreement on Tariffs and Trade: A Map of the World Trade Organization Law of Domestic Regulation of Goods". *JWT*. Vol. 36 n° 5, 2002, 866-870.

<sup>70</sup> The Conference of the Parties to the Convention on Biological Diversity adopted the Cartagena Protocol as a supplementary agreement to the Convention on 29 January 2000; <http://www.biodiv.org/>. The Protocol entered into force last 11 September 2003.

<sup>71</sup> Its focus resides in environmental protection. The text of the Protocol states that its objective is contributing to guarantee an adequate level of protection in the "transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, *taking also into account risks to human health*".

<sup>72</sup> Article 3.g Cartagena Protocol.

<sup>73</sup> M. Mathee, "L'identification et l'étiquetage des OGM: la démocratie existe-elle sur le marché international des aliments génétiquement modifiés", in J. Bourrinet et S. Maljean-Dobois, *La Régulation du commerce international des OGM*. La documentation française, Paris, 2002, 105.

<sup>74</sup> Articles 8-19 and 12. This authorisation, which is obtained through the so-called "advanced informed agreement" (AIA), is provided after the exporting state has made the appropriate risk assessment. See *infra*.

<sup>75</sup> Article 11 Cartagena Protocol.

or the other objective varies between them. In any case, their rules, being the product of international intergovernmental organisations and international treaties, apply directly only to member States. In addition, it is important to note that, except for the SPS and TBT - and indirectly CAC, IOE and IPPC -<sup>76</sup>, the enforcement of these rules rely basically on national systems.

## 2. Recognition of equivalence

The trade-liberalization objective has also relied on the principle of equivalence. In the food safety field it would imply the admission of imports despite their not meeting local safety standards as long as they meet the importing country's appropriate level of health protection. In this regard, article 4.1 SPS requires recognition of other states' regulations "even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing member's appropriate level of sanitary and phytosanitary protection"<sup>77</sup>.

On 25 October 2001, the SPS Committee adopted a decision on the implementation of article 4 on equivalence<sup>78</sup>. It sets up the possibility for other states to serve as "regulatory laboratories" to come up with alternative means to achieve the same regulatory goals. The Decision imposes an obligation on an importing member, upon the request of the exporting Member, to explain the objective and rationale of the SPS measure, to identify clearly the risks that the measure is intended to address, and to indicate the appropriate level of protection which its SPS measure is designed to achieve. In addition, the exporting member must provide reasonable access, upon request, to the importing Member for inspection, testing and other relevant procedures for the recognition of equivalence. Such requests should proceed rapidly, especially with traditional imports, and should not in themselves disrupt or suspend on-going imports. If there was any doubt, it is clear from this decision that recognition or equivalence is not possible without a minimum level of cooperation and harmonization. In this respect, CAC Guidelines for the Judgement of Equivalence Agreements Regarding Food Imports and Export Inspection and Certification Systems<sup>79</sup>, may constitute a basic reference.

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<sup>76</sup> The TBT (article 14.1) and the SPS (article 11.1) refer to the application of the Dispute Settlement Procedure of the WTO. – articles XXII and XXIII of GATT and the Dispute Settlement Understanding -.

<sup>77</sup> Article 2.7 TBT does only require Members to "give positive consideration to accepting as equivalent" other Member's technical regulations.

<sup>78</sup> G/SPS/19. Determining its legal value is a delicate issue. SPS Committee has the power to adopt decisions by consensus for the implementing the SPS Agreement provisions (article 12.1). The decisions cannot not conflict with or contradict the SPS, and, in any case, it is arguable that it constitutes "secondary legislation". Its binding nature would have to be established by a dispute panel considering that many Members take them as gentlemen agreements only. Nevertheless, most experts would agree that such a decision could be viewed as "any subsequent arrangement between the parties regarding the interpretation of the Treaty or the application of its provisions" pursuant to article 31.3.b of the Vienna Convention, or at least a rule of international law applicable to the relations between the parties pursuant to article 31.3.c, which, therefore, shall be taken into account in the interpretation of the SPS Agreement. G. Marceau and J.P. Trachtman, *op. cit.* 843.

<sup>79</sup> CAC/GL 34, 1999. It deals with the inspection and certification systems, including the equivalence aspects of these systems. The equivalence of technical regulations seems to be outside.

Beyond the unilateral recognition of equivalence<sup>80</sup>, the SPS and the TBT Agreements encourages its Members to enter bilateral and multilateral equivalence – also called mutual recognition - agreements<sup>81</sup>. Bilateral agreements on mutual recognition usually establish a general framework for the negotiation and implementation of equivalence accords. Within the agreements' framework, recognition of each other member's measures as applied to specific products can be said to be the result of a sophisticated form of regulatory cooperation<sup>82</sup>.

There is no doubt that TNCs are interested and get involved in the recognition of equivalence beyond the cooperation with their national states. Particularly, it is interesting to note that in US-EC bilateral trade relations<sup>83</sup>, business have a significant contribution. On the one hand, they been called to work together with government representatives in order to make policy recommendations. In this regard, the Transatlantic Business Dialogue (TABD) advocates the harmonisation or regulatory policies and the increment of regulatory cooperation between both economic powers. Regarding nutraceuticals for example, TABD considers that there has been considerable progress for reaching its goal of “approved once, accepted everywhere” on dietary supplements<sup>84</sup>. On the other hand, the Trans-Atlantic Economic Partnership has undertaken talks to improve regulatory processes and scientific cooperation through mutual recognition of testing and approval procedures<sup>85</sup>.

### 3. Self-Regulation

As the ancient guilds did, private international regimes address the issues that a particular industry sector faces. In addition to their individual action, competing firms cooperate in order to establish common grounds for their business purposes: efficiency, security, response to societal demands and action before the state<sup>86</sup>. TNCs have always looked for being involved directly and/or indirectly in the public food safety rule making process. Moreover, they have developed national and international self-regulation: formal and informal norms about business behaviour, decision-making procedures and both informal and formal enforcement mechanisms.

Surely, the emergence of these norms respond to a cost-benefit analysis. Often, the development or assumption of food safety standards is the result of prior costly

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<sup>80</sup> For example, within the seeds field the EC has adopted Council Decision of 2 May 2000 amending Decision 95/513/EC on the equivalence of seed potatoes produced in third countries and Decision 95/514/EC on the equivalence of field inspections carried out in third countries on seed producing crops and on the equivalence of seed produced in third countries, *OJEC* (2000) L 114/30; and Council Decision of 16 December 2002 on the equivalence of field inspections carried out in third countries on seed-producing crops and on the equivalence of seed produced in third countries, *OJEC* (2003) L 8/10.

<sup>81</sup> Article 4.2 SPS and 6.3 TBT.

<sup>82</sup> K. Nicolaidis, “Regulatory cooperation and managed mutual recognition: elements of a strategic model”; in G.A. Bernamm, M. Hedeger and P.L. Lindseth Eds. *Transatlantic regulatory cooperation. Legal problems and Political Prospects*. Oxford University Press. 2000, 594, points that the management of recognition is the trick that regulators have found to satisfy their political masters and trade colleagues while at the same time minimizing the effects of recognition in terms of regulatory competition.

<sup>83</sup> Agreement on mutual recognition between the EC and the USA, *OJEC* (1999) L 31/3.

<sup>84</sup> TABD, *2001 CEO Report*, 36. TABD, *2002 Chicago Conference Report*, 48 refers to the establishment of a Dietary Supplements Working Group.

<sup>85</sup> See it in <http://europa.eu.int/comm/trade/bilateral/usa/1109tep.htm>. Visited in October 2003.

<sup>86</sup> V. Haufler, “Private sector international regimes”, in R.A. Higgot, G.R.D. Underhill and A. Bieler, Eds. *Non State Actors and Authority in the Global System*. Routledge. London-NY. 2000, 126, 128-129. Industry representatives often describe this kind of voluntary effort as a complement to government regulation, but it could also be viewed as an attempt by the industry to pre-empt government intervention.

consumer action; where the savings derived from continuing with certain business practices may in fact outweigh the costs of being “less competitive” in a purely economic definition. Self-regulation is often the result of experience and consultative practices. Its rule making procedures and the rules themselves benefit from great flexibility. However, self-regulation is criticised both technically, due to its lack of a legal mechanism to enforce compliance, and politically, as a public relations gimmick<sup>87</sup>. Obviously, self-regulation *per se* should not be seen as a normative solution but as a complement to public regulation.

Public authorities encourage self-regulation. Sometimes they even offer and support international model codes of conduct, which, hence, can be said to contain international standards of public policy<sup>88</sup>. Codes of conduct are as varied as the corporations that adopt them. They range from rather complete documents to one page statements focusing on the company’s ethical standards and responsibilities. Generally, TNCs self-regulation schemes include the obligation to comply with host country law as the minimum acceptable level of performance, and even they do incorporate international standards by reference. In countries and regions with ineffective domestic governance, self-regulation initiatives may be used to set and promote good business practices<sup>89</sup>.

The International Chamber of Commerce (ICC) is the largest global business organization. Its members include thousands of companies of every size in more than 130 countries. Founded in 1919 with the objective of furthering the development of an open world economy, it feeds business views into IGO on issues that directly affect business operations and encourages self-regulation in different fields. Although ICC has not developed any particular instrument containing principles or recommendations in the food safety area, it has worked on a “Global Roadmap to Modern Biotechnology”. Regarding corporate responsibility, ICC encourages voluntary initiatives and has made practical suggestions to companies in order to help them approaching the issue<sup>90</sup>.

The most relevant standardizing collective action of an industry INGO is developed by the International Standardization Organization (ISO), which is the main source of international standards in a huge range of items. It is composed of representatives of national standards institutes of 147 countries. The legal nature of the organization raises

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<sup>87</sup> As M.T. Kamminga and S. Zia-Zarifi, “Liability of Multinational Corporations Under International Law: An Introduction”, in M.T. Kamminga and S. Zia-Zarifi Eds. *Liability of Multinational Corporations Under International Law*. Studies and Materials on the Settlement of International Disputes. vol. 7. Kluwer. 2000, 9, put it: “(I)t is fashionable, and strongly encouraged by MNCs themselves, to discuss the responsibilities of corporations in terms of social accountability, good governance, responsible citizenship or other such formulations, in lieu of international legal obligations. This approach has some value in terms of creating soft law that could get into hard law. But through the course of our research, we grow increasingly sceptical about the effectiveness of this approach, which centres on making corporations seem more responsible to their shareholders or society in general”.

<sup>88</sup> H.W. Baade, “The Legal Effects of Codes of Conduct for Multinational Enterprises”. *German Yearbook of International Law*, vol. 22, 1979, 13. The traditional device of multilateral conventions was regarded as too unwieldy for quick relief and as too decentralized for pervasive coverage.

<sup>89</sup> In these cases, Codes of Conduct for TNCs have been said to act as devices for the protection of the economy of the host country (and for the host country workers, costumers, competitors and creditors) from unilateral action of the TNCs’ headquarters, especially if influenced by economic or policy factors indigenous to the home country. H.W. Baade, *op. cit.* 12.

<sup>90</sup> *Business in society; making a positive and responsible contribution*. In [http://www.iccwbo.org/home/news\\_archives/2002/bisinsocdoc.asp](http://www.iccwbo.org/home/news_archives/2002/bisinsocdoc.asp). Visited in October 2003.

certain doubts<sup>91</sup>. Considering its foundation<sup>92</sup> and the fact that its members are not delegations of national governments, it has been said to be an NGO. However, although in some countries the national standards institutes are private<sup>93</sup>, in others these bodies are governed by public agencies where the government influence is evident. The ISO process is decentralised with interested national bodies taking the lead in technical committees where the details of standards are developed. Decisions are normally made by consensus. As to food, Technical Committee (TC) number 34 is in charge of standardization.

In May 2000, the Food Business Forum (CIES), an independent global food business network of food retailers and their suppliers, launched the Global Food Safety Initiative (GFSI). The initiative is managed by an International Task Force integrated by representatives of the participating industries, which avail for the 70% of the food retail revenue worldwide. Its aim is introducing benchmarking for product audits which will enhance food safety, ensure consumer protection strengthening his confidence and improve cost efficiency. In particular the initiative priorities are implementing a scheme to benchmark food safety standards worldwide, and building and implementing an international early warning system.

#### 4. Consumers' micro-law

Although consumers participation is established in important organizations, such as CAC, their intervention in international food safety regulation is still implemented in great part through what can be called micro-regulation, which has its own decision making and enforcement procedures<sup>94</sup>. These informal rules may have more force than formal rules because they are developed by the group itself, are easier to enforce, and provide social support for compliance<sup>95</sup>. In the food field, consumers may decide not to buy or to boycott certain food products. The effectiveness of this "regulation" can be demonstrated particularly in the case of the European consumers resistance to GM foods: certain European food producers, like Nestlé and Unilever, adopted a GMO free policy; Grupo Maseca, Mexico largest tortilla producer, announced it would no longer purchase GM corn; in the US, Heinz and Gerber, the two largest baby food manufacturers, also announced a GMO free policy; and two large US food processors, Archer Daniels Midland Company and A.E. Stanley Manufacturing Company

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<sup>91</sup> For example, V. Haufler, *op. cit.* 127, says that "due to the significant industry participation in developing the standards, ISO has been qualified as a quasi-public body or public-private regime".

<sup>92</sup> ISO's roots can be found in 1906, when the international electrochemical commission was founded for standardization in the electrochemical field. For the other fields, the International Federation of National Standardizing Associations was set up in 1926 and developed its work until 1942.

<sup>93</sup> In the US, for example, the American National Standards Institute is a federation of representatives from industry, government, standards group, labour consumer unions and academia.

<sup>94</sup> M.W. Reisman, *op. cit.* 2. "The law of the state is important, but law, *real* law, is found in all human relations, .... Law is a property of interaction. Real law is generated, reinforced, changed and terminated continually in the course of almost all of human activity". "Part of every decision is concerned, not with the immediate decision, but with the structure of decision making itself. Microlaw is effective and sanctioned, although those who look for the familiar enforcement mechanisms and litmus tests of conventional legal theory will not find things like microarmies, micropolice or micropriprisons. They will, however, find functional equivalents".

<sup>95</sup> M.W. Reisman, *op. cit.* 12-13; the sanctioning and enforcing functions do not need to be "carried out by a particular institution or type of institution. In some systems, law is enforced coarchically; in other words, by the actors themselves rather than by specialized enforcers, and is sustained over time by expectations and, when necessary, by actions of reciprocity and retaliation. The same actors are, in rapid alternation, actors and deciders."



announced they intended to reject any GM corn that was not accepted in European markets<sup>96</sup>. However, it is difficult to capture mass consumer attention and achieve this “regulatory” effect in issues which do not reach the level of social impact that genetic modification of food has provoked<sup>97</sup>.

Moreover, consumers recourse to lawsuits against TNC in certain jurisdictions, such as the US, lead to the change of corporative behaviour regardless of the success of the actions before the courts. Kraft and McDonalds products and marketing strategies were accused of carrying high levels of artery-clogging fats and creating obesity. Though central claims against McDonalds have been dismissed, the industry had already started to review its products and marketing strategies. Kraft will adopt new guidelines on marketing (will cut portion sizes, reduce fat and sugar content in its foods) and advertising to children; drop all marketing in schools and review what it puts in school vending machines. This has been said to put pressure on global competitors such as Nestlé, Unilever and Cadbury-Sweppes<sup>98</sup>.

## B. COMMON FEATURES

The international public and private regulatory initiatives regarding food safety have several common features.

### 1. Legal nature

In principle, international public and private food safety standards and certification schemes, as well as the rules of the TNCs codes of conduct, do not have a binding but a voluntary character<sup>99</sup>. Despite their non-binding character, international standards and codes of conduct do have certain legal effects.

Essentially, only the international standards and codes of conduct embodied in national regulations are compulsory for, and enforceable on, TNCs’ and it has to be remembered that international standards can be superseded by national more stringent regulation. However, when these international standards and codes of conduct are sponsored by IGO, hence by states, they constitute multilateral declarations of policy, and, as such, they can be said to have legal effects analogous to unilateral declarations in international law<sup>100</sup>. This means that their provisions are relevant to the interpretation of prior instruments in force between the states parties, including treaty clauses of a general or potentially ambiguous nature. Hence, while TNCs’ host states will be able to gain moral advantages by pointing to relevant guideline provisions and have some strengthening of their bargaining position in a sense that similar conditions will be imposed by other states; TNCs home governments will tend to find their freedom of

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<sup>96</sup> B. Endress, “GMO: Genetically Modified Organism or Gigantic Monetary Obligation? The Liability Schemes for GMO Damage in the United States and the European Union”. *Loyola of Los Angeles International and Comparative Law Review*, vol. 22, 2000, 458 and 460.

<sup>97</sup> J. Braithwaite and P. Drahos, *op. cit.* 409. Other food safety issues with great social impact have been hormones in beef and food irradiation.

<sup>98</sup> N. Buckley, “Kraft to cut fat content and reduce portions”. *FT*, July 1<sup>st</sup>, 2003. It is interesting to note that a US senator even proposed a bill to outlaw obesity lawsuits, <http://story.news.yahoo.com/news>. Visited in July 2003.

<sup>99</sup> The TBT defines the standards as voluntary, Annex 1. Public instruments are considered as recommendations or reference documents and governments are not required to accept them.

<sup>100</sup> H.W. Baade, *op. cit.* 13-14. They are thus neither entirely non binding internationally, non entirely non enforceable domestically.

manoeuvre curtailed by the guidelines though they will point emphatically to the absence of formal legal effect<sup>101</sup>.

It should be noted that states, IGOs and TNCs can choose their contracting partners among those companies which abide by the norms. They are in a commercial position to encourage some direct suppliers and sub-contractors to comply with food safety standards. In other words, through contracts they may be forced or force others to comply with food safety standards and corporate behaviours. This leads to a *de facto* enforcement of the rules, which imply *de facto trading up*: strengthening of the legally applicable standards<sup>102</sup>. As a matter of fact, TNCs have found benefits from doing business with companies who embrace high standards of business conduct and who demonstrate commitment to those standards through their business practices<sup>103</sup>. These initiatives have been very useful in supporting compliance<sup>104</sup> with non legally binding international food safety standards; particularly in developing countries or countries without implemented food safety systems, where TNCs invest to implement a food exporting business. It cannot be ignored that these cases may lead to *de facto* double food safety standards in developing countries (for internal consumption/for exports). However, double food safety standards situations are not an exclusive developing country phenomena, they tend to exist whenever there are differences in market power<sup>105</sup>.

It must be acknowledged that the violation of these norms may be argued before a judge or an arbitrator in building a legal case against a TNC which has failed to comply with them. If the infringed rule is within a public sponsored instrument and the states where the violation takes place and the seat of the company are signatories to it, the violation of the rule may be established. A clear example is the bankruptcy Badger case regarding the workers' rules of the OECD Guidelines for Multinational Corporations<sup>106</sup>. When it comes to the infringement of individual companies' Codes of Conduct, the possibility of establishing direct legal responsibilities is disputed<sup>107</sup>. Nevertheless, national courts

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<sup>101</sup> H.W. Baade, *op. cit.* 51.

<sup>102</sup> For example, in the EC, the Euro-Retailer Produce Working Group (EUREP) developed their normative document for agriculture good practices, "EUREPGAP Fruits and Vegetables". From June 2001, products that do not comply with those standards will not be distributed by the European supermarkets that have signed it.

<sup>103</sup> In this regard, a different problem would be the eventual qualification of the behaviour of an abuse of dominant position in certain circumstances.

<sup>104</sup> OECD Roundtable on Corporate Responsibility; "Supply Chains and the OECD Guidelines for Multinational Enterprises"; *Business and Industry Advisory Committee to the OECD (BIAC) Discussion Paper on Supply Chain Management*. Paris, 19 June 2002, 2-3.

<sup>105</sup> In certain developed countries the stringency and vigilance they apply to inspecting food produced domestically for domestic consumption and food produced domestically for export varies widely. In Australia, exported meat is subject to more rigorous inspection than meat for domestic consumption. Australia cares more about US export market than it does about the health of its own consumers. J. Braithwaite and P. Drahos, *op. cit.* 407.

<sup>106</sup> For an analysis of the Badger case see R. Grosse, "Codes of Conduct for Multinational Enterprises". *Journal of World Trade Law*, vol. 16 n° 5, 1982, 428-429.

<sup>107</sup> In the US several commentators suggest that section five of the Federal Trade Commission Act - 15 U.S.C.S. & 45 (1997) - is a potential legal means for requiring TNCs to comply with their codes of conduct because it prohibits "unfair or deceptive acts or practices in or affecting commerce" and permits the Federal Trade Commission to protect consumers by monitoring and initiating administrative proceedings against advertising, sales and marketing practices that deceive consumers or treat them unfairly. M. Shaughnessy, "The United Nations Global Compact and the Continuing Debate About the Effectiveness of Corporate Voluntary Codes of Conduct", *Colorado Journal of Environmental Law and*

could give them some legal effect<sup>108</sup>, for example, in proving reasonable behaviour in civil liability cases.

Finally, it can be observed that TNCs themselves have generally acquiesced in the guidelines process, not just for the sake of benefiting from certain degree of stability and security<sup>109</sup>, but because of the moral and commercial pressure to which their respective brands are exposed. In this regard, economic reports may well recommend to abide by those voluntary rules.

Hence, the legal nature of international food safety standard and codes of conduct's rules does not fall under a clear-cut concept. On the one hand they may not be qualified as rules of law; on the other, it cannot be denied that they have certain effects and that those effects may be legal. Leaving theories aside, practice speaks well of the effectiveness of these rules. It is a fact that even the mere existence of a standard and of a code of conduct has consequences<sup>110</sup>.

## 2. Industry as addressees

Obviously, international private food safety standards and conducts are designed to be applied directly by TNCs. On its part, IGOs' food safety standards and codes are not created for public national use only, they are reference documents for all those involved in international trade and therefore, they are meant to be applied by TNCs. Governments sometimes express their willingness<sup>111</sup> and others acquire a binding commitment<sup>112</sup> to promote compliance with these IGOs' by TNCs. In any case, TNCs tend to apply international standards and codes of conduct on their own intent, mostly by developing their own Codes of Conduct.

## 3. Sound science

In public and private international food safety regulation the safety decision making criteria is sound science<sup>113</sup>. This is perfectly understandable because the need for objectivity and independence directs towards scientific expertise.

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*Policy*, Yearbook 2000, 2001, 170-171. However, It has been argued that the proposal would fail in practice. M.B. Baker, "Tightening the Toothless Vise: Codes of Conduct and the American Multinational Enterprise". *Wisconsin International Law Journal*, vol. 20 n° 1, 2002, 115-116.

<sup>108</sup> H.W. Baade, *op. cit.* 51.

<sup>109</sup> D.F. Vagts, "Multinational Corporations and International Guidelines". *Common Market Law Review*, vol. 18 n° 4, 1981, 471-472.

<sup>110</sup> P. Sanders, "Implementing International Codes of Conduct for Multinational Enterprises". *The American Journal of Comparative Law*, vol. 30 n° 2, 1982, 244. While some governments do not assume CAC standards, the majority raise the accorded levels. TNCs do also tend to assume CAC standards.

<sup>111</sup> The OECD Guidelines for Multinational Corporations, Concepts and Principles, numbers 5 and 10.

<sup>112</sup> Article 4.1 TBT establishes that Members shall take reasonable measures to ensure that non-governmental standardizing bodies accept and comply with the Code of Good Practice, and shall not take measures which require or encourage them to act them otherwise. When standardising bodies accept and comply with this code, they are acknowledged by Members as complying with the principles of TBT (article 4.2). Along this line, Article 8.1 requires member states to take reasonable measures to ensure that non-governmental bodies which operate conformity assessment procedures comply with the TBT rules in this field and shall not take measures which, directly or indirectly, require or encourage those bodies to act in a manner inconsistent with them. In any case, it must be recalled that Annex 1.8 TBT defines non-governmental body as "a body other than a central government body or a local government body, including a non-governmental body which has legal power to enforce a technical regulation".

<sup>113</sup> The first statement of the Principle Concerning The Role Of Science In The Codex Decision-Making And The Extent To Which Other Factors Are Taken Into Account, *Codex Alimentarius Procedural Manual*, reads: "(T)he food standards, guidelines and other recommendations of Codex Alimentarius

Following CAC, it is generally admitted that the establishment of food safety standards requires a sound risk analysis. Risk analysis is a process composed of risk assessment<sup>114</sup>, risk management<sup>115</sup> and risk communication<sup>116</sup>. Internationally, deliberate risk reconstruction is a formal part of the negotiation process in which perceptual differences and diverging interests are meant to be harmonized into a common understanding of the risk at hand<sup>117</sup>. Sound science is the basis of risk analysis, which is an essentially public responsibility, through establishing the findings on public health risks. The SPS imposes the obligation to justify scientifically the sanitary and phytosanitary measure on the Member adopting it, that is, the importing state<sup>118</sup>. In any case, when the measure conforms to CAC, IOE or IPPC standards it is presumed to be in conformity with the Agreement<sup>119</sup>.

Although science is the most objective available criteria, it is not always certain, especially when considering interventionist food. Sometimes sufficient scientific data is not available, sometimes objective expert analysis are contradictory. Together with other socio-political considerations, these deadlocks may well explain the entry in the risk analysis scene of other legitimate factors, among which consumers concerns are predominant, which may invite the application of the controversial precautionary principle<sup>120</sup>. CAC recognizes that legitimate factors other than sound science can be

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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". SPS deems scientific justification necessary for risk assessment (article 5). In the Cartagena Protocol, the cornerstone of the decision procedure concerning imports of LMOs is scientifically sound risk assessment (Articles 10.1, 15). Particular TNCs codes of conduct argue that their products and production processes are always scientifically tested.

<sup>114</sup> Scientifically based process consisting on: 1. hazard identification; 2. hazard characterisation, 3. exposure assessment, and 4. risk characterization. *Codex Alimentarius Procedural Manual*, Definitions.

<sup>115</sup> Process, distinct from risk assessment, of weighting policy alternative in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices. *Codex Alimentarius Procedural Manual*, Definitions.

<sup>116</sup> Interactive exchange of information and opinions through the risk process concerning risk-related factors and risk perceptions, among assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions. *Codex Alimentarius Procedural Manual*, Definitions. Regarding risk communication, food production, processing and other handling operations should be analysed with a view to identifying hazards and assessing associated risks. This should lead to the identification of critical control points and the establishment of a system to monitor production at these points (HACCP Approach). The introduction of HACCP-based in-house control is important in this regard. It is best achieved by collaboration between the food industry, education and training organizations and the supervisory authorities. Traceability of feed, food-producing animals and food should be established at all stages of production, processing and distribution. Traceability is important: 1. to enable the unsafe food to be traced through the food chains so that the source of the problem can be identified; 2. to ensure fair practices in the food trade (labelling).

<sup>117</sup> G. Sjöstedt, "International Negotiation and the Management of Transboundary Risks", in J. Linnerooth-Bayer, R.E. Löfstedt and G. Sjöstedt *Transboundary Risk Management*. Earthscan, 2001, 287-288.

<sup>118</sup> For LMO-FFP, the Cartagena Protocol does not require any risk assessment, but, for non LMO-FFP, the importing state, while being under the obligation to ensure that its decisions are based on risk assessment, may require the exporter to carry out the assessment.

<sup>119</sup> Article 3.2 SPS.

<sup>120</sup> The precautionary principle emerged in the environment field from the Rio Conference (1992), which states, "Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation". Although there is no consensus on a general definition of the principle nor on its acceptance, it can be

taken into consideration in the risk management process<sup>121</sup>, but establishes that “only those other factors which can be accepted on a world-wide basis, or on a regional basis in the case of regional standards and related texts, should be taken into account”<sup>122</sup> within its framework. In this regard, it is important to stress that, without providing with a definition nor pointing at the moment where it could be considered, CAC recognizes that “precaution is an inherent element of risk analysis”<sup>123</sup>.

Currently, a review of available scientific evidence on interventionist GM food indicates that it “has not been found to be unsafe” – a double negative that highlights the difficulties of balancing consumer concerns, science and international law. Proponents of GM products correctly argue that research has shown no health risks, while opponents argue that such research is not enough to prove that there are not such risks. GMOs risks have been qualified as potentially catastrophic, unknown to science, unfamiliar and are considered to have the potential to affect future generations<sup>124</sup>. A safety assessment of GM foods generally investigates: a) direct health effects –toxicity-, b) tendencies to provoke allergic reactions, c) specific components thought to have nutritional or toxic properties, d) the stability of the inserted gene, e) nutritional effects associated with genetic modification, and f) any unintended effects which could result from the gene insertion. There are many scientific risk assessments with different results. Therefore, there are also disparate national interpretation of precaution. Moreover, different GM organisms include different genes inserted in different ways. This means that individual GM foods and their safety should be assessed on a case by case basis and that it is not possible to make general statements on the safety of all GM foods. This is also the case for nutraceuticals<sup>125</sup>.

Nevertheless, considering that traditional foods often contain natural toxicants that, although detected in toxicological analysis, have not provoked any harm to human health, it is unreasonable and unscientific to expect an absolute standard of safety through traditional toxicological testing in GM food. Therefore, WHO, FAO, OECD and, ultimately, CAC, have resorted to a multidisciplinary approach to GM foods risk assessment, which departs from the principle of “substantial equivalence”. This principle entails comparing the risks associated with GM foods with the foods produced with traditional techniques. It takes into consideration the intended effect of the genetic modification, its nature, and the detectable unintended changes that may occur in the microorganism or in its action in the food.

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said to advise that, in the face of uncertainty, the best course of action is to assume that a potential problem is real and should be addressed (“better safe than sorry”).

<sup>121</sup> The second statement of the Principles Concerning The Role Of Science In The Codex Decision-Making And The Extent To Which Other Factors Are Taken Into Account, *Codex Alimentarius Procedural Manual*, reads: “... where appropriate, to other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade”. So does the Cartagena Protocol (articles 10.6 for non LMO-FFP, 11.8 for LMO-FFP and 26 in general).

<sup>122</sup> Statements of Principle Concerning The Role Of Science In The Codex Decision-Making And The Extent To Which Other Factors Are Taken Into Account, criteria for the consideration of the other factors referred to in the second statement of principle, *Codex Alimentarius Procedural Manual*.

<sup>123</sup> Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, number 11. *Codees Alimentarius Procedural Manual*.

<sup>124</sup> J. Linnerooth-Bayer, *op. cit.* 11-12.

<sup>125</sup> J. Hlywka and M. Harwood, “Ensuring the Safety of Dietary Supplements”. *Nutraceuticals World*, October. 2003, 52.

In this regard, the OCDE has also developed the concept of “familiarity”; which entails the consideration of the knowledge and experience accumulated to determine if it is enough to manage a relatively different new product<sup>126</sup>. Both substantial equivalence and familiarity principles have been criticised as a “trigger” for risk assessment. In the case of substantial equivalence because it is a commercial and political judgement masquerading as if it were scientific<sup>127</sup>. In the case of familiarity, because, on the one hand, it is based on intuition<sup>128</sup>, and on the other, the only way to gain familiarity with commercial releases is to allow commercial releases; therefore familiarity closely binds regulatory oversight with industrial interests and market imperatives<sup>129</sup>.

In any case, it is clear that the concept of risk that food safety regulation faces entails more than just science experts’ assessments; but also the concerns on the part of the public. One way or another, it is clear that public values inevitably influence risk analysis and therefore, it has been said that separating scientific risk assessment from risk management is questionable<sup>130</sup>. CAC admits that the separation between risk assessment and risk management is merely functional - aimed at avoiding confusion over the functions to be performed by risk assessors and risk managers and to reduce any conflict of interest -, and that the interaction between risk managers and risk assessors is essential for practical purposes<sup>131</sup>. In this scenario, doubts over the neutrality of many scientific committees may well increase, particularly due to the “infiltration” of industry experts in the epistemic community<sup>132</sup>. In any case, it has been argued that an apolitical risk assessment is impossible to achieve due to the fact that the relevant science is always framed by values<sup>133</sup>. The influence of politics in the ultimate risk analysis decisions can be seen in EC<sup>134</sup> as much as in the US<sup>135</sup>.

For TNCs the basic issue continues to be market uncertainty about how consumers, mostly in developed countries, will reach to interventionist foods. The private sector may find it needs to change how it introduces and markets the new products of biotechnology in order to maintain market access. As micro-law has proved, regardless

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<sup>126</sup> *Safety consideration for biotechnology: scale up of crops plants*. OECD, 1993.

<sup>127</sup> M.W. Ho and R. Steinbrecher, “Fatal flaws in food safety assessment: critique of the joint FAO/WHO biotechnology and food safety report”. *Environmental and Nutritional Interactions*, vol. 2, 1998, 51-84.

<sup>128</sup> C. Damgaard and H. Lokke, “A critique of the “concept of familiarity” as used in ecological risk assessments of genetically modified plants”. *BioSafety Journal*, vol. 6, paper 1, 2001, 1-8.

<sup>129</sup> P. Newell, “Globalisation and the Governance of Biotechnology”. *Globalisation and the International Governance of Modern Biotechnology*. Mapping Paper. Globalisation and Poverty, 6-7. In practice, both substantial equivalence and familiarity support decisions to de-regulate GE crops by promoting biotechnology as an innovative and competitive technology, while simultaneously downplaying concerns for environmental hazards.

<sup>130</sup> L. Linnerooth-Bayer, *op. cit.* 9-10.

<sup>131</sup> Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, number 9. *Codex Alimentarius Procedural Manual*

<sup>132</sup> See *infra*.

<sup>133</sup> L. Levidow, “Genetically Modified Crops: What Transboundary Harmonization in Europe?”; in J. Linnerooth-Bayer, R.E. Löfstedt and G. Sjöstedt *Transboundary Risk Management*. Earthscan, 2001, 61.

<sup>134</sup> Decision of the EC Council of Ministers to ignore the decision of its own scientific advisory body in the case of beef hormones indicates that scientific assessments are not always acceptable to regulatory officials since the latter must also contend with domestic pressures from both producers and non-governmental organizations.

<sup>135</sup> The US demands of internationally established food safety standards based on science, have been qualified as ironic, as there are few nations whose regulatory procedures and standards have been so frequently divorced from any scientific rationale. D. Voegel, *Trading Up: Consumer and Environmental Regulation in the Global Economy*. Harvard University Press, 1995, 193.

of the science, if consumers decide they do not want to consume GM goods, markets will adjust to satisfy their demands<sup>136</sup>.

#### 4. Industry has a role

Obviously, TNCs play a role in their collective and individual self-regulation. TNCs collective action in the food safety field have gained relevance with the GFSI<sup>137</sup>. TNCs action in these areas is often carried out through trade associations and commodity associations because this way they are more invisible, and avoid the costs of close company identification with controversial proposals or overt political tactics<sup>138</sup>.

Although farmers and small business do most of the value adding to food, it is the presence of TNCs which dominates the IGOs' food safety regulatory fora. Industry gets involved in the risk analysis (assessment, management and communication) process and in the determination of good corporate behaviour. In addition to their lobbying activities, TNCs also participate in the elaboration of IGO's food safety standards and codes of conduct except for the WTO Agreements (SPS and TBT) and the Cartagena Protocol. Within WTO framework TNCs can only intervene indirectly, in the dispute settlement procedures, through presenting *amicus curiae* briefs<sup>139</sup>. However, the Code of Good Practice of the TBT requires Member States, before adopting a standard, to allow a period for the submission of comments on the draft standard by interested parties<sup>140</sup> and, to this end, to provide a draft of the standard upon request of any interested party<sup>141</sup>. It does also require that the comments are taken into account and, if so requested, replied to when there is a deviation from relevant international standards<sup>142</sup>.

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<sup>136</sup> E. Díaz-Bonilla and S. Robinson, "Biotechnology, Trade and Hunger", in P.G. Pardey and B. Koo *Biotechnology and Genetic Resource Policies*. IFPRI. 2 January 2003, 3.

<sup>137</sup> See *infra*.

<sup>138</sup> B. Kneen, *op. cit.* 34. However, while small companies have to work through industry associations, TNCs lobby directly many times. A clear example can be seen in the statement of results of the United States Council for International Business (USCIB) Food and Agriculture Committee. It points as recent accomplishments the successful lobby to the US Government and key OECD staff to ensure the appropriate focus and subsequent conclusion of the OECD Food Safety Program; having provided with industry expertise to all elements of the work program and presented industry views on socio-economic concerns related to food policy and on the role of OECD in food and agriculture policy; and supporting the activities of the Food Industry Codex Coalition to ensure the work of CAC is rooted in sound science, with a particular emphasis on work relating to risk assessment, precaution and labelling. Its current priorities include coordination with the USCIB Trade Policy Committee and U.S. agriculture organizations, follow WTO agriculture negotiations to ensure that the full range of U.S. business views is adequately presented to the U.S. government, promote ICC work on agriculture in the WTO, and work to strengthen ICC links with WTO agriculture negotiators. Directly, and through BIAC (see *infra*), it engages in the work of the OECD Agriculture Directorate to promote agricultural policy reform, elimination of barriers to trade and investment, improved food quality and consumer protection; promotes implementation of the USCIB recommendations on an Open Food System, conducts periodic information sessions for WTO agriculture negotiators on business activity taking place relative to the Open Food System (e.g., sectoral initiatives, work on technology transfer and "precision agriculture"); maintains strong ties with the International Agri-Food Network (IAFN), works to strengthen coordination among its affiliate bodies, stimulates interest among European firms in the agri-food sector and seeks inclusion of agri-food issues in the TransAtlantic Business Dialogue (TABD).

<sup>139</sup> See G.C. Umbricht, "An "Amicus Curiae Brief" on Amicus Curiae Briefs at the WTO". *Journal of International Economic Law*. 2001. 733-794, and J. Pearlman, "Participation by Private Counsel in World Trade Organization Dispute Settlement Proceedings". *Law and Policy in International Business*, Vol. 30 n° 2. 1999, 399-415.

<sup>140</sup> Annex 3 TBT, L, fixes that period in at least 60 days, although it might be shortened in urgent cases of safety, health or environment.

<sup>141</sup> Code of Good Practice, M.

<sup>142</sup> Code of Good Practice, N.

CAC member countries are encouraged to involve stakeholders in the formulation of national positions to be taken in the CAC documents. In addition, it allows for the participation of stakeholders on expert committees as observers<sup>143</sup>. CAC is known as one of the more industry dominated international organizations. TNCs influence CAC decisions through the massive presence of industry representatives on expert committees and sometimes even as members of national delegations<sup>144</sup>. TNCs tend to hire academic and professional experts to research and to present data to support the policies that their clients wish to have implemented. Other times they get directly involved in the epistemic community<sup>145</sup>. The corporations paying the bills can then cite these “independent” studies in support of their policy recommendations<sup>146</sup>. Increased industry funded scientific research raises serious doubts over the impartiality of risk assessment<sup>147</sup>. Moreover, the “revolving door” of public service (private enterprise – public service – private enterprise), very frequent in certain national administrations such as the US<sup>148</sup>, contributes to increased suspicion. It has been said that the biggest funder of the establishment of the CAC was the US food industry, whose money was “laundered through states”<sup>149</sup>.

In this regard, it has been said that states do not choose the CAC committees they will host - assuming their financial responsibility - on the basis of concern for the diffuse interest of consumers, but on the basis of the producers’ interests<sup>150</sup>. Regarding nutraceuticals, the Netherlands, with an important food producing and processing industry, is chair to the Codex Committee on Food Additives and Contaminants (CCFAC)<sup>151</sup>. However, with a relatively small biotechnology industry, Japan is chair to the CAC *Ad Hoc* Intergovernmental Task Force on Food derived from Biotechnology (TFFBT)<sup>152</sup>. As Europe, Japan has strong pressures from consumers against GM food. In any case, the extended participation of industry, together with the lack of means of developing countries and consumer associations to get deeply involved in the process,

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<sup>143</sup> Meetings of the CAC and its committees are open to INGOs as observers, which have voice but not vote. Principles on the participation of INGOs in the works of the CAC; numbers 3 and 5.1.

<sup>144</sup> The majority of observers are industry funded, N. Avery, M. Drake and T. Lang, *Cracking the Codex*. National Food Alliance. 1993, 8.

<sup>145</sup> Corporations get involved in strategic partnerships with Universities as they take more and more corporate characteristics, through university-corporate collaboration. B. Kneen, *op. cit.* 196-197. Beyond Universities, a key industry influence in epistemic communities has been the International Life Sciences Institute. The strategy can be summarized as follows: fund an arm’s-length technical association to the needed science; use the results to lobby for new CAC standards; in the process, engage all national epistemic communities with the need for change in their national laws. J. Braithwaite and P. Drahos, *op. cit.* 410.

<sup>146</sup> B. Kneen, *op. cit.* 30.

<sup>147</sup> D. McCrea, *op. cit.* 157.

<sup>148</sup> Cargill’s example in B. Kneen, *op. cit.* 33-34.

<sup>149</sup> J. Braithwaite and P. Drahos, *op. cit.* 401.

<sup>150</sup> J. Braithwaite and P. Drahos, *op. cit.* 408.

<sup>151</sup> WHO/FAO ID n° CX-711. Its terms of reference include establishing or endorsing permitted maximum or guideline levels for individual food additives.

<sup>152</sup> WHO/FAO ID n° CX-802. Its terms of reference include elaborating standards, guidelines or other principles, as appropriate, for foods derived from biotechnology, taking full account of the existing work carried out by national authorities and international fora; and coordinate and collaborate with the appropriate Codex Committees as related to foods derived from biotechnology.



has resulted CAC being accused of prioritising standards that facilitate trade rather than providing consumers with the highest level of health protection<sup>153</sup>.

Within the OECD, business opinion can be made known formally through the Business and Industry Advisory Committee (BIAC). BIAC is an independent organisation officially recognised by the OECD as being representative of business and industry. Its members are the principal industrial and employers organisations in OECD countries. BIAC's role is to provide the OECD and its Member Governments with constructive comments based on the practical experience of the business community. Within the OECD, BIAC participates in the different food related OECD activities. Moreover, after the 2000 review of the OECD Guidelines on Multinational Corporations, TNCs must be given the opportunity, directly or through BIAC, "to express its views either orally or in writing on issues concerning the Guidelines involving its interests" in the consultation procedure aimed at their clarification. Clarifications are not only communicated to those directly involved but are also published. They are interpretations of what often are very broadly formulated rules of conduct, but are not changes to the rules themselves.

The complex legal nature of ISO is again revealed when considering that enterprises are not eligible for membership. However, most industry associations participate in the ISO process through their contribution to the elaboration of the national proposals, and through the incorporation of individual experts in the national delegations to the particular technical committees<sup>154</sup>. ISO's technical committees comprise experts on loan from the particular industry sector which have asked for the standards and subsequently put them into practice. In any case, the national delegations are required to represent not just the views of the organization in which the participating experts work, but of the other stakeholders too. Finally, international organizations representing an industry sector can gain a liaison status to a particular technical committee, where they will not have a vote, but can participate in the debates and the development of consensus<sup>155</sup>.

TNCs actions within the framework of mutual recognition agreements, in particular in the US-EC bilateral relations, has been already discussed.

### 5. Transparency aim

Be it internationally public or private, transparency is a guiding principle in every action related to food safety. Due consideration is always given to the legitimate concerns to preserve confidentiality. In any case, when a safety hazard arises, it is essential that information is made available and distributed quickly, accurately and clearly to all parties concerned. In this regard, risk communication is essential for the industry.

SPS and TBT require Members to inform on their sanitary and phytosanitary measures as well as to notify any changes in them<sup>156</sup>. WHO and FAO consistently insist on the importance of transparent procedures, whether for risk analysis purposes, for food

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<sup>153</sup> Report of the International Association of Consumer Food Organizations (IACFO) to the FAO/WHO Global Forum of Food Safety Regulators; Marrakech (Morocco), 28-30 January 2002.

<sup>154</sup> V. Haufler, *op. cit.* 127, points that the technical committees are generally are dominated by industry representatives.

<sup>155</sup> For example, in the food sector, the International Commission for Food Industries (CIIA), the Nordic Committee for Food Analysis (NMKL), the European Association for Animal Production (EAAP), and the European Feed Manufacturers Association (ASS) among others, enjoy the liaison status to TC-34.

<sup>156</sup> Article 7 and Annex B SPS and article 10 TBT.

control or for any regulatory action in the food safety field. CAC's committees work, as well as the guidance documents they develop, insists on transparency<sup>157</sup>.

The OECD Guidelines for Multinational Corporations do not expressly refer to transparency, but states that TNCs shall promote workers information on the companies' policies, even through training courses<sup>158</sup>. TNCs Codes of Conduct usually follow this guideline<sup>159</sup>, and, in addition, they pledge to aim at consumers' information<sup>160</sup>.

ISO standards are developed according to strict rules to ensure that they are transparent and fair. Equally, the GFSI has established a detailed regulation on food safety standards certification<sup>161</sup>.

## 6. Process – Food chain

Originally, food control often concentrated on the examination of end products. Control of final products can never be extensive enough to guarantee contaminant levels below established maximum levels and safety and other aspects of food quality cannot be "inspected into" food at the end of the production chain, particularly when new production and processing technologies have been developed. Therefore, in recent decades there has been a growing awareness of the importance of an integrated, multidisciplinary holistic approach considering the whole of the food chain: from farm to fork. The HACCP food safety tool, which puts its emphasis on in-process diagnosis, control and documentation rather than end-product testing, is paradigmatic.

Among the WTO agreements applicable in the food safety field, the SPS approach is clearly process oriented. Where the TBT is applicable, the issue is whether the "like products" condition refers to the product itself or includes the processing methods. The case is not clear yet but, in the negative, GATT-94, which would also be applicable, does cover processing methods<sup>162</sup>. In any case, while GM products may be considered to have a different product characteristic from non-GM (as the new gene changes the character of the product) resulting in their being considered as products related PPMs and hence covered under the discipline of TBT<sup>163</sup>, the question could be even more hotly disputed when considering nutraceuticals<sup>164</sup>.

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<sup>157</sup> Working Principles for Risk Analysis for Application in the Framework of Codex Alimentarius, number 6, reads: "(T)he three components of risk analysis should be documented fully and systematically in a transparent manner. While respecting legitimate concerns to preserve confidentiality, documentation should be accessible to all interested parties". *Codex Alimentarius Procedural Manual*.

<sup>158</sup> OECD Guidelines for Multinational Corporations, General Principles, number 8.

<sup>159</sup> See *infra*.

<sup>160</sup> For example, transparency towards consumers on its products safety is one Monsanto pledges; "Monsanto is committed to make scientific and safety information on its products available, accessible and understandable"; [http://www.monsanto.com/Monsanto/layout/our\\_pledge/transparency/default.asp](http://www.monsanto.com/Monsanto/layout/our_pledge/transparency/default.asp).

<sup>161</sup> The GFSI Guidance Document, 3<sup>rd</sup> Ed. January 2003.

<sup>162</sup> G. Marceau and J.P. Trachtman, *op. cit.* 856-862.

<sup>163</sup> A. Kaushik, "Addressing Developing Countries' Concerns related to Biotechnology and Biosafety in the WTO", *ICTSD Workshop on Biotechnology, Biosafety and Trade: Issues for Developing Countries*. Switzerland 18-20 July, 2001. <http://www.ictsd.org>, 4.

<sup>164</sup> Food additive is any substance not normally consumed as food by itself and not normally used as a typical ingredient of the food, whether or not it has a 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-product becoming a component of or otherwise affecting the characteristics of such foods. *Codex Alimentarius Procedural Manual*, Definitions.

CAC acknowledges that risk management “should take into account relevant production, storage, and handling practices used throughout the food chain, including traditional practices, ...”<sup>165</sup>. The Cartagena Protocol’ approach towards food safety is clearly process oriented<sup>166</sup>.

The ISO<sup>167</sup>, the GFSI<sup>168</sup> and private codes of conduct<sup>169</sup> food safety also focus in process.

Within this context, it is interesting to note that the major international conflicts in GM foods regulation is related to the differing US/EC product/process approach towards its safety analysis. The approach is not only relevant for safety regulation purposes, but for international trade. WTO has not had to pronounce itself on the issue yet, but will probably have to do it in resolving the US complaint against EC measures affecting the approval and marketing of biotechnology products<sup>170</sup>. Industry may have a say through *amicus curiae* briefings. In any case, one cannot avoid pointing to an apparent contradiction in US approaches to health and environmental safety– which does consider the process<sup>171</sup> -. Trends seem to lead to a process approach<sup>172</sup>.

### C. STANDARDS SETTING

International food safety regime is composed of multiple overlapping sources of standards in both the public and the private sectors. Food safety standards can be classified in two major groups: general or horizontal, and special or vertical. The general standards are designed to be applied to any food. General corporate behaviour rules may be included within this group. The special standards are for particular kinds of food. In the following pages references will be made to the most relevant international food safety general and particular standards for biotechnology and nutraceuticals foods, which are set under the food additives umbrella<sup>173</sup>. The existence

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<sup>165</sup> Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, number 30. *Codex Alimentarius Procedural Manual*.

<sup>166</sup> Article 3 Cartagena Protocol.

<sup>167</sup> The fourth Principle for quality management of the ISO 9000, <http://www.iso.ch/iso/en/iso9000-14000/qmp.html>, states that “a desired result is achieved more efficiently when activities and related resources are managed as a process”.

<sup>168</sup> The GFSI Guidance Document, *loc. cit.*, number 2, stresses that the aim is to ensure food safety “throughout the food supply chain”.

<sup>169</sup> See *infra*.

<sup>170</sup> DS 291, request of a panel was made in 8, August 2003. Canada (DS 292) and Argentina (DS 293) did also requested a panel on the same date.

<sup>171</sup> United States import of certain shrimp and shrimp products, WT/DS58/R/ 15 May, 1998.

<sup>172</sup> Speculating on the resolution of a WTO dispute on GMOs, R. Howse and P. Mavroidis, “Europe’s Evolving Regulatory Strategy for GMOs – The Issue of Consistency with WTO Law: Of Kine and Brine”. *Fordham International Law Journal*, Vol. 24, 2000-2001, 317-370, conclude that, if WTO is properly interpreted, GMO-related measures, where non discriminatory to other Members, can pass the test of consistency with even the most stringent relevant WTO rules.

<sup>173</sup> Food additive is any substance not normally consumed as food by itself and not normally used as a typical ingredient of the food, whether or not it has a 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-product becoming a component of or otherwise affecting the characteristics of such foods. *Codex Alimentarius Procedural Manual*, Definitions.

of special standards for biotechnology and nutraceuticals does not obscure the fact that particular GM foods or additives should have their own standards.

## 1. General standards

### a. From IGO

#### ♣ CAC:

- *The Code of Ethics for International Trade* was developed in 1979 and reviewed in 1985<sup>174</sup>. Its aim is to prevent dumping of unsafe food in developing countries by requiring nations to alert one another when they refuse entry to unsafe products. It recommends that “all those engaging in international trade in food commit themselves morally to this code and undertake voluntarily to support its implementation in the larger interest of the world community”. Article 7.1c establishes that the implementation of this Code rests with “all concerned with the international trade in food”; and article 7.2 stresses that “the code should be promoted by national governments in their respective territorial jurisdiction in accordance with their legal and administrative procedures regulating the conduct of importers and exporters”. The Code establishes as a general principle that “all consumers are entitled to safe, sound and wholesome food and to protection from unfair trade practices” (article 4.1); to this end, national food standards should be established and enforced taking account the CAC standards (article 5).

- *The Codex General Principles on Food Hygiene* were established as a Code of Practice in 1969, and have gone through reviews and amendments<sup>175</sup>. They identify the essential principles of food hygiene applicable throughout the food chain – from primary production to final consumer - and indicate how to implement them, recommending the use of a HACCP approach. This Code should be used in conjunction with each specific code of hygienic practice which may be needed for particular sectors, processes or commodities<sup>176</sup>. It states that industry “should apply the hygienic practices set out in this document”.

Annexed to the General Principles on Food Hygiene are the *Guidelines on the Application of the HACCP*, which have also gone through reviews and amendments<sup>177</sup>. The HACCP is a system that identifies specific hazards as well as preventive measures for their control. Prior to the application of HACCP to any sector of the food chain, that sector should be operated according to the Codex General Principles of Food Hygiene and the appropriate food safety legislation. The seven principles of HACCP establish the framework for developing specific HACCP plans for each combination of food product and production line<sup>178</sup>. The development of a specific HACCP plan requires

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<sup>174</sup> CAC/RCP 20-1979 (Rev.1-1985). This Code is presently under revision. However, it seems that none of the aspects mentioned are going to go through substantive changes. Report of the Eighteenth Session of the Codex Committee on General Principles; Paris, France, 7-11 April 2003. ALINORM O3/33A, 6-9.

<sup>175</sup> CAC/RCP 1-1969, Rev. 3-1997, Amd. (1999).

<sup>176</sup> For example, there is a Codex Committee on Meat and Poultry Hygiene that is working on the Draft General Principles of Meat Hygiene. Report of the 9<sup>th</sup> Session, New Zealand 17-23 February 2003. ALINORM 03/16A.

<sup>177</sup> Annex to CAC/RCP 1-1969, Rev. 3-1997, Amd. (1999). This Guidelines are presently under revision. Draft revised guidelines for the Application of the HACCP. ALINORM 03/13A par. 22-30 and Appendix II. Report of the 35<sup>th</sup> session of the Codex Committee on Food Hygiene, Orlando (Florida – USA), 27 January – 1 February, 2003.

<sup>178</sup> The seven principles are: 1. assess the hazard, list the steps in the process where significant hazard can occur and describe the prevention measures; 2. determine the critical control points (CCPs) in the process – CCP is any point in the chain of food production from raw materials to finished products where the loss

identifying all potential hazards “of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food”. The determination of which potential hazards are essential to control will involve a risk-based hazard assessment. This assessment will result in a list of the significant hazards that should be addressed within the HACCP plan.

♣ From 1976, OECD Guidelines for Multinational Corporations provide companies with guidance as to principles of corporate conduct. They are recommendations to enterprises made by the governments of the OECD countries, plus Argentina, Brazil, Chile and the Slovak Republic, to ensure that TNCs respect the policies of the countries where they operate. The standards cover the full range of TNCs operations and are supported by follow up procedures in the participating countries<sup>179</sup>. The reviews of the guidelines have been aimed primarily at assessing experience and not necessarily at revising the text. Few reviews and amendments have been made, the last one in 2000<sup>180</sup>.

The last review of the OECD Guidelines has not introduced any reference to food safety as such. However, it has included new references to consumers and to other issues that are perfectly applicable in the food safety field. In general terms, it is interesting to point to the statements that TNCs should encourage the commercial partners, including suppliers and subcontractors, to apply business principles compatible with the Guidelines<sup>181</sup>, and that they are also encouraged to communicate them any other code of conduct that they subscribe<sup>182</sup>. More connected to food safety are the guidelines through which companies are encouraged to apply rigorous quality rules regarding non-financial information, including the elaboration of environmental and social reports<sup>183</sup>; and also to provide information regarding the more previsible risk factors<sup>184</sup>. Particularly, TNCs have to adopt all reasonable measures to guarantee the safety and quality of their products and services. In this regard, they have to guarantee that the goods and services that they provide comply with all the agreed or legally required rules on consumers health and safety<sup>185</sup>, and to fully and transparently collaborate with public authorities to prevent or eliminate grave health and safety threats for citizens which could be derived from the use or consumption of their products<sup>186</sup>. They will also have the obligation to establish transparent and efficient procedures to respond to consumers claims and to contribute to the rapid and fair resolution of the disputes with the consumers without excessive bureaucracy and costs<sup>187</sup>.

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of control could result in unacceptable food safety risk -; 3. establish critical limits for each CCP; 4. establish procedures to monitor each CCP; 5. establish corrective actions to be taken when monitoring indicates a deviation from the CCP limits; 6. establish record keeping for the HACCP system; and 7. establish procedures to verify that the HACCP system is working correctly.

<sup>179</sup> For a description of the system see J. Karl, “The OECD Guidelines for Multinational Enterprises” in M. K. Addo Ed. *Human Rights Standards and the Responsibility of Transnational Corporations*. Kluwer, 1999, 93-95.

<sup>180</sup> The first review took place in 1979, C(79) 102 (Final). The second in 1984, C/MIN(84)5(Final). In 1991 the text was amended, DAF/IME(91)7/ANN1. The second revision as amended, was repealed and replaced by the OECD Council Decision C 2000/96(Final).

<sup>181</sup> General Principles, Part I, number 10.

<sup>182</sup> Publication of the Information, Part III, number 5a.

<sup>183</sup> Publication of the Information, Part III, number 2.

<sup>184</sup> Publication of the Information, Part III, number 4e.

<sup>185</sup> Consumer Interests, Part VII, number 1.

<sup>186</sup> Consumer Interests, Part VII, number 6.

<sup>187</sup> Consumer Interests, Part VII, number 3.

*b. From industry's INGO*

♣ Within ISO, TC 34 is in charge of food standardization. It mostly acts within the agriculture field, numbered under 65. The general food safety standard is established in ISO 15161:2001, which includes the guidelines on the application of the requirements of quality management systems (ISO 9001:2000) to the food and drink industry. Hence, this guidelines can be applied to the HACCP system. It is important to note that ISO 9001:2000 focus on costumers' needs and expectations, which is to have safe products. Many food processors now adopting ISO's quality management standards<sup>188</sup>.

♣ Up to this point<sup>189</sup>, the GFSI main activity has been the development of a scheme for companies' working throughout the food chain to gain a certificate which credits companies compliance with their requirements for food safety. It establishes the standards and procedures of the safety control system that the GFSI considers adequate. Therefore, it is not food standards, but a standard scheme for food safety certification. It has no binding nature<sup>190</sup>. In the GFSI "Guidance Document", which is divided in three parts<sup>191</sup>, the disclaimer paragraph states: "The fundamental principles embodied in this document have resulted from continuous review to reflect the requirements of both retailers and suppliers. The document is not intended to replace the requirement of any legislation, where the legislation requires a higher standard for a specific industry sector"<sup>192</sup>. Along this line, its reliance on public authorities is clearly acknowledged because the certification system is always dependent on the recognition of the certification body providing certification services by an accreditation body, defined as an agency having jurisdiction to formally recognise the competence of a certification body<sup>193</sup>.

According to their system, the GFSI will decide whether a particular certification body will be authorised to give the GFSI certificate; and whether a standard owner (any private party who invents a standard or a certification system) gets its standard recognised. In this regard, it is expressly acknowledged that the ISO Guide 65 will be complied with. If conformity with GFSI requirements is established, its logo can be used but, departing from ISO Guide 65, never in products, product packaging or

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<sup>188</sup> J. Braithwaite and P. Drahos, *op. cit.* 409. ISO 9000 standards establish quality management practices to enhance customer satisfaction by meeting customer and the applicable regulatory requirements, continually improving performance. They have become an essential international reference for business to business dealings.

<sup>189</sup> GFSI intends to implement an early warning system to address the need of rapid information when a safety issue arises, an internet based Early Warning System is being developed to give retailers and suppliers access to information on food safety incidents, issues and facts. The objective is to provide a mechanism for the exchange of both general and crisis related information, in harmonisation with existing legal and governmental frameworks; encouraging co-operation between the world-wide food sector and national governments and authorities.

<sup>190</sup> GFSI Guidance Document, number 3, states that: "It is at the discretion of retailers and suppliers for which products the schemes will be applied. Over the world this will differ depending on company policies, general regulatory requirements, product liability and due diligence regulations".

<sup>191</sup> These parts are: 1. Requirements for Food Safety Schemes - scope, definitions, general rules, procedure for the application and benchmarking of food safety schemes and logo use -, 2. Requirements for a conforming Food Safety Standard - Food management systems, good agricultural practices (GAP), good manufacturing practices (GMP), good distribution practices (GDP) and hazard analysis and critical control point (HACCP) - and 3. Requirements and Guidance for Certification Bodies - auditors, audit reports, ...-.

<sup>192</sup> GFSI Guidance Document, Introduction.

<sup>193</sup> GFSI Guidance Document, number 4.

advertising. Certified companies can only use it in their business to business communications and standard owners on their standards<sup>194</sup>.

♣ Two particular TNCs Codes of Conduct, Monsanto's<sup>195</sup>, a US based TNC, and Nestlé's<sup>196</sup>, a European based TNC, will be taken as examples<sup>197</sup>. Though the Codes establish and make public the TNCs policies, they are presented as documents addressed to the companies' "employees" for them to "comply" and "find guidance" in their daily work<sup>198</sup>. Though with very different structures, these codes start by identifying the objectives of the corporation and their commitment to comply with the law of the country where they operate. Then, they address the role of the Code in their interaction with their contractors and, finally, they deal with compliance.

Regarding the objectives and the compliance with the law, "Monsanto is committed to consistently delivering the highest quality products. This occurs through processes, including processes that are being continually improved", and "we ensure that our products and technology comply with or exceed all applicable laws regulations and standards. We will also endeavour to make our products safe and environmentally sustainable ...meeting or exceeding customers product quality expectations" and "all regulatory safety and compliance requirements". The Code "applies to Monsanto business and subsidiaries worldwide ... Additionally, this Code will apply to all affiliates with Monsanto. Finally, all entities representing Monsanto such as ... distributors and independent contractors shall agree in writing to follow all applicable portions. Wherever applicable, those entities will be bound by the same provisions that apply to Monsanto". On its part, "Nestlé aims to create value by offering consumers a wide variety of high-quality, safe food products at affordable prices". Regarding the regulatory level for compliance, its code states "(A)s a minimum, its employees must comply with the laws applicable in the countries in which it operates". Differing from Monsanto, Nestlé does not require that its affiliates or representatives comply with its Code.

However, in their relations with other contractors, Nestlé "aims to deal only with reputable suppliers who are willing to apply Nestlé quality standards". "Key suppliers with which Nestlé has a contractual relationship are audited in order to ensure that they comply with the Nestlé Corporate Business principles or that they are working actively to achieve compliance. Whenever instances of non-compliance are brought to the Company's attention, Nestlé will demand that corrective measures be initiated". The decision to establish or maintain a direct procurement system from farmers depends, among other factors, on "company requirements in terms of quality, safety, quantity and cost". Where appropriate, Nestlé "provides agricultural assistance to farmers in order to ... obtain raw materials that meet quality and safety specifications". On its part,

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<sup>194</sup> GFSI Guidance Document, number 6.4.2

<sup>195</sup> [http://www.monsanto.com/monsanto/layout/our\\_pledge/corp\\_gov/code.asp](http://www.monsanto.com/monsanto/layout/our_pledge/corp_gov/code.asp). Visited in September 2003.

<sup>196</sup> Nestlé, *Corporate Business Principles*. Second Edition, March 2002.

<sup>197</sup> Other TNCs, such as Cargill, have less formal codes of conduct. They include general corporate behaviour statements in their web-pages; <http://www.cargill.com/today/corpbrochure.htm>. Visited, October 2003.

<sup>198</sup> Monsanto, subtitles the Code as "Employees Code of Conduct" and states that the Code "explains the basic obligations of all of us". Nestlé do also refer to its "employees" when referring to compliance with national laws of the countries where it operates.

regarding other contractors Monsanto just states: “We are committed to providing tools to our partners and licensees, so they too produce high quality products and offerings”.

From the perspective of GM food and nutraceuticals, it is interesting to note that Nestlé does “support the application of new technologies and advances in agricultural science, including the opportunities offered by today’s bioscience when their positive effect on food safety ... are scientifically confirmed and accepted by consumers”. In this regard, it can be recalled that Nestlé has adopted a GMO free policy. On the other hand, Monsanto, which has in GMOs a great part of its business, mentions its “obligation to explain and promote the proper and responsible use of ... technologies”.

On self-compliance control, Nestlé’s states that its “compliance with its Corporate Business principles is regularly monitored by its internal auditors on the basis of clear auditing instructions, which are certified by the external auditing firm KPMG, and published for all employees to consult on the Nestlé Intranet. Findings and recommendations are reported through the Board Audit Committee to the Nestlé Board of Directors”. On its part, Monsanto leaves the regulatory compliance issue to the “appropriate regulatory authorities”.

## 2. Special

There are special regulations for GM food and nutraceuticals. Nevertheless, it should be remembered that these foods require *ad hoc* analysis and standards for each of the products falling under these categories.

### a. GM food

#### i) From IGO

♣ FAO and WHO jointly organized a series of expert consultations which considered general safety aspects of foods derived from biotechnology<sup>199</sup>. The 2000 consultation reframed the concept of substantial equivalence<sup>200</sup>. The 2001 consultation revised the international guidelines on the assessment of potential allergenicity of novel recombinant proteins to address broader concerns or critics of the previous approach. A second consultation in 2001 was convened to consider the criteria essential for the risk assessment of food and food ingredients produced with the aid of, or containing, viable or non viable genetically modified micro-organisms. The assessment should include an evaluation of both direct effects (from the inserted gene) and unintended effects (that may arise as a consequence of insertion of the new gene)<sup>201</sup>.

♣ CAC established an *ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology, which developed the Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms, adopted last July<sup>202</sup>. It is important to note that it does not cover the substances produced by microorganisms that are used as additives or processing aids, nor specific purported

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<sup>199</sup> In 1990, 1996, 2000, and 2001.

<sup>200</sup> Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology – *Safety aspects of genetically modified plants*, 29 May – 2 June, 2000, Geneva, Switzerland.

<sup>201</sup> Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology – *Safety assessment of foods derived from genetically modified organisms*, 24-28 September 2001, Geneva, Switzerland.

<sup>202</sup> ALINORM 03/34A.



health benefits or probiotic effects that may be attributed to the use of microorganisms in food. Therefore, in principle, nutraceuticals are not affected by its rules.

In this document, CAC sets the framework of GM foods safety assessment. It recognizes the value of the substantial equivalence principle and establish its role as a departing point of the risk assessment process; in which intended and unintended effects of the genetic modification must be taken into consideration. In any case, the safety assessment of the modified microorganism should be performed on a case by case basis “depending on the nature and extent of the introduced changes”.

♣ OECD has actively assisted in harmonizing international regulatory requirements, standards and policies related to biotechnology since 1985.

*ii) From industry's INGO*

♣ The ICC has a Commission on Biotechnology which has developed a Global Roadmap for Modern Biotechnology<sup>203</sup>. This document constitutes an inventory of fundamental business views concerning biotechnology resulting from discussions among a multilateral international business forum. As general statements, the industry within this field acknowledges that it must accept its responsibility to ensure that products derived from biotechnology meet the highest international standards of quality and safety, and submits that it is prepared to be open and transparent, and that it will seek to promote a safe and secure environment through self-regulation. The particular concerns regarding health and environment focus on the international harmonization of risk assessment and risk management.

Regarding risk assessment, industry objectives for international harmonization are the mutual acceptance of information and data used in risk assessments; and finally, the mutual recognition of risks analysis and conclusions. To this end, industry will work to create consensus in the components of the risk assessment programmes which are considered to be basic: 1. the development of mutually accepted protocols, methodologies and similar procedures which are part of (or are related to) risk assessments concerning biotechnology products – including sampling, analytical testing, good laboratory practice and quality assurance, assessments of potential health and environmental impacts, and exposure evaluations -; 2. the risk assessment principles and guidelines for various organisms (i.e. plants) and potential impacts (i.e. human allergies); and 3. the types and amount of information and data that are both appropriate and necessary to carry out risk assessments for various biotechnology products and potential health/environment impacts.

Regarding risk management, industry insist on product specific (and not a process or technology) decisions. A transparent, well defined and consistent risk management should take into consideration cost-benefit and other economic analysis, acceptable levels of risk and uncertainty, and alternative approaches to managing risk as identified in the risk assessment. In addition, the industry recognises its obligation and accepts responsibility for taking voluntary risk management actions in order to address identified health/environment risks associated with specific biotechnology products. In accounting for the residual uncertainty that is present in the outcomes of virtually all

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<sup>203</sup> <http://www.iccwbo.org/home/environment/roadmap/roadmap.asp>. Visited in September 2003.

scientific risk assessments, protective and targeted risk management measures will help ensure that the risk management measures are proportionate to the assessed risks.

In order to provide clear, objective and appropriate information, business advocates the use of “risk communication” as a measure to address potential health/ environmental impacts that have been identified through sound risk assessment.

♣ There is a BIAC expert group on biotechnology. Though its focus is different from ICC, they are complementary organisations with similar objectives of ensuring that business positions are conveyed to policy makers. The BIAC expert group contributes to a wide range of OECD programmes (environment, science and technology, agriculture health and industry). Through its activities on genetic testing as well as biotechnology and ageing, its contribution is particularly significant to the work of the Task Force for the Safety of Novel Foods and Feeds, and to Biotechnology and food safety in the agricultural field.

*b. Nutraceuticals:*

At this point, international food safety regulation touching upon nutraceuticals is developed by IGOs in the additives field. Industry initiatives are essentially national<sup>204</sup>.

♣ The Joint FAO/WHO Expert Committee in Food Additives (JECFA) evaluates food additives, develops principles for their safety assessment and determines the acceptable daily or tolerable intakes. JECFA publishes a compendium of food additives specifications, which are the minimum requirements for the composition and quality of food-grade additives, directly related to toxicological evaluation and to good manufacturing practices<sup>205</sup>.

♣ CAC Committee on Food Additives and Contaminants has developed several documents touching upon nutraceuticals, be it from the more general food additives perspective, or from the perspective of special dietary uses. It must be acknowledged that the provision of necessary ingredients or constituents for foods manufactured for consumers having special dietary needs is one of the limited cases where food additives are justified under CAC.

The *General Principles for the Use of Food Additives in Food*<sup>206</sup>, require that food additives should be subjected to appropriate toxicological testing and evaluation, and that they shall conform with an approved specification. In this regard, CAC has an *Advisory list on the Specifications for Food Additives*<sup>207</sup>. The Guidelines for Simple Evaluation of Food Additive Intake, provides with a system to determine the intake estimates<sup>208</sup>.

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<sup>204</sup> For example, in 1998, the Institute for Nutraceutical Advancement (INA) launched a Methods Validation Programme with the initial funding of 29 US companies. Its goal is to validate and make available analytical methods that fulfil the need of global consistency in testing and, therefore, of harmonization of quality standards. Sponsoring companies include suppliers, manufacturers, growers, marketing companies and independent laboratories. <http://nsfina.org>.

<sup>205</sup> <http://www.fao.org/es/esn/jecfa/database/cover.htm>. Visited in October 2003.

<sup>206</sup> CAV/MISC 1-1972.

<sup>207</sup> CAC/MISC 6-2001.

<sup>208</sup> CAC/GL 3- 1989.

The *General Principles for the Addition of Essential Nutrients to Foods*<sup>209</sup> aims to establish a uniform set of principles for the rational addition of essential nutrients to foods. Essential nutrients may be added to food in order to achieve any of the following: restoration of nutrients lost during processing, nutritional equivalence of substitute foods, fortification<sup>210</sup>, and ensuring the appropriate nutrient composition for a special-purpose food. The basic principles are that: 1. the essential nutrient should be present at a level which will not result in either an excessive or an insignificant intake of the added essential nutrient considering amounts from other sources of the diet; 2. the addition of an essential nutrient to a food should not result in an adverse effect on the metabolism of any other nutrient; 3. the essential nutrient should be sufficiently stable in the food under customary conditions of packaging, storage, distribution and use; 4. the essential nutrient should be biologically available from the food; 5. The essential nutrient should not impart undesirable characteristics to the food and should not unduly shorten the food's shelf life; 6. technology and processing facilities should be available to permit the addition of the essential nutrient in a satisfactory manner; 7. addition of essential nutrients should not be used to mislead or deceive the consumer as to the nutritional merit of the food; 8. the additional cost should be reasonable for the intended consumer; 9. methods of measuring, controlling and/or enforcing the levels of added essential nutrients in the foods should be available; and, finally, 10. when provision is made in food standards, regulations or guidelines for the addition of essential nutrients to foods, specific provisions should be included identifying the essential nutrients which are to be considered or required, and the levels at which they should be present in the food to achieve their intended effects.

In this regard, there is an *advisory list on the Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children*<sup>211</sup>; and a *guidelines document for the nutritional and technical aspects of the production of formulated supplementary foods for older infants and young children*<sup>212</sup>.

### III. COMPLIANCE

The WHO Assembly resolution on food safety requests its Director General “to call upon stakeholders – especially the private sector – to take their responsibility for the quality and safety of food production, including awareness of environmental protection, throughout the food chain”<sup>213</sup>. EC and US laws establish that the primary responsibility for food safety lies with the industry: those who produce, process and trade in food. It is their duty to ensure that the food they produce and handle is safe and satisfies the relevant requirements of food law and they should verify that such requirements are met.

TNCs interest in compliance with food safety regulations lies beyond the willingness to obey by the law facing responsibilities and the traditional fear of sanctions. It is very

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<sup>209</sup> CAC/GL 9-1987, amended in 1989 and 1991.

<sup>210</sup> Fortification is defined as the “addition of one or more essential nutrients to a food, whether or not it is normally contained in the food, for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population or specific population groups”. Nutrient addition for the purposes of fortification should be the responsibility of national authorities.

<sup>211</sup> CAC/GL 10-1979, amended in 1983 and 1991.

<sup>212</sup> CAC/GL 8-1991.

<sup>213</sup> Resolution WHA53.15 on food safety adopted by the Fifty-third World Health Assembly, May 2000, n° 2.17.

much influenced by company and brand-name image and respect. In the food business, customers' trust is essential, and reputation a critical market asset.

Presently, TNCs responsibility in the food safety field is not controlled internationally. The only internationally resolved food safety disputes are the cases presented before the Dispute Settlement Body of the WTO. Those cases only refer to the control of SPS, TBT and GATT-94 compliance by Member states. In principle, TNCs responsibility is determined through direct state control. Whenever direct state control of product safety reaches its limits, private liability law is employed as a corrective. In addition, the implementation machinery of the Codes of Conduct strives to make them as effective as possible through external and/or internal reporting, consultation and clarification. Voluntary initiatives have a crucial, but necessarily only partial role to play in the effective control of business conduct. Self-enforcement needs the support of government agencies or statutory provisions, leading to a system which combines in a rather unclear way elements of both, private and public law. Self-enforcement or private enforcement is often embedded within a public law framework.

#### A. ABSENCE OF INTERNATIONAL CONTROL

Except for particular international crimes and the violation of the European Convention of Human Rights, there is no international mechanism to enforce international law on TNCs. The UN Human Rights Sub-Committee has recently achieved a Draft Code on the responsibility of transnational corporations which includes a so called enforcement mechanism<sup>214</sup>. Food safety could be regarded as a human right whose violation could be prosecuted resorting to these mechanisms<sup>215</sup>. On its part, the Cartagena Protocol failed to clearly address the liability issues which would be applicable to LMO-FPP<sup>216</sup>. Some proposals regarding its development reflect views of private legal persons responsibility along the lines of the UN Draft Code<sup>217</sup>.

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<sup>214</sup> The enforcement mechanisms consists on working groups or special reporters who, after receiving complaints or communications on other States behaviours, elaborate the corresponding "reports". It is understood that publicity is already a sanction. For TNCs it sure would be due to the crucial value of the reputation in the market.

<sup>215</sup> UN Human Rights Commission acknowledges that "technological advances implemented by business may cause a re-definition of human rights ...these are new questions often driven by technological advice that we are only beginning to understand ... How does the development of biotechnology, especially including genetic engineering affect human rights when the definition of humanity might change? ... Few have yet explored the responsibilities that flow from the unintended use of products by ... private actors to deprive individuals of their rights, even when the manufacturer did not intent that use"; and that "new sectors will become more centrally involved in the debate ... like agriculture ... or sectors in the cutting edge of technology will have to come to grips with their social impacts, with human rights being primarily amongst them". *Business and Human Rights: A Progress Report*. <http://www.unhchr.ch/business.htm>

<sup>216</sup> Article 27 states that "(T)he Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analysing and taking due account of the ongoing processes in international law on these matters, and shall endeavour to complete this process within four years".

<sup>217</sup> Convention on Biological Diversity, Report of the Workshop on Liability and Redress in the Context of Cartagena Protocol on Bio-Safety, UNEP/CBD/BS/WS-L&R/1/3, 14 December 2002, 10. It must be pointed that, if it were finally accepted, this private responsibility would imply the establishment of an "international tort". In addition, it would be the first international private responsibility not related to human rights violations.

Nevertheless, following the environmental model<sup>218</sup>, international institutions dealing with food - be it through food aid or through funding agricultural or other food related development projects -, directly or indirectly<sup>219</sup>, could enforce international standards by deciding to work only with companies complying with them<sup>220</sup>. Presently, none of the international organisations expressly refer to food safety requirements<sup>221</sup>. In this regard, for example, the World Bank only acknowledges that it “can ensure that food safety investments are undertaken within the appropriate policy framework so that food markets can develop most efficiently”<sup>222</sup>. Their requiring of food safety conditions would result in a common set of effective safety standards tangentially connected with traditional sources of international law making - customary and conventional -. Beyond the internal legal nature - binding/mere guidelines -, the influence of these rules as a normative framework and the application of the common standards would evidence the crystallisation of a non-State (IGO) quasi-customary international food safety law. Otherwise, it could be characterised as *lex mercatoria* (IGO acting as a private agent)<sup>223</sup>.

## B. NATIONAL PUBLIC ACTION

The best way to monitor and audit safety performance of all firms is for national governments to implement and enforce national laws and regulations. All parts of the production chain must be subject to official controls. Public enforcement should prevent, establish and sanction violations, whether through official or independent agencies. National supervisory authorities have to ensure that the internal food companies control systems are appropriate and operated in a way that food safety standards are met.

## C. SELF ENFORCEMENT

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<sup>218</sup> The World Bank and other international financial institutions’ environmental guidelines require the systematic examination of all development activities under consideration for financing to ensure that environmental safeguards of the development plan conform to their highest standards. This has become a model for many private investors and national governments. R.G. Volterra and A. Bisiaux, R.G. Volterra and A. Bisiaux, “A Brief Practitioner’s View of Foreign Investment and International Environmental Standards: The Developing Custom of Non-State Practice”, in *International Investments and Protection of the Environment. The role of dispute resolution mechanisms*. Permanent Court of Arbitration. Peace Palace Papers. Kluwer. 2001, 176, 181-183. It would be interesting to contemplate whether the responsibility of an international organisation under international law could be engaged because it had failed to ensure that a corporation chose to implement any food-related mission fulfilled the food safety standards.

<sup>219</sup> For example, the nine principles on human rights (labour and environment) of the Global Compact do not endorse food safety directly. However, could contribute to foster convergence around food safety guidelines inspired in Codex standards.

<sup>220</sup> Whether their own internal/institutional safety standards or international, the organisations would probably develop internal guidelines.

<sup>221</sup> The only rules that could be used to this end are found in the International Fund for Agriculture and Development (IFAD). Its General Conditions for Agricultural Development Financing say that “parties shall carry out the project “in accordance with plans, design standards, specifications ...” (section 7.1 c). Even in more general terms, the Lending Policy Criteria establish that “social objectives” will be assigned certain weight in deciding the projects to be financed (section 30).

<sup>222</sup> L. Unnevehr and N. Hirschhorn, *Food Safety Issues in the Developing World*. World Bank Technical Paper n° 269. 2000, viii.

<sup>223</sup> R.G. Volterra and A. Bisiaux, *op. cit.* 181-183.

Self-regulation has contributed to make legal, regulatory or less formal systems of behavioural control effective through building consensus and gaining managerial experience which allows firms to translate general principles into operational response. The widespread agreement or consent of the people and organisations covered by the controls promotes what has come to be known as “voluntary compliance”; that is, adherence to behavioural norms that is not due to formal enforcement. In the same way that there are divergences between TNCs in their commitments; management practices in support of commitments vary significantly. Some firms have adopted advanced practices while others have yet to translate their codes into management controls<sup>224</sup>.

The OECD Guidelines on Multinational Corporations do not call on companies to monitor audit or report on their efforts to promote principles of corporate conduct, but leaves this decision to companies. It is for them to determine what course of action best fits the business reality and the local context. In principle, if private initiatives are successful, this attests not only to the competence of the business community, but also to the abilities of societies to formulate, communicate and channel reasonable pressures for appropriate business conduct. Thus the effectiveness of the broader systems of private and public governance from which they emerge, private initiatives cannot work well if other parts of the system work poorly<sup>225</sup>.

In the food safety industry several TNCs have attempted to fortify their codes by implementing their own enforcement schemes. These enforcement schemes may include internal or/and external monitoring<sup>226</sup>. Internal control mechanisms imply voluntary self-control, which has been said to be questionable since serious doubts arise on the extent to which violations will be disclosed. Moreover, it has been argued that is at least doubtful that such a system is consistent with the principles of the rule of law<sup>227</sup>.

In addition, a number of TNCs enterprises have set up mechanisms for independent external auditing of their suppliers’ observance of their corporate responsibility objectives through hiring independent external monitoring organizations. If a supplier is found to be in continuous violation of certain corporate responsibility objectives contracts can be cancelled. In this regard, many enterprises have committed to assisting suppliers to meet the enterprises’ objectives through training programs. Although the costly nature of monitoring suppliers’ observance of safety or behavioural standards may lead companies to rely on suppliers self-monitoring<sup>228</sup>, TNCs have an efficient alternative in requiring them to obtain particular product safety/quality certificates.

The benefits of self-compliance initiatives are potentially numerous, including improved legal compliance, management of litigation risks, brand and reputation enhancement and smoother relations with shareholders and with society. Some initiatives have also allowed industries to deflect calls for formal regulation. However,

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<sup>224</sup> OECD, *Corporate Responsibility: Private Initiatives and Public Goals*. OECD, 2001, 9.

<sup>225</sup> *OECD Corporate Responsibility*, 10.

<sup>226</sup> In order to disclose social performance of corporations, the Global Reporting Initiative offers the Sustainability Reporting Guidelines, which can be used to support companies’ codes of conduct. <http://www.globalreporting.org>. Several Food and Beverages Companies have resorted to them.

<sup>227</sup> R. Widdershoven, “Enforcement of EC Regulations by Private Organisations: a Public Law Wolf in Private Law Sheep’s Clothing?”, in J.A.E. Vervaele Ed. *Compliance and Enforcement of European Community Law*. Kluwer. 1999, 236.

<sup>228</sup> OECD Roundtable on Corporate Responsibility; *Loc. cit.* 5.

TNCs imposition of self-compliance requirements on their suppliers may also lead to abusive situations.

#### D. PRIVATE DISPUTE RESOLUTION

Private dispute resolution mechanisms become central for resolving certain food safety conflicts. Litigation among companies may take place due to a food safety related breach of contract. National courts or arbitration tribunals would resolve these disputes. However, considering that food safety regulation is aimed at protecting consumers, the more interesting disputes in this area are the civil liability cases brought before national courts. Torts imply a remedy approach. Tort law regulates risky activities *ex ante* through assignment of liability *ex post*. Therefore, it may work as an indirect incentive mechanism to promote food safety.

There has been a marked upsurge in actions initiated by individuals before national courts, particularly in the US, to hold TNC accountable under international law. Companies may be the only available persons to provide any compensation for damages, and litigating where the TNC is seated is an option that, despite its difficulties, must not be disregarded<sup>229</sup>. In this regard, public authorities are developing liability regimes that span national borders<sup>230</sup>. Hence, individuals are taking international law in their own hands, refocusing it on private actors and becoming agents for internalisation in the domestic legal system.

International liability cases brought before US, UK, Canada and Australia courts reflect two main types of legal action: corporate compliance with international norms, and the intent that corporate behaviour as direct investors in other countries matches the standards of care that would be expected at home. The latest cases constitute an ultimate resort for consumers in countries where adequate regulation and/or judicial infrastructure is lacking. Although it has been maintained that TNCs are not only bound to abide by the laws of the host country in which they operate, but must also take into account the expert knowledge on health and safety in their home country<sup>231</sup>, this is not so clear beyond certain labour related cases. In this regard it must be considered that courts should be hesitant in adopting an expansive view of TNCs corporate liability since it could amount to making foreign policy.

In the US no single federal statute regulates GMOs directly<sup>232</sup>. The Aliens Tort Claims Act (ATCA) provides both a federal forum and a cause of action for aliens by giving district courts "... original jurisdiction of any civil action by an alien for a tort ...

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<sup>229</sup> M. Galanter, "Law's elusive promise: learning from Bhopal", in M. Likosky Ed. *Transnational Legal Process*. Butterworths. 2002, 180-182.

<sup>230</sup> R.E. Löfstedt and G. Sjösted, *op. cit.* 309.

<sup>231</sup> J. Woodroffe, "Regulating Multinational Corporations in a World of Nation States", in M.K. Addo, Ed. *Human Rights Standards and the Responsibility of Transnational Corporations*. Kluwer. 1999, 138, states that there are signs which avail for the possibility of courts judging unacceptable that TNCs operate with differing standards at home and abroad.

<sup>232</sup> The EPA ("safe for the environment"), Food and Drug Administration (FDA – "safe to eat") and US Department of Agriculture (USDA – "safe to grow") share minimal supervisory responsibilities to regulate the plant health and pesticide aspects of GMO, while other characteristics remain unregulated. The FDA regulates GM food products under the FFDCA for food safety, but its authority is generally limited to the marketing aspects of GMO products. There is no U.S. GMO labelling law, but some health-food companies voluntarily label their products "non-GMO".

committed in violation of the law of nations or a treaty of the United States”<sup>233</sup>. Arguably, the ATCA’s threat of liability for TNCs as private actors is pressure enough to force them to control their behaviour as to human rights in foreign nations<sup>234</sup>. In the opinion of some, it does little to nothing to coerce good behaviour from TNCs<sup>235</sup>. In this regard, it has to be considered that, since most corporate defendants have assets and wish to avail themselves of business opportunities in the US, the jurisdiction of the courts is easily accepted and acknowledged because defendants are fearful for their current or future economic assets and hopeful that future business opportunity is worth the risk of acquiescing jurisdiction<sup>236</sup>.

In the EC, GMOs regulations do not cover civil liability<sup>237</sup>. Nevertheless, the Products Liability Directive applies to foodstuff, and was reformed in order to include unprocessed primary agricultural products<sup>238</sup>. In torts cases, the Brussels Convention<sup>239</sup> and Council Regulation 44/200<sup>240</sup> on jurisdiction and the recognition and enforcement of judgements in civil and commercial matters recognizes the competence of the courts of the place where the harmful effect may occur when the defendant has his domicile in a Member state.

In any case, without legislation establishing a particular liability regimes, tort litigation implies a burden of proof on plaintiffs which makes it hard to succeed in GMOs cases<sup>241</sup>.

#### IV. CONCLUSION

In today’s search for more open world, the persistent tensions between opposing forces are omnipresent in the food safety field. From the call for international harmonization to the call of respecting diversity; from the intervention of various international organizations and states to the action of private groups; from the cooperation to the competition among food business industries; from the industry’s to the consumers’ interests; from the non intervention to the intervention in food production and processing; from the predominance of objective science to the consideration of the

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<sup>233</sup> Aliens Tort Claims Act, 28 U.S.C.A. & 1350 (1789).

<sup>234</sup> M.D. Ramsey, “Multinational Corporate Liability Under the Alien Tort Claims Act: Some Structural Concerns”. *Hastings International and Comparative Law Review*. vol. 24, 2000-2001, 361, 365-366, stresses that the argument for expansive application of the ATCA rests upon problematic foundations

<sup>235</sup> M.B. Baker, *op. cit.* 110-111.

<sup>236</sup> Describing this situation in the antitrust field, C. Otero García-Castrillón, “El alcance extraterritorial del derecho de la competencia y su utilización como medida comercial”. *Gaceta Jurídica de la Unión Europea y de la Competencia*. 212, 2001, 54.

<sup>237</sup> Directive 2001/18 on the deliberate release into the environment of genetically modified organisms, repealing Directive 90/220/EEC, *OJCE* (2001) L 106/1. Regarding liability, the Commission undertook to bring forward a legislative proposal on environmental liability before the end of 2001. Presently, the Commission keeps on working on the proposal COM (2002) 17 final. Without particular references to civil liability, the EC regulation on GMOs include Regulation 1829/2003 on Genetically Modified Food and Feed, *OJCE* (2003) L 268/1, and Regulation 1946/2003 on the transboundary movement of genetically modified organisms, *OJCE* (2003) L 287/1.

<sup>238</sup> Directive 85/374, *OJCE* (1985) L 210/29, modified by Directive 99/34, *OJCE* (1999) L 141/21. The numerous countries which have recently adopted special product liability rules have followed the EC model. M. Reimann, “Product Liability in a Global Context: the Hollow Victory of the European Model”. *European Review of Private Law*, vol. 2, 2003, 128-154.

<sup>239</sup> A consolidated version was published in *OJCE* (1998) L 27. Article 5.3 and 3.

<sup>240</sup> *OJCE* (2001) L 12. Articles 5.3 and 3.

<sup>241</sup> B. Endress, *op. cit.* 504-505.



socio-cultural concerns in the food safety analysis; from the public to the private systems for regulating and enforcing the rules.

There is no question of TNCs interest in international food safety governance, whose framework may well be qualified as legally pluralist. International harmonization of food safety regulation eases their trade operations. One way or another, they are always the final addressees of international food and trade regulation, and, of course, the ultimate responsible for the food safety of their products. Moreover, brand name reputation is a critical market asset in the food industry.

Despite their lack of international legal personality TNCs play a relevant role in international food safety governance. They not only influence States' international activities in the field, but also they enjoy the possibility of being heard in a number of international organisations and have developed collective and individual food safety self-regulation. However, TNCs can hardly be held accountable before international enforcement institutions for international food safety issues. As today, claims of TNCs responsibility can only be handled nationally by administrative authorities, which may delegate their functions in independent agencies, and courts. In addition, industry self-enforcement may take place in various ways.

TNC can have a positive influence in international food safety regulation, for example, through internationalising non-compulsory food safety standards. Nevertheless, they can also easily abuse their dominant position. Therefore, TNC involvement in food safety needs to be adequately balanced with the corresponding participation of all interested stakeholders.