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Regulating the invisible: Interaction between the EU and Norway in managing nano-risks

1. Introduction

Nanotechnology involves the manipulation of matter and chemicals on an atomic and molecular scale. Over the past 10 years, international attention has begun to focus increasingly on the need for governance of human health and environmental safety risks of nanotechnology (NT). In Norway, this was initially reflected in calls for more public funding for NT risk assessments and in the aim of mandatory regulation (Teknologirådet 2008; White Paper 2012). Recently, however, domestic regulatory attention to NT has lessened, and Norway has not adopted mandatory registration of nanomaterials, or other regulations limiting their production or use. This lack seems puzzling, as Norway has been at the forefront of regulation of seemingly related challenges like GMOs and hazardous substances (Rosendal 2007; Myhr and Rosendal 2009; Andresen et al. 2012). What can explain the state of nano-regulation in Norway?

The scientific uncertainties associated with new environmental challenges have put the relationship between science and politics at centre stage (Andresen et al. 2000). In this article, we explore two main explanations linked to knowledge and politics. The first possible reason for the lack of regulation may be that further research has revealed that there is no need to regulate the environmental and health safety risks of NT in Norway. In other words: that the process towards regulation has not accelerated, due to greater scientific agreement that there is less need for a specifically tailored management system for NT than initially assumed. This explanation presupposes a close relationship between (lack of) further regulations and better information indicating that the danger is over – 'all clear'.

An alternative explanation assumes a gap between management and the evolving state of knowledge: that available information (knowledge) indicates that regulations should have been introduced, but for various reasons this has not been done. Such a gap can be caused by political factors like interests, saliency and organisation. Organisational challenges can affect to what extent and how decision-makers act upon new knowledge. This explanation assumes that there may be a gap between management and knowledge production due to organisational barriers at the national and international levels. A decrease in public saliency is another possibility. Organised public demand for regulation of environmental and health challenges has proven important as an independent factor for

explaining regulatory action in related fields like GMOs and 'traditional' hazardous substances (Hviid Nielsen, Jelsøe and Öhman 2002; Rosendal 2005). Finally, opposition from commercial interests may have increased and stalled regulation as a result of lobbying.

The next section presents the analytical framework, and the focus for our analysis: the state of the regulatory regime for nanotechnology in Norway. In section three we deal with the explanatory factors, describing changes in knowledge, salience, organisation and interests. The empirical data underpinning the analysis come from multiple sources, including seven semi-structured interviews. Interviewees representing the different organisations are listed at the end (personal names on file with authors).

2. Framework for analysis

The focus for explanation is regulation of human health and environmental safety risks of nanotechnology (NT) in Norway. Regulation may vary in goals, scope, bindingness and specificity. Stringent regulation will typically be characterised by legally binding and specific rules that cover a wide range of the causes and consequences of the problem in question.

Since management of NT environmental and health consequences is a very young issue area, change in regulation is likely to be related to change in knowledge production. More specifically, a development towards stringent regulation is likely to be caused by increased knowledge about harmful effects that need regulation. Conversely, regulatory inaction is likely to be caused by increased knowledge on effects indicating that regulation is not needed. Our first explanatory variable is accordingly *the state of knowledge.* Here we hypothesise that the more conclusive and consensual the state of knowledge, the more likely is it to be used as decision-making premise; uncertainty and disagreement can be expected to pull in the opposite direction (Underdal 2000).

However, management and regulation of environmental and health challenges do not necessarily follow the production of information and knowledge. There is general agreement in the literature that *political conflicts of interest* make a difference for the influence of science: The more politically disputed the problem area is, the less likely is scientific evidence to be used as important decision-making premises (Miles et al. 2002; Underdal 2000). We will narrow in on the interests and preferences of non-state actors – those with commercial interests in NT that are/would be affected by regulation. A second knowledge-contextual variable identified is the *public saliency* of the problem. Underdal (2000) has discussed public saliency in relation to the nature of the problem: high saliency increases the demand for information, but the impact on adoption is seen as contingent on the nature of the problem. For problems involving low levels of conflict, public salience will tend to increase scientific influence, whereas in areas with high conflict levels it may serve to increase polarisation, thereby creating difficulties for rational scientific input.

How scientific influence is likely to affect regulation also depends on *organisation*. Organisational structure may constrain or facilitate the integration of science in regulation. Different types of organisational structure – hierarchic, specialised, or loosely structured – have been shown to affect the integration of science in regulation (Haas 1993; March and Olsen 1989; Clark et al. 1998). However, these categorisations pay scant attention to the *conditions* under which they affect regulation, and in what direction. We expect that challenges involving many sectors would need strong governmental coordination in their solution. Coordination will also make it easier for science to speak to the same 'address'. Essentially, 'fragmentation' refers to the distribution of competences among and between governmental agencies (Biermann 2009). The basic assumption is that different regulatory actors will tend to perceive problems differently and will apply differing decision-making criteria. In turn, perceptions and criteria are largely shaped by the formal roles of governmental agencies. This assumption is captured by the aphorism, 'where you stand depends on where you sit' (Allison 1971: 176). We propose that *fragmentation within the state apparatus itself or between various levels of government will tend to reduce the influence of science on management.*

The distribution of regulatory competence also involves organisations at the international level. The more international competence or expertise there is in a specific issue area, the more will domestic regulation depend on rules and regulations developed internationally, as well as on the relationship between science and policy in relevant forums. For Norway as a member of the European Economic Area (EEA) Agreement, the EU is particularly important.

3. Regulation of nanotechnology in Norway

3.1 Policy goals for NT regulation

In 2005, the Research Council of Norway (RCN) issued the report 'Nanotechnology and new materials: Health, environment, ethics and society'. Responding to the RCN's call, the Norwegian Board of Technology (NBT) recommended that Norway develop legislation to cope with the health and environmental risks of NT (Teknologirådet 2008). In their report, based on deliberations by an expert panel, the NBT recommended mandatory registration, greater producer responsibility, and that the government take responsibility for producing information concerning risk assessments of health and environmental effects.

In 2012, the official Norwegian Government's Research and Development Strategy for Nanotechnology (2012–2021) was released (White Paper 2012). Ten ministries were involved – which indicates the high priority given to the matter as well as the broad reach of NT across multiple sectors. As stated in the Strategy: 'Norway may be well suited to be a frontrunner for the responsible use of nanotechnology' (ibid.: 20). The Ministry of Trade was

the responsible body, which can also explain the (main) framing employed. The need for better knowledge about the health and environmental effects associated with the use of nanomaterial was strongly underlined,[1] and it was pointed out that the EU and the OECD have increasingly focused on these risks. It was further emphasised that more information was needed from industry to document their safe use of NT. The White Paper also stressed the necessity of involving the public at large. Finally, as most nano-products are made outside of Norway, the White Paper underlined the importance of standardisation and international cooperation.

3.2 Legal and institutional framework for NT

Norway has no specific regulations or mandatory registration of NT, nor has there been increased funding for independent research and risk analysis. This means that the 2008 recommendations of the Norwegian Board of Technology have not been acted upon. It also indicates that Norway is not a 'frontrunner' in the field, as called for in the 2012 government Strategy. In contrast, Belgium, Denmark and France have all introduced mandatory nano-registry.

In 2009, the Norwegian Pollution Control Authority introduced a voluntary scheme intended to provide a better overview of nanomaterials in chemical products. In 2012, the Norwegian Climate and Pollution Agency (NEA)[2] introduced a minor change in the mandatory reporting of quantities for toxic chemicals to the Norwegian Product Register.[3] The Product Register is the central register for labelling of dangerous chemical products in Norway; at the time, approximately 25,000 products were registered. The Product Register does not target nanomaterials as such: the change simply involved adding to the registry a 'nano-box', where registrants must indicate whether the toxic chemicals listed contain nanomaterials. The list shows a steep increase – from 20–30 nanoproducts registered between 2009 and 2011, to 300 nanoproducts registered in 2014.[4] The definition of 'nanomaterials' follows that of the recommendation of the EU Commission of 18 October 2011.[5]

[1] To promote responsible technological development, the Government will facilitate an increase in the proportion of publicly funded R&D efforts in this field accounted for by HSE and ELSA research to a level which is among the leading internationally. (HSE: health, safety and environment, and ELSA: ethical, legal and social aspects) (White Paper, 2012: p. 55).

[2] The Norwegian Pollution Control Authority was renamed the Norwegian Climate and Pollution Agency in 2010, and then changed its name to the Norwegian Environment Authority in 2013.

[3] This is in line with the EU Classification, Labelling and Packaging (CLP) Regulation.

[4] List provided by the NEA to the authors, 26 April 2016.

[5] In 2011, the EU adopted the following definition of nanomaterial (2011/696/EU): 'A …material containing particles …for 50% or more…is in the size range of 1 nm–100 nm'. In specific cases (health, environment, safety, competitiveness) the 50% criterion may be replaced by a threshold between 1 and 50%.

As regards the calls for better methods of risk assessment and for increased state funding of knowledge production concerning potential risks of NT, little has happened. From 2002 to 2012, the RNC provided approx. € 0.5 million in support for independent legal and social science research on the ethical, legal and environmental aspects (ELSA) of nanotechnology. RCN (2006:37) was explicit that the funding of autonomous ELSA projects is necessary for independent risk assessments in NT. During this period, the share of ELSA research was about one fifth of total state funding for NT. Since 2012, however, ELSA research has been replaced by 'Responsible research and innovation – RRI',[6] which receives only one fifteenth of total public funding for NT.[7] Moreover, RRI projects are initiated and designed predominantly by industry and commercial partners, who are then expected to invite ELSA researchers on board. [8]

Similarly, little has been done regarding societal dialogue to improve communication with stakeholders, based on the need to have informed consumers. The output so far, with a view to public information, is merely that the NBT provides a web-page with NT information.

NT management in Norway has not changed in terms of bindingness or specificity and only very little in terms of scope. Since the mandatory 'nano-box' was added in 2012, nothing has happened. Why has NT regulation never taken off in Norway? Is there consensual knowledge that this is no longer needed – or can we find alternative explanations in interest structures, salience or the organisation of NT management?

4. Explaining regulation of nanotechnology in Norway

4.1 State of knowledge: Uncertainties

The uncertainties of health and environmental risks of nanomaterials and technology are closely related to how properties of materials at the nanoscale can differ greatly from those on a larger scale. These properties make nanomaterials potentially useful in a wide range of new applications, but they also imply uncertainty: understanding the properties of a material at a larger scale is no guarantee for understanding its nanoscale properties.[9] The changing

[6] RRI aims to create space for reflection for those involved in R&D in new technologies; RRI literature has evolved within the EU (Schomberg 2012; Owen et al. 2013). However, limited attention has been given to vested economic interests or indeed any kind of power in the RRI literature, which is recognised as a dilemma for RRI (Owen et al. 2013:33).

[7] Out of a total of roughly€ 2.6 million, about one fifth (€0.5 mill) was applied to fund independent ELSA projects that focused on potential risks of NT. The subsequent NANOMAT/NANO2021 programme is much larger (approx. € 55 million) and is divided into support for industrial, commercial projects and participatory research grants (responsible research and innovation, RRI) for risk analysis and methodology. The RRI part has received one fifteenth of this total, with about €3.5 mill. for environmental testing.

[8] Confirmed in interview RCN, October 2016.

[9] Gold and silver alter their properties at the nano-level, with silver acquiring antibacterial traits and gold changing from one of the most inert to a highly reactive material. Aluminium turns explosive, carbon nanotubes are extremely strong, and silicon becomes a conductor rather than an insulator.

properties of materials may also cause changes in their toxicological properties, and these potential toxicological and long-term environmental properties are not yet well understood (CST 2007). A related challenge is how nanotechnologies provide 'enabling' or 'platform' technologies that might affect every industrial sector (Faulkner and Jaspers 2012). This inclusive and broad scope of NT constitutes a related regulatory challenge. Another complicating aspect is that there is no single, generally agreed definition of what nanotechnology is all about and what it encompasses. The simplest and broadest definition is that nanotechnology is research conducted at the nanoscale – a nanometer (nm) being one billionth of a metre (for reference, a human hair is roughly 20,000 nm in diameter).[10]

The specific nature of nanotechnology should be kept in mind, as adaptive innovation is hardly an option. Unlike the situation in ozone and climate-change issues, nanotech companies can hardly 'clean up' their old, polluting products through technological innovation: it is the new, innovative products themselves that represent potential environmental solutions as well as environmental problems. The state of knowledge must be understood along two dimensions. First, we need to present the state of knowledge associated with improving risk assessments on the effects of engineered nanomaterials. Second, it must be recognised that the state of scientific uncertainty is affected by the technological developments themselves, also when this knowledge does not come from independent non-commercial sources.

State of NT research in Norway

In the report from the Research Council of Norway on 'Nanotechnology and new materials: Health, environment, ethics and society' (RCN 2005) a central concern was the lack of scientific knowledge regarding NT. RCN further issued the 'National strategy for Nano-science and Nano-technology' (RCN 2006) with an emphasis on public consultations, communication and transparency. This was a phase of great expectations for growth relating to nanotechnology, but it was also influenced by the 'asbestos scare': the news that certain nanomaterials (carbon nanotubes) might involve health problems similar to those caused by asbestos. Another concern relates to nano-silver and its propensity to induce antibiotics resistance when released into the environment. Since then, the RCN has paved the way for research through several programmes on NT.[11]

The Norwegian Institute for Consumer Research embarked on a large nano-governance research project through RCN's NANOMAT programme. Their final report noted

[10] However, this definition would include much of traditional chemistry and physics, without capturing how the utility of nanotechnology lies in its transformation of properties of known elements. Nanotechnology spans a wide range of technologies and sciences, including medicine, material science, biotechnology, physics and chemistry and is applied in a great variety of sectors, all aiming to manufacture nanomaterials at the nanoscale.

[11] This includes ELSA (2002-2006, since 2008 linked to NANOMAT) and NANOMAT (2002-2011) / NANO2021 (2012-2021). http://www.forskningsradet.no/prognett-nano2021/Prosjektarkiv/1253969916290 http://www.forskningsradet.no/prognett-elsa/Programme_description/1224698247089 (Accessed 9 April 2016.)

that the respondents revealed significant trust in NT, but that this came along with scant knowledge about the actual existence of nano-products on the market (Throne-Holst and Stø 2007). These findings were re-confirmed two years later in a study (Strandbakken et al., 2009) that also emphasised the strong commercial interests behind the drive for promoting NT. Further, Strandbakken et al. noted the severe lack of awareness of potential health and environmental effects of NT, and questioned whether the *consumer's right to know* was upheld in the current management system for NT. Thus, already in this early period some researchers underlined the potentially negative consequences of NT.

Research challenges and findings

Today, more is known about the nano-field, which appears as more complex, but also more nuanced. Distinguishing between nanotechnology (the ability to examine particles at the nanolevel) and nanoparticles as such has directed attention to the latter as the main target of possible regulation, rather than the technology – NT – as a whole. Another distinction can be drawn between man-made (engineered) and natural nanoparticles, again providing insights important for the definition and scope needed for tailoring management systems. [12]

While uncertainties remain as to the unintended effects of nanoparticles, some concerns have found confirmation and some others have been laid to rest. Similarly, not all health-related threats have been confirmed. For example, nano-sun cream has proved to be less of a health threat than many of the older sun-protection products. We should also note the rapid expansion of environmentally friendly products, like solar energy panels ten times more efficient than traditional ones. These do not in themselves contain nanoparticles but have simply been treated with NT and are hence held to pose no danger to health or to the environment.[13] Some of the worrisome features, however, have been substantiated. Test results indicate that silver nanoparticles are toxic to cells (Asare et al. 2016). Uncertainty remains regarding the carbon nanotubes that were feared to have asbestos-like traits; industry seems aware of consumer worries here and might be phasing out the more serious types, but there is also evidence that carbon nanotubes are still being produced.[14]

While some of the uncertainties have been put to rest, disagreement persists regarding establishing risk-assessment methodologies and the associated need for independent research. A key element of regulatory responses to NT is that of independent risk analysis (Miller and Wickson 2015).[15] This remains a central issue, with reiterated calls for better methods for risk evaluation. There are still several barriers to conducting adequate risk analysis in this field, due to the problematic definitions (triggering an analysis), with the

[12] Interviews, Norwegian Institute of Bioeconomy Research (NIBIO), November 2015 and RCN, October 2016.
[13] These examples and the conclusion were given in separate interviews, first on 10 November 2015 with two senior advisors in the Norwegian Environment Agency, then on 19 November 2015, with a senior researcher at Norwegian Institute of Bioeconomy Research (NIBIO).
[14] Interview, NEA, November 2016.
[15] Interviewees in GenØk, NBT, NIPH and NICR also stressed this.

resultant unsuitability of standardised tests, scientific uncertainty and lack of agreed methods for testing (Miller and Wickson 2015; Faulkner and Jaspers 2012). There is persistent concern that reliable risk assessment of nanomaterials lacks shared definitions, accessible methods for safety testing and reliable information about commercial use (Miller and Wickson 2015).

Moreover, while there is overall and increased funding for research aimed at risk management, such funding is minute in relation to the rapidly increasing investments in commercial R&D. Current research on independent (state-funded) risk analysis is criticised for being inefficient and inadequate (Miller and Wickson 2015). It is especially the lack of independent research that is the subject of criticism. Researchers involved in commercial R&D tend to be the same individuals who conduct risk analyses and who provide policy advice.[16] Technological breakthroughs that can lead to commercially viable products are likely to involve far greater economic returns and value compared to continued state/public support for research that uncovers risks. But is it possible to keep these two 'hats' separate?

The Research Council of Norway represents the central arena for the science–policy interface. As we have seen, state-funded risk-related research has evolved from being independent to becoming primarily participatory in nature.[17] As this is part of the new political paradigm associated with RRI, it is difficult to determine whether the change represents failure on the part of the Norwegian government to support independent risk assessment.[18] This could be seen as a shortcoming in terms of the policy objective of greater funding for independent risk assessments of NT. On the other hand, it may illustrate the general problems involved in identifying agreed methods for NT risk assessment.

Some of the new research points in a less alarmist direction. That may to some extent help to explain why there has been no further tightening of regulations.

Whereas Norway is a small player in terms of domestic research, it is also involved in various international organisations that promote research on NT questions. Many of these, including UNEP and WHO, are entities under the UN, where Norway is known for playing an important role (Rosendal 2007; Sandberg et al. 2010). However, the most important body in this context is the OECD, where work on NT proceeds through two main groups, the *Working Party on Nanotechnology* (WPN) and the *Working Party on Manufactured Nanomaterials* (WPMN). The WPN was established in 2007 to provide advice on emerging issues in science, technology and innovation related to responsible use of NT. The WPMN has worked on safety concerns regarding manufactured nanomaterials, seeking to ensure that the approaches used for hazardous exposure to these are of good quality, science-based and harmonised internationally. This work is coordinate by the OECD Secretariat, in which

[16] Interviews, GenØk, October 2016 and NIBIO, November 2015.
[17] Interview, GenØk, October 2016.
[18] Interview RCN, October 2016.

member and observer states, international organisations and stakeholders are represented. Most importantly, the OECD is involved in developing test methods for risk assessment of nanomaterials. The results of this work are fed into the EU REACH processes as important inputs to NT management. As the NEA meets regularly in this forum, this means the OECD affects Norway in its own right as well as through the EU. [19]

There are still uncertainties related to negative health and environmental risk associated with the use of NT internationally. As we interpret the results from this research, there have been no *main* changes regarding the initial uncertainties.[20] Moreover, despite significant international efforts, no coordinated regulatory approach has been achieved – largely because the two key actors, the USA and the EU, apply very different approaches. This may be a weakness for the system internationally but has less significance to Norway due to its strong ties to the EU.

4.2 Public salience of nanotechnology

We apply two indicators for measuring public saliency: media attention and NGO activity. Media attention provides a snapshot and may give an indication of the general state of public concern about NT. Counting and comparing articles about NT during two phases (2005–2009 compared to 2010–2014) in two major quality newspapers, the *Financial Times* (UK) and *Aftenposten* (Norway), we find a significant decline – in the number of articles concerning the technology in general and articles with a specific focus on NT and health, or NT and environmental issues.[21] For general articles about NT, the number plummets from 441 to 150 in the *Financial Times,* with a much less steep decline, from 126 to 95, in *Aftenposten*. Note that our review does not say anything about the direction (critical or optimistic) of the articles themselves.[22]

Norwegian NGOs have not paid much attention to NT health and environmental risks.[23] This can probably be ascribed to the need to focus on the most pressing issues, in addition to perceived low saliency. Internationally, the situation is somewhat different, as environmental NGOs as well as various consumer groups have been active in this field for more than a decade. For example, Friends of the Earth (FoE) and Greenpeace in Europe called for a moratorium on NM products commercialisation in 2009 until they could be

[19] Interview, NEA, November 2016.

[20] This view was confirmed in interviews, GenØk, October 2016, and Norwegian Institute of Public Health, October 2016.

[21] Data on file with authors.

[22] As pointed out by Strandbakken et al. (2009; referred to in Rosness, 2010:45), attention to NT in Norway has included how NT may be applied to combat environmental problems (reduced and cleaner emissions). This could go some way towards explaining why Norwegian NGOs have not been very critical to NT.

[23] Interview, NEA, November 2016.

proven safe.[24] They also lobbied actively against the Second Regulatory Review of NM in the EU but were not successful in inserting a 'nano-patch' in REACH in 2012. They have been included in the EU decision-making process but have had little influence. The same is said to apply for NGO activities in the USA regarding the Environmental Defense Fund and other initiatives (Justo-Hanani and Daylan 2016).

In summary, public saliency has been low and decreasing in Norway. This means that low saliency can – independent of political conflict – contribute to explain why little is happening, particularly as regards mandatory and effective registration. However, we may still ask: why is salience so low in Norway compared to elsewhere in Europe and the OECD?

4.3 Domestic organisation of the management system

The Norwegian management system for NT is highly fragmented. There are five ministries involved (agriculture & food, trade & industry, health, climate & environment, and labour), relying on six directorates, two dealing with food safety, one public health, two occupational health and one the environment. The Norwegian Environment Agency (NEA) is responsible for executing the government's general environmental policies and is the focal point for REACH. The Ministry of Climate and Environment is responsible for enforcing REACH. The Ministry of Agriculture & Food and the Ministries for Trade & Industry and for Fisheries & Coastal Affairs are responsible for regulation of chemicals, including NT, in food and fish. The NEA is the REACH authority in the occupational setting, but the Labour Inspectorate under the Ministry of Labour has a special role in monitoring compliance with these regulations within the occupational setting. For food, the Scientific Committee for Food Safety (VKM) under the Ministry of Health and Care Services is a key agency. It conducts independent risk assessments of food contaminants for the Norwegian Food Safety Authority, and one VKM panel focuses on NT. The Norwegian Institute of Occupational Health (STAMI), under the same Ministry, conducts research in NT at workplaces. It has an important advisory task in updating regulators on scientific progress in the field. The Norwegian Institute of Public Health (NIPH) also conducts health and safety research on NT and advises the authorities and the public. In short, the organisational picture is quite complex and fragmented.

There has been some collaboration and coordination among these authorities. For instance, in 2009/2010 the NEA collaborated with STAMI in a project group led by the Labour Inspection Authority aimed at mapping NT industries and materials. However, little is known about the exact state of businesses and employees exposed to nanomaterials, and there are no regulations aimed specifically at NT activities (Arbeidstilsynet 2014). In 2009 a working group (the Nano Group) was established, led by STAMI, and engaging the Labour

[24] https://www.euractiv.com/section/innovation-industry/news/industry-ngos-at-odds-over-nanotech-regulation/ Accessed 27 November 2016.

Inspection Authority and the Product Registry (Produktregisteret) in monitoring work-related aspects of NT (Arbeidstilsynet 2014).

Nevertheless, a study by Aune (2015) found indications of an increase in the potentially exposed workforce, coupled with severe lack of knowledge or use of national guidance documents on the safe handling of nanomaterials.[25] Importantly, these shortcomings were particularly evident within the sectors handling carbon nanotubes (associated with asbestos scare) (Aune 2015).[26]

Hence, notwithstanding the collaboration among governing bodies, Aune's findings could indicate that institutional fragmentation represents a problem for managing engineered nanomaterials. Fragmented administration may affect management. There seems to be scientific consensus in Norway on the need to ban nano-silver band-aids in pharmacies. One reason why Norway has not adopted such a ban could be that this falls primarily under the competence of the Norwegian Medicines Agency (Legemiddelverket) or the Directorate of Health (Helsedirektoratet), not the environmental authorities.[27] In Sweden, sales of nano-silver band-aids in pharmacies were in practice halted already in 2005.[28] A cautious conclusion is that administrative fragmentation has not made it easier to regulate NT strictly in Norway.

4.4 Political conflicts and commercial interests

Few Norwegian enterprises and universities/research institutions are involved in nanomaterial/technology activities, and the amount of nanomaterials produced is apparently small. A 2010 survey on safety risks among workers found that 18 R&D facilities and three enterprises were active in the production, manufacturing, use, import and processing of nanomaterials (Arbeidstilsynet 2010:15). A 2015 survey indicates that the number of R&D facilities has dropped (to 8) whereas the number of industrial enterprises has increased to 16 (Aune 2015).[29]

[25] The study found a lack of use of adequate personal protective equipment (PPE) and lack of adequate safety data sheets with information on nanomaterials (Aune 2015).

[26] The nanomaterials most frequently employed in Norwegian businesses are carbon black, carbon nanotubes, -fibres and-threads, polymers, titan dioxide and gold (Aune 2015: 55 and 75). 70% of the 102 businesses that handled carbon nanotubes were found to be only marginally aware of potential health effects, with less than a quarter of the workforce using personal protective equipment when handling these materials (ibid.: 100).

[27] Interview, NEA, November 2016.

[28] http://www.forskningsradet.no/prognett-nanomat/Nyheter/Forbrukerrettigheter_knyttet_til_nanoprodukter/1253953602454&lang=no (accessed 11 November 2016). Confirmed in interview with senior researcher Norwegian Institute for Consumer Research, 22nd November 2016. See also: http://hcwh-newsletter.ecn.cz/article.shtml?x=2084060 Accessed 27th November 2016.

[29] The reason may be linked to the new EU definition of nanomaterials in 2011.

Internationally, industry interests mirror the traditional division between commercial interests and health/environmental protection. According to the International Association of Nanotechnology: 'Since many of our member companies are producing carbon nanotubes and other nanomaterials, the executives from the companies believe that any kind of government regulation frameworks could hinder their research and commercialisation, thus increasing the costs of business'.[30] The position of Norwegian industry differs, as it is more positive to regulation. However, regulation will have to be at the EU or international level, to ensure a level playing field. More than 70% of the enterprise that responded to the 2015 survey considered nanomaterials as a competitive advantage (Aune 2015).

The use and production of nanotechnology and nanomaterials is dispersed among a wide range of sectors and substances, including advanced materials in products (textiles, car polish, sportswear, cosmetics, etc.), renewable energy and environmental technology (solar, bio), food, health/biotechnology and electronics. NT production and use are characterised by few actors, fragmented markets and few effective production methods (White Paper 2012). This makes it difficult to coordinate efforts among companies toward other organisations and the authorities. The branch organisation of the Norwegian employers' association, *Industry Norway,* organises the major companies involved in chemical-related activities. These companies coordinate their positions in a specific working group on chemicals.

The health, environment and safety risks of nanomaterials have low priority in Industry Norway. On chemicals (including nano), Industry Norway has regular meetings with the Norwegian authorities in preparations for EU meetings. It also participates in the Nordic/Baltic Forum and in working groups under the European Chemical Industry Council (CEFIC) – the voice of chemical industries in Europe. Like the government, industry focuses on the EU and not national regulation.[31] EU regulatory processes are 'crucial for regulations in Norway' (White Paper 2012:49). Accordingly, the strategy for the government *and* industry is to work through the EU and other international forums. Industry Norway supports CEFIC's main position: there is no need for national registry systems in addition to those mandated by the EU.[32]

We see that the scale of Norwegian industrial and R&D interests in nanomaterials/nanotechnology is small. These interests are weakly organised, reflecting the dispersed and fragmented markets, sectors and substances. The major companies express their interests through the branch organisation Industry Norway, which participates in CEFIC. As noted, Industry Norway and CEFIC have taken a clear stance against the need for a national regulatory or mandatory registration system in addition to EU legislation. This

[30] http://www.ianano.org/Site/About/Lloyd%20Tran-Interview-Research%20Media.pdf
[31] Interview, NEA, November 2016.
[32] http://www.cefic.org/nanomaterials.

contributes significantly in explaining the lack of interest in mandatory registration and regulation in Norway.

4.5 Regional and global organisation

The EU and Norway

The scientific and regulatory aspects of NT in Norway are closely related to the EU. In Europe, direct employment in the nanomaterial sector is between 300 000 and 400 000. Products based on nanotechnology are expected to grow from a global volume of EUR 200 billion in 2009 to EUR 2 trillion by 2015 (European Commission 2015). Obviously, regulation of health and environmental risks at EU level has major commercial implications compared to the situation in Norway.

In 2011, the EU defined nanomaterials according to size in a formal recommendation. The definition concerns size only – not properties or products. The official reason is that the definition should be applicable across different types of sector regulation. Nobody was happy with the definition. Green groups argued that it was too narrow; CEFIC found it too broad. Various other EU scientific and advisory committees and independent risk assessors have also provided a range of recommendations on regulation.

Concerning scientific consensus, the correspondence with Norway appears to be low. Nano-science is significantly more controversial in the EU than in Norway. It is quite illustrative that the European Commission's second regulatory review (2012) of REACH was dismissed by the European Parliament (White Paper 2012). However, as in Norway, there seems to be a common and increasing understanding that nanomaterials are not uniformly dangerous but are similar to normal chemicals – some may be toxic, others not. As a party to the EU working groups on developing methods for testing and for evaluating the health and environmental risks of exposure to nanomaterials, Norway is well aware of the scientific processes underway in the EU (White Paper 2010).

Scientific disagreement and increasing knowledge that some nanomaterials are toxic triggered a response from the Norwegian government. In a 2012 letter to the European Parliament and the Council of the European Union, the Norwegian Ministry of the Environment, like many other European countries, called for urgent action on improved nano-regulation.[33] The Ministry stressed that legislation must ensure chemical safety assessment for all nanomaterials, have a mandatory registration of nanoform substances, and establish registration deadlines (Ponce Del Castillo 2013).

[33] Letter from the Norwegian Ministry of the Environment to the European Commission, European Parliament, Council of European Union, 23 April 2012: Effective regulation of nanomaterials – comments by Norway. Norway Ministry of Environment (2012) Effective regulation of nanomaterials- comment from Norway. Ministry of Environment. http://www.eu-norge.org/PageFiles/ 606326/Innspill_nanomaterialer_23april2012.pdf [Accessed: 17 June 2013]

Why, then, did not Norway respond unilaterally? The main reason is that Norwegian nano-regulation has been 'outsourced' to Brussels. The EU regulatory process since the 2011 definition has been considerably more politicised than in Norway and marked by significant delays. It has followed three tracks: 1) the suitability of the existing REACH framework for coping with the environmental effects of nanomaterials: a process directly relevant to Norway, which participates in REACH; 2) the need for a separate EU-wide nano-register; this is indirectly relevant to Norway, which has already established a voluntary register; 3) nanomaterial rules in other sector regulations; noteworthy here is the 2008 EU regulation on classification, labelling and packaging, which applies also to Norway.

REACH regulates nanomaterials (manufacture, market placing, use, products) because it is covered by the definition of a 'chemical substance'. There is no provision referring specifically to nanomaterials. The general obligation is that substances manufactured in volumes of one tonne or more are to be registered and informed in the supply chain. Due to their small scale (1 to 100 nm), nanomaterials are rarely produced in volumes of more than one tonne. The European Chemical Agency (ECHA) plays a key role in evaluation and dissemination of substances, including nanomaterials. The Agency has added 65 chemicals to the list of substances to be assessed for environment and human health risks in 2015–17. Nano-form zinc oxide and multi-wall carbon nanotubes are included here.

The Commission has envisaged modifications in REACH Annexes to make them more suitable for nanomaterials. In 2014, the Commission announced planned changes to REACH annexes for nanomaterials that would not involve changes to tonnage thresholds but would include a testing framework better tailored to nanomaterials. The proposal will define the 'nano' form of a substance as a distinct entity. This work has been delayed, but a Commission proposal was expected in the course of 2017.[34] Unlike Norway, the EU is marked by traditional commercial interests vs. regulation conflict, expressed in differing positions between the Commission's DG Environment and DG Growth. [35]

Several EU member states are getting impatient, including Germany and the Netherlands. The need for an EU-wide registry (in addition to REACH) was the subject of public consultation in 2014. Responses from various state authorities indicate support for a register, but disagreement on the scope (how much information to require). All responses from the state authorities acknowledged that REACH was insufficient and that a register could help to assess and control health and environmental effects. Green groups, such as the NGO European Environmental Bureau (EEB), argued in favour of a registry, pointing out that REACH does not include substances made or imported in quantities below one tonne a year, such as carbon nanotubes.

[34] Interview, NEA, November 2016.
[35] Interview, NEA, November 2016.

In conclusion, delayed regulatory response from the EU as a result of political conflicts has clearly affected the regulatory management system in Norway. The conflict level in the EU is high, whereas both salience and conflict level are near zero in Norway. Norwegian politics and management have largely been outsourced to the EU.

5. Conclusions

We set out to explain the state of nano-regulation in Norway. According to the Government's R&D strategy, 'Norway is well suited to be a front-runner for the responsible use of NT'. Irrespective of how to define a 'frontrunner', we cannot conclude that this has been the case. An 'EU follower' seems a more apt characteristic. Ever since the issue was put on the agenda more than ten years ago, Norway has not, in contrast to some other European states, adopted any mandatory regulation or registration of nanomaterials in substances or products. Moreover, public funding for research on nano-risks has declined in relative terms in Norway. The idea of the 'informed citizen' hardly seems to be a political priority with the Norwegian government regarding NT.

One explanation we offered was that this state of affairs might be due to new and more consensual knowledge pointing in a 'less-alarmist direction' than previously assumed, thus indicating less need for strict regulations. That might be part of the explanation for the lack of regulations, but not for abandoning aspirations of a 'frontrunner' role, given the reduced funding for independent research and few efforts in engaging the public. A precautionary approach would – as a minimum – lead Norway to match its ambitions with the most proactive European states.

The second expectation was that there could be a gap between management and evolving science. This could also be said to illustrate the state of nano-risk management in Norway. Regulation in Norway has lagged behind, despite the growing recognition that some nanomaterials need to be regulated. We explored three reasons. First, we examined public saliency, and found declining attention on the part of the media, coupled with very low awareness among environmental NGOs. Since the issue area is characterised by low political conflict with commercial interests, high saliency (as with the GMO issue) could have increased the demand for information and boosted the influence of science. This factor can therefore shed light on the lack of regulations. Second, we expected that fragmented administration would reduce the influence of science. In general, the management of nano risks involves a wide range of governmental ministries/agencies and economic sectors. The rather puzzling failure to ban nano-silver band-aids (involving health, medicine and environmental authorities) despite seemingly unanimous scientific advice suggest that administrative fragmentation may have had some role in hampering sound management of NT in Norway. More research would, however, be needed to examine the effects of administrative fragmentation in this case and possibly other similar NT cases. Third, we

examined commercial positions to regulation and found that industrial and R&D interests oppose unilateral management. This can hence also help to explain the lag. However, in addition, lack of independent domestic knowledge blurs the relationship between science *and* policy. In combination, these three factors interact in creating an a-political and passive strategy concerning management of nano-risk in Norway.

However, the main explanation for Norwegian inaction is to be found at the EU level, as Norway has largely outsourced management to the EU institutions and EU legislation. Norway awaits the results from the EU NT regulatory process. Unlike in Norway, EU nano-regulation has become heavily politicised between traditional commercial and regulatory interests, a conflict that has acted to obstruct the emergence of new EU regulation appropriately tailored for dealing with nano-risks.

Overall, all science/policy factors examined in this paper pull in the same direction for explaining lack of mandatory nano regulation in Norway: 'less-alarmist' international knowledge, lack of independent domestic knowledge, low public saliency, fragmented administration, commercial opposition and regulatory EU competence that has been stalled by conflict of interests.

Further empirical research on NT management is needed as this policy area has so far been subject to very little scholarly attention. Research could examine why and how management of NT varies among European states. Analytically, this paper indicates a mismatch between multi-level governance of NT and knowledge production – a topic that deserves more attention in the science/policy literature.

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Interviewees:

Two senior advisors, Norwegian Environmental Agency (NEA), November 2016

Senior researcher, GenØk – Centre for Biosafety, October 2016

Senior researcher, Norwegian Institute of Bioeconomy Research (NIBIO), November 2015

Senior advisor, Research Council of Norway (RCN), October 2016

Senior researcher, Norwegian Institute of Public Health (NIPH), October 2016

Senior researcher, Norwegian Institute for Consumer Research (NICR), November 2016

Senior advisor, Norwegian Board of Technology (NBT), June 2015.