INSTITUT EUROPEEN DES HAUTES ETUDES INTERNATIONALES

THE ROLE OF HEALTH CRISES IN EU HEALTH POLICY

M.A Thesis

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July 2007

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LIST OF ACRONYMS AND ABBREVIATIONS

AI : Avian influenza

BSE : Bovine spongiform encephalopathy

ECDC : European Center for Disease Prevention and Control

EFSA : European Food Safety Authority

EU : European Union

FAO : Food and Agriculture Organization of the United Nations

HPAI : Highly pathogenic avian influenza

NGO : Non-governmental organization

OIE : World Organisation for Animal Health (Office International des Épizooties)

UK : United Kingdom

WHO : World Health Organization

WTO : World Trade Organization

PREFACE

This research was made possible by three institutions that began collaborating in October 2005. Upon enrolling at Bahçeşehir University in Istanbul,Turkey, I was able to attend EU Studies and International Affairs seminars at the Institut Européen des Hautes Etudes Internationales (IEHEI) in Nice, France, and the Institut für Europaische Politik (IEP) in Berlin, Germany. The opportunity to participate in this academic cooperation facilitated deeper understanding of EU issues, from both a historical and a present-day perspective.

I became interested in public health and health policies as a result of regular community volunteer activities and professional experience in administrative healthcare. One does not need to work in the field to understand the integral part healthcare plays in the lives of individuals, communities and government responsibilities. My personal goal in this research project was to learn more about the global nature of health activities and the emerging actors influential in global health policymaking. I was able to bring together information from the following fields of study: EU and health law, EU integration, international relations and public policy.

I would like to thank my parents for their encouragement, the IEHEI and CIFE for integrating Istanbul into the program, and the IEP for accommodating us during the busy term of German Council presidency. I would like to further extend thanks to my advisors Mr. Nizar Ben Ayed and Prof. Matthias Jopp for their feedback, to the administration at Bahcesehir University, to IEHEI President Claude Nigoul, Director Matthias Waechter, to CIFE Director Hartmut Marhold and to all permanent and participating lecturers of the program.

ABSTRACT

"THE ROLE OF HEALTH CRISIS IN EU HEALTH POLICY "

This study examines the history of issues surrounding, and current debates within the European Union Health Policy. This paper demonstrates how the EU health policy is a manageable window through which the larger debates about the nature and the direction of the EU as a whole can be understood. While health crises provided a strong impetus for health legislation, the legal basis for health policies was an unavoidable consequence of the integration process. By negotiating a balance between free trade and consumer protection member states demonstrated significant political commitment to push the EU forward.

I argue that creating an assertive European Union health policy is advantageous both to the union itself and to the entire world. At the regional level, social policies bring the Union closer to its citizens. At the international level, the European Union contributes further to international law and international cooperation. At the national level, EU coordinates health-related standards, policies and legislation of its member states. Furthermore, a strong commitment to research and development, and creation of funds for capacity and infrastructure at home and abroad strengthen EU's role as a global actor.

INTRODUCTION

A world which is increasingly interconnected physically, technologically, and economically offers both challenges and opportunities for protecting people's health. In the event of a public health crisis, for instance**,** the classical approach dictates that governments must devise national strategies on how to control and manage emergency response. Yet, "globalization has created a permeation of political ideas across borders, influencing economic practices, administrative and managerial concepts."[1] Therefore, globalization allows for a significant change in the role and influence of states. The term *governance* corresponds best to this so-called post-modern form of political organization[2]. In the state context, governance embraces action by executive bodies, national parliaments and national judicial bodies[3]. In the global context, governance acquires supranational and intergovernmental features, also allowing for state-like structures to participate in the decision-making or coordination of public policy. In areas such as public health, international cooperation among states, non-governmental and intergovernmental organization increases efficiency in response to crises.

Governance responses to globalization occur at local, national, international and global levels. The idea of *global governance* came to the field of health from the field of international relations which focuses on the emerging global order[4]. *Global governance* of health is different from *international governance* in that, the former involves not only states and international organizations, such as the World Health Organization (WHO), Codex Alimentarius Commission, but also regimes such as The World Trade Organization (WTO), and non-governmental agencies. In this respect the position of the European Union (EU) is uniquely significant. The Union's legal capacities and public policy activities qualify it under regional, international and global levels of governance. In fact, the EU uses regional influence to monitor these different levels and cooperate with the different actors.

The Union's legislation and activities in the field of public health are worth studying because of the deepening of the treaty reform process and the complicated nature of EU law. Amendments to treaties have implications for political structure changes, particularly as they

[1] Nsibambi, A. (2001) *Globalization and the State*, UN Conference
[2] Governance is a way in which human groups organize themselves to better address and achieve agreed goals.
[3] http://ec.europa.eu/governance/index_en.htm.
[4] Dodgson R., LK., Drager N (2002) *Global Health Governance: A Conceptual Review*, Geneva

relate to dynamics of institutional balance. Such developments within the EU correspond also to changes in the emerging global order, where the social responsibility of the developed world is strongly emphasized.

At the regional level, the EU is an integrated single market with abolished internal borders among its member states. It is also a political project where member states cooperate to achieve common goals regarding, not only economic stability and competitiveness, but also peace and solidarity. The Union's increasing technical and legal responsibilities in the health field has political implications. The EU is stepping up to its political responsibilities in the domain of public policy-making, traditionally an area under state authority. The European Union uses health and consumer protection as a means to bring itself closer to the citizens. However, EU public health regulatory framework aims to achieve a balance between the fast-paced reforms of the internal market, efficient internal trade and social policies which have been relatively neglected vis-a-vis economic growth. Syngellakis further posits that policy-concerning issues which distort the proper functioning of the common market, such as health policy, are better handled when coordinated at the EU level[5].

The EU uses a balance between soft coordination and hard laws to promote health measures. Where formal legal competence is lacking, resolutions, recommendations, communications, action plans and programs promote European standards in health at the national level. For instance, the EU adds to national policy responses of member states through coordination of disease surveillance programs, improvement of consumer protection practices and emergency public health systems.

EU laws and principles constitute a set of international laws, binding in nature for EU member states. International cooperation mechanisms, including international law, are crucial to respond to political, economic and technical challenges of globalization. In economic terms, the European Union has the capacity to complement national policies in order to overcome and make up for the negative effects of trade on health. Through its regional development policies and funds, the European Union focuses on a harnessed globalization in support of the weaker countries or regions to make competition fair. Politically, EU institutional set-up is based on a negotiation process, where every member state participates in formulating a response to political changes. Finally, supranational emphasis on creating

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[5] Syngellakis, A. (1999) *Environmental Europe*. In F. Carr & A. Massey (eds.), Public Policy in the New Europe: Euro-Governance in Theory and Practice, pp.88

networks, especially for information exchange, research and development can help overcome technical barriers.

As a global actor, the European Union has an increasing weight in world affairs as the world's largest trade bloc, as a political actor of significant regional influence and as a participant of bilateral and multilateral negotiations. The European Commission is represented at G8 summits in addition to the participation of its member states, France, Italy, the United Kingdom and Germany. The EU presence within G8 and the World Trade Organization gives it the opportunity to benefit from political priorities that it contributes to at the global level. Having contributed to the establishment of the World Trade Organization, the Union continues to support the WTO *Sanitary-Phytosanitary* Measures (SPS) and *Technical Barriers to Trade* (TBT) agreements. These agreements facilitate the protection of health while preventing trade protectionism. The Union is able to fundraise for health-related programs, and secure funds for infrastructure development worldwide through World Bank and the International Monetary Fund.

1. OVERVIEW OF EU HEALTH GOVERNANCE

Whereas EU health interests were originally limited to occupational health, standardization of medical records, training, and food labeling, over the years, various policies of the internal market have been linked with other public health policies. Legislation on public health and communicable disease were formulated as a response to crises particularly related to food safety. The Community suffered from a number of serious problems relating to food supply throughout the integration process. The classic example was the Bovine Spongiform Encephalitis (BSE) crisis, also known as the 'Mad Cow disease' in the 1990s, which contributed to significant legislative and institutional reforms. In the on-going treaty reform process, we can observe the evolution of EU public health measures from a limited internal market focus to a risk-averse and consumer-friendly approach while dealing case by case with problems that arise.

The EU article for public health, Article 152 EC, was formulated as a response to the ineffectiveness of competing EU institutions, as well as their inability to address the BSE crisis in a transparent manner. The crisis came in the immediate aftermath of the Single European Act. On the one hand, the Community was working on lifting barriers to trade with the recent Act. On the other hand, European countries that were importing livestock and meat products from the UK were alarmed by EU's inability to declare a union-wide ban on British beef. The first country to impose ban on imports was the UK's biggest market for beef exports: France. The decision to impose such a ban without widely accepted scientific evidence of an epidemic risk was considered illegal under the Single European Act. Article 152 was created to empower the EU institutions with legal authority to intervene in the public health field.

Another fundamental consequence of the BSE crisis was the adoption of a consumer protection article in the Amsterdam Treaty. The BSE crisis in beef cattle in the United Kingdom and other member states raised serious questions regarding the effectiveness of EU system for protecting consumers and the decision-making process. Until the EU adopted a consumer policy in Article 153 EC, the consumer dimension of the internal market had been less developed. Article 153 (1) provides that the European Community consumer policy must promote the consumers' interests by "protecting their health, safety and economic interests, and by improving their access to information, education and self-organization." Measures can

be either adopted in the context of the completion of the internal market or to support, supplement, and monitor national measures[6].

A new economic, social and political context in the 1990s promoted change in focus of EU policy towards consumers. The context for these changes in the EU was the Maastricht Treaty (TEU) establishing the Union. The international context pertinent to consumer protection was the World Trade Organization's Sanitary and Phytosanitary Measures (SPS) Agreement which came into effect at the end of the Uruguay Round. The Agreement on the Application of Sanitary and Phytosanitary Measures sets out the basic rules for food safety and animal and plant health standards[7]. Consumer policy was elevated as an EU policy goal and seen as a core component of the objective to improve the quality of life of EU citizens. Most important of all, the EU developed consumer protection laws, in part to address a sustained problem of the EU, which is the *democratic deficit*.

In hindsight, democratic deficit in the European Union is the result of a shift of competences from national to supranational level[8]. EU governments have delegated competences to create the single market and related policies to the EU institutions. Despite the growing influence of the European Parliament, this feature of European integration promoted an increase in the powers of the Commission as the executive body and its subsidiary bodies. Transfer of some competences played down the role of national governments, such as Justice and Home Affairs, moving the security agenda further away from the public[9]. Other than the relatively recent EU involvement in social policy areas, EU

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[6] Article 153 (Title XIV – Consumer Protection) of the Amsterdam Treaty

1. In order to promote the interests of consumers and to ensure a high level of consumer protection the EC shall contribute to protecting the health, safety and economic interests of consumers as well as promoting their right to information education and to organize themselves in order to safeguard their interests.
2. Consumer protection requirements shall be taken into account in defining and implementing other EC policies and activities.
3. The EC shall contribute to the attainment of the objectives referred to in paragraph 1 through:
   (a) Measures pursuant to Article 95 in the context of the completion of the internal market;
   (b) Measures which support, supplement and monitor the policy pursued by Member States
4. The Council acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee shall adopt the measures referred to in paragraph 3(b)
5. Measures adopted pursuant to paragraph 4 shall not prevent any Member State from maintaining or introducing more stringent protective measures. Such measures must be compatible with this Treaty. The Commission shall be notified of them.

Source: EC (1997) Consolidated Treaties incorporating changes made by the Treaty of Amsterdam signed on October 1997 (into force May 1999)

[7] http://www.wto.org/english/tratop_e/sps_e/spsund_e.htm, Understanding the WTO Agreement on SPS

[8] Follesdal, A., Hix,S., (2005) *Why is There A Democratic Deficit in the EU*, EUROGOV Papers C-05-02

[9] The Treaties of Amsterdam and Nice gave the Parliament powers of investiture in the procedure to appoint the Commission. Article 214 EC states that the Council of the European Union, acting by qualified majority,

agenda has widened to encompass long-term projects such as the Common Foreign and Security policy, in which citizens may not necessarily find any interest. To some extent, what citizens vote for and influence at the national level, have no guaranteed effect at the EU level. In order to establish a stronger link between the public interest and policies at the supranational level, the EU must focus on practical rather than technical topics. Policies in the area of consumer protection have more immediate consequences for citizens than the more technical measures on, for example, software patent.

In the EU context, policy has been the product of the elite and, especially in the early decades, Community policies reflected the values and preferences of the civil servants of the institutions. An elite-led politics could achieve the desire to have an efficient integration process, which does not allow the EU institutions enough time to be more responsive to the demands of the constituents. But public policy-makers should be concerned with problems of individuals as well as that of the business community. Governing structures should not only encourage participation of constituents but also be accountable. Therefore in order to reduce the democratic deficit, the EU governments have, on the one hand, increased the powers of the European Parliament since 1987. The co-decision procedure first introduced under the Maastricht (1992) was extended in the Amsterdam treaty's (1997) version of the procedure, where the Parliament is a coequal legislator with the Council. On the other hand, they have used social policy areas, such as consumer protection and health safety to promote citizen participation.

In the field of consumer protection, there are significant opportunities for EU institutions to connect with the citizens. In fact, one of the roles of consumer protection is to review business and other practices on behalf of the government. In some ways, as seen in the BSE crisis, the EU institutions can supervise and coordinate national practices, evaluating them based on collectively upheld standards on behalf of their constituents. Consumer protection is linked to the idea of consumer rights and to the formation of consumer-related agencies which can help inform consumers about choices, as required in Article 153 (1) EC. EU directives and regulations require member states to regulate consumer protection to particular standards. Regulation (EC) No. 2006/2004 of the European Parliament and the Council sets up an EU-wide network of national enforcement authorities with investigation powers[10]. Member states

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appoints the President of the Commission and this appointment must be approved by the European Parliament by simple majority.
(http://www.europarl.europa.eu/parliament/expert/staticDisplay.do?id=55&pageRank=11&language=EN)

[10] EU Consumer Affairs, http://ec.europa.eu/consumers/prot_rules/admin_coop/index_en.htm

are also expected to produce regular consumer reports, allowing for an increase in the transparency of decision-making.

i) ADOPTION OF ARTICLE 129

European Community's involvement in combating health issues has been marked by a combination of increasing responsibilities and strict limitations on the Commission to act outside listed areas of health, e.g. health crisis (Randall, 2001:95). The executive and legislative competences of EU institutions were first delimited in the early 1990s when the Community established the European Union with the Maastricht Treaty (TEU) in 1992. The introduction of Article 129 in the Maastricht Treaty, defined to some extent the EU role in health.

Article 129 provided and expanded role of EU-level disease prevention activities. The Article provided and expanded particularly the Commission's role work on behalf of the European Union to "promote cooperation among member states and ensure a high level of health protection." [11] Article 129 was introduced as a result of necessary cooperation with member states and other international organizations in the sphere of public health. Article 129 (1) formalized the expansion of EU-level activity which states that 'the Community can direct its actions at the prevention of diseases, promotion of research and of health information'. The Article established obligations on the Commission by asserting that 'health protection requirements shall form constituent part of the Community's other policies'. Therefore,

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[11] Article 129 of the Maastricht Treaty (TEU)- the public health article

1. The Community shall contribute towards ensuring a high level of human health protection by encouraging co-operation between Member States and, if necessary, lending support to their action. Community action shall be directed towards the prevention of diseases, in particular the major health scourges, including drug dependence, by promoting research into their causes and their transmission, as well as health information and education. Health protection requirements shall from a constituent part of the community's other policies.
2. Member states shall, in liaison with the Commission, coordinate among themselves their policies and programs in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination.
3. The Community and the Member States shall foster cooperation with their countries and the competent international organizations in the sphere of public health.
4. In order to contribute to the achievement of the objective referred to in this Article, the Council:
   - acting in accordance with the procedure referred to in Article 189b, after consulting the Economic and Social Committee and the Committee of the Regions, shall adopt incentive measures, excluding any harmonization of the laws and regulations of the Member States.
   - Acting by a qualified majority on a proposal from the Commission, shall adopt recommendations.

Source: Treaty of Maastricht – TEU- EUROPA web site

Article 129 was perceived as a flanking policy, a policy governing cooperation in areas that have no direct impact on the four freedoms and in which EU activities are limited to coordination, whereas harmonization is left to member states (Randall, 2001:13). Furthermore, member states are placed under an obligation to coordinate policies and programs with the Commission. In order to incorporate broadly defined responsibilities into its work programs, the Commission also referred to Article 3 EC, where the Community activities are urged to "…contribute to the attainment of a high level of health protection."[12]

The most important aspect of Article 129 was its introduction of the new decision-making procedure. Through Article 129, the Commission was granted a general power of initiative to propose measures that promote member state cooperation in health-related fields. Article 129 (4) provided further legal basis on which the Council and Parliament may adopt 'incentive measures' through the co-decision procedure or adopt recommendations on a proposal of the Commission based on the qualified majority voting rule[13].

Co-decision is the general procedure of law making where the Commission proposes and the Council decides under a procedure giving growing influence to the European Parliament, according to the procedure in Article 251 EC. The procedure is called "co-decision" or "conciliation procedure" because the EU Parliament is allowed to propose amendments and to veto the proposed laws[14].

Despite the introduction of the co-decision procedure and a legal basis in the Treaty for public health, debates over the EU democratic deficit and lack of transparency heightened during the Bovine Spongiform Encephalopathy (BSE) crisis.

ii) PUBLIC HEALTH CRISIS IN THE EU

Spongiform Encephalopathy is a neurological disease found in ruminants, such as sheep. The disease causes brain degeneration and death in the infected animals. A similar disease was discovered in cows only in 1986, when there was a serious outbreak in meat farms in the United Kingdom. Bovine Spongiform Encephalopathy (BSE) was then also widely known as the *Mad Cow disease*. When the UK government discovered Bovine Spongiform Encephalopathy (BSE) they placed a ban on ruminant feed produced from the carcasses of

[12] Randall, E. (2001) *The European Union and Health Policy*, Palgrave MacMillan, pp.113
[13] Hervey,T., McHale,J. (2004) *Health Law of the European Union*, Cambridge University Press, pp.75

other animals. The original ban in the UK caused the price of the British meat and bone-meal feed to drop, making it more attractive for international trade. Prices fell both in response to declining domestic consumption and the implementation of the *General Agreements on Tariffs and Trade* (GATT) reforms, which proposed liberalization of agricultural trade through reduced border protection. Meanwhile, the value of UK beef exports more than doubled between 1985 and 1995, international exports increased but wide-scale trade embargoes did not take place until the end of the 1990s. The World Organization on Animal Health (OIE) followed the spread and the geographic distribution of the crisis. By 2004, in addition to the UK, 22 countries from Europe, North America and Asia reported BSE in farmed cattle[15].

BSE crisis reached a peak in 1996. The Commission published a Communication to the European parliament and the Council on *Food, Veterinary and Plant Health Control and Inspection.* The Communication established a Food and Veterinary Office (FVO). The same year scientists discovered a link between encephalopathy in sheep to cattle as well as the human variant nvCJD. As a consequence of shortcomings of national action, the disease had jumped species from ruminants to humans.

The crises pointed out to the complexity of Community legislation on Foodstuffs provisions and the Commission's ineffective food inspection and control systems. In fact, there were no EU inspections between 1990 and 1994. Furthermore, EU health policies were dispersed between various legislative instruments, contributing to the ineffectiveness of supranational institutions. At the EU-level there was a need for integrated regulatory food laws. At the national level, there was a strong case for "opportunistic exporting" in response to bans imposed domestically on feed in the UK. The failure of UK government to control the spread of BSE and the outbreak of human disease variant nvCDJ decreased consumer confidence in British beef Worldwide.

There was yet another dimension to the crisis concerning the common market rules. The BSE crisis led member states to undermine the credibility of EU regulatory system and to challenge the rules of the internal market by raising barriers to trade inside the EU. As early as 1990, France, the biggest market for British beef, decided to impose a ban on imports from UK[16]. The unilateral French ban was suspected as trade protectionism and considered illegal,

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[14] Conciliation procedure in Article 251 EC, http://eur-lex.europa.eu/en/treaties/dat/12002E/htm/C_2002325EN.003301.html

[15] Kimball, AM.,Arima,Y., Hodges, JR. (2005) *Trade Related Infections: Farther, Faster, Quieter*, Globalization and Health 2005, Vol.1, No.3

[16] BBC News http://news.bbc.co.uk/onthisday/hi/dates/stories/may/30/newsid_2491000/2491407.stm

as there would be no scientific evidence for risks to human health until the discovery of nvCJD in 1996. The Community was under political pressure from member states, businesses and EU-trade partners. Bans were temporarily lifted in return for tougher health controls. However in 1996 EC Decision 96/239/EC collectively prohibited the export of live animals from the United Kingdom. There was an immediate worldwide ban on all British beef exports. This was lifted in 1999 by all countries except France and Germany which lifted the ban in 2000.

The BSE crisis raised serious questions as to the transparency of the EU system for decision-making. The Commission was highly criticized in the Parliamentary Debate in the following year.

iii) INSTITUTIONAL RESPONSE TO THE BSE CRISIS: THE MEDINA REPORT

The Medina Report came out of the parliamentary committee debate in 1997, criticizing the mismanagement of the BSE crisis[17]. The report underlined the original timeframe of the crisis as 1990-1994. The Commission was accused of concealing the truth and the UK government had limited the Commission investigation on the dramatic increase in BSE affected livestock. The Commission, despite the prevalence of disease between 1990 and 1994 issued Decision (96/293) to prohibit the UK from exporting live cattle, semen, embryo or meat of bovine animals only in March 27, 1996. The directive was delayed because the UK objected to the prohibition on the grounds that it contradicted the principles of the borderless common market.

UK animal feed contained meat-based meal to ruminants and yet they were exported to third countries, even at doubling rates, after the 1990 ban. Thus providing evidence that "commercial and trade considerations had been kept superior to public health concerns" and that the Commission was under heavy influence of national pressure from the UK[18]. The Commission failed to meet its responsibilities to EU citizens and non-EU countries in terms of food safety. The BSE example also showed that the subsidiarity principle may be used as an excuse for errors of failure on the part of Council or the Commission to implement or monitor Community Law[19].

[17] Randall, E. (2001) *The European Union and Health Policy*, Palgrave MacMillan, pp.88
[18] (EP Medina Report 1997a: Para. 1.C)
[19] (EP Medina Report, 1997a: Para. 4.3)

The Medina Report concluded that the division of public health responsibilities among Commission Directorates and the compartmentalization for the Commission's health and consumer protection work had "hampered the co-ordination and efficiency of the services concerned and facilitated the shifting or responsibility of maladministration between the various services of the Commission".[20]

In the aftershocks of the BSE crisis, the ECJ judgement against the UK and business actions have provided the Commission with a considerable amount of responsibility to amend the Treaties through proposals to expand legislation. There was also a consensus among the institutions to increase the influence of the European Parliament. Once Article 129 was amended (now Articles 152 EC) at Amsterdam in October 1997, more significant steps were taken towards to involve the European Parliament in the decision-making process[21]. The Parliament was perceived as a necessary actor in overcoming the crisis while acknowledging the short comings resulting from 'contradictions of the system of EU single market governance.'

National intervention mechanisms which are deemed incompatible with free movement should be transferred to Community level.The European Parliament observed that the Commission lacked transparency and organizational capacity in its actions. The Parliamentary debates also emphasized a need for independent multidisciplinary committees to be able to combine efforts in research, surveillance and monitoring crises. Otherwise, the supranational structure is responsible for measures that apply to market movements without distorting the internal market in all member states.

1.2 FOOD SAFETY and HUMAN HEALTH

i) FOOD LAWS

Until the outbreak of the BSE crisis, many of the Community's rules relating to food safety regulation were mainly created on an *ad hoc* basis or developed in the jurisprudence of the European Court of Justice. The BSE crisis, Avian Influenza, much like E-coli and salmonella crises, justified regulatory responses to food health. After the Mad Cow crisis in the United Kingdom, it was no longer appropriate to leave the responsibility for food

[20] EP Report, 1997a, EP BSE Inquiry Report http://www.mad-cow.org/final_EU.html
[21] Randall ,E. (2001) *The European Union and Health Policy*, Palgrave MacMillan, pp.155

regulation to national governments, because changes in food production and food retailing affect the cross-border supply of food[22]. Communicable disease has a staggering impact on consumer confidence and other economic indicators. Since food-borne disease does not respect borders, the regional institutions of the EU are most appropriate for monitoring the standards and movement of foodstuffs. Food legislations are adopted by qualified majority.

EU developed new legislation and more effective Community measures, such as control methods with Regulation (EC) 882/2004, inspection procedures and certification requirements. First, actions had to be grounded on solid legislative means and principles, in order to ensure that new measures complied with existing EU standards. Additionally, legislation was needed to help in coordinating animal health and food safety in international relations with third countries and international organizations. At the last stage, the institutions and member states agreed on certain bodies and organizations to implement and monitor the surveillance systems[23].

Ensuring food safety, safety of agricultural products and protecting consumer protection are instrumental in upholding quality of life. Food is a relatively covered sector in EU law, mostly by means of regulations and objective-defining directives that apply to all categories of foodstuffs. Regulations are directly applicable, becoming the law of the member state as soon as they are enacted. For example, a company in a particular member state must immediately comply with an EC regulation, if there has been no national law relating to its field. This immediacy has advantages particularly when public health protection is concerned. On the other hand, binding directives have a delayed effect, because member states are left to implement legislations by means they consider appropriate. This particular feature of directives allow for national customs and traditions to play a role when legislating in the food sector, where cultural methods are important in production[24].

When a directive or a regulation is adopted, the Commission starts the process, the Council has to adopt a 'Common Position' and finally there must be agreement by both the Council and the European Parliament to the proposed legislation. If they disagree, a *Conciliation Committee* is established to try and renegotiate an agreed document. For food issues, the Commission has established *the Standing Committee on the Food Chain and Animal Health* (SCFCAH) composed of General Food Law, Biological Safety, Controls and

[22] FAO Policy, Legal and Institutional Aspects, http://www.fao.org/docrep/003/X3680E/x3680e03.htm
[23] COM (2005) 2005/0042 http://ec.europa.eu/health/ph_overview/Documents/com_2005_0115_en.pdf
[24] Skogstad,G. (2001) *The WTO and Food Safety Regulatory Policy Innovation in the European Union*, University of Toronto, Journal of Common Market Studies, Vol. 39, No.3, pp. 485-505

Import Conditions, Animal Health and Welfare, among other sections[25]. EU Food Safety laws regulate how farmers produce food, how food is process and how it is sold. EU also has laws in place regulating the safety of food imported into the EU from it trading partners.

Food measures were first introduced in the Rome Treaty (1957) which sought to eliminate quantitative restrictions between trading member states. The first food-related Council Directive of 1962 (amended by Directive 76/399/EEC) concerned food coloring. The directive was only partial harmonization and therefore not specific about which foods or what levels. Eventually, differences between various national legislations were considered significant barriers to trade. The *Elimination of the Technical Obstacles to Trade* and *Industrial Policy Program* set out various areas of harmonizing legislation. Both program proposals failed because member states did not want the EU-level controls to replace national controls. For example, the program proposed in 1969 included legislation regarding dairy products and alcohol.

The internal market requires at least a minimum protective standard based on what is required at the EU level. For example, food produced and marketed in one member state must be accepted in all other member states. EU, via the principle of mutual recognition sets nationally imposed standards and labeling requirements in response to consumer protection demands. Policy harmonization and the principle of mutual recognition are the preferred strategy to reduce trade barriers and protect public health and safety in order to avoid economic costs to trade via restrictions[26]. In the famous 'Cassis de Dijon' case that helped formulate the previous principle, the ECJ stated that member states could not refuse entry to products even if their national legislation prohibited it. The alcohol content of cassis liquor 'Cassis de Dijon' marks the Commission's new regulatory standards[27].

Article 30 EC allows member states to prohibit the marketing of products from other EU countries to protect public health but only where there is scientific evidence and as long as it does not have as purpose restriction on trade. The overall impact of decisions focused on harmonization on only areas where barriers to trade could be justified. Article 226 EC was adopted to prevent member states from discriminating other states' products.[28]

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[25] EU food laws, http://europa.eu/scadplus/leg/en/lvb/f80501.htm

[26] Vogel (1995), *Trading Up: Consumer and Environmental Regulation in a Global Economy*, Harvard University Press, pp.55

[27] Cassis de Dijon Case No. 120/78 where Germany used health measures as an excuse for trade protectionism against French khyrr champagne

[28] Commission Communication 'Completion of the Internal Market'

ii) LINKING FOOD POLICY TO HUMAN HEALTH PROTECTION

In a number of judicial review proceedings concerning secondary laws, the European Court of Justice was asked to rule on a choice of legal basis between internal market laws and legislation promoting or protecting health. Common agricultural policy related cases were most commonly presented to the Court. There are ironies in establishing a legal basis over another, as some laws of the internal market place direct limitations on health policies via the procedure required in the provisions of the Treaties, such as co-decision or consultation. The choice of legal basis is important particularly in determining the role of the Parliament in the decision-making.

The European Court of Justice has in most cases preferred specific Treaty provisions (for example environmental or agricultural bases) over general ones. But more specific articles, such as Article 37 (ex Article 43) on Food law (necessitating the consultation of the Parliament) is preferred over a more general legal basis such as the Article 100a on production and marketing of agricultural products (subject to the co-decision procedure).[29]

The primary management of BSE was claimed by Directorate General for Agriculture. Article 39 (now Article 33) is the basis for agricultural products, but Article 37 EC is also significant component of the common agriculture and health-related agricultural measures. Article 37 EC constitutes the appropriate legal basis for all rules concerning the production and marketing of the agricultural products listed in Annex II to the Treaty, which contributes to the implementation of one or more objectives of the common agricultural policy listed in Article 39 of the Treaty (now Article 33 EC). The protection of health contributes to the attainment of the objectives of the common agricultural policy which are laid down in Article 39(1) of the Treaty, particularly where agricultural production is directly dependent on demand amongst consumers who are increasingly concerned to protect their health.

Regulation No 820/97 establishes a system for the identification and registration of bovine animals and labeling of beef and beef products. The regulation is essentially intended to attain the objectives of Article 39 of the Treaty, in particular the stabilization of the market and also in regulating the conditions for the production and marketing of beef and beef products. There is additionally a component that aims to improve the transparency of those conditions during

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[29] Hervey, T; McHale, J (2004) *Health Law and the European Union*, Cambridge University Press, pp. 93

the identification, registration and labeling procedures and was therefore rightly adopted on the basis of Article 37 of the Treaty. However, Article 37 (ex Article 43) did not provide the Community with necessary legal means to form an action on food safety, particularly as it needs to relate to protection of human health in the BSE crisis. Article 37 also does not contribute to enhancing consumer confidence in EU food safety. On the other hand, the protection of health in Article 152 (1) contributes to the attainment of the objectives of the common agricultural policy laid down in Article 39(1) of the Treaty, particularly where agricultural production directly depend on demand among consumers who are increasingly concerned to protect their health.[30]

It became evident during the BSE crisis that the European Union needed structural reforms to tackle social policies. The European Parliament criticized Commission's failure to separate consumer protection work from the administration and regulation of Union agriculture and agricultural policies. In terms of establishing a link between human and animal health (with a view to food health and impact on consumer protection) the adoption of Article 152 (4) was necessary.

The close association between food policy and health, along with the extension of Community competency into the area of social policy permitted the Union to develop an overt health policy (Moon, 2000: 148).

iii) PUBLIC HEALTH IN THE TREATIES: Article 152

Article 152 amended Article 129 TEU to stress transparency in Community action and strengthen links between related policy areas, such as internal market and consumer protection, and also scientific research.

Article 152 (1) EC articulates the need to 'mainstream the protection of health in all EU policies'. A more complete picture of the Community's power to adopt measures that have an impact on human health protection or promotion in the member state must therefore take account of the various EU policies that have implications for such health protection and promotion. Therefore, according to this article, measures with health implications have lawfully been adopted on the basis of the Treaty provisions such as the following: "Article 37 of the Common Agricultural Policy, Article 71 of Transport, Article 175 of Environmental

[30] EP Common Position, http://www.europarl.europa.eu/commonpositions/2000/pdf/c5-0270-00_en.pdf

policy, Articles 152 of Public Health and Article 153 of Consumer Protection, Article 181 Development Cooperation, and Article 133 in employment strand of EU Social Policy."[31]

Upon the establishment of Article 152, the legal basis for public health, Commission considered that Article 152 of the Treaty is the appropriate legal base for the Council Regulation 820/97/EC (Case C-269/97), concerning bovine meat registration, labeling and handling, since it deals with measures in the veterinary field, which have as their direct objective the protection of public health. On the other hand, the Council wanted to use Article 37 in cases where food safety and human health must be handled concomitantly. Where a measure has several objectives linked with each other, the measure must be based on the various relevant Treaty provisions, provided that they are compatible. The European Court of Justice brought the issue to an end with the adoption of a *double legal basis* in such cases.

Three years after the Amsterdam Treaty, in 2000, the European Court of Justice ruled and the Council unanimously voted on adding Article 37, pressured the Commission to acknowledge and accept a double legal base, with the condition to guarantee the Parliament's prerogatives, acquired under Article 152. A double legal basis was used in Regulation EC/1760/2000 on beef labeling and traceability. According to the Regulation; Article (1) all Member states shall establish a system for the identification and registration of bovine animals, Article (5) all member states shall keep computerized databases and, Article (3) the Commission and the competent authority of the Member States concerned shall have access to all data information covered.

Article 152 (4) provided the procedure through which EU institutions may act in the interest of public health. Furthermore, Article 152 delimits the types of measures that may be enacted. The types of legislation laid out are 'measures' and 'incentive measures'. Measures include harmonization regulations, directives or other acts. Incentive measures are designed to protect and improve human health, "excluding any harmonization of the laws and regulations of the Member States."[32]

Article 152 adopts measures in two further areas. These are 'measures setting high standards of quality' and 'safety of organs and substances of human origin', which refer to well-established EU policy. Additionally, extend the EC powers based on Article 37 EC concerning the effect of common agricultural policy: 'measure in the veterinary and phytosanitary fields which have as their direct objective the protection of public health'.

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[31] Hervey,T., McHale,J. (2004) *Health Law and the European Union*, Cambridge University Press. pp.85

[32] Hervey, T, McHale,J (2004) *Health Law and the European Union*, Cambridge University Press, pp.79

The double use of Article 37 in conjunction with Article 152[33] was justified by the fact that the primary objective of the proposed directive is to protect public health, as well as tighten animal health protection measures.

2. LEGISLATION OF THE INTERNAL MARKET (contributing to Health Policy)

EU soft law measures have been gradually transformed into hard laws over the years. The Union's public health initiatives started out as informally prescribed responsibilities, but within the last two decades the Union's legal capacity in the health fields developed significantly. Public policy coordination may have shifted from the state to other global actors, but international health governance continues to be firmly state-defined. The complementary supranational governance structure of the EU creates opportunities for

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[33] Article 152- the revised public health article following Amsterdam Treaty

1. A high level of human health protection shall be ensured in the definition and implementation of all EC policies and activities. EC action, which shall complement national policies which shall be directed towards improving public health preventing human illness and diseases and obviating sources of danger to human health. Such action shall cover the fight against the major health scourges by promoting research into their causes their transmission and prevention as well as health information and education. The EC shall complement the Member States' action in reducing drugs-related health damage including information and prevention.
2. The EC shall encourage cooperation between the Member States in the areas referred to in this Article and if necessary lend support to their action. Member states shall in liaison with the Commission coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may in close contact with the Member States take any useful initiative to promote such coordination.
3. The Community and Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health.
4. The Council, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee and the Committee of the Regions shall contribute to the achievement of the objectives referred to in this Article through adopting:
    (a) Measures setting high standards of quality and safety or organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures.
    (b) By way of derogation from Article 37, measures in the veterinary and phytosanitary fields which have as their directive objective the protection of public health;
    (c) Incentive measures designed to protect and improve human health, excluding any harmonisation of the laws and regulations of Member States.

   The Council acting by qualified majority on a proposal from the Commission may also adopt recommendations for the purposes set out in this Article.
5. EC action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of services and medical care. In particular, measures referred to in paragraph 4(a) shall not affect national provisions on the donation of medical use of organs and blood.

Source: EC (1997) Consolidated Treaties incorporating changes made by the Treaty of Amsterdam signed on October 1997 (into force May 1999)

increased cooperation that may help national governments to overcome the pressures of internal market and promote the push towards national agenda inclusive of public health.

The strong internal market foundation of EU integration initially limited EU health policies to measures that prioritize free trade over health. The complex relationship between trade and health, however, made it inevitable that health would be considered in the Treaties of the Community, especially because the four movements established in the Single European Act (1986) among member states have implications for communicable disease control.

Over the years, EU's governance achieved a relative balance between social and business interests, reflected in the institutional structures through legislative and decision-making procedures[34]. EU's health policy has developed to include a broad concept of health based on the World Health Organization definition, addressing not only the basic human right to health, but also the universally accepted value 'good health for all'[35]. In this manner, the EU has coupled health-related issues with various policies of the internal market.Article 3 EC states that "the activities of the Community shall include a contribution to the attainment of a high level of health protection[36]." Furthermore, the EU health policy has evolved to include not only occupational health but also consumer protection and eventually communicable disease management through legislation related to human health, animal health and food safety. The EU complements national policy responses, where necessary, through coordination of policies. Coordination requires minimum harmonization. Thus, member states have wider competences in the workings of health policies. Coordination also brings other parties, such as "competent international organizations in the sphere of public health" according to both Article 129 (3) and its amended version Article 152 (3).

On the other hand, harmonization of health laws requires member states to replace their existing legislation with laws created at the EU-level. If regulations are issued then the effect is immediate, if directives are issued then member states can delay the transposition and use any means to achieve the same goals set out in the EU legislation. Although setting quality and safety standards for products is practiced at the EU-level, maintenance of healthcare

[34] Hervey, T, McHale,J (2004) *Health Law and the European Union*, Cambridge University Press:333

[35] The most widely accepted definition of health is that of the World Health Organization (WHO), which states that "health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity". In more recent years, this statement has been modified to include the ability to lead a "socially and economically productive life." (Geneva, 1946. Accessed October 30, 2006.)

[36] Nice Treaty http://europa.eu.int/eur-lex/lex/en/treaties/dat/12001C/htm/C_2001080EN.000101.html

systems, budgets allocated to services and choice of medical technology rests within the scope of the member states[37]

Much of EU law has been taken up with the search for ways of resolving the tensions and balancing the interests of integration and differentiation, of harmonization and diversity, of centralization and localization. Resistance to harmonization was due to a combination of national concerns over the loss of political authority at Member State level, and the lack of an adequate political will at EU level. Member states have used the subsidiarity principle to weakening EU-level health policymaking. The legal framework for health in the European Union is provided by the Treaty articles, secondary laws and case laws from the European Court of Justice. The success of the European Union has been its incremental transformation of soft laws (secondary legislations) into hard laws, such as laws in the Treaties. Health-related issues were addressed by means of non-binding communications, opinions, recommendations along with binding directives and regulations of various policy areas which were coupled with health. Eventually, creation of Article 129 and its amended version Article 152 became necessary in order to uniformly address health risks within the internal market.

Hervey and McHale (2004) have summarized this transformation under "old-style" and "new style" harmonization[38]. This section will tackle the developments from Hervey and McHale's perspective but classify the transformations under the headings 'old style governance' and 'new style governance', summarizing coordination efforts and the eventual harmonization of health-related legislation.

i) OLD STYLE GOVERNANCE

One of the fundamental features driving the European integration process, the internal market holds a significant position in the EU legal order. What Hervey and McHale (2004) describe as the 'Old Style Harmonization' approach is "making provisions for a limited regulatory response to deregulatory mechanisms of internal market". Simply put, even if limited, regulatory attempts are made to balance the negative effects of trade protectionism which contradicts with health standards in the internal market. In the beginning, the internal market was all about trade and free movement of goods (goods, capital, labor and persons).

[37] Byrn Report, 2004 http://ec.europa.eu/health/ph_overview/Documents/byrne_reflection_en.pdf

[38] Hervey, T, McHale,J (2004) *Health Law and the European Union*, Cambridge University Press, pp.86-89

Any social policy regime in the EU had to take place within the framework of the internal market. Any quantitative restrictions of goods moving between member states, workers moving within the Community, and custom duties were prohibited to be able to promote integration and create a single market. The EU pursued harmonization to prevent the disruption of intra-Community trade during such national measures to protect public health, for example a rule banning certain additives in foodstuffs. Nevertheless, different health protection standards imposed at national level continued to create a barrier to the creation of a single market. The most important example is the Cassis de Dijon case in 1979.

A second feature of EU governance is the *comitology*. This feature was heavily criticized during the BSE crisis, due to the lack of transparency in its functions. The system of comitology has no basis in the Treaties and allows EU supranational activities while securing some national interests. Although the Commission must carry out the research on scientific developments through powers delegated to it by the Council, in practice the Commission works with various committees. National representatives who take part in the committees have power over the final decisions of the Commission.

Old Style governance did not work efficiently. First of all because member states resisted adoption of EU-level legislation, and secondly, governments of all members had to agree on standards in order to put them in place. The integration process was therefore slowed down due to both a lack of political will and due to the inefficiency of the decision-making procedure. Lastly, there was a serious lack of transparency in all the negotiations concerning adoption of measures, standards and legislation. Everything was happening within the bureaucratic set-up of the European Union. However, since 1999 the formal committees have to report to the EU Parliament with agendas and minutes.

ii) NEW STYLE GOVERNANCE

The Council Resolution of April 1975 provided for, among other rights, the right to protection of health and safety[39]. Harmonization at this stage involved a minimum of standards to protect essential health and safety concerns. Community policy on health and safety and in particular EC health and safety law developed substantially after the Single European Act was adopted. Overall, the political atmosphere slowly became conducive to

[39] on a preliminary program of the European Economic Community for a consumer protection and information policy OJ 1975 C 92/1) eur-lex.europa.eu

consumer-related measures in parallel with the political and social spirit of the 1990s. Strengthening consumer protection accelerated EC harmonizing legislation.

A lack of progress regarding the creation of a single market led the Community in the mid-1980s to consider a more thorough approach to the objective of removing trade barriers. The aim to create a single European market was primarily set out in the Commission White Paper COM (85) 310 of June 1985, also called Article 14, regarding the completion of the internal market. The paper was incorporated in the revision of Rome Treaty by the 1986 Single European Act (SEA). The preamble to Single European Act states a focus on two objectives of Treaty revisions, "to improve the economic and social situation by extending common policies and pursuing new objectives" and "to ensure a smoother functioning of the Communities"[40]. Member States could set higher regulatory standards, but must recognize the standards of other members, as long as they meet the EU minimum requirements. The lower minimum requirement is a Community standard according to Article 95 (4) EC.[41]

The Single European Act (1986) brought about significant reforms in institutional set-up and functions, namely the decision-making procedure within the Council, powers granted to the Commission to implement rules laid down by the Council, enhancing European Parliament's powers by assent procedure and extending the Community responsibilities. Article 118a EC authorized the Council to take the minimum requirements with a view to "encouraging improvements, especially in the working environment, as regards to the health and safety of workers"[42].

Furthermore, the Act provided for more cases where the Council can take decisions by qualified majority voting, such as common trade and common agricultural policy. By extending the qualified majority voting to measures designed to establish the Single Market, frequent delays to decision-making were avoided. The common market rules and free movement were the guiding principles, but other related policy areas were included in the agenda, such as occupational health.

As a consequence for Community regulations leading to the adoption of Single European Act, provisions of the Treaty Article 100 EEC (now Article 94 EC) called for Directives 'for the approximation of laws, regulations or administrative provisions of the Member States as directly affecting the establishment or functioning of the market'[43]. Health was taken as a

[40] SEA Preamble http://europa.eu/scadplus/treaties/singleact_en.htm

[41] Hervey, T, McHale,J (2004) *Health Law and the European Union*, Cambridge University Press:59

[42] http://europa.eu/scadplus/treaties/singleact_en.htm

[43] Clarified in the ECJ case on Tobacco Advertising, Case No.

component of the internal market to the extent that health-related issues, for example occupational health, directly placed limitations on economic and social development of the common market. The community was then to coordinate occupational health of the common market labor force among the member states[44].

The Single European Act improved this method of protecting workers by further introducing Article 100a (now Article 95 EC). Most control laws have been enacted as internal market measures under Article 100a (now Article 95EC) using the argument that differing national legislations must be aligned to facilitate the free movement of goods and services within the internal market. For example, in case of food safety laws, Community competence to create and maintain the internal market and to protect consumers within it forms the relevant legal basis, Article 95 EC. Article 100a allowed "the Council to adopt harmonization measures by qualified majority voting procedures, and cooperating with the European Parliament". The Community took Article 100a 'as base for a high level of protection in its harmonization proposals on health, environmental protection, safety and consumer protection.' Both Article 100a and amended version Article 95 EC however changed the unanimity procedure required in Article 100EEC to the qualified majority procedure. This procedure for decision-making among the Member States, improved on the time necessary to adopt regulations, creating a more efficient way to address health crises.

Article 129 of the Maastricht Treaty provided the legal basis of public health action and some inadequate grounds for the development of common communicable surveillance arrangements (FT: particularly common action against HIV/AIDS).

3. DEVELOPING RISK ANALYSIS APPROACH

Several reports were published following the parliamentary debate on food health crisis. The Green Paper on *Food Law* (1997) and the Commission Communication on *Consumer Health and Food Safety* (2000) outlined the necessity of a new 'Risk Analysis plan' clearly defining the three stages of risk assessment, management and communication.

In 1998, EU institutions agreed on the Commission's proposal to create of new overall single framework program for more efficient and streamlined administrative arrangements, a position to support a wider variety of more flexible public health initiatives across the EU and

[44] Hervey, T, McHale,J (2004) *Health Law and the European Union*, Cambridge University Press:54

for budgetary reasons. General objectives of the program were founded in the Article 2 of the decision and set out three priorities, improve health information and knowledge, respond rapidly to health threats and address health determinants. The actions are to be implemented by EU-level support for activities in cooperation with the member states. These activities included monitoring and rapid reaction systems, health determinants, legislation and consultation, as well as developing and maintaining network for exchange of information on best practices.[45]

Regulation 178/2002/EC was proposed under a Commission White Paper in 2000. After many discussions, the adopted regulation laid down the general principles and requirements of food law. With the adoption of the regulation, the European Parliament established the *European Food Safety Authority* (EFSA). The regulation stipulated that EFSA should be an independent scientific source of advice, information and risk communication in the areas of food and feed safety. EFSA's focus is mainly two areas of work which are risk assessment and risk communication. Risk management measures and the operation of food control systems are not under EFSA's responsibilities and remain the responsibility of the European Commission and Member States. EFSA's Scientific Committee, its Scientific Expert Panels and other expert groups provide risk assessments on all matters linked with animal health and welfare and plant protection. EFSA's Scientific Expert Panels provide the European Commission, the European Parliament with a scientific basis on which to base legislation and policies related to food and feed safety.

A further requirement is to set up a network enabling close collaboration with similar bodies in the European Union Member States. Along with a definition of food, the concept of 'risk analysis' was formally adopted as the basis of food law, based on Articles 37, 95, 133 and 152 (4) EC, a policy covering the entire food chain. Precautionary principle also promotes the concept of risk analysis. In the Regulation, the responsibility for risk assessment is clearly separated from that of risk management[46].

Regulation (EC) no 851/2004 of the European Parliament and of the Council of 21 April 2004 established the *European Centre for Disease Prevention and Control* (ECDC) in 2005. According to the Article 3 of the founding Regulation, ECDC's mission is to identify, assess and communicate current and emerging infectious threats. ECDC partners with national

[45] Hervey,T., McHale,J. (2004) *Health Law and the European Union*, Cambridge University Press:83

[46] Legal Foundation of EFSA, http://www.efsa.europa.eu/en/about_efsa/founding_regulation.html

health protection bodies across Europe to develop continent-wide disease surveillance and early warning systems and provide scientific opinions about potential risks[47].

i) The Precautionary Principle

In 2000, the European Commission issued a Communication as a response to a Council Resolution (no.7212/99) demanding a clarification on the guidelines for the application of the precautionary principle. According to the Commission, the precautionary principle may be invoked when the potentially dangerous effects of a phenomenon, product or process have been identified by a scientific and objective evaluation, and this evaluation does not allow the risk to be determined with sufficient certainty[48]. Hence use of the principle belongs in the general framework of risk analysis (which includes risk management and risk communication in addition to risk evaluation), and more particularly in the context of risk management which corresponds to decision-making. According to Regulation 178/2002/EC Article 7 "The precautionary principle may be invoked where a food might have harmful effects on health, in order to be able to react quickly and take appropriate measures."

After its adoption, the precautionary principle has come to inform much EU policy, including areas beyond those originally addressed the Maastricht treaty. It is implemented, for example, in the European Union food law and also affects, among others, policies relating to consumer protection, trade and research, and human, animal and plant health, and scientific and technological development[49].

The EC Treaty contains only one explicit reference to the precautionary principle, namely in the title on environmental protection. However, the Precautionary Principle is enshrined in international law, where a general principle may be invoked as a rule of international law when there are situations where neither conventional nor customary international law can be applicable.

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[47]European Centre For Disease Prevention and Control, http:// www.europa.eu.int/smartapi/cgi_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=32004R0=851 &model=guicheti

[48] Precautionary Principle, europa.eu/scadplus/leg/en/lvb/l32042.htm

[49] Precautionary Principle, http://en.wikipedia.org/wiki/Precautionary_Principle and SCADplus http://europa.eu/scadplus/leg/en/lvb/l32042.htm

The establishment of common guidelines on the application of the precautionary principle has positive repercussions also at the international level. The use of the principle has been recognized in various international agreements, notably in the Sanitary and Phytosanitary Measures Agreement (SPS) concluded in the framework of the World Trade Organization (WTO).

3. TRADE and HEALTH COLLABORATION

i) The Agreement on Sanitary and Phytosanitary Measures

There is a strong correlation between the supranational regulation of food safety in the World Trade Organization and the reforms underway in the European Union. The European's economic success and increasing importance in world trade connects it more closely with the rest of the trading world. There is an interesting relationship between trade and health, especially communicable diseases. In the EU context, health crisis were relevant to removal of restriction and open borders which allowed a faster spread of communicable disease in animal and in human health. Over the years, EU has developed significant health legislations related to the internal market, which prefer to protect both health safety concerns and trade priorities of its member states. Furthermore, while the EU Common Trade Policy sets the rules and standards, such rules and standards also fit in to the World Trade Organization agenda and agreements.

EU's institutional framework interacts with global rule-making to create opportunities or constraints to policy reform in the European Union. The Union focuses specifically on developments associated with the global regulation of food safety measures, in the World Trade Organization Agreement on Sanitary and Phytosanitary Measures (SPS). The SPS commits WTO members to a set of rules to ensure that their measures to protect consumers' food safety distort trade to a minimal extent and embraces harmonization among states of food safety measures as a goal. These developments at the global level influence EU food safety regulatory reforms.

The EU is one of the key actors in the World Trade Organization, because first of all, it has a Common trade policy and the Commission represents the 27 Union members at meetings. Secondly, disputes between the United States and the European Union during the Uruguay Round (1986-1994) on hormones in meat products and strategic products, such as

banana, accelerated the establishment of the trade regime. The European Union is a strong proponent of the clearer rules on food safety measures due to various trade-barriers used illegitimately to prevent the Union from accessing different markets. The negotiations have helped to liberalize trade and lower the existing barriers. However, in some circumstances WTO rules support maintaining trade barriers, for example to protect consumers or prevent the spread of disease[50]. In addition, there are two specific World Trade Organization agreements dealing with food safety and animal and plant health and safety and with product standards in general. New in the SPS agreement are the means to achieve food safety measures based on scientific principles and evidence. Countries must commit to harmonize their food safety measures on the basis of international standards and guidelines.

The *Technical Barriers to Trade* (TBT) Agreement requires that "all domestic regulations be 'least trade restrictive' and treat 'like products' the same. Domestic regulations can be higher than international standards only if they can be justified. Negotiated and signed by governments, the goal is to help producers of goods and services, exporters, and importers conduct their business, while allowing governments to meet social and environmental objectives. Consumer and animal welfare concerns are within the scope of the TBT agreement[51].

The significance of the EU's coordination in food safety regulation is revealed by developments subsequent to the ratification of the Sanitary Phytosanitary Measures (SPS). The SPS is a set of measures to prevent trade protectionism. Furthermore, the measures require that "a country's food and drug safety regulations be based on a scientific risk assessment, even if there is no discrimination between domestic and important products[52]. Scientific evidence is a central idea to the SPS Agreement (WTO, 1998a, b, 1999). Like its predecessor General Agreement on Tariffs and Trade (GATT) Article 20, SPS allowed governments to act on trade in order to protect human, animal or plant life or health, provided they do not unjustifiably discriminate or use this as disguised protectionism between countries where identical or similar conditions prevail. The SPS agreement gives the WTO the power to override a country's use of the precautionary principle, which allows them to act on the side of caution if there is no scientific certainty about potential threats to human health.[53] Although

[50] http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm4_e.htm

[51] http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm4_e.htm TBT article

[52] Labonte, R.(2003) *Dying for Trade ,Why Globalization Can Be Bad For Our Health*, CSJ Foundation for Research and Education:14, http://www.socialjustice.org/pdfs/dyingfortrade.pdf

[53] Wikipedia on WTO, http://en.wikipedia.org/wiki/World_Trade_Organization#Articles_on_the_WTO

countries are allowed to use different standards and different methods of inspecting products, member countries are encouraged to use international standards, guidelines and recommendations where they exist. They can also set higher standards based on appropriate assessment of risks so long as the approach is consistent. Article 5.7 of the SPS Agreement allows only temporary "precautionary" measures.

The SPS Agreement demands countries to harmonize their food safety measures on the basis of international standards, guidelines and recommendations where they exist. The designated standard-setting is the Codex Alimentarius Commission (CODEX).

ii) Setting Standard in Food Health: Codex Alimentarius Commission

Codex Alimentarius Commission (CODEX) is a multilateral organization, created by the Food and Agricultural Organization of the United Nations (FAO) and the World Health Organization (WHO) in 1962 to facilitate fair trade in food. The adoption of Codex standards into national law is not mandatory, but domestic food safety measures that conform to Codex standards are judged to be legal. Regarding measures taken to protect human, animal or plant life or health or the environment and related international trade measures, and harmonization of national legislation, the objectives and standards of the European Union match up with those of Codex Alimentarius.

The object of the Codex Alimentarius Commission is to develop and harmonize world-wide health standards and issue guidelines and recommendations on agricultural and fishery products, foodstuffs, food additives, contaminants, veterinary drugs, pesticides, including labeling, methods of analysis and sampling, codes of ethics and good agricultural practice and guidelines of hygiene practice, in view of protecting consumers' health and ensuring fair practices in international trade.

European Community membership in the Codex Commission allows the Union to play a role during the preparation, negotiation and adoption of standards, guidelines or recommendations by the Codex Alimentarius Commission and its subsidiary bodies. Accession of the European Community as a full member of Codex Alimentarius, alongside its Member States, has been essential in order to ensure that European Community public health and other interests are taken into consideration[54].

[54] 2003/822/EC: Council Decision of 17 November 2003 on the accession of the European Community to the Codex Alimentarius Commission, http://www.codexalimentarius.net/web/index_en.jsp

4. NEW CHALLENGES: AVIAN INFLUENZA and EU RESPONSE

The Avian influenza was known to affect wild birds and to some extent it had previously spread to domestic animals, such as poultry. Human deaths in Hong Kong in 1997 were the first detected infection in humans.

The threat of a pandemic influenza is currently prompting governments and international bodies with responsibilities in public health protection. The EU uses contingency plans and resources, including the alert systems and their networks established previously to address crisis like BSE and SARS in order to coordinate member state response to the avian influenza outbreak. Since 2003 the disease spread to other countries, such as Thailand, Pakistan, Turkey, and various European countries during 2005.

We have already seen the adoption of the public health article in the Amsterdam Treaty and regulation 178/2002/EC concerning food law, the creation of EFSA and the adoption of the precautionary principle to be invoked when potentially dangerous effects of a phenomenon, product or process have been identified by an incomplete scientific and evaluation. Precautionary measures are currently applied in European countries where there is a potential risk of the recent Avian Influenza outbreak. Otherwise, there is a significant number of programs in place coordinate at the EU-level, and carried out by member states.

These programs include rapid alert systems, national contingency plans, surveillance of disease networks implemented and expanded since 2002.

The outbreak of Avian Influenza proved once again that it is impossible to protect from health risks in times of global trade and open borders. Yet, there were more provisions and measures in place in the EU to be able to respond in a coherent and timely manner to the outbreaks in 2005.

Influenza is a recurring natural disaster like tsunamis and earthquakes. Avian influenza is a contagious viral disease of poultry and other birds, that has been sighted in Spanish Influenza (1918), Asian Influenza (1957) and Hong Kong Influenza in (1968). The most pathogenic form of the virus is H5N1, which first infected humans in Hong Kong in 1997. Since 2003 the disease spread to other countries, such as Thailand, Pakistan, Turkey, and various European countries during 2005.

While trade in live birds and poultry products can disseminate the disease from one country to another, the recent spread has shown that also migratory birds play a role in propagating the virus. Wild birds are in fact often carriers of avian influenza viruses, and

contact between them and domestic flocks is believed to be the origin of several epidemics. Humans can get infected through close contact with affected birds.

Thus far there is no general pattern for human-to-human contact. Containing the animal disease is essential to protecting human health. Furthermore, the continuing spread of the animal disease raises the prospect of further economic losses, jeopardizes poor livestock farmers, small holder entrepreneurship and commercial poultry production. This could be a threat to regional and international trade.

The initial European legislation on Avian Influenza Decision 92/40/EEC, dating from 1992, only targeted high pathogenic avian influenza (HPAI) in poultries. The decision established a compulsory disease control measure only in case of disease in poultry caused by the various virus derivatives of avian influenza[55]. Among the measures put forward by the Commission, were provisions for protective and emergency vaccination, and measures to eradicate the disease within affected poultries, without economic disrupt. The decision introduced community measures for the control of avian influenza that would ensure the protection of animal health and contribute to development of the poultry sector. Nevertheless, there are founded concerns that avian influenza viruses may mutate into highly pathogenic strains, and cause a public health emergency.

Directive 92/40/EEC was further developed with the recent Directive 2005/94/EEC[56]. This legislation sets out rules on the surveillance, control and eradication measures that must be taken in the event of a highly pathogenic avian influenza outbreak. The new Directive also mentions condition and specific requirements regarding a preventive vaccination.

Legislative decisions on the prevention and control of avian influenza are generated by the Standing Committee on the Food Chain and Animal Health (SCFCAH). Decision 2006/416/EC is considered a legal base for special cases, such as control of highly pathogenic avian influenza in locations or among specific types of breeds. Another such legislative decision was to ban imports from third countries. These bans were implemented at the height of the outbreak in 2005 and 2006.

[55] Europa.eu.int/eur-lex
[56] Directive will be transposed by July 31, 2007

i) Influenza Preparedness

In March 2004, the Commission of the European Union adopted a *Community Influenza Preparedness Plan* developed by The Community Network for Communicable Disease. The Network was set up to form epidemiological surveillance and control of communicable disease. In 2006, 14 Member States reported cases of highly pathogenic H5N1 avian influenza in wild birds, mainly in species dependant on wetlands. According to the figures available, 748 cases of the disease occurred in wild birds in the EU in 2006. Member States' surveillance has been particularly extensive and more than 150 000 wild birds were tested in the period July 2005 to June 2006. Based on the very wide set of data gathered in the EU, it is evident that wild birds have played a significant role in the spread of the virus in Europe[57].

4.1. INTERNAL and EXTERNAL RESPONSE TO ANIMAL DISEASES

The Directorate General for Health and Consumer Protection (DG SANCO) and Directorate F, the Food and Veterinary Office under the DG SANCO are responsible for EU legislation in the veterinary field. The fully harmonised legislation encompasses conditions regarding the import of live animals and products of animal origin from third countries.

FVO is in charge of inspections in order to evaluate the public health situation, the legal provisions, organization of veterinary authority in the country, the control standards and production standards and to assess to what extent the country complies with European Standards. The inspection also tries to determine the membership of the country to other International Organisations such as The World Animal Health Organisation (OIE). Membership to the OIE means that the country conveys regularly information regarding occurrence of infectious or contagious animal disease. If FVO's inspection is favourable and the Standing Committee on the Food Chain and Animal Health (SCFCAH) approve, the Commission will adopt legislation necessary to grant approval for imports.

[57] http://www.europa-eu-un.org/articles/en/article_6553_en.htm

i) Rapid Response Systems

The Commission developed the operational capacity and created several rapid response systems to assist in the response to a wide range of emergencies. Under Decision 2119/98/EC of the European Parliament and of the Council, a network for epidemiological surveillance and control of communicable diseases in the Community was set up in 1998. One pillar of Decision 2119/98/EC is the early warning and response system (EWRS) to address communicable disease outbreak. The main objective of the network is to establish permanent communication between European Union member states' public health authorities. Among the various response systems, RASFF (consumer health in relation to food and feed), SHIFT (health controls on imports of veterinary concern) and ADNS (animal health) are significant to mention for the topic of this paper. They all share the same aim to respond quickly and efficiently to emergencies. The response systems have a track record and communication systems to start alert and information flow to information centers from participating member states[58].

ii) Tracking Systems and Surveillance Plans

In 1998, the European Parliament and the Council adopted the Decision (2119/98/EC) to set up a network for the epidemiological surveillance and control for communicable diseases in the Community. Furthermore, the 1998 Council conclusions on the future framework of Community action, the Committee of Regions in 1998 Opinion, as well as the 1999 Economic and Social Committee Resolution supported the idea that Community action to comprise three general objectives to be carried out during five years. These objectives would encompass 'improving information for the development of public health, reacting rapidly to threats and tackling health determinants through health promotion and disease prevention, and the use of all appropriate use of Treaty instruments.'[59]

In the context of the internal market and the absence of border control between member states, EU has in place measures and specific animal health rules to govern intra-Community trade. These measures emphasize, among other things, traceability and identification, health certification and checks at destinations.

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http://www.hri.org/news/europe/midex/2005/05-11-07.midex.html

[58] http://www.eurosurveillance.org/em/v11n12/1112-224.asp

[59] Decision 2119/98/EC, http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_268/l_26819981003en00010006.pdf

The Commission has introduced a computerised system, ANIMO, linking the veterinary authorities of the Member States to facilitate the exchange of this information. Furthermore, it is an important tool in ensuring compliance, as well as checking the country of origin and veterinary certifications. The network is used to exchange information about the intra-Community trade, importation or transit in the EU of live animals, semen and embryos as well as importation of certain kind of animal products, their transit from a third country to another third country, the specific import under custom supervision of the goods and the importation intended for free zones[60].

The Council Directive 90/425/EEC concerns the veterinary and technical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market. Article 4 of the decision laid down the procedure for tracking of live animals and animal products (semen, ova and embryos) which are transported between Member States. Council Directive 91/496/EEC laid down the tracking procedure of imported or channelled live animals and down the principles governing the organization of veterinary checks on animals entering the Community from third countries.

iii) Banning on Imports From Third Countries

Food products can move within the EU without border checks although national controls may be set where there are risks to public or animal health. Since, there have been avian flu outbreaks in a number of EU Member States, poultry and poultry products from affected parts of EU countries are restricted to protect animal health, as well as human health. In the affected areas the Commission has instructed national authorities to apply restrictions and controls, including a block on live poultry and birds, meat, hatching eggs and poultry products leaving the areas except under very limited conditions.

Commission Decision 2005/760/EC addressed to the EU Member States declared a ban on imports of captive live birds from all third countries, other than poultry for commercial purposes. The Decision applied from October 28 to November 30, 2005.

Import conditions are primarily dependent on the product and the animal. Registration of holdings, animal identification and movement controls (traceability) are required. Live animal

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[60] The Animo Tracking System http://ec.europa.eu/food/animal/diseases/animo/index_en.htm

imports in particular are more comprehensive and necessitate supplementary checks on control and eradication efforts. For some animal products risk management measures are required. During an outbreak of disease, import of live animals and products may be accepted from regions which satisfy the requirements, while banning imports from the regions of the country which do not fulfil the requirements. This is called the *principle of regionalisation*[61]*.it is the* recognition of disease-free areas or low prevalence areas (regionalization) It is an increasingly important concept that facilitates the relatively free flow of products.

Member States backed a series of Commission proposals to reinforce EU preventive and control measures with regard to avian influenza at the Standing Committee on the Food Chain and Animal Health (SCFCAH) in 2006. The Decisions relate to the outbreak of H5N1 avian influenza on a German poultry farm, rules on preventive measures taken with regard to zoo birds and an extension of the import bans for Croatia, Romania and Turkey.

Non –Member Countries	**Legislation**	**Type of Products**
Thailand, China (including Hong Kong), Malaysia, South Korea, North Korea, Cambodia, Vietnam	Commission Decision 2005/692/EC	fresh meat from poultry, ostrich, farmed and wild feathered game, eggs for human consumption, birds other than poultry and unprocessed feathers
Accession Countries		
Turkey	Commission Decision 2006/321/EC	Same as above
Croatia	Commission Decision 2006/563/EC	Same as above
Member States		
Romania, Greece, Netherlands, France Poland, Sweden, France, Germany, Austria, Hungary, Slovakia and Slovenia	Council Directive 92/40/EC amended by Council Directive 2005/94/EEC)	Same as above

Table 1. Commission Decisions to ban imports from various member and non-member countries

The Commission adopted Decision EC 2006/115, following a favorable opinion by the Standing Committee on the Food Chain and Animal Health and in accordance with national surveillance plans and EU co-funding. Several Member States applied the precautionary measures set out in Decision 2006/115/EC, following outbreaks of avian flu in wild birds on

[61] Application of Regionalization in Meat Trade: Why the Reluctance?, Bulletin Fal, Issue 241, September 2006

their territories. These include Poland, Sweden, France, Germany, Austria, Hungary, Slovakia and Slovenia.

Standing Committee on the Food Chain and Animal Health endorsed the Commission to provide up to 50 percent of the co-funding for programs on Member State individual surveillance plans for avian influenza[62]. National surveillance programs aim for early detection of any outbreak of avian influenza in the EU. The approved programs outlined the number of samples that would be taken from both wild and domestic birds in each Member State, and the type and number of tests that will be done.

The EU legislative provisions address new developments in the disease situation to prevent and control avian influenza outbreaks in Europe. All Member States have avian influenza contingency plans, approved by the Council Decision 2004/402/EC and in place for the controls or eradication of outbreak. The EU works closely with international partners such as the World Organization for Animal Health (OIE) and the United Nations Food and Agriculture Organization (FAO) assist with National Disease Contingency Plans on specific diseases, including Avian Influenza. The Commission's public health services collaborate with the World Health Organization (WHO) to improve influenza pandemic preparedness. The European Influenza Surveillance Scheme (EISS) funded by the European Commission provides valuable data on seasonal influenza activity in 22 European countries.

iv) The Current Community Action Plan

The European Parliament and Council Decision 1786/2002/EC to adopt a Community Action in the field of public health followed the precautionary principle in 2002. The action plan of the decision covers an extensive part regarding transparency and claiming balanced participation on behalf of stakeholders. The Decision emphasizes Article 152 of Maastricht where the Community is 'required to take measures in areas where member states can not' (12) The ultimate objective is "to obtain objective, reliable, compatible and comparable information which could be exchanged and would enable the Commission and the Member states to improve information to the public and formulate appropriate strategies policies and action plans." Promote structural arrangements to develop surveillance methods and a basis for rapid and coordinated responses to health threats and establish sustained cooperation with member states.

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http://www.eclac.cl/Transporte/noticias/bolfall/6/26876/FAL241.htm

[62] archives.foodsafetynetwork.ca/animalnet/2006/11-2006/animalnet_nov_9.htm

The WHO European Region discussed national preparedness plans for influenza pandemics during the March 2005, the Commission – WHO Luxembourg meeting. The meeting helped determine the stage of pandemic planning in the different European countries, facilitated planning for influenza pandemic preparedness and discussed the main components of such national planning.[63]

There are critical problems with emergency preparedness worldwide especially regarding how to measure preparedness. Rules and principles of the single market, and open borders in intra-community trade constrain health-related intervention measures, as much as health risks constrain trade movements. In the EU context, emergency preparedness can be measured by the number and scope of legislation regarding food safety and public health. The first step to preparedness is to have a legal basis for action, in order to equip the necessary institutions and agencies with the legal capacity to intervene in emergency situations. Secondly, there must be permanent bodies to coordinate national level activities regarding surveillance of disease and information must be established among various responsible units throughout the member states. National governments must take full responsibility of enforcing veterinary checks, collect data and develop contingency plans according to EU-level standards. They must also report finding of scientific research to a central regulatory authority.

The revisions made at the Treaty of Amsterdam in 1999 contains significant work on EU public health aims and legal competence, where the European Court of Justice came out as a decisive body in the dispute over legal authority: "to act rapidly to control trade when it has good reason to believe that the public health may be threatened".[64] The Amsterdam Treaty also increased the decision-making powers of the Parliament. Currently, the European Parliament plays a role in the EU's legislative and budgeting processes and exercises general supervision over the work of the Council and the European Commission. It cannot initiate legislation but it is more than just a consultative body with the expanded co-decision powers in the Amsterdam Treaty. When a wider scope of Council decisions became subject to qualified majority, the Parliament was granted the co-decision procedure, where it is the only democratically elected body involved in the legislative process. In 2005 work was initiated leading to the approval by co-decision (following a single reading) of a *Programme of*

[63] ec.europa.eu/**world**/avian_influenza/index.htm
[64] ECJ, 1998: paras 54-61

Community Action in the field of health, 2007-2013 (COD/2005/0042A), based on a communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on Healthier, safer, more confident citizens: a health and consumer protection strategy (SEC(2005)425 and COM/2005/0115 final)[65].

Despite the parliament's increasing role, the Commission continues to play a central part in health policy. The Directorate General for Trade on behalf of the Commission negotiates all international treaty agreements. The Commission has representation in both G8 and the World Trade Organization. Officials from the various directorate-generals responsible for Agriculture, Internal Market and Industry and External Trade negotiated the SPS Agreement.[66]

The Commission's Directorate General Consumer Protection and Health Safety (DG SANCO) supports and subsidises the network approach to prevention of communicable diseases. Decision 2119/98 concluded that the best preparation for threats from communicable diseases or chemical incidents, at both the EU and national levels, was to reinforce existing national public health surveillance and response capacity as well as co-ordinating joint international activities[67].

DG SANCO and the Food and Veterinary Office (Directorate F) under the DG SANCO are responsible for EU legislation in the veterinary field. The fully harmonized legislation encompasses conditions regarding the import of live animals and products of animal origin from third countries. FVO is in charge of inspections in order to evaluate the public health situation, the legal provisions, organization of veterinary authority in the country, the control standards and production standards and to assess to what extent the country complies with European Standards. The inspection also tries to determine the membership of the country to other International Organizations such as The World Animal Health Organization (OIE). The third country must be an OIE member and have systems in place for rapid detection, reporting and confirmation of OIE listed diseases.

Directorate General External Relations (DG RELEX) and European Neighborhood Policy contribute indirectly but complementary to EU health efforts. Through its mission, the

[65] http://www.europarl.europa.eu/facts/4_10_3_en.htm

[66] Skogstad,G. (2001) The WTO and Food Safety Regulatory Policy Innovation in the European Union, University of Toronto, Journal of Common Market Studies, Vol. 39, No.3, p.493

[67] DG SANCO network approach, http://www.eurosurveillance.org/em/v07n05/0705-225.asp

External Relations establishes cooperation with neighboring countries in economic, political, cultural and security interests and to strengthen their stability. An *action plan* is negotiated with each country, based on the country's needs and capacities. These documents cover political dialogue and reform, economic and social cooperation and development, trade-related issues and market and regulatory reform, cooperation in sectors such as transport, information society, environment, research and development and a human dimension in civil society, education, and public health. This contribution is therefore a long-term commitment to overall development policy on an international scale. Directorate General for External Trade is significant in playing a role in regimes such as the World Trade Organization negotiations.

Co-operation with third countries and international organisations is an explicit requirement under Article 152 (3) of the EC Treaty. This includes cooperation and participation of the European Economic Area (EEA)/EFTA countries[68] in the Community activities in accordance with the conditions established in the EEA Agreement[69]. The existing European Mediterranean Partnership, the Transatlantic Agenda, the Northern Dimension, the Taskforce on Communicable Diseases Control in the Baltic Sea Region[70].

4.2. INTERNATIONAL HEALTH GOVERNANCE

i) International Health Governance and Global Cooperation

Traditionally states have been the main guardian of public policy and enforcement of legislation protecting human health. Historically, we can trace health governance to the most ancient human societies where agreed rules and practices about hygiene and disease were adopted. Examples can be found in Roman times, through such attempts as to manage human waste and to control water pollution. There were also quarantine measures in Europe in the 19th century against ship-borne cholera and plague epidemics coming from the East. It was during the same period that international health collaboration became necessary primarily due to increasing volume, range and speed of trade and travel. It was during the 19th century that international health collaboration became necessary primarily due to health effects of the

[68] Norway, Switzerland, Iceland, Liechtenstein make up the countries of the European Economic Area.
[69] Article 16 of Protocol 31 of the EEA Agreement describes fields of co-operation.
[70] International Cooperation, http://ec.europa.eu/health/ph_international/international_en.htm

increasing volume, range and speed of trade and travel, such as ship-borne cholera and plague epidemics coming to Europe from the East.[71].

The 19th century witnessed the process of building of institutional structures, rules and mechanisms across national borders. Increased volume and speed of international trade and travel moved states-like functions from national to international governance in the mid-19th century. International health governance focuses primarily on the exportation and importation of infectious diseases. European societies formed a number of international institutions to address collective concerns, such as spread of infectious disease. First institution created was the International Sanitary Conference in 1851[72], which marked the beginning of international governance on infectious diseases.

Various international conferences taking place in early 20th century formalized basic principles that defined International Health Governance (IHG). International Health Governance demands cooperation among states to protect domestic populations from transnational health risks. The conclusion of the 1903 Sanitary Conference led to the acceptance that governments have an obligation to immediately notify other states of existing or potential outbreaks of disease, such as plague and cholera. Yellow fever, plague and cholera became the focus of a set of binding rules set several decades later by the World Health Organization.

International conferences provided for increasing cooperation among states, which inevitably led to an incremental change in governance structures. States established international organizations to manage health-related activities. "There was a shift over the decades from the state regime, to the legal regime, to the trade and access regimes in terms of public policy making."[73] The legal regimes emphasize the role of international laws. Trade regimes focus on measures to allow for free trade with minimum restrictions. In the health-related policy-making states continue to play a vital role, we can see through the functions of the European Union, the World Health Organization and the World Trade Organization that the ability to create global level governance structures largely depends on the political will of states.

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[71] Allen (1950)
[72] Fidler, D. (2003) Emerging Trends in International Law Concerning Global Infectious Disease, Perspectives, Vol.9, No.3
[73] Fidler, D. (2003) *Emerging Trends in International Law Concerning Global Infectious Disease*, Perspectives, Vol.9, No.3

ii) The WHO and the EU

Significant change took place in the aftermath of the Second World War, when in 1948 the ultimate international health coordination and cooperation body, the World Health Organization (WHO) was created within the United Nations system. The World Health Organization serves as the leading representative of the international legal regime and presents a traditional organizational health governance framework. Its primary focus is the set of activities it carries out in its member states, with an emphasis on disadvantaged populations, disease stricken regions, and a long list of disease and conditions. Most importantly, the World Health Organization is a social model of healthcare. The organization resists the idea of market intervention in public health-related areas[74].

Compared to the members of the European Union in Europe, the World Health Organization's Europe Office is composed of a much wider geography. WHO Europe includes members form the East Central European Countries and non-EU members from the West, it extends to the Pacific Shores of Russia and includes Caucasian and Central Asian republics. WHO Europe Office is the most comprehensive and busy of all WHO chapters and the EU has benefited from cooperation with the World Health Organization in its formulation of health projects and programs, e.g. collaboration during SARS outbreak in 2002.

There is an important interdependence between the state and the international health organizations. The WHO and the EU both influence state activity in the field of public health. The WHO interacts with member states by its rules and recommendations in the scope of its work, and the EU coordinates member state harmonization through both soft coordination and hard laws within its competences. There is a limit to the capacity of both of these organizations, because their capacity is controlled for them by the decisions of the member states. As Graham Moon discusses in his 1999 article *Environmental Europe*, what distinguish the health actions of the EU and WHO Europe are, their legal capacities, political area of influence and their varying positions on allowing market forces to act on health.

[74] http://who.int/en

Despite a wider geographic area of influence, the World Health Organization ultimately lacks directive power. The WHO articulates frameworks for international collaboration in Europe, while the European Union coordinates legislation, programs and promotes cooperation among member states. Both organizations play a facilitating role in risk assessment, health monitoring and health promotion among their constituent member states. Whereas the EU has undergone increasing transformation in its institutional and legal capacity in the public health field in the 1990s, the WHO continued to struggle with modernizing the once highly upheld International Health Regulations (IHR). Additionally, the EU by definition of a regional economic integration model supports market-based approach to health systems.

The World Health Organization is formally governed by the World Health Assembly (WHA) where each member state has a delegation. The ministers of health and advisors make up the WHA, and may work with NGOs that are in conformity with the aim and purposes of the constitution of the World Health Organization. The World Health Assembly initiates, adopts, monitors work program for the World Health Organization. But the implementation is decided by member states negotiation process[75].

International cooperation is a process which ranges from simply coordinating viewpoints on certain matters to setting hard rules in some cases. The WHO regulations contain no enforcement provisions nor does it have any incentives to promote adherence to its recommendations. The WHO releases non-binding policy recommendations on a usual policy output to its members. The formulation of WHO regulations named *International Health Regulations* (IHR) were adopted in the World Health Assembly in 1969. These set of regulations contribute to global surveillance of infectious diseases and are "aimed at providing maximum security against transnational proliferation of disease." EU states that are members of the World Health Organization agreed to comply with International Health Regulations.

In 1995, the World Health Organization recognized that the International Health Regulations did not achieve their goals of maximum protection from the spread of international diseases, particularly because its perspective was narrow and inappropriate for the global context. The Regulations also lacked flexibility to respond to particular circumstances surrounding each risk. WHO launched an effort to revise the regulations, in

[75] The World Health Organization, http://www.who.int/governance/en/index.html

order to update the classical regime for new globalization challenges.[76] A revision of the International Health Regulations in 1998, focused on strengthening of national surveillance capacities and inclusion of much broader range of public health emergencies of international concern.[77] The revision was adopted by the World Health Assembly in May 2005, and came into force on 15 June 2007. The new regulations is a set of new legal framework to better manage its collective defences against acute public health risks that can spread internationally and have devastating impacts on human health as well as unnecessary negative interference on trade and travel. It includes all diseases and health events that may constitute a public health emergency of international concern. The revised IHR require all Member States to strengthen their existing capacity for disease surveillance and response. In May 2006, concerned about the public health risk from human cases of avian influenza, the World Health Assembly volunteered to implement in advance some provisions of the revised IHR to contain the pandemic influenza threats.[78]

The set of institutions and organizations involved in EU health policy formulation are far more complicated. All the different institutions of the EU are involved in health policy activities, including the Council as the legislative body, the Commission and its Directorates as the executive body and the Parliament can participate with the co-decision procedure in health-related measures and legislations. Under Article 308 EC (amended Article 235EEC), if the community and the Treaties do not provide the powers then the Council can unanimously act to "raise the standard of living" (Regulation 803/68/EEC). However, where legal base is of concern, the European Court of Justice intervenes to assist with the procedure and the basis of the provision. The adoption of public health measure in Articles 152 and consumer protection 153 empowered the Council and the Commission with coordination responsibilities. Under the 1993 Maastricht certain responsibilities fell under co-decision with the Parliament. This procedure was extended to most areas of environmental, food safety and public health under the 1999 Amsterdam Treaty.

Difficulties of securing widespread consent to new binding rules, whether by treaty or by custom are increasingly overtaken by variations of standards and instruments due to the increasingly complex international system. In the international legislative process, the

[76] Fidler,D. (2003) *Emerging Trends in international law concerning global infectious disease control* , Perspective, Vol.9, No.3

[77] Aginam,O. Globalization of Infectious Diseases, International Law and the World Health Organization: Opportunities for Synergy in Global Governance of Epidemics, 2006:59

[78] What are International Health Regulations? http://www.who.int/features/qa/39/en/index.html

corresponding continuum is from non-binding instruments called "soft law", such as recommendations, guidelines, resolutions, declarations of principles and codes of conduct, to binding ones such as treaties. The WHO most often issues recommendations. The limitations to WHO arise from the non-binding nature of the recommendations it gives its member states. On the other hand, the legal framework for health in the European Union is provided by the Treaty articles, be secondary laws, principles and case law from the European Court of Justice. In this regard, the European Union has secured adequate capacity, at least with respect to significant areas of public health, such as communicable disease prevention and surveillance. Furthermore, the EU has greater political leverage.

The Agreement on *the Application of Sanitary and Phytosanitary Measures* (SPS), *The TBT Agreement*, *the Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS), and, along with the Organization's powerful dispute settlement mechanism made the WTO more important for infectious disease control policy than the International Health Regulations of the World Health Organization. The classical state regime which resists irrational health measures in view of protecting its economic interests has weakened for travel-related measures and migrated to the trade regime for health measures that restrict trade in goods.

At the global level the World Health Organization assumes responsibility in coordination of disease surveillance. The WHO publishes guidelines, organizes technical meeting to assist countries and other organizations, articulates evidence-based policy options and shapes the health research agenda. Most of programs and initiatives are geared towards increasing public communication of health issues, including health risks. But the WHO has a primary focus on action of its member states. Member states would use WHO in order develop criteria to assess whether an outbreak constitutes such an emergency. The criteria would include whether the event is serious, unexpected, and likely to involve international spread and to trigger trade and travel restrictions.

The EU has primarily regional influence over communicable disease surveillance. In the aftermaths of the BSE crisis in the 1990s, it has developed its legislative capacity to set up Communicable disease networks, Surveillance Programs, and Rapid Alert Systems. The EU has linked animal health and food safety with human health and consumer protection. Cooperation with various existing health actors is a necessary approach to help structure a global response to health crises. The EU partners with The World Organization on Animal Health, Food and Agriculture Organization under the United Nations, and the World Health Organization in establishing national contingency plans.

While the World Health Organization focuses on various aspects of human health covering different regions and populations of the world, the World Organization for Animal Health Health (OIE)[79] is an intergovernmental organization working to improve the legal framework and resources of national veterinary services. OIE contributes to EU activities through regularly collected information regarding occurrence of infectious or contagious animal disease. Established by the International Agreement of 1924, its mission includes assuring *transparency* in global animal disease situation holds an important place. Within its mandate under the WTO SPS Agreement, OIE publishes standards for international trade in animals and animal products. The European Union does not have representation among OIE delegates, however it is a member of Food and Agriculture Organization (FAO) of the UN and many of the EU member states have membership to the OIE. The OIE works with member countries on Emergency Preparedness by assisting with National Disease Contingency Plans on specific diseases, including Avian Influenza. Each Member Country undertakes to report the animal diseases that it detects on its territory. The OIE then disseminates the information to other countries, which can take the necessary preventive action. This information also includes diseases transmissible to humans and intentional introduction of pathogens[80].

EU regards cooperation with OIE as significant due to the importance of the key concepts, *transparency* and *information* emphasized in OIE mission statement. In 2003, the European Commission extended an agreement to the OIE on the determination of BSE status based on EU risk-assessment requirements. In 2006, hosted by the Council of Europe, the European Union and OIE adopted a joint declaration committing to greater cooperation on all aspects of animal welfare, aimed at bridging the gap between animal welfare legislation and its practical application and to complement existing activities[81] The document, titled *Animal Welfare in Europe and Achievements and Future Prospects*, committed the three organization to "providing mutual support and cooperating on all aspects of animal welfare, for example elaborating legislation, training of veterinary professionals, and raising public awareness."[82] The document also stressed the importance of the link between animal welfare and the need for adequate scientific knowledge.

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[79] At the time of its creation The World Health Organization was called *Office International des Epizooties(OIE).* The organization is still known as the *OIE* in short.

[80] http://www.oie.int

[81] http://eu.europa.eu/food/animal/welfare/joint_dec_aw_en.pdf

5. EU FRAMEWORK PROGRAMS

i) European Union Research and Fundraising

Research and Technological Development is essential for the support of other policies such as consumer protection. The *Directorate-General for Research* develops the Union's research and technological development policies and coordinates collaborative EU research activities at the member state-level. The legal and political obligation to conduct European research policies and implementing European research programs resulted from the Amsterdam Treaty. The Treaty includes a whole chapter on research and technological development (RTD), so as to underline that RTD is an essential element in the functioning of EU Member States. FT: the competitiveness of companies and the employment they can provide depend to a great extent on RTD.

Framework Programs (FP)[83], are funding programs created by the European Union in order to support and encourage European research and development. The detailed objectives and actions vary from one funding period to another.

The EU supports the emerging influenza research field as well as essential support to EU policies. The European Commission has been supporting research on influenza in both humans and animals under various programs. Already under the 5th Framework (FP5) Program for Research (FP5), 1998-2002, approximately € 6 million were spent on avian and pandemic influenza in 22 institutions and national reference laboratories across 8 European countries.

The 6th Framework Program (FP6), 2002-2006, activities were extended and reinforced with a set of new projects launched in both the animal and human health sectors, with several larger projects dedicated to influenza as well as other viral infections. The new projects addressed research needs identified by organizations such as the World Health Organization, the World Organization for Animal Health and the Food & Agriculture Organization of the UN.

The Commission proposed the 7th Framework Program (FP7) to be carried out between 2007 and 2013. Human pandemic influenza will be a part of the seventh framework, but will be addressed in the *Cooperation Program*. Theme 1 of the program is *health* under the sub-

[82] International Animal Welfare Issues, http://ec.europa.eu/food/animal/welfare/international/index_en.htm
[83] Offical title is The Framework Programmes for Research and Technological Development, web

heading *Emerging (Infectious) Epidemics* and avian influenza in animals constitutes a part of Theme 2 which is *Food, Agriculture and Biotechnology Research*. A heading on emerging infectious diseases in humans will be able to address any unforeseen threats from infectious diseases.

The worldwide animal disease situation is monitored, especially in third country trading partners to allow EU to be adapted to reflect changing risks to animal and human health. If needed emergency safeguard measures are applied[84].

At the Beijing Conference between 17 and 18 Jan 2006, DG SANCO pledged 100€ million on behalf of the Commission to combat avian influenza and prepare for a possible human pandemic. 20€ million spent on scientific research projects via the 6th Framework Program, and the remaining 80 M€ via assistance projects outside the EU.

The EU (Member States plus European Commission) together pledged 214 M€. In total, $1.9 billion was pledged in Beijing, $1 billion in grants and $900 million in loans[85].

Vienna Senior Officials Meeting was organized by the Austrian Presidency of the European Union, in coordination with the Commission, the USA and China. The meeting had the following objectives: to review current situation of Avian Influenza and Human Influenza Pandemic Preparedness, to evaluate the new pledges made in Beijing, and analyze the structure of partnerships. The agreement between the Commission and the World Bank on the set up of a multi donor trust fund called "the Avian and Human Pandemic Influenza Financial Facility" based on the principles agreed in Beijing and administered by the World Bank, was signed on 8 June in Vienna.

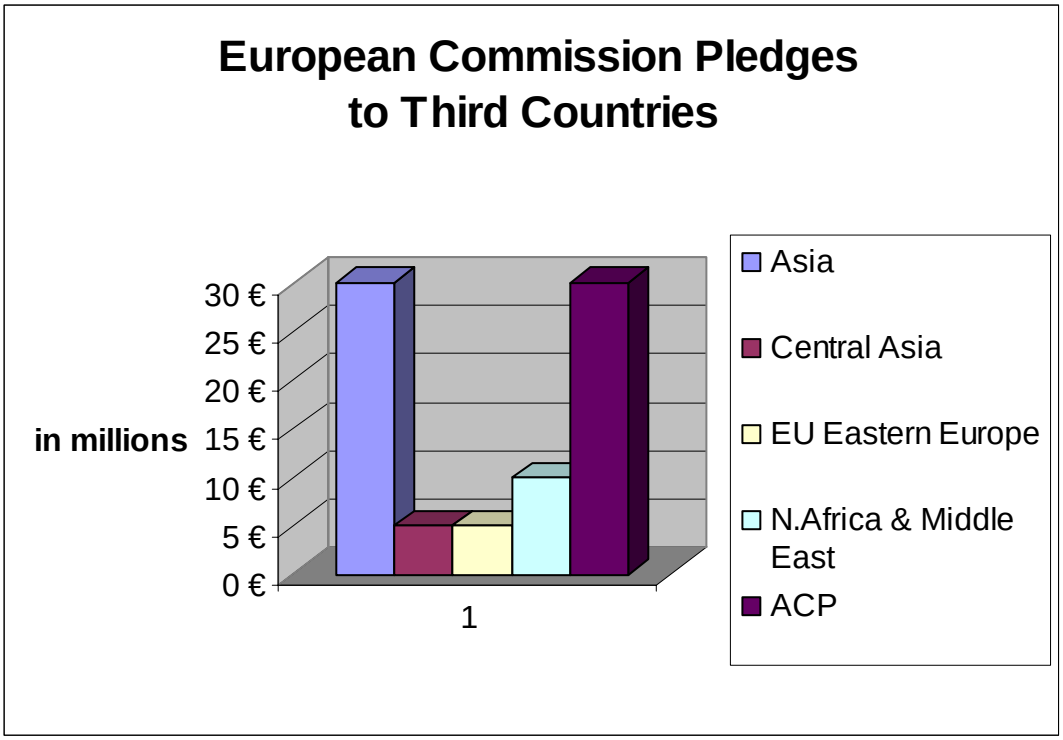
The African Union hosted the Bamako Ministerial Conference which organized by the Inter-African Bureau for Animal Resources of the African Union AU/IBAR between 6 and 8 December 2006, in co-ordination with the European Union, including the European Commission, the technical agencies of the United Nations.

Its objectives were to strengthen the global partnership against Avian and Pandemic Influenza taking stock of what has been achieved after Beijing, exchange technical experience and, to mobilize additional resources, particularly, but not exclusively for Africa[86].

The international community has pledged a total amount of $1.9 billion dollars to fight avian influenza and prepare for a possible human influenza pandemic, The European Commission co-sponsored the conference with the government of the People's Republic of

[84] EU Research, http://ec.europa.eu/world/avian_influenza/index.htm
[85] European Union in the World: The Global Response, http://ec.europa.eu/world/avian_influenza/index.htm
[86] EC Response to the Global Challenge of Avian and Pandemic Influenza

China and the World Bank. The European Commission and in particular Commissioners of External Relations and ENP, pledged €80 million in aid grants from the Commission's External Relations budget and the European Development Fund and committed €20 million in research funds for avian influenza from EU's 6th Research Framework Program[87].



** €30 million is earmarked for the African, Caribbean and Pacific (ACP) Countries, subject to approval.

European Commissioner for Enlargement agreed with Commissioner for Health and Consumer Protection, the Commission adopted by urgent procedure a pre-accession financial assistance program to help Turkey to limit the spread of Highly Pathogenic Avian Influenza infection in domestic poultry and to minimize threats to humans.

The program was implemented by means of a Financing Agreement which was concluded between the Commission and the Government of Turkey[88]. The Community assistance was financed through the 2006 General Budget of the European Communities (Pre-accession

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http://ec.europa.eu/world/avian_influenza/index.htm

[87] International Pledges http://europa.eu/rapid/pressReleasesAction.do?reference=IP/06/49&format=HTML&aged=0&language=EN&guiLanguage=en

[88] COUNCIL REGULATION (EC) No 2500/2001 http://eur-lex.europa.eu/LexUriServ/site/en/oj/2001/l_342/l_34220011227en00010005.pdf

assistance for Turkey). In particular, the Community provided funds for investments in laboratory equipment, rapid test kits and safety gear in order to strengthen animal disease surveillance and upgrade diagnostic testing and early response capacity. Other Community aid covered technical assistance in the form of training and simulation exercises aiming to improve disease control and eradication activities to be carried out by Turkish Veterinary Services.

In 2006 the European Commission tabled a proposal to allow the European Union budget to share the cost of market support measures in the eggs and poultry sector. Regulations 2771/75 and 2777/75 provide the legal basis for support measures in the eggs and poultry sector. The only market support measures provided for in the regulations are export refunds[89].

Since the beginning of the recent avian flu crisis, consumption of poultry and eggs has fallen dramatically in some Member States, leading to a sharp reduction in prices. The regulations do not currently include the possibility to provide EU financial support to farmers affected by a drastic drop in consumption. The current regulations governing the eggs and poultry market allow the EU to co-finance compensation measures only in cases where there is a case of avian flu on a farm or where farmers are prevented from moving their poultry because of restrictions imposed on veterinary orders. Commissioner for Agriculture and Rural Development put pressure on Brussels to extend the scope of the existing regulations to allow EU co-financing of special market measures. Each Member State will then be able to design the measures best suited to its particular situation. Because of the gravity of the current market crisis, the Commission proposed to co-finance 50 percent of the cost of market support measures linked to a drop in consumption and prices of eggs and poultry.

Once the legal base has been adopted, Member States will have to submit their proposed measures for Commission approval[90].

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[89] EU financial aid for eggs and poultry sector
http://europa.eu/rapid/pressReleasesAction.do?reference=IP/06/400&format=HTML

CONCLUSION

In light of particular emergency events leading to worldwide outbreaks of disease, the impacts of globalization on human health and newly emerging actors of global governance in the health field need considerable attention. The Commission Communication COM(2006) 278 on *Europe in the World* proposes the Union to define a strong sense of collective purpose, and outlines the need for European political will in the health field backed by the necessary policies. The European Union is a regional actor, whose legal system based on international laws, strong internal market foundation and a growing interest in social policies, promotes its capacity at the international and global levels. Its membership in the World Trade Organization, the Codex Alimentarius Commission and cooperation with the World Health Organization ensures the EU with a voice in setting global standards in health.

The legal framework for health in the European Union is provided by the Treaty articles, be secondary laws, case law from the European Court of Justice, and principles, such as the precautionary principle. Past experiences with health crisis have been instrumental in the creation of measures, regulations and even policies. EU health policy originated from health and safety provisions, and later developed as a result of free movement of people and goods in the internal market, which required coordination in public health. Occupational health-related measures introduced in the Single European Act were a necessity of the internal market, as they relate particularly to labor standards. The BSE crisis in the mid-1990s put health and consumer protection high on the political agenda. Consumer protection Article 153 in the Amsterdam Treaty had more than just legal capacity implications for EU institutions. The adoption of social policies topic gave an important political message regarding EU desire to address problems of democratic deficit.

There is an increasing emphasis on global programs and global priority setting is problematic from the point of view of national sovereignty. Resistance to conferring competences to the EU in the health-related field was due to a combination of national concerns over the loss of political authority at member state-level, in addition to trade protectionism. In the EU context, EU supremacy of law provides for increased responsibility, but not necessarily full authority to the supranational level. Therefore, prime responsibility for protecting European citizens against outbreaks still rests with each member state. Where

[90] EU financial aid for eggs and poultry http://ec.europa.eu/agriculture/publi/newsletter/80/80_en.pdf

cooperation with other states and actors is beneficial, states are willing to transfer parts of their legislative authority onto other, supranational levels.

In the EU context, delimitation of EU-level competences in the public health field has resulted in a dysfunctional mechanism where a lack of transparency and delayed response to crises dangers standards previously set. Therefore, Article 129 (1) urged health protection requirements to "form a constituent part of the community's other policies". Amending Article 129, Article 152 called for the *mainstreaming principle* where public health should be maintained as an inherent part of other policies. The Commission preferred keeping the definition of complementary responsibilities broad, in order to be able to integrate public health into other existing policy areas as much as they are relevant. In addition to the Commission, the role of the Parliament and its committees is increasing. The Parliament was perceived as a necessary actor in overcoming the BSE crisis while acknowledging the short comings resulting from contradictions of the system of EU single market governance. In the Amsterdam version of the co-decision power, the parliament was granted a co-equal legislator role in areas of public health and communicable disease. The increase in the role of the directly elected EU body was inevitably to link EU activities more closely with public interests.

EU is also responsible for encouraging cooperation with international organizations articulated in Article 152 (3) and among member states with respect to control measures and standards in the field of health. The EU coordinates National Contingency Plans with the World Organization of Animal Health (OIE) and the World Health Organization. Unlike its coordination role within the internal market and legislative responsibilities, a significant part of the EU's global activities in the future are more than likely to revolve around international conferences and fundraising for development related programs.

Most importantly, the effectiveness of EU public health measures depends on Brussels' willingness to keep health policy as a priority issue area. Future amendments to the Constitutional Treaty (2004) must consider not only the global opportunities that await EU in the health field, but also the economic and social burden of health risks that may challenge the growing number of EU members if neglected. [91]

[91] Policies of the Union, Constitutional Treaty, Rome 2004
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