

The Dual Dimension of the Global Governance of Health

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Abstract Although there is a large body of literature that deals with questions relevant to the global governance of health, the legal studies have proved slower in providing systematic approaches to interpreting and analyzing the global governance of health. The case of global governance of health offers a number of interesting insights that ought to advance legal as well as political debates. We begin by briefly outlining the scope and nature of the dual dimension of global governance of health (GHG), arguing that the main challenge for contemporary GHG is to reestablish within the health policy framework the linkage between health care interventions and the underlying socioeconomic context. The understanding of the relationships between health and development as confirmed in the Tallin Charter on Health and Wealth adopted by all WHO (World health organization) European Member States in 2008 is the underpinning of the shift towards more horizontal and inclusive approaches (strategies such those of “The new European policy for health – Health 2020: Vision, values, main directions and approaches” of the Who Europe – 2011 – named “a whole-of-society approach” and “a whole-of-government approach”). In the second part of the paper, we explore recent inputs into the GHG discourse from a wide spectrum of actors, ranging from the WHO to nongovernmental organizations (NGOs). We suggest that in their varying hues, these actors have attempted to reintroduce the wider social concerns constitutive of a more integrated approach to health law, which would locate specific interventions within a broader project of socioeconomic transformations.

Keywords: health law, global governance of health, vertical governance, horizontal governance, civil society organizations

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1. Introduction

The notion of global governance invites to investigate what are the principles of the order at the transnational level: if governance is channeled towards the composition of a public sphere characterized by principles and rules common to a number of international regimes or otherwise encourages the fragmentation of the existing regimes.

In a first place, it is an attempt to identify within the global scenario actors different from States that open the field to the advancing civil society able to provide an attractive alternative to State regulation [1].

It can therefore be held that the concept of global governance involves both, broadly speaking, formal institutional contexts, and frameworks characterized by greater informality [2], and involves the unavoidable necessity of cooperation at the global level [3], since the costs of the lack of cooperation are not more realistically sustainable.

If law, intended in a formal way, insists on the issue of competences and powers, global governance opposes, as a counterpart, the strengthening of horizontal cooperation and coordination between regulatory regimes within the transnational context and the continuous bargaining between a committed wide range of actors, in view of the achievement of specific objectives, within more restricted contexts.

In transnational contexts, global governance of health implies, in a descriptive sense, a “structural coupling” [4] between law and economics, for which coordination between regimes and profoundly different rationality occurs through the use of economic freedoms aimed also at the protection of other rights (commercial clause) and through a use of the “health clause” as a limiting factor.

The balance between interests of various natures is different from that provided within States, since the economic interests become instrumental in the neo-functional logic to the protection of rights such as the right to health, the rights to work, etc., and the “health clause” is linked to scientific demonstrations that prove the necessity to activate the precautionary principle.

A prominent example for the “health clause” is established by the Agreement on Sanitary and Phytosanitary Measures which came into force in 1994 with the adoption of the Agreement Establishing the World Trade Organization (WTO). The restrictions to international trade posed by the States in order to protect health must be consistent with the principles of necessity and non-discrimination and have to be explained scientifically and aimed at the exclusive protection of human health, agriculture and the animal world.

The various rationalities in competition, economical and sanitary, are recomposed within the regime of the WTO and of the WHO through a limitation of their internal logic thanks to the reformulation of the principles

of protection of health and the global formulation of the “commercial clause” and “health clause”, allowing responsive connections between different regimes. Another example is represented by the need for balancing the economic reasons for the protection of intellectual property (protected by the Agreement on trade related aspects of Intellectual Property Rights - TRIPS) and public health emergencies for which access to low-cost drugs through mandatory licensing or parallel imports (as in the case of Brazil in the Eighties and in the South African case, for the Aids emergency) [5] must be allowed.

2. The Breaking Down of a Concept (GHG)

We begin by briefly outlining the specific nature of the global governance of health (GHG). Through the analysis of global documents we can highlight the progressive emergence of a strong link between health and socioeconomic factors.

Starting from the definition of GHG, the governance issue emerges since the Eighties in the global institutions' documents: the International Monetary Fund (IMF) and World Bank (WB) reports define standards and rules of conduct to be used as indicators for the allocation of grants and loans into developing countries, until to arrive at a form of encoding by the Commission on Global Governance of the United Nations in 1995.

In 1987 the WB issued “Financing Health Services in Developing Countries: An Agenda for Reform”.

The WB document was harshly criticized since the same recipe was provided for the Reform of health systems everywhere (payment of benefits, privatization of health services, private insurance schemes, decentralization).

In 1993, the World Bank published its report “Investing in Health”, which announced the importance of growth with equity and the positive correlation between economic growth and health. Some analysts applaud the report for pressing some right buttons, such as the importance of female education and greater access to health care, but others make a more critical assessment.

Some critical issues concerned the decreasing public investment in health services and the favor for the privatization of health services.

Corrective mechanisms to excessively neoliberal logics have been thereafter introduced mainly from the World Bank and International Monetary Fund. The reference to good governance in the Nineties programs (the so-called Social security safety nets), giving importance to the social and health effects of the activities funded in a given country, was very relevant.

The response to health problems and the guarantee of health in low-income countries tended to be promoted through concerted forms of use of the sum of collected money. In particular, MF and WB favored the use of selective actions, recommending the reduction of “user fees” for services such as education and health, or the introduction of appropriate forms of exemption for the weaker parts of the population [6].

It is noteworthy that the existence in all countries of inequalities in access to basic services is highlighted for years by the specialized agencies of the United Nations, including UNDP, WHO and OECD [7].

It is relevant to underline how the strategies of BM, FM, and WHO for global governance of health converge since the early 2000 through the identification of a number of priorities that concern the relationship between health and economy of the developed countries and developing countries [8].

First of all, the focus on non-communicable disease (see the Chart 1 showing the relevance of this kind of disease) allows to shed light on the progressive convergence of health policies effects and economic factors understanding. Some diseases in particular cause a range of adverse economic effects, including reduced labor supply, reduced labor output (resulting from, for example, absenteeism and the diminished economic output of sufferers and caregivers), lower tax revenues, increased government expenditures, lower returns on human capital investments, and higher costs to employers (for example, from reduced productivity and higher employer healthcare costs) [9].

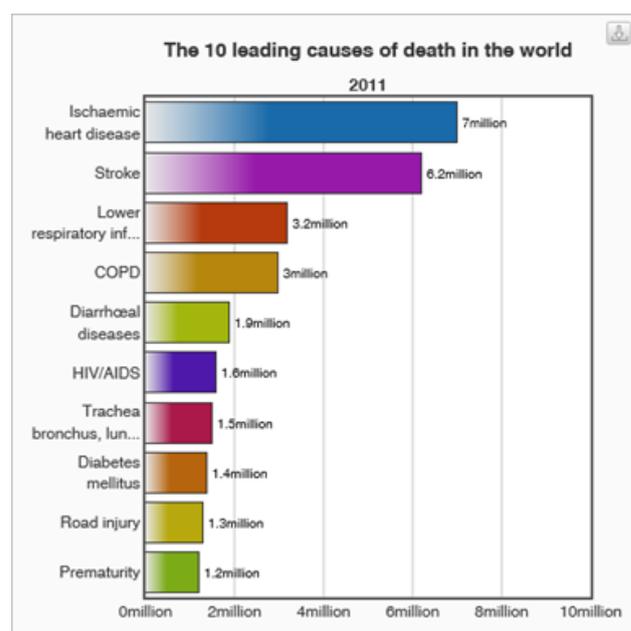


Chart 1. The top 10 causes of death in the world (Source: Who; Date: July 2013)

Ischaemic heart disease, stroke, lower respiratory infections, chronic obstructive lung disease, diarrhoea and HIV/AIDS have remained the top major killers during the past decade.

Tuberculosis is no longer among the 10 leading causes of death, but is still among the top 15, killing one million people in 2011.

Chronic diseases cause increasing numbers of deaths worldwide. Lung cancers (along with trachea and bronchus cancers) caused 1.5 million (2.7%) deaths in 2011, up from 1.2 million (2.2%) deaths in 2000. Similarly, diabetes caused 1.4 million (2.6%) deaths in 2011, up from 1.0 million (1.9%) deaths in 2000.

Non-communicable diseases (NCDs), including cardiovascular diseases, cancer, chronic respiratory diseases, and diabetes, cause tens of millions of deaths each year, many of which are preventable and premature. These diseases have a direct impact on the economic capabilities of a certain State since they diminish the years of productivity and increase the years of disability of the population.

The impact of the NCD challenge cannot be appreciated without considering the full range of direct and indirect effects that NCDs have on economies and health systems, as well as on the affected individual and his or her household. A particularly meaningful tool of evaluation of

the impact of NCDs is the number of healthy years of life lost as a result of the diseases. These measures can be calculated in terms of disability-adjusted life years (DALYs), which is the sum of productive life years lost

due to premature mortality and disability [10]. Recent studies have proven the progressive shift in burden from premature mortality to years lived with disability (see Figure 2).

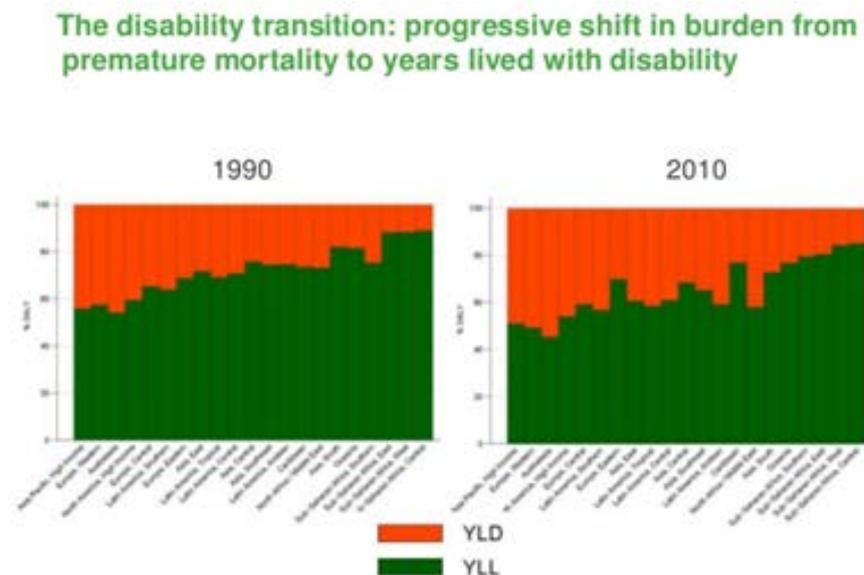


Figure 2. The disability transition. A comparison between 1990 and 2010 (Source: Institute for health metrics and evaluation; Date: December 2102)

3. The Global Governance of Health

3.1. Post-Westphalian Reverberations

Into the global order, the vertical regulation is currently a residual dimension with respect to the horizontal regulation.

The strategy contained in the document of the WHO “Health for all in the twenty-first century” highlights the importance of international law by establishing the elaboration of international instruments of protection and guarantee of health and the encouragement of the Member States to the observance of international standards related to health.

The “statist” perspective uses the language of security to promote health as an issue that should be considered as part of foreign and defense policy.

In contrast, the “globalist” perspective tends to focus on individual health needs and on the ways the State may or may not be meeting these needs. The “globalist” approach does not assume that the State is necessarily the most significant or legitimate actor for protecting the health of individuals.

It is exemplified by some norms provided by the WHO. A prime example is the system of international standards on health (International health regulations system - IHR) approved by the WHO in 1951 on the basis of art. 21 of the Who Constitution. This system of norms is an example “of the present-day soft law approach to global health” [11] aimed at protecting the security against the spread at the international level of disease searching for not to interfere excessively with international trade. This system of norms provides Member States with a surveillance program aimed at monitoring the spread of communicable disease, such as yellow fever and cholera.

The origins of the IHR, the only global rules governing the international spread of infectious diseases, date back to

the first International Sanitary Conference, held in Paris in 1851 to address the European cholera epidemics. In 1903, the International Sanitary Convention replaced the Conferences of 1892 and 1897.

In 1951, the WHO, pursuant to its legal powers under Article 21 of its Constitution, adopted on July 25, 1951 the International Sanitary Regulations (ISR) - the product of nineteenth century public health diplomacy. The WHO renamed these regulations the “International Health Regulations” in 1969, and slightly modified them in 1973 and 1981.

The ISR were renamed International Health Regulations in 1969.

The Sars epidemic in 2003 and the need to ensure a response to the risks of bioterrorism formed the basis of the opening of negotiations that led to the current system of multilateral surveillance. The reference to the existence of a “public health emergency of international concern” as a prerequisite for the creation of obligations on Member States is a noteworthy novelty of the current health regulations. The new regulations are intended to create an early warning system more timely than the previous [12] and have introduced the procedure of verification enacted by the Who and the Member States that triggered the procedure.

The Health Regulations refer to a typically international system and do not create obligations of a collective nature requiring activation of the international community as a whole.

The transition from Sanitary Convention to Health Regulation testifies to the transformation of the role of the territorial State within the international community.

In the first case, we have real international treaties which sovereign States ratify. In the second case, we have a type of binding legislation that is based on the States as public arenas internally moldas an infrastructure and a communication network.

In particular, the territorial State forms the basis of national focus point which is the nodal point of the network and the internal structure that communicates and

interacts with the Who (see the following Map tracing the Who global influenza surveillance and response system).

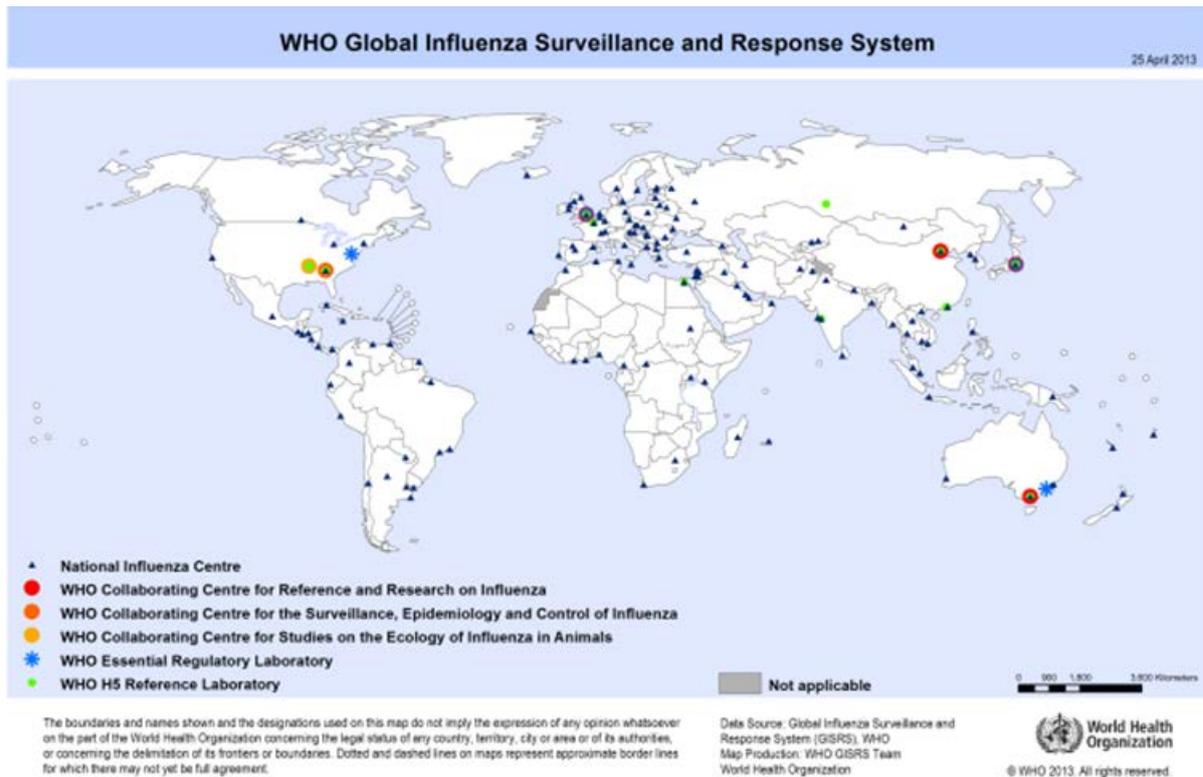
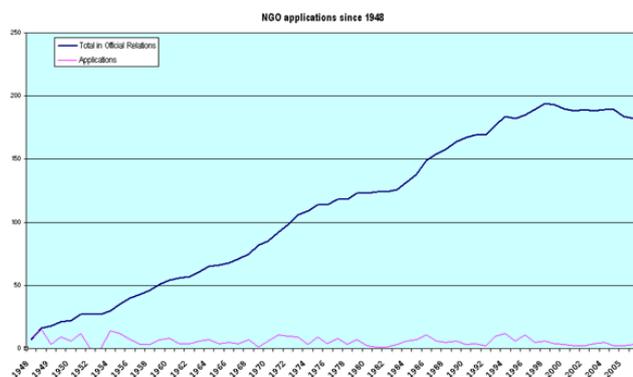


Figure 3. Who global influenza Surveillance and Response System (Source: Who; Date: 25 April 2013)

A second innovation is represented by the role of NGOs. The non-governmental organizations contribute to draft regulations through the elaboration of reports on matters of international scope (Article 9) and through cooperation with the Who in the implementation of regulations and warnings in reference to the spread of diseases (art. 14).

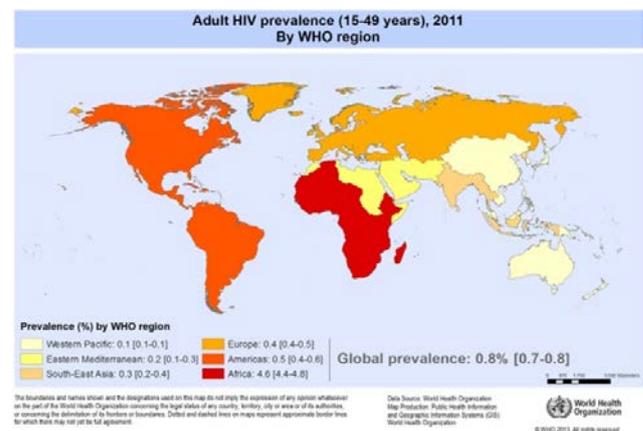
A participation of Ngo is also provided in the composition of the review committee (Article 51) and the preparation of reports and information in favor of the review committee (art. 53 letter. C).

The first two cases are an example of informal relations, while the latter two cases are example of official relations with the Who whose participation has gone to increase since 1948 (see Graph 4).



Graph 4. Ngo applications since 1948

Over the years, health regulations have specialized its action, excluding from its scope of operations diseases such as AIDS, for which a specific strategy was planned and implemented [13].



Map 5. Global situation about HIV/Aids.

Globally, 34.0 million [31.4–35.9 million] people were living with HIV at the end of 2011. An estimated 0.8% of adults aged 15-49 years worldwide are living with HIV, although the burden of the epidemic continues to vary considerably between countries and regions. **Sub-Saharan Africa remains most severely affected**, with nearly 1 in every 20 adults (4.9%) living with HIV and accounting for 69% of the people living with HIV worldwide (Source: WHO, Unaid, Unicef; Date: 21 February 2013).

The strategy promotes a long-term, sustainable HIV response through strengthening health and community systems, tackling the social determinants of health that both drive the epidemic and hinder the response, protecting human rights and promoting gender equity as essential elements of the health sector response. It strengthens integration between intervention for HIV and other health services, improving both impact and efficiency. It calls on the world to build the collaboration,

innovation and investment that have forged hard-won progress to date, establishing the foundation for success over the following five years. The past decade has seen unprecedented commitments to global health and development, beginning in 2000 with the commitments in the United Nations Millennium Declaration known as the Millennium Development Goals with their corresponding set of time-bound targets. In 2001, during a United Nations General Assembly Special Session on HIV/AIDS, United Nations Member States made pledges for a comprehensive response to HIV in the Declaration of Commitment on HIV/AIDS, and expanded those commitments in the Political Declaration on HIV/AIDS adopted in 2006, including a commitment to achieve universal access to HIV prevention, treatment, care and support for all in need.

An effective health policy tends to supplement the fight against specific diseases with national priorities and the aim of strengthening health and community systems (see Chart 6).

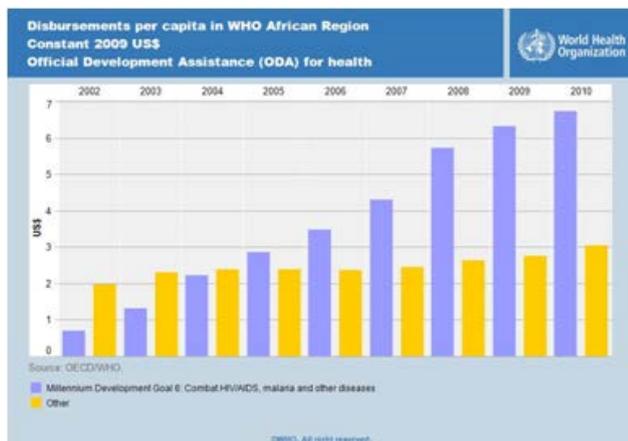


Chart 6. Disbursement per capita in Who African Region (Source: Oecd/Who)

3.2. Second Dimension: the Horizontal Governance of Health

As well known, the horizontal dimension of the global law is relevant, both for what concerns the relationships between international organizations that establish horizontal cooperation not based on international conventions and treaties, both for connections established through the bodies of norms and rules.

For the second aspect, we are witnessing the shift of power to balance the very different interests involved from the national to the global level, where such matters, within States eminently political, become technical as a result of the use of scientific criteria for defining technical standards.

In order to avoid protectionist and discriminatory behavior of some States, or vice versa not respectful of the minimum levels of protection needed, the World Trade Organization requires compliance with minimum requirements of food safety set by the Codex Alimentarius Commission and the World Health Organization, intersecting and putting in balance different interests, such as trade and health [14].

Some case decided by the global judges of the WTO are relevant to understand the coordination between regimes.

Still under the aegis of the Gatt, the Thai Cigarettes case was decided [15]. On the basis of the complaint of the U.S., the Thai domestic legislation, banning the import of tobacco products on the basis of the toxicity of chemicals and additives contained by the American cigarettes, considered by the Thai authorities harmful to human health, was examined in the light of the Gatt Agreement.

The panel's decision of 7 November 1990 found the ban not justified on the basis of Article XX letter. b, given the lack of requirement of necessity and affirming the possibility of pursuing the goal equally with less restrictive measures, in particular by introducing an appropriate labeling system, the prohibition of advertising of tobacco products, the promotion of appropriate information campaigns for consumers about the risks associated with smoking. In this case, the protectionist intent, often masked behind the protection of non-trade values, was easily revealed, subsisting a discriminatory aspect with respect to the foreign import.

Under the aegis of the WTO, the case Beef hormones of 1998 is a crucial case [16], concerning the import ban, which was introduced by the European Union, on meat from animals raised with the help of substances containing growth hormones [17]. The decision of the Appellate Body held the incompatibility with the SPS Agreement [18], and in particular with article 5.1, on the basis of the lack of conformity between the measures taken and the risk assessment [19].

The risk assessment is governed in a flexible manner, and not rigorous, as a matter of fact, referring it back to the States; however, in some cases the judgment of inadequacy has had a significant weight before judges of the WTO [20].

The representatives of the European Union and the United States at the WTO signed in Geneva in May 13, 2009, a Memorandum of Understanding on a provisional agreement over the dispute on hormones-treated meat.

The Memorandum provides a substantial reduction of the sanctions imposed by the United States for the detriment of imported products from Europe. The EU, in turn, has made a commitment to increase the possibilities of access to the EU market for high-quality meat [21].

In the Asbestos case of 2001 [22], the Appellate Body made decisions in the direction of health protection. The Appellate Body confirmed the first instance decision on the legitimacy, on the base of the environment and health exceptions, of the French ban on importation of products containing asbestos, considered seriously risky for human health [23].

The proposal of a controlled use of the products as an alternative to radical ban was not considered sufficient for involving a stay of risk: given the legitimacy of the French choice not to take this level of risk, the ban was therefore considered compatible with the requirements of necessity and proportionality set out in Article XX of the GATT.

A second kind of the horizontal governance of health is represented by the agreements involving public and private actors.

International initiatives sponsored by WHO [24] include the introduction of new forms of collaboration between the public and private sectors, on the basis of the assumption that the partnership between for-profit and

non-profit associations is now essential to cope with the global health problems [25].

Until the first World Assembly, the WHO has established the principles by which manage its relations with the private actors and NGOs, in particular by refining the criteria during recent resolutions [26].

However, the major critics directed at public-private partnerships in health sector concern mainly the presence, in the governing boards of various organizations fulfilling initiatives, of representatives of major pharmaceutical companies and the marginal role played by the WHO.

Emphasis was placed on public-private partnerships and on the role of benefactors to tackle specific health problems, such as malaria (Rollback Malaria Campaign), vaccines (Global Alliance for Vaccines and Immunization, GAVI), and the problem of access to drugs for the treatment of HIV/AIDS (UNAIDS-pharmaceutical industry initiative). At Okinawa during the G8 meeting in 2000, the notion of an enhanced role for the private sector and for public-private partnerships was given further legitimacy.

An eloquent example is represented by the Global Alliance on Vaccines and Immunization (Gavi) whose Board of Directors is made up of two representatives of the pharmaceutical industry in the face of one member representing the WHO [27].

The Board of Directors of the alliance (Gavi Alliance board) sets out the strategies to follow and controls the implementation of the programs.

The members of the Board of Directors are 28 and are appointed (in the proportion of one member and one alternate for each subject) by the World Bank, WHO, UNICEF and the Gates Foundation (4), by the Governments of developing countries (5), the Governments that support the activity of Gavi (5), research institutes (1), pharmaceutical industry (2), the civil society organizations (1), by the international scientific community (9 independent experts), and finally by the Chief Executive officer of the Secretariat of Gavi (a non-voting member).

Decisions are taken by consensus, on the basis of the report made by the President, or in the event that consensus cannot be reached, on the basis of a two-thirds majority of the present members [28].

The Board of Directors organizes their work in committees involving, in addition to members of the Council responsible for the matter, experts appointed to provide specialist advice [29].

For the period 2011-2015, four strategic goals guide the Alliance's mission: accelerating of the uptake and use of underused and new vaccines by strengthening country decision-making and introduction; contributing to strengthening of the capacity of integrated health systems to deliver immunization; increasing the predictability of global financing and improve the sustainability of national financing for immunization; shaping vaccine markets to ensure adequate supply of appropriate, quality vaccines at low and sustainable prices for developing countries.

While in the first five years of the activity the strategic objectives were related to the strengthening of systems for the provision of vaccines and the supply of new vaccines (such as hepatitis B and yellow fever), the last five years of activities regarded main innovation of the investment strategy that would include some new vaccines and

strengthening health systems of countries denouncing backwardness in the methods of vaccination [30].

The application process begins with a request of the country eligible to receive funds, accompanied by an expense project providing details of the supplies of vaccine and a periodical report presentation in the case of admission to the program [31].

The application and the presentation of the spending plan, after being prepared in collaboration with two committees that provide assistance in Gavi programming and in the detection of needs - the Inter-agency coordinating committee and the Health system coordinating committee - are submitted to the Board of Directors of Gavi that requires an opinion from an independent commission - the Independent review committee (IRC) [32], competent on the evaluation of new proposals and periodic reports of the countries admitted to the program.

The establishment of the Global Fund to fight AIDS, tuberculosis, malaria was carried out upon Japanese intervention proposed by the Presidency during the Okinawa Summit of 2000, following a World Bank project. The Fund was approved the following year by the Heads of State and government of industrialized democracies in Genoa.

The process of establishment of the Fund was entrusted jointly to the European Commission and the Japanese Presidency which organized several meetings with experts of the matter, health ministers and the heads of organizations involved.

The Fund became operative at the end of 2002, when the Interim Working Group (Transitional Working Group), established immediately after the summit to determine organization and procedures, passed deliveries to the first Board of Directors.

In the section of Announcement adopted at Okinawa the group reaffirmed their commitment to work in strong partnership with the "governments, WHO, other international organizations, industry (particularly pharmaceutical companies), academic institutions, NGOs" to achieve some critical objectives indicated in the reducing by 2010 of the number HIV-positive people (25%), of TB mortality (the 50%), the incidence of malaria (50%).

The access to available funds is provided, on the basis of the national income level, with a total funding or partial funding mechanisms, not more than 65% of the program costs, or residual, which does not exceed the 25% of the planned expenditure [33].

Another example of partnership is represented by the Booster Program for Malaria Control in Africa, a multi-sectoral program designed to last for 10 years, started in 2005 as a program to revitalize the Roll Back Malaria global partnership.

Another program is the Global Alliance on TB drug development. It is a public-private partnership directed to the discovery of new drugs to control the spread of tuberculosis that can be provided to poor countries at prices commensurate with their resources.

The global health initiatives are criticized however, to put under further stress the health systems in poor countries, fragile and underfunded after decades of neoliberal policies, contributing to the escape of personnel and burdened with high transaction costs. Moreover, the

increase of financial aid in health sector development of the last decade has been almost totally absorbed by the fight with HIV/AIDS. No additional funding has been provided since many resources have been diverted from activities such as the fight with maternal and neonatal mortality.

In this context, the Global Fund has begun a transformation of its strategic policy aimed at improving the effectiveness of aid, focusing on: a) a new architecture oriented to the consolidation of the various projects at the country level in programs of long duration based on national strategies of disease control; b) a new platform to support the strengthening of health systems in conjunction with the World Bank and the Gavi, with a facilitating role of the WHO.

Speaking of this second initiative, which was approved at the last meeting of the Board of the Fund held in Ethiopia in November 2009, it covers more the “how” than the “what” to be financed; it is expected that the three agencies coordinate the implementation of programs aimed at strengthening health systems through the provision of technical assistance and encouraging the development of local expertise [34].

Critical notes to the new platform are related to the ability and competence of the agencies (Global Fund and Gavi) to deal with a complex and multidimensional issue such as the strengthening of health systems in poor countries, or their credibility on the subject (World Bank) [35].

There remains the need for the integration concerning not only the financial mechanisms and architecture of development aid but also health services, to ensure continuity of care for communities, without neglecting, or worse, weakening the basic health care.

4. The Main Channels of Expression of Civil Society

The role of non-governmental organizations (NGOs) [36] in the “global legal space” has increased in recent years, since not only they participate in the development of agreements, conventions, treaties, but are recognized as individual actors capable of intervening in global disputes.

It was given to them, in fact, the opportunity to submit statements and reports directly to the judges of WTO, ICSID (International Centre for Settlement of Investment disputes) [37] and NAFTA (North American Free Trade Agreement) [38]. Regarding the World Trade Organization (WTO), art. 13 Dsu (Dispute Settlement Understanding) provides the right of the panel to obtain further information.

An initial opening has occurred with the case *Shrimps* of 1996, when the eligibility of *amici curiae* was determined regardless of any contrary intention of the parties, considering the choice of admission as falling within the margin of discretion of the judge [39].

The decision was confirmed within the *Sardines* case [40], in which the Appellate Body confirms the power to admit reports formulated by non-governmental organizations concerned by the result of the case [41], subjected to quantitative (length of memories) and qualitative limits (demonstration of the relevance of the

arguments and the importance of participating in the process) [42].

While they cannot become members of the Organization, NGOs have been subject to specific guidelines contained in the General Council guidelines adopted on 18 July 1996, in which it is recognized the role of NGOs as cognitive vehicle of functions of the WTO towards the civil society.

The limited role of non-state actors in global health governance is particularly pronounced at the World Health Organization. While the WHO engages significantly with non-state actors and incorporates them within global governance through such means as public-private partnerships and participation in global health forums, its institutional processes do not provide a sufficient basis to fully realize the potential synergies of collaboration with diverse stakeholders. Non-state actors have highly limited rights of participation in the WHO processes. WHO policy is set by the Principles Governing Relations Between the World Health Organization and Non-Governmental Organizations, which was adopted in 1987 by the World Health Assembly Resolution n. 40.25.116. The WHO recognizes two categories of relations with non-governmental organizations: official and informal relations. The selection process for organizations in official relations is highly limited; only international non-governmental organizations can gain official relations status and the selection is based upon collaboration with the WHO. In addition, the procedure for entering into official relations is long and bureaucratic, taking three to four years on average. Even organizations that do obtain official status have highly limited rights of participation in the WHO governing process. They may attend sessions of the WHO governing bodies and have the right to make a statement (on this issue see Chart 7).

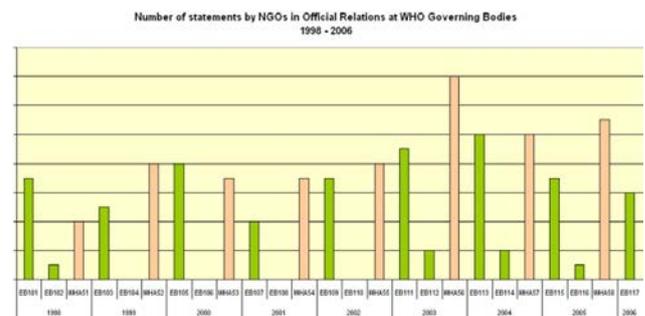


Chart 7. Number of statements by Ngos in official relations at Who Governing Bodies (World Health Assembly and Executive Board) 1998-2006

Notably, during the Framework convention on tobacco control (FCTC) negotiations, the rights of NGOs were also severely constricted. NGOs were authorized to attend plenary sessions of the negotiations, but unlike the Convention on the Rights of Persons with Disabilities (CRPD) where NGOs enjoyed 12 seats at the working group, NGOs were not authorized to attend working group meetings where most of the negotiations took place [43].

With regard to the participation of NGOs in the elaboration phase of international acts, only the Bank for international investment, the OECD and the G8 do not give any status to NGOs; while for OECD this is due to the political value of its documents, the other two remain

anchored to a state-based organization. Accreditation is the most common way through which the participation and the production of reports is realized.

Most of the international organization allow access to documents; ILO (International Labor Organization), UNEP (United Nations Environment Program), UNFCCC (United Nations Framework Convention on Climate Change), WHO (World Health Organization) and WIPO (World Intellectual Property Organization) also distribute texts to negotiate.

According to the WHO rules, the obligations of NGOs are particularly stringent: organizations in the informal relationships and officers must implement a program of cooperation, formulate and revise a number of projects; organizations have also taken charge, in many cases, of cooperating in programs of WHO and those of the Member States.

Another channel of participation of civil society to global governance is represented by the numerous committees scattered in international and global organizations.

The transnational committees, consisting of governmental experts, independent experts and representatives of interest, draw on a organicistic tradition preceding the appearance of the notion of political representation.

There are numerous transgovernmental (not plenary) committees, composed of governmental experts, who work at the UN [44] and at the Codex Alimentarius Commission. The latter have the task to develop and promote international standards on safety and quality of food products [45].

The last example is represented by regional committees of international organizations such as the UN Economic and Social Council [46] and the World Health Organization [47]. The regional committees enjoy considerable autonomy with respect to the Organization of reference and are often equipped with dedicated secretariat at the regional level.

5. Conclusions

The protection of health has gradually acquired a global dimension exceeding the States' borders.

In global governance, the socio-economic implications of health emerge with great force, since institutional and non-institutional actors interact upon equal basis with no hierarchical connections, unlike what happens in the context of public authorities such as the European Union where supranational institutions mediate between different interests on the base of certain unavoidable needs.

This co-operation between different actors, institutional and non-institutional, clarifies the structure of the global governance of health: it is a hybrid system within which vertical and horizontal regulation take place at the same time.

The vertical dimension is actually residual and shows clearly the progressive transformation of the contemporary State within the global system.

The horizontal dimension is more indefinite since many different interest representatives play a meaningful role in the elaboration and implementation of global rules.

As proven in the paper, it could be argued that the participation of civil society, under different guise, has changed the international viewpoint on health matters.

In fact, especially in some agencies (Global fund and Gavi), there has been a shift from an individual way of

looking at health to a more collective and communitarian way of facing the diseases.

Moreover, the blend of different interest representatives in the global and international committee allows to supplement political subjects with scientific evidences.

The committees, global compound tools, along the lateral opening between national administrations, as well as the national and transnational integration between administrations and civil society representatives, provide the possibility of endowing legislative and policy choices with technical evaluations of experts and opinions from civil society organizations.

References

- [1] I. F. Dekker W. G. Werner (editors), *Governance and international legal theory*, Leiden-Boston, MartinusNijhoff, 2004, pp. 13 ss., where economic globalization is believed to be not only the cause of the retreat of the State but also of the emergence of civil society that goes to fill the void left by the regulatory State: "governance is supposed to take over where government has lost its steering capacity".
- [2] M. N. Barnett R. Duvall, Power in global governance, in M. N. Barnett R. Duvall (editors), *Power in global governance*, Cambridge, Cambridge University Press, 2005, p. 17.
- [3] A. Hurrel, Power, Institutions and the production of inequality, in M. N. Barnett R. Duvall (editors), *op. ult. cit.*, p. 41.
- [4] The expression finds its origin in Gunther Teubner, *La cultura del diritto all'epoca della globalizzazione* [The culture of law at the time of globalization], Rome, Armando Editore, 2005, p. 32 ss., where the author speaks of structural coupling between law and economics especially for the phenomenon of *lexmercatoria*.
- [5] N. Bass, "Implications of the Trips Agreement for developing countries: pharmaceutical patent laws in Brazil and South Africa in the 21st century", in *George Washington international law review*, 2002, n. 34, pp. 191-223.
- [6] See the Health Sector Development Project II (evaluation reports approved by the Board on 24 April 2007) granted to Tanzania and directed to a comprehensive reform of the health system.
- [7] See Oecd, *Towards high-performing health systems*, Paris, 2004; Colombo Tapay, *Private health insurance in Oecd countries: the benefits and costs for individuals and health systems*, Oecd health working paper, 2004/15.
- [8] WHO, *Preventing Chronic Diseases: a vital investment*, 2005, Geneva; World Bank, *Dying Too Young: Addressing Premature Mortality and Ill-Health Due to Non-communicable Diseases and Injuries in the Russian Federation*, Washington, 2005.
- [9] See The World Bank, *Chronic Emergency: Why NCDs Matter*, Washington, July 2011; World Health Organization, *Behavior change strategies and health: the role of health systems*, Paper presented at the World Health Organization Regional Committee for Europe Fifty-eight session, Tbilisi, September 15-18 2008; World Health Organization, *Global Status Report on Non-communicable Diseases*, 2010, Geneva; WHO, *World Health Statistics*, 2011, Geneva; International Monetary Fund (IMF), *Macro-Fiscal Implications of Health Care*, 2010; IMF, *Reform in Advanced and Emerging Economies*, Washington, 2011.
- [10] The World Bank, *Chronic Emergency: Why NCDs Matter*, Washington, July 2011, p. 4.
- [11] See WHO, *International health regulation*, Geneva, 2007.
- [12] See Art. 6, which provides an obligation of notification and information of a health emergency of international concern through the medium of more efficient communication within 24 hours of assessment of relevant information.
- [13] See UNAIDS, *Getting to Zero: UNAIDS Strategy 2011-2015*, Geneva, 2010; Global health sector strategy on HIV/AIDS, 2011-2015 (resolution World health assembly 64.15); resolution Wha 64.14.
- [14] In the Sardines case the prevalence of global standards on European rules was established. The WTO Appellate Body said that the European business should work on the basis of global standards set by the Codex Alimentarius Commission and the World Health Organization. See WT/DS 231/AB/R, 26 September 2002.

- [15] Article 27 of Thai law on tobacco of 1966 prohibited the import or the export of seeds, plants, leaves, tablets of tobacco and tobacco fine without license, issued solely by the Thai Tobacco Monopoly. In addition, it imposed a regime of taxation for different internal products from national tobacco (60%) and imported tobacco (80%). The United States, claiming the protectionist intent of the Thai legislation, asserted violation by Thailand of the principle of non-discrimination (Article III GATT), as well as the prohibition of quantitative restrictions (Article XI.1 Gatt). See panel report of 7 November 1990 (DS10/R-37S/200).
- [16] European Communities-Measures Affecting meat products (Hormones), Report of the panel WT/DS26/DS48/R of 18 August 1997; the Appellate Body report WT/DS26/DS48/AB/R of 16 January 1998; the other fundamental case is European Communities measures Affecting the approval and marketing of biotech products, WT/DS 291, WT/DS 292, WT/DS 293, available on the WTO website.
- [17] See Council Directive n. 96/22 of 26 April 1996. The consumption of meat from animals raised with the help of hormones has been considered by European institutions a highly risky behavior for health, in spite of the fact that the state of scientific knowledge does not allow to unequivocally demonstrate the harmful effects on human health or exclude them permanently. Just on the basis of this assumption the Community could not justify the restrictive measures pursuant to art. 5 para. 7 of the Sps, specific expression in the global field of the precautionary principle, but it has called for the application of the precautionary principle in the context of political management of the risk in the absence of sound scientific knowledge.
- [18] The Sanitary and Phytosanitary Agreement (SPS), which entered into force in 1994 with the adoption of the agreement establishing the WTO provides that the restrictions placed by the states to protect the health must be consistent with the principles of necessity and non-discrimination and must be justified scientifically and aimed to the exclusive protection of human health, agriculture and the animal world.
- [19] For the literature on the case cf. C. Joerges, "Law, science and the management of risk to health at the national, European and international level. Stories on baby dummies, mad cows and hormones in beef", in *Columbia journal of European law*, 2001, p. 1 ss.
- [20] Salmon case decided by the Appellate Body in November 6, 1998 (WT/DS18/AB/R) and Agricultural products case, decided by the Appellate Body in February 22, 1999 (WT/DS76/AB/R), focusing on the quarantine procedure imposed on agricultural products imported from Japan: the illegality of the procedure, direct to avoid epidemics and opposed by the U.S., was considered, in the light of art. 5.1 of the SPS Agreement for the inadequacy of risk assessment, protectionist in favor of the internal market.
- [21] The memorandum provides an agenda made up of three phases: in the first (the first three years of implementation), the United States will maintain in force sanctions but reduced to 38 million dollars (instead of 116 million first applied), and shall cease to apply sanctions "carousel", whose afflictive power was formed by the half rotation of ever new products, so as to hit many productions for the strategic European food industry (mineral water, cheese, fruit juices, etc. ...). In return, the EU will grant a tariff quota at zero duty in favor of at least 20,000 tons of meat quality (as long as they fully comply with the EU criteria and without hormones). In the fourth year of implementation of the Memorandum the opportunity to advance to the second phase with the suspension of remaining U.S. sanctions and an increase in the share of import duty zero up to 45,000 tons is provided. The third phase consists of the verification of results from the EU and the U.S. and the eventual consolidation of the agreement before the WTO bodies.
- [22] European Communities-Measures Affecting asbestos and products containing asbestos; panel report WT/DS135/R of 18 September 2000; report of the Appellate Body WT/DS135/AB/R of 12 March 2001. The French Government had adopted a decree that included a prohibition of the manufacture, production, import, export and sale of asbestos fibers and products. In 1998, Canada, the largest exporter of asbestos, countered the adoption of the decree and gave rise to a dispute asserting that the French decree violated Articles III. 4, XI of the GATT and Articles 2.1, 2.2, 2.4, 2.8 of the TBT (Technical barriers to trade). The European Union, in favor of France, stated that the decree was not covered by the TBT Agreement and that it was compatible with Art. III.4. and XX letter. b of GATT, given the necessity of the decree. The panel concluded, in the light of the objective of health protection guaranteed by France (the total elimination of the risk associated with the use of asbestos fibers), there were no alternative measures with the same effect as those adopted from that country, and if hypothetically different measures could be used such measures did not eliminate completely but only partially the risk to human health. Therefore, the panel ruled that the French ban could be justified on the basis of art. XX letter. b of GATT. The same conclusion was reached by the Appellate body before which Canada had appealed the panel report. The necessity of the prohibition was established only after having ascertained the existence of sufficient scientific evidence about the health risks arising from the processing and marketing of asbestos (see paragraphs 8180-8183 of the report of panel).
- [23] The ban was placed by the decree of the Prime Minister no. 1133/96 of 26 December 1996 adopted pursuant to the Labor Code and the consumers Code in force since 1 January 1997.
- [24] See the initiatives Stop TB, Roll Back Malaria, Malaria medicines initiatives, International Partnership against AIDS in Africa, International AIDS Vaccine initiatives, Global Alliance for vaccines and immunization, on www.who.int. The verticality of the initiative concerns the specific indication of disease which is destined to be fought.
- [25] The global health partnerships are characterized by a very solid relationship between at least three subjects, among them at least one company and an intergovernmental organization that overcoming the traditional State limits is marked by transnationality. The sharing of objectives by the actors is associated with the establishment of government bodies and consultation that include representatives from both the public and the private and joint decision-making processes, the use of developed techniques in the private field for the achievement of social objectives. Private enterprise offers thus acquired expertise in research capacity, technology and development to meet the global challenges in the health; public institutions maintain a leadership role, directing the action on the basis of existing health needs.
- [26] See Who, *Principles governing relations between Who and Ngos*, 1987, Resolution of the World Health Assembly, Wha 40.25. In 2001, the WHO launched the Civil Society initiatives, with the objective of promoting greater cooperation and an effective dialogue with NGOs and civil society organizations.
- [27] Gavi is an independent organization which includes governments, institutions, and public health research, technical agencies, the pharmaceutical industry, WHO, the World Bank, and UNICEF. It was established in January of 2000 from an initial contribution of \$ 750 million from the Bill & Melinda Gates Foundation and has been heavily sponsored by WHO.
- [28] See Gavi joint board meeting, *Voting procedures*, 26 February 2008. The rule of consensus or, alternatively, the two-thirds majority is also provided for the votes of the commissions.
- [29] The commissions are six: Executive committee which has a preparatory role of the meetings of the board, Programme and Policy committee, Governance committee, Investment committee, Audit and finance committee, Evaluation advisory committee. The last five committees play an advisory role in respect to the board.
- [30] On the strategies of Gavi, cf. <http://www.gavialliance.org/about/strategy/>. Abandonment of rigidly vertical approaches that had characterized health policy of the first administrations of global partnership matched with a renewed attention to the strengthening of health systems.
- [31] See Gavi, *Guidelines for applications*, 14 June 2013 for HPV Demonstration Programmes 2013 and New and Underused Vaccines Support 2013.
- [32] Candidates of Irc are selected by the Executive Secretary but must be appointed by the Board of Directors on the basis of scientific excellence, integrity and independence by Gavi partners.
- [33] The Global Fund provides the support for programs aimed at the control of the three diseases "in ways that contribute to the strengthening of health systems", cf. The Framework document of the Global Fund to Fight AIDS, TB and Malaria, Geneva, 2002. The eligible interventions for funding are selectively directed to those system functions, such as training of health personnel or the supply of essential drugs for the implementation of the programs objectives such as prevention and treatment of the three mentioned diseases.
- [34] The Global Fund, *Developing a platform for joint funding and programming of health system strengthening with the World Bank and the Gavi Alliance. Policy and Strategy Committee Meeting*, 23-25 September 2009, GF/PSC 12/04.

- [35] See R. England, "Lessons and myths in the HIV/AIDS response", in *The Lancet*, 2009, p. 1647.
- [36] P. Rosiak, *Les transformations du droit international économique. Les États et la société civile face à la mondialisation économique*, Paris, 2003, pp. 253 ss.
- [37] See Aguas de Santa provincials, Santa Fe A. Suez and the Argentine Republic, ICSID Case No ARB/03/17, ARB/03/19, Order in response to a Petition for Participation as Amicus Curiae at 17 of March 2006. See J. Steffek, The evolution of civil society's legal status in international governance and its relevance for legitimacy of international Organizations, in J. Steffek C. Kissling P. Nanz (editors), *Civil Society Participation in European and global governance: a cure for the democratic deficit?*, Basingstoke, Palgrave Macmillan, 2008, pp. 41 ff. In the case Aguas del Tunari, the ICSID Tribunal found that the parties' agreement was a prerequisite for the participation of environmental non-governmental organizations in the process through the presentation of specific report. On 10 April 2006 the rules 32 and 37 of the Arbitration rules of Icsid have been modified in order to allow the participation of third parties in the processes before Icsid.
- [38] See *Methanex Corp v. United States of America*, UNCITRAL (United Nations on international trade law) Case, August 2005.
- [39] United States-Import prohibition of certain shrimp products, the Appellate Body report WT/DS60/AB/R of 2 November 1998.
- [40] See WT / DS 231/AB/R, 26 September 2002.
- [41] However, in the event that the reports are not considered relevant in this respect, the global judge does not have an obligation to state reasons on this point, nor power to appeal against the decision is attributed to non-governmental organization.
- [42] In the General Council meeting of 22 November 2000 on the communication of the Appellate body in the Abestos case, States had expressed some hostility towards this prospect, requiring a specific and more restrictive discipline for the intervention of amicus curiae, stating the need for an amendment of art. 16.1 of the Working procedures for appellate review, not being sufficient a jurisprudential extension of norms, and expressing impatience with what appears, at their say, a deterioration of the position, with respect to NGOs, of the Member States not standing and not intervening. The document containing additional rules for the submission of reports by the amici curiae is WT/DS/135/9 8 November 2000.
- [43] Janet E. Lord, David Suozzi, and Allyn L. Taylor, "Lessons from the Experience of U.N. Convention on the Rights of Persons with Disabilities: Addressing the Democratic Deficit in Global Health Governance", in *J.L. Med. & Ethics*, 2010, n. 38, pp. 575-576.
- [44] For example, the Military staff committee, an Advisory Committee supporting the activities that the Security Council performs in the maintenance of international peace and security; the Committee on the peaceful uses of outer space, established in 1959 by the General Assembly to promote international cooperation in the peaceful use of outer space; the UN Committee on Disarmament (United Nations disarmament commission) with advisory functions and powers of recommendation to the General Assembly, established by general Assembly resolution n. 502 of 1952. Important scientific committees of independent experts have been established by General Assembly resolutions, such as the Scientific Committee for the study of the effects of ionizing radiation founded with resolution no. 913 of 1955, whose analysis flows into the reports submitted every four years to the General Assembly of the United Nations.
- [45] In relation to the generality of products these are named General committees; in relation to specific product categories Food Commodity Committees. The Codex Commission is composed, in fact, of a network of 21 specialized committees, providing technical contributions, among which two are particularly active: the joint meeting of the FAO/WHO on Residue pesticides (Joint FAO / WHO meeting on pesticides residues - JMPR) and the Joint Committee FAO/WHO on Food Additives (Joint FAO/WHO expert committee on food additives - JECFA), cf. codexalimentarius.net/web/committees. The coordination committees check that the activities of the Commission corresponds to regional interests and to concerns of developing countries.
- [46] These are five Regional Committees for Africa, Europe, Latin America and the Caribbean countries, for Asia and the Pacific and the western Asia, established by resolution of the Economic and Social Council on the basis of art. 68 of the Charter of the United Nations. These five Regional Committees are composed of subsidiary bodies consisting of experts from government with the power to establish working groups and subcommittees.
- [47] These Committees are established on the basis of articles 46-50 of the WHO Constitution.