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EU - US Food Safety Disputes
and International Food Safety Regime

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EU - US Food Safety Disputes and International Food Safety Regime

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ABSTRACT:

This paper describes and examines the impact of divergent food safety regulations on the international trade in food. The author presents the regulatory framework developed in the EU and contrasts it with the US approaches to food safety regulations. Next he identifies and analyzes several EU-US trade related food safety disputes in order to determine to what extent they are the result of irreconcilable differences and to what extent they are a part of trade strategies.

EU and US Food Safety Disputes and International Food Safety Regime

Prof. Aleksander Surdej

1. Introduction: Growing Internationalization of Food Safety Regulations

Public regulations regarding the production, transportation and sale of food are by no means an invention of contemporary governments receptive to the pressure of wealthy and susceptible to food scares citizens. Already in ancient Athens beer and wines were inspected for purity and soundness and the Romans had a well-organized state food control system to protect consumers from fraud or bad produce. In Europe during the Middle Ages, individual countries passed laws concerning the quality and safety of eggs, sausages, cheese, beer, wine and bread. Some of these ancient statutes still exist today¹.

Initially food quality and safety legislations were a purely local matter: by the late 19th century however leading countries adopted general food laws and established law enforcement inspections: food safety regulations became national in scope. A multi-ethnic (if not multi-national) nature of some of large imperial states made them precursors of modern attempts at internationalization of food safety regulations as they had to tackle in food safety legislation the question of different production techniques and different consumers tastes. Thus for instance the Austro-Hungarian Empire developed between 1897 and 1911 a series of standards and product descriptions for a wide variety of foods, known as the *Codex Alimentarius Austriacus*, which, although lacking legal force, was used as a reference by the Empire's courts to determine standards of identity for specific foods. The present day FAO/WHO *Codex Alimentarius* draws its name from this Austro-Hungarian code.

For long time food safety regulations seem to be first and foremost a policy response to domestic public health problems, but with the intensification of international trade in foods all countries risk importing threats to public health. International trade in foods predates modern times, but until the end of 1800s this was trade limited in quantity and variety. Large scale imports of products from exotic

¹ This paragraph has been drawn on the information contained in the text „Origins of the Codex Alimentarius” from <http://www.fao.org/docrep/W9114E/W9114e03.htm>.

countries started in mid-1800s when bananas were first shipped to Europe from the tropics. In late 1800s long distance food transportation started with first shipments of frozen meat from Australia and New Zealand to United Kingdom.

Today international trade in foods amounts to 10 percent of the World food production. In 2000 in the group of most developed countries (the OECD area) import penetration of food reached 20 percent showing a steep rise from 7 percent in 1992. The decade of 1990s was a period of rapid growth of international trade in food, but it was, to a large extent, an increase of food trade within an OECD area. In the future however a fast growth of share of less developed countries in the international food trade is forecasted as the index of their food auto-sufficiency decreased from 97 percent in 1960s, to 91 percent in late 1990s and is expected to fall further to approximately 89 percent by 2010. International food trade is likely to grow since there will be an increasing mismatch between areas of food abundance and areas of food shortages.

Food safety regulations are a kind of risk regulations in which public authority issues rules that should reduce the threat to people's health stemming from consumption or from contact with contaminated foods. Contrary to selected environmental regulations which can produce internationally negative externalities domestic food regulations cannot affect directly other countries unless food is internationally traded and physically transported. It might seem thus that food safety is a domain of easy international regulatory co-operation, in which food safety standards are mutually recognized, found equivalent in outcomes or even internationally harmonized.

Protecting own citizens against risks stemming from consumption of imported unsafe food is possible unilaterally, but at high costs of intensive border controls and possibly diminished food variety. A better solution would be to create bi-lateral or multilateral arrangements assuring a minimal level of convergence in food safety regulations and their implementation within food trading area.

The latter would reduce international trade conflicts when spontaneously (in response to emergency situations) or strategically (that is out of intent to exploit regulations to gain advantage over other countries) countries create domestic

regulations which can be considered as technical barriers (invisible tariffs²) to trade in foods.

Even if universalism of science seems to guarantee the common definition of health threats stemming from food consumption, an international regulatory harmony in the domain of food safety is undermined by three main factors: intrinsic uncertainty of scientific knowledge about long term effects of the consumption of certain food; public perception of existing threats and costs of effectively protecting citizens against food safety risks.

International dimension of food safety was recognized long time ago. First international regulatory initiatives in the area started at the beginning of 20th century. Today international sanitary and phytosanitary standards are being developed by three international organizations: *the Codex Alimentarius Commission*; the International Office of Epizootics and the International Plant Protection Convention. The conformity of national standards with the standards set by these organizations prevents from legal challenges under the World Trade Organization (WTO). That is why it is beneficial for countries to stick to these standards, unless countries deem them too low or want to use food safety regulations for strategic trade purpose even at the cost of being challenged in the WTO.

International regulatory bodies take lead in elaborating basic (minimum) food safety standards. Other, be they regional or national, standards can exceed these standards only a country or a regional grouping can show scientific evidence in support of such rules. But even if food safety rules are widely accepted as appropriate, they might not be evenly applied creating food safety risk due to the implementation failure. It seems that as an open challenge to international food safety standards becomes increasingly difficult, international disputes over food safety risks tend to move to the area of proper implementation of international standards³. The issue of properly enforcing implementation of regulatory rules becomes crucial in the construction of the European Union food safety regime and is

² The term invisible tariffs was first used by Percy Bidwell in 1939 in *The Invisible Tariff*, New York: Council of Foreign Relations, 1939.

³ This line of argument has been tried by the EU in the WTO case regarding beef hormones where the EU pointed to the danger of hormone abuse by cattle ranchers, even if the Codex Alimentarius studies are right that hormones are „safe” when used in accordance with good veterinary practices [see: Alan O. Sykes, Exploring the need for international harmonization: domestic regulation, sovereignty, and scientific evidence requirements: a pessimistic view, in *Chicago Journal of International Law*, Fall 2002.

crucial in evaluating the impact of the ongoing enlargement on the EU food safety regime.

2. Food safety regulations: Problems and Methods

It is a widely shared opinion that regulating food out of concern for health and environment is a difficult task due to interplay of scientific uncertainties and risky human comportment⁴. In what follows no attempt is made to give a comprehensive picture of these difficulties and issues discussed have been chosen with view for their relevance to the international trade disputes.

2.1. Basic concepts related to food safety

What is a safe food? An answer to this seemingly easy question can be stated only in general terms like this “a safe food is one that does not cause harm to the consumer when it is prepared and/or eaten according to its intended use”⁵. The safety of food is thus not an intrinsic feature of food, but a product of food’s characteristics and the ways food is handled.

At the very general level food related health problems can be divided into the problems resulting from microbiological and chemicals hazards⁶.

At the origin of health problems resulting from microbiological hazards there is a propagation in food of micro-organisms like *Salmonella spp.*, *Campylobacter jejuni*, *Listeria monocytogenes* or *E. coli* 0157⁷. Sound comparative international statistics of

⁴ See for instance section 1 of the book edited by Julian Morris and Roger Bate, *Fearing Food: Risk, Health and Environment*, Butterworth Heineman, 1999.

⁵ R. B. Tompkin, Interactions between government and industry food safety activities, in *Food Control*, nr 2/2001.

⁶ The major breakthrough in ensuring food safety arrived with the birth of modern chemistry in the 19th century. The development of science has created a scientific base for modern food safety controls as it has allowed to look at the chemical parameters of food composition. Science has begun providing tools with which it was possible to disclose dishonest practices in the sale of food and to distinguish between safe and unsafe edible products.

⁷ *Salmonella* is a rod-shaped, motile bacterium -- nonmotile exceptions *S. gallinarum* and *S. pullorum* -- nonsporeforming and Gram-negative. There is a widespread occurrence in animals, especially in poultry and swine. Environmental sources of the organism include water, soil, insects, factory surfaces, kitchen surfaces, animal feces, raw meats, raw poultry, and raw seafoods, to name only a few. *Campylobacter jejuni* is a Gram-negative slender, curved, and motile rod. It is a microaerophilic organism, which means it has a requirement for reduced levels of oxygen. It is relatively fragile, and sensitive to environmental stresses (e.g., 21percent oxygen, drying, heating, disinfectants, acidic conditions). *Listeria monocytogenes* is a, motile by means of flagella. Some studies suggest that 1-10percent of humans may be intestinal carriers of *L. monocytogenes*. It has been found in at least 37 mammalian species, both domestic and feral, as well as at least 17 species of birds and possibly some species of fish and shellfish. *E. coli* is a normal inhabitant of the intestines of all animals,

the scale of microbiological hazards does not exist as incidence rates of microbiologically caused foodborne diseases (MCFD) are reported according to different national definitions and diagnostic systems⁸. Despite popular beliefs that microbiological hazards haunt only civilizationally backward societies, MCFD never fully disappear in any society and once control measures and public awareness to the risk are weakened they might reemerge as local or regional epidemics as it happened in Latvia and Lithuania between 1985 and 1992 and in the Czech Republic or Hungary between 1995-97⁹.

Although there is no world of zero risk controlling practices aimed at the identification and elimination of MCFD should target as closely as possible the state of no("zero")-microbiological contamination as in favorable conditions micro-organisms rapidly multiply and might threaten human health. MCFD regulations are thus an example of situations in which regulation attempts to eradicate the threat¹⁰.

Health problems might be also due to chemical contaminants in foods. Chemical contaminants in foods include natural toxicants such as mycotoxins, environmental contaminants such as dioxins, mercury, lead or food additives, pesticide and veterinary drugs.

The contamination of food by chemical hazards is a major public health concern in Europe and in the US. The use of various chemicals (like food additives, pesticides, veterinary drugs and other agrochemical substances) is comprehensively regulated and controlled by state inspections.

Chemical hazards to food might result (as for instance in Western Europe) from the "industrialization" of agriculture production, but the contamination of food by

including humans. When aerobic culture methods are used, *E. coli* is the dominant species found in feces. Normally *E. coli* serves a useful function in the body by suppressing the growth of harmful bacterial species and by synthesizing appreciable amounts of vitamins. A minority of *E. coli* strains are capable of causing human illness. [Source: US FDA]

⁸ One of most important postulate would be to harmonize ("regulate") the format in which the data about foodborne diseases are collected and reported.

⁹ Cristina Tirado, WHO, (2002) *Statistical Information on Food-Borne Disease in Europe: Microbiological and Chemical Hazards*, a paper to the FAO/WHO Pan-European Conference on Food Safety and Quality, Budapest, February 2002.

¹⁰ But for instance USDA applies "zero-tolerance" policy to the detection of *L. monocytogenes* in ready-to-eat products, whereas countries such as Canada and Denmark have a "non-zero tolerance" for *L. monocytogenes* for some classes of foods [See the website of "Health Canada"].

chemical hazards might also predominantly arise (as for instance in Central and Eastern Europe) from industrial contamination of air, soil and water¹¹.

Scientific analytical methods usually can establish the thresholds of non-harming doses of agrochemicals in food. But despite the existence of comprehensive regulations and precise standards no one can exclude the re-appearance of cases like that in Spain when in 1981-1982 rape seed oil denatured with aniline killing more than 1,000 people and disabling another 25,000¹². In the Spanish case, the agent responsible was never identified despite intensive investigations¹³.

2.2. The Role of Scientific Evidence in Making Food Safety Regulations

Safety effects of food hazards need to be cautiously and credibly assessed. This depends first and foremost on scientific and technological progress, but also on procedural and institutional factors. The accent on scientific evidence results from the search for objective, scientific truth (science is expected to establish certain knowledge whether and how a given microorganism can harm health) and from an attempt to discipline regulatory rulemaking by demanding scientific justification for any regulatory decision.

Scientific proof is supplied by mainstream science based on reasoning from the experimental evidence. The minority scientific views do of course matter, but only when they bring with them convincing evidence. And if they are convincing, in a normal scientific development, they are expected become a part of new mainstream views¹⁴.

¹¹ The use of fertilizers and pesticides is in Poland several times lower than in the EU countries. See: Rolnictwo i gospodarka żywnościowa w Polsce w aspekcie integracji z Unią Europejską, Raport of the Polish Ministry of Agriculture, Warsaw, 2002, p. 13.

¹² See: The Guardian Weekend, 25 August 2001, <http://www.guardian.co.uk/education/2001/aug/25/research.highereducation> – downloaded 15 April 2009.

¹³ According to the data from the US Centers for Disease Control and Prevention estimate 76 million gastrointestinal illnesses, 325,000 serious illnesses and 5,000 deaths each year from foodborne illness in the United States. The economic impact resulting from medical costs and productivity losses for diseases caused by five key foodborne bacterial pathogens totals \$8.3 billion annually – see Thomas J. Billy, HACCP – a work in progress, in *Food Control*, 13 (2002), p.359-362.

¹⁴ „An interpretation that accepts the minority opinions of consultants as „risk assessment” effectively converts scientific evidence requirements into minimal procedural hurdles that can be met easily by any determined regulators, high-minded and protectionists alike” introducing into an international trade system the element of American tort system with its high litigiousity [Alan O. Sykes(2002).Exploring the need for international harmonization: domestic regulation, sovereignty and scientific evidence requirements: a pessimistic view, in *Chicago Journal of International Law*, Fall.]

The requirement to present scientific proofs for food safety regulations serves, as it was for instance expressed in the WTO SPS (Phytosanitary Protocol), to limit, if not to exclude, the instances of arbitrary use of food safety regulations to protect domestic producers from foreign competition. Food safety regulations should not become technical barriers to trade, not be a part of the strategic use of regulations¹⁵. In the WTO terminology Sanitary and phytosanitary (SPS) measures refer to any of the laws, rules, standards, and procedures that governments employ to protect humans, other animals, and plants from diseases, pests, toxins, and other contaminants. Examples of SPS measures include meat and poultry processing standards to reduce pathogens, residue limits for pesticides in foods, and regulation of agricultural biotechnology.

Strictly speaking food safety regulations, if applied equally to domestic and foreign producers, are not a *discriminatory measure*, but still they can be called *protectionist measures* since they might increase rival's costs as domestic producers are usually better suited to meet them¹⁶.

Uncertainty intrinsic to many scientific results should not serve as an easy justification for the introduction of tighter food safety regulations. Science based regulatory making is contested not because of the knowledge of scientific disputes. The refutation of scientific arguments serves often to exploit ignorance, misunderstandings, people's desire to return to nature and irrational fears so common in contemporary societies which want to enjoy the benefits of technological progress without incurring some of its risks.

3. The Public Quest for Safety: Public Expectations and Regulatory Feasibility

No scientific evidence matters if citizens are frightened enough by influential books, other publications or media¹⁷. This case is best illustrated by a ban on the pesticide DDT introduced in the US in 1972 under the influence of a book by an influential American media person Rachel Carson entitled „Silent Spring” – the ban

¹⁵ See David Orden and Donna Roberts (ed.)(1997)*Understanding Technical Barriers to Agriculture Trade*, The International Agricultural Trade Research Consortium.

¹⁶ They can for instance not apply hormone treatment of animals and the ban on it does not affect them.

¹⁷ See: Joanne Cantor(2002)*Fright Reactions to Mass Media*, in Jennings Bryant, Dolf Zillmann(2002)*Media Effects: Advances in Theory and Research*, LEA Publishers, London.

introduced despite numerous scientific testimonies which concluded that "DDT is not a carcinogenic hazard to man... DDT is not a mutagenic or teratogenic hazard to man... The use of DDT under the regulations involved here do not have a deleterious effect on freshwater fish, estuarine organisms, wild birds or other wildlife"¹⁸.

Governments want to reassure its citizens about food safety risks. But they face difficulties in conveying the simple message that food safety is always a matter of degree, that risks are lower or higher, but there is no world of zero risk. For this reason even "The FDA does not state that American food is so safe that only 1 in 10 million Americans will be killed by bacteria contamination, but rather it declares that food is safe and makes unqualified commitments to maintaining this safety"¹⁹

People do react to what might be called an emotive side of food safety issues, that is to the fact that health is central to other personal values and that the majority of risks to health cannot be organoleptically identified and the causes of these risks are difficult to understand for a layman. What seems to matter for people's attitudes to food related risks to health is not that much the nature of risk as dimensions that do characterize the risks²⁰.

The outcomes of psychological research indicate that attitudes towards risk (these attitudes can be placed on the axe from risk-proness to risk-averseness) depend on the following risk descriptors:

- whether risk is taken voluntarily or involuntarily;
- whether the effects of exposure to risk are felt immediately or with a delay (this delay can sometimes be an intergenerational one)²¹;
- whether the risk is concentrated in space or diffused;
- whether the risk is catastrophic or it is a recurrent risk²²;
- whether the risk is mortal or it is a risk of illness (morbidity)²³.

High scaring potential of foodborne risks makes food safety regulations dependent on today's public opinion pressures, which might make them ill-targeted and thus ineffective and inefficient. „Smart risk regulation” cannot be passed or

¹⁸ See The DDT ban By Steven Milloy, Copyright 2000 Junkscience.com, January 1, 2000, <http://www.junkscience.com/jan00/century.htm>

¹⁹ Richard J. Zeckhauser i W. Kip Viscusi, The Risk Management Dilemma, w *The Annals of the American Academy of Political and Social Sciences*, May 1996.

²⁰ That it might derive from the consumption of food.

²¹ As J.M. Keynes used to say "short run matters because in the long run we are all dead" .

²² That is, it happens once.

implemented in the havoc of media-induced food panic. Risk regulation should be based, as it is argued by Cass R. Sunstein, on science and procedures requiring a comprehensive analysis of its costs and benefits²⁴.

4. Approaches to risk regulation

Approaches to risk regulation can crudely be divided into a technological and economic approach. In principle both could go together, but often there is a strong tension between them.²⁵

Technological approach to risk regulation seeks to find a technical solution to any health and safety risk. Its method is to promote the application of technical devices to risk bearing equipment and technical controls to risk situations. This approach usually does not take into account neither the changes in the behavior of individual risk takers, not the cost tradeoffs. Technological approach would be preferred by governments of rich and risk averse societies.

Economic approach to risk regulation starts from an assumption that the proper role of the government is not to eliminate the risk, but to attenuate market failures which cause an inefficient balance between risk reduction and its costs. When drafting a regulation public authorities should identify cases in which regulation can generate more benefits to society than the costs incurred due to the regulatory intervention and to regulate only when a draft regulation passes this test.

Technological approach to risk regulation favors specification standards, which specify the technology that a firm must use, whereas economic approach to risk regulation tend to favor performance standards which impose the requirements that a firm must achieve a specified level of product quality (safety) without specifying the technology that must be used to achieve the standard²⁶. Generally policy analysts argue that whenever it is possible it is better to rely on performance standard than on

²³ Adapted from Paul Slovic, *The Perception of Risk*, Earthscan, 2000, p.173.

²⁴ Cass R. Sunstein(2002) *Risk and reason: safety, law and the environment*, New York, NY: Cambridge University Press, 2002.

²⁵ Alok Bhargava(2008)*Food, Economics and Health*, Oxford University Press,

²⁶ The typology of standards has been developed by Anthony Ogus in his "*Regulation: legal form and economic theory*, Oxford UP, 1994.

specification standard as the former give firms a chance to find the most efficient way to conform to the standard²⁷.

Table 1. Classification Scheme for Food Regulation

Dimension	Classification
Goals	<p><i>Risk reducing.</i> Regulations that ensure an acceptable level of animal, plant or human health or safety</p> <p><i>Quality.</i> Regulations that provide differentiation of goods based on content and process attributes not directly related to health or safety.</p>
Attribute focus	<p><i>Content attributes:</i> Regulations that target material aspects of the product.</p> <p><i>Process attributes.</i> Regulations that target the processes by which a product is produced, processed, handled or distributed.</p>
Breadth	<p><i>Vertical.</i> Regulations specific to a single product or closely related to products in one or more stages of the marketing chain.</p> <p><i>Horizontal.</i> Regulations applied across products that are not necessarily closely related.</p>
Scope	<p><i>Uniform.</i> Regulations that apply equally to products of domestic and foreign origin.</p> <p><i>Specific.</i> Regulations that apply to imported products, often only of certain origins.</p>

Source: T. Josling, D. Roberts, D. Orden(2004)Food Regulation and Trade, Washington, Institute for International Economics, p. 18.

5. Regulatory Trade-Offs: Safety Effects of Regulation Induced Wealth Changes

Regulations impose costs on food producers and distributors. These costs are called *compliance costs* and they are measured as the change (an increase) in the costs of production induced by compliance with the performance (or specification) standard imposed by the regulator²⁸.

²⁷ See the discussion in: Paulette L. Stenzel(2000)Can the ISO 14000 Series Environmental Management Standards Provide a Viable Alternative to Government Regulation? in *American Business Law Journal*, Winter.

²⁸ Other costs resulting from food safety regulations include: court imposed fines; the cost of civil damages awarded to downstream users, including final consumers; reduced revenues due to the loss of reputation and “goodwill” arising from adverse publicity; the costs of product recalls; the costs of investigating possible negligence by a supplier and the costs of legal services (legal fees).

Usually regulatory costs are justified by a reference to expected benefits from regulation in the form of decreased number of deaths or decreased rate of morbidity. But, as Joseph M. Antle noticed, balancing of regulatory costs and benefits is not an easy task as the calculation of benefits is based on several uncertain assumptions:

“The goal of statutory food safety regulation is to mandate that firms produce higher quality, i.e. safer, products for consumers. The key reason why it is difficult to design regulations to do this, and why it is difficult to measure the benefits and costs of these regulations, is that food safety itself is difficult to measure. Information about the various quality attributes of food products is imperfect for consumers, producers, government regulators, and researchers, and this particularly true when microbial pathogens are involved. These pathogens cannot be readily observed or tested in the production process, and their health effects are often difficult for consumers to identify after a food product is consumed. Thus, a key challenge in modeling and measuring the benefits and costs of food safety regulation is to devise methods that can make the best use of the limited and imperfect data that are available. As recent experience in the United States with regulatory impact assessment shows, the data that are currently available provide, at best, highly uncertain estimates of benefits and costs of new regulations”²⁹.

Measuring benefits of health safety regulations is not a simple task and this difficulty further increases when we allow for an indirect health effects of regulation induced changes (reductions) in consumers income. The underlying idea can be explicated in the following way: food safety regulations impose costs which are expressed as compliance costs, and stemming from them price increases. Regulation induced the increase of food prices in turn reduce people’s disposable incomes with adversarial consequences for their consumption choices. So a given regulation may lead to a reduction of death (or morbidity) by a given percentage, but if its implementation costs (joint compliance and opportunity costs) are too high, the end result might be an offsetting (or even greater) human loss due to increased death and morbidity resulting from the fall in GDP and personal incomes³⁰. The comprehensive analysis of costs and benefits requires broadening the scope of analysis from the effects of a regulation on the likelihood of one hazard, to the

²⁹ John M. Antle, Benefits and costs of food safety regulation, in *Food Policy*, 24 (1999), p. 605-623.

³⁰ An accessible presentation of this argument can be found in W. Kip Viscusi, *Rational Risk Policy*, Clarendon Press, 1998.

analysis of its impact on other hazards and eventually to the analysis of its impact on the society's overall welfare.

6. Alternatives to Statutory Regulation

Statutory food safety regulations are not always the best (that is the most effective and efficient) means to enhance food safety. It is worth remembering that there are alternatives to publicly mandated rules, and as a rule of thumb, before embarking on the path of statutory food regulations one should analyze its least restrictive alternatives whose comparative advantages should be assessed in the specific socio-institutional context. The list of most important alternatives to statutory regulations includes:

A) *Education and information* – Consumers themselves may influence the probability of contracting food borne diseases by properly handling food products. Foods should be properly chilled and kept cold during processing, distribution, sale and storage. Meat and poultry products should be kept refrigerated until just prior to cooking³¹. Informing public about the composition, proper ways of food handling and probable health effects may be a voluntary action by food producers or distributors or may be an obligation stemming from public regulations³².

B) *Technology changes* - New options for controlling pathogens in food might come with the creation of new methods of food treatment. One of such methods, which has been approved by the American food safety agency but is still strongly contested by consumer movements in the US and elsewhere, is irradiation³³.

C) *Stimulating market responses to food safety problems* - Some food safety problems flow from the lack of consumer information and from weak market incentives to provide this information. A preliminary question before embarking on

³¹ A research by Neis and van Laanen (Nies, J. I. And P.G. van Laanen, "Effect of Safe Handling Programming on Participants' Food Handling Behaviors" in *Family and Consumer Science Research Journal*, vol. 24, No. 2, Dec. 1995, pp. 161-179) showed that when consumers were educated about food safety principles, the number of people consuming rare or pink hamburgers (that is undercooked) fell by 73 percent and other unsafe behaviors decreased.

³² See the discussion about the food labelling of food produced with addition of transgenic components in the EU (http://europa.eu.int/comm/food/fs/fl/fl_index_en.html).

³³ Irradiation is a ionizing radiation composed of short wavelengths capable of damaging microorganisms such as those that contaminate food or cause food spoilage and deterioration. For the discussion of consumers resistance to irradiated food see: Nayga, R. M.(2003)Will consumers accept irradiated food products?, in *International Journal of Consumer Studies*, July 2003, vol. 27, no. 3, pp. 220-220(1).

government regulations is whether these market failures cannot be diminished by altering the structure of incentives market players face. The latter can be done by for instance changes in the liability law³⁴.

Regulating food safety, it has to be repeated, is a complex issue, but public authorities have various policy instruments and they have to use them as to optimize combined outcomes of their interventions. The choice of proper ways to regulate food safety should be a part of scientific analysis done by a community of professional regulatory policies analysts and not led by short term political convenience or dominated by irrational public scares³⁵.

In the perspective of this paper it is worth stressing that contemporary food safety regulations rely more and more on mixed solutions which overall evaluation requires an attention to institutional details and in particular to the difficulties in implementing those regulations and limiting their plausible unintended effects.

7. The EU and Food Safety: Between Reliance on Scientific Evidence and Responsiveness to Public Fears

7.1. EU food safety regulations in a pre-BSE era

It can hardly be said that EU food safety regulations have been shaped exclusively by scientific evidence and careful policy analysis. Food scares and especially BSE crises, as documented by scholars³⁶, have been the driving force behind the acceleration of new European initiatives in the area of food safety.

Below I shortly evidence these recent developments in EU food safety policies asking how they might have affected the capacity of the EU to effectively influence the changes in food safety systems in candidate countries in the pre-accession period.

³⁴ Firms' increased attention to food safety may also result their care for good reputation

³⁵ This observation seems obvious, but it should be repeated when one observes a disparity in the expenditures on policy analysis between the US and Europe (see: A. Martino, *Aiutare lo Stato a Pensare*, FGA Torino, 1996).

³⁶ See Ellen Vos, (2000)EU Food Safety Regulation in the aftermath of the BSE crisis, in *Journal of Consumer Policy*, vol. 23, p. 227-255; Sebastian Krapohl(2003)Risk Regulation in the EU between Interests and Expertise: the Case of BSE, in *Journal of European Public Policy*, April, p: 189-207, Skogstad Grace(2001)The WTO and Food Safety Regulatory Policy Innovation in the European Union, *Journal of Common Market Studies*, September 2001, vol. 39, no. 3, pp. 485-505(21).

Ellen Vos³⁷ describes a pre-BSE crisis EU food safety regime as developed ad hoc and predominantly under influence of the jurisprudence of the European Court of Justice. She points out that with regard to food safety assessment the Community used to resort to committees and especially to the Scientific Committee on Foodstuffs (SCF) composed of independent scientists; the Standing Committee on Foodstuffs (StCF) consisting of national representatives and the Advisory Committee on Foodstuffs (ACF) composed of representatives of various interest groups. The SCF was charged to supply scientific evidence, the ACF supplied opinions of interests involved and the StCF has served to ensure the political approval of the Member States at the risk management stage.

Until mid-1990s this pragmatic way of dealing with food safety issues seemed to function relatively well, but the BSE crisis shattered the positive image of the Commission's regulatory actions. The Report of the EP Temporary Committee of Inquiry into BSE from February 1997 revealed the shortcomings of "the committee model" evidencing the political pressure exercised on formally independent members of the SCF, the little coordination and cooperation between the various DGs of the Commission active in the field of food safety and, what was the most serious, a true policy of disinformation on the part of the Commission.

7.2. The European Commission's New Approach to Food Safety

In response to the perception of crisis in the EU food safety regime the European Commission in a series of moves has laid down a conceptual and institutional basis for a new approach to food safety issues.

First change introduced might be called *an institutional streamlining* and it consisted in bringing together all responsibilities for feed and food safety issues within the Directorate General for Health and Consumer Protection called for the sake of simplicity DG Sanco.

Next in a communication on a "Consumer Health and Food Safety" the Commission formulated three basic principles of its new approach – namely separation of the responsibility for scientific advice from the responsibility for legislation and for control from information and communication policies³⁸. This change might be called *the*

³⁷ Op.cit. p: 229-240.

³⁸ „Consumer Health and Food Safety”, Communication (1997) 183 Final. of 30 April 1997.

separation of food safety policies into risk assessment, risk management and risk communication.

In the following “Green Paper on the General Principles of Food Law in the EU”³⁹ the Commission has announced that it would like to ensure free movement of foods within the internal market, science based risk assessment and greater competitiveness of European food exports by placing greater responsibility for food safety on food processing industry and increasing effectiveness of official food control and enforcement. This line of changes is further developed in the Commission’s “Proposal for a Regulation of the European Parliament and of the Council on official feed and food controls” which stresses the need to develop a comprehensive audit system⁴⁰.

Finally in a White Paper on Food Safety from January 2000⁴¹ the Commission announced that the Commission would like to base its food safety policy on a “comprehensive and integrated approach” which covers the whole food chain “from farm to table”. The Commission has proclaimed that risk analysis will be the basis of its food safety regulatory policies, that risk analysis will be based on best scientific advice thanks to another institutional innovation – the establishment of the European Food Safety Authority with task to provide independent scientific advice on food safety issues, collect and analyze data related to food safety issues, identify and warn about emerging risks, support the Commission in the case of crisis and communicate to the general public on food safety related issues⁴².

The direction of changes in the EU food safety regime is summarized in the table below.

³⁹ The General Principles of Food Law in the European Union COM (97) 176 30 April 1997.

⁴⁰ COM/2003/0052 final - COD 2003/0030.

⁴¹ The White Paper on Food Safety of January 12, 2000 (COM(1999) 719 final).

⁴² The Regulation of the Council of Ministers from 28th January, 2002, Regulation EC(178/2002).

Table 2. Evolution of EU Food Safety Control: From Controlling to Auditing

Control approach	Audit approach
	(EU legal base Council Directive 93/43/EEC of 14 June 1993), COM (2000) 438(03) and Proposal for a Regulation of the European Parliament and of the Council on official feed and food controls /* COM/2003/0052 final – COD 2003/0030 */
<i>Reactivity</i> : controls mostly when food has entered the market.	<i>Precaution</i> : controlling producers food operators practices
<i>Virtual comprehensiveness</i> : commitment to control all threats to food safety	<i>Selectivity</i> : intervening in critical points
<i>Sectoriality</i> : controls of different risks are handled differently	<i>Completeness</i> : Controls lacunas and overlapping get canceled
<i>Community financing</i> : Costs of running control system fall mostly on the EU budget	<i>Dispersed financing</i> : Costs of running control systems fall mostly on food businesses

7.3. Dilemmas of the EU Food Safety Regime

In spite of continuing reforms the present European food safety regime is not free from conceptual and institutional ambiguities: it stresses the importance of science in risk analysis, but at the same, via a certain interpretation of the precautionary principle⁴³, remains ambiguous and open to influence of extra-scientific considerations, its administration is not free from political interference which undermines the credibility of European food safety regulations⁴⁴, it intends to rely more on food industry self-regulation and companies' social responsibility but it tries also give enhance controlling power of public inspectors and enforcement services; and it struggles to reduce "the implementation gap" stemming from the fact that regulations are made internationally, but executed nationally.

The European Commission is struggling to develop European food safety policy which tries to balance three goals: to minimize the threat to public safety, to reduce regulatory tensions among the EU member states and to minimize possible conflicts with the rest of the world over food safety issues.

⁴³ Giandomenico Majone(2002)The Precautionary Principle and its Policy Implications, *Journal of Common Market Studies*, March, vol. 40, no. 1, pp. 89-109(21).

⁴⁴ Giandomenico Majone(2000)The Credibility Crisis of Community Regulation, *Journal of Common Market Studies*, June, vol. 38, no. 2, pp. 273-302(30).

The creation of the European Food Safety Authority (EFSA) could have been instrumental to balancing these goals as an independent regulator is better suited to assure scientific excellence, to be impartial with regard to national interests and less susceptible to the accusations of using regulations as a protectionist device. Yet, the EU has not exploited the opportunity to create an independent European food safety regulatory authority and has limited the tasks of the EFSA chiefly to risk assessment⁴⁵.

Conceptual and institutional drawbacks indicated above reduce the capacity of the European Commission to act credibly and effectively vis a vis member states and third countries. Yet, still the European Commission possesses powerful policy safety instruments which can be used to improve food safety risks to European consumers. There is no space to discuss here all policy instruments in the hands of the EU. I will point just to two which seem most symptomatic for the ongoing changes in the EU food safety regime. The first instrument is applied to external trade partners (so called “third parties”), the second is developed in view of being applied to internal agro-alimentary businesses. The former instrument will be called market access requirements, the latter an audit technique. These two instruments will be shortly discussed.

7.4. Market Access as a Food Safety Instrument

The core of the former instrument consists of rules that are applied to imports of live animals and animal products from third countries⁴⁶. The rules impose safety and supervisory standards which are equal or at least equivalent to the rules applied in the trade among EU member countries. Before getting an approval for exports to the EU countries a third country is inspected by an inspection from the Food and

⁴⁵ The EFSA could test among others the idea of regulatory network as many member states have recently created national food safety agencies and have entrusted them the task of regulating food safety. National food safety agencies were created in: Great Britain (May 1997- the Food Standards Agency); in France (April 1999- the Agence Francaise de la Securite Sanitaire des Aliments), in Finland (the National Food Agency), in Ireland (1998 - the Food Safety Authority of Ireland) and in Sweden (the Swedish National Food Administration (NFA), in Belgium (February 2000 - the Belgian Federal Agency for the Safety of the Food Chain).

⁴⁶ The list of veterinary rules applied in such cases has been recently updated and published in the Food and Veterinary Office document entitled: „General Guidance to Third Country National Authorities on the Rules to Be Followed For the Import of Live Animals and Animal Products into EU from Third Countries” 23 January 2003.

Veterinary Office (FVO) which checks on spot whether the EU veterinary requirements are met. This policy instrument had been applied to EU candidate countries before they have become the candidates. The Food and Veterinary Office (FVO) has carried out several inspections in candidate countries⁴⁷. Their purpose was to certificate food producers in order to give them “market access” to the EU⁴⁸. Besides “ordinary missions” the FVO has conducted several special assessment missions to the applicant countries with view to assess their food safety system.

The task of ordinary missions is *to assess the state of individual food processing plants* in order to issue them an export licence. Special missions serve to assess a general state of food safety in a given industry in order *to approve the readiness of a country to join a single market*. The former is a judgment about an individual case, the latter is to a large extent a judgment about the shape of a food safety regime.

It is hard to believe that EU veterinary missions might have been misled by the host country’s manipulation in deciding where they should go, what they should see and whom they should meet since the programme of each mission is set by mutual agreement and mission officers could change the programme at will⁴⁹. So meeting the requests of FVO inspections is test for loyal cooperation in assuring food safety.

⁴⁷ The missions are carried under the provision of the following Community legal acts:

a) Commission Decision 86/474/EEC of 11 September 1986; Commission Decision 98/140/EC of 4 February 1998 and Council Decision 95/408/EC of June 1995.

⁴⁸ The permission for imports of food (meat in particular) are issued based on the following EU regulations:

- a) Council Directive 72/462/EEC on health and veterinary inspection problems upon importation of bovine, ovine and caprine animals and swine, fresh meat or meat products from third countries (as last amended) – OJ No. L302, 31/12/1972, p. 28.
- b) Council Directive 92/118/EEC laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A(I) to Directive 89/662/EEC and, as regards, pathogens, to Directive 90/425/EEC – OJ No. L62, 17/12/1992, p. 19.
- c) Council Directive 94/65/EC laying down the requirements for the production and placing on the market of minced meat and meat preparations – OJ No. L368, 31/12/1994, p.10.
- d) Council Directive 96/93/EC on the certification of animals and animal products – OJ No. 13, 16/01/1997, p.97.

⁴⁹ Accepting the wish of mission’s inspector to alter the route is in itself an act of signaling good will and hence a credibility enhancing device. Just think: if the wish of inspectors is not met, they would register this fact in the final report and suspicion will arise that some irregularities are being hidden.

7.5. The Emergence of Regulatory Auditing

The second policy instrument which is increasingly applied to increase food safety consists of *the move from direct food controls to regulatory auditing*. This move has been facilitated by the propagation of HACCP (Hazard Analysis and Critical Control Points) as a method of producer' self control. HACCP has been originally developed by food businesses. Following the developments in US food safety regulations, the EC has tried to promote indirect methods, including HACCP, for the control of food safety. It does so by requiring all food processing plants to implement HACCP as their own inspection system⁵⁰. HACCP system strives to reduce human exposure to food borne pathogens by requiring processing plants to scrutinize the critical control points in the production process – points where food safety hazards can be prevented, reduced to an acceptable level or eliminated⁵¹.

Placing HACCP at the core of food safety regulatory developments leads to two major changes in food safety policies: firstly, food safety inspections can move from *direct food safety controls to regulatory audits*; secondly, the costs of food safety controls are shifted from the budget of the government to the food processor.

The implementation of HACCP requires the registration of the results of the company's internal controls at critical points. Inspectors of food safety agency can then examine these records virtually "in real time" as these reports might be transferred via internet to the central files of the food safety agency. The auditing is enhanced by a parallel, but rare sampling of processed food for laboratory examinations, but the proportions shift: food testing is above all own responsibility of the food processor. Furthermore such a change alters the distribution of costs stemming from food safety controls. The public food safety agency invests initially in educating the industry in HACCP method and then starts controlling HACCP implementation plans and monitoring the way companies run their own HACCP system. External controls are supposed first to certificate the HACCP and next to

⁵⁰ EU Council Directive 92/46/EEC.

⁵¹ A single and authoritative food safety agency would not only assume full responsibility for risk assessment and risk management, but it would help to streamline the implementation of industry process standards since „Inconsistent HACCP implementation is just one of numerous problems that arise from having several agencies with separate responsibilities for food safety regulation“, Caroline Smith DeWaal,(2003)Safe food from a consumer perspective, in *Food Control*, vol. 14.

control the way it is run. This change entrusts producers, it makes saving on the costs of controls and allows a better targeting of control resources⁵².

It seems justified to say that the European food safety regime shows the characteristics of both⁵³, an enforcement and management regimes since like in a typical enforcement regime the European Commission can monitor and sanction for misbehavior and not unlike in other international management regimes the EC can help member countries to enhance technical and institutional capacities to meet their commitments.

Table 3. Beef Export Food Safety Regulations

Stage of Food Production	Export Related Food Safety Standards
Beef production	EU ban on using animals protein as a source of feeding
Animal welfare	None
Traceability	EU rules regarding an identification system for animals, farms and plants
Food safety	<i>Ante mortem</i> (before slaughter) inspection to detect any diseases <i>Post mortem</i> tests after slaughter, checking: the animal's organs (foot, head, tongue, kidney, among others) and age (teeth). After these tests, the carcass receives a stamp confirming the inspection, then is cleaned and maintained in a cold room.
Pathogens/toxins	Beef to be commercialized should be maintained in a chilled room at a temperature around 4 C. Delivery should be made under a temperature of 7 C
Carcass specification	Classification of carcasses according to quality
Target animal	All animals intended for exports under the veterinary inspection.

Source: Based on L. Marques Vieira, V. Bruce Traill(2007)The Role of Food Standards in International Trade: Evidence from Brazilian Beef Exports to the EU Market, in Journal of International Development, page 760.

⁵² Estimated benefits from the introduction of HACCP in the US vary very widely. Thus for instance Stephen R. Crutchfield et al. [S. R. Crutchfield, Jean C. Buzby, Tanya Roberts, Michael Ollinger and C-T. Jordan Lin, (1997)An Economic Assessment of Food Safety Regulations, USDA, Agriculture Economic Report No: 755] estimate that economic benefits from the introduction of HACCP controls may stay within the range of \$1.9 billion to \$171.8 billion depending on the effectiveness of HACCP implementation.

⁵³ After Jonas Tallberg, see: Jonas Tallberg(2002)Path to Compliance: Enforcement, Management, and the European Union, in *International Organization*, Summer 2002, pp. 609-643.

8. Main Features of the US Food Safety Regulatory System

The United States, like the EU countries, has a comprehensive system to protect consumers from unsafe food and agricultural products and to protect its animal and plant resources from foreign pests and diseases. A variety of statutes and implementing regulations, directives, and administrative procedures underpin this system. These essentially constitute the domestic's SPS measures. Major authorities are briefly described below.

Within the Department of Health and Human Services, the Food and Drug Administration (FDA) oversees the safety of most human and animal foods and drugs, primarily under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §301 *et seq.*). The primary exceptions are meat and poultry and their products, which are regulated by USDA's Food Safety and Inspection Service (FSIS) under the Federal Meat Inspection Act (21 U.S.C. §601 *et seq.*) and the Poultry Products Inspection Act (21 U.S.C. §451 *et seq.*). USDA's Animal and Plant Health Inspection Service (APHIS) has lead responsibility for animal and plant health under the Animal Health Protection Act (7 U.S.C. §8301 *et seq.*) and the Federal Plant Protection Act (7 U.S.C. §7701 *et seq.*). Pesticides are regulated by the independent Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. §136 *et seq.*).

Each of the responsible agencies has promulgated an extensive body of regulations to implement these laws, all of which apply to imports as well as domestic products. For example, plants, animals, and their products require an APHIS import permit. Whether a product can be imported and the conditions for entry are dependent upon an APHIS risk assessment of a product and where it originated, taking into account internationally recognized scientific guidelines (i.e., those established in the international animal health organization OIE and in the International Plant Protection Convention, or IPPC), usually culminating with formal rules in the *Federal Register*. FSIS evaluates foreign meat and poultry programs to ensure their equivalency with U.S. requirements and reinspects samples at the border⁵⁴.

⁵⁴ This section draws on: G. S. Becker(2006)SPS Concerns in Agricultural Trade. CRS Report for Congress.

The basic US guidance for regulating biotechnology products is the Coordinated Framework for Regulation of Biotechnology (51 *Fed. Reg.* 23302), published in 1986 by the White House Office of Science and Technology Policy (OSTP). A key principle is that genetically engineered products should continue to be regulated according to their characteristics and unique features, not their production method — that is, whether or not they were created through biotechnology. The framework relies on existing statutory authority and regulations to ensure the safety of biotechnology research and products, including food and agricultural products.

EU – US food safety cooperation takes place within a broader framework of the WTO SPS agreement. But besides the two sides have also a signed in July 1999. It is aimed at facilitating trade, through mutual recognition by each party that the other's SPS standards for animal products — even where not identical — provide an equivalent level of protection to public and animal health. The agreement has preserved several billion dollars annually in two way trade in animals and products, according to USDA. Despite the agreement, U.S. exporters continue to encounter major barriers to a number of important products. For example, none of the EU's average of \$1.2 billion in annual poultry imports is coming from the United States, a major world supplier. The EU's 1997 ban on the use of anti-microbial treatments for sanitizing poultry carcasses effectively halted US poultry exports to the EU, even though the use of anti-microbial treatments is approved by FDA.

9. EU – US Conflicts over Food Safety

Despite the existence of mutually advantageous rules and agreements occasionally there have been US- EU food related trade disputes. These include among others a European Union (EU) ban on US meats treated with growth promoting hormones, which a WTO dispute panel ruled had not been supported by a risk assessment⁵⁵; and a recent EU moratorium on approvals of biotechnology products. The latter issue is discussed below showing that despite an appearance of

⁵⁵ The EU in 1989 implemented a ban on the production and importation of meat from livestock treated with growth-promoting hormones. The ban caused an estimated \$100-\$200 million in lost U.S. exports annually. The EU justified the ban to protect the health and safety of consumers, but several WTO dispute settlement panels subsequently ruled that the ban lacked scientific justification and was inconsistent with WTO trade rules. The EU refused to remove the ban, and the United States declined an EU offer of compensation in the form of an expanded quota for hormone-free beef. The U.S.

uniform position and the power of the EC to make decisions the EU lacks the real power to constrain its member states to the EC's regulatory decisions.

The European Commission maintains that the EU's regulatory regime for biotech products is well functioning. But, it seems that the EU faces the problem of effective implementation of its food safety rules. Thus, based on the opinion of the European Food Safety Authority (EFSA) the EC has authorized the cultivation of GM (genetically modified) maize 1507 and Bt 11.

Earlier examples show however that national governments introduce bans on GM maize despite positive decision by the European commission (thus for instance France, Greece and Hungary prohibited the cultivation of GM maize MON810. In addition, Austria has continued to ban the cultivation of an insect-resistant maize variety, even though it had been approved by the European Commission before the moratorium and recently found to be safe by the EC's own scientific committee. Member states which did not ban this maize variety were cultivating it in greater quantities without any adverse effects on health, safety or the environment. Notwithstanding all this, the EC had failed to remove this ban by Austria

The EC has been tough enough in face of national resistance to GM products believing that biotech issues have sensitive, political and cultural, nature. Yet such lack of implementation power decreases the credibility of the EU position in global trade agreements.

10. Conclusions

This paper has analyzed the problems of mutually adjusting the food safety regime between the EU and the US. This has been done by firstly discussing the problems intrinsic to food safety regulations and to the choice of regulatory instruments in general, next by sketching the main tendencies of the development of EU food safety regime and then by discussing factors, which have influenced the transposition of EU food safety regulation into domestic laws and regulations and which might influence the implementation of such regulations in the near future.

The growing stress on the control of implementation of international agreements poses enormous challenge to policy research as theorizing policy

government was granted the right to, and did, impose 100% retaliatory tariffs on \$116 million of EU agricultural imports.

implementation and drawing policy lessons is an almost impossible challenge due to the complexities of policy issues and some conceptual problems⁵⁶. The continuation of research on implementation of food safety regulations for the sake of smoothing international agricultural trade is an important and persistent challenge as it should be remembered that food safety is not a domestic issue of any state, but a broader problem in efforts to create such conditions for international trade in food stuffs, which would respect the rules of free trade, while paying attention to the concerns for food safety. The increased internationalization of food safety regulations, as pointed out by Richard S. Silverman, has started and will probably continue⁵⁷.

⁵⁶ For a recent survey of policy implementation theories see: Peter deLeon and Linda deLeon(2002) What Ever Happened to Policy Implementation, in *Journal of Public Administration Research and Theory*, n. 4, pp. 467-492.

⁵⁷ According to Silverman: "Food regulation in the last half of the twentieth century has been characterized in part by an accelerating shift from local regulation to a system of national standards or national "uniformity". We will see the same trend during next fifty years toward an international uniformity, with national agencies giving up authority to international standard setting and scientific organizations. "Emerging" or third world war nations appear to be expecting and planning for this to happen. They do not appear to be creating their own independent scientific/regulatory infrastructure, but seem to be relying on Codex and organizations such as the Joint Expert Committee on Food Additives to serve this function", Richard S. Silverman, Report on the Future of Food Regulation, in *Food and Drug Law Journal*, nr 11/2000.

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