Multi-level Governance: The Regulation of Manufactured Nanomaterials in the Netherlands.[1]

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Introduction

Around the world, governments and stakeholders working in nanosciences and nanotechnologies are engaged in deliberations regarding the proper regulatory response to manufactured nanomaterials[2]. Despite great promise, much uncertainty remains about the long-term consequences of the manufacturing and use of nanomaterials. Such uncertainty causes a regulatory challenge for all actors involved, it being governments, international organizations, industry, labor unions, environmental advocacy groups, etc.: How to advance science and not impede innovation, yet protection the environment, public health, and the people who work with these materials? It leads to questions about which factors shape the regulatory response to emerging nanomaterials, such as which level of governance is most suitable to advance any regulatory action, how does international cooperation support an emerging regulatory regime, which role play non-government actors, and is cross border policy harmonization desirable or could policy divergence be acceptable?

This article reflects on multi-level governance as a useful theoretical concept to understand the emergence of a regulatory regime for the manufacturing and use of nanomaterials. It uses the

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[2] Manufactured nanomaterials, or engineered nanoparticles are deliberately manipulated particles on the nanoscale (1 – 100nm) (SCENHIR, 2010)

case of the Netherlands, a pioneer in nanotechnology[3] research and commercial development, as an example. The Netherlands has a large chemicals and electronics industry that is involved in nanotechnology R&D. Dutch academic standing in nanoscale research is among the world's most cited and patented. The Dutch government has chosen an integrated approach for its support of nanotechnology R&D, which underlines nanotechnology's opportunities, yet acknowledges the need to address its risks and remaining uncertainties (Ministry of Economic Affairs, 2008).

The Dutch government strongly encourages international collaboration, joint international research efforts, and the exchange of information to address risks and remaining uncertainty associated with manufactured nanomaterials (Ministry of Economic Affairs, 2008). The Netherlands has taken a leading position in the international development of nanotechnology governance. Dutch leadership here means simultaneously drawing on and influencing governance of manufactured nanomaterials at the European and other international levels, most prominently the Organization for Economic Cooperation and Development. As such, the Dutch approach offers a telling example of why and how multi-level governance shapes the regulatory regime for the manufacturing and use of nanomaterials.

Multi-level governance takes into account efforts by multiple government and non-government actors at various levels, it being inter- or supranational regimes, national levels of governance,

[3] For practical reasons, this article uses the name 'nanotechnology' to identify the broad field of nanosciences and nanotechnologies, which includes both engineering at the nanoscale and the production and use of engineered nanomaterials or particles, such as suggested by the International Organization for Standardization (ISO): "Nanotechnology is the understanding and control of matter and processes at the nanoscale, typically, but not exclusively, below 100 nanometers in one or more dimensions where the onset of size-dependent phenomena usually enables novel applications" (International Organisation for Standardisation, 2011).

or subnational levels, for instance regulatory action undertaken by local governments or by non-government actors such as industry associations or labor unions. (Hooghe & Marks, 2001) (Hooghe & Marks, 2003). While multi-level governance acknowledges that existing institutional arrangements are strong and national governments remain powerful actors in molding any regulatory regime (Vogel S. K., 1996) (Pierson, 1996), the theoretical concept looks at the interplay of various levels of governance and how the interaction and shifts of responsibilities between levels of governance help to shape the overall regulatory regime (Börzel & Risse, 2010). Multi-level governance sees interdependence and cooperation between actors at different levels rather than one dominant actor, it being a state or an overarching international organization. Compared to other theoretical approaches such as state-driven policy making or liberalization and globalization, multi-level governance allows for a greater ability to respond to new regulatory challenges such as the emerging manufacturing and use of nanomaterials. Going back to [**Rodine Hardy's article (2013) elsewhere in this journal**], the hypothesis of this study assumes that the development of regulations to address the risks and rewards of the manufacturing and use of nanomaterials reflects various influential actors operating at different levels: it sees high-level harmonization of policies, yet divergence in policy implementation, thus avoiding the dominance of a single actor's interests.

This article situates the evolving Dutch regulatory approach to manufactured nanomaterials as part of a larger governance model for nanotechnology and as part of a broader regulatory approach of chemical substances in an increasingly international setting. It describes the developments in this policy-formulating process since the late 1990s, reflecting on the links and

interdependence between the emerging regulatory model on the national level and governance initiatives on inter and –transnational levels. It presents a couple of interlinked examples - the Dutch implementation of EU's Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) protocol, Dutch participation in the OECD's Working Party on Nanotechnology (WPN), and the recently established European NANoREG project - to illustrate whether and why the Dutch governance approach of manufactured nanomaterials can be an example of multi-level governance in the regulatory approach of emerging fields of science and technology.

Developing a Regulatory Approach of Manufactured Nanomaterials in the Netherlands

An Early Uptake of Nanotechnology

The development of nanotechnology in the Netherlands is marked by early initiation of interdisciplinary scientific research at different universities and research institutes and by early uptake of nanoscale research by Dutch industry, in particular by sizeable international corporations based in the Netherlands, such as Philips, ASML, DSM, and Akzo-Nobel (FOM, STW & NanoNed, 2008). In 2006, Dutch economic activity in nanotechnology ranked third in the world relative to the size of its economy. However, in absolute measures the Dutch position is better characterized as leading the group of countries that aspire to become global leaders in nanotechnology (Ministry of Economic Affairs, 2008) (Lux Capital, 2003) (Ministry of Economic Affairs, Agriculture, and Innovation, 2011). In the early 2000s the Netherlands ranked fourth in the European Union when measured in the number of research publications on nanotechnology (Miyazaki & Islam, 2007). Later in the decade the Netherlands placed in the

global top three together with the United States and Switzerland for nanotechnology R&D with highest scientific impact based on the number of citations. This position was partly based on international collaboration in research including Dutch scientists (Nederlands Observatorium van Wetenschap en Technologie, 2010) (ObservatoryNANO, 2011).

Overall Dutch nanotechnology research in the earlier 2000s relied heavily on public funding, with up to 70% of nanotechnology research being funded publicly before 2004 (Miyazaki & Islam, 2007). Like in other countries, more recently this balance has shifted and private enterprise now accounts for more than 50% of all Dutch nanotechnology R&D spending (FES Initiative 2009 HTSM, Oct. 2009).

The two Streams of Nanotechnology Research: Applications and Risks

Government promotion of nanotechnology development in the Netherlands has evolved since the 1990s along two streams – the first focused on research for economic growth, the second on addressing concerns about broader environmental, health, and societal impacts. These streams over time converge.

The first stream, taken up in the 1990s by universities, research institutes, and leading industry, is focused around nanotechnology as an enabling technology that creates ample opportunities of innovative solutions for pressing societal matters, such as energy supply and environmental pollution, while offering a great potential of economic returns. In the Netherlands this stream of nanotechnology research emerged bottom-up: scientists in universities and research

institutes as well as researchers linked to industry started to do studies of the possibilities of nanotechnology, seeking, where needed, possible and desirable, additional funding for their research through existing research funding organizations and channels overseen by the Ministry of Education, Culture, and Science and the Ministry of Economic Affairs (Gielgens, 2012). Such basic research in nanotechnology obviously is the basis for application and commercialization of nanoscale research. In 2002, a newly formed Cabinet with a strong focus on innovation and economic growth partially funded the 45 million euro research budget of NanoImpuls, the first of a range of subsequent Dutch public – private partnerships for nanotechnology R&D that include industry, research institutes, and universities (FOM, STW & NanoNed, 2008).

The other stream involves research into the risks and uncertainties that are associated with nanotechnology and, in particular, with manufactured nanomaterials. In the Netherlands risk-related research has evolved in a more top-down manner: after advances in nanotechnology gained more recognition and the possibilities of nanotechnology seemed frontier-less in the early 2000s, from 2005 onwards government advisory councils for science and public health have begun to steer towards increased government involvement in the responsible development of nanotechnology. Their aim was to make sure that risks of nanotechnology and the remaining knowledge gaps were properly addressed as a condition for the responsible development of nanotechnology and the use of nanomaterials. Government coordination of such risk related research lies with the Ministry of Infrastructure and the Environment.

A better understanding of risks and the need to reduce uncertainty overall is seen as in the common interest of all stakeholders. It is here where the two streams of nanotechnology research come together: a condition for successful technological innovation and economic development in nanotechnology means to address the risks and remaining uncertainties associated with nanotechnology R&D. Different quotes reflect the prevalent opinion of subsequent Dutch Cabinets on this matter:

"It is only by dealing carefully with the risks that the Netherlands will be able to exploit its opportunities to the full" (Ministry of Economic Affairs, 2008, p. 2).

"The Cabinet holds the opinion that these developments should be in balance with risk control and therefore aspires an integral approach of nanotechnology, as to make use of the opportunities in a sensible manner" (Ministry of Economic Affairs, Agriculture, and Innovation, 2011, p. 2).

International engagement

The Dutch government, Dutch industry, and the Dutch scientific community, all strongly connected to a European and broader international environment, acknowledged early on that addressing the risks and remaining uncertainties of nanotechnology within national boundaries would be ineffective and inefficient, as production, use, and commercialization of manufactured nanomaterials takes place in a wider European and international setting (Ministry of Infrastructure and the Environment, 2012). Therefore the Dutch government, arguing that an international harmonized set of agreements would be beneficial to all, urged stakeholders to address these issues through a strong focus on international collaboration within the European Union, the Organization for Economic Cooperation and Development (OECD), and the International Organization for Standardization (ISO). The Dutch Cabinet has

stated a strong preference that any Dutch regulation on the risks associated with nanotechnology to be embedded in European regulation: the Cabinet's 2008 Nanotechnology Action Plan says about dealing with the risks associated with nanotechnology that "the short term aim of the Cabinet is the embedding of European legislation" (Ministry of Economic Affairs, 2008, p. 4).

The Netherlands, a relatively small country with a strong tradition of international trade and international engagement, relies on international collaboration to maintain and grow its position. To the Dutch, such international collaboration can yield faster and better results than a relatively small country like the Netherlands can achieve on its own. Such emphasis on international collaboration has a clear neo-functional aspect: international collaboration in this field is ultimately in the national interest. The Cabinet's 2008 Nanotechnology Action Plan states that "it is only by dealing carefully with the risks that the Netherlands will be able to exploit [nanotechnology's] opportunities to the full" says (Ministry of Economic Affairs, 2008, p. 3). In this regard, Dutch and European policies on nanotechnology research are converging around a strong focus on international cooperative research of risks, an emphasis of the innovative potential of nanotechnology and the possibilities for economic and societal returns, and an increasing notion that diminishing risks and addressing any public concerns is conditional for the success of nanotechnology.

Dutch Public – Private Partnerships in Nanotechnology R&D

Since 2002, a succession of public – private consortia, including industry, research institutes, and universities – yet notably without direct government involvement -, advanced nanotechnology research in the Netherlands. NanoImpuls - labeled a 'National Nanotechnology Program' - was the first in a range of initiatives in this field, followed by NanoNed (2004) and the current installment NanoNextNL (FOM, STW & NanoNed, 2008) (Gielgens, 2012) (NanoNextNL, 2013). These nanotechnology research consortia have received public funding outside of the annual appropriations for public investments in research and development from what has become known since 2005 as the Economic Reinforcement Fund, which allocates public income from natural gas sales for infrastructure projects. The fund includes a specific domain for 'Knowledge, Innovation, and Education' (Commissie Meijerink, 2010). The allocation of public funds for nanotechnology research happens under the condition of 'matching funds' by the participants in the partnerships, which means that the partners need to contribute as much to the total budget as the part that is funded by the government.

Close cooperation between industry, universities, and research institutes in public-private partnerships is quite common in the Netherlands[4]. These partnerships are typically funded jointly. Combined public - private funding of research programs has become the norm for successive national investments in nanotechnology research (Commissie Meijerink, 2010) (FES Initiative 2009 HTSM, Oct. 2009). Since 2002 and budgeted towards 2016, the Cabinet has awarded some 250 million euro ($325 million) of new and additional funds for nanoscale

[4] Another example is MicroNed, a program similar to NanoImpuls and NanoNed, but focused on more conventional ways of miniaturization (MicroNed, 2012). Parts of the MicroNed program have been included in the current installment of public – private cooperation in nanotechnology: NanoNextNL (FES Initiative 2009 HTSM, Oct. 2009).

research to the different public – private nanotechnology consortia in the Netherlands (Ministry of Economic Affairs, Agriculture, and Innovation, 2011).

The current installment, NanoNextNL and its linked network of facilities NanoLabNL, have received government funding through 2016. The government set two clear conditions: it continued to require the consortium partners to match the public funding of these collaborations and it requires that 15% of the budget is dedicated to risk-related research. The NanoNextNL program received 125 million euro in public funding, starting in 2011. Matched by the other consortium partners, NanoNextNL's total budget for 2011 – 2016 is 250 million euro (FES Initiative 2009 HTSM, Oct. 2009). The goals of NanoNext NL are to continue existing research programs, integrate microscale research in the program, and fulfill the so-called Strategic Research Agenda, which outlines nanotechnology research priorities, as presented by the consortium partners to the Cabinet in 2008, in order to expand upon the Dutch academic and industrial position in the field (Gielgens, 2012) (NanoNextNL, 2013).

Nanotechnology Governance Step by Step

The potential of emerging nanotechnology in the 1990s led to general excitement among scientists, industry, and governments. Soon, however, concerns about the risks and uncertainty associated with nanotechnology and the use of engineered nanomaterials paralleled its promises, which moved governments to find ways to address such concerns.

Figure 1 gives an overview of various steps undertaken by actors involved in policymaking in the Netherland, the European Union, and beyond in responding to and fostering nanotechnology R&D since the early 2000s. Direct investments by the Dutch government for nanotechnology research specifically began in 2001, when the government research funding organization NWO - the Netherlands Organization for Scientific Research - and its divisions started to fund basic nanoscale research as part of their annual programs.

Figure 1 Timeline Governance of Nanotechnology in the Netherlands, the European Union, and beyond

Netherlands	timeline	European Union & International Dimension
Start scientific strengths in materials science, biotech, and ICT	1970s	
Start nanotech R&D at universities	1990s	
Industry takes up nanotech R&D	2000s	
NWO & FOM start to fund nanotech in regular programs	2001	
Cabinet co-funds NanoImpuls	2002	EU FP6 2002 - 2006: NMP priority funds 1.3 billion euro nanoscale R&D
KNAW report "How Big Can Small Actually Be?"	2004	EU 1st intention to develop a common strategy for nanotech
NanoNed estblished - BSIK funded - 2004 - 2010		
Universities start joint research facilities for nanoscale R&D		
Specific NWO call for nanotech research	2005	ISO TC 229 Nanotechnologies
1st FES round Knowledge, Innovation, and Education		
NWO strategy "Towards a Multidisciplinary Nanoscience Programme"		EU Nanosciences and Nanotechnologies: Action Plan for Europe
Health Council report on Nanotechnology	2006	OECD Working Party on Manufactured Nanomaterials
Cabinet Vision on Nanotechnology "From Small to Great"		
Towards a National Nanotechnology Initiative		
REACH implemented	2007	EU REACH Regulation on Chemicals
		EU FP7 2007 - 2013: continues NMP priority: 3.5 billion euro
Cabinet requests a Strategic Research Agenda for Nanotechnology		OECD Working Party on Nanotechnology
Cabinet Nanotechnology Action Plan	2008	EU Precautionary principle applicable to nanomaterials: "no data, no market"
Strategische Research Agenda Nanotechnologie		EU REACH to cover nanomaterials
HTSM proposal including Nanotechnology Program	2009	2nd EU implementation status report
		EU Nanotech specific regulations for food and cosmetics
1st Implementation Report Action Plan	2010	EU Horizon 2020: includes nanotechnology priority
NanoLabNL formalized	2011	
NanoNextNL		
2nd implementation report Action Plan		
NanoNextNL part of innovation program Top Sectoren	2012	

In general, Dutch governance reflects a history of structured consensus seeking and mediation among government, civil society, and the general public. This practice of organized political

accommodation of diverse interests emerged in the second half of the 20th century with the aim to reach agreement on controversial social policy matters (Andeweg & Irwin, 2009). Although political and societal circumstances have changed in recent decades, the current Dutch governance model still has a strong legacy of neo-corporatism (Kickert, 2003). It includes a large number of mediating institutional arrangements designed to openly incorporate societal interests, such as industry associations and labor unions, in the policy-making process. Instruments of such incorporation include several highly regarded advisory councils partaking in the process of policy and regulation formulation (Andeweg & Irwin, 2009).

On of such is the Royal Netherlands Academy of Arts and Sciences, which, at the request of the Cabinet, published a report – "How Big Can Small Actually Be?" – in 2004 on the consequences of nanotechnology. The Cabinet used the report to inform Parliament about the significant opportunities offered by nanotechnology while also addressing the remaining uncertainty about potential risks. The report recommended that public funding be made available for fundamental and applied R&D (KNAW, 2004)

Also in 2004, the European Commission announced its intention to develop a common strategy for nanotechnology development within the European Union (EU) (European Commission, 2004), and in 2005 published, "Nanosciences and nanotechnologies: An action plan for Europe 2005-2009." (European Commission, 2005). Representatives of various EU member states including the Netherlands gave input for the European strategy on nanotechnology development. While contributing at the European level to frame the European Commission's

Action Plan, Dutch policy makers and stakeholders were strengthening their capacity to understand and address the risks associated with nanotechnology within the Netherlands.

The 2005 EU Action Plan sought to foster a common approach to the responsible development and commercialization of nanotechnology (European Commission, 2005). It laid out four pillars of government response to nanotechnology that, as we will see, reoccur in the more specific national approach of the Netherlands formulated by the Cabinet in 2006 and 2008: (1) A strong focus on research and business opportunities, as nanotechnology offers a wide range of opportunities for societal and economic returns; (2) The need to address ethical, social, and legal aspects; (3) The condition to foster public engagement and knowledge of nanotechnology to avoid any later resentment because of misinformation; and (4) The assessment of risks and uncertainty associated with nanotechnology. The EU action plan identified the promising possibilities of nanotechnology and aimed to reinforce nanoscale R&D as part of the European Union's research program and innovation capacities. Reflecting wider EU policies to increase the international competitiveness of the European economy, the 'European Nanosciences and Nanotechnologies Action Plan' aimed to stimulate industrial uptake of new knowledge in the emerging field. It also stressed the need for public participation to address potential concerns for public health, worker safety, consumer protection, and the environment.

The European Action Plan concluded by recommending that the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) assess appropriate risk assessment methodologies for manufactured nanomaterials. In so doing, the

Commission placed manufactured or engineered nanomaterials under the larger umbrella of European and international regimes with regard to potentially dangerous chemical substances and requested relevant parties, and in particular the EU member states, to help to develop an overall regulatory approach to manufactured nanomaterials. The European Action Plan stressed its preference for international collaboration, and mentioned the United Nations (UN), World Trade Organization (WTO), and the Organization for Economic Cooperation and Development (OECD) as relevant platforms to exchange information and develop instruments aimed at assessing and ultimately managing any risks associated with nanomaterials. In doing so, the Plan sought to foster a common approach to the responsible development and commercialization of nanotechnology in Europe and beyond (European Commission, 2005).

Other international organizations such as the International Organization for Standardization (ISO) and the Organization for Economic Co-operation and Development (OECD) responded to the opportunities of emerging nanotechnology and the concerns about risks and remaining uncertainty as well. In 2005, ISO established a Nanotechnology Standards Committee (TC229) in 2005. Representatives of the Netherlands have since actively participated in the ISO technical committee (Van Teunenbroek, 2010). Given ISO's stature, the Dutch Cabinet seeks to avoid specific Dutch standards for the manufacturing and use of nanomaterials, preferring instead to express Dutch viewpoints in deliberations about standards within the international decision making of the ISO. In doing so, the Cabinet seeks both to strengthen the influence of Dutch business in setting standards and to position the Netherlands as a leader within the ISO (Ministry of Economic Affairs, 2008).

The OECD's Environmental Policy Committee established the Working Party on Manufactured Nanomaterials (WPMN) in 2006 to address health and environmental safety issues of manufactured nanomaterials. The WPMN aims to develop and coordinate research strategies to fill knowledge gaps about the risks associated with nanomaterials and to stimulate data gathering. One objective is to define a minimum set of data on manufactured nanomaterials that manufacturers should supply in order to get approval for production and use in the market (Organization for Economic Co-operation and Development, 2010). The Dutch Cabinet saw the WPMN as a valuable platform for developing the assessment instruments needed to enable the safe production and use of nanoparticles. Dutch representatives have since participated in four of nine steering groups the WPMN established since 2006 (exposure, regulations and agreements, risk assessments, and description of relevant risk parameters). To help to describe risk parameters the Dutch research institute RIVM commissioned a study of nano-silver particles as a potential case of the representative set of data that companies producing or using manufactured nanomaterials might submit before being allowed to market their products (Ministry of Economic Affairs, 2010), while the Dutch research Institute TNO has contributed research findings to projects of the steering group on exposure to manufactured nanomaterials (Ministry of Economic Affairs, 2008).

A year later the OECD expanded its involvement in nanotechnology when its Committee on Scientific and Technological Policy created the Working Party on Nanotechnology (WPN) (Organisation for Economic Co-operation and Development, 2010). The goal of the WPN is to

help and advise governments to formulate policies for the responsible development of nanotechnology (OECD, 2010).

In the Netherlands in 2006, the Health Council of the Netherlands (Gezondheidsraad), an independent scientific body that advises government and Parliament on matters of public health and health care, published a report concluding that manufactured nanomaterials could be hazardous for human health. Given such uncertainty, the Council advised the Cabinet to stimulate and direct further multidisciplinary nanoscale R&D through financial and other incentives. The Council at that time viewed the existing regulatory framework, both at the national and European levels, as sufficient to cover any associated risks and it stressed that risk assessment should take place within international regulatory regimes on chemical substances such as the European Union's Protocol for the Regulation of Chemical Materials (REACH) (Health Council of the Netherlands, 2006).

The Cabinet informed Parliament of its view on nanotechnologies in the Netherlands in a November 2006 vision statement 'From Small to Great' (Ministry of Economic Affairs, 2006). The content of the document mirrored the outline of the EU's 2005 Action Plan, with sections on business and research opportunities; societal, ethical, and legal issues; public engagement; and risk assessment. The Cabinet stressed Dutch leadership in nanotechnology, articulated its great economic potential, and expressed its intention to contribute to a supportive research climate and to the economic competitiveness of Dutch industry. In the document, the Cabinet focused attention on the uncertainty and risks associated with nano-scale materials, and the

lack of standardization of definitions, methodologies, and research strategies in the field. As one of next steps, the Cabinet requested a collaboration of Dutch research funding organizations, research institutes, universities, and industry – at that time informally working together under the name 'Netherlands Nano Initiative' - to put together a so-called Strategic Research Agenda for nanotechnology R&D, outlining research priorities and a request for continuing funding (Reinhoudt, 2006).

In 2007, the Dutch government adopted the EU's directive on the Registration, Evaluation, Authorization of Chemical Substances, or REACH (EC 1907/2006). REACH was implemented as part of Dutch legislation and it replaced all existing policies with regard to the use of materials and chemicals in the Netherlands, which may include manufactured nanomaterials (Ministry of Housing, Spatial Planning, and the Environment, 2008).

In June 2008, the Dutch Cabinet presented its 'Nanotechnology Action Plan.' The 2008 plan continued to reflect the pillars communicated by the European Commission: strengthen research and business opportunities, seek an inclusive governance approach addressing societal and ethical concerns, and address risks and remaining uncertainty associated with nanotechnology for health and the environment. The 2008 Nanotechnology Action Plan has become the basis of Dutch government support for nanotechnology research. The Dutch Cabinet seeks to create a climate for responsible and economically viable development of nanotechnology, based on four premises: (1) an ambitious agenda for research and business opportunities in the Netherlands; (2) an inclusive approach to address ethical, social, and legal

issues pertaining to nanotechnology; (3) a program to stimulate public engagement in the development of an overall governance approach; and (4) an emerging regulatory model that acknowledges the risks and remaining uncertainty associated with the use and production of manufactured nanomaterials . In the plan the Cabinet articulates that further risk related research should take place through European and international collaboration, in particular within the OECD and the ISO. The Cabinet concluded that existing legislative and regulatory framework, already embedded in European legislation like the protocol for chemical materials REACH, would be sufficient to address the manufacturing and use of nanomaterials, yet it repeats that new knowledge about risks could result in amendments to existing laws and frameworks (Ministry of Economic Affairs, 2008). The action plan's goal is to build a viable nanotechnology R&D system based on backing so-called 'winners,' supporting the development of areas of expertise and specialization in which Dutch industry, universities, and research sectors have proven strength and success, such as high tech systems and materials, clean water, food, and energy (Ministry of Economic Affairs, 2012).

Also in 2008, the participants in the informal 'Netherlands Nano Initiative', consisting of several research funding organizations and the public – private partnership for nanotechnology R&D NanoNed, presented their 'Strategic Research Agenda' (SRA) for nanotechnology, as requested by the Cabinet (FOM, STW & NanoNed, 2008). The SRA has since become the guideline of nanotechnology research in the Netherlands. It is used as the scientific basis of the cooperation between government, industry, and research institutes in nanotechnology development as put forward in the Cabinet's 2008 Nanotechnology Action Plan. The 2008 Strategic Research

Agenda included a proposal for a continuous annual investment of 100 million euro over a ten-year period (2010 – 2020). Of the total funding of the research programs proposed under the SRA, 50% was to be carried by industry, and 35% by public funding, while European research programs were expected to contribute 15% of the annual budget.

The SRA budget proposed an allocation of some 45% of the funds to nanoscale research, 20% to building and maintaining a nanotechnology research infrastructure, 10% to invest in education and training of scientists, and 15% to risk-related research (FOM, STW & NanoNed, 2008). The 15% budget allocation for risk-related research follows the explicit request of the government as stated in the 2008 Action Plan that "at least 15% of the research agenda will be devoted to risk-area research for a minimum of five years" (p. 11), which shows the focus on integration of specific risk-related research in general nanotechnology research (Ministry of Economic Affairs, 2008).

Where the Governance of Manufactured Nanomaterials Stands Today

As shown, both the Netherlands and as the European Union have put forward action plans for integrated and responsible development of nanotechnology and the manufacturing and use of nanomaterials. These plans are the basis of governance of nanotechnology in the Netherlands and the European Union. The programs address both streams of nanotechnology research: research, development and innovation in one, and risk research and public engagement in nanotechnology in the other (European Commission, 2005) (Ministry of Economic Affairs, 2008).

Dutch government involvement has evolved over time from a program of rather detached non-centralized funding of basic nanotechnology research towards a more directed and integrated national effort, in which nanotechnology, as an enabling technology that is closely linked to other so-called NBIC and KETS technologies[5]. Today, both in the Netherlands and in the European Union, nanotechnology is embedded in broader innovation programs - in the Netherlands, as part of the so called *TopSectoren* Program and in Europe as part of *Horizon 2020* - under the condition that risks and uncertainties associated with nanotechnology are addressed at the same time (European Commission, 2011) (Ministry of Economic Affairs, Agriculture and Innovation, 2012) (European Commission, 2012).

The Dutch Cabinet and the European Commission regularly give updates on the status of the implementation of the action plans for nanotechnology (Ministry of Economic Affairs, 2010) (Ministry of Infrastructure and the Environment, 2011). In its 2012 update to Parliament, the Dutch Cabinet acknowledged that still many knowledge gaps remain about the risks of the manufacturing and use of nanomaterials. The Cabinet indicated that it would seek an acceleration of risk related research (Ministry of Infrastructure and the Environment, 2012), as it sees understanding risks as conditional for successful application of nanotechnology. From the government's point of view, the slow pace of risk related research threatens Dutch prominence in nanotechnology. Moreover, the Cabinet in its letter to Parliament on this matter

[5] NBIC: Nanotechnology – Biotechnology – Information technology - Cognition sciences and technologies, which are increasingly converging because of their inter- and multidisciplinary character (Ministry of Economic Affairs, Agriculture, and Innovation, 2011). The EU uses the KETS acronym for 'Key Enabling Technologies', which include nanotechnology, biotechnology, and other specific fields of science and technology (European Commission, 2012)

dated on May 22, 2012 stressed the need to address these gaps through international collaboration, in particular within EU and OECD, by stating that "The Netherlands depend on international agreements, preferable in the form of a harmonized European approach"6 (p. 2) and pledged Dutch cooperation in sharing research results and funding international research initiatives (Ministry of Infrastructure and the Environment, 2012).

One finds a notable convergence of governance at different levels in dealing with the risks and remaining uncertainty of the use and production of nanomaterials. Updates by the European Commission reflect this convergence. In the EU's second implementation report of the status of the 2005-2009 Action Plan (October 2009), the EC also concluded that risk-related research is lacking: between 2007 and 2009 only 5% of the total research expenditure on nanotechnology within the EU was allocated to risk research. The Commission stated that it preferred international collaboration, in particular within the OECD and the ISO, to address issues about testing methods, toxicity of manufactured nanomaterials, characterization of materials, and exposure levels to manufactured nanomaterials. It sees international collaboration in the OECD and the ISO as a help to "facilitate a global convergence in standards for the implementation of regulation" (European Commission, 2010, p. 8). In its 2010 implementation report on its Nanosciences and Nanotechnologies Action Plan, the Commission concludes that international cooperation in nanotechnology research is strong and it mentions the European Union's participation in the OECD working parties as well as the ISO technical committee on nanotechnology (European Commission, 2010) (European Parliament, 2009). A more recent

[6] Translated from Dutch by author.

review concludes that progress is slow, yet existing regulations such as REACH are suited to cover manufactured nanomaterials (European Commission, 2011)

Seeking an acceleration of results and harmonization within and beyond the European Union, the European Commission recently approved the NANoREG project. NANoREG aims to develop a common approach to test nanomaterials continues based on the findings of various OECD Working Party on Manufactured Nanomaterials (WPNM) projects and other sources such as the ISO technical committee to generate metrology for manufactured nanomaterials. It seeks close cooperation between regulators and industry to develop tools for assessment of the risks associated with the manufacturing and use of nanomaterials, which should be implemented by 2016 (NANoREG, 2013).

Examples of Multi-level Governance for Manufactured Nanomaterials in the Netherlands

This study sets out to test whether the development of regulations to address the risks and rewards of the manufacturing and use of nanomaterials reflects various influential actors operating at different levels: Do we see high-level harmonization of policies, which yet allow for variation in implementation, such as a specific Dutch approach? Is there support for how and why the Dutch governance approach of manufactured nanomaterials is an example of multi-level governance in the regulatory approach of emerging fields of science and technology?

We notice the convergence of policies at the European and the Dutch level, and even beyond. A couple of small case studies add to our understanding of how such convergence of policies

happens and how higher-level agreements and recommendations are interpreted and implemented at national levels. Next is a closer look at the Dutch implementation of the EU's protocol for chemicals REACH, some more insights in the Dutch participation in the OECD's Working Party on Nanotechnology, and a view of the Dutch involvement in the European NANoREG project.

The European Union's REACH Protocol for Chemical Substances

As nanoscale research started to offer opportunities to develop, fabricate, and use new materials of existing materials at an unprecedented small size, national and international regulators of, for instance, chemical materials needed to address these novel materials.

Through its application of the precautionary principle[7], REACH gives greater responsibility to industry to manage the risks from chemicals and to provide information on the chemical substances they intend to use in production. Manufacturers are required to gather a specific set of data on the properties of the chemicals they produce or use. These data are registered in a central database operated by European Chemicals Agency (ECHA). In doing so, REACH seeks to fill remaining gaps in information about chemicals in use as well as new substances entering the European market (European Commission, 2010). As REACH requires industry in the chemical branch to report data on the use of chemical materials in new ways, often disclosing more details than previously demanded, concerns about implementation costs of REACH for the

[7] A strict interpretation of the principle argues that as knowledge of the risks associated with such materials remained incomplete and insufficient, they should be considered as potentially hazardous for humans and the environment until proven otherwise. From an economic perspective, however, such strict interpretation of the precautionary principle might hinder technological advancement and economic growth (Van Calster, 2008).

sizeable Dutch chemical industry – as mentioned prominent international companies as Akzo Nobel and DSM originate in the Netherlands - were part of the REACH-related debate in Parliament in 2006, before the actual implementation of the protocol in 2007. Industry interests argued that the REACH requirement, based on the precautionary principle, that data are to be supplied by industry before a chemical can be used or marketed –paraphrased as "no data, no market" – places a undue burden on industry. They argue that such data are often unavailable because of the lack of methodologies to fully assess the risks of certain chemicals, as is the case in many manufactured nanomaterials, so the strict application of the REACH requirement would unnecessarily prohibit the current production and use of nanomaterials. Partly in response to industry concerns, the Dutch Cabinet, while acknowledging the precautionary principle as the basis of its risk governance policies, has promoted a more pragmatic interpretation of the precautionary principle in the form of "no data, no exposure," meaning that workers or consumers should not be exposed to risks in the production and use of such materials (Ministry of Infrastructure and the Environment, 2011).

Originally, REACH did not specifically address manufactured nanomaterials. A review on behalf of the European Commission concluded that nanomaterials are covered under the substance definition of the REACH protocol and reconfirmed that it considered the existing legislative and regulatory framework sufficient to cover all aspects of nanotechnology. Yet, the Commission added that amendments to REACH might be needed, as new insights would come available[8]

[8] Yet, in April 2009 the European Parliament passed a resolution that disagrees with the Commission's assumption that existing regulatory and legislative frameworks sufficiently cover nanoscale technology and manufacturing. The resolution required the European Commission to start a full review of existing legal and regulatory frameworks and

(European Commission, 2010). The Dutch government, clearly favoring European collaboration in achieving harmonization of any efforts to regulate the production and use of manufactured nanomaterials, explicitly shared its concerns about the slow progress being made to achieve a proper oversight of nanomaterials under REACH and the consequences for nanotechnology development with the European Commission and ECHA. In 2008 at the request of, among others, the Dutch Cabinet, the European Commission, set up a subgroup under the REACH Competent Authority on nanomaterials (CASG oN) to address regulation of engineered materials at the nanoscale under REACH (Ministry of Economic Affairs, 2008). The government agreed with the conclusion of the European Commission that the REACH regulatory framework in principle offered sufficient possibilities to cover manufactured nanomaterials (Ministry of Economic Affairs, 2008), however felt that the assessment of how this should be done remained slow in reaching conclusions. Through Dutch participation in this group, the Cabinet aimed to stimulate, ensure, and accelerate European collaboration in developing a common strategy for the risk assessment of manufactured nanomaterials under the REACH protocol (Van Teunenbroek, 2010). Such strategy supports responsible development of nanotechnology in the Netherlands and the EU and it helps Dutch industry in expanding their position in such a promising field of science and technology. The implementation of REACH shows the interplay between levels of governance. It also shows interdependence: the Dutch favor a 'European' protocol that caters to Dutch preferences and addresses Dutch concerns.

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to adapt them where necessary to fully cover nanoscience and nanomaterials (European Parliament, 2009) (European Commission, 2009). The review concluded that the REACH protocol is suited to cover new manufactured nanomaterials (European Commission, 2011).

NANoREG

As part of the European Union's '7th Framework Programme for Research and Technological Development' (FP7), the NANoREG project, approved in 2013, looks to find ways to accelerate risk-related research for new manufactured nanomaterials. The project aims to provide regulators in the European Union, its members states, and beyond with common instruments to assess the risks and remaining uncertainties of nanomaterials (NANoREG, 2013). NANoREG seeks to bring together all available knowledge on the risks of manufactured nanomaterials. It aims to overcome slow progress in the OECD's Working Party on Manufactured Nanomaterials (WPMN), which appears to be limited by a lack of research budget and a lack authority in pushing its participants to results[9] (Van Teunenbroek, 2013), yet it seeks collaboration and exchange of information beyond the European Union.

The Dutch Ministry of Infrastructure and the Environment, represented in the WPMN and displeased with the slow and fragmented progress in the working party, proposed the NANoREG project to the European Union in 2012 (Van Teunenbroek, 2013). The European Commission approved the project and awarded 10 million euro of NANoREG's proposed budget. Participating countries in the project add some 40 million euros to the overall budget. NANoREG is expected to present its results in 2016 (NANoREG, 2013).

Membership of NANoREG is not limited to government representatives. It explicitly seeks collaboration between various actors: around sixty partners – many from independent research

[9] The OECD takes decisions based on consensus. Its conclusions tend to be recommendations, whereas the European Union has the disposal of more binding instruments (Van Teunenbroek, 2013) (Mout, 2013).

organizations and industry – from around fifteen European countries have joined the NANoREG project (NANoREG, 2013). The chemical industry, not pleased with the REACH requirements, which lay the burden of proof that materials are safe – and the costs to provide such evidence -, appears to join NANoREG with a certain apprehension. It appreciates NANoREG's goal to find a common approach to allow market access for manufactured nanomaterials in the EU and possibly beyond, yet it argues that engineered nanomaterials generally are materials already on the market, be it on a different, much smaller scale (Van Teunenbroek, 2013) (Minstry of Infrastructure and the Environment, 2013). The NANoREG project acknowledges the wish of various actors involved – industry, academia, and governments – to reap the benefits for multi-disciplinary innovation offered by nanotechnology and seeks to include the various interests of the actors involved in its results.

The Dutch Ministry of Infrastructure and the Environment leads NANoREG. In addition several Dutch research institutes and companies participate in the project (Ministry of Infrastructure and the Environment, 2012). The Dutch initiative, leadership, and participation in NANoREG exemplifies how the Netherlands seeks to contribute to harmonization of decisions taken at different venues and at different levels of governance, bringing together Dutch knowledge and viewpoints with broader European and international expertise, and allowing various government and non-government actors to join in finding an accelerated common approach for the assessment of risks associated with new and engineered nanoscale materials.

The OECD Working Party on Nanotechnology

In addition to the Working Party on Manufactured Nanomaterials established in 2006, in 2007 the OECD created a Working Party on Nanotechnology to advise its members on policy and governance matters for responsible development nanotechnology and the safe use of manufactured nanomaterials (Organization for Economic Co-operation and Development, 2010). Some twenty-five members of the OECD join in the WPN meetings. Of those around fifteen members are actively involved, among them the United States and Canada, South Korea, and a number of European countries (Mout, 2013). The compilation of the members' participation in the WPN varies: though often government representatives join, at times scientists and industry experts join. The Ministry of Education, Culture & Science coordinates the Dutch participation in the WPN. The Dutch delegation consists of representatives of the Ministries of Education, Culture & Science and Economic Affairs, as well as a representative of the public – private nanotechnology research consortium NanoNextNL, which includes industry, research institutes, and universities. Since 2012 the Netherlands chairs the WPN. The WPN selects its chair based on a country's position in nanotechnology and its contribution to the WPN.

The different members may propose various research projects. Countries do so based on their expertise and based on their needs. Whereas the Netherlands and other European countries focus on public engagement in nanotechnology, other countries focus on growth (United States, South Korea) or statistics (Canada) (Mout, 2013). Past and ongoing projects of the WPN include work on public engagement, indicators & statistics, and an inventory of responsible development policies for nanotechnology and their implementation (Mout, 2012).

The WPN has three policy priorities to which all members agree:

1) How nanotechnology may foster economic growth;
2) How nanotechnology may help to address so-called global challenges such as climate change;
3) How nanotechnology may develop in a sustainable way (OECD Working Party on Nanotechnology, 2013)

Obviously these priorities are rather general and implementation of the WPN's recommendations might show great variance between members.

The Netherlands has actively participated in the WPN since its inception. It sees the WPN as an opportunity to help to shape international agreements and policy directions. The attention for nanotechnology within the OECD has help to push attention for nanotechnology and the need for government research funding in this field on the Dutch political agenda. The composition of the Dutch delegation to the WPN reflects a range of actors, which are actively involved in nanotechnology development at various levels.

Conclusion

This article situates the regulatory approach in the Netherlands on the risks and remaining uncertainty associated with nanomaterials within a much wider international approach of dealing with emerging nanotechnologies. As so much activity takes place, and so many parties (including government agencies, industry, universities and research institutions, and civil society organizations) are involved in national and international settings, this article can only

offer a bird's eye view of the landscape. However it provides examples of multi-level governance by describing how the Dutch regulatory approach shapes and is shaped by participation in European and other international platforms like the OECD and the ISO.

This study set out to test whether the development of regulations to address the risks and rewards of the manufacturing and use of nanomaterials reflects various influential actors operating at different levels. As the international regulatory approach evolves, a convergence of policy priorities is discernible between the different levels of governance: the focus to stimulate research and industrial uptake in the emerging field on nanosciences and nanotechnologies in order to benefit from its great opportunities; the urge to address any social, ethical, and legal concerns; the wish for public engagement in the development of nanotechnology; and the need to balance opportunities with a clear assessment of the risks of nanomaterials and the uncertainty that remains, preferably in international collaboration. Clearly, and by outspoken preference, the Dutch governance approach is embedded in a European and international setting. The Dutch government actively seeks acceleration of risk-related research in this field and harmonization of various regulatory approaches within the European Union and beyond. However, while there is a multi-level agreement on the steps towards a general approach and on the research priorities of dealing with nanotechnology, Dutch points of view, shaped, for instance, by its sizeable chemical and electronics industry and by its prominent research institutes and universities, sometimes differ from those of other participants in European or other international platforms in how to achieve results. Dutch actors, be it the government, research institutes, or industry, actively contribute to

international regulatory initiatives to shape its outcomes and to expedite the policymaking process at interdependent international and national levels.

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