Changing me softly.

Making sense of soft regulation and compliance in the Italian nanotechnology sector

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Abstract

Soft-regulation has increased its importance in science and technology governance. Despite such indisputable significance, the literature on technology policy and regulation so far seems to have dedicated only a limited attention to a systematic understanding of the factors affecting compliance with these soft rules. This article addresses this limitation. By way of a literature scoping exercise, we propose a taxonomy of the mechanisms affecting the compliance with soft regulation. We subsequently apply the taxonomy as a guide to examine the opinions of a small group of scientists and company managers in the Italian nanotechnology sector. The case study does not assess compliance in a direct way, i.e. observing how organizations comply to regulation, but it explores the opinions on what the factors affecting compliance are (and why they work).

Keywords: soft-regulation, compliance, taxonomy, nanotechnology, stakeholders.

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1. Introduction

The governance landscape of science and technology is seemingly characterized by the growing role of soft-regulatory instruments. This increasing significance is not limited to the scientific and technological fields and it reflects the increasing reliance of public policy and regulation on “consensus-based” instruments implying “some degree of

agreement among the targets of policy" ([1], 188). Nanotechnology is by no means an exception: in this priority research and policy field, cutting across several R&D domains from pharmaceutics, food and electronics, soft regulation has been hailed as a solution to combine freedom and control, thus seizing the expectations about the positive impacts of nanotech on the environment, human health, and society (e.g. [2], [3]), mobilizing social actors and, at the same time, relying on them to foster a responsible approach to risks and uncertainties that nevertheless characterize the field (e.g. [4]). Despite the indisputable significance of soft law in technology regulation, questions have been raised on the capacity of soft regulation to steer actors to act in conformity with (soft) rules [5]. In other words, it is doubted that soft regulation can effectively induce actors to comply to rules themselves, thus contributing to the efficacy of policymaking [6]. The literature on technology and regulation so far seems to have dedicated only a limited attention to a systematic understanding of the factors through which soft regulation exerts (or not) its behavioral influence, making compliance a concept that is "agnostic about causality" [7]. The next pages will try to address this aspect in two steps.

Firstly, the article will briefly discuss the most relevant factors explaining the growing role of soft regulation in nanotechnology governance and will illustrate selected soft-regulatory initiatives in nanotechnology in Europe and the US (Section 2). Then, the results of the literature review on the factors explaining compliance will be presented to provide a systematic assessment of their characteristics (Section 3). Secondly, the article will instead examine empirically how some of these factors influenced the acceptance

and diffusion of a soft regulatory standard for consumer safety, by presenting a case study in the Italian nanotechnology sector. The case study will be introduced and the methodological approach of the research will be presented (Section 4). Finally, empirical evidence from this case study is presented to illustrate the heuristic value of our taxonomy in mapping the various factors that affect the compliant behaviour in nanotechnology sector (Section 5).

The case study discussed in this article is about the European Center for the Sustainable Impact of Nanotechnology (ECSIN), a knowledge transfer facility that has long been part of the Veneto Region Research Cluster in Nanotechnology (Veneto Nanotech), a public-private venture established by the Veneto Regional Government, the Italian Ministry of University and Research, the Veneto Region Industrialists Association and three Italian universities in 2004. ECSIN was established to support a responsible use of nanotechnology by doing toxicological and eco-toxicological research and by supporting SMEs that use nanomaterials in their productive processes. The Center has pursued its mission by transferring scientific knowledge about nanomaterial efficacy and toxicity, by using its technical infrastructure in contract research, and by elaborating and diffusing voluntary standards and other technical guidelines related to consumer and occupational health protection for firms. This twofold emphasis on Laboratory testing and regulatory compliance, including the development of original certifications and standards, makes ECSIN a unique case of this sort in Italy. This uniqueness made ECSIN a good candidate for the “single case” research design. Since the closure of the

Veneto Nanotech research cluster in 2015, ECSIN became part of a private R&D company[1], maintaining its mission and activities.

2. Nanotechnology and soft regulation[2]

"Soft regulation" generally refers to a broad group of normative instruments, such as resolutions, declarations, guidelines and recommendations, codes of practice and conduct. In general, soft regulation is a set of explicit rules, which are utterly voluntary or have either a non-binding character ([10], [11]). Nonetheless, soft norms have a legal relevance, though they lack immediate, uniformly binding, direct effects, precision, and clearly delineated monitoring and enforcement authorities [12]. Because of this characteristic nature, soft norms have been often placed in the middle way between law and politics or defined as 'non-legislative modes of policy-making' (Héritier in [10], 53; [6]) or even as "quasi-legal instruments" [13]. Soft regulation describes a shift "from direct intervention ('rowing') to indirect intervention ('steering') in terms of enabling, motivating and pressing the regulated parties to regulate and to comply with self-regulation" [5].

2.1.The growing significance of soft regulation

In general, it can be said that the importance of soft regulation results from the intersection of three processes. Firstly, the fundamental transformation induced by globalization provides the general framework for soft regulation to establish its

1 ECSIN is now part of EcamRicert srl, a company specialized in laboratory testing and analysis.

2 This section draws upon and expands previous works of the Author [8, 9].

relevance. Affecting the previously unchallenged role of the nation state in setting regulations domestically (through traditional command-and-control mechanisms) and internationally (through the forms of international public law) [14], globalization opens up the regulatory space to non-state actors. Secondly, soft regulation is useful to regulators as it leverages the information advantages of regulatees. This is an important asset in emerging technological fields, in which uncertainty is high and for which regulators lack the resources or information needed to develop sound "discretion-limiting rules" of mandatory nature [5]. These areas "often require frequently changing cognitive and material resources for effective regulation, which state actors often do not have and lie with industry as the primary rule target. This is particularly the case in highly technical areas where the state depends on individual producers for crucial regulatory information related to product characteristics and production processes" [13]. Thirdly, in uncertain situations, decision-makers seek to improve the legitimacy and sustainability of decisions on matters whose uncertainty pushes "regulatory decision-making into a more political direction" [15]. This 'politicization' of regulatory decisions demands "the weighing up of sometimes competing values, such as technology promotion versus harm prevention. Scientific risk assessment criteria alone cannot guide regulators and policy-makers in such situations. Instead, a wider range of factors enters the calculations that inform regulatory action, from political ideology and societal risk attitudes to national or sectoral economic interests" [15]. In this context, soft regulation is used in processes where "there is the need to build a participated consensus on legal and political decisions" [16] and the institutional and organizational

configurations of regulatory actions “provide little space for different and conflicting interests to be articulated. This does not mean that conflicts disappear, but that they may take other routes, or are put ‘on hold’, as it were” [17]. Soft regulation aptly translates some of the distinctive features of this “new mode of governance”: integration of different levels of governance, diversity and decentralization, participation and power sharing, expansion of the space for stakeholders' deliberation, flexibility and revisability. Its experimental and tentative nature is seen as an asset for making regulation adaptable to distinctive economic, environmental, social, and administrative, a condition that cannot be achieved through uniformly binding legislative requirements [18] and that reduces transaction costs of regulators and regulatees [13].

soft regulation does not exclusively assume the form of 'self-regulation', that is of an 'unilateral commitment' of regulated parties, but also takes “a partial form as either regulated self-regulation or co-regulation, i.e. joint decision-making with public actors ('negotiated agreements')” ([6], 3). This expansion of soft regulation and its forms does not replace hard law as such, but creates “hybrid” regulatory frameworks [19]. This hybridization has institutional and normative implications. On the institutional level, the formal enforceability of a binding norm is softened by the cooperation between state and non-state actors. On the normative level, “the legal landscape is increasingly populated with norms which cannot straightforwardly be classified into either category. This happens when, for instance, a voluntary good practice code is used as a benchmark for compliance with a ‘hard law’ prescription” [19] or, on the contrary, when hard law is referred to in broader soft regulatory instruments. Commenting this fuzzy situation in

the sector of forest responsible exploitation and preservation, Hickey and his colleagues. notice that “soft law processes tend to reflect inter-governmental, shared-sovereignty aims (i.e. national-level treaties and processes to encourage SFM [Sustainable Forest Management]) and non-governmental, civil society values that are often promoted through trans-national social movements (TSMs)” [20].

As we said in the introduction, this more general trend shifting from a hard-law and command-and-control regulatory policies to soft and self-regulatory practices affected nanotechnology as well. Bowman and Hodge [21] provocatively spoke of a governance “without government” for nanotechnology in their comment on the private sector's efforts to develop innovative regulatory instruments. “These developments have led to new relationships and partnerships, shifting the attention from traditional state regulation to polycentric regulatory structures in which the government is not the sole source of decision-making authority” [22]. In this context, soft regulation has emerged as an useful tool for the international harmonization and coordination of regulatory frameworks [23].

2.2. Examples of soft-regulatory initiatives

The attention to soft regulation is not limited to the academic debate. On the contrary, soft regulatory solutions are widely implemented, as several examples can show. The European Commission’s Code of Conduct for responsible nanosciences and nanotechnologies research is a prominent one [4]. The Code defined a set of general principles and guidelines for stakeholders and aimed to foster efforts by EU member

states and non-state (public and private) actors in the governance of nanotechnologies. At the national level, instruments like the ‘Voluntary Reporting Scheme for Engineered Nanoscale Materials’, which was promoted by the Department of Environment, Food and Rural Affairs of the UK government in 2006-2008, was aimed to engage importers and manufacturers of engineered nanomaterials to provide the Department with comprehensive information on material characteristics, as well as with data on toxicity and ecotoxicity ([24], [25]). Similarly, the US Environmental Protection Agency (EPA) formally implemented its own voluntary ‘stewardship program’ for nanoscale materials under the Toxic Substances Control Act (TSCA) in years 2008-2009. This voluntary scheme was intended to foster collaboration of manufacturers, importers, and processors of nanoscale materials in the collection of data and information. Through this initiative, EPA aimed at generating more detailed information of certain specific nanoscale materials. This collaboration between EPA and industry was expected to generate data and analyses for a more complete characterization of materials, and to increase the knowledge available on the environmental health and safety implications of manufactured nanomaterials, so that their safe manufacture, processing, distribution, use, storage and disposal can be ensured [26].

While these examples of soft or voluntary regulation share the fact that they are initiated by public authorities, private organizations as well launched collective, voluntary regulatory initiatives. A prominent example is the Responsible Nanocode, which "aims to provide clear guidance about the expected behaviour of companies in relation to their nanotechnology activities" [27]. The Code sought to implement a set of "principles"

ranging from "board accountability" (Principle 1) and "worker health and safety" (Principle 3) to "wider social, environmental, health and ethical implications and impacts" (Principle 5). Individual companies such as DuPont and BASF voluntarily developed policies, frameworks, and codes of conduct to ensure the safe production, use and disposal of nanomaterials [28]. In addition, multistakeholder platforms such as the ISO Technical Committee 229 and the Working Party on Nanotechnology (now part of the Working Party on Bio-, Nano- and Converging Technologies) provide opportunities for exchange and coordination of stakeholder in issues like policy and commercialization, terminology and nomenclature, metrology and instrumentation, and test methodologies, health, safety, and environmental assessments [29]. Finally, although not "nano-specific", initiatives like ResponsibleCare© for the chemical industry are equally relevant. ResponsibleCare© adopts cooperative and voluntary activities with government and other stakeholders, thus going beyond legislative and regulatory compliance [30] and committing the “(t)he global chemical industry (to) extend existing local, national and global dialogue processes to enable the industry to address the concerns and expectations of external stakeholders to aid in the continuing development of Responsible Care” ([30], 4).

Despite its diffusion, soft regulation is not exempted by criticism and skepticism about its efficacy. This is true for the academic literature and for stakeholders' opinions. For instance, Maynard and Rejeski [31] argue that voluntary reporting systems have failed and that the existing international soft regulation initiatives have had a limited impact to date. According to these Authors, mandatory measures would be a step in the right

direction. Other Authors notice that, in the face of uncertainty, regulatory stakeholders often prefer more conventional command methods of regulation [32]. In Europe, the European Trade Unions Confederations (ETUC) has asked for stricter rules and for an extension of the current mandatory reporting systems for chemicals under the REACH (cf. [33], [34]).

As Ruggiu [35] documented, a significant turn gradually happened in EU regulation. In 2009, the European Parliament called for the application of the precautionary principle, the principle of producer responsibility and the 'polluter pays' principle, asking, in addition, for the legislation on chemicals (REACH), food, workers' conditions, air quality and waste to also address nanotechnologies as well. A regulation on cosmetic products containing several provisions specifically referring to nanomaterials followed immediately this parliamentary resolution. In 2011, the European Commission issued the first definition of nanomaterials in EU legislation and a new regulation on food labelling explicitly considered nanomaterials. Finally, at the beginning of 2012, another resolution of the Parliament on biocidal products, which explicitly considered nanomaterials, started a revision process in this matter. In the United States, EPA has proposed early in 2013 a mandatory reporting programme under the TSCA for several nanomaterials [36].

Acknowledging both the diffusion and importance of soft regulation and the questions surrounding its efficacy, the next section will explore this latter aspect by considering one of the dimensions of regulatory effectiveness: compliance.

3. Exploring the link between soft regulation and compliance

Compliance can be generally understood "as 'rule-following behavior', as acting in conformity with the rules" [37] or "a state of conformity or identity between an actor's behavior and a specified rule" [7]. In general, compliance deals therefore with behaviour and the behavioral influence of (legal) rules ([7], [38]). In a soft or hybrid regulatory context, compliance is tightly related to effectiveness, insofar the effectiveness of such systems is determined by the degree to which certain policy goals are achieved ([5], 156). Hey and co-authors have spoken of "output-legitimacy" of soft regulation, which is consistent with the "consensus-oriented and participatory style" of governance it embodies [39].

Research on compliance is coupled with the exploration of the "various mechanisms, or incentives, that may induce formally independent actors to comply with non-binding recommendations or agreements" [10]. Indeed, while compliant behavior necessarily requires an active attitude by regulated actors [37], it is important to investigate why actors adopt a behavior that is consistent with non mandatory norms. The attempt to explore the prerequisites [40], conditions [37], components [7], preconditions [41], factors ([12], [42]), or, on the contrary, barriers [38] to compliance, are numerous, yet their distinction and characterization is subject to considerable terminological and conceptual variability. To classify this vast landscape, we propose a taxonomy which distinguish factors of compliance according to the fact they pertain to *rules* themselves

or to the *actors* who enact the regulation or whom, in turn, are regulated[3]. For each of these two dimensions, we discriminate then their properties and sub-properties, consequently differentiating the factors which enable compliance and are identified in the literature (for an overview, see Table 2).[4]

The properties of rules concern:

3 The literature on classifications, typologies and taxonomies is vast and its analysis is beyond the scope of this article. The taxonomy presented in this article is an example of "intensional classification", as proposed by Marradi [43]. Intensional classifications "may be seen as a process of conceptual elaboration (...). The concept whose intension is articulated in one of its aspects is 'explicated' or 'unpacked', hence enriched and clarified (...). Concepts corresponding to individual classes are either formed or clarified by the definition of their boundaries with contiguous concepts. Different terms or expressions are univocally allocated to each class concept, and the concept-term ties are fastened (...) by the implicitly oppositive nature of any systematic allocation" [43]. The result of our classification operation is a taxonomy, as it is obtained "when *fundamenta* (the aspects according to which the classes are distinguished) are considered in succession" [43]. This definition of taxonomy is not universally used. For instance, Bailey [44] defines taxonomies as empirically based, inductive classifications. From this perspective, taxonomies are opposite to typologies, which are instead theoretically based, deductive classifications. As the reader can see, our taxonomy is instead a deductive, theoretical exercise.

4 The advantage of this taxonomic classification is that complex notions like legitimacy [22] or solution process [7] can be considered as constructs based on the combination of different, simpler properties. Eventually, this classification differs from part of the literature as it treats the targets of norms more properly as objects/dimensions (actors) rather than properties (targets, as objects, are distinguishable because of their properties, and their performance in compliance is different because of the properties that distinguish them) [12].

(1.) their contents, i.e. what they prescribe and how they are written,

(2.) the process of their making,

(3.) their context, i.e. their relations with other norms.

The properties of actors concern:

(1.) their beliefs, attitudes, and knowledge about the world and themselves,

(2.) their resources, in terms of expertise, money, etc.,

(3.) their relations with other actors.

(TABLE 2 HERE)

For what concerns rules, the first aspect to consider regards their *contents*, in terms both of what they prescribe and the way in which they are written. Clarity and precision of the norms ([5], [12], [42]) and the inclusion in the provisions of vigilance and enforcement mechanisms ([5], [12], [42]) increases actors' compliance. As Heyvaert [19] specifies, precision can be also "potential precision", as the norm can identify clearly an actor who is delegated to its interpretation [11]. In the context of soft regulation, 'precision' has not much to do with clearly stated, one size fits all regulation. It rather refers to the possibility of flexibly adapting "to the states that are included, the sectors of government that participate, or the aspects of a larger problem that are singled out for norm-building" [11], so that the contracting costs for regulated parties can be

reduced when compared to binding regulation. Oversight does not necessarily implies the presence of a sanctioning mechanism. It can refer instead also to all sort of audit (e.g., periodic monitoring, peer review, benchmarking, evaluation, follow-ups, performance indicators, reporting measures, rankings) [40]. For instance, it has been noticed that the elaboration of measurement indexes and quantitative indicators fosters "coordination among participants" and creates a positive mechanisms of competition and imitation, but also, and related to that, of knowledge sharing and collaboration [45]. The publicity of these indicators and of the related performance can multiply also the effectiveness of "soft sanctions" and reputational pressures (see below).

When the *rule-making process* is concerned, the literature links compliance to deliberation and dialogue processes that precede the adoption of norms and that involve the (future or potential) regulatees [5]. In the same vein, the existence of a preliminary "negotiation processes" is seen as a factor fostering the commitment to comply with soft norms through actor involvement or integration, through networking and by virtue of various forms of partnership [6]. The transparency of [22] and accountability in ([22], [5]) the deliberation process are seen as improving the compliance of the regulatees as well. Responsiveness of the promoters of regulation is considered as a condition to embed these features in the process and to ensure "that actors have a realistic chance of being heard" [22]. In commenting the "accountability deficit" of hybrid regulatory arrangements, Heyvaert [17] notices that "hybridization (…) is problematic when we consider law's communicative role. The adoption of laws and regulations, whether domestic or international, informs the public about governmental policies and priorities.

(…) Thus, they are instruments of public accountability". As a solution, the Author suggests to improve the accountability and transparency of the institutions managing these arrangements and to coordinate the activities of their parties, so governance standards transforms "from a quasi-voluntary, self-regulatory enterprise into a globally binding norm" [19].

A third group of aspects concerns the *context* in which soft rules are framed, i.e. their relation to other norms. Their inclusion in a broader set of vigilance and enforcement mechanisms ([42], [46]) or of incentive systems assigning rewards/benefits or costs/sanctions ([5], [42], [46]) improves the chances of a compliant behavior. A particular attention has been dedicated to the existence of links to hard law, in a direct [12]) or indirect way [10]. Observing the effectiveness of labour soft regulation, Toffel, Short and Ouellet [47] report that adherence to private voluntary regulation is likely to be positively influenced by the embeddedness of companies in States that actively participate in the relevant international treaty regime and that have protective domestic labor regulation. In case of policy disagreement, Fredriksson, Blomqvist and Winblad argue that compliance can be achieved in the "shadow of hierarchy", i.e. as a consequence of a the threat of binding regulation or hard law by regulatory authorities which define "legislative threat or inducements" ([6], 2). Similarly, De Nevers notices that industries adopt self-regulation for defensive purposes, as "they seek to preempt further government regulation" ([46], 222).

Compliance is not only a matter of rules and their characteristics, but also of the *actors* which are called either to elaborate or to abide these rules. From this point of view,

actors' *beliefs, attitudes, and knowledge about the world and themselves* are considered to exert an important influence on the behavior with regard to compliance [5]. In a soft regulatory environment, willingness to comply has been considered to depend most, amongst other things, on the "sufficient overlap of private interests with public interests" [39]. In other words, commitment to compliance augments with the political saliency of issues to be regulated ([11], see also [10]). Arguments derived from rational choice theory can be also grouped under this label, including market incentives and returns for compliant actors [41]. On this aspect, Hooghiemstra and van Ees [48] state that firms have economic motives to comply with code recommendations as shareholders are perceived to use this information in their portfolio decisions. In this view, compliance positively correlates to firms' size and distributed ownership. This is coherent with the Authors's view that "codes of good governance are aimed at providing solutions to problems of asymmetric information between managers and shareholders" ([48], 483) and the conflicts of interest between the stakeholders of the firm ([48], 482), which are most pressing in bigger firms with a broader portfolio of stakeholders. Beliefs about the social division of tasks and responsibilities, including normative commitments like political and moral obligations, have sometimes been highlighted as a specific condition, distinct from other beliefs of the actors [5] (see also [39]). Finally, trust in regulators has seen as a condition as well [5] and it has also been linked to the deliberation processes leading to the adoption of soft regulation, which are seen as sites and processes producing trust [22].

A second set of factors that refers to actor characteristics groups the different *resources* that are used to (and necessary for) ensuring compliance with soft regulation. From this point of view, human resources and their expertise played a crucial role [37], especially in technology-related fields. In a similar vein, financial resources are crucial as well [37]. As noted by Koutalakis, Buzogany and Börzel [13], "material and cognitive resources of domestic regulators as well as their capacity to mobilize the knowledge and expertise of non-state actors are crucial determinants of effective (soft regulatory) responses". Therefore, the application of soft regulation "is hindered by the very same institutional conditions that generate a growing demand for the departure from generally binding regulation" through leveraging actors' capacities in regulatory problems. Similarly, Skjærseth, Stokke and Wettestad establish a direct relation between the state of knowledge backing soft regulation and compliance with the norms, as "soft law backed by scientific evidence that is well established or generated by widely respected bodies" is expected to have a higher degree of compliance ([11], 119). Technology facilities, like infrastructure and equipment that are necessary to build up the knowledge-base needed to set up regulation, are a particular set of resources that is mentioned in the context of soft regulation in emerging technological fields [5]. The bargaining power of the proponents of soft regulation is referred as a resource on its own, which increases the chances for compliance of those who are reluctant to take up soft rules [11].

The last aspect that the literature considers concerns the *relations* that regulatees have with other actors. The participation of regulatees to broader professional, business or

institutional networks, for instance, increases their exposure to reputational pressures from their peers ([10], [12], [42]). Hooghiemstra and van Ees [48] speak of "soft sanctions" to describe concerns for the negative impact that failure to comply can have on the reputation of firms [46]. In their study on the adherence to labor standards in global supply chains, Toffel, Short, and Ouellet [47] find greater compliance among factories that are embedded in states with high levels of press freedom and that serves countries with wealthier and more socially aware consumers, a fact which potentially exposes those firms to reputational pressures[5]. Homogeneity of opinions and consensus about the norms in sectors and amongst organizations affect the willingness to comply, as homogeneity decreases the costs of compliance ([12], [39]).

4. Assessing the factors of compliance in the Italian nanotechnology sector: a case study

The second part of the article presents an empirical explorations of the factors driving compliance with soft regulation in the Italian nanotechnology sector. The analysis follows a deductive qualitative approach (DQA) as described by Cho and Lee [49] and especially, among others, by Gilgun [50]. DQA is an approach of theory-guided research, where initial conceptualizations guide the researchers in content analysis, though they remain open to revision and validation throughout the analytical process. Distancing from more grounded approaches, this perspective is consistent with the aim

5 In their analysis of PVC and paper industries in Europe, the Authors dispute however that NGO mobilization has a direct sizeable impact on the emergence of sectoral voluntary standards [41].

of this empirical work, which is preliminarily appraising the heuristic meaning of the taxonomy of compliance factors presented in Section 3. “The unit of analysis of DQA is the case” ([50], 110). As specified in the introduction, we selected the European Center for the Sustainable Impact of Nanotechnology (ECSIN), a knowledge transfer facility in the Veneto Nanotechnology Research Cluster, as the “complex case” to analyse in this work. As part of the now dismantled Veneto Nanotech Research Cluster, ECSIN had the mission to support a responsible development of the field by doing toxicological and eco-toxicological research and by supporting SMEs that use nanomaterials in their productive processes. ECSIN mission was to support SMEs by transferring scientific knowledge about nanomaterial toxicity, by using its technical infrastructure in contract research, and by elaborating and diffusing voluntary standards and other technical guidelines related to consumer and occupational health protection. This twofold emphasis on Laboratory testing and regulatory compliance, including the development of original certifications and standards, makes ECSIN a unique case of this sort in Italy and, thus, an appropriate candidate for a “single case” research design [51] like the one presented here.

How does this research investigate the factors that foster compliance with soft regulation? It does not look at them in a direct way, i.e. observing a case in compliance, but it examines the opinions on what these factors are (and why they work) in a small group of scientists and company managers working in or with the ECSIN Laboratory. This perspective seems apt to achieve the goal of preliminarily testing our taxonomy, in the context of the ongoing dynamics of technology regulation we have highlighted in

Section 2. As we described above, more space for soft regulation grants more significance to stakeholders; they in turn gain more influence to shape regulatory instruments in a "softer" system [8]. Therefore, opinions can be aptly used to assess the (perceived) effectiveness and influence of the different factors that lead (or lead not) actors to comply with specific soft regulatory instruments.

Opinions of the researchers and collaborating firms on soft regulation in nanotechnology and on the factors influencing the compliance of firms to these non mandatory rules were collected by administering semistructured interviews to key informants from the ECSIN Laboratory (4), from a sister nanofabrication facility in the Nanotechnology Cluster (1), and from collaborating firms (2). One of this firms is a company delivering certification and inspection services that has partnered with ECSIN to develop a standard for the responsible management of nanomaterials in consumer products and a standard for health and occupational safety in companies using nanomaterials in their productive processes. The second firm collaborated with ECSIN in various projects involving the testing of particles and material for toxicologic impacts. Data collection took place in February-May 2014. While we will discuss here the findings related to soft regulation and compliance, interviews were broader in scope and their topics included: (1) the modalities for setting up and coordinating contacts between ECSIN and firms, (2) the types of intervention by the ECSIN laboratory, (3) the goals and needs of firms, (4) the actors involved in the collaboration, (4) the changes in firms' operations after ECSIN’s intervention, (5) the relevance of the European Commission Code of Conduct for responsible nanosciences and nanotechnologies

research and other (hard and soft) international regulatory instruments in developing the collaborations and in partners' activities.

5. Results and discussion

The combination of toxicological assessment and regulatory advice the Laboratory provides is aimed at offering a “full package for responsible innovation” in SMEs (Researcher #4, 12:30). This approach intends to address all the elements that have potential impacts on the firms' production and market operation, including regulatory issues, and worker and consumer safety. What is the perceived role of soft regulation? Interestingly, the interviewees are generally skeptical. As we have said, the Laboratory has initiated soft regulatory initiatives and scientists themselves “introduce these topics” (Researcher #1, 39:10) in their conversations and contacts with firms. Yet, researchers themselves see the mandatory character of regulations as the crucial incentive for the compliance of reluctant firms ("Not everybody is willing to invest [in assessing the safety of nanomaterials]", Researcher #1, 22:40). The successes (and failures) of ECSIN in promoting its regulatory and assessment services can be seen through the lenses of the taxonomy described in Section 3, in order to explore the factors affecting compliance with soft regulation, and their relative importance, in the opinions of scientists and officers in the firms that have been interviewed.

5.1. Properties of rules

Precision of the norm: one the reason hampering compliance with soft regulation is that the *contents* of many soft regulatory documents are seen as not precise enough to provide sufficient guidance to firms and this shortcoming limits their role in the activities of knowledge transfer that are performed by the Centre. This is true for documents like the EC Code of Conduct, which was indeed rarely mentioned and which, in one case, was dismissed as "just blah blah" (Researcher #4). One firm delivering certification and inspection services agreed with this opinion altogether, affirming that the Code is “irrelevant” for firms (Firm #1, 8:00). In the context we analyed, the Code and other soft regulatory documents that are often mentioned (the BASF Code of conduct and the DuPont Nano Risk Framework) in the literature failed to make an impact on ECSIN’s networks of collaborating firms because of their vagueness. This is the chief reason why (soft) regulatory documents need clear implementation guidelines to provide firms a “codified modus operandi” for compliance (Firm #1, 4:50) to be useful and effective. It is for this reason that, when firms and researchers mention non mandatory sources as important for their activities, they consider standards like ISO or other practical and operational instruments, like guidelines, checklists and protocols.

Vigilance and enforcement mechanisms: this practical and operational characterisation makes more general principles meaningful to the operators and the consumers (Researcher #4, 25:00). An essential element is the inclusion of indicators in guidelines, standards and protocols, which give the possibility to measure and assess behavioral

change. This is seen as “the best way to understand if you are doing better or worse” (Researcher #4, 25:00), thus creating the premises for compliance. In the case of voluntary standards, third party monitoring is considered to be an added value, encouraging their adoption and positively influencing users' compliance. “[B]eing certified by a third party means a huge increase in the value of the activities we propose [to our clients] (Researcher #4, 8:40), says an ECSIN researcher.

Deliberation/dialogue: the dialogue between different stakeholders in the regulatory process is seen as a crucial factor in improving the applicability of soft regulation. Two themes can be distinguished under this broad topic. The first one is a general point on the need to establish connections between the “scientific world, legislators and stakeholders [to] increase the applicability of basic research [to regulation]. We, the scientific world, must provide the tools to define what sustainability means” (Researcher #2, 33:30). The second and more specific point concerns voluntary standards and their validation. In the words of the certification company we interviewed, the collective nature of validation is crucial to their effective implementation: “in the path toward a standard, there is the moment of validation, which has the function of correcting potential pitfalls before it enters into force (…). If it is a public standard, those who approves it are clearly collegial bodies like UNI or ISO, but this are very specific cases. When a standard is elaborated by a certification body like us, it is approved by a committee, which is called 'value-chain committee' (*comitato di filiera*) where all the stakeholders are represented” (Firm #1, 5:50).

Transparency/Accountability/Responsiveness: these three aspects should be commented with reference to the specific context we are considering. The literature we cited in the taxonomy refers to soft and hybrid international instruments whose complexity makes the issues of transparency, accountability and responsiveness of regulators most often problematic. The case this article examines is, however, utterly different. The limited number of actors involved (ECSIN, firms and a certification company), the contractual relations between the regulatees and those who issue the regulation or verify its implementation makes these issue appear much less problematic. Collegial processes of validation, third party certification, and the existence of binding contractual provisions are all significant in improving these aspects of the regulatory process.

Link to hard law: when the regulatory context of the norms is considered and given the widespread skepticism surrounding soft regulation, it is not a surprise that the "shadow of hierarchy" suggested by Friedriksson and his colleagues [10] is considered as an important factor fostering compliance. From this point of view, the effectiveness of soft regulation can hence be strengthened through the link with hard law instruments ("The legislator now includes [the reference to soft law instruments] in legislative provisions", Firm #1) or because soft or voluntary regulation are issued by technical and administrative bodies that are linked to public authorities. On this aspect, the following passage is telling:

Researcher #2: [Guidelines] are non mandatory instruments, but they are issued by a body that is part of a ministry. Formally, they are formally not mandatory, they are informally so.

Interviewer: [Mandatory] for you, scientists.

Researcher #2: No, [they are mandatory] also for the entrepreneurs (Researcher #2, 30:10).

5.2. Properties of actors

Attitudes, motivations, interests: Besides the qualities of norms, actor characteristics play a similar crucial role in defining the possibility of compliance. Small and medium firms, which are the primary target of ECSIN's activities, want "solutions" (Researcher #4) for their operational problems. They want to: "improve their products" (Researcher #4, 3:00), "a specific, practical problem" (Researcher #"2, 16:50), which is related to competitiveness (Researcher #2, 12:10) or risk (Researcher #4, 11:00). In adopting a "public voluntary standard", a firm seeks "an internal improvement (in terms of process efficiency and control) or an external one, in terms of communication with consumers or clients" (Firm #1, 08:05). Commercial and industrial interests are therefore seen as the main drivers for firms to approach ECSIN, in general, and to commit for the adoption and implementation of voluntary regulation, in particular. However, opinions seem to differ between scientists and firms, but also the two groups of scientists and firms are internally differentiated. We commented the researchers' belief that firms interested in these aspects of nanotechnologies are, after all, a small minority. With

regard to scientists themselves, one ECSIN researcher notices that his colleagues who work in the nanofabrication facility are less aware of issues related to regulation and, more generally, to the safe and responsible management of nanomaterials. The Laboratory therefore tries to align the interest of the scientists working in the other facilities of the Nanotechnology Research Cluster to inform them about ECSIN's work and to make them aware that there are things "that come before technology development and that are never considered" (Researcher #4).

Beliefs about tasks and responsibilities: The active commitment of actors to responsibility is seen as a powerful force behind the willingness to comply. Compliance is seen as the result of this genuine responsibilisation of actors (Firm #1). "There is a minority of firms who believe [in the responsible management of nanomaterials]", affirms a Researcher (Researcher #4, 10:30). The engagement with soft and voluntary regulation is sometimes seen as a domain of these "virtuous" companies. "Surely, there are virtuous firms who try to prevent [adverse impacts of nanomaterials] or to go beyond what legislation states for reaching higher standards" (Researcher #3, 12:00).

Trust: As we noted in Section 3, trust has a twofold nature. On the one hand, it is generated by the dialogue processes which precede and shapes soft rules formation. On the other hand, it can be seen as a property of the actors. From this second perspective, some entrepreneurs and company managers are perceived to trust more ECSIN and to partner with the Laboratory in assessment and regulatory activities and, therefore,

keener to engage with the safe and responsible management of nanomaterials. “Some entrepreneurs are parochial and fearful while others trust [us] and invest. Those who have been trusting us, continue to do so in the same way” (Researcher #3, 22:30). The existence of previous relations is seen as a factor fostering trust and facilitating further collaborations (“We already knew each other [ECSIN and the firm] and we already visited [the Laboratory] because they have equipments we do not have”, Firm #2, 9:10).[6]

Human resources (expertise): This aspect is primarily related to the specific traits of the target groups of ECSIN activities: small and medium enterprises. SMEs lack the resources in terms of expertise and technical equipment that are required to deal with the complex problems associated with the management of nanomaterials in manufacturing processes. Not surprisingly, the possession of knowledge resources is correlated to the position of actors in the value chain. ECSIN’s network of collaborating firms sees the prevalence of SMEs that are intermediate users of nanomaterials. This means that most of them have a limited knowledge of their properties and of their potential risks for customers and workers, as well as of the procedures to treat them safely and responsibly (Researcher #4, Firm #2). An exception are the (few) R&D companies that produce nano materials. In particular, spin-offs or, in broader terms,

6 As the literature affirms [22], trust is reinforced also by the specific features of the regulatory process. To this extent, the notes in the corresponding sections complement this short discussion of trust as a characteristic of actors.

firms that are "closer" to R&D (for instance firms that are run by former researchers, like Firm #2, or large firms with R&D departments) are perceived to be more aware of safety and responsibility issues (Researcher #4).

Financial resources: Costs pressure firms, especially SMEs, to invest "as little resources as possible" in issues that are not the core of their activity (Researcher #4), especially in times of economic crisis (Researcher #5). This is reflected on the collaboration with ECSIN as well. Because of the lack of standard testing protocols and the need to realize ad hoc studies for each request companies make, the services related to impact assessment and regulatory compliance provided by the Laboratory are often considered too expensive by firms and then eventually declined (Researcher #3, Researcher #4).

Infrastructure and equipment: Similarly to expertise, the lack of appropriate infrastructure is key to implementing voluntary regulation in emerging technological sectors. While this deficiency hampers firms (SMEs, in the case we are examining), this need opens the room for collaboration with organizations like ECSIN. As a researcher says, "the equipment we have is quite specialized and firms do not have it" (Researcher#3, 20:00). Interestingly, the lack of knowledge and technical resources jeopardize firms' possibility to even define the issues to be addressed, explored and, then, regulated. "[ECSIN works] in an area that completely lacks of protocols". The laboratory copes with the situation by referring to "the problems of the firm, our

experience and the available [research] equipment. The potential client does not know what their needs are" (Researcher #3, 05:20).

Reputation: Handling nanomaterials safely and responsibly is considered an element for gaining a potential competitive advantage for the firm. Intangible assets like reputation are seen as an essential component of this advantage, from two perspectives. Firstly, "using nanotechnologies [firms] take risks" (Researcher #4) and reducing uncertainty about nanotechnology impacts (Firm #2) is therefore important to anticipate possible reputation damages. Secondly, responsibility can be an element of an active communication strategy aimed at building reputation in business to consumers and, for companies that work with intermediate users of nano materials, business to business relationships (Researcher #2, Researcher #4, Firm #1). From this point of view, soft regulation is part of these strategies of prevention of and protection from adverse public reactions and, in more positive terms, it is a potential element that positively differentiates the company from its competitors.

6. Closing remarks

Soft regulation has increasingly gained space in the governance of emerging science and technologies, as an attempt to cope with the uncertain nature of their consequences and the wider and more heterogeneous constellations of actors that accompany their development. Nanotechnology exemplifies well this trend in the flourishing of soft regulatory initiatives, both privately and publicly initiated.

The question of compliance with soft regulation is therefore crucial in assessing the effectiveness of these instruments in governing the developments and consequences of transformative technological innovation. Yet, to the best of our knowledge, a systematic classification of the main factors affecting behavioral conformity to soft rules is lacking. Based on a literature review, this article addressed this limitation. We have introduced a taxonomy founded on the central distinction between the features of rules themselves and the features of actors concerned by rule-making, be they either regulators or regulated parties. Such predominantly theoretical focus has been complemented by a case study in the Italian nanotechnology sector, which explores how scientists and company managers view these different features and their role in fostering compliance. As our interest was mainly conceptual and exploratory, the analysis did not have the purpose to assess which factors (or combination of factors) exert more influence on compliant behaviour. Instead, it has tried to map their variety, spanning from rules' contents to rules' context and ranging from actors' characteristics to actors' relations. However, the very fact that respondents identify a broad range of components at work, suggests that compliant behaviour is influenced (positively or negatively) by various elements. The choice of a taxonomic perspective was a preliminary, but necessary, step towards an explanatory approach able to address the agnosticism about causality that the literature associates to the study of compliance [7].

Precision and extensiveness of details in norms are seen as a requirement to comply with regulation because, in the context we have examined, most of the regulated parties (SMEs) do not have the cognitive and technological resources to manage the complex

scientific and regulatory issues raised by the management of nanomaterials. External factors push companies towards compliance as well: opinions confirm the importance of market pressures to stir compliance, as a strategy to prevent possible averse attitudes of the public and to make the responsible management of nanotechnology a competitive advantage vis-à-vis competitors. Yet, market pressures can drive towards an opposite direction: the need to reduce costs for competitiveness may oblige firms to turn down (outsourced) research on impact assessment and regulatory compliance, as they are often considered too expensive. Though it is not intended as a "check-list", the taxonomy proved valuable to guide the exploration of the informants' opinions and the results confirm that, in concrete institutional settings, multiple drivers are considered to play a role in influencing (positively or negatively) behavioral consistency with soft regulation.

Compliance is not the sole dimension of soft regulation effectiveness, which can be negatively affected by the diverse (and possibly conflicting) logics of the different regulatory instruments. Similarly, the institutional environment in which soft regulation is developed and diffused can enable or hamper such effectiveness (for both aspects, see [39]). The study of ECSIN helped unveil a specific aspect of the institutional environment of soft regulation which seems important in appraising its enabling factors: the presence and role of intermediary organizations [52]. Observing a knowledge transfer facility, our case study shows that organizations might have a peculiar importance in establishing collaborations between heterogeneous actors, coordinating relevant expertise (e.g. scientific, technical, regulatory, etc.), matching interests and

motivations, linking research and the market. This connecting activity bridges firms' requests on the one hand, and technical and regulatory requirements, on the other. Intermediary organizations are thus an important site for the development, circulation, sharing, standardization, and adaptation of the scientific and technical knowledge base upon which regulations can be established. This role is key insofar it has the potential to foster consistency and uniformity in regulatory instruments design and application. A similar role is played by third party certification bodies. Third party certification activities positively affects compliance, and they define operational guidelines for risk management and regulatory adherence that combine firms' needs and objectives, scientific knowledge and technical options in a standardized way. In doing so, certification provides standards and procedures that can be applied with a certain degree of uniformity to a plurality of organizations, fostering convergence and coherence.

As it has been explained above, the ECSIN Laboratory had to elaborate instruments and strategies that are meaningful for researchers and firms alike. In playing this role, the Laboratory has become an intermediary between business, science and regulation. In acting to overcome limitations and deficiencies that can hamper rule adoption, this experience shows that compliance is not only a question of individual behavioral adaptation but a matter of collaboration and partnership. This peculiar role of intermediaries invites further investigation to comprehensively understand how they support the diffusion and acceptance of soft regulatory instruments and enable the capacity to comply of regulated parties.

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