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Social Implications of Europeanisation of Risk Regulation and Food Safety: Theoretical Framework for Analysis

Abstract: *A commonly overlooked aspect of current Europeanisation of food safety policy in the common market are the often unintended, sometimes counterproductive, and always complex social consequences caused by this type of risk regulation. Contemporary research has largely been concerned with analysing the institutional problems of risk regulation, focusing upon the role of science in the policy making process, the separation of risk assessment and risk management, and related problems of legitimacy and accountability. Very little attention, however, has until now been given to the economic and social impact of risk regulatory decisions and matters of distributive justice involved. It is here argued that the economic and social dimensions of European risk regulation can – if not duly recognised, analysed, and integrated with the political and legal process – lead to potentially critical challenges to European solidarity and social policy. This article attempts to address these currently marginalised aspects by reference to three different – yet interrelated – regulatory mechanisms, namely scientific risk analysis, mutual recognition and standardisation. Through examining those mechanisms, which affect diversity and competitive advantage and which are in various degrees used in the EU food safety regulation, the article asks about possibilities to improve social embeddedness of regulatory decision in the field of food.*

Introduction

Contemporary research on legal aspects of transnational risk regulation has largely been concerned with analysing the institutional problems of risk regulation, focusing upon the role of science in the policy making process, the

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principle of precaution, the separation of risk assessment and risk management, and related problems of legitimacy and accountability. Accordingly, most of the regulatory reform efforts initiated by the European Commission, who had been trying to establish a reliable risk assessment system, have so far concentrated on those aspects which could provide a solid basis for regulatory decisions and gain accountability and trust of the European public. Little attention, however, has until now been given to the economic and social impact of risk regulatory decisions and distributive concerns involved in the regulation process. As if it was somehow forgotten that risk regulation, just as any type of regulation, does not happen in some kind of vacuum, but is tied to the system which gave rise to it and the society which it affects. I argue, therefore, that the economic and social dimensions of European risk regulation can – if not duly recognised, analysed, and integrated with the political and legal process – lead to potentially critical challenges to European solidarity and social policy.

The main objective of this paper is to show that the major challenge facing contemporary risk regulation in Europe, namely the one of its social disembeddedness, is not given sufficient attention. My conceptual framework for the analysis will follow three regulatory principles and legal methodologies, which have been used in the EU product regulation, and which reflect dominance of different sets of objectives influencing the legal structure of the European market. All those three regulatory structures, namely scientific risk regulation, mutual recognition and standardisation, have constituted important phases and steps of development of the EU legal structure in the field of food. Their importance, however, has been changing over time as one was gaining preference over the others. This evolution was neither accidental, nor driven solely by legal considerations. It was rather an outcome of particular settings of different factors affecting legal developments. In the case of EU food safety regulation, those factors can be organised in three basic categories: internal factors (such as the common market project or outbreak of the BSE crisis), external factors (such as the influence of the WTO and Europe's participation in the global market), and external-internal factors (such as enlargement, which from being external has gradually become internalised). The problem I would like to emphasise is the balance of factors influencing regulatory developments, and the question whether by following blindly one set of objectives Europe is not missing on some vital values, which not only objectively seem important, but which are at the roots of European project. I am not trying to suggest a precise value balance to be adopted, but rather to identify those values which seem to be neglected, and to discuss regulatory mechanisms which could help to determine a weigh to be

given to each of those values, as well as to increase transparency of their social and economic implications.

In the following parts of this paper I will, first, provide a short overview of the developments of the European food safety regulation and highlight the landmarks of its evolution as well as the most important regulatory aspects at stake, which should serve as a background for development of my theoretical framework. In the third part I will present my proposal for the theoretical framework of analysis of the socio-economic aspects of risk regulation, and present the three approaches I have outlined above. Finally, in the conclusions I will summarise my findings and put forward a number of issues for further discussion.

1. Development of European food safety regulation in a nutshell

European food safety regulation can be perceived as an ideal example of development of EU policies, which illustrates the quintessence and the meanders of the ‘European project’. It has followed the mainstream way of thinking about the European Union and its role in national legal systems, and it mirrored developing policy approaches.

Common EU food policy was not an intentional, carefully planned project on the European agenda. On the contrary, food regulation emerged on the outskirts of other Community undertakings. It is probably one of the reasons why neither far-reaching programming nor comprehensiveness was ever at the premium. The Treaty of Rome did not originally contain any reference to food issues. Some of the Treaty provisions, however, indirectly required regulation of particular aspects of the foodstuffs field. These were mainly questions of agricultural production and of free trade. On the one hand the Treaty called for a unified approach to organizing the production and marketing of agricultural products, and on the other, the Single Market provisions envisaged elimination of trade barriers to allow free circulation of goods from all member states within the Community.¹ This particular decoupling, which left food policy issues hanging between two contrasting market regulation paradigms, namely interventionist and ‘total regulation’ agricultural scheme on the one hand, and free market rationale on the other, has left a schizophrenic legacy to food regulation and contributed to its fragmentation.

¹ See: C.Lister, *Regulation of Food Products by the European Community*, London 1992, p.7.

Until the mid-1980s, Community activity in foodstuffs regulation, similarly to other areas of the Common Market, followed a retail approach.² Following this technique, the Community developed a separate set of detailed and comprehensive standards and requirements for each and every category of regulated products, which included the definition, the content, the authorised ingredients and unauthorised residues, as well as rules for market preparation, presentation and labelling. Complexity and density of such harmonising legislation, however, grew so enormously that a couple of years later, following the landmark *Cassis de Dijon*³ judgment, the Commission had to revise its initial position and come up with a new, more efficient strategy for the completion of the single market, with mutual recognition as a central market management rule. New Approach to Technical Harmonisation and Standardisation⁴ developed into an original transnational mode of governance, where essential safety requirements were laid down in harmonising European legislation, while the task of providing technical details was delegated to non-state standardisation bodies at the European and national level. The public-private partnership in development of product safety regulation was however not the only case of such specialised delegation in areas of high technical complexity, such as food safety. Establishment of the committee system, which assists the Commission in performance of its delegated legislative and executive duties, marked a transition of the European regulatory system towards a ‘cognitive opening of law’.⁵ The committee system structures the transfer of knowledge into the realm of law through organised cooperation and deliberation of field experts appointed by member states, which additionally facilitates acceptance and implementation of European measures by giving member states a sense of participation and control over European

² The retail approach was described and strongly criticised by the 1985 White Paper on the Completion of the Internal Market, COM(85)310 final, 14.06.1985, and in an accompanying document entitled Completion of the Internal Market: Community Legislation on Foodstuffs, COM(85)603 final, which will be evaluated below.

³ C120/78 Rewe-Zentral AG v. Bundesmonopolverwaltung für Branntwein, [1979] ECR 649.

⁴ European Commission, The New Approach to Technical Harmonisation and Standardisation, COM(85)19 final, 31 January 1985. Among rich literature see for example J.Pelkmans, *The New Approach to Technical Harmonisation and Standardisation*, “Journal of Common Market Studies” vol. 25/1987; C.Joerges, H.Schepel, E.Vos, *The Law’s Problems with the Involvement of Non-governmental Actors in Europe’s Legislative Process: The Case of Standardisation under the ‘New Approach*, EUI Working Papers LAW, No. 1999/9; H.Schepel, *The Constitution of Private Governance – Product Standards in the Regulation of Integrating Markets*, Oxford 2005.

⁵ N.Luhmann, *Law as a Social System*, Oxford 2004, p.106, (translated by K.A.Ziegert, original title: *Das Recht der Gesellschaft*, Frankfurt am Main 1993).

developments. Throughout decades, it seemed to have functioned rather smoothly, but the number of omitted problems and mistakes was rising to reach its peak during the BSE crisis of the 1990s, which probably changed the way of thinking about food safety regulation in Europe forever. Reforms propelled by the crisis, reflecting the consumer concerns and concentrating around the safety paradigm, led to new legislation and control systems, and even more advanced development in the field of technocratic and national involvement in supranational governance. It culminated with the establishment of the European Food Safety Authority, responsible for independent and professional scientific risk assessment.⁶ What has remained unresolved, however, are questions which were not challenged by the BSE crisis and were therefore not discussed and resolved during the post-BSE reforms. It is, in particular, the problem of looking at the EU food safety regulation from the perspective of not only regulation of risks but also regulation of the market. The market which since 2004 is becoming bigger and more diverse, and at the same time more and more contingent on the developments at the international level.

2. Theoretical framework for analysis of socio-economic implications of risk regulation

The conceptual framework I would like to suggest here is based on three regulatory approaches used in contemporary risk regulation, which have in varying degree been used in the European food safety regulation. Such conceptualisation will show various methods of including a wider scope of socio-economic concerns in regulatory decision making, as well as potential impact of such concerns on regulation and on the market, which differ under each of the discussed approaches. The first one advocates better ways of embedding risk regulation by going beyond the technocratic recourse to science and into its natural social contexts. The second one follows the market regulating pattern of mutual recognition as means of balancing the aim of

⁶ E.Vos, *EU Food Safety Regulation in the Aftermath of the BSE Crisis*, "Journal of Consumer Policy" no. 23/2000; G.Chambers, *The BSE Crisis and the European Parliament in: EU Committees: Social Regulation, Law and Politics*, eds. C.Joerges, E.Vos, Oxford 1999; S.Krapohl, *Risk Regulation in the EU between Interests and Expertise – The Case of BSE*, "Journal of European Public Policy" vol. 10/2003; G.Little, *Reports. BSE and the Regulation of Risk*, "The Modern Law Review" vol. 64/2001; E.Millstone, P.van Zwanenberg, *Politics of Expert Advice: Lessons from the Early History of the BSE Saga*, "Science and Public Policy" vol. 28/2001, p.99; J.Neyer, *The Regulation of Risk and the Power of the People: Lessons from the BSE Crisis*, "European Integration online Papers" vol. 4/2000; K.Vincent, 'Mad Cows' and Eurocrats – Community Responses to the BSE Crisis, "European Law Journal" vol. 10/2004.

creating a common market with challenges of its diversity. The third way analyses standardisation as a risk regulatory tool and explores its effects on the market.

2.1. Risk regulation: regulating trade via consumer safety paradigm

2.1.1. Risk regulation

Risk regulation is a chapeau concept used for referring to a whole range of activities performed at different levels of governance structures. Risk analysis, in its ideal archetype, comprises of three basic elements, namely, scientific risk assessment, political risk management and risk communication. In reality, however, strict division between the phases of the process is not so clear, which basically means that the dividing line between the technical and the political elements is often vague and difficult to draw. While the role of policy in risk assessment has openly been acknowledged, functional separation of assessment and management activities reflects the continuous belief in the possibility of separation of the scientific and the political. It underpins the quest for de-politicising scientific risk assessment and handing the ultimate political management decision to democratically accountable entities.⁷ This complexity of decision-making in face of uncertainty has, thus, led to increased proceduralisation of both generation of knowledge and generation of decisions based on that knowledge.⁸ It is especially valid in transnational situations, where variety of interests, multi-level character of governance and problematic nature of democratic legitimacy pose additional challenges to risk regulation. In such circumstances, however, basing risk regulation solely on science tends to compromise its social embeddedness, and disregards its socio-economic implications. Risk regulation as much as any aspect of the market has to be embedded in the social structure that gave rise to it and that contextualises its existence and development. I am making this argument inspired by Polanyi's social embeddedness theory,⁹ and applying his ideas to contemporary risk regulation as a vital element of market governance. Borrowing from Polanyi, I am trying to show that regulation of the market, such as the market itself is embedded in a certain society, in a way that both are

⁷ See: C.Button, *The Power to Protect. Trade, Health and Uncertainty in the WTO*, Oxford 2004, p.100.

⁸ Cf. K.-H.Ladeur, *The Introduction of the Precautionary Principle into the EU Law: a Pyrrhic Victory for Environmental and Public Health Law? Decision-Making under Conditions of Complexity in Multi-Level Political Systems*, "Common Market Law Review" vol. 40/2003, p.1464.

⁹ K.Polanyi, *The Great Transformation*, Boston 1957.

interrelated and cannot function properly when disconnected.¹⁰ Disconnecting risk regulation from its social basis causes gradual disembedding of the market in which it is exercised, which in effect deprives it of its social legitimacy, and is detrimental for that market. I claim, therefore, that in order to ensure their acceptance and efficiency, risk regulatory decisions must be socially embedded. They must relate to the societies which they are directed to and reflect their particular context.

2.1.2. Scientific risk analysis and its limits

Science, perceived as an autonomous and universal arbiter, has been expected to give uncontroversial ground for regulatory solutions, which go beyond borders of national divides and interests and which can be accepted by all actors in play. Experiences, however, have shed a doubt on these expectations revealing that scientific expertise is neither that autonomous, nor that universal. Scientific expertise, in fact, has often shown to be more of a weapon in transnational conflicts than a conflict arbiter that it was intended to be. Moreover, focus on science in risk regulation, tends to suppress all other important values and interests which should ideally be taken into consideration.

Scientific risk assessment has its external and internal limits. External limitations stem from the fact that science follows its own clearly-cut logic and therefore remains blind to other interests and values. This, it has to be emphasised, is mainly perceived as an advantage of science rather than its drawback, since ideally other values which should be considered in decision-making process are included in the risk management phase, where they are represented and deliberated by legitimate entities. In reality, however, this is questionable. Very often risk managers simply apply decisions of risk assessors without further and more value-inclusive deliberation, and, consequently, other interests simply get ‘lost in translation’ of scientific expertise into regulatory decision-making.

Internal limitations of scientific risk assessment reflect limits of scientific method itself. In contemporary circumstances science is frequently faced with various uncertainties and gridlocks, which can be of such gravity that will preclude application of proper scientific methods. Scientists faced with such situations and still expected to provide scientific answer, will use various techniques and assumptions in order to circumvent limitation of classical scientific method and fill in the knowledge gaps. Such assumptions and techniques referred to as ‘science policies’ become a part of mainstream

¹⁰ Ibidem, p.57 and 67.

scientific method nowadays.¹¹ This creates a situation where different regulatory regimes may apply different science policies and, consequently, assessment of the same risk will produce different results and lead to adoption of different management decisions. Both such decisions will be based on universal science, but they will reflect different science policies, which have employed different sets of assumptions and methodological manoeuvres. This does not mean, however, that any of those two decisions can be considered wrong. Just to show that this problem is not a purely hypothetical one, let me supply two examples of transnational trade conflicts, where the possibility of invoking science as a universal judge showed its limitations, namely the WTO disputes between the Old and the New World over use of hormones in beef¹² and over acceptance of genetically modified organisms.¹³ In both those cases, conflicting regulatory decisions were, according to the parties, supported by sound scientific expertise. Nevertheless, in both those cases, only one decision (and one science) could be maintained. The examples bring back the question of the limitations of governance by science as well as of consideration of other foundations for the final regulatory decision.

2.1.3. Beyond scientific recognition: social embeddedness of risk regulation

In my view, in order to ensure their acceptance and efficiency, risk regulatory decisions must not only be scientifically sound, but also socially embedded. They must relate to the societies which they are directed to and reflect their particular context. Evaluation of information, as well as choice making based upon it, is highly constrained by the context in which they take place, especially in terms of culture and social structures.¹⁴ Risk perception is always determined by a cognitive system of norms, values and beliefs which form the culture of a given society, as well as trust and confidence that the society has in risk management performance by its institutions.¹⁵ Hence,

¹¹ Cf. C.Button, *op.cit.*, p.97-99.

¹² See: European Communities – Measures Concerning Meat and Meat Products (Hormones), Report of the Appellate Body adopted 13 February 1998, WT/DS26/AB/R, WT/DS48/AB/R.

¹³ See: European Communities – Measures Affecting the Approval and Marketing of Biotech Products, Panel Report adopted 29 September 2006, United States (WT/DS291/R), Canada (WT/DS292/R), and Argentina (WT/DS293/R).

¹⁴ See: K.Purcell, L.Clarke, L.Renzulli, *Menus of Choice: the Social Embeddedness of Decisions* in: *Risk in the Modern Age. Social Theory, Science and Environmental Decision-Making*, ed. M.J.Cohen, Hampshire 2001, p.62-79.

¹⁵ See: *Analysis of the role of trust in risk perception* in: P.Slovic, *Perceived Risk, Trust and Democracy*, “Risk Analysis” vol. 13/1993, p.675-682.

cultural mediation not only has great influence on risk perception, but also brings important implications for legitimacy of the exercise of power in relation to risk, which depends on the extent to which the society trusts its regulators and their ability to protect them by productive risk-decisions.¹⁶ Thus, in an ideal model of risk analysis, scientific risk assessment shall only give an informative basis for regulatory decisions to be taken in the management phase. Therefore, regulatory decisions should, apart from the scientific results, take into consideration other relevant factors such as economic feasibility, intended level of protection, social demand for regulation and impact of planned regulation on the market, trade and production patterns. The important question needs to be posed here, however: how far can considerations of those ‘other factors’ influence regulatory decision-making?

Despite the fears of diluting and diminishing the consistency of international trade regulation based essentially on scientific risk assessment, some commentators seem to acknowledge the existence of ‘other factors’ in the harsh reality of risk regulation in global trade. It may be argued, that if states were free to restrict trade in response to public fears and against rational scientific background, it could undermine the whole carefully designed and negotiated system of international trade regulation. It would open up a possibility to introduce the kind of protectionism that the WTO system was intended to avoid. It must, however, be pointed out clearly, that there is a whole galaxy of options between the sole reliance of science and reliance on public dreads. And it is this galaxy that needs to be explored in order to find the right balance of inclusion of both the rational science and the far less rational, but relevant and legitimising public perception. Howse, for example, clearly imagines ways of combining the goal of eliminating discriminatory barriers to trade by recourse to autonomous science paradigm with the quest for democratisation and global welfare maximisation.¹⁷ He suggests that the WTO can very well remain true to its mission of trade liberalisation, while acknowledging that social factors are not necessarily irrational, and although the SPS Agreement is built upon the idea of universal science, it should not be interpreted as forbidding any recognition of cultural and social features.¹⁸ If, he argues, global trade liberalisation is supposed to happen at a cost of democracy, than its general value and its promise of global and domestic welfare maximisation become questionable. As a consequence, WTO system,

¹⁶ See: K.Purcell *et al.*, *op.cit.*, p.67-68.

¹⁷ R.Howse, *Democracy, Science, and Free Trade: Risk Regulation on Trial at the World Trade Organisation*, “Michigan Law Review” vol. 98/ 2000, p.2330, 2333 and 2340.

¹⁸ R.Howse, *Adjudicative Legitimacy and Treaty Interpretation in International Trade Law: The Early Years of WTO Jurisprudence* in: *The EU, the WTO and the NAFTA: Towards a Common Law of International Trade*, ed. J.H.H.Weiler, Oxford 2000, p.65-68.

as a whole, risks losing its ‘social legitimacy’.¹⁹ Promises of democracy are more likely to be fulfilled when citizens are given adequate information about the risks at stake as well as costs and benefits of alternative regulatory solutions, and when their popular choices, even if different from those which are the outcome of experts’ deliberation, but made in awareness of the facts and in a legitimate manner, are given due respect. The system would be seriously impeded, if citizens, who believe that they need certain regulation, would be deprived of it and left feeling exposed to a risk that they deem significant. That is because utility of regulation does not only come from reduced likelihood of an undesired event, but also from psychological security that results from one’s belief in the protection received.²⁰ Sunstein and Pildes, along the same line of reasoning, argue that although scientific expertise has an important role to play in appropriately structured deliberative process of regulation, for example as a corrector of empirical mistakes and misinformation-based prejudices, many other factors that are not considered in scientific assessment have, from a democratic perspective, a legitimate place in risk determination.²¹

2.2. Mutual **recognition**: regulation of diversified markets

2.2.1. Unity in diversity: ideological foundations of the common market

Building of the common market for goods, persons, services and capital through liberalisation of internal trade has always been at the core of European integration process. The idea, however, was to unite respective national markets of the member states, without necessarily unifying them. Although formally acknowledged as an official motto only in the making of the Constitutional Treaty, ‘Unity in Diversity’ has been the idea of European integration since its very beginning, illustrating its quest to reconcile the interests of ‘the common’ and ‘the individual’. Retaining the ‘regional flavour’ of goods circulating freely in the realm of European trading area was supposed to be the distinctive feature of the European Community as well as a kind of self-regulating stabilisation mechanism. That is because the ‘regional

¹⁹ The concept as used by Weiler in the European context, distinguishing between ‘social legitimacy’ and ‘formal legitimacy’, where the former one is understood as ‘a broad, empirically determined societal acceptance of the system (...) (and) occurs when the government process displays a commitment to, and actively guarantees, values that are part of the general political culture, such as justice, freedom, and general welfare’ in: J.H.H. Weiler, *The Transformation of Europe*, “Yale Law Journal” vol. 100/1991, p.2468-2474.

²⁰ R. Howse, *Democracy, Science, and Free Trade...*, op.cit., p.2330, 2337 and 2350.

²¹ C.R. Sunstein, R. Pildes, *Experts, Economists and Democrats* in: *Free Markets and Social Justice*, ed. C.R. Sunstein, Oxford 1997, p.128-148.

flavour', is not only the result of differences in geographical and climate circumstances, not only a fruit of various national cultures and traditions. It is also a consequence of varying market conditions, which influence the production process and the economic state of affairs. Such diversification may go further than the eye can see as it brings about not only the richness of different goods on the same market, but also the situation where products which are seemingly the same, are in fact different. It is both the visible and the invisible differences that the single market mechanisms were initially meant to protect. Mutual recognition is one of those mechanisms.

2.2.2. Mutual recognition principle

The principle of mutual recognition is an intermediate device which helps in reconciling tensions stemming from regulatory diversity in an integrated market.²² It can be defined as a contractual norm between governments which commissions transfer of regulatory power from the country in which the transaction takes place to the country where the good was produced.²³ Recognition, in that context, means acceptance of equivalence of a foreign regulatory system while mutuality implies reciprocity of such acceptance. The bottom line is that goods complying with essential technical requirements of one state can be marketed freely in another, provided that standards applicable in the first state are functionally parallel to standards of the recipient state. But there is much more to the meaning and impact of the principle that deserves careful consideration. Thanks to its inherent characteristics, mutual recognition is the key to global administrative law. Breaking away from conceptualisation of global governance in terms of national *contra* international dichotomy, mutual recognition suggests a third, 'middle' way of transnational economic regulation.²⁴

2.2.3. Application of the mutual recognition principle

Even though one might easily be misled by the name and an *a priori* reading of the definition of the concept, it has to be pointed out clearly, here, that application of mutual recognition principle in the EU is far from

²² See: J.H.H.Weiler, *Mutual Recognition, Functional Equivalence and Harmonisation in the Evolution of the European Common Market and the WTO* in: *The Principle of Mutual Recognition in the European Integration Process*, ed. F.Kostoris Padoa Schioppa, Basingstoke 2005, p.25-26.

²³ See elaborate definition in K.Nikolaidis, *Globalisation with Human faces: Managed Mutual Recognition and the Free Movement of Professionals* in: *The Principle of Mutual Recognition in the European Integration Process*, *ibidem*, p.132-133.

²⁴ Cf. K.Nikolaidis, G.Shaffer, *Transnational Mutual Recognition Regimes: Governance without Global Government*, "Law and Contemporary Problems" vol. 62/2005, p.266-267.

automatic. It stems from the jurisprudence of the European Court of Justice and the Commission's communications that the principle does not *per se* imply automatism. In fact, it is very rare these days, both in Europe and globally, that the principle of mutual recognition is applied in its pure form, which would imply full unrestricted right of market access with reallocation of control authority from the host to the home state. Instead, mutual recognition systems worldwide vary in their regulatory scope and frequently allow the host state to retain some vestigial powers. They may include mutual monitoring and cooperation between regulatory authorities as well as introduction of ex-ante or ex-post conditions.²⁵ The question therefore arises to what extent are we really 'recognising' and to what extent this recognition is 'managed'. According to many commentators, mutual recognition, irrespective of its incarnation is always conditional and involves a political process of assessment of compatibility between two national regulations.²⁶

2.2.4. Economic and social benefits of mutual recognition

Among the direct and most straightforward benefits of mutual recognition one should mention not only the reduction of costs of compliance for international companies, but also the enhancement of regulatory competition which is a dynamic process of regulatory adjustments in national legislation encouraged by the impact of cross-border exchange of goods.²⁷ With increased international trade under the mutual recognition regime, systems with costly regulation may find themselves under pressure from their national business operators who faced with import competition from less costly states will plead for reduction of their regulatory burden. Hence, as the fears of a 'race to the bottom' or creation of a 'regulatory gap', have not proven right in cases of regulatory competition, one can expect that it will be beneficial for the internal market.²⁸ The market will, one can assume, enforce a degree of regulatory convergence between states at least with regard to the essential requirements, and will discipline states in their regulatory activities. Moreover, in some cases, states may chose to retain stringent regulation for the sake of satisfying local quality preferences. Higher costs for producers and the economy in general in those states due to more stringent regulatory conditions, will be outweighed by the demand for the specific quality they represent,

²⁵ See: K.Nicolaidis, *Mutual Recognition of Regulatory Regimes: Some Lessons and Prospects*, Jean Monnet Working Papers, No. 1997/7, p.6.

²⁶ See: K.Nicolaidis, G.Shaffer, op.cit., p.264.

²⁷ This phenomenon relates as well to cross-border exchange of services and persons, but for the sake of clarity of the analysis I mention explicitly products only.

²⁸ J.Pelkmans, *Mutual Recognition in Goods and Services: An Economic Perspective in: The Principle of Mutual Recognition in the European Integration Process*, op.cit., p.114-115.

which in the long run will protect local products from import competition. From that perspective, regulatory competition implies that maintenance of regulatory differences gains economic justification due to diverse preferences.²⁹

This leads us to the most refined, and probably the biggest benefit of mutual recognition, namely, its sensitivity and respect for diverse needs and circumstances. Mutual recognition allows more developed and financially stronger economies to accept higher production costs as they can expect their consumers to be willing and able to pay for the extra quality they gain. But more importantly, as every coin has two sides, it allows states which are worse-off to retain the regulatory stage they can afford. Following the same logic, it allows less developed states to take advantage of their specific economic circumstances, such as, lower labour costs or cheaper commodities, and use those extra benefits for the betterment of their economic performance instead of pushing them to invest in technologies they do not have the resources for. In the long run, such developments lead towards the same kind of regulatory convergence, but the transition is smoother, and the negative impact on the markets and economies of poorer states is reduced. Allowing such smooth transition is also advantageous for the consumers. They will be able to benefit from the increased choice of the open market and enjoy safety guaranteed by the essential requirements imposed by it. At the same time they will avoid getting exposed to a radical price increase, which otherwise usually results from cost-passing by producers confronted with overburdening and costly requirements. That is why it is surprising that the mutual recognition which initially played such an important role in European food regulation is being more and more abandoned now although market diversity increases and regulatory tools which provide means of managing it are very much in demand.

The re-inclusion of the mutual recognition rationale into risk regulation could provide a useful tool for acknowledging its social implications and retaining 'regional flavours' without endangering the consumers and the economies.

2.3. Standardisation: what price safety?

2.3.1. Standardisation as a regulatory concept

Development of new technologies as well as growing dynamics of market conditions have presented traditional forms of regulation with new set of challenges. The response of the market itself can be observed in the emergence of a new wave of voluntary self-constraint mechanisms, such as guidelines,

²⁹ See: J. Pelkmans, *ibidem*, p.114.

codes of conduct and standards which provide a minimum level of uniformity and contribute to improvement of market efficiency. Standardisation, being one of those phenomena, is in simplified terms, a regulatory technique where the essential requirements are laid down by law, while development of technical specification is left to private standard-setting bodies.

Self-regulation as an alternative governance method offers a wide range of important advantages. It operates in an environment of advanced expertise and technical knowledge and can therefore rely on them to a larger extent than a public institution. On the other hand, while operating closer to stakeholders, it can be more responsive to their needs as well as more flexible and adjustable to changing circumstances. At the same time, engagement of stakeholders in the rulemaking increases their readiness to implement and enforce decisions. These features, according to many commentators, explain why in most of the industrialised countries technical standardisation has with great success been delegated to self regulatory organisations.³⁰ Private rule making, however, is certainly not free from criticism.³¹ Not only its legitimacy is questioned, but it is also contested whether delegation of responsibility for the safety of citizens to private organisations can at all be accepted. Nowadays, technical standardisation is an outcome of a public-private cooperation and consensus where involvement of governmental authority makes up for some of the shortcomings in terms of legitimacy and democratic deficit. In such public-private setting standardisation should ideally become a deliberative exercise of a network of interested stakeholders where knowledge, concerns and competences of all parties are represented in the final outcome. Unfortunately, however, standard developing practices are often less inclusive.

Standardisation provides a response to growing complexity of life and consequently to the need for more extensive controls of products' quality. Standards, to quote Sullivan, '*are the documents that carry these controls throughout the social structure*'.³² Standards may control different aspects of products or services on the market: their quantity, quality, value and methods of their production.

As consumers are often not able to judge all the important qualities of a product, the standard is there to substitute their control capacity. Knowing that the good was produced in accordance with an acknowledged standard, the

³⁰ G.Majone, *Dilemmas of European Integration. The Ambiguities and Pitfalls of Integration by Stealth*, Oxford 2005, p.102; see also: H.Schepel, op.cit.

³¹ See the discussion in C.Joerges, H.Schepel, E.Vos, op.cit., especially pp.14-39.

³² C.D.Sullivan, *Standards and Standardisation. Basic Principles and Application*, New York 1983, p.x.

consumer can trust that it possesses all the necessary qualities, which the standard entails. At the same time, it has to be pointed out that the effectiveness of standards varies depending on the acceptance of the value they serve, and the amount of willingness of market participants to observe them.

This is where the notion of ‘voluntary’ standards needs to be given some consideration. Although the literary meaning of the notion indicates that we are dealing with standards that one can choose to observe or reject, the regulatory reality is different. When a society places a high value on conformity and a considerable part of it accepts a common standard, the remaining part will be almost automatically expected to follow the standard, and those who insist on diverging from it will sooner or later find themselves in a seriously disadvantaged position. To simplify it a bit, a standard adopted as a voluntary one by an unforced action of a group of interested parties will become much less voluntary when put into practice.³³ And it will affect the market and its participants in many important ways that are elaborated further in the next section.

2.3.2. Market implications of standardisation

Vital problems of standardisation are those of origin, legitimisation and recognition by national or international authority. Among them, a question arises about the people, entities and organisations who have voluntarily developed and committed to the standard, as well as about the basis for enforcing the standard on the rest of the market participants without real voluntarism involved. It has to be borne in mind, here, that in the majority of cases standards are developed by minorities, hence, those who need to obey standards in order to be able to participate in the market on equal grounds, have often very little or no influence on their formation.

The issue becomes even more obvious when analysed in the context of international standardisation. Here, differences in levels of technical and economic development between the advanced countries and the less developed states are not reflected in the standardisation process which as a result may lead to *de facto* discrimination, by preventing those who lack the facilities to meet the set standards from competing in the world market.³⁴ Both European and the WTO systems have chosen standardisation as a regulatory tool in many areas involving risk to consumers, and in both *fora* similar problems arise.

³³ Cf. C.D.Sullivan, *ibidem*, p.8-10.

³⁴ *Ibidem*, p.11.

International standards are generally developed by a minority of strong states,³⁵ and enforced on less developed states without regard to their socio-economic situation. This can have very far reaching effects on markets and economies of those states which often had no say in standard setting and have no resources for their implementation. If standards are unilaterally imposed on poor states, without offering them either some degree of moderation or financial support the consequences may be twofold. The states may choose either not to comply with the standards and risk trade restrictions, or to implement standards against their national economic rationality at a cost of other sectors of economy and citizens. Although in Europe, where scientific and consumer safety discourse have dominated the discussion on risk regulatory reform, the issue is given very little attention, it has already been recognised in academic analysis of the WTO. Trachtman, for example, raises the problem of market foreclosure for developing countries which may lack the capacity to participate and resources to comply with international standards.³⁶ He advocates that international trade arrangements should avoid placing poor states at a disadvantaged position, or requiring excessive expenditure from their own limited resources which would have negative effects on their economies. He foresees the possibility of technical assistance arrangements which would help to prevent it. Howse and Regan go even further in their critique, and ask simply who should pay for internalisation of standards. Then, the solution that they envisage is a possibility of assistance for poorer states.³⁷ In Europe, these aspects of standardisation seem to be somewhat disregarded. There is pre-accession assistance for adjustment, but states that have become members are expected to provide the same level of compliance despite discrepancies in stages of economic and technical development which with the last two accessions are bigger than ever before.

Conclusions

This paper was an attempt to shed light on the question of social implications of internationalisation of risk regulation which seems to lack appropriate recognition in contemporary academic and political debate in

³⁵ See: D.L.Post, *Standards and Regulatory Capitalism: The Diffusion of Food Safety Standards in Developing Countries*, "Annals of AAPSS" vol. 598/2005, p.171, where she discusses the discrepancy between formal membership and practical participation in the development of standards in the Codex Alimentarius Commission.

³⁶ J.P.Trachtman, *Embedding Mutual Recognition at the WTO*, "Journal of European Public Policy" vol. 14/2007, p.794-795.

³⁷ R.Howse, D.Regan, *The Product/Process Distinction – An Illusory Basis for Disciplining 'Unilateralism' in Trade Policy*, "European Journal of International Law" vol. 11/2000, p.282.

Europe. Following three regulatory concepts used in European and international product regulation, I tried to highlight the main concerns, and suggest available solutions offered by the three mechanisms at stake. I tried to weigh out the openness of each and every of the three regulatory mechanisms to socio-economic concerns, and to suggest how the possibilities that they offer can or should be developed to allow the balance of values to be included in the regulatory procedures. The question remains whether Europe is able and ready to address these concerns. Does current state of integration and solidarity enable reaction to socio-economic consequences of Europeanised regulation of risk? Undoubtedly, this is a highly political issue, but bringing it into the academic debate can facilitate its path towards due recognition. It might be interesting to point out, here, that some steps towards inclusion of a wider range of social concerns have been made in other areas of European product regulation, such as the GMO field and regulation of chemicals under the new REACH scheme, which may serve as a valuable example of how those concerns can step by step be included and tackled on the EU market.

My theoretical discussion of the three regulatory mechanisms, namely scientific risk regulation, mutual recognition and standardisation, confronted with the short presentation of the evolution of the European legal framework for food, which includes the use of all those three methodologies, was meant to show that socio-economic concerns deserve due recognition in the European food safety regulation. It was also intended to show that, to a certain varying degree, they have in fact always been present in the regulatory structures. Although they may not always be clearly visible, they are relevant, and in terms of regulatory adjustments, they are often accepted by default, for example as far as mutual recognition is concerned. It is, thus, important to emphasise again that socio-economic factors are not new to the European legal system, but they have often simply been not explicit. When, however, one analyses in more detail the regulatory mechanisms governing the common market, one can see traces of sensitivity for the socio-economic consideration in the *diversity* preserved by mutual recognition, the *consumer* protected by scientific risk analysis, or the *stakeholders participation* in the standardisation process.

It is crucial, though, to remember that shifting from one regulatory mechanism to another, changes the value balance of a given regulated field. Moreover, changing circumstances of the market and the society require constant rebalancing of regulatory objectives in order to respond to the current situation and to embed the regulation in the best possible way. This article was meant to show that within the field of food safety regulation this necessity was not observed. Regulatory developments shifting market regulation from one scheme to another, and in particular developing it towards

unification rather than retaining flexibility, have led to significant detachment in that area. That detachment can in the longer run pose a serious challenge to both the regulated field, as well as the European social policy at large. Hence, it has to be concluded that in view of the above analysis, legal instruments to allow for more value-inclusiveness and more social embeddedness can be made available in the existing regulatory structure, if there only was a political will to modify the emphasis and allow more openness.