Sieps
Swedish Institute for European Policy Studies

European Policy Analysis
JUNE · ISSUE 5–2009

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When Lab Results are not Sufficient:

On the Limitations of Science in Tackling Modern Food Regulatory Concerns

Abstract

This article argues that the current EU regulatory system in the field of food safety fails to live up to the objectives it has set for itself. The existing decision-making scheme is based on a classic risk analysis model that relies heavily on scientific risk assessment. Critical historic occurrences in European food trade, especially the BSE crisis, have shaped food legislation in a way that assigns such a prominent role to science that social and economic considerations are not sufficiently reflected in the regulatory process. This science-based approach has important implications for the regulated field and can be criticised for a number of reasons. It is argued that not only do inherent limitations of the scientific method cast doubt on its capacity to act as a universal and objective arbiter, but also that the system faces important new external developments such as EU enlargement, growing global trade interdependence, new food production technologies and the rise of conscious consumerism. It is also argued that a regulatory system based on the scientific method cannot adequately respond to these new challenges. Hence, it is suggested that, in view of the changing conditions of food production, consumption and trade, a more inclusive regulatory approach should be considered.

1. Introduction

Food safety regulation in Europe is subject to constant revision in response to the changing needs of societies, states and international organisations. It also needs to respond to rapid technological change. Indeed, food safety regulation in the European Union (EU) can be seen as a prime example of regulation *in response* to major crises rather than in anticipation of everyday problems. This emphasis may seem rather natural and reasonable considering that recent changes in EU food safety regulation have largely been driven by crises such as Bovine Spongiform Encephalopathy (BSE). However, this emphasis has had far-reaching consequences both for the regulatory philosophy and EU legislative practice regarding food.

This article sets out, first of all, to show how these consequences have not always been consistent with the overall aims of EU food regulation as such. Secondly, it examines to what extent these counterproductive consequences are due to a heavy reliance on a very narrow definition of "science" that currently prevails in food regulation. Thirdly, and in conclusion, it suggests that many of the shortcomings of EU food safety regulation could be remedied if a more inclusive concept of food *quality* were given a place alongside the concept of food *safety*. Meanwhile, it argues that mono-dimensional regulation through a scientific lens, combined with the lack of institutional capacity for Member States to intervene without breaching the prin-

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ciples of free movement, leaves important areas of food regulation outside the reach of intervention. Nevertheless, especially given the many new challenges now facing the European food safety architecture, it is argued that the current approach should be reconsidered because not only is it insufficient to respond, but even more so to *anticipate*.

Contemporary legal research on food regulation has largely been concerned with analysing institutional problems, examining the role of science in the policy-making process, precaution, the separation of risk assessment and risk management, and problems of legitimacy and accountability. Until recently, however, only little attention has been paid to the economic and social impact of risk regulatory decisions in the field of food safety and their influence on the overall development of this policy sector. Like any form of regulation, risk regulation in the food sector is tightly related to the system that originally gave rise to it and the society it affects. It is therefore highly embedded in that society and its particular circumstances.[1] There is a danger that the current form of EU food safety regulation is not capable of taking full account of this interrelation.

I will begin by looking at the current approach to European risk regulation, namely a regulation via safety paradigm. I will then move on to theorise on risk, science and regulation by looking at the interplay of these three factors in contemporary regulatory philosophy. Next, I will present empirical support for this analysis by looking at the application of the scientific method in European risk regulation. To conclude, I will discuss some new challenges to contemporary food regulation in Europe, assessing the capacity of the existing scientifically framed regulatory solutions to tackle these challenges and argue that alternative approaches are needed.

2. Scientific risk regulation as a tool in European food safety regulation

The current European food safety regime is based on classic risk analysis, which comprises three important components: risk assessment, risk management, and risk communication. Theoretically, the first phase in the risk analysis process involves conducting a technical and scientific assessment of risk, the results of which are then weighed against other considerations in the risk management phase – the second and more "political" phase. The third component of risk analysis – risk communication – ideally refers to a more interactive exchange of information and opinions on risk among the parties involved, the dissemination of information to a wider public and eventually opening up the risk regulation process to feedback.

The first phase of risk analysis – risk assessment – is thus perceived as best left to highly specialised scientific experts who are regarded as having the knowledge and skills required to perform this kind of analysis. Their expertise is what legitimises the public confidence vested in them by the regulatory process. The aim of risk assessment is to provide decision makers, on the basis of hazard identification, with underlying factual information for determining what should be regulated, to what extent, and how.[2] On the other hand, risk management aims to establish the acceptable level of risk after careful consideration of the outcomes of the scientific risk assessment process and political, economic and social factors.

In practice, however, this *functional* division of risk analysis between technical "assessment" and the more political "management" is very often difficult to maintain, not least in food regulation. The tension between science and politics becomes even more charged as it relates to risk.

3. Risk, science and regulation – theoretical reflections

Risk is undeniably one of the most prominent catchwords of our time. Defined in the modern context by Ulrich Beck – and often redefined in the postmodern context – risk has given rise to a full-fledged paradigm shift in the social sciences.[3] Although risk theory initially developed in response to certain new practical developments, it soon became a point of reference of its own, and part of the way in which social reality is now constructed in contemporary public discourse, legal and otherwise. Risk has become a favoured way of assessing certain critical aspects of our existence and it is more often than not through the lens of risk that we apply solutions to deal with these.

It is thus hardly surprising that legal theory and practice usually regard risk as merely a tool. But even if one accepts such a subordinate approach to risk, its significance for regulatory structures must not be underestimated. For example, in modern legal theory, risk is often perceived as enabling decisions and helping to explain the possibility of responsible action.[4] Globalisation in trade, culture, and conflicts has forced us to measure contemporary risk on a different scale than before. The development of mass communication and new technologies has also contributed to raising awareness of risks, effectively

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1 Karl Polanyi argued that regulation of the market, and thus the market itself, is embedded in a certain society, and therefore a society and market are interrelated and cannot function properly when disconnected. K. Polanyi, *The Great Transformation,* Beacon Press, 1957 [1944].

2 See for example: C. Button, *The Power to Protect. Trade, Health and Uncertainty in the WTO*, Hart Publishing, 2004, p.96.

3 U. Beck, *Risk Society. Towards a New Modernity,* London, Sage Publications, 1986, 1992; N. Luhmann, *Risk. A Sociological Theory,* Aldine Transaction, A Division of Transaction Publishers, 2005, and D. Garland, *The Rise of Risk,* in D. Garland, Risk and Morality, University of Toronto Press, 2003.

4 J. Steele, *Risks and Legal Theory,* Hart Publishing, 2004, p.4., and her subsequent reasoning reflecting the current debate on the role of risk in legal theory.

bringing risk closer to the citizen. These developments have led to a paradoxical situation where risks are increasingly defined, assessed and managed internationally rather than regionally or even nationally. Expressed differently, the response to abstract risk is determined further and further away from the individual, even though the consequences of concrete risks *per se* – and of their regulation – draw closer and closer.

Given these problems, it would only seem appropriate to resort to science when defining the nature of these risks and determining relevant countermeasures. Indeed, in the commonly applied model of risk analysis, science has been projected as an independent and objective judge, contributing to the universality and impartiality of the decision-making process. However, there have been instances when regulators have not been able to rely on scientists to provide sufficient grounds for regulatory decisions in due time. At least two different yet closely related reasons exist for this. And since more such cases are highly likely in the future, it seems relevant to take a closer look at these shortcomings.

Firstly, science has not always been able to reach appropriate levels of objectivity and universality in its analysis of increasingly complex problems of food safety. In fact, both in the European and international regulatory context, science has not seldom been part of the problem rather than part of the solution. [5]

This tendency has been further exacerbated by the growing importance of scientific technology in food production, which has increased the significance of science in the regulatory procedure even further. This development, too, has presented scientists with questions to which they have not always been able to find unanimous answers. [6]

A good example of the practical implications of these problems may be found in WTO disputes between the "Old World" and the "New World" over the use of hormones in beef and acceptance of genetically modified organisms. [7]

This example may also illustrate how scientists – in the field of food safety as well as other problematic fields – are expected by the regulator and/or legislator to provide definite answers to regulatory problems that may often be urgent and pressing but that science may not be able to solve categorically. Thus to legitimise their role in the decision-making process, scientists are required to make assumptions about problems they cannot yet fully grasp and at the same time develop techniques to bypass the shortcomings of their own methodology. However, such circumventing techniques also run the risk of undermining the main asset of science, i.e., its purported objectivity, which gave it a place in regulatory procedure in the first place. This may seem harmless insofar as alternative foundations for risk analysis and decision-making may be even more fluid than a multivocal and speculative science. Yet, it should be noted that one of the main consequences of this type of regulatory regime is exactly the way in which hypothetical assumptions and circumventing techniques may develop into a virtual body of science policies and thus become part of mainstream scientific method. [8]

More specifically, the application of individual science policies by risk assessment bodies may lead to a situation where different regulatory regimes adhere to *different* science policies and where their assessment will therefore vary. If this is the case, assessment of the same risk by different scientific bodies applying different science policies will produce different results and consequently suggest the adoption of different regulatory decisions. Such conflicts, where varying scientific opinions claim their right to both truth and universality, may have serious consequences in the international regulatory context. Conflicting decisions will be both based on and supported by science, so it will be difficult to judge which are right and which are wrong. And science will probably offer little help on that matter.

What, then, should the choice be based on? When science is incapable of delivering unanimous answers, must we be prepared to allow other legitimate factors to influence regulatory choices? Here, it may be enough to note that science most likely will retain its important role in risk analysis, despite these serious shortcomings, not least due to the internal logic and established patterns of problem-solving of science itself, which makes it relatively immune to external influences from other types of methodologies or value systems. Expressed differently, if a

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5 See extensive literature on the BSE crisis in Europe, e.g. 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.

6 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', CMLRev., vol.40, 2003, p.1462-1463.

7 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.

8 Compare C. Button, *The Power to Protect…*, op. cit., note3, pp.97-99. Compare also Joint FAO/WHO Consultation, 'Risk Management and Food Safety', FAO Food and Nutrition Paper 65, Rome, 1997, available at http://www.fao.org/docrep/W4982E/W4982E00.htm, especially part 8.

particular perspective on a particular problem has successfully been made "scientific", it is difficult to challenge it by political means or any other means for that matter.

4. Regulating food in Europe

The evolution of European food safety regulation has recently received considerable academic attention.[9] With its roots in agricultural legislation, objectified under internal market product regulation, and re-defined in the name of science after the BSE scandal, EU food regulation is a specific and rather complicated system. Bearing a legacy of various stages of its developments – often simply side effects of other fields of regulation or results of *ad hoc* legislative actions, it has become a patchwork of remains of those three regulatory philosophies, and is neither sufficiently coherent nor properly balanced. Due to an approach to food regulation lacking in forethought and consistency, it has been bound to follow the current stream of regulatory developments, and respond only to values and concerns of immediate interest to Brussels at a given moment. Therefore, the post-BSE reforms that originally aimed to install order and coherence throughout the food regulatory system – including the many economic, political and social concerns activated along the farm to fork continuum – only led food regulation into yet another mono-dimensional stream of regulation, completely dominated by consumer protection, precaution and scientific justification. Consequently, the EU food safety regulatory system had to face its next big challenges – posed by globalisation and enlargement – in an improved but still fragmented and arguably imperfect form, as the promise of total reform had not been fulfilled by post-BSE amendments.

Reforms following the BSE crisis did, in fact, deal with many important aspects of food regulation. First and foremost, it included consumer protection as a valid aspect of regulatory activity. It settled a number of institutional and procedural issues, which resulted in greater inclusiveness and transparency of EU decision-making and better mechanisms for conflict prevention and settlement. In other words, if another BSE-type crisis were to occur in Europe, the EU would now be better prepared to deal with it. However, the reform did not address the full range of issues, and this may well have detrimental effects on future developments in food safety.

For example, although the risk assessment phase of the decision-making procedure was indeed significantly improved, the risk management phase was left virtually unchanged. Indeed, the wave of reforms that responded to the food crises of the 1990s, culminating in Regulation 178/2002,[10] reinforced a decision-making system based on scientific risk assessment. The assessment provision was strengthened and professionalised by the establishment of a specialised scientific agency, namely the European Food Safety Authority (EFSA), which was blended into the existing comitology structure, replacing the previous network of scientific committees. Strengthening the risk assessment phase meant further strengthening the position of science in the decision-making process; this has had a considerable impact in its position in the overall regulatory approach, leaving precious little room for other interests and values to be taken into consideration.

This issue is particularly sensitive today as recent developments in the European and international arena are confronting EU regulation with new challenges, most notably EU enlargement, technological progress, changing consumption patterns and the changing role of the EU as world trade becomes increasingly globalised. The way in which post-BSE reforms failed to prepare the EU food safety system for these new challenges will be discussed and illustrated in the following section.

5. Reaching beyond science

The food regulatory reforms that followed in the wake of the BSE crisis were the result of a specific setting. The legal and administrative mechanisms in place before the crisis not only failed to prevent the BSE crisis but also to deal with it *post factum;* this failure has continued to shape post-BSE reforms. Firstly, immediate reforms were needed to counter the criticisms of inefficiency, mismanagement, obstruction and institutional confusion. Secondly, they needed to be spectacular and consumer-centred to regain consumer confidence in EU regulation. Finally, they had to have an unquestionable and indisputable basis, which in this case was science. Hence, reforms were dominated by a myopic emphasis on scientification and consumer protection, making them incomplete. Caught between the acute BSE trauma and the uncertainty over the impending EU enlargement, the reforms were born of an anxiety that forced them into providing radical and short-sighted solutions to ever-increasing and complex problems.

Such mono-dimensional regulation resulting from partial reform, which only takes into consideration selected aspects of a wide regulatory area, can be problematic in the market in many ways. Partial regulation emphasising only certain features of a problem, or regulation creating an unbalanced approach to a matter, are just two possible

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[9] Just to mention a few of the most recent works: E. Vos, F. Wendler, *Food Safety Regulation in Europe. A Comparative Institutional Analysis,* Intersentia, 2006, C. Macmaoláin, *EU Food Law. Protecting Consumers and Health in a Common Market,* Modern Studies in European Law, Hart Publishing, Oxford – Portland Oregon, 2007, M. P. Broberg, 'Transforming the European Community's Regulation of Food Safety', SIEPS Report No. 5, 2008.

[10] Regulation No 178/2002/EC of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31/1, 1.2.2002.

negative outcomes of such scenarios. In the case of European food law, the situation was such that, first, market rationale was the driving force behind legislative harmonisation, and then, consumer protection rationale took over and became the dominant dimension of the reform. Consequently, post-BSE reform could not be anything but partial.

The paradoxical result of the partial nature of post-BSE reform is that while we might now be better prepared for the unexpected, it is doubtful whether we are any better prepared for the *expected*. What if the risks connected with a potential outbreak of some sort of crisis are, in fact, far outweighed by the risks connected with our legal and potentially safe everyday practices? What I am referring to here is the problem of food quality – *quality,* which by extension translates into *safety*. But the risks connected with bad quality food are not as spectacular and explosive as those of disease outbreak. They are however, much more common, as the deterioration of quality of food we consume everyday as well as wrong nutritional habits, which our societies have developed, have become part of our "room-temperature reality". This is not to say that science-based regulation is to blame for this development, but rather that this type of regulation is not able to properly address such problems and concerns, nor to intervene in the situation at hand.

The mono-dimensional focus of European food regulation since the BSE crisis has been on potential outbreaks, scandals and scares, while existing food-related problems, specifically those that are related to nutrition (e.g. obesity, which in its turn contributes to other devastating health consequences such heart diseases, blood pressure diseases, cancers and strokes) and in practice affect a much wider population, escape any EU regulatory control. Moreover, the nature of EU regulations on free movement makes it impossible for Member States to intervene and counteract these negative developments by means of national legislation. Consequently, no significant action can be taken against nutritional problems or obesity at any level of EU governance. Hence, EU regulation omits important aspects of food safety by overemphasising potential crises and overlooking everyday threats to consumer health. [11] While the cause of this imbalance may seem obvious and natural enough – namely the priority of a serious crisis over acceptable risks – it is argued here that the regulatory system itself allows this imbalance to be reproduced indefinitely and contributes to its demonstrated inability to tackle the full spectrum of food safety concerns as it has been politically mandated to do.

Furthermore, and following the science-based logic discussed above, the reformers have placed enormous emphasis both on improving the quality of science involved in regulatory decision-making, but also on the ways in which this inclusion takes place and the procedural guarantees of transparency, professionalism, and impartiality. This approach meant that the reformers concentrated on the risk assessment phase of the decision-making process, leaving aside the most consequential phase, namely risk management. Strong emphasis on reforming expertise provision and scientific assessment conditions naturally strengthened this part of the procedure, which inevitably affected the functioning of those new rules in the market. Very often in the risk regulatory process, decision-makers in the risk management phase tend to follow blindly the risk assessors' decisions, which are based solely on science. This phenomenon leads to a situation where science is the only basis for a regulatory decision, as other values – economic, social or ethical – have little chance of gaining consideration. Further strengthening of the science-based risk assessment phase of the process aggravates the risk of such a tendency dominating. Science can now become such a strong foundation that risk managers will find it difficult to provide arguments based on other values and interests that should ideally be taken into consideration in a regulatory procedure. In such a situation, deciding against the findings of a risk assessment can be very problematic, if not impossible.

This situation could also result in non-scientific arguments – or perhaps rather insufficiently scientificised arguments – not being given due consideration and recognition. Instead, traditional science will dominate the decision-making process to such an extent that it will become the only overriding rationale behind decision-making, despite the fact that decisions might have to be passed on problems that have not been exhaustively treated by such traditional science. Basing decisions solely on science not only goes against common sense. It also, and more importantly, goes against the established and approved rules of risk regulation, according to which the risk management phase should take precedence over the scientific risk assessment phase and take a comprehensive stance on passing decisions, including all the relevant values in the deliberations. These relevant values include societal concerns, social and economic impacts of regulation and consumer preferences.

Although this problem is rarely discussed in the literature, numerous voices have advocated the inclusion of concern assessment in risk regulatory procedures. [12] Hence, it seems that under contemporary conditions, the problem should be given more attention; new regulatory challenges (e.g. increased diversity following EU enlargement, the growing influence of global trade rules on European

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[11] Compare: C. Macmaoláin, *EU Food Law…,* op. cit., note 10, p.12, 14–15, 221–239.

[12] M. Dreyer, O. Renn, A. Ely, A. Stirling, E. Vos, F. Wendler, 'A General Framework for the Precautionary and Inclusive Governance of Food Safety. Accounting for Risks, Uncertainties, and Ambiguities in the Assessment and Management of Food Safety Threats,' Responses to Feedback Elicited at a Series of Four Workshops with Key Actors in Food Safety Governance, paper presented at the Presentation Workshop on a General Framework for the Precautionary and Inclusive Governance of Food Safety in Europe, Brussels, 11 May 2007.

legislation and the growing sensitivity of consumer issues) are making the impact assessment of regulatory decision-making even more problematic and the traditional science-based regulatory approach may find itself incapable of addressing all the necessary regulatory issues.

A particularly illustrative example of the regulatory issues at stake can be found in the deliberations and disputes over the regulation of genetically modified organisms (GMOs) both in Europe and worldwide. While numerous examples could be discussed, I have chosen to revisit the recent case of EU regulation of GMOs and its reception in Poland.

In a letter dated 13 April 2007, Poland made a notification under Article 95(5) and (6) EC, which allow Member States to introduce, after the adoption by the Council or by the Commission of a harmonisation measure, national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure. Poland officially notified two articles of national legislation, namely Articles 111 and 172 of a draft law on genetically modified organisms, in derogation of the provisions of the Deliberate Release Directive.[13] The first notified provision, namely Article 111 of the Polish draft law on genetically modified organisms, pertains to deliberate release for experimental purposes and lays down the content of an application for the issuing of a decision on a deliberate release of a GMO. According to Article 111(2), the application should be accompanied by, among other things, certification from the mayor of the municipality that in the local spatial development plan, with regard to the need to protect local environment, nature and cultural landscape of the area in question, provision is made for the possibility of deliberate release, as well as by written declarations from the holders of farms neighbouring the location of the deliberate release that they do not object to the release.

The legislative objective, presented by the Polish government in the explanatory note, is that conditions for assessing the safety of a given field experiment in the context of its safety to the environment, should be set as strictly as possible. Since the effects of GMOs on the environment are unknown and potentially harmful, special safety conditions should be maintained in accordance with the EU precautionary principle. This is particularly important, the Polish explanatory note claims, in view of the richness of biodiversity in Poland, where the introduction of GMOs into the environment could cause serious disturbances to its functioning. In the view of the Commission, it is clear from the wording of both the proposed provision and the explanatory note that the notified provision will have an impact on the release of GMOs for any other purpose than for placing on the market, and primarily for field trials.[14]

According to the system established by Directive 2001/18/EC, if a GMO receives consent for cultivation in the EU, Member States are not allowed to introduce any additional restrictions on its cultivation. Consequently, application of Directive 2001/18/EC is affected as the Polish draft law restricts cultivation of all GMOs, unless designated in specific zones, even if already approved for the placing on the market under Community legislation. Thus, the notified Polish provision restricts cultivation of GM seeds for experimental releases by establishing additional administrative requirements for the authorisation of such releases, and has, therefore, to be considered as contradictory to the Directive.[15]

The second notified provision, namely Article 172 of the draft law, refers to the establishment of special zones for the cultivation of GMOs and states that cultivation of genetically modified plants shall be prohibited, subject to the provision of paragraph 2. Paragraph 2, for that matter, grants to the Minister responsible for agriculture – in consultation with the Minister responsible for the environment and after the opinion of the municipality in question has been obtained – the authority to issue a decision concerning the creation of a zone designated for cultivation of genetically modified plants in a specified area situated within a territory of that municipality. An application for the issuance of such a decision shall, among other requirements, be accompanied by written declarations from holders of land within the area of spatial isolation from the land on which it is planned to cultivate genetically modified plants that they do not object to the intention to create a zone designated for the cultivation of genetically modified plants.

According to the Polish explanatory note, the rules on commercial cultivation in the national provisions are based to a large extent on Commission Recommendation 2003/556/EC of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming.[16] In line with

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[13] Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms, OJ L 106, 17.04.2001, p.1, as amended, for a recent comprehensive study of the European GMOs regulation see P. Dabrowska, *Hybrid Solutions for Hybrid Products: EU Governance of GMOs,* PhD thesis, EUI, 2006.

[14] Commission Decision 2008/62/EC of 12 October 2007 relating to Articles 111 and 172 of the Polish Draft Act on Genetically Modified Organisms, notified by the Republic of Poland pursuant to Article 95(5) of the EC Treaty as derogations from the provisions of the Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms, OJ L 16, 19.01.2008, par.13.

[15] Ibid., par.38.

[16] OJ L 189, 29.07.2003, p.36.

this Recommendation, which concerns *inter alia* the voluntary clustering of fields and cooperation between neighbouring farms, the draft law limits cultivation of genetically modified plants to areas which do not contain elements of value from a nature conservation standpoint and whose agrarian structure enables safe cultivation of transgenic plants, without damaging the operations of other farmers. This should, in effect, permit minimisation of the risk associated with the mixing of reproductive material or crossing of genetically modified plants with unmodified plants.

According to the Commission, this general ban is in breach of Article 19 of Directive 2001/18/EC, which stipulates that if written consent has been given for the placing on the market of a GMO as or in a product, that product may be used without further notification throughout the Community in so far as the specific conditions of use and the environments and/or geographical areas stipulated in these conditions are strictly adhered to. Furthermore, the ban is also in breach of Article 22 of the Directive, which stipulates that Member States may not prohibit, restrict or impede the placing on the market of GMOs, or products, which comply with the requirements of this Directive.

In its notification, Poland presented the following three main arguments to justify introduction of these restrictions:

- deliberate release of GMOs requires special safety measures in accordance with the EU precautionary principle, in view of the richness of biodiversity in Poland and the need to prevent serious disturbances to the functioning of the environment;
- the structure of Polish agriculture is among the most fragmented in the EU with almost two million farms with an average size of less than 8 hectares;
- domestic legislation concerning coexistence of three types of cultivations – GMOs, conventional and organic – does not exist, nor do regulations concerning the compensation for damage or loss of crops in case of uncontrolled cross-pollination.

As a main ground for the introduction of derogations in the national provisions with regard to the restriction of cultivation of transgenic plants, Poland points to "the need to fulfil the expectations of Polish society". The provisions restricting the cultivation of GM crops, Poland explains, have the purpose of preventing the potential damage which may result if transgenes spread to conventional crops. In this context, the impossibility of elimination of risk of cross-contamination is presented as the main source of concerns associated with cultivation of GM plants.

Another aspect of this issue is the highly fragmented structure of Polish agriculture: almost two million farms with an average size of less than 8 hectares. Additionally, Polish agriculture is characterised by a conventional production system and is observing an increasing interest in organic farming and production. Due to this high level of fragmentation and a particular production profile, it is impossible to isolate GM crops from conventional and organic crops; this poses a considerable threat to the farmers, and specifically to organic farming. In such a situation, Poland argues, uncontrolled introduction of transgenic plants into cultivation may inflict serious losses on farmers. The resistance of Polish farmers to GM crops is intensified by the Polish legal system containing no provisions on compensation for agricultural losses resulting from the uncontrolled crossing of varieties, nor on the coexistence of the three types of agriculture at stake, namely conventional, organic and agricultural production using transgenic plants.

Additional, but no less interesting, justifications presented by the Polish government touched on a number of other important aspects of the problem. The first one points to the uncertainty surrounding the first stage of research where the new GMOs come into contact with the environment, and where the effect of such an organism on the environment is unknown and may potentially be harmful. Another point concentrates on the need to limit the cultivation of genetically modified plants to areas that do not contain elements of value from the point of view of nature conservation, and whose agrarian structure enables safe cultivation of transgenic plants, without damaging the operations of other farmers.

To better understand the relevance of Polish arguments, it is important to bear in mind that agricultural and food production form the core of Poland's economy. Since Poland's entry into the EU, Polish farmers faced with stringent EU standards and low investment capacity have found their market potential in traditional and organic farming, and this is where the development effort was primarily channelled. This type of production is particularly threatened by cross-contamination, which would lead to a loss of production and market shares.

Resistance towards GMOs is similarly strong at the other end of the food chain, namely with consumers. According to a recent survey, 60 % of Poles are certain that consumption of genetically modified food is harmful [17] and 55 % want GMO farming in Poland to be banned. Moreover, 45 % of respondents think that Poland should ban the cultivation of GMO plants even if it caused a conflict with the European Commission. Finally, 49 % go further to say that such a ban should be implemented even if it led to an increase in food prices. In this light, the arguments referring to "a problem specific to a Member State" and fulfilling "societal expectations" should be given due consideration by the EU system, which takes pride in protecting diversity and consumers.

[17] According to the opinion poll carried out by PBS DGA for 'Gazeta Wyborcza', published in fragments in Gazeta Wyborcza, *Jak ja sie boje GMO,* (How I am afraid of GMO), 12.03.2008.

However, the European Commission has made little reference to these arguments as presented by Poland. In fact, it has not addressed the possible validity of the Polish concern at all. In its decision, the Commission observed that no reference was made to any new information relating to the protection of the environment either in the notification or in accompanying documents. Neither was there any indication of new evidence concerning the protection of the environment or working environment. Under those circumstances, the Commission saw no reason to submit the Polish notification to EFSA for its opinion in accordance with Directive 2001/18/EC. Instead, it took an immediate decision on the case. As the absence of new scientific evidence results in one of the cumulative conditions of Article 95(5) EC not being fulfilled, the Commission rejected the Polish notification without examining the possible fulfilment of any other relevant conditions, whether social, economic, or political.

The reluctance of the Commission to examine all arguments presented by the plaintiff, as curious as it may seem given the stated objective of post-BSE food regulatory reform to control the safety of all food in Europe, is even more critical for the lawyer, as it would have been very interesting indeed to see the Commission's response to such unconventional arguments. Instead, there was no response at all, as the Commission chose to base its dismissal of the Polish notification on formalities, just as the European Court of Justice did in the French BSE conflict a number of years ago.[18] The end result has been that the Commission has avoided taking a stand on the critical regulatory issues at stake.[19] And the problem is that this avoidance – as stifling as it is at a time that demands more and more critical attention to widening concerns of food safety in Europe – is less the result of a single odd occurrence than a systematically derived result of the shortcomings of EU food safety regulation.

6. Concluding remarks

This article has addressed a rather overlooked but important aspect of food safety regulation, namely its social consequences. It is argued that food is not produced in a social vacuum; food is produced for nutritional and social purposes as well. For a long time, several traditions have ensured certain values of this kind (i.e. social values) in food production but these values have now come under increased pressure with the introduction of EU harmonisation measures. The irony of the matter is that while western Europe still has a perception largely shaped by the BSE crisis, it does not perceive that future crises could be successfully avoided if these traditional patterns of production and consumption were allowed to remain in place. Instead, EU enlargement can contribute to the weakening of such traditions and thus, paradoxically, to the risk of a reoccurrence of crises in the future.

The lack of concern over this issue probably has its roots in a wide variety of political, social, and, above all, economic factors. Here, however, I have deliberately limited my analysis to the role that regulatory emphasis on science has played in these processes. It is argued that regulation dominated by reliance on science – at least as currently defined and institutionalised in the EU framework – has despite (or perhaps precisely because of) its alleged objectivity failed to take into account the social dimensions of food regulation.

This omission is not only grave due to its scientific shortcomings at a time when nutritional issues are becoming increasingly important in view of rising obesity in Europe and related health problems, but also because it affects different Member States differently. At the same time, with the development of new technologies and the opening up of the global trade arena, it is also possible to detect an inability of this science to reach unanimous conclusions with regard to food regulation. Thus, one of the central arguments for its legitimacy is seriously weakened. Moreover, regulatory imbalance resulting from the mono-dimensional approach can have adverse effects not only on the important task of responding to food crises, but also on the possibly even more critical task of anticipating and preventing deterioration in the quality of the food we produce and eat, thus preventing the full range of food safety concerns in Europe from being adequately addressed. Possibly, in the end, we should be just as concerned about the *quality* of our food and the way we produce, distribute, prepare and consume it as we have, since the 1990s, been obsessed with its *safety*. ●

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[18] Case C-1/00, *Commission v. France,* [2001], ECR I-9989.

[19] See discussion on the case, including the analysis of this issue, in K. Szawlowska, 'Risk Assessment in the European Food Safety Regulation: Who is to Decide Whose Science is Better? Commission v. France and Beyond…,' German Law Journal, Vol.5, No.10, October 2004, pp.1259–1274.