Stakeholder Participation in European Standardization: A Mapping and an Assessment of Three Categories of Regulation

Morten Kallestrup
Department of Political Science and Public Administration
University of Southern Denmark
kallestrup@sam.sdu.dk

Abstract

The continuum of Internal Market regulation comprises various kinds of regulatory measures, including legislation, harmonized and non-harmonized standards, and private ‘self-regulation’ of different origins. Public, as well as private actors, participate in the continuous development of European regulation. The different actors’ competences and roles vary during the processes, but it is evident that both public and private actors obtain a vital position in the collective production of European regulation. This article contributes with a mapping and categorization of the applied regulatory ‘means and measures’ related to Internal Market regulation and an assessment of stakeholder participation in three categories. Firstly, this article provides an outline of contemporary EU regulatory policies applied in the Internal Market regulation, and discusses the concepts of regulatory governance and regulation. Secondly, the different variants of regulation are allocated within three main categories: a) public legislation; b) co-regulation, and; c) private self-regulation. Case examples of the different categories of regulation are explicated to illustrate the variances among the three types and of the ex-ante participatory processes. Finally, the article provides an assessment of stakeholder participation vis-à-vis the three categories of regulation.
1. Introduction

The regulatory means and measures of the European Union (EU) Internal Market are continuously evolving. Standardization as a regulatory tool has, however, managed to obtain a prominent position over the last two decades. This article addresses the question of the legitimacy of using EU standardization for regulatory purposes and explores whether there is sufficient input legitimacy through stakeholder participation in current European standardization-related regulatory processes. Are there adequate participatory mechanisms for stakeholders in the light of recent developments?

The article provides first an outline of contemporary regulatory techniques in order to contextualize standardization as a regulatory tool in the Internal Market. The continuum of Internal Market regulation comprises various kinds of regulatory measures, including legislation, harmonized and non-harmonized standards, and private ‘self-regulation’ of different origins. Public, as well as private actors, participate in the continuous development of this regulation, yet the actors’ competences and roles vary during the different processes. But it is evident that both public and private actors have a vital position in the collective production of Internal Market regulation. Henceforth, this article introduces a conceptual discussion vis-à-vis regulation and classifies the different variants of current Internal Market regulation in a typology of three different but interrelated categories; respectively public regulation, co-regulation, and private regulation.

In doing so, this article, firstly, discusses the concepts of regulatory governance and regulation. Secondly, the different variants of regulation are allocated within three main categories: a) public legislation, b) co-regulation, and c) private self-regulation, and case examples of the different categories of regulation are explicated to illustrate the variances among the three types and of the ex-ante participatory processes with the main focus on standardization processes. Finally, the article assesses stakeholder participation vis-à-vis the three categories of regulation.
2. The rise of transnational private regulation

Within the regulatory governance literature it attention has recently been directed towards the role of transnational private regulation and governance. It is presumed that ‘governance powers once considered the prerogative of the nation-state have emerged into a form where they are exercised by actors distinct from national governments’. During the past three decades, transnational regulation and privately developed standards have gained importance and momentum at the global level. Standards have come to play a vital role as regulatory measures, not only in the private sector, but also in public regulation. Transnational private actors have become pivotal in developing and administering such standards.

Private regulation is, according to Cafaggi and Renda, emerging as a viable solution for a number of problems faced by contemporary societies, and it can be superior to traditional command and control regulation due to “informational asymmetries, superior coordination, the need for transnational cooperation and standardization, and also the superior flexibility and adaptability of de-ossified, privately implemented, designed and enforced rules”. Cafaggi points out that transnational private regulation constitutes a new body of rules, practices, and processes, created primarily by private actors. Such private regulatory regimes are sector specific, driven by different constituencies, and are often conflicting because they protect divergent interests. The recent growth in transnational private regulation reflects a reallocation of regulatory power from the domestic to the global sphere and redistribution between public

---

6 Supra 2.
and private regulators. Transnational private regulation is transnational, rather than international, in the sense that the effects are cross-border, but are not constituted through the cooperation of states as reflected in treaties. They are non-state (private), in the sense that key actors in such regimes include civil society and/or non-governmental organizations as well as firms (individually as well as in associations).

Büthe and Mattli provide a detailed outline of what is termed as the ‘privatization’ of the production of regulation of the world economy. They focus on how standardization organizations make rules and regulation through standardization processes leading to formal standards for products and services. As opposed to the statements by standardizers themselves; that standardization is an apolitical, consensus-driven scientific process, the authors argue that global standardization: “… is rarely about reaching a compromise among different regulatory models and approaches (...) but instead about battles for preeminence of one approach or solution over another”. Standardization processes are thus to be considered political processes throughout which divergent interests battle for recognition from public and private actors – and hence market power.

3. Internal Market regulation vis-à-vis standardization?

The concept of regulation is a contested concept in the social sciences. Over the last decade, the concept has attracted increased attention from a broad spectrum of social scientists, including political scientists,
lawyers, economists, sociologists, and even psychologists. Though being a concept with strong legalistic roots, it has been, and is, indispensable in many disciplines, also in recent developments in political science. From a political science perspective, the concept of ‘regulation’ has been articulated and applied mainly as an instance of ‘regulatory policy’ (thus distinguishing regulation from law). A classical understanding of ‘regulatory policy’ is that it comprises policies, which specify conditions and constraints for individual and collective behavior in society. In essence, then, regulatory policy defines behavioral constraints. The concept differs from ‘redistributive policy’ and ‘distributive policy’ in the sense that such types of policies are characterized by the allocation and provision of resources, often based on economic numbers, among and between societal actors of various kinds. Hence, while ‘regulation’ has already been thoroughly addressed from numerous perspectives, no common definition of the concept of ‘regulation’ has emerged, neither as a distinct, authoritative definition, nor as a sufficiently broad and yet precise definition covering the phenomenon as such.

According to the operational definition of regulation by the International Standardization Organization (ISO), regulation is ‘a document providing binding legislative rules (legal acts), adopted be an authority and, as such, mandatory’. Henceforth, the ISO is relying on a rather narrow understanding of the concept. This as opposed to the political science handbook definition by Levi-Faur stating that regulation is comprised of: ‘ex-ante bureaucratic legalization of prescriptive rules and the monitoring and enforcement of these rules by social, business, and political actors on other social, business, and political actors’. This definition

---

implies a much broader understanding of e.g. regulatory actors (regulators). Recent literature has also focused on the distinction between rule makers, rule-takers, and rule-intermediaries.\textsuperscript{17}

Koop and Lodge provide a thorough conceptual analysis and discussion of the appliance of the concept of ‘regulation’ in the social sciences.\textsuperscript{18} In their interdisciplinary conceptual analysis of how the concept of ‘regulation’ has been used in six social science disciplines, Koop and Lodge draw four overall conclusions: a) There is a remarkable absence of explicit definitions; b) the scope of the concept is vast; c) there is an overall agreement among scholars that ‘prototype regulation’ comprises interventions that are intentional and direct and exercised by public-sector actors on the economic activities of private-sector actors, and; d) in spite of interdisciplinarity there is an overall shared conception of regulation. Henceforth, Koop and Lodge provide two new definitions of regulation; one essence-based and, respectively, one patterns-based. Based on essence, regulation is defined as ‘the intentional intervention in the activities of a target population’.\textsuperscript{19} The intervention can be direct and/or indirect; the activities economic and/or non-economic; and the actors (regulators and regulatees) may be public-sector or private-sector. The patterns-based definition of regulation is on the other hand: ‘intentional intervention in the activities of a target population, where the intervention is typically direct – the economic activities of private-sector actors’.\textsuperscript{20} In the latter version, the regulator is a public-sector actor with the ability to impose direct interventions on private-sector actors.

With a view to standardization as the research object, this article will adopt the definition by Koop and Lodge stating that regulation is about intentional intervention in the activities of a target population, based on the supposition that regulatory actors are comprised of actors of both public and private origin. Based on this definition, one may distinguish in essence three types of regulatory techniques: a) public legislation;

\textsuperscript{18} Koop and Lodge (2015), supra 13.
\textsuperscript{19} Koop and Lodge (2015), supra 13, p. 10.
\textsuperscript{20} Koop and Lodge (2015), supra 13, p. 11.
b) co-regulation, and; c) private self-regulation. The adoption of this definition therefore implies that European standardization, which is the focus of this Special Issue, certainly constitutes a form of ‘regulation’, and specifically of ‘co-regulation’, as it is developed by public and private actors in a collaborative process and aimed at and capable of intervening and shaping the behavior of internal market actors.

In Table 1, the variants of contemporary EU regulatory techniques in the Internal Market regulation are allocated within the three above mentioned main categories. Case examples of the various types of regulation are provided to illustrate the differences among the three broad categories.
<table>
<thead>
<tr>
<th>Table 1: A categorization of Internal Market regulation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Public regulation – hard law</strong></td>
</tr>
<tr>
<td><strong>Public regulation – soft law</strong></td>
</tr>
<tr>
<td>Co-regulation (public-private regulation)</td>
</tr>
<tr>
<td>Self-regulation (private regulation)</td>
</tr>
<tr>
<td><strong>International (global)</strong></td>
</tr>
<tr>
<td>International treaties</td>
</tr>
<tr>
<td>Common goals, recommendations, etc.</td>
</tr>
<tr>
<td>International standards (ISO, IEC, ITU)(^{21}), e.g. on social responsibility</td>
</tr>
<tr>
<td>Private fora and consortia standards and certifications schemes (e.g. FSC(^{22}) and ‘Fair Trade’)</td>
</tr>
<tr>
<td><strong>Regional (European Union)</strong></td>
</tr>
<tr>
<td>EU treaties, regulations and decisions</td>
</tr>
<tr>
<td>Recommendations and opinions, communications, Open Method of Coordination, etc.</td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>Private standards (CEN, CENELEC and ETSI)(^{23})</td>
</tr>
<tr>
<td><strong>Multi-level (European/national)</strong></td>
</tr>
<tr>
<td>Directives (must be implemented via national legislation)</td>
</tr>
<tr>
<td>Informational campaigns, nudging, etc.</td>
</tr>
<tr>
<td>European harmonized standards (take effect via national standards)</td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td><strong>National</strong></td>
</tr>
<tr>
<td>Laws and ministerial decrees</td>
</tr>
<tr>
<td>Informational campaigns, nudging, etc.</td>
</tr>
<tr>
<td>Publicly requested, national standards</td>
</tr>
<tr>
<td>Formal and informal private standards</td>
</tr>
</tbody>
</table>


\(^{22}\) FSC (Forest Stewardship Council).

\(^{23}\) CEN (European Committee for Standardization), CENELEC (European Committee for Electrotechnical Standardization), ETSI (European Telecommunications Standards Institute).
3.1. Public regulation

With regard to the concept of public regulation, it must be pointed out that the latter concept is not only comprised of public regulation exercised through classical legislative measures, such as hard legislation. In classical nation-states, such measures comprise indeed not only hard law and binding legislation, but also softer measures, such as non-binding political statements and public agenda-setting and/or informative campaigns of various kinds. In the case of the EU, ‘public’ regulation covers hard and binding legislation, i.e. European regulations, directives, and decisions (hard law), as well as softer and non-binding measures, such as recommendations and opinions, communications, high level meeting declarations, and action programs, ‘soft law’, etc.

To exemplify public regulation in the case of the European standardization policy: Until 2012 the European standardization system was regulated by three legislative acts, i.e. directive 98/34 on the notification procedure, decision 1673/2006 regarding financing of European Standardization, and decision 87/95 regarding ICT standardization. In June 2011 the European Commission published a package of legislative acts on the regulation of the European standardization system. The package comprised, among others, a communication on a strategic vision for European standardization towards 2020 and a proposal for a regulation on European standardization. Eventually, the negotiations of this package led to Regulation 1025/2012 on the European Standardization System, which is now the foundational legislative act

---

regulating European standardization, and as such an ideal-type example of public regulation of the Internal Market.30

3.2. Co-regulation

The second category of regulation comprises specific types of regulatory measures developed in public-private partnerships or by private actors themselves, e.g. formal and/or harmonized standards and even de facto standards in the case of ICT. When such regulatory measures are developed in public-private partnerships, the type of regulation can be conceptualized as co-regulation, whose main feature is that governments set the top level legal requirements and leave to market actors (e.g. through standardization processes) the delivery of the technical solutions through standards. Prime examples are EU harmonized standards that are the product of ‘New Approach’ directives.

The ‘New Approach’ is a regulatory technique for technical harmonization whereby product legislation is restricted to the requirements necessary to protect the public goals of health and safety. It was adopted by the Council in 1985.31 Since then the ‘New Approach’ has been an important policy instrument as it provides for the essential requirements to be combined with technical specifications agreed to by stakeholders in the field, usually through harmonized European standards.32 The detailed requirements in standards are being negotiated between stakeholders in the field instead of through legislation adopted by the EU institutions. A formal request for a harmonized standard provides guidelines which standards must respect to meet the essential requirements of a ‘New Approach’ directive or another relevant directive. The introduction of the ‘New Approach’ in 1985 provided flexibility into the legislative process by allowing the

---

harmonization of only the essential requirements, and left the definition of technical requirements to the economic actors and by reducing the burden of control by public authorities prior to a product being placed on the market. The ‘New Approach’ was introduced because the traditional method (the ‘Old Approach’) for harmonizing product legislation often was too slow and unsuitable for several product sectors. The traditional way of harmonizing products was carried out through legislation in order to oblige certain product types produced in EU to have the same technical specifications. This approach to harmonization of rules consisted of often very highly detailed legislation as it had the objective of meeting the individual requirements of each product category. Manufacturers could still manufacture in their own non-standard way if they wished so, but they were required to explain how their products met the requirements, if called upon to do so by member-state authorities.

An important issue when discussing co-regulation techniques is to what extent the products of co-regulation are binding. In general, the transnational standardization process is defined as an apolitical and scientific process of developing technically optimal solutions. Standards are shaped by consensus among enterprises, public authorities, consumers, and trade unions, through a consultation process organized by independent, recognized standardization bodies at international and national levels. Interested parties come together and agree voluntarily on (usually technical) matters, which permits them to compete in the market more efficiently. Also according to the ISO, a ‘standard’ is a document, established by consensus and approved by a recognized standardization body, that provides, for common and repeated use, rules,

---

34 According to estimates referred to by the European Commission, standards amount to up to 1 percent of annual growth in GDP (COM (2011) 311 final). Other economic analyses reach much higher figures, e.g. the comprehensive examination of the economic contribution of standards to the UK economy (CEBR 2015), which points to a collective contribution of standards to app. 28 percent of annual GDP growth. The total amount of harmonized European standards have increased from 4 percent to 20 percent (>4000) of all European formal standards during the last two decades. During the same period of time, the total number of standards has risen from approximately 4000 to approximately 25,000.
35 Rf. Büthe and Mattli, supra 2.
guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context. 37

When looking at the EU level, the picture does not change significantly. According to EU definitions 38, a ‘standard’ is a technical specification, adopted by a recognized standardization body, for repeated or continuous application, with which compliance is not compulsory. A ‘European standard’ is a standard adopted by a recognized European standardization organization (ESO), such as CEN/CENELEC and ETSI; while a ‘harmonized standard’ means a European standard adopted on the basis of a request made by the Commission to an ESO to develop a standard that provides solutions for compliance with a legal provision and hence application of Union harmonization legislation. Hence, a harmonized standard is requested by the European Commission, but developed by a private standardization organization. A formal request for a harmonized standard provides guidelines, which standards must respect to meet the essential requirements of a ‘New Approach’ directive or another relevant directive. European harmonized standards are, according to the official EU documents, formally not binding. 39

However, while formally (de jure) voluntary to abide to, European harmonized standards in support of Internal Market legislation are de facto almost as obligatory as legislation in itself, as the cost of proving conformity with requirements if not following the standard, are considerable. “In theory, European standards are voluntary. (...) In practice, then, the effect of standards is direct and binding since the costs of difficulty and proving equivalence are enormous”. 40

3.3. Self-regulation

38 Supra 29.
39 The Council, Resolution of 7 May 1985 on a New Approach to Technical Harmonization and Standardization, OJ No C 136/1, Annex II; European Commission (2016), The ‘Blue Guide’ on the implementation of EU product rules. Brussels: The European Commission, pp. 40–42. See also recital 1 of Regulation 1025/2012, supra 29, which states: ‘The primary objective of standardization is the definition of voluntary technical or quality specifications’. 40 Büthe and Mattli, supra 2, p. 17.
When regulation is being developed without request or obligation from public authorities, the regulatory measure can be conceptualized as *self-regulation or private regulation*. In that case there is no regulatory intervention by governments or other public authorities, which means that private actors (usually businesses, organizations, fora and consortia) can apply this approach on a voluntary basis. Examples are e.g. FSC certification of woods, Fair Trade-marking of coffee and chocolates, etc. Another example, closely linked to Internal Market regulation and European standardization, is the case of ICT standards. With the adoption of the new EU standardization regulation in 2012, a new legal opportunity to recognize and refer to privately developed ICT specifications as common European standards was introduced in European standardization legislation. ICT specifications developed outside the officially recognized standardization bodies such as CEN, CENELEC, and ETSI, e.g. specifications and standards developed by private ICT fora and consortia, could now be officially recognized and referenced in public procurement documents. The logic is that privately developed standards, i.e. standards developed outside the formally recognized standardization bodies, can be officially recognized and thus referenced in formal legislation. There is a clear link between private regulation with public regulatory and legislative implications. The introduction of Articles 13 and 14 in the standardization regulation (Regulation 1025/2012) and the Commission decision of setting-up the European Multi Stakeholder Platform on ICT Standardization in 2011 thus provided for a legislative ‘swift’ move opportunity resulting in that privately developed specifications were to be recognized similarly to European standards. In other words, when identified and recognized, the privately developed ICT specifications are in essence publicly legitimized international legislation, though the standards were developed through market-based competition among private firms, fora and consortia.

---
43 See Kallestrup (2017), supra 3.
44 Supra 29.
46 See Kallestrup (2017), supra 3.
4. Input legitimacy and stakeholder participation?

Based on this typology of three categories of regulation, the stakeholder participation and input legitimacy can be assessed vis-à-vis each category. In general, EU public regulation, i.e. hard and (to a lesser extent) soft law adopted by EU legislators, builds upon and is developed through the EU treaty-based legislative procedures. The development of public regulation is thus based on the present EU variant of representative democracy. Whether these legislative procedures and political processes of the EU institutions are sufficiently input legitimized is a classical question in the literature on European democracy, which for many years discussed whether the EU is suffering from a ‘democratic deficit’. The Lisbon Treaty in 2009 provided new impetus to the democratic character of the EU institutional structure, in particular due to the new co-legislative nature of the European Parliament and the European Citizens’ Initiative, as well as improvements of the participation and influence of citizens, associations and civil society in EU, not least in the great emphasis put on stakeholder participation by the latest European Commission’s Better Regulation agenda. Therefore, the current state of affairs regarding input legitimacy and stakeholder participation in EU public regulation is certainly more advanced than a few decades ago.

European Internal Market co-regulation, e.g. harmonized standards developed by recognized standardization organizations through a formalized co-regulatory set-up, is developed in a different manner. As mentioned above, the ‘New Approach’ method was introduced as an alternative to the traditional way of harmonizing technical requirements for products, requiring an adoption of formal legislation in order to oblige certain product types produced in EU to have the same technical specifications: the ‘New Approach’ implies that the European Commission puts forward a formal request

for a harmonized standard with guidelines on how to meet the essential requirements of a ‘New Approach’
directive or another relevant directive. Subsequently, the detailed requirements in standards are being
negotiated between stakeholders in the field instead of through legislation adopted by the EU institutions.
Broadly agreed-upon principles recognized by the World Trade Organization (WTO) prescribe specific
procedural requirements. Standardization processes are thus required to be based on a) openness,
meaning that standards are to be developed on the basis of open decision-making accessible to all
interested parties; b) consensus, meaning that the decision-making processes are collaborative and
consensus based and do not favor any particular stakeholder, and take place through a process that
involves seeking to take into account the views of all parties concerned and to reconcile any conflicting
arguments (does not imply unanimity); and c) transparency, meaning that all relevant information is
archived and identified through suitable and accessible means and that all relevant categories of interested
parties were heard. Yet, whether access is a *de jure* right or a *de facto* right to all stakeholders or just to
the stakeholders able and willing to pay for obtaining access to the standardization process, is a yet
unsettled issue among stakeholders, organizations, and authorities. According to the EU Regulation on
the European Standardization System, it is important that all relevant interested parties are appropriately
involved in the national and European standardization process. It is emphasized that standards can have a
broad impact on society, and it is therefore “necessary to ensure that the role and the input of societal
stakeholders in the development of standards are strengthened ...”. According to Article 5 of the
Regulation, “European standardization organizations shall encourage and facilitate an appropriate
representation and effective participation of all relevant stakeholders, including SME’s, consumer
organizations and environmental and social stakeholders in their standardization activities. They shall, in

49 See recital 2 in Regulation 1025/2012, supra 29.
50 See also annex II to Regulation 1025/2012, supra 29.
51 One may further elaborate on this issue based on the classical distinction between corporatist and pluralistic
European state structures, where different traditions of stakeholder involvement in public affairs and political
processes already facilitate different methods of public-private co-operation and interaction.
52 See recital 2 in Regulation 1025/2012, supra 29.
53 See recital 22 in Regulation 1025/2012, supra 29.
particular, encourage and facilitate such representation and participation through European stakeholder organizations receiving Union financing...”.

Without being able to carry out a comprehensive empirical analysis of the realities of input legitimacy in the European standardization process within the remit of this article, it is nevertheless interesting to quote a passage from the main environmental stakeholder organization, ECOS’, website, which does indeed shed some light on this specific issue: when discussing the participatory improvements brought about by Regulation 1025/2012, it is stated that “ECOS regrets that the system does not currently guarantee such effective participation of societal stakeholders, neither at European nor national level. Supported by its 38 member organizations, ECOS advocates for a truly inclusive and transparent standards’ setting process which delivers standards reflecting societal and environmental interests most appropriately”. Hence, the intentions and obligations to ensure stakeholder participation by Regulation 1025/2012 may not have materialized in a sufficient manner.

Finally, self-regulation, such as standards and technical specifications developed and promoted by private fora and consortia, are increasingly publicly recognized, but is the development process sufficiently legitimate vis-à-vis the public importance such private standards have obtained? As mentioned above, a legal opportunity to recognize and refer to privately developed ICT specifications as common European standards was introduced in European standardization legislation in 2012. However, if the private regulation is to be recognized as and referred to as common European standards, it is a prerequisite that the development process lives up to specific procedural requirements similar to the ones required for European harmonized standards. So despite the fast development in the ICT sector, which is explicitly recognized by European standardization regulation and by the European Commission, the self-

54 See article 5 in Regulation 1025/2012, supra 29.
55 http://ecostandard.org/about-standards-2-2/
56 Supra 49 and 50.
57 See recitals 30-37 and chapter IV in Regulation 1025/2012, supra 29.
regulation imposed in this area, is being monitored as to whether the development processes fulfill criteria focusing on openness, consensus, and transparency.\textsuperscript{59}

5. Concluding remarks

This article has mapped different regulatory techniques in European Internal Market Regulation in order to assess whether they provide for adequate participatory mechanisms to ensure representation of all stakeholders. Based on the typology of regulation outlined above and on the analysis of stakeholder participation and input legitimacy in relation to the three regulatory categories, it can be concluded that there is room for improvement in the case of co-regulation and in particular the EU-induced standardization processes, but also with regards to self-regulation, i.e. purely private regulation with direct public implications and regulatory consequences. Despite significant improvements in the category of public regulation, the two other categories are still faced with certain challenges. In the light of the increased prominence of standards and standardization in general over the last two decades, and of the absolute and relative growth in the collective amount of existing standards in Europe and beyond, it should be an incessant quest to assess and address the question of stakeholder participation and input legitimacy. Based on the above, authorities and stakeholders in the field, including European standardization organizations, still have some way, but also leeway, to enhance real participation of all relevant stakeholders in the European standardization processes.

\textsuperscript{59} See Kallestrup (2017), supra 3, for a more elaborate analysis of the new governance of European ICT standardization, and for a discussion of input legitimacy in the European ICT standardization system.