Defining the Invisible: Between Soft Norms and Hard Realities in the European Regulation of Nanotechnologies

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I Introduction

Dwarfs, nános in Greek, are on the rise. Nanomaterials are slowly but surely infiltrating the EU market. The tiny materials can already be found in various product groups, such as in food, textiles, chemicals, pharmaceuticals and cosmetics. 1 Frequently, nanotechnologies are associated with important economic and social advances. In 2009, the European Commission classified them as a key enabling technology “at the forefront of managing the shift to a low carbon, knowledge-based economy”. 2 Inseparably linked with nanotechnologies’ advances are, however, their potential negative side effects. Indeed, the impact and possible harms nanotechnologies might inflict upon the human body and the environment are yet unknown. 3 Take, for instance, a PET bottle coated with a nano-layer. The nano-layer shall preserve the bubbles in fizzy drinks, thereby

prolonging its expiry date and, ultimately, reducing food waste. At the same time, it remains unclear whether the nano-components in the packaging can migrate into the drink. Whilst first studies have indicated a low risk of migration, representative testing is still lacking. The persistence of these scientific uncertainties has so far made an objective calculation of the implied risks and benefits impossible. Value judgements inevitably enter the debate, rendering nanotechnologies’ regulation a contentious matter. “Sooner or later”, Ulrich Beck infers, “the question of acceptance arises and with it anew the old question: how do we wish to live?”

The controversy surrounding nanotechnologies starts with the fundamentals: when do we define a material a ‘nanomaterial’? Where does the ‘nano’-scale begin? And is ‘size’ the only characteristic that should be taken into account? At the same time, the rapid scientific and technological progress in the area has cast doubts as to whether norms enshrined in legal texts are still the appropriate way forward: isn’t “relentless change [...] best controlled by keeping options open”? Along this line, also the European Commission has in recent years attempted to respond to the emergence of nanotechnologies not via its right of legislative initiative but through regulatory measures in the executive sphere, including the use of ‘softer’ options, such as recommendations or guidance documents that should aid the preparation of new and enhance the implementation of existing legislation.

The endeavour of this paper is to provide a critical analysis of this increasing reliance on soft law instruments. To this end, the paper will review in detail the adoption and implementation of one very specific measure, namely the European Commission’s recommendation for a definition of ‘nanomaterial’. Firstly, this paper will hence introduce the controversy accompanying the quest for a definition of the term ‘nanomaterial’, mirrored by the various (conflicting) reactions of stakeholders that followed the recommendation’s adoption. Notwithstanding the technical nature

commonly associated with the adoption of such a definition, it will thus be shown that decisions taken in the course of this process extended well beyond the mere 'technical or scientific' sphere (Section II). Thereafter, the paper turns to the practical impact of the definition. It will be shown that the definition has been incorporated, almost verbatim, into regulatory frameworks not only at the EU but also at national level. This translation process deserves careful scrutiny, taking into account its two dimensions – the definition’s wandering from the European to the national level, as well as its evolution from a soft to a hard norm (Section III). The definition’s significant impact, in turn, raises vital questions, most notably as to its adoption process. The last part of this paper therefore analyses the recommendation’s drafting process at the European level, in particular the involvement of stakeholders therein (Section IV). The paper will conclude with some critical remarks touching upon the definition’s legitimacy (Section V).

II Defining the Invisible: A Tightrope Walk

II.1 ‘Nanomaterial’ and its Definitional Confusion

Regulating nanotechnologies naturally presumes that the regulator comprehends what he or she is intending to regulate, and is then able to define it. The inclusion of definitions in legislative frameworks forms the prerequisite for delineating an instrument’s scope and subject matter.¹² Yet, the tenacious gaps in scientific knowledge in the area of nanotechnologies have hindered standardisation efforts. Different working definitions of ‘nanomaterial’ and ‘nanotechnology’ exist (and compete), elaborated by international organisations such as the International Organisation for Standardisation¹³, the European Commission’s scientific committees as well as several individual countries such as Australia, Canada, Denmark, the UK and the US.¹⁴ By inference, international agreement on a definition could not be reached until to date.¹⁵

At European level, the regulation of nanotechnologies has its origin in a Communication of 2004 on a European Strategy for Nanotechnology.¹⁶ Therein, the Commission proposed an ‘incremental approach’, which denotes the adaptation of relevant existing horizontal and sectorial legislative frameworks to the specific characteristics of the

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nanoform.\textsuperscript{17} Yet, the Commission has so far been careful in introducing nano-specific provisions, including definitions, into the legal texts.\textsuperscript{18} It hardly used its right of legislative initiative. Instead, it is the Parliament, partly even the Council, that drive the legislative review wherever possible.\textsuperscript{19} In a Resolution of 2009 the Parliament clarified its position by stating that it

"does not agree, before an appropriate evaluation of current Community legislation, and in the absence of any nano-specific provisions therein, with the Commission’s conclusions that a) current legislation covers in principle the relevant risks relating to nanomaterials, and b) that the protection of health, safety and the environment needs mostly be enhanced by improving implementation of current legislation, when due to the lack of appropriate data and methods to assess the risks relating to nanomaterials it is effectively unable to address its risks."\textsuperscript{20}

The Parliament eventually asked the Commission to review all relevant legislation until June 2011.\textsuperscript{21} Yet, the Parliament did not intend to wait two more years, but started introducing nano-specific amendments into on-going recasts and revisions of relevant legal texts within the ordinary legislative procedure. The pattern is best illustrated by taking one legislative review process as an example. Suitable for this purpose is the recast of the Cosmetics Directive, which was adopted in November 2009\textsuperscript{22} and which constitutes the first EU legislative framework to explicitly mention ‘nanomaterials’. Whereas the Commission’s original legislative proposal for a recast did not contain any specific mentioning of ingredients in nanoform,\textsuperscript{23} it was the Parliament that seized the opportunity to introduce particular, more stringent nano-specific provisions at first reading stage.\textsuperscript{24} So does the new Cosmetics Regulation contain a definition of nanomaterial\textsuperscript{25} and, based on that definition, a specific pre-market notification\textsuperscript{26} and

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labelling requirement for nanomaterials, as well as a public register for all cosmetic products containing nanomaterials on the EU market. Following this pattern, the European Parliament subsequently proposed similar amendments for other legislative frameworks under revision and recast. However, the definitions of ‘nanomaterial’ that the Parliament inserted on this ad hoc basis differ. So does the new Cosmetics Regulation contain a different definition of ‘nanomaterial’ than, for instance, the final negotiated text of the first attempt to revise the Novel Food Regulation in 2011.

The European Parliament recognised the potential (legal) complications arising from treating a material as ‘nano’ under one legislative framework and as not ‘nano’ under another. In its resolution of 2009 it noted that “the current discussion about nanomaterials is characterised by a significant lack of knowledge and information, leading to disagreement starting at the level of definitions”. The Parliament therefore called on the Commission “to promote the adoption of a harmonised definition of nanomaterials at the international level and to adapt the relevant European legislative framework accordingly”.

II.2 The Commission’s Recommended Definition

The response of the Commission was the adoption of Recommendation 2011/696/EU in October 2011, which lays down a definition of ‘nanomaterial’. The recommendation is addressed to Member States, EU agencies and industry, who are invited to use the definition in the adoption and implementation of legislation and policy. According to the Commission, a recommendation was preferable to a legally binding instrument, as it would have the advantage of flexibility, and “does not contain any direct obligations for Member States and economic operators” but whose “implementation will happen through various pieces of specific legislation”.

26 Arts. 13(1)(f) and 16(3).
27 Art. 19(1).
28 Art. 16(10)(a).
Unlike the definition that was inserted into the new Cosmetics Regulation and suggested by the European Parliament in the first attempt to revise the Novel Food Regulation, the recommended definition is not restricted to engineered nanomaterials but also embraces natural and incidental materials. Secondly, it is solely based on the size of the material's constituent particles. Two core elements of the recommended definition thereby distinguish nanomaterials from non-nanomaterials: a material is considered a nanomaterial where at least 50% of its constituent particles are in the size range of 1 to 100 nanometres.

II.3 Mapping the Reply

Given the scientific uncertainty and the resulting continued contention about, for instance, the appropriate size range or whether size should be the only characteristic to be considered,36 the Commission’s recommended definition has been reproached by virtually all affected stakeholders. The European Environmental Bureau (EEB) announced in a press release on the same day that it “is deeply disappointed by the European Commission’s decision released today to use a narrow definition for the term ‘nanomaterial’, indicating that industry lobbying has won over the Commission’s own scientific advisors”.37 The EEB particularly criticised the chosen threshold of 50% as being too restrictive, stating that it “had called upon the Commission to stick to a 1% threshold of the particle number size distribution as a way to put under scrutiny, certain materials, which may exhibit nano specific hazardous properties in the larger size range”.38 In a similar vein, the European Consumers’ Organisation BEUC wrote that

“we are critical of the fact that the threshold for the number of ‘nano’ particles needed in order for the product to qualify as a ‘nano-product’ has been raised from 0.15% to 50% and deviates in key points from the opinion of the scientific risk assessment committee and a previous Commission draft. Furthermore, the upper limit of 1-100 nm is too narrow and may lead to a situation in which products with bigger particles could escape the definition and thereby remain unregulated”.39

Also the European Chemical Industry Council CEFIC, however, expressed severe criticism.

“[T]he Commission’s recommendation released today is too broad in scope and therefore difficult to integrate into existing legislation in a meaningful way. ... CEFIC fears implementing the proposed definition will add unnecessary burden for companies, leading to added costs and less efficient use of resources. In addition, its current form would define as nanomaterials some decades-old

substances such as mineral pigments used in paints and other everyday products".40

The Commission's definition of ‘nanomaterial’ appears hence all but void of political choices. As the Dutch National Institute for Public Health and the Environment (RIVM) underlines, “at present, the particle size range of 1nm-100nm has no scientific basis” but the decision “remain[s] a political one”.41 Likewise, the chosen particle number threshold of 50% “has been a political decision because no scientific reasoning can be given for a threshold value”.42 The recommended definition therewith accommodates a sensitive balancing exercise between the different rationalities at stake, most notably between the economic interest, on the one hand, and the environmental, health and safety rationalities, on the other.

III Reconstructing the Translation Process: Its Two Dimensions

Despite the substantial resistance of stakeholders, the Commission's definition has, in its merely two and a half years of existence, found its way into several legislative texts as well as guidance documents at European and national level. The two dimensions of this translation process will be analysed, firstly, the definition’s wandering from the European to the national level and, secondly, its development from a soft norm to a hard reality for affected actors.

III.1 First Dimension: From European to National Level

The Commission’s recommended definition has most recently been used to formulate nano-specific laws in the Member States of the EU. Generally, the fields in which nanotechnologies are or will be applied, such as in chemicals, food, cosmetics, or medicines, affect competences, which are harmonised at the EU level.43 Most of the regulatory attention in the area of nanotechnologies has therefore focused on the European rather than on the national level of the Member States. Yet, the Commission’s stagnant implementation of its ‘incremental approach’ has progressively caused discontent in several Member States.44 France45 and Belgium46 therefore introduced

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43 The legislative frameworks identified by the Commission in its Communication ‘Regulatory Aspects of Nanomaterials’ are predominantly based on Art. 114 TFEU (internal market), Art. 153 TFEU (worker protection), Art. 43 TFEU (Common Agricultural Policy), Art. 168 TFEU (public health), Art. 192 TFEU (environmental protection).
45 France adopted a decree for mandatory reporting of products containing nanomaterials in February 2012, which entered into force on 1 January 2013, Décret n° 2012-232 du 17 février 2012 relatif à la déclaration annuelle des substances à l’état nanoparticulaire pris en application de l’article L. 523-4 du code de l’environnement.
When France announced its intent to adopt a respective law in 2009, commentators immediately cried foul, raising doubts as to its compatibility with EU law, especially with the legislative framework for chemicals, i.e. the Regulation on the Registration, Evaluation and Authorisation of Chemicals (REACH). In a nutshell, the argument goes as follows. Since “REACH should be considered as seeking full harmonisation for all chemicals produced and marketed in the EU”,49 “Member States cannot simply adopt measures on nanomaterials on the grounds that REACH is not specific enough to regulate nanomaterials”.50 France, however, carried on notifying its draft decree to the Commission in 2011 under Directive 98/34, which lays down a procedure for the provision of information in the field of technical standards and regulations in order to scrutinise their compatibility with EU law.51 The Commission itself, Germany and the UK provided comments on the notified draft decree. Yet, neither a Member State nor the Commission issued a “detailed opinion”, which would have extended the normal ‘standstill period’ of three months, precluding the French law to enter into force, at least temporarily. This way, the French law entered into force on 1 January 2013.52

The French draft decree was agreed upon before the Commission’s recommendation for a definition of ‘nanomaterial’ was adopted in 2011. Initially, the draft decree hence contained a different definition, resembling the one incorporated into the EU Cosmetics Regulation. Following the recommendation’s adoption, however, and the comments provided by the Commission to France’s notification under Directive 98/34, “France adapted its definition to take into consideration the Commission’s recommended definition”.53 Indeed, Directive 98/34 stipulates that the Member States “shall take such comments into account as far as possible in the subsequent preparation of the technical regulation”.54 The final version of the decree therefore features a definition of a

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54 Art. 8(2).
substance in nanoform that follows the Commission’s recommendation. It, accordingly, features the 50% threshold for particles in a size range of 1 to 100 nanometres. Belgium is currently developing a similar register, also with the Commission’s definition at its roots.

Consequently, the Commission’s recommended definition of ‘nanomaterial’ constitutes the fundament of the, to date, only two national laws on nanomaterials in the EU. The recommended definition therewith wandered, or it was “transplanted”, from the European into the national legal order.

III.2 Second Dimension: From Soft Law to Hard Realities

The recommended definition’s transplantation into national law furthermore alters its legal status from a ‘soft law’ measure to a legally binding norm enforceable in front of public courts. Evidence for such a “legalisation” or “hardening” of the recommended definition is also found at the European level. After the recommendation’s adoption in 2011, the definition was incorporated, almost verbatim, into the ongoing revision process of the Biocidal Products Directive. The new EU Biocidal Products Regulation thus contains a definition of nanomaterial that comprises substances containing particles of which more than 50% are in the size range of 1 to 100 nanometres. Moreover, in case of ambiguity, Member States may request the Commission to “decide, by means of implementing acts, whether a substance is a nanomaterial, having regard in particular to Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial”.

However, this automatic “hardening” process of the Commission’s recommended definition experienced a major setback in February 2014 in the context of Regulation 1169/2011 on the provision of food information to consumers. Regulation 1169/2011 was adopted simultaneously with the Commission’s recommended definition in October 2011 but originally contained a different definition of ‘nanomaterial’, which neither solely referred to size nor did it feature the size range of 1 to 100 nanometres. After the Regulation’s entry into force, however, the Commission proposed a delegated regulation, intended to bring the definition in line with its recommendation. This time, however, the Parliament, a premiere since its introduction with the Lisbon Treaty, used its right of objection to a delegated act. The Parliament contested, inter alia, the

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56 Belgium notified in July 2013 the Commission, under Directive 98/34, of its Draft Decree to create a register of nanomaterials, based on the Commission recommendation for a definition of nanomaterial, see notification to COM 2013/368/B.


60 Regulation (EU) No 528/2012, Art. 3(3).

61 Art. 2(2)(t), Regulation 1169/2011.

controversial 50% threshold included in the Commission’s recommendation for “run[ning] contrary to the basic aim of the directive to pursue a high level of protection of consumers’ health and interests”.63 Instead, the Parliament considered a threshold of 10% “more appropriate”.64 Also stakeholders used this opportunity to speak out. The European Consumer Organisation BEUC sent an open letter to the Members of European Parliament before the plenary vote, urging them to support the resolution.65 The association of the European food industry, FoodDrinkEurope, to the contrary, evaluated the European Parliament’s decision as “regrettable”, “caus[ing] great confusion for consumers”.66 The Parliament’s use of its right of objection hence (re)exposed the controversy underlying the nano definition. It remains to be seen whether the Parliament will continue its approach in the updating of further definitions, such as in the new Cosmetics Regulation.67

At the same time, the Parliament is not always able to perform this ex ante scrutiny function in the “hardening” process of the Commission’s recommended definition, most notably where it is not inserted into legally binding acts (via a legislative or non-legislative procedure), but where it serves to prepare further soft law measures – such as Agency guidance documents. This is exactly what happened in the context of the EU chemicals legislation REACH. Here, the European Commission announced in 2013 that it would not propose amendments to the REACH Regulation’s legal text. Instead, it proposed the updating of the REACH Regulation’s annexes and the development of respective guidance documents by the European Chemicals Agency (ECHA).68 The Commission justified its decision with reference to “legislative stability and predictability”.69 In the course of 2012, the ECHA hence adopted updates to its REACH guidance documents in order to make them ‘fit for nano’.70 All of these updates have at their roots the Commission’s recommended definition of ‘nanomaterial’.

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What’s more, despite their formal non-bindingness, the ECHA’s guidance documents occupy a central role in REACH’s day-to-day operation. Their significance is illustrated by a search of the ECHA’s frequently asked questions database, which features 175 Q&As on REACH, 62 of which are answered by reference to a REACH guidance document. An ECHA staff member confirmed that in communicating with stakeholders, guidance documents are constantly pointed to. In view of their practical weight, Korkea-aho even argued that these guidance documents should also function as “an aid” to the EU courts, as a way to ensure that the REACH Regulation “delivers the intended benefits, providing the courts with the requisite (technical) information”. And indeed, the significance of the REACH guidance documents seems to have surpassed a pure practical effect. In their as yet short lifetime, they have at least once been evoked in front of the EU Courts. In her opinion to a preliminary reference, Advocate General Kokott relied upon the REACH guidance for monomers and polymers to support her conclusions that an obligation to register reacted monomer substances entailed in polymers is not disproportionate, a question, which was posed to the ECJ by the High Court of Justice of England and Wales. Beyond REACH, the EU courts find it increasingly “useful” for national courts to “take into account” interpretations of secondary law stipulated in Commission guidance documents, but also consider such

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<td>73 Interview with an ECHA staff member, 25 November 2013, Helsinki, notes on file with the author.</td>
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documents themselves when interpreting EU legislation.\textsuperscript{78} Notwithstanding their ‘soft’ form, ECHA’s guidance documents – including the Commission’s recommended definition of ‘nanomaterial’ used to formulate their contents – therewith turn into hard realities for affected actors.

IV Putting the Recommendation’s Legitimacy to the Test

The recommended definition’s “hardening” process, in turn, raises vital questions, most notably as to its legitimacy. This last part of the paper firstly zooms in on the recommendation’s drafting process at European level, in particular on the involvement of stakeholders therein: could affected actors participate in the recommendations adoption? Secondly, to what extent could the Commission be held accountable for its behaviour during the drafting process? Before engaging in this analysis, the underlying understanding of legitimacy is briefly explicated.

IV.1 The Concept of Legitimacy

In order to study the recommendation’s legitimacy, this paper builds on a normative understanding of the term that takes as its reference the democratic self-determination of the citizens.\textsuperscript{79} The concept of democratic self-determination, in turn, is understood to comprise Scharpf’s “two faces” of input and output legitimacy.\textsuperscript{80} According to this analytical distinction, political decisions are input legitimate where they reflect the will of the citizens,\textsuperscript{81} which is determined via their participation in the decision-making process.\textsuperscript{82} Output legitimate, on the other hand, are decisions that serve to further the ‘common interest’ of the people, i.e. that allow for an effective solution of the problem.\textsuperscript{83} Furthermore, output legitimacy requires the prevention of abuse of political power by holding a regulator accountable for its decisions \textit{ex post}.\textsuperscript{84}

Fritz Scharpf argues that today, due to the absence of a collective European identity, input legitimacy is impeded to develop at the EU level.\textsuperscript{85} Attention, in his view, should instead be paid to the output aspect of legitimacy. This, however, conflicts with ideas

\textsuperscript{79} J. Habermas, \textit{Between Facts and Norms: Contributions to a Discourse Theory of Law and Democracy} (The MIT Press, 1996), at p. 73.
\textsuperscript{80} F. Scharpf, \textit{Governing in Europe: Effective and Democratic?} (Oxford University Press, 1999), at pp. 6-13.
\textsuperscript{81} F. Scharpf, \textit{Governing in Europe: Effective and Democratic?} (Oxford University Press, 1999), at p. 6.
\textsuperscript{82} F. Scharpf, \textit{Governing in Europe: Effective and Democratic?} (Oxford University Press, 1999), at p. 7.
\textsuperscript{83} F. Scharpf, \textit{Governing in Europe: Effective and Democratic?} (Oxford University Press, 1999), at p. 6.
\textsuperscript{84} F. Scharpf, \textit{Governing in Europe: Effective and Democratic?} (Oxford University Press, 1999), at p. 13.
\textsuperscript{85} F. Scharpf, \textit{Governing in Europe: Effective and Democratic?} (Oxford University Press, 1999), at p. 12.
presented earlier, according to which an objective calculation of the most effective result in nanotechnologies’ regulation is rendered impossible by the scientific uncertainty dominating the area. The ‘common interest’ of the citizens and the accordant ‘effective solution’ to the nano problem depends on the subjective perception of the inherent risks and benefits. Output legitimacy therefore conditions input legitimacy. Simultaneously, the citizens’ input in the decision-making process is meaningless where the regulator is afterwards allowed to proceed as he or she pleases without the prospect of being held to account. Legitimacy, for the purpose of this paper, eventually comprises the two elements of participation and accountability.

IV.2 The Spectacle of Participation

Participation, meaning the input face of democratic self-determination, is looked at first. It may take two forms. On the one hand, citizens may participate via their elected representatives, at European level mostly via their representatives in the European Parliament. On the other hand, citizens may directly participate in the decision-making process, such as via public consultations or dialogues. In 2002, the Commission adopted to this end a Communication entitled ‘Towards a reinforced culture of consultation and dialogue’, in which it laid down minimum standards for direct participation in the decision-making process. With these standards, the Commission committed itself, for example, to ensure a balanced representation of affected parties in the consultation process, an adequate publicity of the consultation, a consultation period allowing the respondents sufficient time to reply (a minimum of eight weeks) and a display of the results of the consultations on its websites, including the provision of an ‘adequate feedback’.

Turning to participation in the adoption of the Commission’s recommended nano definition, clear is that the European Parliament was not involved in the recommendation’s drafting process. Yet, to what extent were affected actors able to participate directly in its adoption? In the drafting of the recommended definition, the Commission decided to request an opinion from one of its expert groups, the scientific committee SCENIHR. In the course of the drafting of this opinion, the scientific committee opened a draft thereof to public scrutiny. Furthermore, also the Commission launched a public consultation on the draft of its subsequent recommendation before final adoption. At first glance, it hence appears that affected actors were very well able to participate, even twice, in the recommendation’s adoption.

Figure 1: Adoption of the Commission Recommendation on a Definition of ‘Nanomaterial’

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86 See Section I.
90 For the request, see http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_q_024.pdf.
Closer scrutiny, however, unveils a different picture. Firstly, both consultations were performed in the absence of procedural standards. On the one hand, public consultations performed by DG Sanco’s scientific committees are generally not subject to the Commission’s 2002 minimum standards (1st consultation). Indeed, these standards only apply to “major policy initiatives” of the Commission. On the other hand, the “majorness” of a policy initiative is indicated by the presence of an impact assessment requirement. Whilst the performance of an impact assessment, in turn, is compulsory for all legislative proposals, non-binding acts – such as recommendations – only fall under its scope where they are likely to “define future policies”. What exactly this criterion entails is not specified. Does a measure “define future policies” merely where it contains proposals for legislative or policy action, or is the trigger reached where a recommendation defines key concepts that will be inserted into future legislation or policies, such as the definition of ‘nanomaterial’? To be sure, in the drafting of its recommendation for a definition of ‘nanomaterial’, the Commission considered the impact assessment rules not applicable. An impact assessment, i.e. a transparent evaluation of the recommended definition’s economic, environmental and social effects, was hence not performed. Neither, by implication, were the Commission’s minimum consultation standards applicable to the Commission’s public consultation on its draft recommendation (2nd consultation).

Secondly, an analysis of the two consultations’ practical operation yields sobering results. This is firstly due to imbalances in participation between different societal

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91 These are SCENIHR, SCCS, SCHER.
interests, most notably between industry representatives, on the one hand, and environmental NGOs and consumer organisations, on the other. Hence, whilst in SCENIHR’s public consultation 49% of the participants were industry representatives, only 15% represented NGOs.\textsuperscript{96} Even more pronounced was this imbalance in the second public consultation organised by the Commission, where roughly 63% of the respondents represented industry as opposed to merely 4% that came from NGOs.\textsuperscript{97}

Secondly, the ability of participants in the first consultation to influence the recommended definition was substantially reduced, if not nullified, by the fact that the Commission published its draft recommendation for a definition of ‘nanomaterial’ before SCENIHR adopted its final opinion. Indeed, the Commission opened its draft recommendation for public consultation in October 2010,\textsuperscript{98} i.e. several weeks before SCENIHR even adopted its final scientific opinion in December 2010. This means that all the comments that SCENIHR received from participants to its consultation were not reflected in the Commission’s draft recommendation.

Figure 2: Timeline for the Adoption of the Commission Recommendation

\textsuperscript{96} See Explanatory Note how the Comments received during the Public Consultation were taken into Account for the final SCENIHR Opinion on the Scientific Basis for the Definition of the Term Nanomaterial, SANCO C7, Brussels, available at: http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_032_note.pdf.

\textsuperscript{97} See http://ec.europa.eu/environment/consultations/nanomaterials.htm.

\textsuperscript{98} See http://ec.europa.eu/environment/consultations/nanomaterials.htm.
Even worse, the Commission’s subsequent public consultation on its draft recommendation closed after only four weeks (contrary to the eight weeks prescribed by the Commission’s minimum consultation standards), because

“The SCENIHR pre-consultation opinion on the ‘Scientific basis for the definition of the term ‘nanomaterial’ was closed after 8 weeks of consultation on 15 September 2010. This draft proposal for the term ‘nanomaterial’ builds on the scientific opinion.”

Beyond doubt, this reasoning is highly irritating, above all since the results of SCENIHR’s public consultation were not even considered by the Commission in its draft recommendation.

IV.3 A Weak Ex Post Scrutiny

Having analysed affected actors’ (weak) participation in the drafting of the Commission’s recommended nano definition, this Section turns to the accountability question. Accountability, i.e. the output aspect of Schröff’s reformulated conceptualisation of legitimacy, must be narrowly construed in this paper in order to distinguish it from the input that the citizens’ participation feeds into the decision-making process. Accountability is therefore understood as an ex post oversight mechanism. The regulator is held to account for activities that have already taken place. There are several kinds of forum to which an actor may render account, including the political, the legal, the administrative and the social forum.

The locus of political accountability at the EU level is the European Parliament, which supervises, ex post, the EU’s regulatory activities. Besides the Parliament’s ‘grand supervisory powers’ over the Commission – including its budgetary control function, its right to ask parliamentary questions and its right to approve and dismiss the college of Commissioners – the Parliament’s ability to hold the Commission to account in its day-to-day executive functions is limited. There is no particular parliamentary scrutiny over recommendations adopted by the Commission (as it exists, for instance, with regard to delegated or certain implementing acts). The relevant annual activity report of the Commission merely informs the Parliament (and the Council) that “the Commission took an important step towards greater protection for citizens by recommending a definition of ‘nanomaterials’ which will help determine which materials need special treatment in specific legislation”. What is more, the European Parliament did not use its supervisory powers to further investigate into (the adoption process of) the

recommendation. Members of European Parliament neither addressed questions to the European Commission concerning this measure,\textsuperscript{104} nor was its content subject to discussion in the parliamentary committees.\textsuperscript{105}

As inherently problematic appears moreover the provision of accountability through the legal forum, i.e. through the EU courts. This is because recommendations are explicitly of non-binding character.\textsuperscript{106} Accordingly, Article 263(1) TFEU states that the Court of Justice shall review the legality of “acts of the Council, of the Commission and of the European Central Bank, other than recommendations and opinions”.\textsuperscript{107} Following the Court’s substantive approach in determining whether an act produces legal effects, however, even recommendations could in exceptional cases undergo an examination before the Court excludes ‘legal effects’.\textsuperscript{108} The challenge is to prove that the recommendation \textit{de facto} affects the legal position of third parties, for instance, by introducing a new obligation. There are two aspects that must be considered.

Firstly, there is room to argue that the Commission’s recommendation for a definition of ‘nanomaterial’ merely constitutes a ‘preparatory act’, which, only once inserted into the legislative framework (at national or European level) creates legal effects vis-à-vis third parties. Here, reasoning similar to the Court’s argumentation in \textit{Olivieri} is conceivable, according to which a preparatory measure is incapable of directly affecting the legal position of the regulatee.\textsuperscript{109} Yet, the situation becomes tricky where the nano definition is not only used to “prepare” legally binding regulation, but also soft law, such as Agency guidance documents as, we saw, it is the case in the chemicals sector. The \textit{Olivieri} reasoning would then not hold anymore, since also the legal effect of the subsequent instrument, which is “prepared” by the nano definition, is uncertain. Only binding decisions, which are adopted based on the guidance document, could then be judicially challenged, rendering it more and more difficult to retrace the proper preparatory act out of the emerging ‘soft law construct’ underlying the final decision. Besides, treating the recommended definition as a mere ‘preparatory act’ would ignore the practical effects that it certainly exerts on the behaviour of affected actors – without resulting in a (binding) act at all.

Secondly, in determining whether a recommendation could \textit{de facto} affect the legal position of third parties, the Courts have in the past especially looked at the measure’s wording.\textsuperscript{110} In the recommendation at hand, the Commission merely “invites” – as opposed to “requires” – its addressees to follow the proposed definition.\textsuperscript{111} The wording

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\textsuperscript{105} According to a search of documents of the parliamentary committees, see http://www.europarl.europa.eu/commission/en/documents-search.html.
\textsuperscript{106} Pursuant to Art. 288 TFEU.
\textsuperscript{107} Emphasis added.
\textsuperscript{108} This approach was pursued by the Court in \textit{Grimaldi}, see Case C-322/88 \textit{Salvatore Grimaldi v. Fonds des maladies professionnelles} [1989] ECR 04407.
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is hence far from imperative.\textsuperscript{112} It is therefore unlikely that the Court would not consider the nano definition, in the Court's words in \textit{Grimaldi}, a "true recommendation".\textsuperscript{113}

A remedy to the potential lack of legal accountability might be provided by the \textit{administrative} forum, in particular by the European Ombudsman. The Ombudsman can investigate into complaints of 'maladministration', which "occurs if an institution fails to act in accordance with the law, fails to respect the principles of good administration, or violates human rights".\textsuperscript{114} The Ombudsman could hence assume an important function in compensating for the lack of judicial review of non-binding acts, such as recommendations. At the same time, however, it is questionable whether there are many procedural rules that the Commission could have failed to comply with, most notably due to the vague scope of application of the impact assessment guidelines and, by inference, the Commission's minimum consultation standards.

Finally, the \textit{social} forum consists of civil society, which may not only participate in the decision-making process, but which may also scrutinise the regulator \textit{ex post}. A prerequisite for social accountability to take place is transparency,\textsuperscript{115} often understood as the accessibility and visibility of relevant information.\textsuperscript{116} Whilst the Commission is certainly subject to Regulation 1049/2001 on access to documents, it is doubtful whether there are any documents regarding the adoption process of the recommendation that should have been directly accessible in electronic form via the Commission's public register. This is because this requirement of 'direct accessibility' in Regulation 1049/2001 only applies to "documents drawn up or received in the course of procedures for the adoption of acts which are legally binding"\textsuperscript{117} – not to those which are non-binding. The public is therefore required to explicitly request potential documents, which arguably requires a profound knowledge of the EU's regulatory process.

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  \item \textsuperscript{113} In the seminal \textit{Grimaldi} case, the Court first established whether the recommendation it was confronted with – a Commission recommendation laying down a European schedule for occupational diseases – was a "true recommendation, that is to say a measure which, even as regards the persons to whom they are addressed, are not intended to produce binding effects", see Case C-322/B8 \textit{Salvatore Grimaldi v. Fonds des maladies professionnelles} [1989] ECR 04407, at para. 16.
  \item \textsuperscript{114} See \url{http://www.ombudsman.europa.eu/media/en/default.htm#hl1}. To establish what the Ombudsman captures under the notion of 'good administration', it has adopted the \textit{European Code of Good Administrative Behaviour} in 2001. This Code, so the Ombudsman, shall "help citizens to know what administrative standards they are entitled to expect from the EU institutions. It also serves as a useful guide for civil servants in their relations with the public. By making the principle of good administration more concrete, the Code helps to encourage the highest standards of administration", European Ombudsman (2013). \textit{The European Code of Good Administrative Behaviour}, at p. 4, available at: \url{http://www.ombudsman.europa.eu/resources/code.faces#/page/1}.
  \item \textsuperscript{115} This, however, does not imply that once the decision-making process is transparent, civil society scrutiny exists. Other factors, most obviously the existence of a European public sphere, need to be considered.
  \item \textsuperscript{116} D. Curtin, \textit{Executive Power of the European Union} (Oxford University Press, 2009), 205. Reflected is the transparency principle in Art. 11(2) TFEU, complemented by the right to access to documents in Art. 15(3) TFEU.
  \item \textsuperscript{117} Art. 12(1) and (2), Regulation 1049/2001.
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V     Conclusions

Next to dwarfs also soft law is on the rise in the EU’s regulation of nanotechnologies. This is exemplified by the adoption of the Commission’s recommendation for a definition of ‘nanomaterial’, which served as the object of this paper. And indeed, in an area characterised by severe scientific uncertainty, the Commission’s recommended definition was shown to entail sensitive political choices and must therefore be understood as a balancing act between the conflicting interests of the different stakeholders. Yet, is this problematic? After all, it is ‘only’ a non-binding soft law measure, which, as the Commission is not getting tired of repeating, does not contain any “direct obligations” for affected actors.

This, however, proved to be a farce. Via a two-dimensional translation process from the European to the national level and from soft to hard law, the recommended definition has long become a hard reality for affected actors. Whilst the European Parliament tried to halt this automatic “hardening” of the recommended definition at European level, in other cases the recommendation slipped almost verbatim into the legal texts. Even further, the European Parliament is unable to exert its policing function where the recommendation is used to formulate guidance documents, which, despite their formal non-bindingness, bear critical practical (even indirect legal) effects. The de facto significance of the recommended definition and its influence on affected actors is therefore difficult to overestimate.

This, in turn, has drawn this paper’s attention to the definition’s drafting process and the potentiality of scrutinising its content ex post. In other words, is the recommendation legitimate? Closer scrutiny of this question, however, yielded rather bleak results. Whilst affected actors where invited to participate in its drafting via two public consultations, both of these consultations were, firstly, conducted in the absence of procedural standards and, secondly, coined by significant imbalances in affected actors’ representation. Overall, the recommendation’s input legitimacy is therefore extremely fragile. Simultaneously, it seems difficult to hold the Commission to account for the adoption of the definition, be it through the political, the legal or the social forum, which is mostly due to the definition’s formal non-binding nature.

This paper hence identified, in the resolution of controversial issues, a move from the political fora to the realm of the EU executive. In other words, politics “migrated from the official arenas”. In one sense, this has certainly led to a depoliticisation of the nano controversy: divisive questions are no longer exposed to an open public debate. At a different level, however, it also politicises the decisions taken by the EU administration. Normative choices inherent in defining the term ‘nanomaterial’ are concealed behind scientific or technical terminology. Overall, this migration of political choices is not currently matched by adequate procedures ensuring the recommendation’s legitimacy. The Commission remains trapped in its illusory strive for effectiveness. This has become clear from the spectacle of participation in the

recommendation’s drafting, but also shows in the ineptness of existing *ex post* oversight mechanisms. What seems urgently needed is hence a critical scrutiny of the EU’s reliance on soft law instruments, especially in light of these measures’ *de facto* influence on the behaviour of affected actors, which would extend beyond the façade of their formal non-bindingness and eventually takes a careful look at their respective adoption processes.