

lenges facing the WTO in its attempts to regulate the varied and complex field of public health. Nevertheless, *“Trade and Public Health – The WTO, Tobacco, Alcohol and Diet”* is an unbiased and comprehensive endeavour to explain and criticise the interaction between the WTO and public health issues.

Risk Regulation in Europe: Assessing the Application of the Precautionary Principle

by Jale Tosun

New York: Springer, 2012, 102 pp.,

€ 41,64; Softcover

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Jale Tosun’s *“Risk Regulation in Europe: Assessing the Application of the Precautionary Principle”* (Springer Briefs in Political Science) is a focused, tightly written and clearly structured study that applies conceptual tools from public policy analysis to the field of risk regulation in the European Union (EU). In specific, the book analyses the variation in the use of the precautionary principle across three case studies, all within the area of food safety. The cases concern, respectively, the regulation of growth hormones in meat, the genetically modified corn MON810, and stevia-based sweeteners. It is argued that all of these cases represent instances of policy-making under scientific uncertainty and therefore they can provide useful and systematic insights into how the precautionary principle has been applied in the EU. As the author notes, even though the first two cases have received ample attention in the literature, the book offers a novel analytical perspective on these cases which generates new findings. In addition, the case of stevia-based sweeteners is a recent one and thus also contributes new empirical data.

The two main research objectives of the book are to explain policy launch and policy change. In specific, the study is interested in what factors influence the initial setting of a regulatory standard and what explains subsequent policy change (or lack thereof). In the context of the empirical cases, these questions translate into inquiring about what led to the initial approval or ban of a particular substance or organism (growth hormones, GM corn, stevia-based sweet-

eners) and what determines whether these initial decisions were subsequently retained, modified or reversed.

The theoretical framework, elaborated in Chapter 2, is firmly grounded in public policy analysis. One of the outcomes of interest, policy change, is disaggregated into three components: likelihood of occurrence, direction of change (more or less restrictive), and scope (major, moderate, or minor).

The study brings together two theoretical frameworks to generate expectations about the above mentioned dimensions of policy change. The first framework is the subsystem adjustment model, developed by Howlett and Ramesh (2002). It stipulates several mechanisms which drive policy change. The first two, endogenous to the policy subsystem, are policy learning and venue change. The other two – systemic perturbations (e.g. food crises and scandals) and subsystem spillovers, which introduce new actors, institutions or ideas – are exogenous. According to the model, the presence of the endogenous conditions is sufficient to effectuate policy change but they are made more effective by the other two.

A central contention of the book is that conditions surrounding the agenda-setting stage of the initial policy-making cycle have a strong influence both on how the precautionary principle is first applied and on whether subsequent policy change occurs. Therefore, the subsystem adjustment model is complemented to take into account not only of the mechanisms of policy change but also the starting point. For this purpose, the study draws on the agenda-setting models developed by Cobb et al. (1976). According to them, agenda setting can take place in the context of ‘outside initiation’, ‘mobilization’, and ‘inside access’ and that carries different implications for the final policy outcome.

In the first model (outside mobilization), policy is initiated because of external popular demand for regulation. As a result the precautionary principle will be applied strictly and subsequent policy change is unlikely or will go in the direction of minor to moderately more restrictive policy. In the second model (mobilization), the issue is initially contained to policy-makers but spills into the public domain at a later stage. As a result, policy change is likely to occur due to popular pressure but the direction and scope of change is indeterminate. Finally, in the third model (inside access), policy is defined by an inner circle of policy-makers. Under this condition policy change,

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driven without the participation of mass publics, is also possible (although the direction and scope of change are again indeterminate).

The theoretical model is applied to the three cases in Chapters 5–7 and its performance is evaluated against the empirical facts. These chapters follow identical format, which facilitates cross-case comparability. The chapters briefly introduce the respective regulatory issue and present a timeline of the regulatory reforms. Then policy launch and policy change are explained in light of the theoretical framework. Conclusions are drawn about the extent to which the empirical cases conform to the theoretical expectations. Each empirical case corresponds to one of the three agenda-setting models.

The regulation of growth hormones in meat production represents a case of agenda setting through ‘outside initiation’ due to negative public opinion surrounding that issue from the outset. In part as a result of that, the initial EU policy was to restrict the use of growth hormones. Later, the restriction is converted to a ban (both for domestic and imported products). This development is characterized as moderate policy change with precautionary measures becoming more restrictive. The fact that the ban remained in place despite a WTO ruling and retaliatory sanctions against the EU confirms the theoretical expectations of unlikely major policy change and the importance of initial conditions.

The case of the regulation of the GM corn MON810 is characterized as falling under the mobilization model of agenda setting. When MON810 first came up for authorization in front of the French authorities, the public was not yet mobilized against agricultural biotechnology and the GM corn variety received pre-market authorization by the EU, which is in accordance with the policy initiation aspect of the analysis. The case becomes more difficult to interpret with regard to policy change because the renewal authorization for MON810 is now pending and also due to the bans that several member states instituted at the national level. Nonetheless, the case is categorized as one of gradual and moderate tightening of the regulatory regime. Tosun acknowledges the ambiguity of the MON810 case and the importance of veto players in explaining regulatory developments in this case.

Finally, the regulation of the stevia-based sweeteners is a case of ‘inside access’ with regards to the agenda-setting model. The public was not involved in the

initial policy setting and did not become mobilized subsequently. This arguably allowed top-down regulation by internal group of experts and policy-makers and enabled the switch from a ban of the additive to its approval for use in the EU, once more scientific evidence became available in favor of its safety. The approval of the stevia-based sweeteners represents the clearest case for policy change.

One of the main findings of the analysis seems to be a confirmation of the importance of the processes leading up to policy launch and their influence on subsequent policy change. However, it is also acknowledged that other factors, not originally included in the theoretical framework, such as changing actor preferences also play a significant role. Another finding draws attention the fact that the application of the precautionary principle in the EU is not uniform across issues and in fact reveals some inconsistencies.

The analysis could have drawn a stronger distinction between changes in the understanding/interpretation of the precautionary principle in the EU versus changes in the conditions underlying its application (e.g. more scientific evidence available as in the case of stevia-based sweeteners). In this last case, even though the regulatory measure changed from ban to approval, it might be argued that the application of the precautionary principle remained the same.

The theoretical framework, consisting of three agenda-setting models and four drivers of policy change, appears both complex and often indeterminate. Given the evidence from the empirical cases, it is perhaps conceivable that it can be simplified. For example, the crux of the agenda setting models seems to boil down to the importance of mass involvement and public opinion. In the cases where public anxieties were present (hormones in beef and GM corn), policy change was only moderate and the regulatory frameworks grew more restrictive. In contrast, the regulation of the stevia-based sweeteners took place outside of the scope of public attention and in this case we saw a major policy change that made the measure more lenient.

Overall the book makes an important contribution to the literature with its novel approach, which brings public policy analysis to the study of the precautionary principle. Another contribution is the systematic examination of policy launch and policy change across three issues, which interestingly reveals that

the EU's application of the precautionary principle is not always consistent. Finally, the thought provoking application of the theoretical framework to the empirical cases as well as the comparison of some aspects of the three cases raise insights that can serve as starting points for future research.

The Law and Policy of Harmonisation in Europe's Internal Market

by Isidora Maletić

Cheltenham: Edward Elgar Publishing, 2013,

224 pp.,

€ 81,76; Hardcover

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The Treaty of Rome, according to its Article 2, was to establish amongst the Member States a common market as a means to promoting 'throughout the Community a harmonious development of economic activities, a continuous and balanced expansion, an increased stability, an accelerated raising of the standard of living and closer relations between its Member States'. The common market thus constituted a crucial part of the foundation for what has since developed into the European Union. For a common market to work, it must be possible to sell a good (etc.) originating in one Member State in all the other Member States. In other words, there is a need to harmonise the Member States' requirements applying to goods (etc.) that are to be placed on the market.

Today's European Union has been engaged in harmonisation for decades. One of my personal favourite harmonisation measures is the directive adopted by the Council of Ministers on 17 September 1984 under the incredible title *Directive 84/538/EEC on the approximation of the laws of the Member States relating to the permissible sound power level of lawnmowers*. The first official proposal for this harmonisation measure was published six years earlier, in 1978, as Proposal for a Council Directive on the Ap-

proximation of the Laws of the Member States Relating to Noise Emitted by Lawn Mowers.¹ The directive's legal basis was (then) Article 100 of the EEC Treaty according to which '[t]he Council shall, acting unanimously on a proposal from the Commission, issue directives for the approximation of such provisions laid down by law, regulation or administrative action in Member States as directly affect the establishment or functioning of the common market'.² In other words, when the European Union tried to harmonise the sound power level of lawnmowers, all Member States would be able to veto the proposal.

Obviously, if it took six years to harmonise 'the permissible sound power level of lawnmowers' amongst the then 10 Member States, we would probably have to wait in all eternity to have a fully harmonised common market. Therefore, on 7 May 1985 the Council adopted *Resolution on a New Approach to Technical Harmonization and Standards*. According to this resolution the European Union legislator should only define the 'essential requirements' such as protection of health and safety that goods must meet when they are placed on the market. In contrast, the European standards bodies (CEN, CENELEC and ETSI) would undertake the extensive and time-consuming work of drawing up corresponding technical specifications meeting the directives' essential requirements. The standards would not become binding law; instead compliance with the standards would provide a presumption of conformity with the essential requirements. In other words, if a producer complied with a CEN standard that was tied up with a directive, it would be for the Member States that wanted to keep the producer's product out of the market to prove that the product did not comply with the directive. This was unlikely to happen so by complying with the standards, in practice a producer would have free access to the full European Union market. The standardisation bodies' specifications were referred to as "harmonised standards".

Another reason for the slowness of the harmonisation was the fact that whilst the European Union tried to harmonise Member State measures, the Member States continued to introduce new and diverging measures; thereby in reality creating new barriers. To handle this Sisyphean situation the European Union, in 1983, adopted *Directive 83/189/EEC laying down a procedure for the provision of information in the field of technical standards and regulations*

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1 COM (78)387 final.

2 With the entry into force of the Lisbon Treaty on 1 December 2009 the original Article 100 EEC (subsequently Article 94 EC) became Article 115 of the Treaty on the Functioning of the European Union (TFEU) whereas the original Article 100a EEC (subsequently Article 95 EC) became Article 114 TFEU. In other words, somewhat symbolically, the internal order of the two provisions was reversed.