Toxic Chemicals, Environmental Organizations, and the Governance of Science and Technology in the EU and the US - The Case of Nanotechnology

by

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ABSTRACT

This dissertation explores the involvement of various CSOs (NGOs, TUs, think tanks, and other advocacy groups) in the debate about the regulation of nanomaterials in the EU and the US. How do these two political structures involve advocacy groups in the development of regulatory policy? What are the results of such involvement? The findings of this research indicate that even though the EU and US think differently about regulation and involve CSOs in distinct ways, the results of the advocacy activities in both political structures are similar. Why is it that CSOs do not successfully influence regulatory outcomes in the EU even though there is an elaborate system with official participation from CSOs, a very strict framework based on the precautionary principle, and a Green Party with opinions very similar to these of the CSOs and with abilities and political opportunities to influence one of the co-legislators, the EU Parliament? This dissertation suggests that the unequal distribution of power in the government structures, unequal distribution of power within the areas where advocacy groups usually are involved, mainly very powerful industrial interests, CSOs with moderate position and professionalized approaches, and a regulatory focus on the implementation level, which is very technical, results in outcomes other than those that CSOs have supported.

1. Introduction

Nanotechnology is formally defined as "the creation of functional materials, devices, and systems through control of matter on the nanometer (1 to 100 nm) length scale and the exploitation of real properties and phenomena developed at that scale" (Los Alamos National Laboratory, 2002). Research on nanostructures and at the nanoscale is not entirely new; most biological processes take place at the nanoscale. However, scientists now possess sophisticated techniques that can be used to isolate, synthesize, and manipulate matter at this scale. From the perspective of molecular composition, many of the resulting new "nanomaterials" are the same, or very nearly the same, as other bulk materials. However, their scale and size means that these materials can exhibit unique physical and chemical properties. Thus, nanomaterials exhibit new potential for industrial and medical uses, but they also pose new risks.

Nanomaterials could be used for benefit in many products, such as cheaper solar panels, easy-to-use water filters, effective medical devices and medicines; however, a growing body of research has already shown that there might be some risks posed by their release into the environment and by ingestion into animal bodies. Most of these risks are connected to the particles' small size, which can avoid immune system recognition and affect biological processes (Biswas & Chang-Yu Wu, 2005; Brumfiel, 2003; Oberdörster, 2004). Some scientists have raised concerns about the similarity of certain types of nanomaterials to asbestos, which causes cancer when introduced into the body (Poland et al., 2008; Sanchez, Pietruska, Miselis, Hurt, & Kane, 2009). However,

research on the applications of nanomaterials overshadows the research on the possible negative effects, and nanomaterials remain mostly unregulated, even though many products containing them are already on the market.

This project begins with two assumptions: nanotechnology offers tremendous economic, environmental, medical, and other benefits, but the risks are substantial enough that regulatory action is needed in order to avoid repeating the history of other toxic materials, such as asbestos and chlorinated chemicals. Those materials were released into the environment before adequate testing for safety was completed, and remediation costs have been huge. Despite this need for a strong regulatory framework for nanotechnology, the major producing countries in the world have not put in place adequate regulatory frameworks. This regulatory gap has been identified by many stakeholders, especially civil Society Organization (CSOs), which are defined here to include environmental nongovernmental organizations (NGOs), health advocacy organizations, public-interest think tanks, consumer organizations, professional associations, and trade unions. CSOs have provided leadership to encourage both industry and government to develop better safety testing, analysis, and regulatory frameworks. These organizations have started campaigns, issued reports, and signed petitions in order to encourage governments to do something about filling this regulatory gap. However, their efforts have been largely ineffective to date.

This project focuses on two of the most important regulatory frameworks in the world, those of the US and EU, and it examines the similarities and differences in the two frameworks. I began with the assumption that the governance system in the EU had

developed a stronger regulatory framework for nanomaterials than that of the US, and my hypothesis was that one of the reasons for the stronger framework was that public participation processes for CSOs were stronger in Europe, because the EU wanted to avoid the public backlash experienced for genetically modified (GM) food. However, after extensive interviews and fieldwork on both continents, I came to the conclusion that the policy outcomes were similar and that in both regions CSOs had relatively little effect. The puzzle that I then attempted to solve was why there were similar policy outcomes even though the political structures and regulatory frameworks were substantially different.

European governance structures create more official opportunities for CSOs, including environmental NGOs and trade unions, to participate in formal discussions about the regulation of new technologies. The EU is built as a social partnership; this means that groups such as professional associations and trade unions have to be consulted on issues of policy developments that affect them. In addition, in 2001 the European Commission published a white paper on European governance that officially established the involvement of civil society in discussions about policy developments (Commission of the European Communities, 2001). With that change, CSOs were positioned to represent the absent European public interest, which was needed to legitimate the decision-making of EU institutions. Prior to this change, regulatory decisions in the EU were made by appointed bodies based on expert advice.

In contrast, the American political system provides fewer opportunities for the CSOs to participate. In the US, the two-party system and the lack of the official

involvement of CSOs in governmental decision-making make it more difficult for CSOs to be engaged in the political process. Nevertheless, there are numerous informal mechanisms, and there is substantial informal involvement from organizations with staff scientists, such as Environmental Defense Fund. Furthermore, some environmental organizations use litigation. Even though the US has an outdated regulatory scheme, it has nonetheless managed to regulate more than 130 nanomaterials. Nevertheless, the general outcome is the same as in the EU: CSOs find that regulatory policy has fallen far short of their calls for adequate evaluation of environmental, health, and safety issues.

The fact that the regulatory results are about the same in the two political systems is an unexpected outcome, especially in the case of EU, where a strict framework is in place for chemical regulation, there is an inclusive system for CSO participation, and the European Green Party (also known as European Greens or EGP), advocates for increased regulatory oversight. I explain the similarity of outcome as the result of three factors: the CSOs' moderate positioning and professionalized approach to the debate in the EU, which weakens connections with broad social movements that could trigger a regulatory response; a shift of the discussion in the EU from regulatory policy to regulatory implementation, which is very technical and therefore restricts the role of public participation; and the power of the chemical industry in both the EU and US, which has a tremendous influence on the political process.

1.1 CSOs and the Regulation of Nanotechnology

After the integration processes in Europe, policy decisions in all arenas were

addressed centrally at the EU level. The executive body of the EU, the EU Commission, is the only body that can propose a new legislative framework or reform an existing one. To initiate a legislative procedure, the Commission usually develops a white paper that describes the framework, then the paper goes into discussion and voting by the two legislative bodies: the EU Council and the EU Parliament. Thus, the Commission, which is an appointed executive cabinet consisting of one representative appointed from each of the member states, initiates legislation, but it does so without the sanction of directly representing European citizens through an electoral process. Although the Council consists of the elected heads of state of the European countries, it is also not directly elected. Thus, only the EU Parliament is directly elected. The lack of direct public representation in the governmental structure has created difficulties, and the EU government underwent a democratic crisis in the 1990s, when the EU Commission was making decisions about the introduction of GM food in the EU market against the will of most member states. In order to correct the democratic deficiency, the EU granted more rights to the EU Parliament, the only EU body directly voted by the EU citizens. In 2009, with the Lisbon treaty, the EU Parliament became co-legislator with the Council. Also, the member states were given the right to make decisions about how the legislative frameworks were going to be implemented in their state. Another solution to the democratic deficit in the EU system was to include CSOs officially in political decision-making. In a white paper written in 2001, the Commission made possible the participation of civil society, including CSOs, in the discussions and procedures of policy developments (Commission of the European Communities, 2001). This shift is

significant, as it potentially signaled the democratization of decision-making about science and technology and the recognition of alternative forms of expertise.

In the US, the political structures did not go through major changes such as the ones that occurred in the EU, and the political scene has been mainly dominated by two parties for almost a century. There are also three main policymaking bodies—the House of Representatives, the Senate, and the President—and all three are democratically elected. State governments are represented in the Senate by having two senators for each state (a total of 100 for the 50 states), and although governors of the states do meet and have councils, unlike the EU the outcomes of their deliberations do not play any official role in the federal policy-making process. CSOs, even though they might get some opportunities to participate, do not have a formal role in decision-making equivalent to that of the EU. In the US, CSOs can be part of expert groups in some cases, but these positions are not permanent. Usually, CSOs advocate for their requests through testimonies in hearings, petitions, lawsuits, and lobbying. The lack of a formal role for CSO participation is not associated with a democracy crisis in the US, because the system is already based on electoral representation. Although there is no equivalent crisis of political representation in the US to that of the EU, there is instead a problem of "gridlock," because frequently one party controls one House of the legislature and another party controls the other House and the presidency. Because the president can veto legislation and senators can issue filibusters against legislation, it becomes very difficult to move significant legislative reform through the system.

Nanotechnology regulation takes place within these very different political

structures. In the late 1990s, the first consumer products containing nanomaterials found their way onto the market, including, but not limited to, golf balls that fly straighter, tennis rackets that are stiffer, nanosilver antibacterial socks, and clear sunscreens (NNI, n.d.-a). In 2000, the Clinton administration announced the creation of the National Nanotechnology Initiative (NNI) (NNI, n.d.-b), and in 2004, the European Commission adopted the communication "Towards a European Strategy for Nanotechnology" in the EU (European Commission, 2004). Thus, the first policy initiatives of both the US and EU were aimed at supporting the growth of that new technology, and there was talk of nanotechnology as the "next industrial revolution." Given the enormous potential of nanotechnology in many industrial fields as well as for the military and weapons, there was broad consensus in the US and EU that they should assume world leadership in the development of the new materials.

Environmental, health, and safety issues became part of the policy discussion in the early 2000s. The first papers on risk issues for ultra-fine particles made their appearance in the early 1990s (Ferin et al., 1990; Ferin & Oberdörster, 1992; Oberdorster, 1996), and according to the NNI's official webpage health and environmental issues have been part of the federal commitment since 2001 (NNI, n.d.-c). The development of the field of nano-toxicology, which made its debut around 2004, produced potentially alarming results about possible risks (Borm & Kreyling, 2004; Dreher, 2004; G. Oberdörster, Oberdörster, & Oberdörster, 2005). The first report by environmental organizations was published in 2003 by the ETC group (ETC Group, 2003), a radical organization that called for a complete moratorium on nanotechnology until safety issues

had been addressed. The more moderate Project on Emerging Nanotechnologies (PEN), a think tank that was established in 2005 in the US, discussed responsible oversight of nanotechnology development (PEN, n.d.-a), and the Environmental Defense Fund (EDF) also became involved (EDF, n.d.). In 2008 the NNI's first strategy on such issues came out: the strategy announced that the NNI in 2009, will invest 254 million dollars for research on the possible risks posed by nanomaterials (National Science and Technology Council, 2008). The report also prioritizes the areas of research on environmental, health and safety issues connected to nanomaterials that needs most attention (National Science and Technology Council, 2008). The field of nano-toxicology, which made its debut around 2004, produced alarming results about possible risks (Borm & Kreyling, 2004; Dreher, 2004; Oberdörster et al., 2005). The NNI federal funding for research and development was $1 billion in 2000 and it will be $1.8 billion for the year 2013, but the expenditures on risk assessment have been minimal. For example, in 2005 the US spent $35 million on research related to environmental and health issues, and NNI requested $105 million for 2013 (NNI, n.d.-c). CSOs argued that the expenditures on “ESH” (environmental, health, and safety) aspects should be at least 10 percent of overall funding (Hess, 2010).

The EU was very careful in framing nanotechnological developments as requiring a responsible approach, meaning that the EU would ensure that environmental and health concerns would be addressed promptly and reference the regulatory issues that might arise. Broadly, however, public discussions about the possible risks in the EU started in 2004, with Britain’s Royal Society and the Royal Academy of Engineering publication,

"Nanoscience and Nanotechnologies: Opportunities and Uncertainties" (2004). The discussions initially took place within the scientific community but soon became an issue for the trade unions. Discussions of the PEN Project in the US also had some influence on such discussions in the EU. In 2006, the Commission funded a project for CSOs to discuss environmental, health, and regulatory issues for nanomaterials. The same year, a report by Friends of the Earth (FoE) Australia and Friends of the Earth (FoE) United States (Miller, 2006) on the possible risks from nanomaterials in cosmetics was picked up by the FoE groups in Europe, and the debate about the regulatory gap was officially open. The EU Commission devoted 1.3 billion Euros for nanotechnologies between 2003 and 2006 (Hullmann, 2006), and approximately one third of this amount (350 million Euros) in 2003 were devoted for research on possible risks (European Commission, 2004). The EU devoted 3.5 billion Euros for research on nanotechnologies for the period 2007 – 2013 (European Commission, 2007), but as in the US only a small amount (50 million Euros) have been spent for research on EHS for the years 2007 and 2008 (European Commission, 2009). Overall, only 5% from this amount is allocated for closing the knowledge gaps and on health and environmental risks, and European CSOs have argued that this amount should be higher (EEB, 2009).

Even though nanomaterials pose many new questions about possible risks, the debate over their regulation is still unresolved. All over the world, the regulatory gap has been identified by environmental organizations, health organizations, consumer organizations, and trade unions. Most of these CSOs have argued for more regulation and for the responsible innovation of nanomaterials; however, in both the EU and the US,

there has been little public controversy. Only a small number of CSOs are involved in the debate, and most of the organizations take what they call a "balanced approach" towards nanomaterials, their regulation, and their possible developments. These CSOs do not request complete moratoria. They see potential for some applications of nanotechnologies and thus advocate for their appropriate regulation and the responsible governance of the technology. Only a few CSOs, such as the French group PMO (*Pieces et main d'oeuvre*) and the ETC Group, are against the development of nanotechnologies altogether. These groups have been criticized by other CSOs working on the issue, which have been reluctant to call for a complete ban on nanotechnology. Many CSOs are interested in some of the applications that nanomaterials promise, especially the ones that may benefit the environment or resolve environmental problems. This makes their strategies less oppositional, a striking difference from the debate on genetically modified food. There was great social movement opposition to GM products in the EU, and protests led by international CSOs resulted in a vigorous public debate. In contrast, the case of the nano-debate in the EU is completely different, because the CSOs involved have moderate opinions and there is no vigorous public debate about the issue.

In the EU, nanomaterials as substances fall under the regulatory framework of Registration, Evaluation, Authorization and Restriction of Chemical Substances (REACH), the framework that regulates bulk chemicals. Of course, other sectoral frameworks that regulate specific products like food, cosmetics, drugs, electric and electronic devices, etc. are available and apply for certain nanotechnology uses. With respect to nanomaterials, REACH is not scale-based and has been developed for the

needs of regulating bulk substances based on existing scientific knowledge and classification, which does not necessarily apply to nanomaterials. As a result, most nanomaterials are not subject to regulation, or they slip through loopholes. Because nanotechnology has not been regulated directly, discussions on reforming REACH to include nanomaterials have been ongoing since 2006 (European Commission, 2008). To this day, however, the issue is mainly unresolved.

In the US, the main regulatory framework is the Toxic Substances Control Act. This law is even less stringent than REACH, because it grandfathers many chemicals that were already on the market prior to the passage of the law in 1976. Like REACH, it also has no specific provisions for nanotechnology, and because chemical structures are similar for nanoscale materials and existing chemicals, manufacturers of nanomaterials can claim that at least some of their materials are pre-existing chemicals and therefore outside the scope of regulatory reform. The Environmental Protection Agency (EPA), in a 2008 report, stated that nanomaterials would not have special consideration under TSCA (US EPA, 2008b). In the US, the debate over nanomaterial regulation was attached to, and in some cases over-shadowed by, the debate over the reform of TSCA for all chemicals. While nanomaterials remain mostly unregulated, some CSOs have tried to use them as a way to shift the focus toward TSCA reform. Because CSOs tend to view TSCA as an out-of-date regulatory framework, regulatory reform for nanomaterials in the US has been linked to broader debates about the need for general TSCA reform.

Even though there is little public controversy over nanomaterials, CSOs see themselves as representing an often absent public interest. When the need to regulate

nanomaterials was not yet even an issue, CSOs were the first to point out that, there might be consequences from the use of nanomaterials. They also highlighted the fact that regulation was absent or not adequate and that something needed to be done. In the EU, CSOs raised awareness and expressed their concern at the EU level. CSOs acted as agenda setters, because there was not really a discussion about nanotechnology as a regulatory issue in either the US or EU prior to 2000. As an environmental advocacy organization representative told me, "Everybody thought that it is regulated already, and Europe should be taking advantage of the opportunities" (J. Vengels, personal communication, February 4, 2011).

In the US, CSOs were the first to bring attention to the possible risks that nanomaterials might pose to human health and the environment. CSOs were also the first group that addressed the lack of regulation and the assumption made by the government and industry that nanomaterials were covered by existing regulation. They have played a central role in working with some members of the Democratic Party who have agreed to initiate legislation for broader TSCA reform. However, their role is one of unofficial advocacy organizations who identify a public interest and attempt to find members of Congress who are willing to support the issue. In the US, the debate over nanomaterial regulation was attached to, and in some cases over-shadowed by, the debate over the reform of TSCA for all chemicals, which has been a more prominent issue affecting nanomaterials. While nanomaterials remain mostly unregulated, some CSOs have tried to use them as a way to shift focus for TSCA reform.

In summary, the EU structures present a case where CSO participation is more official and apparent, where the structures actually are built in such way that participation by CSOs is easy. Also, the European Green Party in the EU has close relationships with the CSOs, and the Parliament has adopted a position (similar to that of CSOs) opposite to that of the Commission on the issue of the regulation of nanomaterials. In the US, such relationships are not apparent and chances for participation in the debate are less fixed. This dissertation will explore the role of CSOs, their participation and influence in these political settings, and draw conclusions about the implications that such political structures have not only for the participation and influence of CSOs but also for policy outcomes.

1.2 Research Methods and Data Analysis

My original research questions were based on the assumption that nanotechnology policy in the EU was more advanced than in the US and that one of the factors that explained the difference might be the role of CSOs in the policy process. However, as the project evolved, I came to focus more on the problem of policy stasis and the extensive under-regulation that appears in both countries. Thus, my questions evolved to the following:

1. What are the central differences in political process, governmental structure, and CSO participation for nanotechnology regulation in the EU and the US?
2. What explains the relatively high level of formal CSO involvement in the EU policy process for nanotechnology regulation?

3. What are the similarities and differences in policy outcomes in the US and EU?

4. What factors account for the continued policy stasis on the regulation of nanotechnology in both the US and EU?

Because this study takes a comparative approach by looking at the US and the EU, I explored the stakeholders involved in reforms and discussions that take place. Although I conducted research on nanotechnology regulation in the US, my research was more extensive in the case of the EU. This is because I spent more time in Brussels, where most of the nanotechnology debate is taking place in the EU level. In the US the debate is more decentralized, and more activities are taking place in the state level. In this research, CSOs, including environmental NGOs, think tanks, and trade unions were considered as important stakeholders.

The study was based on data collected through the analysis of policy documents, semi-structured interviews, participant observation, and secondary sources. My main European site and where I spent more than four months was Brussels, where the European government bodies are based (European Commission, DG Environment and DG Enterprise, and the EU Parliament), and where many environmental organizations have their offices. In the US, my main field site was Washington, DC, where the EPA offices are located and where many environmental organizations have their offices. In addition to the document analysis, it was necessary to conduct interviews, because the nanotechnology debate was not a well-known and well-documented controversy. Furthermore, it was not clear from publications and other written material who the stakeholders were, especially in the EU. I used the interviews as a way to guide me to the

main actors involved in the debate. For example, many times CSOs will participate in a petition for a nanotechnology issue, but otherwise they are not really active on the issue.

1.2.1 Document Analysis

Because nanomaterials fall under the jurisdiction of regulations associated with different industrial sectors, I limited my analysis to documents that had a focus on REACH or general issues of nanotechnology regulation in the EU and on TSCA in the US. Nanomaterials have many applications, and thus there are documents on their regulation under different frameworks. These documents would offer valuable data as well, but by limiting the analysis to only REACH and TSCA my research I was able to make a focused comparison and identify key differences between the US and EU in the area of chemical regulation. For the purposes of this project, I reviewed a variety of documents concerning nanotechnology regulation, from existing official policy documents to blog posts, with attention to the broader cultural frameworks, such as the relative role of precaution and industry respectively, in which different policies develop their values and their influences. As mentioned above, my study was not limited to just formal policy and governmental documents but also included environmental organizations' reports, reports from panels, conference proceedings, and workshop meetings, as well as official web pages and blogs. Analysis of policy documents was focused in two areas: documents and reports from governmental bodies and agencies, and documents and reports from environmental organizations and other interest groups involved in nanotechnology and chemical regulation. In both areas, important documents

were accessed from official websites.

In the US case study, policy documents, such as Congressional testimonies and legal texts, were retrieved from the Congress and the House of Representatives official web pages. Also, policy documents were accessed through EPA's official web page and from the TSCA Reform Center web page. Additionally, great attention was given to the reports and blog posts of environmental organizations active in the case of nanotechnology and chemical regulation and reform. Many environmental organizations publish reports and maintain blogs on the issue. In the case of TSCA reform, part of the research and review of environmental organizations' reports and blogs took place during the summer of 2009, while I was a fellow at the Chemical Heritage Foundation. At that time, I reviewed posts and reports by three organizations: the Environmental Defense (EDF), the Friends of the Earth (FoE), and the Project on Emerging Nanotechnologies (PEN). I also reviewed Congressional hearings concerning the reform of TSCA and where CSO representatives testified. The CSOs on which I focused were chosen to be analyzed because they were the ones most involved in nanotechnology regulation. EDF, in particular, is very active, and the EDF's senior advisor on chemical issues, Richard Denison, maintains a blog about chemical and nanomaterial regulation. Also, PEN was one of the first CSOs to work on nanotechnology regulation issues and has produced numerous reports on TSCA and how it might cover nanomaterials, with suggestions on how TSCA can be reformed.

For the European side of the research, I began my document analysis at the Commission's official web page. I accessed many documents on policies that the

Commission developed for nanomaterials. The second location that I visited was the European Chemical Agency's (ECHA) web page, where I found all the policy and legal documents of REACH. Both the Commission's and ECHA's web pages are easy to access, and they have all the documents, proceedings, and minutes from expert and technical panel meetings, as well as fact sheets. I focused most of my analysis on documents that came from the DG Environment and DG Enterprise, the two Commission's divisions that are responsible for REACH. Activities and documents were also accessed from other divisions of the Commission, such as, for example, the division responsible for health and consumer protection, also known as DG SANCO, which is not involved in the REACH regulation but has jurisdictions in other sectorial regulations that cover nanotechnology. The work of the division was of interest to my research because of the public dialogue on nanotechnology regulation that the DG SANCO, the Commission's division dedicated to protect health and consumers, organizes every year.

I also paid attention to the reports produced by the EU Parliament, which has been heavily involved in the debate about nanotechnology regulation and usually opposes the EU Commission. The Parliament's role in the nanotechnology debate is very interesting and of great importance, something that became clear during my fieldwork in Brussels. I also extensively analyzed the publications, presentations, and conference proceedings of the NanoCap project, the starting point of the CSO involvement in the discussions about nanotechnology regulation in the EU. It took place between 2006-2009, and all materials available from the project's webpage and all materials connected to it, such as the resolutions, reports, and publications that CSOs produced because of their participation in

the project, were analyzed. Finally, I analyzed the relevant regulation reports and blog posts from CSOs' official web pages. As mentioned above, I focused mostly on CSOs that are active at the EU level. I analyzed the publications of the European Environmental Bureau, the big umbrella organization with which most local European CSOs are affiliated. I also looked at the publications of The Center of International Environmental Law (CIEL), an international environmental organization based in Geneva that is very active in the nanotechnology debate in EU level, as well as the publications of the European Trade Union Confederation (ETUC), the umbrella trade union organization for EU local trade unions who is very active on issues of nanotechnology regulation.

1.2.2 Semi-structured Interviews

I conducted over 40 formal interviews and I had many informal conversations with stakeholders involved in the regulatory debate. Most of the questions revolved around the issue of participation, the relevant role of CSOs, and the relevant role of the political bodies and structures in affecting participation. Some questions are focused on specific frameworks and regulatory issues for nanomaterials within REACH and TSCA. Finally, some comparative questions about differences between the EU and US were also asked. The interview questions changed as the project developed and as I gained a more thorough understanding of my cases. The interviews were semi-structured, so many times I changed or developed questions on the spot based on my informants' replies. However, all informants were asked similar questions in order to create a point of reference and accurate comparison.

I started the interviews in the US, where I initially had interviews with two people from American CSOs involved in the debate. The interviews included representatives from FoE and PEN. After these first interviews, which took place in the summer of 2009, I visited Washington, DC, and with the help of my external committee member, I conducted interviews with five EPA employees involved in the regulation of nanomaterials under TSCA. I did not have much difficulty contacting people in the US, but initially I did not find more people granted interviews. For example, EDF representatives refused to talk to me initially, directing me to their organization's web page for more information.

Difficulties in the US with obtaining interviews was nothing compared to the resistance I found in Europe. In 2010, I traveled to Europe to start my fieldwork. In July, again with the help of my external committee member, I traveled to Paris and had three interviews with key stakeholders from the DG Environment involved in nanotechnology regulation at EU level. After completing these interviews I had confidence that my trip to Brussels and the continuation of my research would be easy, as it was mostly CSOs that I would be interviewing. After the trip to France, I had a summer fellowship in the European Environment Agency (EEA) in Copenhagen. I debated about whether or not to go, but I fortunately did, because this fellowship was the key to being able to conduct my research. In Copenhagen, I worked with someone very important who was respected by all the European CSOs. David Gee had been working on occupational health and environmental issues for years and was well connected and respected by each and every CSO, as well as people in the government. His name was the key to opening doors for my research. With him I worked on a project about REACH, and at the same time I learned

who the important stakeholders involved in the nanotechnology debate were, and I tried to make contact and connections with them.

After Copenhagen, I moved to Brussels, where I tried to schedule interviews for my research. This was quite a difficult task, especially with the CSO representatives. The people did not know who I was and why I wanted to talk to them, plus they had limited time to spend talking to someone they did not know. In the beginning of my fieldwork I tried to contact people from the EU Parliament. I had no luck on my own, but using Gee's name, one of the most important stakeholders in nanotechnology regulation (the European Green Party's consultant from the EU Parliament) scheduled an interview. This was fortunate, because the interview was so revealing that it changed the way I was thinking of my project and my idea of what I thought it was happening in the field. I realized that there is a tension between the EU Commission and the EU Parliament on the issue of nanotechnology regulation. These two political bodies have opposite opinions on how nanomaterials should be regulated. I also realized that the European Green Party has very strong connections with European CSOs. After that, a few other people talked to me because I knew David Gee, and then it was again a dead-end. The CSOs did not respond to my requests for interviews.

However, before I left Copenhagen I met with a local CSO to discuss the project I was doing in the EEA at the time. The person I talked to informed me about a meeting in Brussels where all the European CSOs talk about REACH chemicals and nanomaterials. With David Gee's recommendation, the event organizers let me attend as a representative of the European Environment Agency (EEA). Through contacts made at

that meeting, I was able to talk with everyone who was involved in the nanotechnology debate at the EU level. I was also able to conduct more interviews with officials from the DG Environment and DG Enterprise. I conducted eight interviews with employees from the governmental bodies, more specifically the EU Commission, the EU Parliament, and twenty interviews with CSO representatives.

In April, 2011, I returned to the US and conducted more interviews in Washington, DC, mostly with CSO representatives. I also interviewed the staff of Senator Lautenberg, one of the leading politicians who was working towards the reform of TSCA, having introduced several new legislative frameworks to overhaul TSCA. In 2012, in the light of some new findings that came about in my research and while I was writing this dissertation, I conducted three more phone interviews with individuals in Europe. I again went back to Washington in March, 2012, and conducted three more interviews with individuals working on nanotechnology and chemicals with whom I had been not able to get in touch prior to my trip to Europe. In the US, I conducted eight interviews with employees in governmental bodies (EPA) and senator employees and six interviews with CSO representatives in total. In summary, I conducted 31 interviews in the EU and 14 interviews in the US.

1.2.3 Participant Observation

I was also able to observe several sites of interest to nanotechnology in Brussels. The first was the second annual meeting of the European CSO nanotechnology working group and chemical working group. This is where I initially learned how CSOs

work, what they think is important to their work, and what strategies they used to overcome their lack of resources. I realized how closely trade unions and environmental NGOs were working together on chemicals and nanotechnology issues: when I asked who was active in the nanotechnology debate, they said that I should talk with the trade unions. This was a remarkably different situation from the US, where there was trade union involvement in general environmental issues under the Blue-Green Alliance but not for nanotechnology regulation (Hess, 2012). In March, 2011, I attended the REACH in Practice conference, organized by the Academy of European Law. The conference was about REACH and how it has performed during the five years it has been in practice. The conference was of particular interest to me because I could observe the positions of four very important stakeholders: CSOs, the EU Commission, industry (through lawyers), and the EU Parliament. It was also interesting because this observation happened towards the end of my fieldwork, when I knew all the stakeholders and it was easy for me to observe and keep notes. I focused on observing the interactions among the different stakeholders and how they framed the regulatory issues with regard to relevant themes, like risk and precaution. I also was lucky enough to sit next to the European Green Party's representative and the CSOs representatives during lunch and hear their informal conversations. Through this I learned which groups were working together, how they were going to act together on certain regulatory issues, and finally how they share information with each other.

Finally, in March, 2011, I attended the 4th Annual Nano Safety for Success Dialogue, an open discussion meeting where many different stakeholders discuss

nanomaterials and their regulation. The workshop was organized and run by the EU Commission, particularly the health and consumer protection division of the EU Commission (DG SANCO). Again, this workshop was an opportunity for me to observe how different stakeholders discussed issues of nanotechnology regulation, what their positions are, and how much power they have when pursuing them.

1.2.4 Secondary Sources

As I was analyzing my data and as I was framing my research with theory, I realized that the nanotechnology debate presented interesting differences when compared to the GM debate that took place during the 1980s in the EU. The two debates are similar because they are about highly technical issues; however, they took completely different routes. In order to explore this aspect and compare the two debates, I gathered data from secondary sources. In particular, I used the published work of Les Levidow and his collaborators as sources (Levidow & Carr, 2007, 2009; Levidow & Marris, 2001; Levidow, Murphy, & Carr, 2007; Levidow, 1998, 2009). The specific reason that I chose this scholar and his work was because he has extensively explored the GM debate in the EU and the implications this debate has had on issues connected to democracy and expertise. He also explored in depth the role that CSOs played in the GM debate. Finally, I found the argument he makes about the GM controversy in Europe very compelling and related to what I have observed on the nanotechnology debate within my research. These issues made his work appropriate for me to use as a secondary source. During the collection of secondary data I focused on identifying the main events that took place

during the GM controversy, the groups that were involved, and the relative role that governmental bodies played in the debate at the time. I compared this data with the data had I gathered from my research on the nanotechnology debate.

1.2.5 Data Analysis

After the interviews were transcribed, I analyzed all the material (documents, interviews, notes from participant observation, and secondary sources) by organizing it according to the major themes I was exploring, with keyword coding and indexing evolving from the research questions. I initially organized the material according to the different groups involved in the nanotechnology debate, for example, CSOs, EU Parliament, Commission, Council. Then I coded it using themes such as participation, expertise, REACH, and implementation. I did the same for the US case study. From the analysis of the documents, I extracted conclusions about what was driving the policy discussion. Through the interviews, I compared the arguments and reconstructed the histories of these debates. Finally, I drew conclusions about what the conflicts were, what the modes of participation were, and what the role of political structures and expertise was in the discussions of policy developments and in shaping and affecting CSO participation. When analyzing the comparative aspects of this project, I looked at what appeared to be different and what appeared to be similar in the different debates and the different political structures. I identified the debates and the compromises, power issues, and the role of participation; in particular I used the data I had accumulated through participant observation to accomplish this. I also identified the role of deliberative

institutions, the role that new technoscientific developments and their regulation can play in policy making, and the extent to which public participation is valued and used.

1.3 Chapter Outline

Chapter 2 is the literature review chapter entitled, "Conceptualizing Nanotechnology Governance." In this chapter I position my argument within the STS and broader social science literatures. I examine first the normative, policy literature on what regulation is needed ideally, then I discuss the empirical social science literature on public participation. The literature on public participation includes various forms of technology assessment and deliberative institutions such as consensus conferences, as well as participatory research. I show that many researchers have drawn skeptical conclusions about the effectiveness of deliberative mechanisms that rely on lay public participation. Instead, I turn to the literature that views CSOs as an alternative approach to public engagement in science and technology policymaking. Finally, I look at the comparative policy literature, which tends to emphasize how differences in policy cultures and governmental structures lead to differing policy results. Because my results point to a similar condition of policy stasis with different cultures and structures, I finally turn to the literature on industrial power and the scientization of regulatory politics. Thus, I contribute to a strand of STS literature that focuses on public participation associated with mobilized publics or social movements, and I contribute to the comparative policy literature by showing how industrial power can be so overwhelming that significant structural and cultural differences do not make much difference in policy outcomes.

Chapter 3 describes the nanotechnology debate in the US and the involvement of CSOs, other advocacy groups, and think tanks in the procedures of nanotechnology policy at the US federal level. In particular, this chapter attempts to answer three questions: what CSOs including environmental advocacy groups and think tanks advocate, how they advocate, and what their successes are. The chapter focuses especially on TSCA, the framework that regulates bulk chemicals in the US, and it concludes that CSOs utilize multiple pathways to achieve their goals: lobbying Congress, involvement in regulatory rule-making, litigation and judicial review, and petitions. Although CSOs have achieved some regulatory results, the central goal of TSCA reform and a comprehensive approach to nanotechnology regulation has remained elusive.

Chapter 4 describes the nanotechnology debate in the EU and the involvement of CSOs, including various types of environmental NGOs, and trade unions in the procedures of nanotechnology regulatory policy at the EU level. This chapter focuses on the same three questions as the previous chapter: what CSOs, including various types of environmental NGOs and trade unions advocate, how they advocate, and what their successes are. This chapter revolves around REACH, the framework that regulates bulk chemicals in the EU. As in the previous chapter, this chapter also gives background information about the way legislative and regulatory policy is developing at the EU level. The chapter concludes that the EU political structures give many political opportunities for CSOs to participate in nanotechnology regulatory policy making at the EU level. CSOs benefit from a division in the European Commission (DG Environment) dedicated to their causes, from EU funding, and from a European Green Party that has abilities to

influence the opinion of the EU Parliament, which is co-legislator. However, besides one request, CSOs have not had much success in influencing policy outcomes.

The fifth chapter, "Comparing the US and the EU Nano Cases," compares the two cases at five main points. It compares the laws, decision making processes, advocacy groups, debates, and levels of public participation in the US and the EU. From this systematic comparison, the chapter concludes that the main difference between the EU and the US is the way the policy and political systems work. The EU and US develop laws and implement them differently. In the US, EPA is a more independent body when it comes to implementation and states do not have a big role in implementation activities. In the EU, the European Chemical Agency (ECHA) is dependent on the Commission, and the member states play a prominent role in the implementation decisions and processes. There are also differences in the ways and opportunities for CSOs to participate. In the US, CSOs find more opportunities when they work on the state level. In the EU, there are many more opportunities for CSOs at the EU level, including official positions in expert groups and boards and many places to lobby, most prominently the EU Parliament and its European Green Party. Surprisingly, however, the two debates present similarities, especially in what the advocacy groups request and the regulatory outcomes.

Chapter 6 explains why the EU political structure enables more official participation for CSOs. The chapter begins by comparing the GM debate in the EU with the nanotechnology debate. Whereas the GM debate was shaped by the intensive European integration procedures, the nanotechnology debate happened towards the end of these events, and it was shaped by procedures for the development of a more

transparent and open more democratic European governance structures, with official participation of more stakeholders, including CSOs. These procedures have changed not only the CSOs' advocacy styles but the CSOs themselves. The chapter goes on to explore the NanoCap, a participatory project funded by the EU Commission in order to build the capacity of CSOs to participate meaningfully in the discussions about the regulation of nanomaterials at the EU level. The project was very important in building the knowledge of the CSOs, and also in shaping their opinions on nanotechnology. Finally, the chapter explores the role of the European Green Party in creating political opportunities for CSOs. The European Green Party is a very important ally because it has an opinion similar to that of CSOs and can influence the opinion of the whole Parliament. None of these characteristics of the EU are present in the US. The chapter also looks at why the two debates have similar results. It seems that even though CSOs have more opportunities to participate in the EU, they have the same outcomes as CSOs in the US. This is because CSOs in the EU have expressed moderate opinions about the regulation of nanomaterials and have employed professional approaches in pursuing such requests. The fact that they can participate officially has diminished their radicalism. The debate also is more focused on the implementation level, which is more technical. CSOs do not have the resources to compete with the industry and they are not permitted to make non-scientific arguments.

1.4 Conclusion

The debate over the regulation of nanomaterials in the EU and the US is ongoing.

This dissertation offers just a glimpse of the history of the debate, which gives an opportunity to explore political structures and how they affect participation and policy outcomes in the two political systems. The EU is more open to participation. Its political structures, especially the EU Parliament's European Green Party, offers more political opportunities for the CSOs to participate and influence policy developments. However, the EU political structures shape the type of participation in a way that positions CSOs against industry, whose resources they cannot match.

In the US, the structures are less open to CSO participation, and CSOs rarely have broad support from inside the structures, especially in the federal level. This is why many CSOs prefer to work at the state level. Even though official participation exists, in the EU policy making, outcomes favoring the CSOs come only when the latter get the support of the EU Parliament behind their requests. Even then, the results seem to be shaped by pro-industry demands. In both the EU and the US, nanomaterials remain unregulated, and the legislative and regulatory bodies keep the issue at the discussion level and favor the requests of the industry. The finding that regulatory policy for nanotechnology in the EU is not fundamentally more comprehensive than in the US raises questions about the EU's precautionary approach to regulation. It also undermines the assumption that more political participation and openness to participation from groups such as CSOs leads to more influence in pro environmental policy developments. The fact that regulatory frameworks may be based on the precautionary principle and the fact that high levels of political participation by CSOs may exist does not directly translate to pro-environmental

regulatory policy outcomes. The conclusion will discuss my explanation of why such different political structures and governance process have led to such similar outcomes.

2. Conceptual Frameworks for the Study of Public Participation and Regulation

Studies of nanotechnology regulation and public participation can be divided into two broad groups. Policy scholars have pointed out that existing frameworks for the regulation of nanotechnology are inadequate, and they have proposed various strategies to achieve better regulation. This work is mainly prescriptive in the sense that it focuses on how governments can develop better nanotechnology regulatory frameworks. In contrast, STS researchers have focused on exploring and proposing changes in governance processes, especially public participation and frequently in comparison with the GM controversy. My project builds on both types of approaches, but I am particularly concerned with the role of CSOs in the governance of nanotechnologies. Although CSOs claim to represent a broad public interest, they are mobilized publics rather than individualized, lay publics that are often the topic of inquiry in studies of public participation and technology regulation (Hess, 2011). I am also interested in the comparative dimensions of CSO participation, an issue that requires a discussion of the broader literature on the comparative analysis of political institutions and their effects on policy outcomes. Of the comparative studies of political institutions and policy outcomes, the most relevant literature is the study of the comparative studies of different political structures and social movements. However, because comparative institutional differences were significant but policy outcomes were similar, the literature on industrial influence on regulatory power also became relevant. Thus, four major literatures were relevant for this research project: prescriptive analyses of nanotechnology policy, studies of public

participation in nanotechnology governance (including deliberative-participatory and social movements approaches), comparative research on public participation and regulatory policy, and studies of industrial power and regulatory policy.

2.1 Prescriptive Scholarship on Public Policy

The regulation of nanomaterials has primarily been an issue for developed countries. The US and the EU are in current discussions about how to best regulate and govern the development of the technology and its products. The main problem faced with the regulation of nanomaterials is uncertainty, and both the EU and the US have been faced with knowledge gaps, which they have attempted to fill by funding research on "EHS" or environmental, health, and safety dimensions of nanotechnology (Frickel, 2008; Hess, 2010). The attempts to regulate nanotechnologies through existing frameworks highlight the lack of scientific knowledge known about the risks, as well as the lack of knowledge about what nanotechnology products are on the market. Policy scholars suggest that by unifying the ways risk assessment and management are discussed, and by involving the developing countries, the gradual development of global governance will be able to respond to the risks posed by nanotechnologies in a flexible and informed way (Robert Falkner & Jaspers, 2012).

Whereas advocacy groups and activists push for strict regulation, regulators struggle with the problem of balancing innovation with regulation, especially in cases where there is limited knowledge. Regulators are confronted with the dilemma of developing premature regulations and preventing the introduction of valuable products

and services or being too late to develop regulation, which would result in losing the confidence of the public and possibly exposing the latter and the environment to risks. Policy researchers suggest that a regulatory framework should be flexible and adaptive and, because of insufficient knowledge, it should be innovative (Abbott, Marchant, & Sylvester, n.d.). Approaches should not be traditional and should include guidelines for working practices, gathering of information, and also disclosure (Bowman & Hodge, 2006). Also, regulatory processes should include cooperation between the industry and scientific experts. Finally, the framework should be an international one, with a harmonized approach (Abbott et al., n.d.). If there is a need for an international agreement, previous frameworks can be used, but they will have to be modified (Marchant & Sylvester, 2006).

Nanotechnologies present a variety of complex policy and regulatory challenges for both industry and government. For example, Bowman and Hodge (2007) have concluded that the regulatory debate will evolve around issues such as environmental and international law, intellectual property, product safety, and occupational health and safety. At the moment, the existing laws form the immediate response to the regulatory needs, and problems in regulating nanomaterials properly are increasingly becoming apparent, while no development of regulations specific to nanomaterials law has taken place. In the future, Bowman and Hodge suggest, regulatory gaps of existing frameworks will be magnified at the international level. Thus, nanotechnology requires the re-evaluation of the existing frameworks and provides an opportunity to overcome the difficulties experienced in the past in regulating new technologies.

Jaspers (2010a) adds that regulatory developments could combine scientific freedom, technological innovation, and the responsible development of the technology. These same challenges are present in the attempt to regulate nanotechnologies internationally. Once again, the existing models are not up to par, but they can at least teach important lessons. By examining existing frameworks, it becomes evident that there is a burden that comes with balancing the beneficial uses and possible risks. Additionally, CSOs will play an important role in the development of new technologies and should be involved in the discussions. It is likely that nanotechnologies will require a new model and approach. If there is a need for an international agreement, previous frameworks can be used and adapted to nanotechnology (Marchant & Sylvester, 2006).

Several policy scholars argue that the development of international agreements on sound scientific risk assessments is of great importance in achieving that goal (Breggin, Falkner, Jaspers, Pendergrass, & Porter, 2009; Falkner, Breggin, Jaspers, Pendergrass, & Porter, 2010). Also, governments should close existing knowledge gaps by advancing risk related research and establishing a market register so the governments are aware of the nanomaterials on the market. All of these approaches should be also addressed in a harmonized manner by also considering the development of common standards of labeling in order to avoid international marketing problems (Breggin, Falkner, Jaspers, Pendergrass, & Porter, 2009; Falkner et al., 2010). Even though neither the US nor the EU has yet developed general rules for the labeling of nanotechnology products, some labeling may apply to such products. Because the two governments have different approaches, the governments should consider the implications of such criteria in

international trade (Falkner, Breggin, Jaspers, Pendergrass, & Porter, 2009).

One of the questions concerning nanotechnology is how regulators can achieve responsible development of nanotechnologies while increasing public trust and safety and avoid ineffective regulation. Because the technology is surrounded with uncertainty, until more is known and research has been conducted, researchers suggest that regulators should identify the most important points of uncertainty and develop mechanisms to reduce such risks. Something else they suggest is to avoid using size criteria, especially for risk managing processes. This is because nanotechnology is more complex than the size and such an approach is unlikely to lead to useful results (Jaspers, 2010b).

Finally, some of the research on how to improve nanotechnology policy builds on comparisons with biotechnology policy. Even though a comparison between the two debates is complex, scholars are searching for lessons from biotechnology that can be used as an example of failure to regulate and to govern new technologies in the early stages of their development (Einsiedel & Goldenberg, 2004; Kearnes, Grove-White, Macnaghten, Wilsdon, & Wynne, 2006; Mehta, 2004). For example, Kearnes and colleagues (2006) state that government and industry should acknowledge the inherent limitations of risk assessments and to look instead at broader sociocultural process and public involvement. Mehta (2004) is among the researchers who point out that the failure to regulate appropriately is due to the fact that the governments did not involve the public in decision making. He observed that the use of substantial equivalence[1] to regulate genetically modified (GM) food products and to distinguish the process from the product

1 The "substantial equivalence" principle states that when a new food or food additive is substantially equivalent to an existing food or food additive then no additional safety investigation should take place, and it should be treated as if is the same as the existing food or additive.

excluded the public from participation. This might also happen with nanotechnology if similar procedures of scientific based assessments are used. Other comparative research between nanotechnology and biotechnology points to involvement of the public as well (Einsiedel & Goldenberg, 2004). However, Sandler and Kay (2006) have argued that the two debates might not be analogous, and their comparison can lead to shallow observations about the lack of public engagement, because participatory mechanisms frame the issue so as to how to avoid a specific public response (Sandler & Kay, 2006).

In summary, policy research in a prescriptive mode points to two general conclusions: there is a need for better regulation of nanotechnology, and achieving the better regulation requires higher levels of public participation and greater openness of governance processes. The next two sections will discuss two approaches to governance: technology assessments and associated deliberative processes, and social movements.

2.2 Participatory and Deliberative Approaches

By 2020, nanotechnology is expected to reach mass production, and some have argued that in order for these challenges to be addressed successfully, governance approaches should include accountable, anticipatory, and participatory mechanisms and use real-time technology assessment (Roco, Harthorn, Guston, & Shapira, 2011). Thus, the regulation of technology is not simply an issue of finding the appropriate technical guidance for the safe production, use, and disposal of nanotechnology; regulation must also involve public participation processes and governance processes that create public trust and confidence. This issue can be described as “risk governance,” with the caveat

that there is an STS literature that is critical of the technocratic approach to risk and argues instead that broader concepts such as uncertainty and ignorance are needed, as well as a precautionary framework (Wynne, 2002, 2005). Researchers have argued that the politics of new technology (how it affects the social world, and who benefits and who gains by those social changes) are excluded from risk-centered decision-making (Kinchy, Kleinman, & Autry, 2008; Kinchy, 2012; Kleinman & Kinchy, 2007; Kleinman & Kinchy, 2003).

Risk governance of nanotechnologies includes "the totality of actors, rules, conventions, processes, and mechanisms concerned with how relevant risk information is collected, analyzed and communicated and management decisions are taken" (Renn & Roco, 2006, p. 156). In my view and that of most researchers who study nanotechnology policy, risk governance processes today are not adequate for governing the possible risks of nanotechnologies. The case of nanotechnology is quite different from other technologies because of the degree of speculation and the variety of possible applications and impacts (Sarewitz & Guston, 2004). In order to create a better governance system, there is a need for research to assess EHS issues accompanied by full disclosure and transparency and the identification of possible hazards and exposures through scenarios, but there is also a need to involve the stakeholders in open governance processes that define the questions to be determined by EHS research. Sound regulatory policy and effective public participation require that there is independent research from organizations such as universities, full public disclosure of chemical hazards and risks from industry, transparent oversight procedures and participation mechanisms from the

government, and channels of communication with the public and other stakeholders and also facilitate public participation (Renn & Roco, 2006). Industry has also initiated self-governance structures, with guidelines and frameworks that can be described as "soft law." Due to the lack of appropriate "hard" regulation, initiatives such as private governance will be part of a hybrid regulatory regime, with the involvement of the private and public sector. According to Bowman and Hodge, "the successful governance of nanotechnology is therefore likely to require knowledge of the inherent limitations associated with many different forms of regulation, and a combination of different instruments" (2008, p. 484).

STS scholars have developed an approach to nanotechnology called "anticipatory governance," under which "effective action is based on more than sound analytical capacities and relevant empirical knowledge" (Barden, Fisher, Selin, & Guston, 2008, p. 991). The term "anticipatory" is understood as an awareness of "the co-production of sociotechnical knowledge and the importance of richly imaginative sociotechnical alternatives," and the term "governance" is understood as management of technological change from the bottom up, rather than from the top down (p. 992). The activities are diverse and consist of the ability of lay and expert stakeholders to imagine, critique, and shape the issues posed by emerging technologies, like nanotechnology, at early stages of development. Anticipatory governance can incorporate plausibility as an important catalyst for initiating discussions in future deliberations. This is especially true in the case of nanotechnologies, where implications are still unknown (Selin, 2011).

Anticipatory governance in turn is part of a broader family of approaches to

technology governance known as technology assessment (TA), or a set of activities that vary from very technocratic to participatory and focus on guiding technological innovation to produce desirable societal outcomes. Arie Rip (2008) utilizes the concept of Constructive Technology Assessment (CTA), a type of TA that was developed in Denmark and the Netherlands and focuses on improving the design, development, and implementation of new technologies (Schot & Rip, 1997). Rip has also coordinated many programs focused on applying CTA for nanotechnology assessment. One example is the NanoNed, a consortium of Dutch institutions working on nanotechnologies, where a team, working with Rip, explored expectations, built agendas, and developed exercises using socio-technical scenarios (2005). CTA scenarios can be helpful in adjusting to continuous socio-technical changes (Rip & Kulve, 2008).

According to Sarewitz and Guston (2002), the most promising type of TA for nanotechnology assessment is Real Time TA (RTTA), which consists of various exploratory aspects, such as communication and early warning, technology assessment and choice, research program mapping, and case studies in order to inform research and provide a way of critiquing and influencing social values. They argue that Real Time TA is a promising tool because its case studies may "encourage contextually sensitive innovation" (2002, p. 109). As they comment,

> Its research program mapping improves opportunities for strategically oriented innovation. Its communication and early warning component helps assure awareness about innovation among researchers and the public, and its technology assessment and choice component provides a mechanism for such awareness to be

reflexively incorporated into innovation (Guston & Sarewitz, 2002, p. 109).

Another type of TA, Participatory Technology Assessment (pTA), involves the participation of lay people and is characterized by intensive cognitive and deliberative demands. The participants must read and understand a significant amount of material and must then achieve consensus (Guston, 2011). One example of a pTA is the National Citizens' Technology Forum (NCTF), conducted in 2008 by the Center for Nanotechnology in Society at Arizona State University. The project involved a number of citizens from six locations who discussed and deliberated on various issues related to nanotechnology and human enhancement. The results of the project showed that citizens want to be involved in discussions about technology developments, especially if they feel that these technologies might have an impact on their lives. Although citizens are supportive of the development of new technologies, they also ask for more information. If they are informed and assisted by experts, they can have an insightful input in decision making procedures (Hamlett, Cobb, & Guston, 2013).

Even though the various pTA projects are promising, scholars have raised concerns about implicitly imposing their own set of values, arguments, views, and proposed actions of participation—essentially a romanticizing picture of participation—on the participants. Researchers have suggested that in order to "make the participatory approach more reflective and critically discursive, pTA must acknowledge power dimensions in participation such as conflict, politics, and bargaining, and it must expose participants' different ways of seeing and acting if 'participation' is to incite mutual learning beyond the interests of dominant actors" (Van Oudheusden, 2011, p. 687). In

response to such critiques, supporters of such projects argue that pTA is a form of engagement, and the NCTF project in particular was designed to demonstrate the possibility of large scale citizens' deliberation. Even though the NCTF did not have an impact in policy for nanotechnology, researchers think that it will soon mature and contribute politically on a greater scale (Guston, 2011).

A related approach to TA involves mechanisms developed from the deliberative tradition of governance, which in turn is based on Habermas's (1991) concept of the public sphere (see also Fraser, 1996). Against the ordinary argument that the lay citizens have neither the competence nor the passion to be involved in policy discussions, advocates of broad deliberative practices argue that given a chance, the public assimilates and integrates enough information to reach a well-reasoned collective judgment (Sclove, 1995). Consensus conferences have been the leading example of deliberative mechanisms of governance. Originating in Denmark in the late 1980s and developed to assist public participation in the debate about GMOs, consensus conferences have traveled the globe and adapted to different cultures and subjects (Einsiedel, Jelsøe, & Breck, 2001; Kleinman, 2000; Kleinman, Powell, Grice, Adrian, & Lobes, 2007). During the consensus conferences lay citizens who are invited to apply, are given enough information about a technology in order to be able to assess it. The citizens address their questions to experts who give them all the views on the issue. The final product is a report of policy suggestions. There are various discussions on the limitations and potential of deliberative institutions, both for environmental issues in general (Hess, 2010; Wynne, 1996) and for nanotechnology policy more specifically (Hodge, Bowman,

& Ludlow, 2007; Powell & Keinman, 2008; Rogers-Hayden & Pidgeon, 2007; Toumey, Reynalds, & Aggegelopoulou, 2006). Consensus conferences have been seen as a model for deliberative democracy, however, they are not without their limitations.

Deliberative types of citizen involvement have many positive aspects, such as enriching citizens' knowledge about scientific and technical issues, making them more informed, empowering them with the ability to participate, and involving them more in policy development; however, they present serious limitations (Einsiedel et al., 2001; Kleinman, 2000; Kleinman et al., 2007). Most research on consensus conferences and other deliberative institutions such as town hall meetings has shown that they have a limited impact on policy development. One of the critiques is about the fact that these projects maintain a division of labor, expertise, and power between lay and expert knowledge (Hess, 2011; Kleinman, 2000). There will always be lay people and there will always be experts who will educate the lay people. It is taken for granted that the task of technology assessment primarily depends upon the professional and technical skills of research scientists. As a result, the hierarchical difference between lay and expert knowledges and the power that comes with that knowledge is maintained (Kleinman, 2000).

Irwin (1995) has also argued that the gap between lay and expert knowledge is an obstacle to democratic participation in decisions about science and technology policy making. In most of the types of public participation, citizenship, in the sense of the right to participate in democratic procedures, begins only when experts have set an environmental agenda (ibid.). In order to fill the gap between the two knowledges and to

achieve democratic participation that is not characterized by a division of labor, Irwin argues for a citizen science that will be willing to engage with non-scientifically generated understanding and expertise. He describes this science as heterogeneous in form, prepared to engage with the problem situation, reflexive, and institutionally flexible and open to change.

The most important critique of participatory projects is that there is a lack of connection between deliberative institutions and public policy (Hess, 2011; Wynne, 2005). Even in the case of the Danish consensus conferences, which have been used as a model case for other countries, policy results are not the ones expected. Up until 2005, the year of the last consensus conference in Denmark, no recommendation has been turned into policy (Horst & Irwin, 2010). Deliberative projects are also financially difficult to scale up, and even if there was a possibility of doing so, any policy recommendations would likely encounter serious resistance from the mainstream policy regimes and not have impact on policy outcomes (Hess, 2011). Einsiedel and colleagues (2001) have shown that reports resulting from such attempts have not achieved much beyond the limited media attention. Because consensus conferences and related forms of public consultations do not have a connection with policy outcomes, they only play the role of informing the policy regimes of the public opinion. However, their effectiveness may also depend on scale of governance, and they may be more effective at a local level (Maasen & Weingart, 2005).

Another problem with consensual procedures is that they may be adapted to particular cultural settings. Horst and Irwin argue that consensus conferences must be

understood as an activity deeply connected to the broad consultative traditions of Danish political culture. Such an approach raises questions about the effectiveness of consensual procedures when they are borrowed by different countries with completely different political cultures. According to Horst and Irwin, such "international export of one form of consensusing is likely to create fresh hybridities and performativities—not simply 'false' consensusing, but new forms of identity-creation with their own roots and aspirations" (Horst & Irwin, 2010, p. 122).

Although Horst and Irwin appear somewhat optimistic about the potential for new and more effective forms of consensual deliberation to emerge, Wynne argues more generally that such projects that are increasingly developed to democratize policy practices have been a "mirage" and impose rigorous framing limits (2005). He argues that participation focuses on impacts or risks "reflecting the false assumption that public concerns are only about instrumental consequences, and not also crucially about what human purposes are driving science and innovation in the first place" (Wynne, 2005, p. 67). Furthermore, according to Wynne, participation carries the assumption that citizens are not capable of creating public meanings and as a result "standardized and supposedly objective universal public meanings are imposed—'risk issues'—which also imposes a normative standardized model of citizens" (2005, p. 67).

Another problem with the consensus conference and related deliberative mechanisms is that what the government wants from the citizens and what the citizens want from the participatory project might be completely different. The citizens who participate might want more than just to provide an opinion to the government about a

technical issue. For example, in the case of the GM food debate in the UK, the public wanted to be an active participant that could influence the policy outcome (Joss, 2005). Also, researchers have raised many questions about the fact that despite many attempts, lists, and guidelines about how to achieve public participation, public opinion loses its importance and meaning if it is not clear how it contributes to problem solving. Looking at the many different methods for participation, there are numerous examples, ranging from very inclusive to very exclusive and from highly deliberative to highly technocratic (Maasen & Weingart, 2005). As Maasen and Weingart (2005) argue, no type of participation "is by itself a guarantee for bringing about better knowledge and better politics...technocracy will not simply disappear exactly because scientific expertise is operating in an increasingly politicized environment" (2005, p. 13).

A case of public participation where there does seem to be an effect on outcomes is participatory science (Brown, 2007; Epstien, 2007; Moore, 2006). As Kleinman argues one such example is popular epidemiology:

> First, laypeople are engaged in practices typically reserved for certified scientists…they are engaged in hypothesis formation, research design, data collection, and data analysis. Second, popular epidemiology challenges the very idea that a hermetic boundary can be established between the technical and the non-technical (Kleinman, 2000, p. 147).

Citizens also acknowledge that their personal interests influence the questions they ask and the standards of certainty they find acceptable. Although popular epidemiology and participatory science represent a way in which public involvement in science can be more

meaningful than consensus conferences, they tend to affect research programs rather than policy processes. Thus, they do not end up solving the problem of connecting public deliberation with policy outcomes.

2.3 Social Movements and Regulatory Governance

Because of relatively weak outcomes of deliberative and consultative approaches to regulatory governance, some researchers have argued that a better way to think about public participation is based on collective participation through social movements, advocacy groups, and various other environmental organization. This form of public participation may hold more hope for realizing the goal of effects on policy outcomes. Research on social movements and environmental activism has shown that such groups contribute not only to the development of scientific knowledge but also to the development of regulatory policies for such technologies. Such groups have overcome the problem of lack of expertise by disputing expert knowledge and fighting for access in the policy making arena and by generating pressure needed to influence policy outcomes (Frickel et al., 2010; Hess, 2007; Moore, 2006, 2008). The larger and more well-funded organizations can also produce "civil society research" (Hess, 2009), in which organizations fund scientists and shape research programs directly. In contrast with the lay individual as the model of public participation, social movements offer an alternative, mobilized, and collective model of public participation, and the participation can include policymaking in addition to agenda-setting for scientific research (Hess, Breyman, Campbell, & Martin, 2008; Hess, 2011). Thus, CSOs that advocate for nanotechnology

policy reform are not "the public" in the sense of representing lay opinion, but they claim to represent the public interest and can be considered as a "counterpublic" (Hess, 2011). The CSOs studied in this project are part of broad social movements such as the environmental or labor movement, but the CSOs involved in nanotechnology policy also frequently have an officially sanctioned role in political processes, particularly in the EU, where their participation in policy deliberations has been formalized, but also in the US as professional lobbyists.

Beginning with Yearley (1992) and Jamison (2001, 2006), the STS literature on social movements, science, and technology has explored the many ways in which social movements have advanced scientific knowledge and challenged scientific power and its privileged position in scientific and policy procedures. This research has shown us that social movements, environmental organizations, and other citizens' groups often discover environmental risks, identify flaws in government regulations, and highlight problems of undone science (Frickel et al., 2010; Hess, 2007). According to that literature, social movements do not just rely on scientific claims; they change them and actively participate in changing norms, practices, and scientific facts (Moore, 2008; Tesh, 2000; Yearley, 1992). Their activities have undermined the political authority of science through participatory science (Moore, 2006) and have even spurred the creation of new scientific disciplines (Frickel, 2004). As a result, they influence and change policies. Research has also shown that risks, hazards, safety issues (Perin, 2006; Purdue, 2000), a shift towards neoliberal policies, and concerns with globalization (Harper, 2004) have been used as political opportunities to mobilize environmental movements.

Social movement organizations are one example of the broader category of CSOs, which include NGOs, trade unions, and other organizations that may advocate for a broad public interest but are not necessarily part of broad social movements that use disruptive tactics. In some cases, the distinction between a social movement organization and a CSO is often blurry. For example, environmental organizations advocate for a broad public interest on nanotechnology policy, but some of them play an insider role in the political process rather than organizing mass protest. Environmental advocacy groups have drawn attention to research on environmental health and safety issues that have been underfunded in nanotechnology initiatives (Hess, 2010), and they have also played a prominent role in the GM debate, particularly in the EU. The opposition to GM food was primarily led by environmental groups (Levidow & Carr, 2009; Levidow, 2009). In the case of the development of the EU's chemical regulation regime, environmental CSOs were part of the small group of actors that included northern member states, the Parliament's Greens, and DG Environment that advocated for the development of the new chemical regulatory framework (Selin, 2007).

In the US, researchers have investigated the role and influence of CSOs with regards to four areas: agenda setting, access to decision making arenas, achieving favorable policies, and monitoring and shaping implementation (Andrews & Edwards, 2004). With regards to the first issue, Herbst (2002) has shown that because political leaders lack knowledge about what the public wants, they rely heavily on the information given to them by interest groups. A problem for grassroots organizations and agenda setting is that lobbying might be ineffective, because unlike more powerful groups, they

do not have access in the early stages of policy making (Berry, 1999). With regards to the second issue, CSOs' access to arenas of policymaking gives them a legitimacy and recognition that is very different than agenda-setting activities. Andrews and Edwards (2004) have shown that lobbying is essential in order for groups to maintain relationships with officials, and Andrews (2001) has shown that local groups had more successes when they were directly involved. Even though it is difficult to evaluate lobbying activities and to connect them with influence, there is an expectation that politically weak organizations will form allies with politically weak government groups (Andrews & Edwards, 2004).

With respect to the third and fourth areas of the role of CSOs on policy outcomes —achieving favorable policies and monitoring implementation—Smith (1995) argued that interest groups in general have limited influence on Congressional outcomes. In many areas, protest also had very modest positive results on Congressional voting, which, in combination with lobbying influence, shows an overall modest influence by groups in Congressional outcomes (Burstein & Freudenburg, 1978; McAdam & Su, 2002; Soule, McAdam, McCarthy, & Su, 1999). Furthermore, even when a policy is developed along the lines of advocacy requests, it can be implemented in the opposite way, making the groups' success symbolic. In particular, implementation monitoring is a hard task for groups, because it needs continuing work and resources and also high levels of professionalization (Andrews & Edwards, 2004). Even though advocacy groups have modest influence on outcomes at the federal level, they seem to be more successful at the subnational level (states, municipalities, and counties), particularly in the US (Andrews, 2001).

Another factor that affects the success of CSO advocacy is the relative openness of political institutions. Public engagement in policy development is the new trend especially in the EU, and the openness to political participation there emerged from the desire not to repeat the public rejection that occurred with GM food (European Commission, 2002; Hagendijk & Irwin, 2006). The democratic deficiency of EU institutions, as noted in the previous chapter, is another reason for such an interest in the inclusion of the public (Levidow & Marris, 2001; Ruzza, 2007). As a result, in the EU, there are various types of participatory initiatives that present different types of science and technology governance (Hagendijk & Kallerud, 2003). As policymaking has shifted in the EU from nation-states to the EU level, CSOs have shifted their claims to that level and modified their repertoires of action to work in the new environment, shifting from contentious activities such as protest to lobbying (Imig & Tarrow, 2001; Majone, 1996; Ward & Lowe, 1998). Studies of women's groups have also suggested that groups that have the least involvement in protest activities have succeeded in advancing their goals through the use of the European institutions and the treaty (Caporaso & Jupille, 2001; Hoskyns, 1991). For example, by lobbying the women's group was able to achieve the inclusion of a provision on gender equality in the Amsterdam treaty (Helfferich & Kolb, 2001). In an international environment, it seems that the CSOs have become more official, have more opportunities to play the role of agenda setters, and have better opportunities to monitor what other governmental institutions are doing (Jacobson, 2000).

Even though CSOs are given opportunities, it does not mean that participation is easy. Research has shown that for CSOs, "maintaining the expertise necessary to

produce informed criticism and constructive alternatives is expensive and requires an ever-increasing flow of funds" (Rootes, 1999, p. 157). Not only is the expertise costly, it is also very important in order for the CSOs to meaningfully participate at the debate. Researchers have observed that CSOs that do not possess the technical and scientific expertise have limited influence (Hallstrom, 2004).

2.4 Political Cultures: Comparative Studies between the EU and the US

In addition to the normative literature on what kind of nanotechnology policy is ideal and the descriptive literature on public participation, the third relevant background literature is work on comparative political institutions and policy outcomes. Comparative research reveals that policymaking entities in different countries and world regions proceed and discuss policy issues in distinct ways (e.g. Brickman, Jasanoff, & Ilgen, 1985; Kelman, 1981; Wilson, 1985). Many comparative studies have shown that the US uses an adversarial model of policy-making, whereas European countries use a relatively cooperative or consensual model (e.g. Badaracco, 1985; Jasanoff, 1986; Vogel, 1986). As Jasanoff argues, despite similarities between Western cultures, different "political cultures" produce diverging policy procedures and outcomes. By political cultures, Jasanoff (2007) refers to the policy choices and ways of thinking that are formed and become necessary within communities, through particular cultural mechanisms, meaning the prevailing ways for achieving joint decisions about science and technology.

Comparisons of the US and EU have identified a variety of key differences. Examining the case of biotechnology policy, Jasanoff identifies differences not only in

governance procedures but also in public understanding and participation in policy making (2007). Various comparative studies on risk taking between the US and Germany have also shown that, in the US, regulatory agencies and experts are openly criticized and their arguments and data can be challenged in public (Jasanoff, 1997; Lehmbruch & Schmitter, 1982), whereas "Germany and other northern European countries typically feature consensus-based politics that protect regulatory authorities from public criticism and maintain expertise in `closed-door' settings" (Daemmrich & Krücken, 2000, p. 507). With respect to policy for recombinant bovine growth hormone (rBGH) regulation, EU policymakers took into account not only the traditional three criteria for technology regulation—safety, efficacy, and quality—but also, at least in discussion, a fourth one: the evaluation of socio-economic effects. Because of this fourth criterion, the evaluation of rbGH in the EU had a different outcome from that in the US (Kleinman & Kinchy, 2003).

This project contributes to the literature of comparative policy cultures in various ways. Most of the existing literature explores national styles in policy making of different countries (Jasanoff, 2007; Vogel, 1986); work that has been done on exploring EU-level policy-making procedures in comparison to those in the US is limited (Kleinman & Kinchy, 2003). Furthermore, most studies of comparative regulatory policy for Europe and the US focus on the activities and relationships between industry and government (Badaracco, 1985) or between science and government (Jasanoff, 2007) without exploring the role and contribution of social movements and environmental organizations in these processes. This study addresses the gap and focuses on how public participation through environmental organizations affects the development of policy choices.

2.5 Industrial Power and Regulatory Outcomes

My research found that even though there are significant differences in public participation and institutional decision-making for nanotechnology policy in the US and the EU, the results turned out to be similar: CSOs were frustrated in their attempts to create a political consensus in favor of a comprehensive regulatory regime. Therefore it became necessary to explain the similarity of outcomes. Interviews with CSO leaders suggested that a crucial factor that influenced political outcomes in both the US and the EU was industrial power. Thus, a fourth literature became relevant to this project. The relationship between industrial power and policy outcomes is an issue of interest for STS scholars. John Abraham (1993, 2008) has conducted extensive research on industrial power and public policy, especially in the case of drug regulation. For example, commercial and corporatist interests have strongly influenced the policies concerning the carcinogenic risk assessment of benoxaprofen in the United Kingdom (UK) and the US (Abraham, 1993). Other studies have shown that because "significant differences are found to exist in the criteria used to infer carcinogenicity, in the type of scientists providing the authoritative interpretations, and in the choices with which the respective public authorities were faced," different governments have issued opposite conclusions using the same scientific data (Gillespie, Eva, & Johnston, 1979, p. 267). Abraham (2008)has also argued that corporate interests have biased and shaped research and regulatory reviews towards the interests of the pharmaceutical industry instead of that of patients and the public health. Especially in the case of the EU, even though drug regulations are becoming better because of the integration processes and the attempts for

all EU countries to comply under one law and the development of one common market, still regulatory work is biased by the interests of the industry rather than those of the patients and is focused more towards the interests of the trade than that of the public health. In order to approve more drugs faster to strengthen its single market, decisions within the EU lack the consideration of factors such as improvements in democratic accountability and independence of regulators and experts from commercial interests (Abraham & Lewis, 2000).

According to Abraham, there are many ways through which industry influences regulatory policy making for drugs. One main way is through revolving doors, meaning individuals who start their career in the industry move on to regulatory agencies, only to return back to a higher position in the industry. Another way is through the development of neoliberal arguments claiming that excessively strict regulations will be devastating for the market and employment. In response to these arguments, agencies have many times accommodated the industry. Because regulators need expert advice, industry has been more than happy to contribute its expertise directly or indirectly, and thus it plays a major role in risk benefit assessments and drug testing. Finally, the industry has convinced governments and regulatory agencies that involvement of the public in the regulatory processes is unnecessary (Abraham, 2002).

In the case of categorizing pharmaceuticals as carcinogenic, what counts as knowledge during regulatory procedures? Abraham and Ballinger (2012) argue that the neoliberal movement has increasingly shaped the regulatory processes to benefit the industry's interests and in particular with regard to the acceleration and cost reduction of

drug production and regulation. Furthermore, agencies responsible for regulating drugs have increasingly responded to industry's demands by lowering standards and validating drug testing with the least possible resistance. Abraham and Ballinger also argued that by approving a neoliberal regulatory state, the "pharmaceutical industry framed the process and interpretation of validating these new test systems, thereby influencing what counts as knowledge about the carcinogenic status of new pharmaceuticals" (2012, p. 446). That framing was not developed based on scientific logic but rather on the "sociopolitical goals of the controlling institutions" (Abraham & Ballinger, 2012, p. 446).

Besides the case of pharmaceuticals, neoliberal bias in regulatory policy has also been observed in the case of the tobacco industry and second-hand smoking, the chemical industry generally, and environmental health policy. With respect to smoking, the industry spent enormous amounts of money to industry-directed research in order to dismiss conclusions that relate second hand smoking with cancer and other diseases. Such industry-directed research is still on-going, undermining scientific research on the issue (Ong & Glantz, 2000). With respect to toxic chemicals in general, research about the carcinogenicity of specific chemicals has increasingly been guided to serve industrial interests. This has been the case of the International Agency for Research on Cancer within the World Health Organization (WHO), where many chemicals have been evaluated following limited scientific evidence in alignment with industry's interests. This is because the management selects people who make decisions that favor the industry. Even in cases where representatives from governments are part of the process, it does not mean that they represent the public interest (Huff, 2002). The same observation

has been made about occupational and environmental health research. Governments are increasingly failing to support independent organizations and their work towards the protection of public health and instead they join corporate interests (Huff, 2007).

One of the most interesting findings in the literature on industrial power and regulatory policy involves the role of expertise in policy-making. Uncertainties have been used to benefit industrial interests and standards have been also developed and shaped according to the same interests (Abraham, 2003). At the same time governmental agencies seem to trust corporate research on risks for specific drugs, translating scientific uncertainty to regulatory inaction (Abraham & Sheppard, 1999; Abraham, 1994).

The heavy reliance on industrial expertise in the formation of regulatory policy is in turn part of the broader scientization of regulatory policy, which narrows the criteria for decision-making and the opportunities for a broad debate that includes lay perspectives and CSOs. For example, Drori views science's institutionalized social authority as a general cultural model that "rests on and elaborates on basic cultural assumptions linked to science" (2003, p. 10). Besides the increase in science-based activities and institutions, scientization has become part of everyday life activities, penetrating formal organizing. Scientization is establishing concrete sets of practices and institutions, providing rationalized and empowering scripts of action, but also it empowers social actors to lead such action, while society is pressed to take formal responsibility for the management of more and more scientifically constructed uncertainties (Drori & Meyer, 2006; Kinchy, 2012).

STS researchers have paid much attention and explored intensively the

scientization of controversial debates over the regulation of new technologies, meaning the separation of the debate from its social context and its reduction to a scientific matter to be resolved amongst scientific experts. One example is the debate of the regulation of genetically engineered crops. Especially in the United States, scientists can best resolve controversies over possible risks of new technologies, because they are viewed as producing accurate, unbiased, objective knowledge. Even though genetically engineered crops raised issues that were beyond scientific assessments, such as property rights and seed saving, these issues became scientized. Kinchy (2012) argues that the combination of neoliberal and scientized processes minimized the ability for participation of other actors such as farmers in the agri-biotech debate. Governments around the world operate under the free market ideals that downplay the political implications of genetic engineering in order for the debate to be focused on scientific assessments about possible environmental and health risks (Kinchy, 2012).

The ideologies of scientism and neoliberalism have been identified by other researchers as the reason for the lack of regulation in the case of agricultural biotechnology in the EU and US. The commitment by governments not only to neoliberal ideals but also to basing policy developments on narrow scientific definitions of risk has led to the development of policies that benefit the industry and not the interests of small farmers. However scientism seems to have an uneven dimension in different regions (Moore, Kleinman, Hess, & Frickel, 2011). For example, the EU and US have taken different regulatory decisions about agricultural biotechnology products, with the EU taking into account socio-economic criteria and adopting a more precautionary stance

(Kleinman & Kinchy, 2007). However, even in the case of the EU, where the recombinant bovine growth hormone was banned and a temporary moratorium on genetically engineered food also took place, attempts to institutionalize socio-economic evaluation for biotechnology products failed (Kinchy et al., 2008).

Sarewitz (1996) has argued that scientism cedes the responsibility for defining environmental risks to experts instead of elected officials, and as a result policy decision making is becoming less democratic and more heavily influenced by industrial perspectives on risk and benefit. Especially in the case of the nanotechnology debate, risk has been framed very narrowly based on technical terms that are reduced to hazards and exposures and based on technical understanding. The narrow definition prohibits broader participation by CSOs and other stakeholders that have a different understanding about the issue. Also, it eliminates additional deliberation that probably would improve the decision- making of policies for nanotechnologies. Thus, power operates through the use of scientific expertise as an apparently neutral way of resolving public disputes, but the neutrality is limited by the influence of industry in defining the terms of expertise and criteria for regulation. Furthermore, even CSOs that decide to participate in regulatory governance must do so within the parameters of a scientized and neoliberal policy arena (Morris, 2012).

2.6 Conclusion

Prescriptive work on nanotechnology policy by public policy researchers suggests that both the US and EU still need to develop a comprehensive regulatory framework for

nanotechnology that will protect the health and safety of the public and the potential threats to the environment. Much of that prescriptive work also points to the value of ensuring public participation in the policy process in order to improve both the quality of the policy and its public acceptance. Most research on public participation and regulatory policy has focused on the involvement of lay people through consensual and deliberative projects, but the research has shown that the existing mechanisms of public participation have limited success in influencing policy making. Another approach to public participation has been to focus on mobilized publics associated with social movements, and research on environmental CSOs has shown them to be involved in policy discussions and sometimes effective in influencing policy outcomes. However, their involvement and effectiveness depends in part on the political structure, because the political structures present different political opportunities and involve groups in different ways. Both the EU and the US are interested in the development of nanotechnology and lack appropriate regulatory frameworks, but they have traditionally different approaches and different participatory patterns. The EU has been more open to CSO participation, even on an official basis, and it adopts a more consensual approach to policymaking, whereas in the US the role of CSOs has been that of unofficial agents in a relatively polarized and confrontational political environment. However, despite the very significant differences between the EU and the US in the governance of chemicals and nanotechnology, the CSO leaders whom I interviewed complained of a lack of effect and a general failure for nanotechnology policy on both continents. Thus, it became necessary to explain the similarity of outcomes rather than the differences, and the literature on

industrial influence on regulatory policy became relevant.

This study advances research on nanotechnology policy and regulation in three ways. First, it builds on the literature on public participation and regulatory policy by focusing on the role of CSOs as representatives of the public interest and their potential effect on policy outcomes. Second, it builds on the literature on comparative regulatory policy in the US and Europe by considering the EU level rather than national governments in Europe. Finally, the project departs from the comparative policy literature by showing that even though the political opportunity structure for public participation and other institutional features of governance are quite different, the outcome is similar, and the similarity can best be explained by the role of industrial power in regulatory policy in general, but especially where there is no countervailing mass protest movement.

3. Nanotechnology Policy and Politics in the US

Chemical policy making in the United States takes place at three levels, the federal, the state, and the local/municipal. This project focuses only on the federal level for two reasons: the federal level legislation gives an overall picture of the US approach, and the project of evaluating 50 different state regulatory regimes was beyond the resources available for the project. Because federal-level chemical legislation applies to all states usually as a minimum regulation, each state can have its own, stricter legislation unless it is unconstitutional or in conflict with federal law. For example, the State of New York has special provisions for the regulation of Bisphenol A (BPA) in baby bottles, something that is not required by a federal law. This chapter will review five main aspects of CSO participation and nanotechnology policy in the US: government structure and agency jurisdiction, the current regulatory structure for nanotechnology, a description of the leading CSO advocacy organizations in the nanotechnology field, their goals and policy priorities, and some examples of their attempts to change the regulatory process.

3.1 Government Structure and Agency Jurisdiction

In all elections and with very rare exceptions, the president and members of Congress belong to either the Democratic Party or the Republican Party. Regulatory policy affects all the states, and the legislative powers rest with the Congress, which consists of the Senate and the House of Representatives. Each of the 50 states is

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represented by two senators regardless of its population. The House of Representatives consists of 435 voting members, and the number of representatives for each state is based on the state's population. Any representative of Congress can introduce a proposal for new legislation in the form of a bill, and lobbyists can draft legislation and ask a member of Congress to sponsor it. After its introduction, each bill goes through several stages and discussions within committees. The committees are chaired by a member who belongs to the majority party, and their deliberations are part of the public record. Depending on the importance of the legislation, the committee may request public hearings in which experts and witnesses are invited to testify for or against the bill. After the debate, the committee votes whether or not the bill will be presented to the full House or Senate, and a second debate follows. If the bill is approved, it is sent to the other legislative body, which debates the bill and either rejects it, passes it, or amends it. In order for a bill to pass, both houses need to agree on the same text. If the second house requests amendments, the differences are discussed by a committee with members from both houses. Both houses need to pass the bill, in order for it to become a law. If the second house rejects it, the bill fails ("United States Congress," 2012). Once a law is enacted, the executive branch's agencies implement it. The main federal-government agency responsible for the regulation of chemicals in the US is the Environmental Protection Agency (EPA), which was established by President Nixon in 1970. The EPA is also responsible for air and water quality, pesticide control, and other environmental regulations.

Interest groups, environmental organizations, trade unions, and various other

groups monitor the EPA and attempt to influence Congress. In particular, environmental organizations have been very active in addressing problems with the regulation of chemicals and in identifying gaps in the regulation of new technologies and their products, such as for nanomaterials. As industrial chemicals that are not used in medical or food contexts, nanomaterials fall under the jurisdiction of the Toxic Substances Control Act (TSCA), which does not refer to nanomaterials specifically, and secondarily under other acts, such as the Federal Insecticide, Fungicide, and Rodenticide Act (FIRFA), which regulates pesticides. There are also other laws and agencies that can be responsible for regulating specific types of nanomaterials, for example the Food and Drug Administration, which regulates nanomaterials used in food and cosmetics. Discussions about how nanomaterials can be regulated appropriately by existing regulation are ongoing. With some exceptions, such as when they are treated as new chemicals under TSCA, most nanomaterials remain unregulated or fall through loopholes.

3.2 Background on Chemical Regulation in the US

The EPA is the executive body for most of the regulatory frameworks that are responsible for air and water quality and for controlling pesticides and toxic chemicals. US regulations concerning hazardous waste and industrial chemicals were established in 1976 with the introduction of Resource Conservation and Recovery Act (RCRA) and the Toxic Substances Control Act (TSCA).

Under TSCA, chemicals are classified as either existing or new substances (US

EPA, 2008a). Existing substances are identified as those that already exist in the EPA inventory; they account for almost 99 percent of all chemicals in the market and are grandfathered under TSCA (Applegate, 2008). Therefore, these substances are not subject to TSCA pre-manufacture or pre-market review, although exceptions to that rule may occur by applying the Significant New Use Rule (SNUR). This regulatory tool gives authority to EPA to reassess existing substances for risks if their use has changed. As a result, the SNUR allows the EPA to prevent or limit possible exposure and effects from the new use of these substances (US EPA, n.d.-a). Manufacturers of new chemicals must file a pre-manufacture notification, which provides the EPA with any known or reasonably accessible data concerning the new chemical they want to produce. Using those data, the agency assesses the extent to which the substance poses unreasonable risks. If no unreasonable risks are detected, permission is granted for the manufacture of the substance (US EPA, 2005). The EPA can also use Section 5 of TSCA to require data for new chemicals.

Efforts to reform and update TSCA have to date met with little success, despite three attempts between 2008 and 2012. Discussions about reforming TSCA began in 2008, with the introduction of a new bill in Congress called the Kid-Safe Chemicals' Act (S.3040; Lautenberg, Menendez, Whitehouse, Clinton, & Kerry, 2008). The bill was introduced by Senator Lautenberg, and its purpose was to overhaul TSCA. However, although testimonies took place starting in February of 2009, it never became a law (Davies, 2009a; Denison, 2009; Dooley, 2009). On July 22, 2010, Chairmen Bobby L. Rush and Henry A. Waxman introduced H.R. 5820, the Toxic Chemicals Safety Act of

2010. Once again, the purpose of the bill was to replace the TSCA with a new law that included minimum data requirements, introduced prioritization and safety standards, and requested disclosure of ingredient information. Substances that did not meet the safety standards would be prohibited. In July of that year, new testimonies took place, but again the bill did not leave committee (Bosley, 2010; Denison, 2010; Dooley, 2010). In April, 2011, Senator Lautenberg introduced the Safe Chemicals Act of 2011 (S. 847; Lautenberg, 2011). New testimonies took place again in the summer of 2012, and despite the absence of Republican support, an amended version of the bill passed the committee with a 10-8 vote. Approval of the committee does not mean that the bill will become law. It is not certain if it will pass the Senate, and if it does, it will then need to be approved by the House of Representatives, which is unlikely.

TSCA has been developed for the needs of regulating bulk substances and does not specifically address particle size. Because of isomorphism with existing chemicals, most nanomaterials derived from substances that are already on the TSCA inventory are not subject to regulation, because they are considered existing chemicals, or they pass through loopholes[2]. However, under TSCA substances such as quantum dots, a type of nanomaterial metal-based substance, are not on the TSCA inventory, and as a result they are considered new chemical substances. Such substances are regulated under the EPA's new chemical program. In addition, the EPA determines on a case-by-case basis if particular types of nanomaterials are new or existing chemical substances. For example, all allotropes of carbon are also considered new chemicals, because they are not on the

2 Even if nanomaterials are considered new chemicals, such materials will not qualify for extensive review because they are produced in low quantities. Also in the cases that they qualify for registration, any assessment is going to be mainly based on existing knowledge for their bulk counterpart that does not necessary apply to the nanotechnology form.

TSCA inventory. Carbon nanotubes and fullerenes have unique molecular identities that are distinct from graphite and diamond, the two existing allotropes of carbon on the TSCA chemical inventory, and therefore types of carbon nanotubes and fullerenes are considered new chemical substances under TSCA. The majority of the nanoscale chemical substances that require pre-manufacture notification and go under review are allotropes of carbon, mostly carbon nanotubes and fullerenes (US EPA, n.d.-b). In 2011, the EPA announced that since 2005 it has developed pre-manufacture notifications under the new chemicals program for more than 110 nanomaterials (Alwood, 2011). As of December, 2012, this number has increased to an estimated 137 nanomaterials.

Because many nanomaterials are classified a pre-existing chemicals and are not subject to review, in 2005 the EPA initiated a working group to address the risk issues posed by substances in nanotechnology form. The working group's proposal was the development of a voluntary program known as the Nanoscale Materials Stewardship Program, which encouraged manufacturers to develop and submit information for nanomaterials to the EPA (US EPA OPPT, 2009). Although the program did lead to the development of some useful information, by the end of 2008, the Nanoscale Materials Stewardship Program had received only 29 submissions covering 123 different nanoscale materials, corresponding to just 10% of nanomaterials on the market (Maynard & Rejeski, 2009; US EPA OPPT, 2009). In 2008, following the Nanoscale Materials Stewardship Program, the EPA issued a report that discussed nanosubstances within the framework of TSCA (US EPA, 2008b). The report stated that the law does not classify substances on the basis of scale. According to TSCA, a chemical substance is

characterized by its molecular identity, i.e., “features like the types and number of atoms in the molecule, the types and number of chemical bonds, the connectivity of the atoms in the molecule, and the spatial arrangement of the atoms within the molecule” (US EPA, 2008b, p. 3). According to TSCA, a molecular identity that is not identical to any chemical substance on the TSCA Inventory is considered a new chemical substance. For example, because silver and nanosilver consist of the same type and number of atoms, and because their only difference is the size, under TSCA they are considered the same substance. However, the report does allow for a case-by-case analysis might be possible for certain nanoscale substances.

When the Nanoscale Materials Stewardship Program ended in 2009, significant gaps concerning environmental, health, and safety data still remained (US EPA, n.d.-c). As a result, the EPA decided to take additional action in order to regulate existing nanomaterials under the TSCA by developing Significant New Use Rules (SNURs) for nanomaterials, which require manufacturers and importers of certain nanomaterials to submit a Significant New Use Notice (SNUN) to the EPA at least 90 days before manufacturing or importing the substance (US EPA, n.d.-d). Based on data from the SNURs and information from the Nanoscale Materials Stewardship Program, the EPA would evaluate the intended uses of nanoscale materials and would be able to prohibit or limit activities that may present an unreasonable risk to human health or the environment. Thus, the EPA had developed a non-voluntary mechanism under TSCA that could require the submission of more information by manufacturers and importers of nanomaterials, as well as to require testing for certain nanomaterials (US EPA, n.d.-d).

In September, 2010, the EPA issued two SNURs, one for multi-walled carbon nanotubes and one for single-walled nanotubes. Thus, firms that intend to manufacture, import, or process either of these two chemical substances for a use that is designated as a significant new use are required to notify the EPA (Bergeson, n.d.-a). Following these two SNURs, the EPA started to develop categorical SNURs for all nanomaterials (Duvall & Wyatt, 2011). These SNURs would apply to nanomaterials that are considered existing chemicals and to substances that have more than 10% of their size between one and 100 nanometers. To accompany the development of the SNURs, the EPA planned to develop new mandatory information-gathering rules under Sections 4 and 8 of TSCA (Monica, 2010). The rule under Section 4 would have required manufacturers to notify the EPA of certain information, such as exposure, release, and available health and safety data on nanomaterials. The rule under Section 8 would have required the testing of nanomaterials for chronic exposure and environmental fate. The EPA planned to publish the two rules and the categorical SNUR for all nanomaterials by the end of 2011. In December, 2011, a review by the EPA's Office of Inspector General determined that the EPA lacked sufficient data; for this reason, the original plan to issue the two rules and the categorical SNUR by the end of 2011 was delayed (Hanson, Harris, Joseph, Ramakrishnan, & Thompson, 2011).

In February, 2012, the EPA made available its fall 2011 Regulatory Agenda availability, which included a test rule under Section 4(a) of TSCA. Unlike the broad rule under Section 4 that had been discussed in 2011, the new test rule of 2012 required manufacturers of only specific types of multiwall carbon nanotubes to “conduct testing

for health effects, ecological effects, and environmental fate, as well as provide material characterization data" (Bergeson, 2012a). The notice of the proposed rule-making was intended to be issued in March, 2012. In June, 2012, the EPA announced the development of a SNUR for 17 substances that were subjected to Pre-Manufacture Notifications, including a SNUR for infused nanostructures, that is, carbon nanotechnology tubes and fullerenes. Based on information on similar substances, the agency stated that the specific infused nanostructures may impact lungs (Bergeson, n.d.-b). In October, 2012, the EPA declared the development of a new SNUR for potassium titanium oxide that bans the manufacture of particle size less than 100 nm. The SNUR was developed because the agency concluded that the substance could cause unreasonable risk of injury to human health. In particular, concerns were raised that inhalation could cause lung toxicity and fibrosis to workers who might be exposed. The EPA issued a consent order, which stated that there would be no manufacturing of this material if it has a particle size of less than 100 nanometers. According to the SNUR, more testing would be necessary in order for the EPA to characterize the possible human health effects, in particular a 90-day inhalation toxicity test. The SNUR went into effect on December 4, 2012 (Bergeson, n.d.-c).

In 2012, the EPA continued its discussion of the categorical SNUR and the proposed modifications of the rule under Section 8, both of which had been under consideration since early 2011. The notice of the proposed rule-making was planned to be issued in March, 2012, but again there were delays. As of early 2013, the categorical SNUR and new rule under Sections 8 and 4 were still not issued. Thus, the EPA made

significant progress on a piecemeal basis during 2011 and 2012, but the more comprehensive rules were delayed.

In addition to the EPA's attempts to regulate nanomaterials within the framework of TSCA, the agency also attempted to regulate nanomaterials that have antibacterial properties such as nanosilver under FIRFA. In 2010, the Government Accountability Office recommended changes in the law in order for nanomaterials to be regulated appropriately. In January 2010, the EPA recommended additional information for the registration of nanosilver under the act. That same year, the EPA also invited comments for a review of the "Nanomaterial Case Study on Nanoscale Silver in Disinfectant Spray," and in 2011 the agency held a public information meeting (Duvall & Wyatt, 2011). The report was finally published in August, 2012. This report identified what was known and unknown on topics that are important for the assessment of the implications of certain nanomaterials (US EPA, 2012a). In July, 2012, the EPA published a notice announcing the establishment of a registration review docket for nanosilver and 22 other chemicals, requiring a review decision by 2016. The registration review includes two products containing nanosilver that were conditionally registered in 2011 (US EPA, 2012b).

In addition to regulation by the EPA, there is also legislation that authorizes the Federal Drug Administration (FDA) to regulate nanomaterials that are used in food, cosmetics, medical devices, and drugs. The FDA held various public meetings on nanomaterials beginning in 2006, and in 2007, the FDA's Nanotechnology Task Force published a report with recommendations to develop guidance to address risks and benefits of using nanotechnologies (FDA, n.d.). In 2011, the agency released draft

guidelines in order to assist the industry in identifying specific properties of nanotechnologies in products. The guidelines did not include a definition of a nanomaterial, and they did not change the regulatory requirements for nanomaterials (US FDA, 2011)). The FDA welcomed public comments on the guidelines until August, 2011 (Andorka, 2011). In April 2012, the FDA issued a second draft of guidelines on how food and cosmetic producers can get approval for products containing nanomaterials. Again, the guidelines did not offer a definition of a nanomaterial but stated that the FDA will proceed on a case-by-case basis and will not consider products containing nanomaterials as a class (US FDA, 2012).

3.3 Advocacy Organizations

In the US six main organizations are active at the federal level and advocate for the regulation of nanomaterials: the Project on Emerging Nanotechnologies (PEN), the Environmental Defense Fund (EDF), Friends of the Earth (FoE), the Natural Resources Defense Council (NRDC), the International Center for Technology Assessment (ICTA), and the Environmental Working Group (EWG). This section will describe the organizations in brief and their role in nanotechnology policymaking.

PEN was first established in April, 2005, as a partnership between the Woodrow Wilson International Center for Scholars and the Pew Charitable Trusts. Chartered by Congress and administered by the Smithsonian Institution, PEN is a think tank of experts fueled by a common interest in transparency and better nanotechnology regulatory policy. It does not have a public membership base but rather is an organization offering expertise

and knowledge for the resolution of regulatory issues. PEN supports its mission of proposing strategies for responsible research and development of nanotechnology and its regulation by informing an already knowledgeable public, such as policymakers and scientists, about these issues, through the creation of publicly available reports and search tools. In comparison with other organizations, PEN is narrowly focused on issues surrounding nanotechnology oversight, specifically policy and responsible research and development for nanotechnology. PEN is not an advocate for or against particular nanotechnologies; instead, it seeks to ensure that as these technologies are developed, the potential human health and environmental risks are anticipated, properly understood, and effectively managed. Its goal is to generate objective knowledge about nanotechnology and to propose objective policy. Since May, 2005, PEN has published 77 reports concerning nanotechnologies and nanomaterials (PEN, n.d.-b).

The EDF is an environmental organization founded by scientists in 1967 that has a public membership base and a history of success in environmental and chemical regulation. The EDF's activities cover a broad spectrum of environmental and health issues, including nanotechnology regulation, with a mission aimed at “finding the ways that work” (EDF, n.d.). While litigation provided the main vehicle for action in the early years of the EDF, its staff now works to develop partnerships with industry and the government. The EDF staff members have advanced degrees in science and law, and they hold positions on expert and policy boards and participate in a broad range of activities that encompass both environmental and health issues, including nanomaterials. The EDF argues that nanotechnology is a very promising field, but it must be regulated for

environmental and health risks. Following this argument, the EDF wrote letters cosigned with members of industry that urged both the EPA and the FDA to use their authority to regulate nanomaterials. In 2007, EDF representatives helped to initiate an EPA Federal Advisory Committee, in which they also participated. This committee proposed an overall approach for the agency to address potential risks of nanomaterials (NPPTAC, 2005). The EDF also issued a joint statement of principles with the American Chemistry Council. The EDF's partnership with DuPont in June 2007, and the development of a six-step nano-risk framework, as well as its participation in the EPA's voluntary framework was somewhat controversial among other environmental organizations (EDF, n.d.; see Hess, 2010, on the reaction of other environmental organizations to the partnership).

FoE is a grassroots environmental organization that works directly with the public and has been working on a broad range of environmental issues for more than forty years. FoE is an international organization that often coordinates activities in the United States with those in the European Union and consists of a web of 77 national member organizations and five thousand local organizations. FoE is typically involved with food and agricultural issues, but it has also taken a keen interest in nanotechnology policy development. FoE advocacy uses direct action involving the public and is the only organization discussed here that has requested a partial moratorium on the manufacture of products containing nanomaterials. Since 2006, FoE United States has published three reports in cooperation with FoE Australia and FoE Europe. FoE argues, "The failure of government regulators to take seriously the early warning signs surrounding nanotoxicity suggests that they have learned nothing from any of the long list of disasters that resulted

from the failure to respond to early warning signs about previous perceived ‘wonder’ materials (like asbestos, DDT, and PCBs)” (FoE, n.d.-a). FoE has joined a broad coalition of public interest, environmental, and labor organizations for the development of reports and has filed petitions with the EPA and the FDA asking for the regulation of nanomaterials (FoE, n.d.-b).

The NRDC is a non-profit environmental advocacy group founded in 1970 in New York City, with offices in Washington, DC; San Francisco; Los Angeles; Chicago; and Beijing. The NRDC has 1.3 million members and more than 350 lawyers, scientists, and experts of its staff. One of the most successful and powerful environmental organizations, its priorities include but are not limited to curbing global warming, reviving the world's oceans, and protecting human health by preventing pollution. The NRDC's purpose is “to safeguard the Earth but also to foster the fundamental right of all people to have a voice in decisions that affect their environment” (NRDC, n.d.). The organization gets its funding primarily from private foundations, but a very small part of funding comes from the government.

Nanomaterials and their possible risks became part of the NRDC’s activities in 2006, and they published their first report on nanomaterials in 2007 (Sass, 2007). For the NRDC, the regulation of nanomaterials is an issue that can be resolved with the reform of the TSCA for all chemicals (NRDC, n.d.). In January 2012, the NRDC filed a federal lawsuit to block nanosilver from markets. The EPA had conditionally registered nanosilver for specific uses in textiles. “Conditionally” meant that even though the EPA did not have all the toxicity data necessary to assess the substance, the agency allowed

the manufacturer to produce the substance as long as it provided the remaining data within four years (Sass, n.d.). In April 2012, the NRDC filed a brief, which argued that the EPA's decision to permit conditional registry of the substance was not supported by significant evidence. Later that month, the ICTA, the Center for Food Safety, FoE, Beyond Pesticides, the Center for Environmental Health, and the Institute for Agriculture and Trade Policy filed a motion for leave to file a brief as amici curiae in support of the NRDC. Essentially the amici curiae argued that many products on the market contain nanosilver and that the EPA did not account for the possible exposure to these products. In July, 2012, the EPA replied with an answering brief that argued that the NRDC failed to prove that their members face a real and actual risk (Bergeson, 2012b).

The ICTA is a non-for-profit bipartisan organization established in 1994 with offices in Washington, DC. The organization is committed to providing the public with full assessments of the impact that new technologies have in society. The ICTA works on a variety of projects, from synthetic biology to nanotechnology, global warming, and human biotechnology. In the case of nanotechnologies, the ICTA was one of the first organizations to take action on the issue of nanomaterial regulation. In 2006 the ICTA filed a legal petition with the FDA for its inability to regulate products containing nanomaterials, in particular sunscreens. In 2008, the organization, together with other environmental and consumer groups, filed another petition that requested that the EPA use its regulatory authority for pesticides to stop the sale of products containing nanosilver. In 2011, ICTA filed the first lawsuit against the FDA on the risks of nanotechnologies and demanded a response to a petition that public interest organizations

had filed with the agency in 2006. The ICTA continues to remain active in regard to the regulation of products containing nanomaterials but focuses only on the frameworks that regulate products and not on frameworks like the TSCA (ICTA, n.d.).

The EWG is a non-profit public health and environmental research and advocacy organization that was started in 1993. Also based in Washington, DC, the mission of the EWG is to use public information to protect public health and the environment. The EWG specializes in providing useful resources to the public and in pushing for the development of national policies to protect the health of the more vulnerable populations from exposure to toxic contaminants. The organization promotes change in federal policies that do not appropriately protect the environment, and it also promotes sustainable development. The EWG obtains its funding from foundation grants and from individual donors, and it is active on many environmental and health issues. In the case of toxic chemicals and nanomaterials, the organization focuses on consumer products, especially products containing nanomaterials, and the EWG has assessed the components of over 25,000 products since 2000 (EWG, n.d.). Based on that data, the EWG created an online tool that allows consumers to assess 15,000 products. In 2006, the EWG reported to the FDA that there was widespread use of nanomaterials that have not been assessed for safety by the FDA in personal care products. The EWG has an ongoing online tool that informs the public about what products are safe. In 2007, the organization launched an online database that rates sunscreen safety and effectiveness. Besides the activities that were mentioned above, the EWG also comments on governmental activities connected to nanomaterials and their regulation in products (EWG, n.d.).

Of the organizations described above, only two are active on the issue of regulating nanomaterials under the TSCA: the EDF and the NRDC. PEN was active but subsequently lost its funding. The others are involved in the regulation of specific products or informing consumers of the presence of nanomaterials in specific products. All of the organizations involved agree that the TSCA presents many issues that make the regulation of nanomaterials exceedingly difficult. According to Richard Denison, a senior scientist with the EDF, for the EPA to take any regulatory action for existing substances under the TSCA, the agency must first prove that a chemical "presents or will present an unreasonable risk or injury to health or the environment. Since 1976, EPA has done that for only five existing substances" (Denison, 2008c).

All the organizations that are involved with TSCA reform identify the same problems with the TSCA. The first is the three exemptions that give manufacturers the right not to disclose information to the EPA and make the regulation of nanomaterials especially difficult:

- The Low-Volume Exemption (LVE). This is the main issue with nanomaterials because it applies to chemical substances manufactured in quantities equal to or less than 22,000 pounds; nanomaterials are not manufactured in such quantities.
- The Low-Release/Low-Exposure Exemption (LOREX) - Manufacturers can argue that the substances they produce and use are maintained under circumstances of low release and exposure (Denison, 2008a).
- The Confidential Business Information exemption (CBI) - Manufacturers can argue that certain information is confidential, and therefore EPA is prohibited

from sharing that information with the public.

The second concern of the CSOs refers to the way new substances are regulated under the TSCA. Even if nanomaterials are considered new substances, a pre-manufacture notification for a new substance does not have to contain any hazard data, and few actually do. Additionally, the model currently used to estimate hazard is based on traditional chemistry that may or may not apply to nanomaterials, and the EPA has only ninety days to review a substance after a pre-manufacture notification has been submitted, which creates important time and data limitations. At the moment, data for nanomaterial safety is not available, and the EPA cannot prove that a substance poses unreasonable risk, because under TSCA the absence data is interpreted to mean the absence of risk (Denison, 2008a).

The third concern is the way existing substances are regulated under TSCA. While the burden on the EPA to regulate new substances is significant, the burden for regulating existing materials is larger. The obstacles are greater because all existing substances in the United States are grandfathered in and are not subject to pre-manufacture or pre-market review, and most nanomaterials are considered to be existing substances. The EPA must meet a number of challenges to regulate the production, use, or disposal of an existing nanomaterial under the TSCA. The Inventory Update Reporting program is the source of basic screening-level and exposure-related information on chemicals that the EPA uses to develop risk assessments. Inventory Update Reporting takes place every five years and only for substances produced in amounts of more than 25,000 pounds (US EPA, n.d.-b). Nanomaterials are not produced in such large quantities. At the same time,

all of the previously mentioned exemptions apply (LVE, LOREX, and CBI). As a result, most nanomaterials are missed by TSCA's current reporting mechanisms (Denison, 2008b).

3.4 Goals of Advocacy Organizations

As of 2007, PEN, EDF, NRDC, FoE, and ICTA were disappointed with the methods that the EPA was using in an attempt to resolve the issue of the regulation of nanomaterials under the TSCA, particularly the development of the Nanoscale Materials Stewardship Program. Although Richard Denison represented the EDF in the working group that had developed the program and supported the measure, the environmental CSOs viewed the measure as a temporary one until mandatory regulations were put in place. According to the EDF, the program established no deadlines and no regulatory backstop. By this point it was too late for voluntary programs to be helpful, because the EPA had developed the Nanoscale Materials Stewardship Program without a plan for mandatory rules (Denison, 2007a). In 2008, as a result of the program's deficiency, Denison argued, "We are nowhere near having even a basic understanding of the nature and extent of nanomaterial-related activity in the US" (Denison, 2008c).

FoE representatives also argued that even the Nanoscale Materials Stewardship Program fell short of their expectations for regulating nanomaterials (FoE, 2008). The program lacked deadlines for participation, launch, and evaluation, and it failed to require concurrent development of mandatory TSCA oversight measures. According to FoE and ICTA, enforcing the program as mandatory under TSCA would better ensure compliance

from all nanotechnology industries and would achieve better the urgent goals outlined by the EPA in the program concept paper (International Center for Technology Assessment and Friends of the Earth (ICTA–FoE), 2007). PEN appeared as disappointed in the program as the other two organizations.

According to all of the organizations, TSCA has serious deficiencies that make it almost impossible for the framework to allow the EPA to regulate nanomaterials and ultimately toxic chemicals. Furthermore, they believe that the EPA has offered inadequate solutions for overcoming these deficiencies. Even though TSCA has some useful tools, like the SNUR, for regulating nanomaterials, the CSOs argued that the EPA has either limited authority or a limited desire to use those tools, although, as noted above, during 2012 the EPA was moving ahead with limited use of SNURs.

PEN's four published reports on nanotechnology regulation do not advocate a new law focused specifically on nanomaterials. Instead, because TSCA is currently the most meaningful of the existing laws that can apply to nanomaterials, the first steps in regulating nanomaterials should involve changes to accommodate the regulatory capability of TSCA and the EPA. Thus, under TSCA, nanomaterials should be considered new chemical substances, and the EPA should develop a categorical SNUR that covers all nanomaterials. With regard to voluntary programs, PEN states that they can be useful by including small manufacturers that would otherwise be excluded in regulatory procedures (Davies, 2007, 2008). At the same time, there must be internal and external cooperation with the EPA and other agencies, such as the FDA, the Occupational Safety and Health Administration, the Consumer Product Safety Commission, and the US Department of

Agriculture (Davies, 2007). For example, the EPA should have the power to require testing of substances in order to determine that the absence of data is sufficient evidence that the substance may present an unreasonable risk. More specifically, manufacturers should "report on the uses, risks, amount manufactured, by-products, and other information about a chemical or a category of chemicals" (Davies, 2008, p. 62). Additionally, the EPA should have greater power to share Confidential Business Information (Davies, 2007).

PEN supports the idea of a new law that would provide adequate oversight of nanotechnology. This new law should be focused on products, "because the same substance will have widely different impacts depending on the products in which it is used" (Davies, 2009b, p. 22). A law focused on products would be more effective than the current system because such a law would increase attention to the way a material will be used and how it will be combined with other materials (Davies, 2009b). PEN also states that a product law is an effective solution for all chemicals because it could lead to more efficient risk assessments (C. Davies, personal communication, July 1, 2009). As for TSCA, it argues that the law would be a valuable tool if it was reformed (Davies, 2008). Even though PEN recognizes that the TSCA needs to be reformed for all chemicals, in a 2009 Congressional hearing a representative from PEN argued that the problem is that "the United States is trying to deal with twenty-first century problems using mid-twentieth-century tools" (Davies, 2009a). One of the reasons why TSCA is falling short in regulating nanomaterials is that the law was not developed with nanotechnology in mind (Davies, 2006). As a result, a new regulatory framework focused

on products might be the best solution to oversee nanomaterials and protect the public and the environment.

The EDF takes a broader approach to TSCA reform by stating that the United States is the only Western country that has failed to ban chemicals already banned elsewhere, such as China, and that the US continues to regulate substances under a law more than thirty years old (Davies, 2009a). The problem with nanotechnology regulation, according to the EDF, is not that the law was developed without nanotechnology in mind but that the law is not efficiently regulating toxic chemicals in general. EDF does not advocate a nanotechnology-specific law but instead argues for careful consideration of the special features of nanomaterials and for incorporating the appropriate regulations into the broader process of bringing TSCA into the twenty-first century (Denison, 2008d). Among EDF's main recommendations is the identification of chemicals based on their hazard or exposure characteristics and not just on risk (Denison, 2008b). EDF also asserts that the EPA should have more power to initiate action in cases presenting less than absolute evidence of harm and should not have to prove potential or actual risk to require data on certain substances from industry. Furthermore, the EPA "should be able to impose controls that address potential harm as well as uncertain, but potentially significant, harm" (Denison, 2009). EDF suggests that in order to introduce and maintain chemicals on the market, manufacturers should be responsible for demonstrating that their products are safe. At the same time, the EPA should have the authority to request submission of minimum data sets of all chemicals, both new and existing.

As a first step toward better regulation for nanomaterials, the EDF argues that

nanomaterials should be considered new chemicals under TSCA and that unless the exemptions mentioned previously (LVE and LOREX) are appropriately revised, nanomaterials should be ineligible for such exemptions (Denison, 2008a). Although the EDF thinks that other environmental organizations' proposals are excellent, it argues that it is detrimental to forget the other chemicals. A better regulatory framework for all toxic chemicals, developed on the principles of transparency and data collection, would be sufficient to regulate nanotechnology if some of the specific characteristics of nanomaterials are included. For example, the EU's REACH framework does not wait for complete scientific proof of cause and effect; rather, it uses the precautionary principle as a foundation and requires action to be taken when chemicals pose possible threats to human health and the environment. REACH also shifts the burden of proof to manufacturers, who have to demonstrate to the best of their ability the safety of their products before they can be released to the market.

In structuring REACH in this way, the European Commission acknowledges that industry has not only the burden but also the ability to generate data to ensure the safety of their products (European Commission DG Environment, 2007). According to the EDF, REACH was not developed with nanotechnology in mind but can regulate it more effectively (Denison, 2008e). In contrast to TSCA, REACH classifies chemical substances as "phase-in" and "non-phase-in." Phase-in substances are already listed in the European Inventory of Existing Commercial Chemical Substances. Non-phase-in substances can be broadly defined as the "new" substances, meaning they have not been manufactured, placed on the market, or used in the European Union before June 1, 2008.

Both phase-in and non-phase-in substances are evaluated for risk. In this way the law achieves the regulation of existing chemicals that did not receive attention under the previous law or under TSCA in the United States (Denison, 2008e). With regard to nanomaterials, for both REACH and TSCA scale has not been used to characterize chemical substances. Additionally, the fact that a substance has different properties cannot be used as the only factor to decide whether or not a chemical is a new substance (European Commission, 2008). Under REACH, most nanomaterials are considered phase-in substances. EDF seems to support the development of a regulatory framework like REACH and has been supportive of all the attempts for reforming TSCA since 2008 (Lautenberg et al., 2008). EDF believes that by controlling all chemicals effectively, the United States will also be able to better regulate nanomaterials (Denison, 2008e).

FoE, unlike the other two organizations, requests partial moratoria on products containing nanomaterials (I. Illuminato, personal communication, July 28, 2009). FoE and the ICTA believe that TSCA should authorize the EPA to prevent the release of nanomaterials into the environment until more is known about them (International Center for Technology Assessment and Friends of the Earth (ICTA–FoE), 2007). More specifically, in the case of nanosilver, a substance regulated by the FIRFA, the organization argues that "in the interim and the long-term the precautionary principle should be applied and all products containing nanosilver should be removed from the market for the time being" (Senjen & Illuminato, 2009). Beyond that, using the reports developed by Davies for PEN (Davies, 2007), FoE argues that even if the voluntary program developed by the EPA to help regulate nanomaterials is made mandatory,

"without further statutory or regulatory change, the amount of oversight EPA can provide is limited due to the inherent weaknesses and outdated nature of the law" (Senjen & Illuminato, 2009). FoE and ICTA also argue that the EPA should develop a nanomaterial inventory and tracking system (International Center for Technology Assessment and Friends of the Earth (ICTA–FoE), 2007). FoE agrees with PEN and EDF that all nanomaterials should be declared "new" chemical substances under TSCA and as a result should require a Pre-Manufacture Notification and review, accompanied by toxicity testing for nanomaterials intended for commercial use.

FoE and ICTA also argue that the "EPA has legal powers to compel nano-agrochemical manufacturers to provide toxicity data and to demonstrate product safety—that is, to place the burden of proof on the manufacturers" (International Center for Technology Assessment and Friends of the Earth (ICTA–FoE), 2007). FoE and ICTA also suggest that the EPA must act in accordance with the principles of oversight for nanotechnologies and nanomaterials (International Center for Technology Assessment and Friends of the Earth (ICTA–FoE), 2007). These principles include: 1) a precautionary foundation, 2) mandatory nanospecific regulations, 3) health and safety of the public and workers, 4) environmental protection, 5) transparency, 6) public participation, 7) inclusion of broader impacts, and 8) manufacturer liability (ICTA, 2007). Furthermore, oversight of nanomaterials must be based on an open and full assessment of the adequacy of current regulatory mechanisms and the adoption, with meaningful public participation, of a more comprehensive, mandatory, and robust regulatory system based on producer responsibility for the life-cycle impacts of nanomaterials (International Center for

Technology Assessment and Friends of the Earth (ICTA–FoE), 2007).

FoE believes that TSCA, even if reformed, cannot provide an adequate framework to regulate nanomaterials efficiently. Consequently, the reports from FoE focus more on products and materials that fall under other agencies and frameworks. FoE representatives also argue that these very novel technologies should be assessed in new ways and that currently TSCA offers neither the technical nor the technological abilities to provide assessment resources. FoE argues that ultimately a new framework must be developed that moves away from TSCA. For example, Ian Illuminato, FoE's health and environment campaigner, asserted that parts of TSCA are still usable, but a completely new regulatory package and a restructuring of the regulatory agencies is necessary. Currently the agencies (FDA, EPA) do not have the expertise or the budget to truly assess these products (I. Illuminato, personal communication, July 28, 2009).

3.5 Pathways to Political Influence

Because most of the implementation issues are technical (the question is usually how nanomaterials can be included under regulatory law), and most CSOs do not have the technical and/or scientific knowledge to propose solutions to that level of regulatory processes, it is easier and more productive for CSOs to participate in and influence the development of regulatory policy in the legislative arena. However, some CSOs also work directly with regulatory agencies, especially the EPA. This section will discuss first the pathway of legislative influence, then it will discuss the relations between the CSOs and regulatory agencies.

3.5.1 Congress

The responsibilities and the powers in the legislature are distributed among various committees of the House of Representatives and the Senate; this dispersed authority gives the advocacy groups many access points to influence policy making (Delmas & Terlaak, 2002). Traditionally, most interest groups, including environmental NGOs and trade unions, focus on developing informal relationships with elected legislators. In particular, the fact that some legislators are sensitive to the influence of such groups makes lobbying on legislative issues the main focus of US groups and usually the activity with the most fruitful results (Brickman et al., 1985). However, the informal relationships are hard to define, and consequently it is difficult to determine the amount of influence that advocacy groups have.

In addition to lobbying Congress, members of CSOs have increasingly taken part as witnesses in hearings. Hearings are held by different Congressional committees in order to discuss various science and technology policy issues. This is a formal way to participate that actually springs from years of informal relationships between CSOs and the legislator. CSOs that have been involved in policy development acquire a stakeholder status, which sometimes affords them the opportunity for one of their representatives to testify as a witness when legislation is under discussion. For example, the EDF has been a very active advocacy group in the issue of chemical regulation and enjoys recognition as a stakeholder in discussions of chemical policy making. Thus, even though there is no formal process for CSO involvement in nanotechnology policy in the US, the informal processes allow a relatively similar level of access to that of the EU. However, because in

the EU the CSOs have a close relationship with Parliament and relatively strong support from Parliament as a whole, it may be more accurate to say that the level of access in the US is only similar to that in the EU when Democrats control both houses of Congress.

CSOs can be recognized stakeholders in discussions about policy development and testify before committees of the Senate or the House of Representatives when a regulatory framework is introduced or discussed for reform. Those who testify make a case for or against the regulatory framework. When a bill is up for discussion by a committee in the Senate or in the House of Representatives, the majority party usually has the right to choose and invite the most witnesses, and "Congressional staff decide whom to invite, based in part on input from stakeholders, such as groups like EDF and industry"[3]. The EDF, especially Richard Denison, has been invited several times to testify before committees for issues such as TSCA reform, nanomaterial research, and regulation. In 2007, Denison testified before the house Committee on Science and Technology on the issue of environmental and safety impacts of nanotechnologies (Denison, 2007b). In February, 2009, and again in July, 2010, Denison testified for the reform of the TSCA to include all chemicals at least twice before the House Committee on Energy and Commerce, Subcommittee of Commerce, Trade, and Consumer Protection (Denison, 2009, 2010). Also, Clarence Davies, the senior advisor from PEN, has testified twice on issues connected to nanomaterial research and regulation, and about TSCA and its ability to regulate nanomaterials (Davies, 2006, 2009a).

The amount of influence that CSOs have in the legislative arena depends on which party is in power. CSOs think that that the status of the majority parity of the two

3 From e-mail communication with US NGO representative.

Houses, Republicans or Democrats, is crucial:

> [In] Congress last year (2010), when both Houses were controlled by Democrats, environmentalists had more clout, I think. And some of the provisions in here on nanotechnology (meaning in the Safe Chemicals Act of 2011 (S. 847)) were ones we helped to inform and helped to get in there. Environmentalists have less leverage now, less influence – certainly in the House of Representatives because the leadership has shifted (R. Denison, personal communication, April 22, 2011).

Both the S. 847 and the H.R. 5820, the Toxic Chemicals Safety Act of 2010, contain provisions that make size and size distribution part of the substance characterization, pointing out that variations in such characteristics may bear on the toxicological properties or the exposure potential.

The CSOs do not have too many political opportunities when Republicans control the executive branch or at least one of the houses of Congress. When I asked an environmental advocacy organization representative in 2011 if she thought that the US will adopt a more precautionary approach, she said "No, I don't think the US is headed in that direction at all" (J. Sass, personal communication, April 18, 2011). When I asked if her gloomy assessment was because the political scene is changing as well, meaning that the Republicans had regained control of the House of Representatives in 2010, she replied that it was depressing. The same person continued by making a comparison between the US and Europe:

So I think in Europe people see a role for government as regulating these toxics and making sure that things are safe, and making sure all sorts of other things. What I think is

happening in the US is that the Republican Party extremists [meaning the Tea Party] do not see a role for government... And that's a real problem for this kind of stuff. They see only two things for government. One is military and the other is – that's probably about it. So it's going to be a lot harder (J. Sass, personal communication, April 18, 2011).

Many of the Republican politicians do not see a role for government in regulating chemicals and nanomaterials. As a result, when the Republican Party has more control, there are almost no political opportunities to influence legislative policy development at the federal level. CSOs feel that this makes their jobs very difficult.

3.5.2 Regulatory Agencies

In addition to influence through the legislative process, CSOs can influence policy through the executive branch's regulatory agencies, for which responsibilities are also divided and granted to various players. For example, the EPA shares its responsibilities for protecting the environment with the Departments of State, Energy, Agriculture, and the Interior, and even for nanotechnology policy, there are two main regulatory agencies (the EPA and FDA) as well as research bodies that can support environmental, safety, and health research. As a result, advocacy groups can find many access points in the executive branch of the government to influence policy-making and implementation (Delmas & Terlaak, 2002). Advocacy groups usually communicate their opinions to the agency responsible for implementing regulation during critical stages of the regulatory policy-making process. These groups are usually pursuing "official publications, tracking rule making, participating in organized hearings, and petitioning administrators"

(Brickman et al., 1985, p. 257).

Environmental organizations can also become part of working groups led by administrative agencies. For example, the EDF was part of the group that discussed and developed the Nanoscale Materials Stewardship Program. The EDF actually initiated and participated in the deliberations of an EPA Federal Advisory Committee that proposed an approach for addressing nanomaterial's potential risks, part of which was the development of the Nanoscale Materials Stewardship Program (EDF, 2007; NPPTAC, 2005). In 2005, the National Pollution Prevention and Toxics Advisory Committee (NPPTAC) developed an Interim Ad Hoc Work Group on Nanoscale Materials, which consisted of ten representatives from small and large companies, NGOs, and welfare organizations. The group was responsible for discussing possible elements of the EPA's voluntary pilot program for existing chemical nanoscale materials, approaches that may be appropriate for putting such a voluntary pilot program in place, and issues that may be relevant to the review of new nanoscale materials under TSCA (NPPTAC, 2005). Also, the EDF, through its relationships with the administration, urged the EPA to use existing tools to regulate nanomaterials, something that PEN suggested as well. The development of SNURs is one example of the EPA using existing tools. CSOs are invited to stakeholder meetings to discuss implementation issues for nanomaterials: "Where there is a stakeholder panel, then they would have NGOs on it...but that's only when there's other non-government people on it, like industry representatives or something" (J. Sass, personal communication, April 18, 2011). In general when a regulatory framework is under discussion, or when the developments of new guidelines are under discussion,

agencies initiate stakeholder meetings, which usually include industry and environmental NGOs. However, stakeholder groups are not invited to intragovernmental meetings.

Another way for participation is through commenting during the process of guideline development or regulatory reform. Regulatory agencies invite comments when they develop guidelines for the regulation of specific substances or when they discuss new regulatory issues. In the case of nanomaterials, there have been numerous cases where CSOs have offered comments. For example, a number of CSOs commented on the development of SNURs for 17 substances, including some in nanoform. ICTA commented that the EPA is handling nanotechnology substances like any other toxic chemical and not considering the specific risks that such substances may pose, and the organization urged the agency to redesign the SNURs (Rizzuto, 2012). It is unclear if the EPA took the comments under consideration; however, the agency extended the comment period per the ICTA's request. Commenting periods have been in place under other regulatory frameworks like FIRFA, which allowed comments on a review about a Nanomaterial Case Study on Nanoscale Silver in Disinfectant Spray, and the FDA, which allowed comments on its guidelines (Duvall & Wyatt, 2011; US FDA, 2011).

3.5.3 Other Pathways

The third major way for US advocacy groups to make their positions heard is through the judicial branch of government and the litigation system, a pathway to influence that is relatively underused in the EU. The main reason is that in the US legislation makes it easy for advocacy groups to use legal petitions and lawsuits

(Brickman et al., 1985). In the US, most environmental laws enable citizens to file suits against the administration for either wrongful action or no action as well as for the right to access information. The system also encourages citizens to participate in the judicial review of environmental policies. As a result of these legal aspects and the required transparency of the environmental procedures, advocacy groups have another pathway to influence policy making other than directly lobbying Congress or administrative agencies (Delmas & Terlaak, 2002).

The CSOs have used lawsuits effectively to improve regulatory oversight of nanosilver. For example, the ICTA filed a legal petition in 2006 against the FDA for failure to regulate products containing nanomaterials, and it filed another petition in 2008 that requested that the EPA use its pesticide regulation authority to stop the sale of products containing nanosilver (ICTA, 2006, 2008). In 2011, it joined with other organizations (the ETC Group, FoE, the Center for Environmental Health, Food and Water Watch, and the Institute for Agriculture and Trade Policy) to file a lawsuit against the FDA in order to receive a response to the petition they filed with the agency in 2006 (ICTA, 2011). As of 2013 the FDA had not replied. The NRDC also filed a federal lawsuit with the EPA to ban nanosilver from specific uses in 2012 (Sass, n.d.). NRDC gained the support of ICTA and other groups (the Center for Food Safety, FoE, Beyond Pesticides, CEH, and Institute of Agriculture and Trade Policy) for that suit (ICTA, 2012), but the EPA replied through an answering brief that the NRDC failed to prove that their members faced an injury that is "actual or imminent," rather than "conjectural or hypothetical" (Bergeson, 2012b).

A final pathway for participation is through the appointment of certain people from the advocacy groups to high administrative positions. An example of this is the appointment of various environmental advocates in high-level administrative positions during the Carter administration. All these people were dismissed after the Republicans gained power in 1980 (Brickman et al., 1985). Although the pattern of career transition does appear in the state governments, there is little evidence that CSOs involved in nanotechnology have nurtured any leaders who have subsequently taken positions as nanotechnology regulators in the federal government.

In summary, although there are several possible pathways for CSOs to influence nanotechnology policy—legislation, regulatory rule-making, litigation and judicial review, and career transitions into the government—the overall effect of the CSOs on nanotechnology policy has been far short of what they would like to have achieved. One problem is the relatively high level of expertise that is required to participate, that is, the scientization of the nanotechnology policy field. There is no room for debate based on a simple approach of asking for a moratorium until all research is complete. To be influential at the regulatory level, an organization needs to have specific knowledge of the issues and a capacity to engage in a risk-based assessment of specific issues and chemicals. However, the two organizations that work on the TSCA and nanomaterial regulation in the US, the EDF and the NRDC, believe they are an exception to this. A representative said,

> At EDF, many of us that are working on chemical issues on TSCA have science backgrounds but most groups do not. So we tend to be more involved in the

> implementation of the law. So we are following agency regulation, we are filing comments on those regulations, we are doing analyses of the data that the agency is collecting, but we still work publicly mostly. Most of our clout comes from being able to speak publicly and mobilize public support for what we're doing. But we're sitting on panels that the EPA is convening that have industry people on the same panel. Whereas I think most environmental groups tend to work more in lobbying and so on, so they are not always sitting down with the industry and trying to hash something out there. They are more fighting political battles (R. Denison, personal communication, April 22, 2011).

The same representative added,

> Most environmental nonprofit groups are good at waging battles in the legislatures of the states or federally, and they're less good at working with the agencies or implementing laws. So they often can get good laws passed, but then the implementation of those laws is an area of weakness, and part of that is many of the issues are very technical on chemicals and certainly on nanomaterials. A lot of the environmental NGOs don't have scientists, don't have strong science in the backgrounds of the people that they employ (R. Denison, personal communication, April 22, 2011).

According to the EDF, the politics of the administration are another issue that sometimes make influence straightforward and other times more difficult. Depending on who is leading EPA and other agencies, environmental organizations have different levels of influence and different results. According to an environmental advocacy organization

representative, part of it is political: when Democrats are in charge, the political opportunity structure for chemical regulation opens, and when Republicans are in power, the opportunities close down significantly. For example, Denison compared the Obama and the Bush administration and noted:

> In the regulatory process now, at the EPA, we have a lot of influence. I would say in the last administration in the EPA we had much more limited influence. Part of that is political. Part of it is that the new EPA is really trying to be much more proactive, not necessarily precautionary, but proactive getting ahead of things. They believe they need more information to do their job. And since we've been saying that, they're receptive to our recommendations on things like that (R. Denison, personal communication, April 22, 2011).

3.6 Conclusion

In the US, the regulation of nanomaterials remains an unresolved issue. Furthermore, Congress has not been able to develop a comprehensive, new regulatory framework similar to that of REACH in the EU, and consequently nanotechnology regulation proceeds under the dated TSCA framework. Within those limitations, the EPA has made some steps towards regulating some nanomaterials for specific uses through SNURs and its review of pre-manufacture notifications under the new chemicals program. In 2012, the EPA had reviewed over 130 nanomaterials through the notifications. From the perspective of CSOs that are involved in nanotechnology policy, the EPA's work represents a good first step under a weak regulatory framework.

However, comprehensive nanomaterial regulation for all substances in the nanotechnology form remains elusive.

CSOs participate in both the legislative and the regulatory arenas, but significant expertise is required due to the scientization of the policy field. Litigation is also one of the main ways for CSOs to participate to regulatory policymaking, but such activities have to date only had limited effects for specific materials. CSOs have been advocating for changes through multiple pathways of influence, but only some of the issues they advocated for have become policy, and their achievements are far short of their goals. The EDF, for example, has played a very active role from the beginning of the debate. The EDF and PEN requested the development of a SNUR for all nanomaterials, and the EPA announced that they would do this in 2011. However, there have been no new developments, and only specific SNURs for specific nanotechnology substances and specific uses have been developed. Some CSOs, such as the ICTA, have pushed for better development of specific SNURs, and it is unclear if the agency has replied positively to such requests.

Furthermore, the overarching goal of reforming the TSCA for all chemicals, which has become a central goal for the EDF and the NRDC, has also remained elusive. The two CSOs believe that by resolving that issue, it will be enough, at least in principle, to regulate nanomaterials, but three attempts to initiate bills in Congress have not led to enactment of a new law. Although Democrats tend to be more sympathetic to regulatory reform for TSCA, and conversely Republicans are sceptical of more government regulation, neither party has made the issue a priority. The fact that neither party has a

great interest in chemical regulation suggests that industrial power is so significant that it successfully blocks regulation no matter which party is in power.

In contrast to other types of industries, the chemical industry consistently supports the Republicans at a higher rate than Democrats, mainly because of the fact that Democrats are more supportive of environmental legislative reforms. For example, during the 2008 election, the chemical industry contributed more to the campaign of Republican presidential candidate Senator John McCain's campaign than it did for that of Democratic candidate Barack Obama, and for over two decades the chemical industry has allocated more than three quarters of $75 million to Republicans. In 2009, the chemical industry spent $45.3 million on lobbying in federal level, and the American Chemistry Council spent $7 million, three times as much money as it had spent in 2007 (Spires, 2010). The total amount that the chemical industry spent in lobbying has being increasing since 2009. In 2010 the chemical industry spent almost $52 million, with the American Chemistry Council spending $8.13 million, whereas in 2011 the industry as a whole spent $52.4 million with the American Chemical Council spending $10.28 million (Center of Responsive Politics, n.d.-a). Although the chemical industry is not the largest of industries in terms of total campaign contributions, its donations facilitate its lobbying efforts. Although it supports Republicans more heavily than Democrats, the industry supports both parties and wins sympathetic members of Congress across the partisan divide.

4. Nanotechnology Policy and Politics in the EU

Policy making in the European Union takes place at two levels: the EU level and the nation-state level. EU-level legislation applies to all member states, but each member can develop its own legislation, and in turn the EU Commission, the executive body of the EU, can stop the member states from doing so. I will focus only on the EU level of regulatory and legislative activities, because the EU legislation applies to all the member states and gives a more complete picture of the EU approach, and because it is also more feasible to focus on the EU level rather than trying to evaluate 27 member states and their individual approaches. EU-level legislation and regulation takes place in Brussels, where interest groups, environmental organizations, trade unions, and various other groups lobby to make their requests heard. These groups contribute in various ways to the development of regulatory policy, such as by addressing regulatory gaps for new technologies and their products, especially the lack of a specific regulatory framework for nanomaterials. Some implementation-level changes are in place, but most nanomaterials remain unregulated or fall through loopholes in the current regulatory structure. CSOs are the main advocates for the development of better nanotechnology regulation in the EU.

This chapter will follow the structure of the previous one, beginning with a discussion of the background governmental structure and agency jurisdictions, followed a background on chemical regulation in the EU. After the two introductory sections, there is a description of the main CSOs that are involved, the unique NanoCap project to encourage CSO participation, the goals of CSOs for nanotechnology policy, and the

pathways in which they influence policy.

4.1 Government Structure and Agency Jurisdiction

The Commission is the executive body of the European Union and responsible for representing the interests of the EU, proposing legislation, and upholding the Union's treaties. It is also the body responsible for ensuring the proper implementation of the legislation by the member states. The Commission was first established in 1951, and since then it has been through many functional and structural changes. The Commission currently has 27 members, one from each member state.

The Commission is divided into several departments known as Directorates General (DGs). Each department is assigned a specific role and agenda and is responsible for handling different areas of policy and providing a variety of services. The Commission is supposed to be an independent body that provides the appropriate support and knowledge for decision making in order for the EU to function in the best possible way. The Commission has enormous power within the EU, even though the European Council holds power as well. The executive powers of the Commission have been criticized in the past by the member states. One of its more prominent abilities is that it holds the only right to initiate legislation.

The EU has essentially a bicameral legislature comprised of the Council of the European Union and the EU Parliament. The Council and the EU Parliament can request legislation, but the Commission initiates the procedures, develops the proposals, and also has the right to refuse such requests. After the Lisbon treaty, citizens also gained the right

to initiate legislation through a petition carrying one thousand signatures, but once again the Commission is not bound to follow the petition. When a law is passed, the Commission has the obligation to ensure its implementation with help of specific agencies and the member states.

The Council of the European Union, also known as the Council, represents the executives of each of the 27 member states, and it depends upon the issue as to what the configuration will be. In the case of environmental issues, for example, the Council is composed of the environmental ministers of each member state, who meet approximately four times a year. The president is appointed by the European Council, and the remaining 26 members are appointed by the Council of the European Union. The Council of the European Union should not be confused with the European Council, which is comprised of the heads of the member states, the president of the Commission, and the president of the Council. The European Council has become the EU's crisis solving body.

The EU Parliament is the only body of the European Union that is directly elected by the EU citizens, and it is currently composed of 754 members, each of whom holds a five-year term. The members come from the national states and belong to a variety of political parties, from conservative ones to very leftist and green parties. The Parliament is organized in seven different party groups, of which the European People's Party, the Socialists, and the Democrats are the largest groups. However, no single party has ever had the majority.

Most legislative decisions (including environmental legislation) are made through a co-decision procedure. This procedure was introduced by the Maastricht Treaty in 1992

and strengthened through the Amsterdam Treaty in 1999, but it became the ordinary legislative procedure with the Lisbon Treaty of 2009. The ordinary procedure gives the same power as legislative bodies to the EU Parliament and the Council, and as a result most of European laws, including environment and consumer protection, are now decided by both the EU Parliament and Council. The procedure follows the introduction of a legislative proposal to the two legislative bodies. As mentioned above, the Commission is the only EU body that has the authority to initiate legislative procedures. The proposal can go through three readings by the legislative bodies before it is adopted. During the first reading the Parliament develops its position. A Parliament's rapporteur prepares a report that is discussed within the political parties and the appropriate committees, and in plenary the Parliament adopts its position through simple majority. If the proposal does not contain amendments and it is also approved by the Council, then it is adopted by the Council through a qualified majority. It is then published in the official journal and becomes law. The same applies if the Parliament's proposal contains amendments that the Council accepts. In cases when the Council does not agree with the amendments that the Parliament proposes, the Council adopts its position through qualified majority and sends the bill back to the Parliament for a second reading.

During the second reading, the Parliament reads the Council's proposal and has a time limit of three months to respond. The Parliament can then approve the position, take no action, or propose amendments, but such amendments must have the support of an absolute majority. In that case, the new position is submitted to the Council, which has four months to respond. If the Council accepts the position, the law is adopted; if not, the

third reading and conciliation procedure must start within six weeks. During the third reading and the conciliation procedure, the discussion is taken to a committee that consists of representatives of the 27 state members and the Parliament. The committee discusses the proposals and amendments from the two previous readings. If the committee cannot reach an agreement within six weeks, the procedure is terminated. If the committee can agree and develop a text within six weeks, then it is forwarded to both the Council and the Parliament, which must approve it through a majority vote within six weeks ("European Parliament," n.d.).

The regulation of chemicals in the EU developed from the broader frameworks of environmental regulation and the concept of sustainable development, which is a pillar of the Lisbon treaty. EU environmental policy, even though it was not mentioned in the treaty of Rome, remains one of the most regulated areas in the EU. One reason is the political mobilization of the environmental movement during the 1970s and 1980s. The first Environmental Action Program (EAP) was developed in 1973 and was followed by four more programs. With growing global environmental threats, environmental policy has been at the top of the EU agenda since the 1980s. As the result of a growing interest in environmental EU policy, in 1981 the Commission established a separate Directorate General (DG) responsible only for environmental issues, the DG Environment, which became an avenue for environmental groups to push for greener policies. On the country level, Denmark, Germany, and the Netherlands, also known as the green troika, pushed for stricter regulations, with the poorer countries of southern Europe having the most problems and resistance in implementation (Dinan, 2005).

In 1985, the environmental policies were integrated into the European treaty, and the Single European Act gave the European Community a wide environmental scope. However, that scope was limited by the subsidiarity principle, that is, the principle of European law that allows the EU to act only when the laws of individual countries are insufficient. In 1992, the EU established the Financial Instrument for the Environment (LIFE) in order to assist in the implementation of EU environmental policy through co-funding environmental activities. In 1996 and 1997, after pressure from the Netherlands and Nordic countries, discussions about treaty reform involved three main issues: sustainable development, extending co-decision, and higher environmental standards. As a result, the Amsterdam Treaty included the principle of sustainable development as one of the EU's main goals. However, even though the Amsterdam Treaty allowed exceptions for environmental decisions to be made at the national level, provided that they were based on new scientific facts and specificities to the member state, the Amsterdam Treaty also gave the Commission the right to reject such national decisions. The sixth Environmental Action Program (2001-2010) has priorities such as tackling climate change and global warming, protection of nature, addressing environment and health issues, and preserving natural resources and managing waste (Dinan, 2005, p. 468).

In the EU, nanomaterials fall mostly under the regulatory framework of Regulation, Evaluation, and Restriction of Chemical Substances (REACH). The framework is very new; it only came into effect in 2007 and is considered to be one of the strictest regulatory frameworks in the world. However, like TSCA in the US, REACH does not specifically refer to nanomaterials, and discussions about how to regulate

nanomaterials within the framework of REACH are ongoing. The European Chemical Agency (ECHA), the agency responsible for implementing REACH, was also founded in 2007. It is governed by a managing board which consists of 27 members from the EU member states, two representatives from the EU Parliament, and six representatives from the Commission, including three members without voting rights who represent interested parties. Two of the three members who represent interested parties represent the interests of environmental NGOs (EEB) and trade unions, and the third represents the interests of industry (CEFIC) ("Management Board Members - ECHA," n.d.). The DG Environment and the DG Enterprise and Industry divisions of the Commission are also responsible for all issues concerning REACH. This shared responsibility is an unusual one because these two divisions have opposing, or at least very different, goals and interests.

Also like the US, other regulatory frameworks apply to nanomaterials, especially ones responsible for regulating food and cosmetics. For example, in December 2008, the EU adopted a regulation (EC/1333/2008) on food additives, which combines the regulations of all food additives in one act. The guidelines laid out in the regulation are focused on ensuring a high level of protection for human and consumer health. As a result, a food additive can only be approved if it does not pose a safety concern to the consumer's health. According to article 12 of the regulation:

When a food additive is already included in a Community list and there is a significant change in its production methods or in the starting materials used, or there is a change in particle size, for example through nanotechnology, the food additive prepared by those new methods or materials shall be considered as a different additive and a new

entry in the Community lists or a change in the specifications shall be required before it can be placed on the market (European Parliament & Council, 2008, p. 23).

In November, 2009, the EU adopted a new cosmetic products regulation, EC/1223/2009. This new regulation defines a nanomaterial as "an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm" (European Parliament & Council, 2009, p. 65). Before a manufacturer or importer puts a cosmetic product that contains nanomaterials on the market, the manufacturer or importer needs to inform the Commission about it. According to article 16 of the regulation, the information that must be submitted for cosmetics containing nanomaterials includes, but is not limited to, the toxicological profile of the nanomaterial, the safety data of the nanomaterial, and the reasonable foreseeable exposure conditions. Thus, the rules potentially ensure a high level of protection for human health in cosmetic products that contain nanomaterials (European Parliament & Council, 2009).

In March, 2011, discussions on passing the novel food regulation failed. The proposed regulation had provisions about the use of emerging technologies, including nanotechnologies in food production (European Parliament, 2008). The discussions failed because of the refusal of the EU Parliament to compromise on its request for mandatory labeling for foods derived from the offspring of cloned animals (Council, 2011). Finally, in 2012, the directive 2012/19/EU on waste electrical and electronic equipment was passed. This directive addressed the possibility of special handling of devices containing nanomaterials, but further amendments are necessary to address nanomaterials contained

in electrical and electronic equipment (European Parliament & Council, 2012).

4.2 Background on Chemical Regulation in the EU

Since 1967, chemical substances have been regulated under multiple directives and regulations, including the Dangerous Substances Directive of 1967 (67/548/EEC); the Classification Packaging, and Labeling of Dangerous Preparations Directive (1999/45/EC) of 1999; the Evaluation and Control of Existing Chemical Substances Regulation of 1993 (EEC No. 793/93); and the Restrictions of Marketing and Use of Chemical Substances Directive of 1976 (76/769/EEC). The problem with these frameworks is that they did not adequately regulate existing chemicals. Similar to the TSCA in the US, in the EU existing chemicals were also grandfathered. The member states and the Commission were responsible for putting together a priority list of chemicals that needed to be evaluated. Until 1998, only four substances had undergone evaluation, and only 38 had even been discussed (Williams, Panko, & Paustenbach, 2009).

One impetus for deeper reform was the 1996 report on the status of chemical regulation in Europe published by the Danish Board of Technology. The report, "The Non-assessed Chemicals in the EU," also included recommendations from an interdisciplinary group of Danish experts (Danish Board of Technology, 1996). The report mainly addressed the problems with the current regulatory framework, which regulated bulk chemicals, and what must be done in order for its deficiencies to be resolved. The main problem with that regulatory framework was the lack of knowledge

about the number and the effects of chemical substances on the market. The system also lacked a precautionary approach, a good classification system, and a post-marketing surveillance system.

In 1998, the European Environment Agency (EEA) also published a report on the state of chemical regulation in the EU titled "Low Doses, High Stakes?" Several points of concern raised by the agency were similar to those of the Danish report. The EEA report addressed the serious lack of monitoring and information in the current system, specifically the insufficient toxicity and eco-toxicity data for basic OECD risk assessment for 75% of the 2000 to 3000 large-volume chemicals that were being produced (EEA, 1998). At the same time, the report addressed the issue of risk assessments being based on single substances and not on mixtures to which humans and the environment were usually exposed. Also, besides the fact that the system lacked a more advanced method for calculating risk assessment, it focused on specific toxicity of single substances and not on the chemical properties of groups of chemicals, something that made the development of risk assessment a very time consuming process (EEA, 1998).

In 1998 at an informal meeting, representatives from Austria, Denmark, Finland, the Netherlands, and Sweden met with experts to discuss the issue of chemical regulation in Europe. The meeting produced a common position paper in which the five ministries supported the need for a new law that would be based on the precautionary principle and that would shift the responsibility for proof to industry. During the same informal ministry meeting, the ministries welcomed the idea of the European Commission ascertaining the facts in regard to the regulation of existing chemicals (Maxim &

Spangenberg, 2009).

On a related note, Greenpeace issued a report in 1999 called "Forward out of the Chemicals Crisis," which criticized the current chemical regulatory framework and proposed potential reforms. The Greenpeace report stated the same problems as the previous reports and argued that the system was failing by design. Greenpeace also stated that there was a lack of knowledge about the hazards that chemicals pose and that most chemicals had not gone through any assessments or that the assessments were not adequate. Greenpeace concluded that a successful system should be based on the principles of sustainability or substitution, where the development of clean production alternatives is essential, and would be able to provide information about chemical substances to the public free of charge. Finally, they argued that the systems should not limit regulation procedures for the substances but instead for the whole product cycle (Greenpeace, 1999).

In 2001, the EU Commission replied to these and other critiques with a white paper called "Strategy for a Future Chemicals Policy," which more or less addressed the criticisms of the regulatory system (European Commission, 2001). First, it stated that there was a general lack of knowledge about the properties and the uses of existing substances. It stated that more than 99% of all marketed substances were not subject to the same testing requirements, and complete risk assessments existed only for a small number of substances (European Commission, 2001). At the same time, risk assessments are slow and resource-intensive, and the available testing methodology limits the identification of endocrine disrupters. Consequently, the system does not work efficiently

and effectively. The same applies for the classification system, which does not serve regulatory purposes well. The lack of information results also from the fact that only manufacturers and importers, and not downstream users, are required to provide information about substances.

More generally, the European Commission's white paper stated that the precautionary principle is fundamental to achieving higher level of protection of human health and the environment (European Commission, 2001). A shift of the allocation of responsibilities to industry might be necessary in order to create better laws. A good regulatory system needs to have provisions that encourage the substitution of harmful substances with less dangerous ones when suitable alternatives are available, and it must provide incentives for technical innovation and development of safer chemicals, while setting clear goals aimed at sustainable development. The same system should also provide a way to make an adequate amount of information publicly available, as citizens should have access to information about chemicals to which they are exposed. This could be accomplished through use of the Internet.

The inauguration of REACH and the European Chemical Agency in 2007 entailed two major changes: the REACH framework shifted the responsibility of proof to the industry, and it called for the removal of the distinction between new and existing substances. Under REACH, the manufacturers and importers of chemical substances have to prove that their products are safe in order to be able to introduce them into the market. This means that they have to prove that their products are safe by developing risk assessments for their chemicals. This is a very costly procedure that regulatory agencies

had to fund prior to the development of REACH. REACH would also provide information about all substances, new or existing, in the market. This is the reason why REACH distinguishes between phase-in and non-phase-in substances. In general, phase-in substances are the substances that are listed in the European Inventory of Existing Commercial Chemical Substances (EINECS), or have been manufactured in EU but have not entered the market after 1992, or substances that are qualified as "no-longer polymers." Non-phase-in substances are new chemicals that have not been manufactured or placed on the EU market before 2008. Manufacturers or importers of non-phase-in substances need to register their non-phase-in substances with ECHA before they manufacture them or import them. The difference in registration of the two phases is that the phase-in substances may have later registration deadlines according to their production volume (as late as 2018), but phase-in chemicals must be registered eventually, unlike the situation for pre-existing chemicals in the US. In contrast, non-phase in substances regardless of the volume have to be registered before production. REACH, however, requires information and risk assessments for all chemicals, and differences in information are based on the volume production alone: the more the production volume, the more information is required for registration (European Commission DG Environment, 2007).

As the name implies, REACH consists of four main processes: regulation, evaluation, authorization, and restriction. Regulation is achieved through a number of steps. First, manufacturers and importers have to register the chemical substrates they produce or import. Phase-in substances are registered under REACH according to three

deadlines: November 2010, for substances produced to 1000 tons or more; May 2013 for substances produced to 100-1000 tons; and May 2018 for substances produced at 1-100 tons. In order to register substances in quantities of 1 ton or more per year, manufacturers and importers have to submit a technical dossier. For substances in quantities of 10 tons or more per year, they must submit a technical dossier and a chemical safety report. These dossiers will contain "information on the environmental and health properties of their substances, assess the risks arising from the uses of their substances, and ensure that these risks are properly managed" (ECHA, n.d.-a). After the dossiers are submitted, the ECHA is responsible for checking them and deciding if they are complete. Evaluation of the dossiers includes a compliance check, checking of proposals, and substance evaluation. Substance evaluation may lead to procedures such as authorization and restriction, labeling and classification, or regulation under a different legislation (ECHA, n.d.-a).

An authorization process applies only to substances of very high concern (also described as "Annex XIV substances"), which will gradually be included in Annex XIV and will not be allowed on the market unless the manufacturer/producer/importer is granted authorization. The candidate list of substances of high concern, which is identified by the competent authorities, includes carcinogenic substances; substances that are mutagenic or toxic to reproduction (CMR); persistent, bioaccumulative and toxic (PBT) substances; and very persistent and very bioaccumulative (vPvB) substances. They are identified on a case-by-case basis based on whether or not there is scientific evidence that they cause harm to humans and to the environment. An example of such a substance

would be one that acts as an endocrine disrupter. At the moment the candidate list contains 84 substances (ECHA, n.d.-b).

The substances on the candidate list will be prioritised by the authorities in order to determine which can be subject to authorization and currently includes 14 substances. Using prioritization, the competent authorities are making decisions about what substances will be a subject to authorization, which uses of the substances will not need authorization, and the sunset date that the substance will stop entering the market if it is not authorized. Industry can submit applications for granting authorization. Companies must include a chemical safety report, an analysis of possible alternative substances, and if they wish, a socio-economic analysis. An authorization will be granted if the applicant demonstrates that the risks posed from the substance are adequately controlled or, in some cases, if the applicant can show a case where the socio-economic benefits outweigh the risks (ECHA, n.d.-a). A substance may be restricted "if it is demonstrated that risks need to be addressed on a Community-wide basis" (ECHA, n.d.-a). The restriction may apply to all or to specific uses, and there is no tonnage threshold. The proposals for restriction would be made by the member states or the agency.

In all steps and processes of REACH implementation, interested parties will have the chance of giving comments and input (ECHA, n.d.-a). Finally, when it comes to classification, REACH regulates neither the criteria nor the obligations relating to classification and labeling. Instead, REACH builds in pre-existing laws that require industry to classify and label dangerous substances and preparations according to standard criteria (ECHA, n.d.-a). Both the authorization and restriction processes are

subject to public consultation. Presently, there are two substances under consideration for restriction.

The initial implementation of REACH took place between 2007 and 2010. The information that REACH gathers will fill in the gaps of knowledge about most of the chemicals on the market. REACH also found a solution to the huge costs of risk assessment, because it places the financial responsibility for covering costs of risk assessments on the industry. Additionally, in response to the fears that ECHA will be overwhelmed by paperwork, ECHA reported in November, 2010, that review of the dossiers is on schedule. By August, 2012, ECHA had received over 27,000 registrations. In its last progress report, ECHA stated that it had completed 70 compliance checks in order to determine "whether or not the information submitted is in compliance with the law. At least 5 % of the dossiers received by ECHA per tonnage band are compliance checked" (ECHA, 2010, p. 2).

Even though it is too early to judge how well REACH will perform in regulating chemicals, the framework's regulatory procedures raise questions about its abilities to produce good quality information and adequate protection for sensitive groups, to apply effectively the precautionary principle, to spur substitution and promote green alternatives, to provide information to the public, and to monitor adequate the environment. One of the main issues that REACH fails to address is that of the regulation of nanomaterials, even though they fall under its jurisdiction. In order for such issues to be addressed, REACH will continue to be under review in 2012. The issue of nanomaterial regulation has raised many concerns and discussions among different

interest groups. It has also initiated the creation of many expert groups to work on the issue and has led to a large dispute between the EU Commission and the EU Parliament about how nanomaterials can be best regulated.

As mentioned above, nanomaterials fall under the jurisdiction of REACH, but it was not developed with nanomaterials in mind, and its provisions are not based on scale. These shortcomings create many problems, the main one being whether or not nanomaterials are going to be considered phase-in (existing) or phase-out (new) substances. According to a 2008 report by the Commission, so far substance identification in REACH is completed on the basis of the information on chemical structure and purity, the chemical name (IUPAC and CAS), and other supporting spectral and analytical data. For the case of nanotechnology characterization, the REACH working group has identified the need for more information on the type of parameters that may be of significance for nanomaterials, for example, their particle size and their geometry. However, the working group found that the fact that a substance has different properties cannot be used as the only factor in when determining whether or not a chemical is a new substance. Under REACH, as a result of this, substances in nanoform that are in the EINECS Inventory are regarded as existing substances, and likewise those in nanoform that are not in EINECS Inventory are regarded as new substances. In certain circumstances, the working group may have to decide on regulatory issues about nanomaterials on case-by-case analysis. However, for the REACH working group, the identifying question is whether a nanomaterial should be considered a separate substance or whether it should be considered a particular form of a bulk substance (European

Commission, 2008). Along the same lines, in 2008 the Commission issued a communication paper concerning the regulation of nanomaterials. In this paper the Commission argued that nanomaterials are already covered by the existing legislation, highlighting the fact that specific action might need to be taken in specific cases. In effect the paper shifted the importance of the issue from the legislative arena to that of implementation (Commission of the European Communities, 2008).

Since 2009, ECHA has been revising its REACH guidance documents to include technical instructions to help companies include nanomaterials in their registration dossiers (Bergeson, n.d.-d). In 2009, ECHA also established the CARACAL group, which stands for Competent Authorities for REACH and the Regulation on Classification, Labeling, and Packaging (CLP)[4]. The task of the CARACAL group, according to its official webpage, is to "assist the Commission in the preparation of legislation or in policy definition, to coordinate with the Member States, to monitor the development of national policies and the enforcement of EU legislation by national authorities, and to provide expertise to the Commission when drafting implementing measures" (European Commission, n.d.-a).The CARACAL group is composed of two sub-groups, one devoted to the Annexes and one devoted to nanomaterials. The CARACAL subgroup for nanomaterials, also known as CASG Nanotechnology, is specifically devoted to the application of REACH to nanomaterials.

The same year ECHA developed and ran three REACH implementation projects

4 The CARACAL group "is an expert group which advises the European Commission and ECHA on questions related to REACH and CLP" (European Commission, n.d.-a). Previously the CARACAL group was known as "REACH Competent Authorities (REACH CA)" and before that as the "European Commission Working Group on the Practical Preparations for REACH" (European Commission, n.d.-a).

on nanomaterials, one on substance naming and identification (RIP-oN1) and two more on inherent properties of nanomaterials (RIP-oN2 and RIP-oN3) (Bergeson & Goulden, 2010). For RIP-oN1, consensus was reached only on one of the issues discussed, the identification of carbon nanotubes. According to the advisory report on RIP-oN1,

> The aim of the RIP-oN1 was to develop scientific/technical advice on the substance identification of nanomaterials. However, the discussions have revealed that certain aspects cannot be solved alone on the basis of technical/scientific arguments but will involve policy decisions such as previous decisions concerning polymers or alloys (Joint Research Center, 2011, p. 65).

As a result, the CARACAL group will continue to discuss the issue. RPI-oN2, which looks at information requirements, and RPI-oN3, which addresses chemical safety assessment, also made some suggestions for the development of appropriate guidelines for nanomaterials within REACH.

In 2009, the EU Parliament responded very negatively to the Commission's communication paper about the regulation of nanomaterials. The Parliament's 2009 report essentially argued the complete opposite of the Commission's recommendations. The Parliament stated that the existing regulatory frameworks are not adequate to regulate nanomaterials and that more legislative actions should be taken for the regulation of nanomaterials. The legislative body urged the Commission to start regulatory procedures from the development of a scientific definition for nanomaterials (European Parliament, 2009). The Commission replied to the Parliament's report by actually shifting slightly from what they wrote in the 2008 communication paper, stating that a regulatory change

might be necessary and that the Commission is committed to introducing changes in regulation where necessary (European Commission, n.d.-b). Furthermore, in 2011, the Commission actually developed a definition for nanomaterials. The use of the definition is necessary in order to determine if certain materials require special provisions. Under the definition a nanomaterial is:

- A natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm.
- In specific cases and where warranted by concerns for the environment, health, safety or competitiveness, the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %.
- By derogation from the above, fullerenes, graphene flakes, and single-wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials (European Commission, 2011, p. 40).

Because nanomaterials fall under the provisions of REACH, ECHA currently makes the decisions on how to implement REACH for nanomaterials. ECHA bases its decisions on the information and conclusions from the RIP-oN2 and RIP-oN3 and the definition developed in the paper on REACH and nanomaterials that was written by the Commission. ECHA makes such decisions in close cooperation with the CARACAL subgroup. The deadline for substances that are produced in quantities more than 100 tons but less than 1000 tons is in 2013, and the Commission expects that this is also when

nanomaterials will be registered (EC DG Enterprise, n.d.). However, the Commission determined in a follow-up communication paper on the regulation of nanomaterials the following:

> In the light of current knowledge and opinions of the EU Scientific and Advisory Committees and independent risk assessors, nanomaterials are similar to normal chemicals/substances in that some may be toxic and some may not. Possible risks are related to specific nanomaterials and specific uses. Therefore, nanomaterials require a risk assessment, which should be performed on a case-by-case basis, using pertinent information. Current risk assessment methods are applicable, even if work on particular aspects of risk assessment is still required (European Commission, 2012).

The Commission is confident that REACH is the best framework to cover nanomaterials and that special guidelines and requirements might be necessary in specific cases. ECHA is encouraged by the Commission to modify guidelines after 2013.

In 2012 REACH was undergoing its first review, and results were expected by the end of the year. During the review project, REACH dossiers containing nanomaterials were selected and reviewed for the quality of information and assessment. Following that the review, improvements, either legislative or technical, for the regulation of nanomaterials will be proposed. Finally, there will be an assessment of such decisions on the companies and on human health and the environment. In addition to the REACH dossiers, information will be gathered from the RIPoNs report and new scientific developments. CARACAL and CASG nanotechnology will also be informed. A first

project report is expected in November 2012 (DG Enterprise and Industry, n.d.-a).

4.3 Advocates for New Nanotechnology Regulation

There are six groups (mainly I will use the term CSO to refer to them) that work on nanomaterial regulation at the EU level: one EU umbrella environmental organization, two international environmental law organizations, one consumer organization, one national environmental organization, and one EU umbrella trade union organization.

The European Environment Bureau (EEB) is a large umbrella environmental organization that brings together more than 140 grassroots environmental and citizen groups from all over Europe. Created in 1974 with the aim of providing a focal point for its members to monitor and to respond to the EU's environmental policies, the EEB describes itself as the "environmental voice of European citizens, standing for environmental justice, sustainable development and participatory democracy" (EEB, n.d.). EEB representatives are involved in discussions of policy development at the EU level and are in constant contact and dialogue with all three European institutions, the Commission, the Parliament, and the Council. The EEB provides expert insight on various environmental issues including nanotechnologies. Funding for the EEB comes from a variety of sources, including three foundations, the United Nations Environmental Program (UNEP), and the Organization for the Economic Co-operation and Development (OECD); however, the majority of funds comes from European governments, especially environmental ministries, the EU Commission, and more particularly the DG Environment. For example, in the case of nanotechnologies, the EEB's involvement

started in 2006 with the NanoCap project, which was funded by the EU. With the funding from that project, EEB published four reports under the series title "Nanotechnologies in the 21st Century" (Fedrigo & Senjen, 2010; Senjen, 2009a, 2009b, 2009c). EEB is involved in many public dialogues with the goal of ensuring sustainable and responsible development of nanotechnologies. On the policy side, EEB works closely on regulatory policies that cover nanomaterials, such as the novel food regulation and REACH. However, EEB has a strong focus on nanosilver, with one individual working specifically on this topic. In the case of REACH, the focus is more towards bulk chemicals.

The Center for International Environmental Law (CIEL) is an international not-for-profit environmental law organization created in 1989. CIEL strengthens and uses international law to protect the environment, promote human health, and ensure a just and sustainable society. CIEL has offices both in the US (Washington, DC) and Europe (Geneva, Switzerland). Supported primarily by private foundation grants but also by some governmental grants, the organization works more as a consulting firm and provides counsel, advocacy, policy research, and capacity building on issues like biodiversity, chemicals, climate change, and human rights. Nanomaterial regulation is part of CIEL's chemical program, and it is handled by the Geneva office. The organization advocates for precaution in the use and development of nanotechnologies internationally. More specifically, within the European Union, CIEL collaborates with other European CSOs in order to assist European institutions in the development of appropriate legislation for nanomaterials. The involvement of CIEL on the issue of nanomaterials started in 2009, when CIEL hired attorney David Azoulay to lead the then

new nanotechnology program from the Geneva office. Since then CIEL has participated in many activities connected with the regulation of nanomaterials. At the EU Level, in 2010 CIEL, together with EEB, led the submission of a proposal for the definition of nanomaterials to the EU Commission. This proposal was supported by over 40 organizations. Also, in 2012, CIEL published a report on REACH and nanomaterials (Azoulay, 2012). CIEL is currently one of the few organizations that works on issues of nanomaterial regulation within REACH.

ClientEarth is a non-for-profit environmental law organization that was founded in 2008. The organization uses law, science, and policy to find solutions to environmental problems. With offices in London, Brussels, and Warsaw, ClientEarth works on various environmental issues from biodiversity to climate law and corporate law. Part of the health and environment program of ClientEarth is the toxic chemical program, which is focused mainly on REACH and its implementation. ClientEarth's work on the regulation of nanomaterials began in 2010, when attorney Vito Buonsante was hired to lead the program. ClientEarth works through litigation and searches for ways to use the law to benefit the environment. For example, in 2011, they filed a lawsuit against ECHA requesting data that they believed should be public but that ECHA refused to disclose. Their expert on REACH is one of the few who focuses on issues about nanotechnology regulation in the EU. ClientEarth is funded through philanthropic foundations and also through the European Commission's Life+ program.

The Bureau Européen des Unions de Consommateurs (BEUC), the European Consumers' Organization, is the consumer's organization formed in 1962 by the consumer

organizations of Belgium, Luxemburg, France, the Netherlands, Italy, and Germany. BEUC was created in order to serve the EU citizens from Brussels and was one of the first lobbying organizations based in the European capital. As an umbrella organization for member organizations from more than 30 countries, financing comes from members and the EU government. BEUC's main task is to represent its members and the interests of all European consumers by advocating for safe products and services that do not put human health and the environment at risk. BEUC also investigates EU policies and strategies that might have an effect on consumers having a specific focus on issues of sustainability and energy, financial services, food, health, and safety. Nanomaterials are an issue for BEUC because they are found in consumer products, and BEUC follows regulations that affect especially food and cosmetic products. Their involvement in nanotechnology issues started in 2006, when they asked for precautionary regulations in the use of nanomaterials in food. BEUC also advocates the labeling of products that contain nanomaterials and the right for consumers to know what products contain nanomaterials.

BUND, or Friends of the Earth Germany, is a German non-for profit grassroots NGO with more than 480,000 members. The organization was founded in 1975 and has the mission “to foster the use of renewable energies, to ban the production of genetically modified food and fodder, and to reduce the amount of toxic chemicals in everyday life is always based on concrete alternative options and solutions” (BUND, n.d.). BUND is probably the most active environmental organization in the EU working on nanotechnology issues. The funding for their nanotechnology program comes mostly

from member fees and donations but also from the German Environment ministry. BUND's involvement in nanotechnology issues started around 2006, and the organization follows many aspects of nanotechnology and its products at multiple levels. Their concerns include risk issues, everyday consumer products that contain nanomaterials, dangers and risks that are posed from the use of nanomaterials for both humans and the environment, ethical issues, and also regulatory and policy issues. For the last topic, BUND is probably the only NGO that follows all regulatory frameworks that cover nanomaterials at the EU level, that is, food, cosmetics, and REACH.

The European Trade Union Confederation (ETUC) is the EU level umbrella trade union association, which was founded in 1973 to promote the interests of the EU working people and to represent them in the EU institutions. The ETUC counts 85 members from National Trade Union Confederations, and it is also recognized as one of EU's social partners. As a social partner, ETUC is involved in policy-making at the EU level and works with all the EU institutions. In addition to having the right to consultation with the other European social partners and a close connection with a cross-party Intergroup of MEPs in the European Parliament, ETUC works in a number of areas at the European level, from defending the European social model to environmental issues. One environmental issue that ETUC focuses on is chemical regulation and more specifically REACH and nanomaterials. One of the most active organizations on nanotechnology regulation in the EU, ETUC has been active in the arena since 2006. ETUC has its own independent research and training center, the European Trade Union Institute (ETUI), which places its expertise at the disposal of the workers. Since 2008, ETUI has organized

meetings on nanomaterials and also provided support and advice for ETUC representatives in their work on nanomaterial regulation. ETUC gets its funding from its memberships fees, but funding also comes from the European Union.

Of all six advocacy groups, only CIEL, ClientEarth, and the ETUC work on REACH and nanomaterials at the EU level. However, EEB is the organization that appears at the majority of meetings and working groups. This is because many environmental organizations work under EEB as the umbrella organization. As a result, I will consider EEB as one of the active organizations in REACH and nanotechnology regulation. Also, all of these organizations, including the ETUC, work very closely together and have so many opinions and requests in common that it is sometimes hard to distinguish between the different organizations and approaches. In the case of BUND, even though they work mainly in Germany, their extensive knowledge of nanotechnologies and the fact that they exchange information with EEB and other organizations means that the organization has significance at the EU level, too.

It is a common understanding among advocacy groups that REACH covers nanomaterials in principle, but the actions of the Commission and ECHA make it impossible for the framework to accomplish the goal. For example, a CSO representative involved in the EU nanotechnology debate describes the problem as follows:

> First they (meaning the Commision and ECHA) write a document saying, "Oh, REACH already covers nano." Then, in this guidance for substance identification, they put a disclaimer saying: "There is not enough technical knowledge to distinguish properties from others. So the identity of the substance cannot be

discriminated by the size" (Anonymous, personal communication, December 17, 2010).

As a result, it is impossible to register a substance in nanotechnology form because there are no ECHA guidelines for doing so. For example, in 2011, carbon nanotubes were registered as black carbon, sometimes also called soot (Buonsante, 2011).

4.4 The NanoCap Project

An important spur to the involvement of NGOs in nanotechnology policy was the "Nanotechnology Capacity Building NGO" Project, or NanoCap, which the EU funded in 2006. The project ran until 2009 and was developed along the lines of consensus conferences, but it included only CSOs, and the discussions were on the EU level. Its main goal was to build the capacity of CSOs to participate in the EU debate about nanotechnology regulation ("NANOCAP NanoCap," n.d.). The project was developed in the anticipation of the nano-debate about to happen, and thus it is an example of anticipatory governance and technology assessment, as discussed in Chapter 2. The development and funding of similar projects that are vital for CSOs has not been a part of US federal practice or spending.

The CSOs were pleased to have the opportunity to gain from experts, and the project was successful in initiating the CSOs' involvement in the nanotechnology debate in the EU and in enabling CSOs to participate actively in the debates about the regulation of nanomaterials in the EU. Also, the CSOs that took part in the project, especially the ones that work at EU level, felt that the project enabled them to influence regulatory and

legislative procedures concerning nanomaterials. Through the NanoCap project, CSOs gained valuable knowledge about the issue and used it to influence policy development through the connections that they had with the government.

Pieter van Broekhuizen, who was involved in a consultant agency and who had been working with CSOs for many years, became involved with the issue of nanomaterials regulation in 2005. Van Broekhuizen was able to create an opportunity for CSOs to have a good position on the nanotechnology debate, which was still in its infancy. Industry already knew a great deal about nanomaterials, so it was a good idea to organize a project that would increase the knowledge on nanotechnologies of CSOs, and contribute to their positioning on these issues. The idea was to set up a capacity building project for European CSOs (P. van Broekhuizen, personal communication, March 7, 2012). The three-year project would take place at semi-annual conferences, combined with training and awareness-raising sessions. A consortium was set up consisting of five environmental NGOs and five trade unions, while five universities would have the task of producing academic material and providing necessary information on the different aspects of the nanotechnology debate. Another aspect made this idea worth developing--the possibility of getting funding from the EU Commission.

In order to develop and submit the project for funding, Van Broekhuizen had to recruit partners for the consortium. The recruiting activities started locally with the university that the IVAM Research and Consultancy on Sustainability belonged to, the University of Amsterdam, and more specifically its Institute for Biodiversity and Ecosystem Dynamics, which would cover hazard issues connected with nanotechnology.

Van Broekhuizen also recruited the environmental NGO Stichting Natuur en Milieu (SNM), the Netherlands Society for Nature and Environment, and the trade union FNV, the Federation of Unions of the Netherlands. After recruiting members from the Netherlands, the organizer turned to the European umbrella organizations, including the EEB and the European Trade Union Institute's Health and Safety Department.

After securing the cooperation of umbrella organizations, the idea was to represent Europe as much as possible. Involving Germany was crucial because of its large chemical industrial activities related to nanotechnologies. From Germany the Kooperationsstelle Hamburg, an independent department that works in the area of Occupational Safety and Health (OSH), established in 1987, participated as an intermediary for the German trade unions. Even though Van Broekhuizen wanted to involve Eastern European countries, this was impossible because of language barriers. Instead, Van Broekhuizen developed contacts with trade unions in Austria. However, because of the constitutional crisis the unions were facing at the time, a consulting company, called ppm focusing on occupational health and safety issues and the working environment, participated in place of the Austrian trade unions. The team of trade unions was complete with the addition of Amicus the Union, an organization of approximately 800,000 members from Ireland, England, Scotland, and Wales.

In addition to the EEB and the Netherlands Society for Nature and Environment, three other environmental organizations were chosen in order to include the rest of Europe. Because Italy is a large country with industry, Legambiente (an Italian, non-profit association that focuses on protecting the environment and on promoting the

sustainable lifestyle) was included. After securing the support and involvement of that organization, Broekhuizen wanted to involve Poland, but he found out that language was a barrier so instead he contacted the Baltic Environmental Forum, an environmental NGO based in Lithuania that works on both national and international issues. Finally, he recruited an organization from the Balkan countries, the Mediterranean Information Office for Environment Culture and Sustainable Development, and recruited the Federation of Mediterranean Non-Governmental Organizations for Environment and Development. It was established under a joint project of the European Environment Bureau and the Hellenic Society for the Protection of the Environment and Cultural Heritage in 1990 as a network of NGOs and works in close collaboration with the Arab Network of Environment and Development. Thus, the Mediterranean organization was not only a connection with southern Europe but also with the Arab countries.

The academic part of the consortium consisted of five universities, each contributing in a different area. The University of Amsterdam's Institute for Biodiversity and Ecosystem Dynamics (IBED) is active in the field of environmental sciences and has expertise in hazards and hazard reduction related to nanotechnology. The Interdisciplinary Nanoscience Center (iNANO) at University of Aarhus provided the NanoCap with information on fundamental and applied nanotechnology R&D, and the Technical University of Darmstadt's Institute for Philosophy, in combination with the Office for Interdisciplinary Nanotechnology Studies, also contributed on the topic of ethical issues connected with the development and the use of nanotechnologies. The Lung Toxicology Research Unit of the K.U. Leuven, which has extensive experience in

hazard assessment through its involvement in regional hospitals, contributed to the issue of occupational risks. Finally, the University of Essex completed the consortium by contributing in identifying environmental implications of nanotechnology and occupational health and safety issues[5].

The NanoCap might not have been representative of all the NGOs with nanotechnology activities, but it played a very important role in initiating and contributing to the participation of civil society stakeholders in EU policy debates. The way the NGOs were chosen to participate was such that there would be representation from the whole of Europe. Van Broekhuizen recruited the NGOs he thought would be representative geographically for the remaining four NGOs. It is not clear why he did not include BUND, Friends of the Earth Germany, which is the most active group in nanotechnology in the EU. One assumption might be that he had already included a trade union consultancy from Germany, so there was some representation from that area. Another possibility is that BUND works locally in Germany. Other international organizations were not included either, such as Greenpeace. One possible explanation is that Greenpeace may refuse to participate in a project funded by the EU government. In

5 The NanoCap was funded by the Science and Society Program for Research, Technological Development and Demonstration, "Structuring the European Research Area" (FP6-SOCIETY), and it cost 1,306,180 Euro. The FP6-SOCIETY was a program with the goal of bringing science and society closer to one another and encouraging the harmonic relationship among science, technology and society, part of the European Commission's six framework program FP6 (Multi-annual Framework Program 2002-2006 of the European Community for research, technological development and demonstration activities aimed at contributing towards the creation of the European Research Area ("CORDIS," n.d.). From 2002 to 2006, the FP6 was the main financial program that contributed to the creation of a genuine European research area by structuring and strengthening it ("CORDIS," n.d.). FP6 consisted of two specific programs, one on integrating and strengthening research and a second on structuring the European research area. FP6 received 17,883 million euro for funding from the European Union. The NanoCap was one of the projects that was funded in order to build a relationship between society, in this case CSOs, and science, and to promote the responsible research and application of science and technology.

any case, NanoCap was just one project, and it was not representative of all NGOs and all organizations active in the nanotechnology debate. However, it is important to note here that EEB, the main umbrella organization that represents all the NGOs across Europe, did not have nanotechnology in its agenda before the NanoCap, and most of the NGOs in Europe started using the word "nanotechnology" in their press releases after 2006 (Gaude, 2006).

The NanoCap project started in September, 2006, and ended in September, 2009, with a conference in which the participants presented their conclusions to the EU Parliament. The project also produced reports and material to be used to inform the participants about the relevant research and developments that surround nanotechnologies. The information was made available on the project's web site and was developed in such way to help CSOs to participate in a constructive discussion. The publications covered many areas and focused on the development of a balanced view about nanomaterials. More specifically, the first of the publication series was a general introduction that provided background information, definitions, and also some details on the special nanotechnology properties (Filipponi & Sutherland, 2007a). The other publications discussed possible applications of nanotechnologies. Two were devoted to energy: the first discussed the potentials in solar energy developments from the use of nanomaterials in photovoltaics, and the second discussed hydrogen conversion (Filipponi & Sutherland, 2007b, 2007c). There was also a publication on the possible environmental benefits of nanomaterials, for example, in techniques of pollution remediation, pollution prevention, and environmental sensors (Filipponi & Sutherland, 2007d). Two other

publications addressed the medical benefits that nanotechnologies can provide, such as new diagnostic tools and effective drug delivery systems (Filipponi & Sutherland, 2007e, 2007f). Another one considered applications of nanotechnologies on catalysis (Filipponi, n.d.).

The project evolved much like a consensus conference; however, the objective of encouraging CSOs to develop a position was more open-ended than the goal of arriving at a consensus statement. The universities were responsible for introducing and explaining the issues, and CSOs then discussed the issues and formed their own positions and opinions. The project was carried out through five working conferences, with each focused on a different aspect of nanotechnology. Presentations were given at each conference and also additional reading material was presented to the participants. Some conferences, except for presentations and the introduction of new information on nanotechnology, had agendas built in such way that the CSOs had time to meet and develop their opinions about nanotechnologies. The NanoCap project ended with a final conference that was held at the EU Parliament on April 2, 2009, when the CSOs presented their positions. Members of the Parliament, the chemical industry, consumer organizations, and the EU Commission were participants at the final conference.

The NanoCap project contributed toward building the knowledge of CSOs and gave them the capacity to involved actively in the nanotechnology debate. The CSOs' resolutions that resulted from the NanoCap project became the main guide for their policy goals for the following years. For the ETUC, the policy platform developed during the NanoCap process became its official position. CSOs think that their NanoCap

experience was invaluable and gave them the resources to be involved in a very important debate on more equal terms with the industry. Many of the CSO representative I interviewed indicated that before the NanoCap project, nanomaterials and their regulation did not appear on the organizations' web pages, press releases, projects, or publications. Most of the CSOs involved in the NanoCap and others that are currently active in nanotechnology issues started their involvement after 2006. Only BUND, Friends of the Earth Germany, mentioned nanotechnology in a press release in 2006 (Gaude, 2006). Most of the CSOs started seriously working on the issue in 2009, that is, after the conclusion of the NanoCap Project. One of the NanoCap participants added:

> [We] learned a lot about nanotechnologies from the NanoCap. The project deepened considerably our understanding of the environmental, occupational health and safety issues and related ethical aspects of nanotechnologies and enabled us to inform our member organizations and through them also the general public. If it wasn't for the NanoCap our members and network would most probably have very limited information about the issue and its implications... Without the NanoCap we wouldn't be able to be active in the policy debate on nanomaterials and nanotechnologies. Now we have developed our capacity to bring to the relevant European and International fora an objective and representative view and perspective of the Mediterranean civil society on emerging nanotechnology issues, many of which might have a significant influence on the sustainable development of the region (T. Vlachogianni, personal communication, March 5, 2012).

In summary, NanoCap essentially built up the knowledge of CSOs from scratch.

The presentation by the Natuur en Milieu, the NGO from the Netherlands, during the first NanoCap conference illustrates the lack of knowledge: the presentation simply identifies the basic problems and promises of nanomaterials. There are some general suggestions but no specific points about what actions the Commission should take. At the third conference, the presentation by a representative from the trade unions, ETUI, on how REACH might cover nanomaterials, is much more informed. The trade union representative gave important details about the tonnage of coverage and the appropriate registration of such materials, citing parts of the legislation and the responses by the Commission to the issue. The presentation concluded, "REACH does not cover all marketing and uses of nanomaterials (e.g. biocides, cosmetic, food applications)" (Tony Musu, n.d.). The presentation also noted that REACH has many loopholes, even for nanomaterials that fall under its scope, and it concluded that in order for REACH to cover nanomaterials, there should be an amendment to the regulatory framework (Tony Musu, n.d.).

An indicator of how important NanoCap was for CSOs is the fact that the positions they developed about the regulation of nanomaterials in the final NanoCap conference are the positions and goals they still had as of 2013. The ETUI prepared the trade unions' position and the European Trade Union Confederation agreed with its resolutions and adopted the position in 2008 (ETUC, 2008). The ETUC argued that manufactured nanomaterials and nanotechnologies can have great potential for improving life and creating new jobs, but concerns about potential risks, not only to the human

health but also the environment, are present and should not be dismissed. This is why the trade unions stressed the need for an "in-depth debate" (NanoCap, 2009, p. 8). The trade unions' resolutions touch upon many different issues, from marketing to workers' protection to consumer protection. Their first point requested the application of the "no data equals no market" principle of REACH regulation for products containing nanomaterials. They also requested modifications to the registration procedure of REACH "in order to cover all nanomaterials, including those produced or imported in quantities below 1 ton/year" (NanoCap, 2009, p. 8). Additionally, they argued that a standardized definition was needed in order for adequate regulation to be accomplished. Finally, the trade unions requested the involvement of workers in risk assessment procedures, the increase of the budget for research on health and environmental risks, and the labeling of all consumer products that contain manufactured nanoparticles (Decaillon, 2009). The ETUC was also able to publish two official position papers (ETUC, 2008, 2010) on nanomaterials, which essentially described the views and demands of EU workers, ETUC organizers, and more than 60 million workers in Europe, and the statement by the ETUC drew general attention within the EU.

The environmental NGOs developed goals similar to those of the trade unions. The NGOs also requested that the current voluntary codes that are developed for the safer use and development of nanomaterials become mandatory. As for the research and development of the field, NGOs requested sustainability issues and societal needs be used to guide the development of the field, and they argued that "[a]ll new nano-related projects receiving EU funding should be required to include a sustainability assessment

and appropriate decision making mechanisms, including public participation" (NanoCap, 2009, p. 14). Finally, the NGOs urged the European Commission and the member states to communicate with the public with transparent information about the possible risks of nanotechnology and to involve the public in the debate and the decision making processes (Hontelez, 2009). The EEB also published four reports on issues surrounding nanotechnologies and their products because of the NanoCap. The first one was dedicated to the challenges and the opportunities of the field (Senjen, 2009a), the second to the health and environmental concerns (Senjen, 2009b), the third to governance issues (Senjen, 2009c), and the last one to innovation challenges (Fedrigo & Senjen, 2010).

Beyond the position statements and publications, the NanoCap project provided the knowledge required for CSOs to participate in expert panels. Before the NanoCap, they did not have the knowledge to participate meaningfully in the regulatory procedures. Even if they thought that nanomaterials should be regulated, they could not make an accurate or detailed argument in defense of their position. A trade union consultant said, "Without this background knowledge (from NanoCap), you cannot participate. You only have an uneducated position. I mean you can only have gut feelings but you cannot use arguments that are developed" (Anonymous, personal communication, March 6, 2012). They have been also able to follow policy and implementation trends in the field of nanotechnologies and have participated in several events of relevance such as the NanoCap & STOA conference "Working and Living with Nanotechnologies" (April 2009), the OECD conference on "Potential Environmental Benefits of Nanotechnology" (July, 2009), the EU "Scientific Hearing on Nanotechnologies" (September 2009), the

DEEPEN project event "Reconfiguring Responsibility: Deepening Debate on Nanotechnology" (September 2009), etc. (T. Vlachogianni, personal communication, March 5, 2012).

At the national level, in the case of Germany, for example, a representative from the trade unions who participated at the NanoCap told me that trade unions, because they had the knowledge and understood the possible risks from working with nanomaterials, could influence implementation:

> In Germany trade unions managed to get this issue of occupational health and safety for nanomaterials onto the agenda of the Hazardous Substance Committee, which is the committee that advices the ministry for labor social affairs. Currently a guideline promoted by the Unions is under development. This was also initiated by the NanoCap project (Anonymous, personal communication, March 6, 2012).

In summary, the NanoCap project was an important moment in the EU level nanotechnology debate, and it is in striking contrast with the absence of funding for similar CSO involvement in the US.

4.5 Goals of the Advocacy Organizations

All groups involved in the debate about the regulation of nanomaterials under REACH agree that the framework does not regulate nanomaterials adequately, even if REACH covers nanotechnology in principle. The problems that most groups identify can be classified in two main areas: problems with the framework itself and problems with the administration. The first group of problems, those particular to nanomaterials, include

the lack of a definition as to what a nanomaterial is. Because REACH does not distinguish between nanotechnology and bulk substances, advocacy groups are concerned with the following question:

> When is the nanomaterial a nanomaterial and not a bulk material anymore? And even within one nanomaterial, you might come to the conclusion that you actually need to distinguish them into different forms of the same substance but still have different registrations (J. Vengels, personal communication, February 4, 2011).

They also ask questions like "how to distinguish between two different nanotechnology materials and when they need to be considered as different substances" (T. Musu, personal communication, December 13, 2010). The lack of definition within REACH is the main problem that all groups identify.

A second big issue that all groups identify as a deficiency of REACH is the tonnage trigger. As a representative from an international NGO explains;

> Theoretically REACH does apply to nanotechnology, because the definition of substances does not mention size, so the whole question is how you make it efficient for nano. What information that is not required for bulk chemicals would be necessary for risk assessment to be done for nano? What risk assessment paradigm has to change to make it adequate for nano? These things are in the process of being changed. But there is another aspect of REACH that needs to be changed for it to apply adequately for nanotechnology, including the question of tonnage trigger. In REACH the way the tonnage trigger is designed is completely inappropriate for nanotechnology (Anonymous, personal communication,

December 16, 2010).

REACH has three tonnage thresholds for registration: 1 ton, 100 tons, and 100000 tons. The more tons of production per year, the more data are required by ECHA and the more quickly the registration procedure will occur. Substances that are produced in lower quantities are not subject to registration, but this is exactly the problem with nanomaterials: they are produced in much lower quantities than bulk substances. If any nanomaterials are going to be registered, according to the existing REACH guidelines, then their registration will take place in 2013 or even later (2018). Additionally, even in the case of nanomaterials that are produced in large quantities, a phase-in status will actually require limited information only for the physicochemical properties of the substance. No toxicological, eco-toxicological, or exposure information (required only for substances of very high concern) is required, because such information is assumed to be known and transferable from the parent bulk substance. However, the assumption is not applicable to nanomaterials, because they might not share the same toxicological properties with a chemical that has the same structure. According to CIEL, "Because most nanomaterials currently on the market are derived from 'parent substances' that benefit from a phase-in status, the vast majority of nanomaterials currently marketed benefit from delayed registration deadlines in direct contradiction with the 'no data, no market' principle underlying REACH" (Azoulay, 2012, p. 2).

Another important issue that groups believe makes REACH inadequate for the goal of regulation of nanomaterials is the lack of nano-appropriate risk assessment provisions. As a representative from BUND put it, "Can you test nanomaterials in the

same way as bulk materials, or do you have to test them differently?" (J. Vengels, personal communication, February 4, 2011). As REACH works now, any information on the development of an assessment for nanomaterials will be based on guidelines that are developed for bulk substances without any specific consideration of the unique characteristics of nanomaterials. Furthermore, a nanomaterial might be characterized as non-hazardous just because the bulk substance from which it is derived from is considered non-hazardous (Azoulay, 2012).

Beyond the issues that are specific to nanomaterials, advocacy groups identify many issues that are problematic within ECHA and the way ECHA handles registrations and performs reviews. In 2010, during the second EEB Chemicals Working Group meeting, NGOs and trade unions expressed concern about information dissemination. ECHA does not publish information that should be public under the Directive 2003/4 IEC on public access to environmental information, and furthermore the agency has very poor data. According to the CSOs at the meeting, presently ECHA publishes only the substance name, the identification number, and the registration number of phase-in substances, and many of the fields that are not supposed to contain confidential information are left empty. More information is in previous inventories, making ECHA and REACH look like they are moving backwards. Also, concerns were raised about the fact that ECHA does not check the information provided by the industry and that the industry can easily enter inaccurate information. Also, once a registration number is given there is no mechanism for it to be taken back[6]. In reality, ECHA will only check five

6 Observational material during the participant observation at the EEB Nanotechnology and Chemical Working Group Meeting, 2010, Brussels: this was a comment made by a trade union representative.

percent of the dossiers, and in 2011, at an Academy of European Law Conference on REACH, ClientEarth stated that there are incidents of dossiers getting registration without having proper information. Until then, ECHA had refused only 26 registrations out of 20,723 (Buonsante, 2011).

Advocacy groups are also concerned with ECHA's independence in processes of decision making. In 2010, a representative from ETUC made a comment about the famous shift of the responsibility to prove safety of a substance to the industry, essentially asking the question, "For whom does ECHA work?[7]" The comment raised concerns that ECHA may be making its decisions for the benefit of the industry, and similar concerns have been raised about ECHA's independence from the Commission. For example, an environmental consultant from Greenpeace who works on chemical issues stated that ECHA receives much guidance from the Commission, even though it is supposed to be an independent body (Anonymous, personal communication, November 29, 2010). Along the same lines, in 2011, ClientEarth stated that the ECHA takes the Commission's legal opinions, which are kept secret, as the basis for decision making, even though ECHA should be an independent body. Furthermore, participation in ECHA meetings is limited on the basis of unclear criteria (Buonsante, 2011).

Even though REACH is built on the precautionary principle, the framework is not yet appropriate for nanotechnology, and advocacy groups believe that the precautionary principle, especially in the case of nanomaterials, has not yet been applied. In fact, the first request of all groups (EEB, ClientEarth, CIEL, BUND) is for the ECHA to apply the precautionary principle for nanomaterials. In particular, ETUC urges the Commission and

7 See footnote 6.

ECHA not to repeat the same mistakes with bulk chemicals. Instead, it asks them to apply the "no data, no market" principle of REACH (another way to describe the precautionary principle) (T. Musu, personal communication, December 13, 2010).

Advocacy groups also pushed to get a scientific definition for nanotechnology that can be used to identify substances in nanoform within REACH registration. In particular, ETUC has published a detailed concept paper on how nanomaterials can be identified appropriately. The paper notes that the unique characteristics of nanomaterials are not limited to size, but they also include the particle size distribution (PSD) and the shape of the nanomaterial (ETUC, n.d.). In its 2009 position paper, the EEB also suggested that the nanotechnology definition should include substances with sizes between 0.3nm and 300nm and also substances that have nanomaterial-like properties, even if they fall beyond the 0.3nm – 300nm size range (EEB, 2009). In 2011, the Commission, as mentioned in a previous section, developed a recommendation for a definition for nanotechnology. EEB, BEUC, and CIEL welcomed the fact that the recommendation was adopted and hope that this new development will be an important step towards the adequate regulation of nanomaterials; however, some of the CSOs found the definition narrow (Azoulay, 2011; BEUC, 2011; Duprez, 2011). Additionally, CIEL, BEUC, and EEB expressed their disappointment about the cut-off limit for a material to be identified as nanomaterial. The recommendation sets this limit at 50%, meaning that if 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm to 100 nm, then the material is considered a nanomaterial, while the initial proposal by DG Environment and advocacy groups was 1%, and 0.15% by the

Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and DG SANCO (Health and Consumer) (Azoulay, 2011; BEUC, 2011; Duprez, 2011). In a press release EEB stated, “The European Environmental Bureau (EEB) is deeply disappointed by the European Commission’s decision released today to use a narrow definition for the term 'nanomaterial,’ indicating that industry lobbying has won over the Commission’s own scientific advisors” (Duprez, 2011).

Besides the definition, advocacy groups request the development of appropriate guidelines for nanomaterials that will be identified and undergo the registration process under REACH. Such guidelines should at least include specific lower tonnage triggers for substances identified as nanotechnology and new testing and assessment specific for nanomaterials. In addition to this, EEB (through its 2009 position paper), ETUC (through its 2010 second resolution on nanotechnologies and nanomaterials), and CIEL (through a 2012 report) requested that REACH specify that nanomaterials are not considered phase-in substances and that registration dossiers for nanomaterials include a Chemical Safety Assessment, in order to reach the “high level of protection of human health and the environment” (Azoulay, 2012, p. 4).

CIEL and EEB also developed an additional suggestion for the regulation of nanomaterials. They suggest the development of a new nanotechnology-specific framework for the regulation of nanomaterials. EEB justifies the position as follows:

> Given that nanotechnologies and nanomaterials can be used in many different ways and in different types of products, a policy and regulatory framework which can address these various applications coherently and comprehensively is needed.

> This framework should also be able to address future developments, as detailed in our demand for a pre-market registration and approval framework (EEB, 2009, p. 5).

This framework would include pre-market approval, necessary implementation tools, and robust safety assessment standards. CIEL also suggests the need for a regulation that will provide a list of general principles "for the management of nanomaterials, indicate that all terms would be consistent with their definition in REACH and define nanomaterials using the Commission proposal" (Azoulay, 2012, p. 5). Provisions will include a production threshold of 10 kilograms for registration.

Finally, the Commission's second communication paper on the regulatory aspects of nanomaterials was received with great disappointment by the CSOs (European Commission, 2012). In a joint response, the advocacy groups stated that the European Commission's approach is inconsistent with its own analysis. Even though the Commission's working paper acknowledges the existence of possible risks that nanomaterials might pose and the fact that REACH does not at the moment adequately regulate nanomaterials, the Commission considered only a minimal amendment to the REACH annexes, which would not close the existing loopholes. The groups concluded that "when information is lacking on the toxicity of a substance, rather than assuming that no data means no harm, the Commission should enforce a precautionary approach and regulate the production and collection of data, and adequately restrict, ban, or tightly regulate the marketing of the substance concerned" (EEB et al., 2012).

4.6 Pathways to Political Influence

In Europe, lobbying is also one of the main ways that advocacy groups achieve participation and influence at the legislative level of policy making. Traditionally, political parties play a very important role by intervening in legislative policy making, and the lobbying takes place according to partisan affiliations. The trade unions have many ways to access policymaking, because the EU is built on a social partnership between capital and labor (Brickman et al., 1985). More generally, political scientists have observed that the EU political structure presents many political opportunities for CSOs to participate and influence policy making (Ruzza, 2007). For example, Imig and Tarrow note, "European environmental groups profit from vigorous ecological movements in the member states, a DG dedicated to their claims, and generous subsidies from the Commission" (2001, p. 21). This section will consider three main pathways to political participation in the EU: the Commission, the EU Parliament, and the regulatory agencies such as the European Chemical Agency. In contrast with the discussion for the US, there are only limited uses of litigation, such as the lawsuits by ClientEarth mentioned above. Unlike in the US, litigation and judicial mechanisms are not widely used and are not discussed here. The role of the courts is more restrictive in the EU. Because of more vague statutes, advocacy groups do not have the advantage to use the courts as groups do in the US and they do not usually use legal means to pursue their requests[8] (Brickman et al., 1985).

8 The problem with the EU litigation system is access to justice which for CSOs is limited only to access to information through the regulation (EC) No 1367/2006 on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies. Based on that regulation two European CSOs (ClientEarth and ChemSec) filed a lawsuit against ECHA in 2011 regarding the secrecy on public information about specific chemicals.

4.6.1 The Commission

Advocacy groups have many political opportunities to participate in policy developments and discussions at the EU level. According to the EU Commission, "Civil society plays an important role in giving voice to the concerns of citizens and delivering services that meet people's needs" (2001, p. 14). The involvement of civil society in EU governance "is a chance to get citizens more actively involved in achieving the Union's objectives and to offer them a structured channel for feedback, criticism and protest" (Commission of the European Communities, 2001, p. 15). Unlike in the US, environmental and other advocacy groups have official roles in committees and expert groups. Also, the Commission has to go through a consultation period before any legislative decision is made, and CSOs are official stakeholders in the consultation process.

Because the EU Commission is the only body that can initiate legislative procedures, it has enormous power. However, as an appointed powerful body, the Commission is more or less a coalition of expert divisions, each specializing in a different area of policy, and consequently it has a democracy deficit, which is attempted to be neutralized by having formal mechanisms for public and stakeholder consultation periods before the development of any law. This allows the Commission to obtain the opinion of the public about the framework that they are about to develop. Civil society then plays the role of a consultant through the public consultation period. CSOs have informal relationships with individuals in the Commission, and they lobby those individuals in an attempt to influence opinions. For advocacy groups the consultation

period is a very important tool especially because the CSOs are recognized stakeholders. As an EEB representative stated, "At least the Commission has to consider what we are saying. This is an obligation that they have to respond to and take into account the opinions expressed by all the stakeholders, and we are a recognised stakeholder" (Anonymous, personal communication, December 1, 2010). In 2003, CSOs sent their comments to the Commission during the consultation period for REACH (DG Enterprise and Industry, n.d.-b). In 2011, when the commission was developing the recommendation, they sent comments for the nanotechnology definition (EC DG Environment, n.d.).

The CSOs also have unofficial ways to participate too, and they lobby like every other interest group. As previous research has shown, lobbying at the EU level is quite easy, and the various institutions facilitate access to such activities. According to most of my informants, "Lobbying is apparently easy in the sense that you can just walk in the room of an MEP (Member of the European Parliament), or you can just meet somebody in the Commission or go to the Council" (Anonymous, personal communication, December 17, 2010). As lobbyists, CSOs try to influence the individuals with power in the Commission, and Commission legislators, especially from DG Environment, know CSO representatives very well. In meetings, conferences, and workshops they talk to one another and sit together. Because they have a division devoted to their cause, the DG Environment, CSOs use their informal relationships with that DG to influence policy making. In response to this, representatives from the DG Environment state that CSOs are an important stakeholder, because they represent a certain interest and, unlike

industry, generate information in a way that is not biased by economic means (Anonymous, personal communication, February 23, 2011).

However, even if advocacy groups have access points to the Commission, a DG devoted to their cause, and established relationships with legislators, these benefits do not guarantee successful influence on policy outcomes. In the opinion of an environmental advocacy group representative, that seems to be the case with nanotechnology regulation:

> I think the EEB has good contacts to the Commission, but I don't think that they are heard very well. I mean, if you look at what the Commission is saying about nanotechnology, they are very reluctant to do anything" (J. Vengels, personal communication, February 4, 2011).

In the case of nanotechnology regulation, CSOs do not get exactly what they advocate for. Even though the latter advocated for major REACH reforms in relation to the regulation of nanomaterials, the Commission's 2012 communication paper on the regulatory aspects of nanomaterials proposed minimal changes and case-by-case approaches based on existing assessments for bulk chemicals (European Commission, 2012).

Of all the requests that CSOs made, they achieved a successful response for only one, the development of a recommendation of a definition for nanomaterials. Even in this case the final definition was substantially different from what the CSOs advocated. For example, EEB considers the definition too narrow to protect the human health and the environment (Duprez, 2011). As a representative from an EU based CSO noted:

> Of course the Commission's initiative is secret. More or less they can do what

> they want. But at least they have to justify why they take this or the other approach....Even though the NGOs may shape or at least try to shape the general policy objectives, when it comes to the actual proposals that the Commission finally proposes, it is difficult to have access to that (Anonymous, personal communication, December 1, 2010).

The same individual continued:

> Even though we work a lot with DG Environment, who should be our allies, it is very difficult to get access to the drafts positions which are debated, because if you have a proposal, it's always the Commission which adopts a proposal, but there are different services which have to be consulted (Anonymous, personal communication, December 1, 2010).

The same observation has been made in political science literature before (Rucht, 2001).

From that last statement, it is obvious that besides the secrecy issue, there are two more issues at play, the different services within the Commission that need to be consulted and the different powers that these services possess. The case of REACH, as an employee from the Commission's DG Enterprise put it, is "a bit atypical, because here we do not have one department clearly in the lead, as is usual in the Commission, but we have a joint responsibility of DG Enterprise and DG Environment, so it means that we have to closely work together on everything we do on REACH" (Anonymous, personal communication, February 22, 2011). But holding hands appears to be a bit difficult for these two DGs. These two divisions represent completely opposite interests. As EEB's policy officer for REACH stated:

> There are often very big differences in approaches when it comes to DG Enterprise and DG Environment and what the line would be of the Commission. So here the internal fights are going on and well...we of course want to strengthen the position of DG Environment (Anonymous, personal communication, December 1, 2010).

The Commission normally tries to balance interests, because the regulation of chemicals and nanomaterials is a special case, because of the shared responsibilities between DG Environment and DG Enterprise. Although the DG Environment is always looking for a balanced approach, they place an emphasis on the environment (Anonymous, personal communication, February 23, 2011). However, the same is not true of DG Enterprise, as an employee from DG Enterprise explained:

> From a DG Enterprise perspective, competitiveness, innovation, and the free movement of goods on the internal market are always issues to be considered as well...And I don't think it means that whatever we do in REACH must be, therefore, steered by the precautionary principle as such. It's something to bear in mind, but REACH also very much relies on the issue and the concepts of risk, risk assessment, and risk evaluation (Anonymous, personal communication, February 22, 2011).

The difference in interests between the two DGs creates conflict within the Commission during discussions about REACH. Adding to the conflict is the fact that CSOs feel that DG Environment has inferior powers to that of the DG Enterprise, and even the DG Environment is not always loyal to their environmental interests: the DG Environment is

"only one DG, and the DG Enterprise is always more powerful" (J. Vengels, personal communication, February 4, 2011).

One reason why DG Enterprise is more powerful, or why CSOs feel that the DG Environment is not always on their side, is the fact that industry has the ability to lobby much more effectively than the CSOs. The limited capacity of CSOs due to their limited financial resources is a serious issue for them, and it was addressed in interviews with comments such as: "Our capacity to [provide] input is limited by our limited resources and especially in comparison with industry resources" (Anonymous, personal communication, December 16, 2010). The unequal influence is also noted in the literature (Rootes, 1999). Due to their limited resources, the CSOs usually only lobby at the DG Environment. Generally they do not bother to go to the DG Enterprise, because that DG clearly has different interests than their own, plus the industry already has more affinity on that DG's activities, including for REACH. As an employee from DG Enterprise stated:

> They appear to naturally see us as negative towards their concerns. It's a bit different from what I see industry doing. We also see approaches from industry associations, from individual companies. And my impression is that what the industry and the companies do is approach both DG Enterprise and DG Environment (Anonymous, personal communication, February 22, 2011).

The ability of the industry to lobby more gives them a quantitative advantage. That advantage, together with the understanding that DG Enterprise has more power in decision making than the DG Environment, gives the CSOs little opportunity to have

much influence, even in the DG Environment. Thus, the CSOs focus their limited lobbying resources on the DG where they expect to have the greatest influence, but even for the DG Environment, legislators stated that there are more individuals from industry than from CSOs who come to discuss nanotechnology regulation with them (Anonymous, personal communication, February 23, 2011).

Industry has an advantage in consultation as well. While REACH was developing and after the white paper was out, the consultation period that followed had many responses from various organizations, industry, and other third parties. Some comments are more powerful than others. In the public consultation for REACH, the contributions from industry were more numerous than the ones from the CSOs (DG Enterprise and Industry, n.d.-b). This was especially the case with the consultation period in the case of the nanomaterial definition. During that period the Commission received 200 responses. Only one was from the CSOs, which filed jointly one position, while there were numerous responses from industry.

In summary, even though many environmental advocacy groups have various opportunities, both official and unofficial, to participate and influence policy making in the DGs of the Commission, this does not mean that the groups are successful. Distribution of powers within the different DGs and between the advocacy groups and the industry converge to limit the influence of CSOs. For example, the Commission's second communication paper was received with great disappointment by the CSOs but was welcomed by the European Chemical Industry Council (CEFIC, n.d.).

4.6.2 The EU Parliament

As with the Commission, various advocacy groups lobby the EU Parliament in order to influence policy developments. The CSOs have no official way of accessing the Parliament's procedures or decision making as they do in the case of Commission, where they have the consultation periods, rights as stakeholders, and also the ability to participate in committees that discuss the implementation of regulations. Any relationships that they have with the Members of the European Parliament (MEPs) and advisors who work with the MEPs are usually informal and can be described as lobbying.

Nevertheless, most advocacy groups involved in the nanotechnology debate think that lobbying in the EU Parliament is easier than in any other body of the EU government. For example, an EEB representative explained that from his experience, it is much easier to lobby at the EU Parliament:

> MEPs are very busy with a lot of things, and they do not really know the subject. So we are briefing them: that's what the role is. Everyone is doing it, industry and us. So they have two sides of the coin. And then they can make the decision on their opinion based on what the different positions are (Anonymous, personal communication, December 1, 2010).

This sentiment was also confirmed by the advisor of the European Greens, who said the following:

> [MEPs] are very open to outside information or, you could also say, vulnerable to lobbying pressure depending on the people and the interest group. It is a lot easier for lobbyists to work via the Parliament, because it's a limited number of

> individuals, so you can work with them to try to influence them, thereby basically shape potentially the position of the Parliament... to decide on the most diverse things: on economics, on social issues, on health, on environmental issues. Nobody in this house can possibly oversee, let alone understand, all the laws that have been adopted. So, it will always be a handful of people who dive into this subject and look into it, but they themselves often start (some of them might already have a good background on the issue) but often they don't...I mean, people by definition have to be generalists and listen to different people and then make up their minds. They are far more open but also vulnerable to all the pressures (A. Singhofen, personal communication, November 17, 2010).

The EU Parliament, especially its Green Party, creates many opportunities for CSOs to influence nanotechnology policy. Unlike the positions of the Commission and the practices of ECHA, the EU Parliament takes a position that is very supportive of environmental and human protection. In many meetings, representatives from the European Green Party are not afraid to call out the Commission and ECHA; they complain about how badly the Commission and ECHA have handled the case of nanotechnology regulation and how they made false promises about taking action. For example, at a meeting about REACH in March, 2011, the Greens' advisor mentioned that there is almost no information on nanomaterials in the registration dossiers, even though the Commission and the European Chemical Industry Council (CEFIC) said otherwise. In reality, until 2011, the dossiers that industry submitted to ECHA indicated the presence of substances in nanotechnology form for only three substances with no specific information

(Singhofen, 2011). Also, the Green Party appears to have informal relationships with CSOs, where they exchange information as well as their frustrations about what the Commission has not done. At the same March meeting, the advisor of the Greens always asked questions about what the Commission or ECHA did not do and, while presenting at the meeting, openly confronted the representative from the Commission about the lack of regulation for nanomaterials and the empty promises that both the Commission and ECHA had made (Singhofen, 2011).

The EU Parliament has also worked with CSOs in opposition to the Commission. According to the advisor of the Greens, although usually the Commission has a period of consultation both for the public and the stakeholders, this was not the case for nanomaterials. In the case of nanomaterials, the Commission released a communication paper in 2008 on the regulatory aspects of nanomaterials, which argued that nanomaterials are already covered by the existing legislation and highlighted that specific action might need to be taken in specific cases. Essentially the Commission shifted the importance of the issue from the need for new legislation to a problem of implementation (Commission of the European Communities, 2008). To the advantage of the CSOs, the EU Parliament replied to that communication paper with a resolution in 2009 that argued the complete opposite of what the Commission argued in 2008. The Parliament stated that the existing regulatory frameworks are not adequate, that more legislative actions should be taken for the regulation of nanomaterials, and that the Commission should base regulatory procedures on the development of a scientific definition for nanomaterials (European Parliament, 2009). According to the advisor of the Greens:

> The Parliament does not agree with an absence of any nanotechnology-specific provisions and with the Commission's conclusions that current legislation covers in principle the relevant risks and that protection is achieved, mostly in hands by improving implementation. And this was adopted unanimously. We said that the safe response is jeopardized by the lack of information of the use, the safety, and what's on the market and so on, and so we call for specific review (A. Singhofen, personal communication, November 17, 2010).

This particular act from the EU Parliament was very important for the CSOs. Even though the pattern of inequality is present between the industry and CSOs, in the case of nanomaterial regulation the CSOs had the Parliament on their side. The lobbying activities of CSOs were far more successful that the lobbying coming from industry, because Parliament's resolution had the same main points that CSOs were requesting. The EEB policy officer heading the nanomaterial project stated that all the points of the EU Parliament's resolution are relevant:

> If you look at all they ask for...basically I would say that the EEB position pretty much matches with that. In its resolution, the European Parliament calls for the precautionary principle to be applied to nanotechnology, and that the 'no data, no market' principle of REACH is also applied to nanotechnology to make sure that products containing nanoparticiles or produced with the help of nanotechnology are safe before you put them in the market...and this is also what we are asking for (L. Duprez, personal communication, December 1, 2010).

Despite this widely recognized difference between the Parliament and the

Commission, the DG Environment did not even admit that there was a difference of opinion between the two. The DG Enterprise, on the other hand, did recognize the difference. According to the opinion of an employee from the DG Enterprise, the Parliament is mainly composed of elected politicians:

> As opposed to the Commission, where the large part of the staff is appointed as staff, so they're not elected or anything, the Parliament represents the people's view if you like, and its composition reflects the ideas of the people. And yeah, we have a Parliament that, on the one hand, has, I would say, a rather strong base in parties that you can see traditionally as rather representing the industry side, but it also has I think a fairly strong base in parties that tend to take more protective viewpoints (Anonymous, personal communication, February 22, 2011).

As a result of the legitimacy of the EU Parliament based on its electoral base, its resolutions are taken seriously by the Commission, which in the case of nanomaterials regulation initiated the procedures for the development of a scientific definition for nanotechnology. The Commission actually shifted slightly from the stance that they stated in the 2008 communication paper, saying that regulatory change might be necessary and that the Commission is committed to introducing changes in regulation where necessary (European Commission, n.d.-b). This roadmap progress paper produced by the DG Enterprise as an initial reply to the EU Parliament's resolution was, according to the advisor of the Greens, “a piece of shit. It is empty basically...and there basically, they kind of rephrase it a little bit, which is not correct, but the most important thing is that the commission intents to review relevant legislation instruments and report on this.

So they came out with it" (A. Singhofen, personal communication, November 17, 2010). Even though the report was not of the quality that the EU Parliament expected, the Commission did recognize the need to do something about the issue of nanotechnology regulation, and in 2011 it developed a scientific definition for nanomaterials, albeit not one that was welcomed by CSOs.

> The CSOs know that it was the EU Parliament that made the difference: Because the parliament now basically said, 'Listen, you have to do something. You cannot keep on going like this.' Well, now, they changed their position a bit, but before that, they always said, 'Well, it's regulated. Regulation is enough. We don't have to do anything about it. The regulation only has to be implemented and that's not our issue; it's for the member states to do.'...So they didn't do anything and basically I think they would like to keep on with that position" (J. Vengels, personal communication, February 4, 2011).

4.6.3 REACH and the CSOs

The third main pathway for influence for the CSOs in the EU is through the regulatory regime. REACH covers all materials in any size and form; however, nanomaterials need specific guidelines and approaches, and only the European Chemical Agency (ECHA) has the authority to issue new guidelines or update old ones. CSOs play an advisory role to ECHA through the working groups and committees composed of experts who discuss the development of guidelines and ways of implementing REACH for nanomaterials. In these committees and groups, CSOs have representatives who

discuss these issues with experts from ECHA, the Commission, the member states, and the industry. Industry, NGOs, and trade unions have no voting rights, and they are considered to be observers.

One of the expert groups in which CSOs participate as observers is the CARACAL group. The task of the CARACAL group is to "assist the Commission in the preparation of legislation or in policy definition, to coordinate with the member states, to monitor the development of national policies and the enforcement of EU legislation by national authorities, and to provide expertise to the Commission when drafting and implementing measures" (European Commission, n.d.-a). The CARACAL group consists of two subgroups, one devoted to the Annexes and one devoted to nanomaterials. In both subgroups, CSOs are observers. In the nanomaterials subgroup, also known as GASG nanotechnology, EEB and ETUC each have a representative.

The GASG nanotechnology subgroup discusses implementation issues for nanotechnology, as a CSO representative that participates to the subgroup explains:

> REACH is the main regulation, but [there are] also the thousands and thousands of pages of guidelines that say how you should interpret and implement the actual regulations [that] we are discussing here and the guidelines that we are changing. We are not even changing the guidelines; we are coming up with recommendations for the guidelines to be changed by ECHA, because ECHA has the legislative right to change the guidelines. Theoretically REACH does apply to nanotechnology, because the definition of substances does not mention size, so the whole question is how you make it efficient for nano. What information is not

> required for bulk chemicals and would be necessary for risk assessment to be done? What risk assessment paradigm has to change to make it adequate for nano? These things are in the process of being changed (Anonymous, personal communication, December 16, 2010).

The CASG nanotechnology group is a way for CSOs to be formally involved in the implementation of REACH for nanotechnology. When I asked a ETUC representative if participation is feasible and meaningful at the EU level, he agreed that it was and gave me an example of his participation in the CASG nanotechnology group:

> In the CASG competent authorities' subgroup on nanotechnology, there are maybe ten people. Well it might be more than ten—let's say that ten people are really contributing to the work...including the trade unions are among them. They contribute. They propose solutions to a very technical problem (T. Musu, personal communication, December 13, 2010).

Because of their official role in groups such as the CASG, CSOs have more opportunities to influence regulatory policymaking. In 2009, the Commission initiated three implementation projects known as RIP-oNs for nanomaterials, the purpose of which was to evaluate how well REACH applied to nanomaterials. The RIP-oN1 project, which was devoted to Substance Identification of Nanomaterials, was carried out in cooperation with a group of experts from Member State Competent Authorities, industry, CSOs (EEB and ETUC), and the European Chemical Agency (ECHA). These experts were chosen by the CARACAL group, and the project was coordinated by the European Commission's Joint Research Center. The CSOs were included in that implementation project. Not only

were their members among the experts, but they also decided who these experts were going to be (Joint Research Center, 2011).

According to the advisory report for the RIP-oN1 project, much of the discussions ended up in disagreements, and consensus could not be reached (Joint Research Center, 2011). According to the report, most of the disagreement was coming from the industry, which had a different position from that of the relatively high level of agreement among member states, ECHA, and the CSOs. Although industry experts argued that size should not be regarded as an identifier, the expert from the Swedish member state argued that size should be an identifier, the Irish and the ETUC experts argued that size could be an identifier, and the EEB expert argued that without a doubt size was an identifier. Likewise, with respect to the issue of surface treatment[9], industry once again argued that it should not be regarded as an identifier, the ECHA expert that it could be an identifier, and the EEB and Swedish experts also argued that surface treatment is an identifier. Agreement was achieved in only one area, the identification and naming of carbon nanotubes. However, the CSO experts developed a separate report about the issues to which agreement was not achieved (size and surface treatment as identifiers) that proposed their preferred concrete guidance, which included suggestions on size and surface treatment as identifiers. According to the RIP-oN1 report, "This work is appreciated and will be made available in the further process and can be used for the concrete guidance updates should decisions go in that direction" (Joint Research Center, 2011, p. 48). The fact that the discussion is ongoing and presents opposite positions

9 One of the specific characteristics of substances in nanotechnology form is the high surface area to volume ratio. Because of this characteristic, nanomaterials are usually surface treated and as a result surface treatment can be of higher importance for the identification of a substance in nanotechnology form than it is for bulk substances.

shows that the various experts, including the ones from CSOs, are heard. When they have the support of member states, their position is stronger, but still the industry has the capacity to block action even when there is relatively high level of consensus among the other participants.

In contrast with the RIP-oN1 implementation project, CSOs were excluded from RIP-oN3 and RIP-oN3. Work concerning RIP-oN2 (the implementation project on information requirements on intrinsic properties of nanomaterials) and RIP-oN3 (the implementation project on information about safety evaluation and risk management of nanomaterials) was led by Europe's Center of Excellence on Nanotechnology Hazard and Risk. This center is based at the Institute of Occupational Medicine (IOM) and has as partners the European Chemical Industry Council (CEFIC), Nanotechnology Industries Association (NIA) and Soluzioni Informatiche (S-IN); basically it is a part of industry[10] (Aitken, Chaudhry, Boxall, & Hull, 2006; Hankin et al., 2011). The structure of participation in these two groups shows that the industry has more power and more say in the overall implementation processes, even though there is some moderation of industrial power through stakeholder participation in the first group, that is, the RIP-oN1.

CSO representatives also acknowledged the overwhelming power of industry. I was told by the advisor of the Greens, “If you now look at the implementation for REACH, there are working groups there. There are all kinds of committees and so on. There the CSOs are trying to participate to the extent possible; the industries of course are sitting on every single committee there can possible be” (A. Singhofen, personal

10 Except S-IN, which is a competence center providing expert consultancy on issues such as computational toxicology, CEFIC and NIA represent the industry. More specifically, CEFIC represents the European chemical industry, and NIA represents the industrial nanotechnologies supply chains.

communication, November 17, 2010). Likewise, the ETUC representative gave his perspective of how expert groups work:

> Again, the NGOs and also trade unions, we are, let's say, representing the society somewhere in those technical meetings….Well, the solutions and the way for work are proposed by the participants of those meetings--some member states, plus the NGOs, and the trade unions, and of course, the industries. As I mentioned...they are quite influential...because they have experts and they have much more resources than we have (T. Musu, personal communication, December 13, 2010).

CSOs that participate in these groups also think that ECHA is intimidated by industry's power. CSOs want the public's interest to come first and they fight for transparency and access to information when it comes to implementation, but industry demands that ECHA put industry's confidential information property rights first. If the ECHA does not do so, it becomes liable, and if something goes wrong, they threaten to make ECHA pay. As the EEB representative described the situation, "ECHA seems to be very much under defence mode you know, and they scared of doing something wrong and getting something from the industry" (Anonymous, personal communication, December 1, 2010).

Another factor that weakens the capacity of CSOs to influence the ECHA is the control of ECHA by the Commission, which in turn is heavily influenced by industry, especially through the DG Enterprise and Industry. The ECHA is supposedly an independent body, but according to the environmental advocacy groups (EEB, ClientEarth), it is very much influenced by the Commission. As a representative from

EEB comments, “The Commission influences this whole (implementation) work. Normally just ECHA should do this. [The influence includes] how the REACH regulation should be interpreted, how it should be implemented” (Anonymous, personal communication, December 1, 2010). ECHA also still relies a lot on “the commission because actually people working in ECHA are recruited from the Commission” (ibid.).

In conclusion, the implementation processes that take place in order for nanotechnology to be regulated appropriately are formally open to the CSOs; however, meaningful participation in such processes is limited because of the resources needed in order for CSOs such as environmental NGOs and trade unions to have influence. It is also limited by the unequal distribution of power between the CSOs and industry. Additionally, advocacy groups think that ECHA's decisions are influenced by the Commission, which in turn is overly influenced by industry’s perspective.

4.7 Conclusion

The various advocacy groups have identified many issues with REACH that need to be fixed in order for nanomaterials to be regulated appropriately. The EU governance structures involve CSOs officially in the procedures of regulatory and legislative policy making, and CSOs also benefit from informal relationships with the Commission, especially DG Environment, and the EU Parliament. The latter has taken a position along the same lines as the CSO requests, and the EU Parliament's European Green Party creates many opportunities for CSOs to lobby and influence the position of the Parliament. An example of this is the development of the nanotechnology definition.

However, even though there are multiple pathways through which advocacy groups can participate in policymaking, they face many problems in achieving their goals. Advocacy groups have a disadvantaged position in comparison with the industry, which has much more resources for participation and lobbying. Also, advocacy groups feel that the two DGs responsible for REACH possess different powers, with the DG Enterprise and Industry being more powerful. The Commission as a whole takes a more friendly position towards the requests from the industry. An example is the Commission's second communication paper on the regulatory aspects of nanomaterials, which basically did not take into account any of the CSOs' requests but was received with great enthusiasm by industry.

5. Comparing Regulatory Governance for Nanotechnology in the US and the EU

The EU and US have many similarities, such as a single major lobbying center (Washington, DC, and Brussels) and a federated political structure. Although the EU is not a country, its member states are increasingly bound by common laws and policies. There is also a role for interest groups and CSOs in the political process. But despite the similarities, there are many significant differences. This chapter will discuss five major areas of difference with respect to nanotechnology policy: regulatory frameworks, regulatory and legislative processes, the type of CSOs and their relationships, the issues under debate for nanotechnology regulation, and the political structure of public participation[11]. Even though the differences are substantial in all areas, I will argue that the outcomes are remarkably similar.

5.1 Differences in Laws and Regulatory Frameworks

Because nanomaterials as substances fall under the frameworks that regulate chemicals, this section will focus on how chemical laws differ between the EU and the US. These differences affect the way nanomaterials are regulated as substances in the two governments. The main difference is that environmental regulation in the EU is based upon the precautionary principle, which is officially sanctioned in the treaties of the European Union[12] and is the main principle underlying REACH. Essentially, the

11 The term "political structure" is being used here to refer to institutions and groups that are involved in public policymaking, their relationships with each other, and their patterns of interaction with the political system.

12 The precautionary principle as a base of EU legislation was introduced through the Maastricht Treaty in 1992.

precautionary principle is an approach to regulatory guidance that values preventative action even when evidence of safety or risk is not completely settled. As a result, by applying this principle to the regulation of chemicals and nanomaterials, REACH has as its main principle the rule that without data regarding safety, chemicals cannot be marketed. In contrast, in the US, the precautionary principle is not part of any of the regulatory frameworks for either chemicals or nanomaterials, and there is a presumption of safety unless a risk can be demonstrated with data. Thus, in principle there is a lower barrier to marketplace entry.

A second difference between the two frameworks is how they handle and regulate existing and new chemicals. Under TSCA, no data are needed for existing chemicals to enter the market, because such chemicals are grandfathered. As a result, toxicological or ecotoxicological data do not exist for these chemicals, which account for 99% of the chemicals on the market. In the EU, REACH was developed to resolve just the issue of many existing substances being grandfathered by requiring risk-assessments for all chemical substances; both phase-in (existing) and non-phase-in (new) chemicals undergo risk assessments. The only difference is that for phase-in substances, registration, especially for chemicals that are produced in smaller quantities (1-100 tonnes), has a much later registration deadline (May 2018).

A third difference is the burden of proof. Under TSCA, the government agency has the obligation to prove that a substance may cause harm. This is an obligation that is very expensive and time consuming. The agency usually has neither the data nor the time to prove definitively that a substance may cause harm. Even more problematic is the

requirement that the EPA has only 90 days from the day the agency receives a notification for a new chemical, to prove the substance might pose risks. If the agency fails to do so, then the substance can enter the market according to the principle of "no data no risk." This principle applies only for new chemicals, which account for approximately only 1% of substances in the market. In contrast to TSCA, REACH in the EU brought about a significant shift. Under REACH, the industry is responsible for showing that the substances that enter the market, both "phase-in" and "non-phase-in," are safe. This is because industry has the money, experience, expertise, and knowledge to do such work. Before REACH the government was spending a large amount of money, which can now be spent in other areas.

The major question regarding nanomaterials is whether or not they will be considered new or existing substances, an unresolved issue under both TSCA and REACH. If a substance in the nanotechnology form is the same as an existing one in bulk form, then the substance in nanotechnology form is considered existing. In the US, no more data are required and the nanosubstance is grandfathered. In the EU, if nanomaterials are considered existing, in other words,"phase-in," then the requirements for registration are delayed in comparison with a situation in which the nanomaterials are considered "non-phase-in" materials. Manufacturers benefited from a late registration deadline if the substances were preregistered.

In both the US and EU, there are additional issues that make the regulation of nanomaterials difficult under the existing frameworks of REACH and TSCA. For example, in both cases there are weight triggers for the amount of a substance produced.

The more quantity of a substance it is produced, the more information the agencies request. For nanomaterials, this is a significant issue in both the EU and the US, because the trigger is much higher than the amount of nanomaterials currently being produced. As a result, they do not need to be reported (TSCA) or registered (REACH).

Because neither of the regulatory frameworks references nanomaterials explicitly, the issue has become a regulatory problem in both the US and the EU. In the US, by using an existing tool within TSCA, the Significant New Use Rule (SNUR), specific nanomaterials are regulated for specific uses. Four SNURs are already in place for single-wall carbon nanotubes, one for multiple wall nanotubes, one for potassium titanium oxide, and one for infused nanostructures (carbon nanotechnology tubes and fullerenes)[13]. Also the EPA does not necessarily consider substances in nanotechnology form as de facto existing and proceeds on a case-by-case approach. Through pre-manufacture notifications the EPA has regulated many nanomaterials. In the EU, the implementation of REACH for nanomaterials will incorporate and use the newly developed definition of nanomaterials in order to identify and appropriately register them. Guidelines for this process are still under development. At the moment, it is unclear how many substances have been registered as nanomaterials under REACH. The dossiers are still under review.

Even though TSCA has not yet been reformed, two of the recent reform bills change the substance identification of chemicals to include size and size distribution. This provision would apply to nanomaterials. REACH, on the other hand, was under review in 2012. Appropriate coverage of nanomaterials is one of the main issues that is under

13 Fullerenes are the one of carbon's allotropes. They are a molecule in nanotechnology form. They are composed entirely of carbon and can have the shape of a sphere, ellipsoid or tube.

discussion in the review of REACH.

In summary, in both the US and EU, the regulation of nanomaterials has become a question of implementation of existing rules. The EU has proceeded towards the development of a definition for nanomaterial substances, but the difference from the US may be misleading, because the Commission is more interested in keeping the guidelines as they are, with minimal changes, and completing case-by-case reviews when needed (European Commission, 2012). In both the EU and the US, there are disagreements about the adequacy of the existing knowledge and scientific information on nanomaterials. Both the EPA and the Commission emphasize that there are not enough data available to assess nanotechnology substances properly. However, the second communication paper released by the Commission simultaneously argues that existing assessment techniques for bulk chemicals are appropriate for assessing the risk posed by nanomaterials (European Commission, 2012). In contrast, the EPA is developing some requirements especially for reporting nanomaterials under TSCA, and some nanomaterials are already considered new chemicals under TSCA, provided that their molecular identities are not in the inventory or have been under a case by case review. As a result, from 2005 to 2011, the EPA has regulated about 110 nanomaterials through pre-manufacture notifications and SNURs (Alwood, 2011). As of December 2012 the number of nanomaterials that have been regulated under TSCA is 137.

5.2 Differences in the Regulatory and Legislative Processes

In regulating chemicals and nanomaterials as substances, both the EU and the US

base their decisions on expert committees and groups. Science is the basis, or is at least presented as being the basis, for all decisions that take place. Committees develop scientific reports and opinions about how these materials should be handled, what kinds of guidelines should be followed, and what kinds of final decisions will be made. However, there are several important differences in both the regulatory system and the legislative process that produces the regulations. This section will discuss both sets of differences, beginning with the regulatory systems.

One important difference in the regulatory systems is that in the EU there is a whole agency, the ECHA, devoted only to REACH, whereas in the US, only one office within EPA, the Office of Pollution Prevention and Toxics (OPPT), is responsible for TSCA. The EPA is relatively independent of both houses of Congress, whereas the Commission has a very active role in ECHA's activities, committees, and groups. According to CSOs, ECHA is very much influenced by the Commission, which in turn is influenced by the industry, especially in the examples of the nanotechnology definition and the second communication showcase (European Commission, 2011, 2012).

Another difference involves the role of advisory boards. The EPA has a science advisory board, which bases its actions on scientific data, analyses, and interpretations. The EPA also informs the public through the federal registrar notices, ensures that the committees conduct activities in public, and provides opportunities for the public to provide input (EPA, n.d.-a). The OPPT has developed a National Pollution Prevention and Toxics Advisory Committee (NPPTAC); this committee provides information and recommendations to the office for the programs it manages and for the discussion of the

regulatory implications of manufactured nanomaterials (Hanson et al., 2011). The EPA also has various working groups that have been formed to work on specific issues. In the EU, the ECHA has various committees that discuss different issues and represent different interests. There is a member state committee, a committee for risk assessment, and a biocidal products committee. In contrast with the US, the ECHA also has a committee of socio-economic analysis, which advises the ECHA on the socio-economic impact of possible legislative decisions regarding the processes of restriction and authorization of specific substances (ECHA, n.d.-c).

There are also differences in implementation processes. Nanotechnology regulation is at the moment an implementation issue in the EU, with the member states being responsible for such implementation. The expert groups that discuss the nanotechnology guidelines are composed mainly of representatives of the member states. In the US, the states are not very involved in the policymaking procedures. The EPA does have the Office of Congressional and Intergovernmental Relations, which is the main point of contact between the EPA, the Congress, and the state and local governments (EPA, n.d.-b). Although the Office consults with state and local governments and Congress, it does not do so to the same degree as the member states in the EU, where member states are the main actors involved in the implementation of REACH.

Another major difference between the regulatory systems is the amount and the type of public participation, as well as the public dissemination of regulatory activities and information of the two agencies. The EPA has a more public face, with activities open to public input and a requirement to publish information on its activities and data.

The ECHA's activities, in contrast, are closed to the public, but the expert groups, and more importantly the management board, have members representing CSOs, which is not the case for the EPA.

The US has also embraced voluntary solutions for nanotechnology regulation, whereas in the EU voluntary proposals are not considered. In the US, the development of a voluntary program was the first attempt to regulate nanomaterials under the Nanoscale Material Stewardship Program, which was developed in 2007 and encouraged manufacturers to register their products. It was supposed to be the first step in evaluating how much nanotechnology there is and where it is. The Nanoscale Materials Stewardship Program was a way to gather information and to encourage collaboration with industry; however, the program did not achieve the expected results. Because the project was voluntary, companies did not have any obligation to register their nanotechnology products, and the project resulted in developing information only for 123 substances in nanotechnology form, corresponding to just 10 percent of nanomaterials in commerce (Maynard & Rejeski, 2009; US EPA, n.d.-c).

Turning now to the differences in the legislative systems, the main difference in the two legislative systems is how they allocate the right to propose a new legislative framework and initiate legislative procedures. There are also differences in the deliberation processes in order for legislation to be adopted. In the US, any member of the Congress can propose a new regulatory framework in the form of bill. Even a lobbyist can introduce a bill if a member of Congress agrees to sponsor it. In the EU, only the Commission has the right to introduce new legislation; however, as a result of the Lisbon

Treaty, citizens also have the right to petition the Commission to initiate legislative procedures if they gather enough signatures.

There are also differences between the EU and the US in the deliberation processes in order for a law to be adopted. The Commission usually develops a white paper that goes under discussion in the two legislative bodies, the Council and the Parliament. The two bodies discuss the issue and decide whether or not to pass the proposed legislation. There is also a consultation period during which the Commission receives comments from the public and from the stakeholders. In the EU, proposed legislation can go through three readings between the two legislative bodies. In the US, if a bill is approved by the committee to which it is introduced, then the bill is introduced into the full house, and if it passes, it goes for the discussion to the other house.

In the EU, because of the parliamentary system and higher level of direct participation from the member states, there are more diverse voices to be heard. There are also more opportunities for environmental advocates to be heard. During the readings for the adoption of a new law, the EU Parliament chooses a rapporteur to present the case. This rapporteur can be from a small party like the European Green Party, a feature that can enable a small coalition to influence the whole Parliament, as occurred with the Parliament's report on the regulation of nanomaterials (European Parliament, 2009).

In the US, because of the fact that two parties form the government, neither of which has an interest in environmental issues and a socialist ideology, passing an environmental law is very difficult, especially if the more industry-oriented Republicans are in power. There are no opportunities for more opinions to be heard, and even if there

are some pro-environmental voices, the structure does not assist them. Of course, passing environmental laws is not completely impossible and has happened in the past, for example with TSCA during the 1970s. However, TSCA reform efforts have floundered so far.

In both the EU and the US during the initial steps of the legislative procedures, CSOs have the opportunity to provide input. In the US, testimonies take place when a bill is under review, but only a few people get to speak during the hearings, and they are chosen by the committee. Because of the long involvement in the regulatory debates, EDF has been invited to testify a number of times. In the EU, after a white paper is up for discussion, there is a consultation period, which is open to everyone, but the EU Commission may, like Congressional committees in the US, ignore the discussion. Thus, in both the EU and the US the goal of influencing a legislative proposal is challenging for CSOs.

5.3 Differences between the CSOs

On both continents the advocacy groups involved in the nanotechnology debate are highly professional and advocate regulatory adjustments rather than wholesale rejection of nanomaterials. They do not rely on protest tactics; rather, they publish reports, inform the public through their blogs and official web pages, have their advisors lobby politicians, and have their experts participate in expert groups and committees. They also follow the regulatory developments and discussions for nanomaterials and file complaints, petitions, and, in some cases, lawsuits. In the case of nanotechnology

regulation, CSOs in both the US and the EU have shown themselves to be cooperative, and they are more interested in developing appropriate regulation rather than completely ending the development or use of nanomaterials in products. In the EU, most CSOs rely on money that they receive from the Commission, whereas in the US most advocacy groups, except PEN, receive money primarily from individual donations and from foundation grants.

Like government regulators, CSOs recognize the advantages and risks of nanotechnology. As a US CSO representative put it, "Nanotechnology is scary, and it's interesting. It's promising and it's creepy" (Anonymous, personal communication, April 18, 2011). Industry also hypes nanotechnology by suggesting that it can solve many environmental problems. As a CSO consultant put it:

> They link the nanotechnology products to a problem. We have climate problems, so nanotechnology solves the climate problem. Now we have energy supply problems, and suddenly the energy supply problems are solved by nano (Anonymous, personal communication, November 29, 2010).

None of the CSOs working at the EU level said that they wanted to stop research on all possible uses of nanomaterials; instead, they just want to be sure that whatever is being used is safe. Until then, most CSOs will ask for the "no data, no market" principle of REACH to apply rather than the "no data, no risk" principle of the US. The consumer organizations will request labelling for products that contain nanomaterials, the environmental advocacy organizations will ask for partial moratoria, and trade unions will request that the mistakes that happened with bulk chemicals, including occupational

safety hazards, not be repeated with nanomaterials. Even environmental CSOs see potential in nanotechnologies, especially in the development of green technologies and the energy sector. Likewise, in the US the NRDC mentioned the possibilities for developing filters for water cleaning, and PEN focused its activities on developing reports on responsible governance (PEN, n.d.-b; J. Sass, personal communication, April 18, 2011).

There are a few exceptions, such as the French group *Pieces et main d'oeuvre* (PMO) and the ETC Group in North America, but in general no CSO has been completely against the development of nanotechnology, and the mainstream groups are opposed to the positions of the more radical groups. As a representative from another environmental advocacy group said:

> The PMO (*Pieces et main d'oeuvre*) is…basically saying that you have not consulted the society about whether we need it, and it just should not happen. They are the most radical, they are very vocal, and they have advocacy techniques close to guerrilla. And they manage to spend a lot of the debate in the discussions in which I am not favourable (Anonymous, personal communication, December 16, 2010).

In North America, the most radical critic is the ETC Group, which early on in the nanotechnology debate demanded a complete moratorium. However, the ETC Group is not prominently involved in the US nanotechnology regulatory debate today. In both the EU and the US, professional CSOs tend to criticize radical strategies and radical groups are not part of the debate. However, the ETC Group is involved in the international level

through the UN.

In both political systems, expertise is a big issue for CSOs. Without it they feel that they cannot have meaningful participation in the debate. At the same time, maintaining the expertise and building on it is an expensive activity. Advocacy groups feel like they are always in an inferior position with respect to industry, which has much more resources and does not struggle with maintaining expertise. However, US CSOs are less worried about expertise and complain less about it. One reason might be the fact that the two most active CSOs in nanotechnology regulation and TSCA reform in the US have people with PhDs in science, Richard Denison from the EDF and Jennifer Sass from the NRDC. As Richard Denison commented:

> Most environmental nonprofit groups are good at waging battles in the legislatures of the states or federally, and they're less good at working with the agencies or implementing laws. So they often can get good laws passed, but then the implementation of those laws is an area of weakness, and part of that is many of the issues are very technical on chemicals and certainly on nanomaterials. A lot of the environmental NGOs don't have scientists, don't have strong science in the backgrounds of the people that they employ...[but] we are an exception to that. Many of us who are working on chemical issues on TSCA have science backgrounds, but most groups don't. So we tend to be more involved in the implementation of the law (R. Denison, personal communication, April 22, 2011).

In the case of the EU advocacy groups, the policy officers come from different backgrounds, but most of them are political scientists or lawyers. It is hard for them to

establish their expertise on issues as technical and complex as nanotechnology implementation. For example, EEB hires an expert for its position on ECHA's management board[14]. Whereas EDF does have less expert capacity than industry, in the EU[15] the CSOs often express concern over their lack of resources, expertise and capacity, especially in comparison to the industry.

Another significant difference is relationships with industry. Although some of the American environmental organizations, such as Friends of the Earth, do not work much with industry, the EDF is actually interested in working with industry and finding common solutions that are good for all stakeholders. One example of such cooperation is EDF's 2007 partnership with DuPont in the development of a nanotechnology risk framework. In the EU, there has not been a similar example of cooperation with the industry.

Another interesting difference is the role of trade unions. In the US, at least at the federal level, the trade unions do not appear to be very involved in the debate, at least at the federal government level. Trade unions in the EU are very active, probably more active than other environmental and advocacy groups in nanotechnology issues. One reason is the fact that trade unions have more funding than many other groups and represent a particular public, the EU work force. Trade unions also work very closely with other environmental and consumer advocacy groups by exchanging information and

14 The difference here between the experts of EDF and EEB is that in the US, the staff of EDF and NRDC are the experts. In the EU, EEB is hiring someone, as a consultant to be the expert and represent the organization.

15 In the EU, the main CSOs involved in the debate complained about the lack of expertise. That was not the case in the US where the CSOs that participate in the nanotechnology debate, mainly NRDC and EDF, have expertise and feel like they can participate in the debate. Other US CSOs that are not involved in the debate might not feel the same way.

publishing press releases and other documents together. Even when they publish separately from other CSOs, trade unions have many common points with the publications of other environmental NGOs, which means that the trade unions share opinions with them. The result of the cooperation with trade unions is that CSOs' requests can be more relevant for more people and have more power. At the same time CSOs' requests may gain attention from other social Parties within the EU Parliament, which may have an interest in workforce well-being and environmental protection.

A final aspect involving the differences between the EU and the US is the amount of knowledge that the US CSOs have about EU regulatory procedures, CSO activities, and especially REACH. This is because REACH has been an example of a good regulatory framework for US advocacy groups. Also, according to the NRDC, while REACH was under development, the US groups worked to support the EU CSOs in their fight for REACH to become law. The EU advocacy groups, in contrast, know almost nothing about the way the US regulates chemicals or nanomaterials. They also know very little, if anything, about TSCA. With a few exceptions, they answered that they did not know anything about the US when I asked comparative questions during my research interviews.

5.4 Differences in the Debates

In general the debate about nanotechnology regulation in the EU and the US can be described as one in which CSOs advocate for the development of an appropriate regulatory framework for nanomaterials. Although the two debates do have some

similarities, they center around different ideas and show different focus areas. Advocacy groups request that nanomaterials be considered new chemicals under TSCA or non-phase-in chemicals under REACH. Additionally CSOs highlight the inappropriateness of specific guidelines within the frameworks that do not apply for nanomaterials, such as the weight triggers that are too high, as well as what they think are inappropriate test guidelines for nanomaterials.

In the US, the debate was initially about how inappropriate TSCA was for the regulation of nanomaterials. The advocacy groups highlighted the fact that TSCA did not give the EPA any authority to take action in regulating nanomaterials or existing chemicals. As a result, the debate, especially for the groups working on TSCA and nanomaterials (EDF and NRDC), centered on how TSCA fails to regulate chemicals and how it needs to be reformed. From this perspective, REACH becomes a model for legislative reform in the US. For example, the EDF has made a point about the amount of data and information that REACH is going to gather for both new and existing chemicals and how well it applies the precautionary principle. In other words, EDF has emphasized the "no data, no market" principle and how well it resolves the issue of expenses for ECHA by shifting the burden to prove the safety of products before they enter the market to the industry.

In the EU, the debate is centered on appropriate implementation of REACH for nanomaterials. There is an expectation, even from CSOs, that regulation will take place. Consequently, the CSOs are reluctant to criticize REACH, because it is new, and a significant effort was put into developing it. Rather, CSOs are more focused on issues

that go beyond the framework itself. They still emphasize issues with REACH guidelines, such as the tonnage threshold and how it is inappropriate for nanomaterials. However, they think that the threshold can change if ECHA and the Commission make the appropriate decisions and change the guidelines. According to a CSO representative:

> The Commission says that whenever you have to register a substance, you need to share data in REACH, so there is a forum where you identify the property of the substance, the identity of the substance. If you find out that the substance is different from another, you create another registration. So under REACH, in my opinion, you can already identify the nanotechnology properties as a separate substance. It is just what the Commission and the European Chemical Agency have done to prevent this from happening. First, they write a document saying, 'REACH already covers nano.' Then, in this guidance for substance identification they put a disclaimer saying, 'There is not enough technical knowledge to distinguish properties from others. So the identity of the substance cannot be discriminated by the size (Anonymous, personal communication, December 17, 2010).

As this passage suggests, in the EU CSOs tend to argue that the main problem is a broader political one about the independence of the ECHA and the influence of industry on both the ECHA and the Commission. This same point about the Commission and how it handles REACH has been raised by all the CSOs I interviewed during this research.

European CSOs also worry about the fact that the industry is responsible for providing the appropriate information, and they point out that the precautionary principle

is not being applied for nanomaterials. The Commission mainly argues that there is a need for the development of more scientific knowledge about the properties and risks posed by nanomaterials, but at the same time it maintains that existing frameworks are good enough for regulation. A precautionary approach would not allow unproven nanomaterials to be on the market. However, nanomaterials are not even being registered at the moment in the EU.

In both the EU and the US, the debate is centered around the issue of appropriate regulation of nanomaterials. As an initial solution, US CSOs requested that the EPA use existing tools like the Significant New Use Rule (SNUR) to regulate nanomaterials. The EPA has actually shifted slightly its original argument that nanomaterials are existing chemicals, and since 2010 it has regulated a number of materials in nanotechnology through the use of SNURs. As a result, TSCA reform has become a separate issue, although advocacy groups such as EDF and NRDC would still like to see the regulation of nanomaterials come under a stricter, REACH-like framework. Although ending the grandfathering of chemicals and requiring the burden of proof to rest with industry would be significant improvements over TSCA, REACH is hardly a perfect model for the US. Whereas by 2012 the EPA had actually managed to regulate 137 nanomaterials under TSCA, REACH had mainly failed to regulate most nanomaterials. Furthermore, the ECHA is not independent of industry, and advocacy groups are increasingly criticizing the abilities of the agency and the Commission. Although REACH offers several regulatory advantages over TSCA, as of 2012 its record of regulation of nanomaterials did not surpass the US.

A major difference between the two debates is that in the EU, the two legislative bodies have contrasting opinions about what should happen with the regulation of nanomaterials. In the 2009 report in response to the 2008 Commission's communication paper on the regulatory aspects of nanomaterials, the EU Parliament addressed and supported most of the regulatory changes that the CSOs had requested. The elected body's position is very important for the advocacy work of groups in the EU, because it gives them a powerful ally in their requests and fights. In the US the CSOs do not have such a powerful ally in the legislative bodies. They have some senators and Congressional representatives who support their goals, but the CSOs rarely get broad support similar to that of the EU Parliament.

5.5 Differences in Public Participation

As has been discussed, public participation for CSOs in the US is largely informal, in contrast with the formal mechanisms in the EU. In both systems there are many informal interactions among the advocacy groups, the administration, and the legislative bodies. These groups are involved in lobbying activities, and lobbying is what primarily brings results. Thus, the differences in formal participatory mechanisms may not be as important as they might first appear.

In the EU, advocacy groups are officially part of the legislative and regulatory processes, and the CSOs also have a special legitimacy, because they can claim to represent the absent EU public, whereas in the US the Congress and the President can also claim to represent the people directly, because they are elected. In addition to formal

mechanisms of participation, CSOs are involved in lobbying efforts in both the DG Environment and in the EU Parliament. The latter, in particular, creates numerous opportunities for advocacy groups to influence policy developments, and the alliance of the EU's one elected body with the CSOs, as two representatives of Europe's absent public, provides a degree of legitimacy that alliances of progressive political leaders and CSOs cannot claim in the US[16]. Furthermore, the European CSOs benefit from a single umbrella organization and the extensive participation and support of the trade unions, both of which are absent in the US.

Thus, on the surface, the CSOs in Europe have a great advantage over their American counterparts, but there are several factors that compensate for the lack of official stakeholder status. First, CSOs can claim to speak for an absent public interest, because they can claim that Congress and the President are paying too much attention to industry and not enough attention to the general public good. Thus, the legitimacy difference may not be as great as first appears. Second, the American CSOs have staff scientists at the NRDC and EDF, and these scientists have attained significant political capital that allows them to have access to advisory bodies. Thus, the lack of official status may not be as detrimental as first appears, and the knowledge of the staff scientists allows the American CSOs to match industrial expertise. Third, the CSOs in the US also use lawsuits and judicial review, which provides another powerful pathway of influence that is relatively under-utilized in the EU.

16 In the US all political and legislative bodies are directly voted by the US citizens, this is not the case in the EU where the Commission is appointed and where the EU public is absent. The CSOs seem to cover the gap of an absent public. This particularity of EU gives a more privileged (legitimate) position to the CSOs who can claim that they represent the interest of that public. In the US, CSOs cannot claim that they represent the public interest in the same way.

Another significant difference in CSO participation involves the role of relations between the states and federal government in the US and the member states and EU government in Europe. In the US, many environmental organizations have significant opportunities to influence the state governments. As a representative from a CSO with offices in both DC and other states explains:

> Overall, across all the groups working on chemicals, probably their strength is that in the state level work they have more influence...In certain states, especially more progressive states, they have strong environmental policy track records: California, Washington, Maine. Those groups can have a lot more influence because it is easier working at the state level. The federal system is just much bigger (R. Denison, personal communication, April 22, 2011).

This is also what an interviewee in the EU said about the US when comparing the two governments with regards to policy making influenced by environmental organizations:

> We have kind of an advantage here [in the EU], in the sense that we can expect the government to undertake certain initiatives, and we can try and influence them. In the US tradition, there is just no hope to get anything done at the federal government level. So people have to work at the state level or try to change the markets, to work via the market, and that has quite an effect in the US, but here it is more effective to work on the policy (A. Singhofen, personal communication, November 17, 2010).

Furthermore, the centralized political opportunity structure in Europe enables CSOs to concentrate limited resources on Brussels, where they can have a concentrated effect. In

contrast, as one European CSO representative comments, in the US the decentralized political opportunity structure implies that "your movement is going to be dispersed and therefore not as concentrated and weaker" (Anonymous, personal communication, November 29, 2010). In the US, CSOs have more political opportunities at the state level, and if enough of the states refuse specific products in their markets, or a big enough state does (e.g., California), then the industry may stop producing the chemical for the entire country. Also if there is a consumer backlash in buying specific products then a retailer might pull it out of the market resulting in market regulation for the whole country. One example is Walmart which voluntarily pulled BPA out of baby bottles before California passed a ban. However, by spreading efforts over various state governments, CSOs dilute precious organizational resources.

5.6 Conclusion

The politics of nanotechnology regulation in the two political systems presents many differences but also many similarities. In both the EU and the US the regulation of nanomaterials remains mainly an unresolved issue. In the US, the Obama administration has already used existing tools to regulate specific nanomaterials and for certain uses. At the moment, the US has moved ahead and has already regulated more nanomaterials than the EU has regulated under REACH. Currently, the European Chemical Agency (ECHA) and the Commission are developing guidelines and have already developed a definition of nanotechnology, but the European CSOs disagree with the definition. In the US, the EPA is also working on rules that apply to nanomaterials, and as of 2012 it had regulated

more nanomaterials than had the ECHA.

In both places the debate is institutionalized and moderate, and the most prominent CSOs involved are very professional. They see potential in nanotechnology but believe that adequate regulation is needed to protect the public and the environment. Groups that have been against the development of any and all nanomaterials and that have requested a full moratorium, such as the ETC Group, do not play a significant part in the debate. There are differences between the American and the European CSOs in terms of organization, funding, role of staff scientists, trade union involvement, use of litigation, official stakeholder status, and other issues. However, the main ways of achieving, or trying to achieve, their goals are the same: having educated responses, offering expertise, publishing reports, and lobbying.

One of the significant differences involves the status of the general regulatory framework. In the EU, CSOs support REACH as a regulatory framework but think that the ECHA and the Commission do not do their jobs properly. In the US, CSOs argue that TSCA as a framework does not work properly and prevents the EPA from taking action, but the EPA is viewed as relatively independent in comparison with the perception of the ECHA in Europe. The reform of TSCA for all chemicals is still not a reality, but within the limited powers under TSCA the EPA has taken some important steps towards the regulation of nanomaterials.

Another significant difference is the role of the member states. REACH implementation practices and many of the ECHA's practices are primarily guided by member states, whereas the EPA’s relations with state governments is mediated primarily

through its relationship with Congress. Nevertheless, the regulatory framework in Europe is more centralized, and CSOs have the ability to focus their limited resources on Brussels, whereas in the US, the relatively closed political opportunity structure at the federal government level has driven CSOs to dilute their limited resources by focusing on regulatory reform in state governments.

CSOs in Europe have a unique role as political insiders due to the EU's democracy deficit and their official role as stakeholders. They nonetheless find that their reform efforts are thwarted because of the high level of industrial influence on the Commission, the DG Enterprise and Industry, the ECHA, and to some degree also the DG Environment. The CSOs have the advantage of relatively high support from the EU Parliament and the Green Party within it, but the Parliament is unable to bring about significant changes due to the lack of support from the Commission. This situation is similar to that in the US, where frequently Democrats control one of the houses of Congress, and it is possible to find some support for TSCA reform among progressive Democrats, but Republicans in the other House or in some years in the presidency block the completion of reform efforts. Furthermore, the mainstream of both parties is relatively unenthusiastic about TSCA reform. In summary, notwithstanding the many differences between the EU and US on nanotechnology policy, the outcome is similar: a relatively blocked political opportunity structure for the full regulation of nanotechnology.

6. Explaining the Differences in Political Participation

Although political outcomes for the regulation of nanomaterials are similar in the US and EU, the EU has a much more precautionary approach to regulation and allows CSOs to have an official position in policymaking. For some American CSOs, the REACH framework and more open pathways for participation represent an ideal to which they aspire. By understanding the causes of the differences, it may be possible to identify the factors that prevent reforms from occurring in the US. From previous chapters, the issue of the democracy deficit of the EU has emerged as an important factor, because the EU seeks CSO participation to respond to the lack of legitimacy based on a government that only has one elected body, the Parliament. However, two other important factors have also conditioned the form and extent of civil society participation in the EU: the history of the debate on genetically modified (GM) food, and the multiparty system of the European Parliament.

6.1 The GM Food Debate in Europe

The history of the GM food debate and its significance in changing the EU political structures is the first aspect this chapter will address. The GM food debate, especially in the EU, is very significant, not only because it can teach lessons not to be repeated with nanomaterials, but because the debate caused important changes in the EU political structures and procedures.

Controversies surrounding the nanotechnology debate have often been compared

with the debates about GM food issues. The phrase “not to have another GMO disaster” is popular, appearing in a variety of publications, from popular media to scientific journals to political talks. The two technologies and the debates surrounding them have been connected, compared, and discussed as being very similar. Because the nanotechnology debate chronologically followed the GM food debate, it carries with it a prediction about how public acceptance of nanotechnology will develop and what actions should be taken in order to avoid what happened in the GM food case. Although the nanotechnology and GM food debates are not developing in similar ways, especially in the EU, the GM food debate has played a significant role in shaping the political scene in which the nanotechnology debate takes place. The GM food debate has also developed very differently in the EU and the US.

In the EU, the GM food debate became one of the biggest political controversies of the day, sparked massive protests, and was accompanied by opposition to the introduction of any GM food in the EU market. The GM food controversy was picked up by many CSOs and got great support from other interest groups and governments. In contrast, the nanotechnology debate is less contentious. A few CSOs participate, taking what they call a balanced position on the issue. The nanotechnology debate, and specifically the CSO involvement in shaping the debate, has been affected by broader issues besides the technology itself. As Levidow and Carr have previously argued:

> We hear recurrent appeals 'to avoid another GM' controversy over other innovations such as nanotechnology. In such appeals, the agbiotech conflict is often attributed to deficient pubic understanding, inadequate public consultation

> and poor communication – mainly about a technology....however, agbiotech acquired its public meanings through wider policy agendas – European integration, regulatory harmonization, 'objective' expert advice, the internal market, trade liberalization and the marketization of public goods (Levidow & Carr, 2009, p. 4).

Whereas the bio debate was shaped by the intensive European integration procedures, the nanotechnology debate happened toward the end of the integration process, and it was shaped by new procedures for more transparent and democratic European governance structures with official participation of more stakeholders including CSOs.

As a result of integration problems within EU, in the 1980s the GM debate became a highly contentious conflict between the EU Commission and a coalition of the environmental advocacy organizations (NGOs) with farmers' groups who had the support of national states and the EU Parliament. The GM debate led to changes in the structures of decision making in the EU to avoid any kind of GM controversy in the future, and it also made the EU integration processes friendlier for the member states that were finding themselves losing authority over their own countries. As a result of these changes, the member states were granted the right to implement EU regulations, the EU Parliament got equal powers on legislative issues and became co-legislator with the Council, and CSOs received the right to participate as stakeholders in the procedures and discussions of policy development in the EU level.

In the 1980s, the European Commission introduced GM food and promoted it in the EU as a symbol of European progress and political-economic integration. By the

1990s, GM food was part of the way forward for a transition to a competitive dynamic and knowledge-based society, and this position was declared at the Lisbon summit of the EU Council in 2000. However, EU-wide opposition to GM food emerged in the late 1980s in the EU Parliament's Rainbow Group (known later as the Green Group, which campaigned against biotechnology and argued, according to Levidow:

> "This way forward may never be reversed." GM foods pose "social and economic risks, as well as risks to our world view and culture," they warned (Levidow, 1998, p. 214).

The debate focused on "value conflicts over how or whether nature should be conceptualized, controlled, and/or even redesigned" (ibid.). Following that, genetically modified organisms (GMOs) were portrayed by the opponents as pollutants, and the activists actually used biohazard symbols to label such products. In this context, the EU Parliament called for legislation with a stronger environmental orientation (Levidow & Carr, 2009).

The opposition that started in the EU Parliament in the late 1980s was immediately picked up by NGOs, which started campaigns to inform the public and to push for adequate regulation. Friends of the Earth Europe (FoEE) initiated its anti-biotechnology program and attacked the technology as aiming to turn agriculture into an industrial activity. Opponents argued that GM food "products bring unpredictable, uncontrollable risks, while increasing farmers' dependence on commodity inputs and multinational companies" (Levidow & Carr, 2007). What started as a small, loose network of activists during the 1980s resulted in a huge anti-GM movement by the late

1990s, mainly led by Greenpeace Europe and Friends of the Earth Europe (Levidow, 2009). In particular, these two international NGOs were against the development of biotechnologies altogether (Levidow et al., 2007). According to a 1997 Greenpeace report, “The only safe way to avoid such limitless difficulties and risks is to avoid the release of genetically modified organisms into the environment or the food chain altogether” (Greenpeace, 1997). Greenpeace connected GM food with food scandals like BSE, also known as mad cow disease, and the organization published various reports that referred to GM foods as pollutants (Levidow et al., 2007).

Even though consumer NGOs such as BEUC (the European's Consumer Organization) did not oppose GM foods, they did make food safety an issue and advocated for adequate labeling. They centered their arguments on the right to know and the right to choose safe food. They argued:

> GM food carries uncertain risks which must be clarified through more rigorous methods. Safety depends on adequate, reliable, and accountable science. Such science is essential for improving regulatory procedures and thus gaining consumer confidence (Levidow et al., 2007, p. 54).

The consumer NGOs gained great momentum because of the BSE scandal, which was also used by environmental NGOs as a way to strengthen their arguments.

NGOs and consumer organizations also gained the support of farmers' groups. The Coordination Paysanne Européenne and its national affiliates were key opponents of GM food. The organization represented relatively less technology-intensive and small-scale farmers who opposed the agricultural biotechnology as an agri-industrial model and

called for extensification measures as an alternative. These measures meant that land would be farmed less intensively and that losses in income from lower production would be balanced through savings in expending practices (Levidow, 2009).

By the late 1990s, the opposition movement was so powerful and had gained so much public support that most retailers in the EU were removing GM ingredients from their products (Levidow et al., 2007). At the same time, the opposition movement had gained support not only from the EU Parliament, which was the initiator of the anti-biotech movement, but also from the member states.

In response to the public mobilization against GM food, many of the EU countries initiated and funded dialogues and participatory projects with the public and NGOs in order to find a way to resolve the debate. Different countries framed the problems in different ways, but such participatory projects influenced the development and regulation of biotechnology in the EU. In the Netherlands, the parliament banned GMOs in the country in 1986, as a response to the requests by environmental NGOs. The Dutch government also funded NGOs to work on the issue and educate the public, and they also initiated the first consensus conference on GM foods in 1987 (Levidow, 1998). In the early 1990s, as a response to GM opposition, the German government funded a technology assessment exercise about biotechnology. The exercise was designed to include broad participation but had a risk -benefit analysis and focused on the possible benefits of the technology. The NGOs refused to participate in such procedures, and they preferred to use their resources for public protest (Levidow, 1998). In the UK, a consensus conference was funded by the government in 1994. It focused on the

participation of a lay panel but had a clear distinction between lay people and experts, and the NGOs had to prove their expertise. Although the experts were supposed to have an objective scientific opinion, they showed a preference towards pro-biotechnology arguments, which the lay public often challenged (Levidow, 1998).

While the UK and Germany served the existing regulatory framework, the Netherlands was more accommodating towards the NGOs and the public's concerns (Levidow, 1998). The ban that the Netherlands initiated was the beginning of what later became known as the de facto moratorium of the EU Council. At the same time, the way the UK and Germany developed their public projects showcased the dependence on expert objective advice and pro-biotechnology bias.

Initially, when the GMOs were first going to be introduced in the EU, the Commission expressed interest in developing a new regulatory framework in order for the GMOs to be adequately regulated. The EU legislators thought that GMOs posed new risks for the human health and the environment, so in 1990 the Deliberate Release Directive (90/220) had a brief life as the EU's regulatory framework for the assessment of GM food. It was developed to deal with the deliberate release of GMOs into the environment, and its goal was to prevent “adverse effects on human health or the environment” (Levidow et al., 2007, p. 36). Under the 90/220 directive, the producers had a legal duty to get approval through the submission of a dossier, which would include information appropriate to evaluate all possible risks of introducing any GMO in the European Union (Levidow et al., 2007). In 1997, however, the legislators changed their minds. A new regulation was developed that included the concept of substantial

equivalence, which was also used in the US in order for GM products to enter the market without risk assessments. It was based on the idea that if a GM product is similar to a non-modified one, then no risk assessment is needed. More specifically, regulation 258/97 had a simplified procedure for novel foods, so "if a GM product was substantially equivalent to a conventional counterpart, then no risk assessment was required" (Levidow et al., 2007, p. 36). Many GM foods that were introduced in the EU market in the late 1990s were approved through this framework.

The 258/97 regulation came into use despite widespread opposition to agri-biotech in the EU. The Commission refused to acknowledge the opposition and maintained its position as the main body responsible for the EU integration and for achieving the goals that would make the EU a successful knowledge-based global power. In the case of biotechnology, "The Commission has sought to soften public demands for restrictions on GM in order to pursue its normative role of producing harmonious trade relations, especially in pursuit of what the Commission still regards as an area of technical progress" (Toke, 2004, p. 188). Consistent with this goal, when the BSE outbreak happened, the Commission tried to cover up the problem because it was worried that the internal market would be damaged. As Levidow and colleagues comment:

> Subsequent revelations led to a legitimacy crisis that was often diagnosed as a 'democratic deficit.' In particular, EU regulatory procedures were illegitimately equating expert advice with science, as a basis to preempt or conceal political decisions (Levidow, Carr, & Wield, 2005, p. 263).

There was no place for other participants, stakeholders, and citizens. The Commission

soon realized the crisis and initiated new procedures and structures. They determined that supra-state regulation could be more democratic by being more transparent, which allowed more opportunities for the public to participate (Levidow et al., 2005).

The crisis, however, was beyond the Commission's ability to manage. In a 1999 meeting of the EU Environment Council, many EU member states blocked the EU regulatory procedures, arguing that more precautionary approaches were needed. The member states requested that the procedure become more transparent and be based on precaution. In response to that request, the Commission initiated more regulatory procedures that tried to address the issues that the Council requested (Levidow et al., 2005). However, the member states were more persistent. A 1999 parliamentary report argued that the Italian government must "prevent Italian agriculture from becoming dependent on multinational companies due to the introduction of genetically manipulated seeds" (Levidow, 2005, p. 106). In 2000, Italy suspended the authorization of more GM products under regulation 258/97, arguing that "substantial equivalence was not demonstrated under the simplified procedure" (Levidow et al., 2007, p. 29). That same year the Commission requested that Italy lift the ban. Italy not only kept the ban, but it went on to criticize regulation 258/97 for using the substantial equivalence principle in order to approve GM products. The Commission had no choice other than to propose a new regulation that was not based on substantial equivalence, arguing that the principle had brought controversy over regulation of GM food in the EU community (Levidow et al., 2007).

In 2002, the European Food Safety Authority (EFSA), an independent body, was

created. This body was charged with providing the Commission with the necessary scientific knowledge and expertise to develop risk assessments for GM food. EFSA included NGOs and industry representatives in its panels as partners who would help with the goal of achieving public confidence. Such processes were part of the EU integration plan, with committees used to balance the transition to an EU-level authority, where decisions would be made by the Commission and expert bodies and at the same time committees that represented the EU countries. The NGOs, however, criticized the body for having experts with pro-biotechnology interests and for being biased because of previous positions that the experts had held (Levidow et al., 2005, p. 263). Even though the Commission included the NGOs in its implementation procedures, such procedures were not connected to policy development. Between 2003 and 2004, attempts by the Commission to overcome the crisis and to make GM food products and their regulation less contentious within the community had no support from the member states. According to Levidow and colleagues, "This low support indicates a gap between EU regulatory procedures and public–scientific concerns among member states" (Levidow et al., 2005, p. 274).

NGOs, mainly Greenpeace and FoEE, built up their arguments using threats about globalization, neoliberalism, and the industrialization of farming, and they gained the support of other groups, especially farmers, in their requests. They also successfully linked the GM food issue to food crises like BSE. However, because of the integration processes that were taking place at that time in the EU, the GMO debate had broader political significance. A shift of the legislative powers from the national governments to

the EU Commission was enough to make many EU countries oppose regulations that extended the Commission's authority. NGOs did much of the work through protest and informing the public, but at the time many EU counties were also in conflict with the Commission, thereby overlaying a specific regulatory policy issue with a general governance crisis. Thus, the GM food controversy went beyond issues of risk assessment and environmental and health threats to issues of governance. The crisis of EU legitimacy during the integration processes coincided with the GM controversy, making the inclusion of civil society in expert and stakeholder panels possible. It also changed both the NGOs and the way policy making was taking place at the EU level. In order to fix the crisis and to accommodate the EU member states, the Commission initiated procedures of more participation from civil society, more transparency in decision-making, and devolution of implementation powers to the member states. The member states, in conjunction with their experts in regulatory agencies, are involved in the implementation and development of guidelines for the regulatory frameworks. The NGOs earned a place in expert panels and stakeholder meetings, and they had to make sure they had the expertise needed in order to achieve their goals.

In summary, the GM debate received a great deal of support from the public and from other groups, in particular farmers. The NGOs managed to create an oppositional movement in many EU countries and at the same time got access to political regimes. Their arguments opposed any introduction of GM food in the EU, and they managed to achieve most of their goals. This happened, however, because they had the support of many national states that went on to impose a de facto moratorium on GM foods. Many

member states did not like the fact that they were not heard by the Commission, which continued to maintain its position of covering up the food crisis, which in the end led to a legitimacy crisis. In order to overcome this crisis and have successful integration for EU, many structures changed. More powers were given to the EU Parliament, and the Council was given the authority to implement the regulatory frameworks. Also, the Commission made it possible for CSOs to have official positions in decision making procedures.

Thus, when the nanotechnology controversy arose, the governance processes in the EU had been transformed by the prior GM food controversy and the broader political crisis. As a trade union representative described the situation, since the beginning of nanotechnology debate, "occupational, safety, and health issues and ethical issues were taken on board, having learned from the experience with the GMO issue" (H. Wriedt, personal communication, February 16, 2011). The EU government has been characterized as "scared" that nanotechnology will have a similar political fate to that of GMOs. (A. Singhofen, personal communication, November 17, 2010). Even though the GM food and nanotechnology debates are different, the two are very connected in the thinking of the EU government. As an environmental advocacy group representative told me:

> Whenever you go to a nanotechnology conference, you hear about GMOs, as well, because they always say, "Oh, we have to take care that it doesn't develop in the same way as GMOs did." They still think GMOs were a great idea, but people just didn't understand it, and the NGOs ruined everything. So they want to avoid that, in a way (J. Vengels, personal communication, February 4, 2011).

The solution was clear: in order to overcome any similar problems in the future, the EU government should involve civil society. The same environmentalist went on:

> I think in Europe, they try to involve NGOs more and more, especially with nanotechnology....well, maybe with their background....they thought if they involve us, we will be happy with the technology and they can prevent another GMO nightmare (J. Vengels, personal communication, February 4, 2011).

Such involvement takes place at both the EU and national level. Germany, for example, started its nanotechnology dialogue "because they said that they wanted to have civil-society involvement in the development of the technology" (J. Vengels, personal communication, February 4, 2011).

Although the nanotechnology debate came at a time when the integration processes did not have significant opposition from the member states, and the Commission was working in a more cautious way, the idea that the transformation was complete might also be misleading. The EU government funded projects such as the NanoCap to discuss nanotechnology developments and the possible risks, but at the same time it did not initiate regulatory oversight of nanotechnology. The EU Parliament was in favor of a more precautionary approach and supported the CSOs' claims, pushing the Commission to take action as it did in the case of the GM food controversy. The EU Parliament also had more powers after the Lisbon treaty, and the CSOs could rely more on its powers because the EU Parliament had shown a support for their positions. Although the Commission had to include civil society in decision making procedures, as I have indicated previously, the Commission still leans toward industry goals rather than

those of the CSOs.

Unlike the broad social movement opposition that occurred in the GM food debate, the debate over nanomaterial regulation has taken place within institutional channels. When the nanotechnology issue started to become a more serious debate, CSOs were already part of the policy-making regime. They did not have any other reasons to engage in oppositional protests or any kind of contentious politics. Their reasoning was not to bother if they can make their argument just as well in a panel setting or at a meeting with someone from the Commission or from the Parliament. Furthermore, the counter-mobilization by national states had also been muffled, because nanotechnology regulation focuses on implementation, where the national states have the power to implement the law in the country at that level. The national states do not have to listen to the Commission and at that level the details are technical.

The difference suggests that the CSOs would have more success in getting the Commission to accept its reform goals if they had not been brought inside the system. However, getting people onto the streets for nanotechnology is likely to be much more difficult than for GM food, because of the different cultural meanings associated with food and the absences of an occupational group such as small farmers. In the case of the GM, the connection to possible health effects was obvious and easy to make with consumers being interested in protecting their food and health. Also the CSOs involved were able to connect the GM to broader arguments about globalization, trade liberalization and the marketization of public goods. Such framing could get broad

understanding and support, and it needed much less technical knowledge and expertise to develop.

In contrast to the GM debate, in the nanotechnology debate, the public does not seem to be anxious about possible effects, because the risks are not as clear as in the case of GM. The public has not yet made connections to nanomaterials and how they may affect everyday life, let alone their food and health. Partly the CSOs involved have failed to connect the debate to broader issues, and the debate has been kept in technical levels. As a CSO representative put it:

> Public opinion is important...There is a perception that there is a risk probably. There starts to be that perception. But if we keep on having technical discussions about size, about agglomeration, stuff like that – the wider public is not going to be involved that much (Anonymous, personal communication, December 17, 2010).

This level of technicality requires even from the CSOs specific knowledge. In order to participate, the CSOs need to have expertise; otherwise, they cannot make any contribution to the policy issues.

6.2 CSOs and the EU Parliament

In addition to the background of the GM food controversy and the associated governance crisis of the EU that led to official inclusion of CSOs in decision-making, another significant factor that contributes to the inclusion of CSOs in policy processes is their close relationship with Parliament and Parliament's strong support for precautionary

regulation. Although the European Green Party within Parliament is the channel through which CSO influence occurs, the party's positions have also been adopted by the Parliament as a whole. In this sense, the position of the CSOs is quite different from the parallel relationship that CSOs have in the US with the progressive wing of the Democratic Party, because the progressive wing is not able to convince the full house of Congress to adopt regulatory reform.

The Green Party has always been an advocate of stricter environmental regulation, and in the GM food issue it was as much a leader as the environmental organizations were. The Green Party had a prominent role in the contentious and controversial GM debate and assumed the same position of leadership in the nanotechnology debate as well. As a result of the Green Party's leadership, the various advocacy groups had a powerful European body on their side. Since 2009, when the EU Parliament acquired powers equal to the Council, there were new political opportunities for the CSOs, who, through the Green Party, can influence legislative policy making. This section will focus in detail on some of the exchanges between members of the Parliament and CSO members because of the pro-environmental position that the Parliament has supported in the case of nanotechnology regulation: along the lines of CSO requests and against the lines of the Commission's legislative inaction.

The conflict between the Commission and the EU Parliament on nanotechnology policy dates back at least to 2008, while the NanoCap was still ongoing and the EU Commission published a communication paper to the EU Parliament arguing that nanomaterials are, for the most part, covered under the existing laws. According to that

communication paper, the EU Commission concluded:

> Current legislation covers to a large extent risks in relation to nanomaterials and that risks can be dealt with under the current legislative framework. However, current legislation may have to be modified in the light of new information becoming available, for example as regards thresholds used in some legislation (Commission of the European Communities, 2008, p. 3).

The EU Parliament replied to that communication paper with a report on the regulatory aspects of nanotechnologies, which was released a few days after the NanoCap's final conference in April 2009, and argued the complete opposite position. The report argued that nanomaterials were not covered by existing legislation and that regulatory frameworks should change in order for adequate regulation to take place (European Parliament, 2009).

The points that the EU Parliament made in that the 2009 report were very similar to the resolutions that both the environmental NGOs and trade unions requested at the final NanoCap conference. The Parliamentarians requested the application of the "no data equals no market" principle, the amendment of relevant community legislation to address nanomaterials adequately, the development of labeling for products containing nanoparticles, and the assurance that legislative provisions and instruments of implementation reflect the particular features of nanomaterials to which workers, consumers and/or the environment may be exposed. According to the European Parliament, the first step for the implementation of adequate regulation should be the development of a harmonized and comprehensive science-based definition of the term

“nanomaterial” (European Parliament, 2009). As has been discussed, the Commission responded only to the last demand, and it did so by developing a definition at odds with the one desired by many CSOs and members of Parliament.

After the final NanoCap conference in 2009, the EU Parliament sided with the CSOs in the debate that emerged with the Commission and industry. Member of Parliament Jan Cremers stated that when dealing with health and safety practices regarding nanomaterials and products, the precautionary principle should guide the discussion (NanoCap, 2009). Occupational, health, and safety management at the time was uncertain, and as a result many workers were working under uncertain conditions with regards to health risks. ETUI representative Tony Musu came to agree with Cremers, adding that the best way to resolve the issue would be to address the issue at the EU legislative level. In a reply to this position, Antonis Agelidis, from the EU Commission, stated that the European Commission is open to a dialogue on the issue but highlighted that there was a gap in knowledge about the behavior of nanomaterials, adding, “Gaps should be identified and a strategy should be developed to fill them” (NanoCap, 2009, p. 11). Axel Singhofen, the Greens' Adviser for Health and Environment Policy, responded to that statement, arguing that there was a need to change legislation, as the resolution of ETUC stated. As MEP Jan Cremers mentioned, “The Commission still states that the current legislation is sufficient. Is the Commission now going to revise its statement?” (NanoCap, 2009, p. 11). To that Agelidis replied that there was a need for more scientific information in order for policy making to take place and, until more is known, employers are the ones responsible for dealing with risks.

The European Commission, specifically the DG Environment, was very defensive about the fact that there was some information on how to assess nanotechnology but that it was not being used. Henrik Laursen from DG Environment argued, "We have tools to assess the risks of many nanoparticles. The challenge will be to bring all the information together and make it operational. More work is needed, but we have a good base to start from" (NanoCap, 2009, p. 16). When the CSOs replied that the precautionary principle and the "no data equals no market" principle could be applied, Laursen replied that REACH refers to the precautionary principle, but it was difficult to say how the principle would apply to the substances, because risk management is different from risk assessment. When there are no data, the precautionary principle will be used but only in addition to other assessment tools. The EU Parliament, through its member Carl Schlyter, replied that at the moment REACH was not capable of regulating nanomaterials. Also, the Environmental Committee voted that the loopholes of REACH should be closed within the next two years. The consumer groups, which had not been part of the NanoCap, made a point about access to information and the fact that consumers should have the right to know about the toxicity of products. Labeling of products containing nanoparticles needed to be mandatory. Again, Schlyter pointed out that:

> Parliamentarians have a responsibility for what is allowed onto the market: it should be safe. This guarantee cannot yet be given for nanoparticles... Responsibility expresses a feeling. The European Parliament gives it meaning in its report. It also gives directions how to translate responsibility into legislation (NanoCap, 2009, p. 17).

Even though it is hard to prove that there is a clear-cut connection between the European Parliament's report and the NanoCap project, the Green Party's close relationship with the NGOs and trade unions, the common points in the NGOs and trade unions' resolutions, and the Parliament's report that was more or less developed by the Green Party suggest the alignment of thinking.

In support of the interpretation of a close relationship between the EU Parliament's positions on nanotechnology and those of the CSOs, an ETUI representative who participated at the final conference and the NanoCap said, "In my view we certainly had an influence on the EP position paper"[17]. Another environmental NGO representative and NanoCap participant told me, "Some MEPs were in close contact with the NGOs, and there was a ferment...Certainly to some extent the project contributed to the intense debate... that led to the observed result"[18]. When I asked the organizer of the NanoCap if he thought that the EU Parliament's 2009 report on the regulation of nanomaterials and the general position of the Parliament in the case of nanotechnology regulation was influenced by the NanoCap, he replied, "The position of the Parliament, in large part, was also influenced by our finding, by the positioning of the groups that they were active in nano....I think that the NanoCap was important stimulus for them to take a serious stand in the nanotechnology debate" (P. van Broekhuizen, personal communication, March 7, 2012). Even if there is not clear proof that the NanoCap influenced Parliament's position with regards to nanomaterials, one thing is certain: the CSOs' achieved their first aim for the development of appropriate nanotechnology regulation, the development of a

17 From e-mail communication with trade union representative.
18 From e-mail communication with CSO representative.

scientific definition.

The close relationship between the CSOs and Parliament has translated into greater political power after the reforms that granted the Parliament co-legislation powers. As the Greens representative put it:

> The Parliament as a co-legislator has enormous powers, because we have the same powers as all 27 member states....And because the Parliament is co-legislator, we have been the driving force at European level. [F]or example, we have politically agreed on hazardous substances and electric electronic equipment and we will also have reference to nanomaterial. So clearly the Parliament is the more active player and yes, the Greens make a difference (A. Singhofen, personal communication, November 17, 2010).

The Greens' representative also pointed out that because the EU Parliament does not elect an executive, a situation that is different from other parliaments throughout the world, there is not a majority or minority that remains stable. Instead, there is a more flexibility and more opportunity for even the Green Party, which is a minority party, to affect policy outcomes. For example, the Greens end up drafting about 90% of the legislation associated with nanotechnology (A. Singhofen, personal communication, November 17, 2010).

This situation is strikingly different from that of the US, where CSOs can find some sympathetic members of Congress and help to craft legislation, but the two-party system blocks any further progress. Richard Denison from the EDF comments on the role of the parliamentary system in the EU:

> I think one of the things that helps in Europe is the parliamentary system of legislature. Here we basically have to try to get either the Democrats, or the Republicans, or sometimes both to embrace an issue. And citizens do not tend to vote for candidates on the basis of an environmental issue. It's rarely going to be. Very few people vote for a candidate based on their views of environmental issues. But in Europe I think the existence of the Green Party and the ability to actually have someone representing your issue in parliament, [enables] the party to be more influential in trying to get policies adopted... I mean, the NGOs I know in Europe always say that their main leverage is through parliament (R. Denison, personal communication, April 22, 2011).

Likewise the Green's advisor explains that their situation of influence "is impossible" in the US:

> [In the US], the minority has no role to play, and due to the winner-takes-it-all system, you have a dual system which doesn't allow third voices. So therefore, I think that our system is more diverse and reflecting more of different views, and less dependent on industry. Of course, industrial interests are not entirely underrepresented and have a huge weight, but you can win against the chemical industry here. Which is I think that is impossible in the US (A. Singhofen, personal communication, November 17, 2010).

Singhofen suggests that it is easier in the EU for lobbyists to work with Parliament, but there are also difficulties in the EU, especially when attempting to work with the Council or Commission.

6.3 Explaining Similar Outcomes

Even though the EU and the US present differences, mainly in the way they involve the advocacy groups and the participation opportunities they create for them, the two cases have similar outcomes: most nanomaterials are still unregulated in both the EU and the US. In both cases, CSOs have failed to bring the issue of nanotechnology regulation to the political level. Some progress on regulating nanotechnology in the US has taken place, and in the EU a definition has been developed. However, TSCA has still not been reformed to include provisions for the regulation of nanomaterials, and REACH has not been amended as advocacy groups have requested. Many other requests of advocacy groups in both the EU and the US have not come to fruition. For example, the request to consider all nanomaterials new chemicals (non-phase-in chemicals under REACH) has not been met.

One result from the research is paradoxical: although the EU has the comprehensive regulatory framework that CSOs in the US can only aspire to have, and CSOs have much more access to policymaking by virtue of their ties with the Parliament and their official status as stakeholders, in the US more steps have been taken towards the actual regulation of nanomaterials. An example is the regulation of nanomaterials under TSCA using the Significant New Use Rules. Likewise, the EPA does not necessarily view all nanomaterials as existing substances anymore, and some pre-manufacture notices have been developed for materials in nanotechnology form (a regulatory step was likely a result of EDF's lobbying work with the Obama administration). This approach was something that EDF had been requesting as a first step for the regulation of

nanotechnology since the beginning of the debate. However, even though EDF might be happy with how the EPA has moved to regulate nanomaterials under TSCA, at the moment the organization still believes that reforming TSCA for all chemicals and having explicit legislative provisions for nanomaterials is the best solution.

Why, however, do CSOs and trade unions seem to be unsuccessful in the case of the EU, where the political opportunity structure is more favorable? The findings of this dissertation suggest four factors that weaken the influence of CSOs and trade unions even in the EU system: (1) the unequal distribution of power in the government structures, (2) the unequal distribution of power within the areas where advocacy groups usually are involved, (3) the professionalized approaches of the advocacy organizations, and (4) a regulatory focus on the implementation level, which is very technical. Those four factors result in outcomes other than those that advocacy groups have supported. Thus, the institutionalization of official participation does not guarantee influence of policy outcomes.

To some degree, CSOs and trade unions are co-opted by the inclusive policy process in the EU, and comparison with the role of CSOs in the debates over genetically modified food is instructive. In the case of genetically modified food, there were large-scale social protests that led to a temporary moratorium and long-term labeling. In contrast, CSOs and trade unions generally express moderate opinions about the regulation of nanomaterials; they have been very professional and have not engaged in any type of contentious activities. This is partly because the EU has learned from the case of genetically modified food that CSOs need to be included in the debate and partly because

CSOs recognize the potential benefits, including environmental benefits, of a properly regulated nanotechnology industry. Furthermore, CSOs involved in nanotechnology policymaking are heavily dependent on EU funding, and their opinions were developed under the influence of the EU funded NanoCap project. Because they have official positions in the proceedings, they are not engaged in contentious practices, and all the groups that have opted for more contentious strategies and for a full moratorium are excluded from the debate.

Another reason for the lack of success of CSOs in the EU is that the nanotechnology debate focuses on implementation, which makes the discussions very technical. Whereas the issue of genetically modified food involved a more fundamental strategy of opposition, in the case of nanotechnology the CSOs need resources in order to participate in such discussions. CSOs struggle to obtain the knowledge and money needed to participate in all the places where they have official positions. This is a simple task for industry, which has extensive financial resources. Also, industry has significant influence over the Commission, as CSOs have pointed out and which has also been showcased through regulatory activities. Within the Commission, the DG Enterprise and Industry is more powerful than the DG Environment, and the former influences the opinion of the whole Commission, which in turn influences the activities of the European Chemical Agency (ECHA). Thus, the ECHA tends to go along with the Commission, even though ECHA should be independent.

In the EU, the only achievement that CSOs and trade unions have gained through their lobbying activities was to force the Commission to develop a definition for

nanomaterials. However, their achievement was possible because they worked with the Parliament and the Green Party, whose rapporteur drafted the European Parliament's position. Even though the new definition is in place, it was not developed based on the suggestions of the CSOs. On the contrary, the Commission proposed a definition based on criteria that went against DG Environment's suggestion, against DG SANCO's suggestion, and also against what their own scientific reports were suggesting. The CSOs also realize that there has been slow progress on the actual regulation of nanomaterials; only three had been registered by the end of 2012. REACH is new and the European Chemical Agency has not yet reviewed all the dossiers, but REACH guidelines are not applicable for nanomaterials, and specific tools have not been used to register nanomaterials, like the Significant New Use Rules in the US. Also, because nanomaterials are considered phase-in substances and are produced in lower volumes than bulk substances, their registration has a deadline as late as 2018. This is one main reason why nanomaterials have not been registered yet. And why as a result only three substances in nanotechnology form have been reported.

In the US, the EPA has already used some existing tools and under its new chemical program has regulated 137 nanomaterials. This is because CSOs involved in the debate in the US have suggested the use of existing tools from the beginning. EDF in particular has been very active in working with both the industry and the administration on the issue, and they have found the EPA under the Obama administration to be receptive to their views. In general, the EPA administration is very interested in gathering scientific information and even regulating more appropriate bulk chemicals.

Another factor that favors the relative success of CSOs in the US is that they have developed partnerships with industry. One example is the 2007 EDF-Dupont Nano-Risk Framework, which was developed in order to assist responsible development of nanomaterials. It is a guidance tool to accommodate practices towards the responsible development of nanoscale materials, for companies and industry to inform the development of risk evaluations. The tool also provides guidance on how to perform risk management in cases of incomplete or uncertain information. These partnerships also carry with them risks of co-optation, because when CSOs like the EDF put forward policy initiatives with industry support, they must make compromises with industry. Partnerships with industry can also lead to divisions within CSOs. For example, the CSOs became divided over an early voluntary strategy worked out by the EDF and DuPont (Hess, 2010). Although the strategy was intended only as a bridge to regulatory reform, it provoked criticisms of the EDF by other environmental organizations. It also did not produce the desired results.

In effect, the overarching conclusion is that in both the US and EU industry plays an overwhelming role in limiting, slowing, and directing regulatory reform for nanotechnology. In the US, the chemical industry works extensively with the Republican Party and, in contrast with other industries, has been supporting financially Republican candidates at a much higher rate than Democratic candidates (Center of Responsive Politics, n.d.-b). As a result, the Republican Party has mobilized to block the reform of TSCA. All but one of the proposed reform bills have failed to pass the committee, and the one that actually passed was supported only by the Democrats. There was a window of

opportunity for TSCA during 2008 through 2010, when the Democrats controlled both houses of Congress, but the issue was not a priority even for Democrats, and the window closed in 2011, when the Republicans regained control of the House. During the testimonies for the introduction of a new bill, the chemical industry (supported by the Republicans) has supported the claim that TSCA is working well but then later suggested the need for a modernization procedure with minimal changes (Bosley, 2010; Dooley, 2009). Likewise, in the executive branch, the chemical industry has created obstacles for the EPA to regulate nanomaterials by complaining about additional information and testing that the EPA requested in order to regulate nanomaterials[19]. At the same time, the EPA has conditionally approved nanotechnology substances even though there might be risks connected to their use.

In the EU, the chemical industry also has substantial influence over political outcomes. Because the nanotechnology debate is a technical one, industry has the power to support their requests with extensive technical details. Industry representatives have the financial and expert ability to participate in every possible panel. The technicality of the debate gives them a superior position. Industry was responsible for the development of two of the REACH implementation projects for nanomaterials because these two projects were very technical and industry is the only one with the expertise and financial capacity to produce the scientific data. And because the issue is so technical, in the EU the Commission depends heavily on knowledge and information supplied by the

19 In 2010, when EPA was developing the new rules to accommodate the SNURs, requested some companies to do 90-day carbon nanotube inhalation studies in rats, a very expensive activity. ACC seemed to comply with these requests, but ACC's customers are not consumers - they are other businesses, and even though their customers are curious about nanomaterials, according to an ACC representative, consumers in general do not seem to care (Halperin, 2010).

chemical industry, and the decisions that the Commission has made with regard to nanomaterials (e.g., the definition and the second communication paper) have been welcomed by the industry.

6.4 Conclusion

After the GM controversy and the democratic crisis in the EU, structures changed in order to permit more official participation by CSOs. Parliament achieved co-legislation authority, member states achieved implementation authority, and CSOs attained access to decision-making as official stakeholders. To prepare CSOs for participation in governance, the NanoCap project provided them with an opportunity to build their knowledge and develop opinions and resolutions for nanotechnology regulation in the EU. The resolutions they developed, especially for the EU-based organizations, had many common points with the Parliament's report on nanomaterial regulation. The EU Parliament, especially in the case of nanomaterial regulation, is one of the most active stakeholders in the debate and is fighting for appropriate regulations similar to those that the CSOs request. This research suggests that CSOs have played an important role in influencing Parliament's position and that there are close relationships between the Green Party and CSOs. However, the wishes of the Parliament are often in conflict with those of the Commission, and the outcome is that, as of 2012, the regulation of nanomaterials had not yet been achieved.

Unfortunately, there is little that American CSOs can learn from the European experience. The political structure of the American government is a 235-year-old

institution, and a shift to a parliamentary system is unthinkable. Likewise, there is no way to go back and form a massive anti-GM food movement. It also seems unlikely that the US will change its political process to provide official ways to involve CSOs in policy development procedures, and the federal government has shown no interest in accommodating their involvement through participatory projects comparable to NanoCap. In the US, some successes are a result of EDF lobbying, mostly to a Democratic administration and with the support from sectors of the industry. As a result, even without the advantages that CSOs have in the EU, the CSOs in the US can point to 137 nanomaterials that have been regulated, and American CSOs may even point to the effectiveness of partnerships with industry.

On both political systems the appropriate regulation of nanomaterials is still an unresolved issue. In the EU, this is because CSOs have to compete with industry in committees, groups, and boards that they participate on. They also need resources and knowledge in order to be involved in a highly technical debate. This makes their influence even more limited. Also, through their lobby work, CSOs also have to compete with the industry, which can lobby in every possible legislative and executive body. With the DG Enterprise much stronger than the DG Environment, the Commission's decisions about REACH and nanomaterials satisfy industry more than any other stakeholder. In the US, the CSOs have more expertise due to the staff scientists at the EDF and NRDC, but their effectiveness is blocked due to the general absence of interest of both parties in regulatory reform. That absence of interest is attributable to the general political climate of passivity on environmental issues, which is a product of decades of funding by large

corporations to support political candidates, conservative foundations, and conservative media. It is also the result of the industry-specific spending of the chemical companies on political candidates of both parties, but with more spending going to Republicans. Finally, the military sees tremendous opportunities in nanotechnology[20], so the government in general is more focused on nanotechnology development than regulation. In both the EU and the US, however, the CSOs have been unsuccessful in bringing about comprehensive nanotechnology regulation. Perhaps the primary lesson is that both need to rethink the strategy of insider participation and the importance of having a popular mobilization similar to that of the GM food movement.

20 For some of the research and products of nanotechnology that are of interest and military use visit the Foresight Institute at: http://www.foresight.org/nanodot/?cat=80.

7. Conclusion

This project began with the assumption that nanotechnology has the potential to be highly beneficial to society, but there are serious safety and environmental risks that current regulatory frameworks do not adequately address. I assumed that there were significant differences in nanotechnology regulation in the EU and the US and that the more institutionalized role of CSOs in the EU accounted for some of the differences. However, as the research progressed, I realized that in both the US and EU, CSOs have a relatively modest role to play in nanotechnology policymaking. CSOs remained highly frustrated on both continents because regulatory policy has not addressed pressing environmental, health, and safety issues. Thus, my focus shifted gradually from understanding differences to understanding why the goals articulated by CSOs for the ideal regulatory framework for nanotechnology policy remained unrealized in both settings.

My research found that the debate is politically moderate; in other words, the CSO participation involves institutionalized mechanisms rather than disruptive tactics such as street protest, which were more common in the policy debates over genetically modified food in the EU. Furthermore, the debate is connected to the broader issue of the regulation of toxic chemicals, because nanomaterials fall under the jurisdiction of frameworks that regulate bulk chemicals. This situation, which can be described as one where in principle nanomaterials are regulated but in reality they are not, creates many implications for regulatory practices. Although the EU and the US approach regulation in

different ways, and they have different institutional relationships to advocacy organizations, the results of the advocacy activities on both continents are the same. Even though there are some small successes from the work of advocacy groups, in both the EU and the US the main requests that groups have for the appropriate regulation of nanomaterials have not yet been heard. Where there was a policy response, it was highly altered to suit industrial interests.

One would expect to find significant differences, because the EU has an elaborate system with official participation from CSOs and trade unions, a very strict framework based on the precautionary principle, and a Green Party with opinions very similar to those of the advocacy groups and with the capacity to influence the EU Parliament. But even with these significant political differences, the advocacy groups do not successfully influence regulatory outcomes. This chapter will discuss the broader implications of the similarity of outcomes.

7.1 Differences of Structure, Similarities of Outcome

The EU and the US present a variety of structural differences. The two political systems are very different as are the legislative procedures. In the EU, legislative initiatives are assigned only to the Commission, which has the sole right to introduce new legislation. The fact that the Commission is appointed has created a democratic deficit and a legitimacy problem for the EU. In the US, on the contrary, bills can be introduced by any member of Congress or even by lobbyists, as long as a member of Congress agrees to introduce the bill on their behalf. In a way, the system in the US is more

democratic in the sense that the process for legislative initiatives is more open. However, in the EU the parliamentarian system permits more voices to be heard, and it has more complicated procedures that may require a unanimous decision-making process. Those procedures provide an opportunity for smaller parties and voices to be heard. Thus, the European Parliament's Green Party gets many opportunities to influence policy outcomes toward more environmental ends. In the US, the two party system that dominates the government tends to marginalize the smaller constituencies. Republican members do not have a strong interest in environmental protection and are more likely to support industry's interests, but many members of the Democratic Party also have a weak interest in environmental regulation and have close connections with industry. Because the decision-making process is based on majority where the winner "takes it all," environmental laws are very difficult to pass, especially when the Republican Party is in power. Thus, progressive, environmentally oriented Democrats—that is, the American equivalent of the Green Party in the EU Parliament—can be found, but they are in a structurally weaker position due to the two-party system.

The regulatory frameworks for nanomaterials in the two political structures are also very different. In the US, the existing framework, TSCA, is outdated and does not even regulate bulk chemicals. Thus, the debate over the regulation of nanotechnology has become an opportunity to address the issue of the regulation of toxic chemicals in general. CSOs and other advocacy groups advocate for TSCA reform in order for nanomaterials to be appropriately regulated. They argue for changes in the framework, for nanomaterials to be considered new chemicals, and also for the use of specific tools

within TSCA that could regulate nanomaterials until TSCA is reformed. They advocate for these requests through their participation in working groups, open comment periods, lawsuits and petitions, hearing procedures, and, most importantly, lobbying in the two houses and in the administration.

In the US, the effectiveness of advocacy organizations depends on who is in power, the Republicans or the Democrats. But even with the situation of "gridlock," in which one party blocks the actions of the other, the advocacy work of American CSOs has resulted in the development of various Significant New Use Rules for specific nanomaterials and for specific uses. When Democrats have power in the administration, opportunities open for the CSOs to influence policy. They can successfully lobby because there is an interest to regulate. Furthermore, EDF, one of the most active CSOs in the regulation of nanomaterials under TSCA, has tried to work with the industry on the issue. They have actually sent common requests shared by industry to the EPA, which requested the latter to use exiting tools to regulate nanomaterials. In Congress, however, CSOs have made little progress, even though CSOs may have good contacts, especially when the Democrats are in power. Even though they successfully included provisions for nanotechnology in the 2011 bill that was designed to replace TSCA, the political system makes it impossible for them to achieve reform because Republicans, who usually support industry interests, have blocked reform either by controlling one of the bodies of Congress (such as the House of Representatives after 2010), or by having veto power through control of the presidency (2000-2008), or by the Senate filibuster.

Whereas in the US, the politics of nanotechnology regulation are still mired in the

problem of the overarching need for TSCA reform, the EU has a relatively new regulatory framework, REACH, which is based on the precautionary principles and promises to regulate all chemicals adequately, including nanomaterials. Thus, in the EU the debate about nanotechnology regulation has evolved into an issue of implementation under REACH. Even though CSOs and trade unions emphasize that REACH is a good framework, at the same time they argue that it is inappropriate for the regulation of nanomaterials in its current form and that REACH must be implemented appropriately so that nanomaterials are covered. Appropriate implementation includes a definition for nanomaterials, for the guidelines to change appropriately in order to apply to nanomaterials, and for nanomaterials not to be regarded as phase-in (new) substances under REACH.

Another important difference between the EU and the US is the form of CSO participation. In the US, CSOs do not have official positions in working groups, and instead their influence derives from informal means. Furthermore, there is no Parliamentarian system with a Green Party by their side; the closest parallel is a group of environmentally oriented Democrats in Congress, but they generally lack the political influence that the Green Party has in the EU Parliament. In the EU the CSOs have official permanent positions into the policy decision-making procedures, something that it is not the case in the US. There are many ways for CSOs and trade unions to participate in policy development in the EU. They are members of working groups, they are members of managing boards, they comment on regulation, they are recognized stakeholders, and they are also lobbying to the EU bodies, the Commission, the Parliament, and the

Council. In particular, they have good opportunities to exert influence through the Parliament's Green Party. As a result of the structure of the Parliament and the way decisions are made, the Green Party, which has opinions very similar to CSOs and trade unions, can influence the opinion of the entire Parliament.

Even though, in the EU, NGOs and trade unions have many ways to influence the regulatory outcomes for nanomaterials, with a DG dedicated to their requests (DG Environment) and the Green Party by their side in the Parliament, they have only achieved one of their goals, the development of a definition for nano. Likewise, although NGOs and trade unions highlighted the importance of making changes in the implementation process and guidelines, the Commission announced minimal changes to the guidelines that went against what NGOs and trade unions had been lobbying for. The only stakeholder that was happy with these developments was the chemical industry. Because of the focus of the regulation of nanomaterials on implementation, the nanotechnology debate has become a very technical issue. This scientization of policy debate has favored the chemical industry because it is the only stakeholder financially capable of producing scientific knowledge necessary for the regulatory procedures. Through this powerful position, industry influences policy outcomes towards its interests.

Thus, even though there are significant differences in the political opportunity structure for the role of CSOs and trade unions in nanotechnology regulation, in both cases CSOs have failed to achieve their goals, and in neither case did CSOs achieve their most important requests. This is because in both cases the chemical industry has much more power than the CSOs. The power of the chemical industry manifests in different

ways in the two political structures, but in both cases it dominates the procedures and influences the regulatory and legislative discussions and outcomes.

7.2 Policy Implications

Given the conclusion that industrial power is so significant in the nanotechnology regulatory field, and that the differences in policy outcomes in the EU and US are relatively minor, what policy reforms might facilitate a more rapid pace of nanotechnology regulation and a more comprehensive reform process? Industrial power is stronger because of scientization of this policy field. A first step towards a more comprehensive and rapid nanotechnology regulation would be the disconnection between industry and policy procedures. One might argue that to be symmetric, this would probably mean a disconnection between CSOs and policy procedures as well, but CSOs claim to represent the broader public interest and the environment, and the goal would not be so much a complete separation of stakeholders from the policy process but a leveling of the playing field between industry and CSOs.

In the US, the central policy mechanisms for reducing industrial influence on the policy process are campaign finance reform and filibuster reform. If politicians had little to gain from industry, then they would be less prompted to support the industry's position. At the moment the Republican politicians are benefiting greatly from the chemical industry, which is offering them financial support. In the Senate, even when the Republican Party is a minority, they can block chemical reform through a filibuster. The Senate must get 60 votes to overcome the filibuster and bring the debate to a quick end.

However, it is rare that Democrats have a 60-40 “super-majority” in the Senate. In general the US legislative system would greatly benefit if the filibuster was not allowed through such an easy procedure, and Senators were not allowed to keep the debate open until the bill dies.

In the EU, industry has another role not connected to financing campaigns but rather to influencing legislative bodies through the industry's ability to produce knowledge. There is a shift in the EU with respect to who is responsible for providing the knowledge, especially for the nanotechnology debate. There is so much technical uncertainty about the issue that financially only industry can provide and finance appropriate scientific research. However, this creates problems of bias, and the development of an independent body that conducts scientific research is necessary. This scientific body will stand alone as a body financed by taxes or fees levied on specific companies for the assessment of chemical safety. Scientists who have had no previous connection to any other governmental body or the industry should be recruited. The appointment of such scientific staff could be done by direct voting by the citizens and even represent every European member state. There is also a need for the ECHA to be more independent from the Commission, with ultimate responsibility to the EU elected body, the Parliament.

The development of an independent scientific and regulatory body also requires reducing the phenomenon of the “revolving door” relationship with industry. Especially in environmental policy development there are many incidents where administrative staff or even government consultants started their careers in the industry, then switched to a

position in a legislative or administrative body, and then moved back to industry. Bias in their decisions is unavoidable. The issue of revolving doors is present in both the EU and the US and creates problems in the development of appropriate regulatory policy for nanotechnologies. A person with connections to the industry should not be appointed to any governmental position, or there should be a minimum required waiting period between a position in industry and one in the government.

The second issue is the role of scientific data in the regulation of nanomaterials. Even though science is necessary in defining possible risks, this is not the only factor for the development of regulation. The superior position of science in the debate creates two problems: it favors industry because of its ability to develop data, and it results in decisions of nonregulation (either because of the lack of scientific information or because of arguing that existing science is appropriate, even if it is not). For better policy results there is need for an approach that is less framed and based on scientific data and costly procedures. Each new technology that poses new risks should be approached through a holistic way with the development of new legislation based on the precautionary principle. Existing frameworks require approaching new technologies with more science and more involvement by the industry. If nanotechnology regulation were framed from the beginning as a legislative issue, then it would become a political issue, and broader criteria involving health, occupational safety, and pace of regulation could be addressed through a political debate. Of course, the shift of regulatory policy from a scientized, technical forum to a politicized, legislative forum can only be successful if the other proposals (campaign finance reform and, in the EU, independence of the regulatory body)

are first accomplished.

The descientization of regulatory reform can be achieved by incorporating other issues to develop risk assessments and achieve risk management. A broader frame of the term and activities could apply. A technology assessment can have other aspects such as how and when this new technology is going to benefit society. In order for de-scientization to be achieved the independent scientific body, proposed above, will require a broad scientific mission that includes not only assessment from a technical perspective but also assessment that includes social, economic, environmental, health, and occupational issues.

Broadening the framework of risk management raises a question of whom we should include so that decisions are more representative of broad societal concerns. As this project has shown, the mechanisms developed by the EU to include CSOs in decision-making have not been successful, at least from the perspective of the CSOs. A new structure of public participation is required in both the EU and the US. There is a need for an institution akin to that of the jury in the court system, in which citizens are selected, but their recommendations have political effects. Citizens will serve two-year terms, and they will meet for about four times a year. In the case of the EU, the citizens should represent all national states and in the US all major regions. The other two bodies will be responsible to inform the citizen body about a specific legislative issue. The citizens chosen for the citizen body will be paid for the time they will spend working on the legislative issues. The citizen body will discuss the information that the independent scientific body has developed but also other policy issues with the governmental

legislative bodies and all together will decide how they should proceed with regulation. Rather than having a role of merely recommending policy, as occurs in the current versions of citizen-based consensus conferences, these citizen juries would be able to pronounce a "verdict" on a proposed regulatory framework, and their verdict would require a policy outcome from the legislature within a specific time period.

7.3 Theoretical Implications

In addition to policy implications, this study has general theoretical implications for three major referent literatures: comparative regulatory policy, public participation in technology policy, and social movement studies of political strategies.

7.3.1 Comparative Regulatory Policy

One general implication of the research is to offer some refinements of work that focuses on comparative differences in political structures as a variable that explains policy outcomes. Comparative studies have focused on differences in political cultures or structures to explain differences in policy outcomes. The most prominent work on comparative technology policy is Jasanoff's research on the biotechnology debate in Germany, Britain, and in the US (2007). She argues that differences in the civic epistemologies of these countries—contentious in the United States, communitarian in Britain, and consensus-seeking in Germany—resulted in different ways of discussing policy issues, different ways of validating scientific knowledge, and finally different ways of deciding about policy procedures. These differences, according to Jasanoff,

resulted in different policy outcomes, for example, the uncontested embryo research in Britain and the deeply contested response to the same issue in the US. My research suggests that different epistemic cultures discuss policy issues in different ways; however, they do not necessarily produce different policy outcomes. The case of nanotechnology regulation that this dissertation discusses shows that two political structures, with different civic epistemologies, make similar policy decisions. As a generalization, I suggest the hypothesis that where industrial power is strong and mobilized in a policy arena, it can overcome policy differences that might otherwise occur due to differences in civic epistemologies.

Another example of comparative policy research is analysis that points to the relatively technocratic approach to regulatory policy in the US versus the more precautionary approach in the EU. Previous research has shown that because in the EU there was a consideration of socio-economic criteria besides technocratic and scientific ones, especially in the case of bovine growth hormone, the EU made the decision of banning the product, whereas the US made the completely opposite decision and allowed the growth hormone to go on the market (Kleinman & Kinchy, 2003). Likewise, as I have discussed, this was also the case with the GM debate, where the EU adopted a much more precautionary stance after the mobilization of CSOs and considerable public uproar. However, in the case of nanotechnology it appears that the EU is not considering potential negative social consequences of the technology. Furthermore, although the precautionary principle underlies the REACH framework with its emphasis on the review of all chemicals (in comparison with the grand-parenting status of many chemicals in the

US), the actual implementation of nanotechnology regulation in the EU has not shown much evidence of precaution. In fact, with its last communication paper on the regulation of nanomaterials, the Commission has completely thrown out the precautionary principle and shown that decisions are taken based on rationales that favor market development. This surprising result shows that policy decisions are not only connected to the culture and structure of a government; instead, they are also connected to the different powers within the policy arena. Again, because industrial power is so strong and so well mobilized in the case of nanotechnology policy, differences in cultural styles of policymaking are swamped by industry. Even though the EU structure permits more official participation in the implementation level and has adopted a precautionary framework in general for its chemical regulation, the scientific knowledge about how to implement and resolve the policy issues comes almost exclusively from the industry.

Neopluralists have noticed that there are many competing interest groups participating in the policy domain (McFarland, 2007). Not all groups have the same power to influence policy making. In particular, businesses are not just another interest group, they have a prominent position (Manley, 1983). In contrast to the assumption of traditional pluralists that "given equal stakes, all social strata are equally able to mobilize themselves for political action" (Wilson, 1995, p. 14), equality of opportunities to participate in the policy procedures and influence policy making does not lead to equality in results. These differences in the capacity to affect outcomes lead to a small number of winners and a large number of losers (Manley, 1983). In the case of nanotechnology policy, corporations have used new techniques and found the way to influence policy

making according to the governmental system by forming organizations that have common policy interests. For example, the American Chemical Council (ACC), the coalition of all major chemical industries, and the Society of Chemical Manufacturers & Affiliates (SoCMA), the coalition of smaller chemical industries, are the main organizations that lobby against TSCA reform, by initially arguing against any chemical reform and later arguing for reforms according to the industry's needs. In the case of TSCA reform in the US, the representatives of ACC and SoCMA are the ones invited to testify. But also in the EU, the CEFIC (European Chemical Industry Council) is the only organization that welcomes the Commission's lack of regulation.

In both the EU and the US, the chemical industry is more commonly represented by trade organizations than it is by individual companies. As a result, the power is concentrated in a few large corporations, which put a lot of effort and money in advocating for less regulation. In the US, the chemical industry spends an enormous amount of money in lobbying to the Congress, and to get support from Republican members who they exclusively lobby to. In the EU, where the parliamentarian system is more diverse, the industry seems to play another role, yet still dominant. In the technical debate about the implementation of REACH for nanomaterials, they provide the knowledge and they shape what type of knowledge needed in order to regulate such substances. In both cases the industry seems to win the battle.

In summary, different political structures have different ways of discussing policy making about new technologies. They present different civic epistemologies, and previous comparative research has shown that the differences in political institutions and

cultures result in different, sometimes even opposite, policy outcomes. However, this is not the case with nanomaterial regulation in the EU and the US. Even though the civic epistemologies are different, in both cases the powerful role of industry is the reason why both governments have taken minimal actions towards adequate regulation. The power of the industry can manifest in different ways in the two political structures. In the US, the power of industry operates directly through campaign funding and lobbying, but CSOs have some highly qualified expert scientists who can contest industrial knowledge. In the EU, industry provides the necessary knowledge they can provide for the debate, and the political structure itself has empowered industry through a more powerful DG (the DG Enterprise), which has a market orientation, and a weak Parliament that has little power over the regulatory body.

7.3.2 Public Participation

Another theoretical implication involves the STS literature on public participation. Increasingly, the literature has shown skepticism of public participation and suggested that it leads to political co-optation. In particular, Brian Wynne (2005) has criticized such participatory projects as a mirage, because they impose severe limits on framing issues and project a model of a citizen who must see issues only connected to risk, with risk defined in institutionalized terms. As Wynne argues, "If people try to bring other meanings to the issue, they are likely to be excluded and patronized by expert institutions" (2005, p. 71). This is especially the case in the EU, where participatory projects for nanotechnology took place in anticipation of a contentious debate along the

lines of the biotechnology debate.

Other scholars have also criticized participatory projects as being non-representative (Van Oudheusden, 2011); maintaining the division of labor, expertise, and power (Hess, 2011; Kleinman, 2000); and having no influence in policy outcomes, mainly because they lack connection to the policy procedures (Einsiedel et al., 2001; Hess, 2011; Kleinman, 2000; Kleinman et al., 2007). This research project confirms the same types of problems that critics identify with projects of lay participation, but in another type and level of participation: the official participation of CSOs in the EU debate for the regulation of nanotechnologies. This participation, even though it cannot be characterized as lay in the sense of a focus group or consensus conference that selects individuals who have no particular stake in or knowledge about the issue, can be viewed as public participation because CSOs claim that they represent the interests of the public, including the lay public, and the environment. The official participation of CSOs in the EU presents the main problems along the same lines with the issues identified by the critics of participatory projects.

The official participation of CSOs in the EU is mainly taking place in the implementation level. Where CSOs have representatives in expert working groups, their participation is framed by the scientific focus of the issue. The implementation level is very technical, where discussions are focused on the scientific understanding of definitions, risks, exposure scenarios, etc. Even though CSOs have different approaches than the industry, they still have to have an approach that is framed within the technical parameters established by the political process. Along the lines of Wynne's criticisms, the

participation mode in the EU and the official position of CSOs in policy procedures present severe limits in representing the public opinion and produce a democratized policy outcome. For example, the highly technical framing excludes CSOs that have different non-scientific opinions and resolutions on the issue.

Furthermore, public participation in the form of CSO participation is shaped by the government, as was demonstrated in the analysis of how profoundly the EU NanoCap project shaped CSO policy positions. Through this project, the NGOs and trade unions gained knowledge and actually started working on the issue of the regulation of nanotechnologies. Besides the fact that the debate was initiated by a project with invited participants much like a lay project, in general, participation in the debate of the implementation is selective, and only the organizations that have the requisite knowledge and agree to the terms of participation are allowed to be part of the decision-making process. Thus, CSOs that advocate more radical positions, such as a complete moratorium until all safety research has been completed, are excluded from the political process. The CSOs have to have a "balanced" opinion because otherwise they will not be able to be part of the debate at all. The balanced position on nanotechnology regulation is a position where no moratoria are requested and the argument is focused around the development of adequate regulation. The balanced opinion is something that most of the CSOs that participate in the institutionalized debate are articulating as what they want and what they learned under the NanoCap process. It framed a balanced approach and shaped a balanced opinion through information that highlighted the possible benefits of nanotechnology. EEB's publications from NanoCap highlight nanotechnology's

possibilities.

The most important constraint on the official participation of CSOs in the policy procedures is that participation takes place in such way that the division of knowledge, power, and labor still exists, especially when it comes to final decision-making. In the case of the EU nanotechnology debate, there is an issue of distribution of power especially between the CSOs and the industry. This issue is more obvious in the case of nanotechnologies just because the issue has become a technical one where knowledge is necessary. Knowledge and as a result power seem to be circulating in the hands of the industry. This power has been given to the industry by the government because the latter desperately needs the industry's expertise to resolve the technical issue of nanotechnology regulation. This type of division is not the same one found in many lay participatory projects, where typically the experts have the knowledge to explain and frame the issue. However, it is along the same lines: still the participants lack equal abilities when it comes to knowledge and expertise, and the decisions are influenced mainly by the opinions of the industry.

Finally and most importantly, as in the case of lay consultation exercises such as consensus conferences, the official participation of CSOs in the EU debate has no impact, or in the best-case scenario, limited influence on policy-making. The lack of influence is not because the participation is not connected to policy procedures but because CSOs (and also Parliament) do not have enough power. It seems that at least in the case of CSO participation where there is connection to policy procedures, the final decision is shaped by the more powerful players of the debate. The governmental bodies that actually make

the final decisions may or may not take into account the CSOs recommendations. More chances are they will not, especially if other more powerful actors can influence policy-making more successfully. As a result, participatory projects should be developed in a different way.

If participatory projects continue to be invited, selective, institutionalized, and mainly developed around the idea of scientific risk and scientific knowledge, participation by CSOs will have the same minimal results that are found in lay consultation processes. Even in the case of CSOs, where in contrast to lay people they have more knowledge and connection to policy procedures, the participatory processes have yet to succeed. Only if governments were to create a separate citizens' jury that has the power to pronounce verdicts on policies (or require a response to no policies), no participatory project will succeed in democratizing policy development and representing citizens' concerns.

7.3.3 Social Movements and Political Strategy

A third implication involves the strategy of CSOs. If participatory projects are condemned to having only a minor effect on policy outcomes, then the effects of CSOs on policy can be successful only if they mobilize in a way that is uses contentious repertoires of action and is not initiated by governments influenced by the dominant presence of industry's interests. The comparison of CSOs in the genetically modified food controversy and in nanotechnology regulation, which was developed in Chapter 6, suggests that more contentious repertoires of action may be necessary in order for insider

CSOs to have political effects. In other words, there is a need for street protest and massive public anger in order for the insider CSOs to have political effectiveness; otherwise, industrial power will be paramount in the political process.

As was discussed in chapter 6, even though nanotechnology and biotechnology have many similarities, the debates over their regulation developed in completely different ways in the EU. The nanotechnology debate lacks mobilization and massive opposition that would probably lead to more strict regulation as in the case of biotechnologies. However, the nanotechnology debate presents some issues that do not facilitate mobilization. Also, the socio-political environments in which the two debates have taken place are different, partly because the political system has responded to the outcomes of the biotechnology controversy by developing participatory institutions.

One of the primary obstacles to a strategy of contentious mobilization is that there is a big difference in the cultural understanding and significance of food and chemicals. Food is very important, and possible risks coming from scientific and technological activities connected to food can become very contentious. Food is digested, it directly affects health, and it is deeply woven into cultural identities and social relations. This is a big difference with chemicals and especially with nanomaterials, which are basically invisible. Even historically, before the development of nanotechnologies, chemicals and their possible effects only became contentious issues after there were severe effects in human health and the environment, and often years of work and coalition building were required to make those connections credible enough to have policy effects. In the case of biotechnologies, the issue became contentious before there was even any health issue,

because the idea that industry can play with the natural production of food was enough to create opposition.

The use of nanomaterials and nanotechnologies and the connection to everyday practices is not clear. Where do we use nanomaterials? The answer is everywhere, even in food, but this is not what the public knows. Nanotechnologies have been connected more with their use in computer chips and not with their use in cosmetics, one of the most prominent uses of nanomaterials at the moment. On a similar note, cosmetics can be viewed by the public as not as important to everyday life and not as threatening to health as bioengineered food might be. People can choose to not use cosmetics but they cannot stop eating. Part of the absent connection is the fact that CSOs have failed to make good connections in the media between nanotechnologies and their possible health and environmental effects, but most importantly they have failed to frame the issue in general political terms. In contrast, the issue of genetically modified food in Europe involved issues of European pride, rejection of American corporations, the quality of local "terroir" brands, and the European lifestyle in general.

Furthermore, CSOs are not opposed to the development of nanotechnologies altogether, as they were in the case of biotechnologies, because nanomaterials are presented as being able to resolve many environmental and energy problems. For example, better crop production can be achieved by using the land in a specific way and without the need of biotechnologies, but clean water, especially in places where it is desperately needed, is not something that can be achieved as effectively as with a nanotechnology filter. Thus, nanotechnology offers opportunities in the context of

environmental justice and low-income communities. Likewise, nanotechnology also presents many advantages in terms of energy efficiency, energy storage, and energy production (such as for solar energy); thus, it can be aligned with arguably the paramount environmental issue of the time: the reduction of greenhouse gases. By presenting such benefits and possible uses, most CSOs involved in the debate do not see the problem as a simple one of framing an oppositional campaign based on the goal of a complete moratorium.

Biotechnologies were introduced as resolving issues of hunger and food production as well, and there were cases of "appropriate" biotechnology development such as versions of rice that provided new levels of nutritional support. However, in the developed countries the adequacy of the food supply is not an issue, whereas its quality is much more important. Thus, arguments about the benefits of biotechnology did not convince many advocates of sustainable agriculture, because the production of food can be successful in many other traditional and less scientifically and industrialized ways. Joining the aggressive pursuit of farmers whose fields were contaminated by biotechnology crops, CSOs were able to broaden the argument from scientific terms to cultural and socio-economic ones and connect their concerns to that of farmers. In the case of nanotechnologies, however, an industry sector just expands the scope of its manufacturing. It does not conflict in obvious ways with other fields. The industry that produces nanomaterials is basically the same industry that produces chemicals. CSOs that are working on the topic of nanotechnology do not have the support of any other interest groups such as farmers, as in the case of biotechnologies. They only have the support of

trade unions, which do not greatly oppose the technology because they basically are in a double bind: the people who they represent are working in the chemical industry.

CSOs have failed to develop broad political arguments that go beyond risks. The regulation of nanomaterials has become an implementation issue which is very hard to dispute outside of scientific terms because it is a very technical level of discussion. The public will not be interested if the CSOs discuss the issue in scientific terms. In the biotechnology debate public opinion was mobilized not only because food has a special significance but also because the opposition movement framed the issue of biotechnology in more broader terms that the public and other interest groups could make a connection worth fighting about.

In order for mass mobilization to take place in the issue of nanotechnology regulation, a few conditions would be required. First, the issue must be presented as potentially affecting everyone's health and everyone's environment. Nanotechnologies and nanomaterials are being used in a variety of procedures and products from cosmetics to agricultural applications. As a result, humans and the environment can be exposed to them in many more ways than they can be exposed through biotechnologies, for example. Biotechnology is mainly used in food products. Nanotechnologies, because they are used in a large variety of products and procedures, can easily reach the human body and interfere with the environment through the cycle of production, use and disposal, and can have many unknown toxic effects. This narrative should be articulated more clearly by the CSOs.

Another way for mobilization to happen is for CSOs to frame the issue of

nanotechnology regulation as a new legislative issue. This means that CSOs should make an argument about a completely new regulatory framework and not consider the coverage of nanomaterials under existing regulatory frameworks. In connection to the previous point, because the nanotechnology debate has become an implementation issue the discussion is very technical, highly scientized, and hard to communicate to the public. Also, this scientific and technical discussion takes the focus of the real issue, the regulatory free development of a new technology full of unknown risks, to a narrow discussion of defining nomenclature and understanding how size distribution affects risk. By discussing the issue at this technical level, it is much more difficult for the public to connect and start worrying about it.

In order to achieve mobilization, CSOs would also have to take a more oppositional stance on the issue. A balanced position on the issue of nanotechnologies, mainly stating that the technology is useful but better regulation is needed because of possible risks, is not only confusing but it is also a dead-end for getting public mobilization and achieving regulatory goals. The CSOs should frame their arguments differently. If they keep arguing that more scientific research is needed, they keep framing the issue in technocratic terms that will not get public support. Instead, CSOs could change the narrative of their argument to focus on other issues connected to the technology. These issues could be: who is really benefiting from the technology, why new technologies develop in such a way, why we have limited understanding of impacts positive and negative, and why governments should invest in the development.

CSOs should also fight for equal participation. Instead of trying to compete with

the industry, they should raise different criteria for establishing their arguments and empowering their position. It is unlikely that CSOs will ever have the same command of scientific knowledge as does the industry, just because they do not have the same financial capacities. CSOs should instead focus on making broader arguments about the necessary regulatory and legistlative actions. As has been discussed in the previous paragraph, risk need not be defined in strict scientific terms, but can encompass a broader social understanding of the issue.

7.4 Conclusion

The debate over the regulation of nanotechnologies in the EU and the US reveals an interesting relationship about the relative role of industrial and civil society power in the policy arena. Even though the two political structures are very different in terms of procedures and participatory patterns and access, the case of nanotechnology regulation shows that such differences do not always result in different policy outcomes. To the contrary, in this case, both resulted in the same minimal legislative activities. This observation is in contrast with previous research and observations about differences in political structures that account for differences in policy outcomes, especially in the case of biotechnology regulation, which is often compared to nanotechnology. As this present research shows, industrial power that manifests in different ways in the two political structures is the reason why similar results are observed.

In the EU, the political structure provides CSOs easy and official access in the policy-making procedures. This observation by itself generates assumptions about better

regulatory outcomes because of openness in participation. Other reasons are because the EU environmental legislation is based on the precautionary principle, and the EU Parliament has a Green Party with pro-environmental interests and power to shape legislation. However, the reality is that none of these achievements in the EU structure play an important role in the regulatory outcomes for nanomaterials. Even though the CSOs have access and are recognized stakeholders in the debate, their participation is not on equal terms. The chemical industry, especially in the case of the nanotechnology debate, enjoys a privileged position as being the main expert capable to produce the necessary scientific knowledge for nanomaterial regulation. But also the industry is benefiting from a very powerful DG Enterprise which seems to be able to influence Commission's regulatory decisions.

In the US, the political structure gives CSOs much fewer opportunities to participate officially, but the chemical industry also does not have power as the expert and the stakeholder responsible for knowledge production, as the industry has in the EU. The industry in the US plays the role the legitimate job provider, responsible for keeping the economy going. It also influences the legislature and executive branch through extensive lobbying and campaign contributions, and it influences some CSOs by forming partnerships with them in favor of relatively moderate regulatory reforms. Thus, whereas industry tends to influence outcomes in the EU through technocratic processes and influence over the Commission and the ECHA, in the US it achieves similar outcomes through control of campaign financing, lobbying, and partnerships with some CSOs.

In both cases the CSOs are a weak countervailing force and are not able to

compete with the power of the chemical industry. In both the EU and the US the chemical industry is represented by large trade associations, which are well-funded and are capable of influencing government policy at diverse points in both the legislative and executive branches. It is impossible for CSOs, even in the event that they have official positions as stakeholders (as in the EU) or are called to provide testimony (as in the US) to shape outcomes toward environmental ends. In the EU, the official inclusion of CSOs has actually minimized the ability of CSOs to mobilize a broad social movement similar to that of biotechnology controversy. However, CSOs in the US have also not mobilized such a movement, and the strategy is likely to be a difficult one to adopt because of the many differences between food and chemicals. The ineffectiveness of CSOs, including in some cases even a pattern of co-optation, and the relatively slow pace of nanotechnology policy reform and regulation raise many questions about how to adjudicate industrial power, public participation, and democratic processes.

REFERENCES

Abbott, K. W., Marchant, G. E., & Sylvester, D. J. (n.d.). A framework convention for nanotechnology? *SSRN eLibrary*. Retrieved December 11, 2010, from http://papers.ssrn.com

Abraham, J. (2002). The pharmaceutical industry as a political player. *The Lancet*, *360*(9344), 1498–1502.

Abraham J. (2003). The science and politics of medicines control. *Drug Safety*, *26*(3), 135–143.

Abraham, John. (1993). Scientific standards and institutional interests: Carcinogenic risk assessment of benoxaprofen in the UK and US. *Social Studies of Science*, *23*(3), 387–444.

Abraham, J. (1994). Distributing the benefit of the doubt: Scientists, regulators, and drug safety. *Science, Technology & Human Values*, *19*(4), 493–522.

Abraham, J. (2008). Sociology of pharmaceuticals development and regulation: A realist empirical research programme. *Sociology of Health & Illness*, *30*(6), 869–885.

Abraham, J., & Ballinger, R. (2012). The neoliberal regulatory state, industry interests, and the ideological penetration of scientific knowledge deconstructing the redefinition of carcinogens in pharmaceuticals. *Science, Technology & Human Values*, *37*(5), 443–477.

Abraham, J., & Lewis, G. (2000). *Regulating medicines in Europe: Competition, experts and public health*. New York, NY: Psychology Press.

Abraham, J., & Sheppard, J. (1999). Complacent and conflicting scientific expertise in British and American drug regulation clinical risk assessment of triazolam. *Social Studies of Science*, *29*(6), 803–843.

Aitken, R. J., Chaudhry, M. Q., Boxall, A. B. A., & Hull, M. (2006). Manufacture and use

of nanomaterials: current status in the UK and global trends. *Occupational Medicine (Lond)*, *56*(5), 300–306.

Alwood, J. (2011, May 10). *Regulation and assessment of nanoscale materials under the Toxic Substances Control Act*. Presented at the JRC and ENPRA Stakeholder Workshop.

Andorka, F. (2011, June 14). FDA invites public comment on nanotechnology. *Industry Week*. Retrieved September 17, 2012, from http://www.industryweek.com

Andrews, K. T. (2001). Social movements and policy implementation: The Mississippi civil rights movement and the war on poverty, 1965 to 1971. *American Sociological Review*, *66*(1), 71–95.

Andrews, K., & Edwards, B. (2004). Advocacy organizations in the US political process. *Annual Review of Sociology*, *30*, 479–506.

Applegate, J. S. (2008). Synthesizing TSCA and REACH: Practical principles for chemical regulation reform. Retrieved March 25, 2011, from http://works.bepress.com

Azoulay, D. (2011, October). CIEL welcomes new EU definition of nanomaterials as a necessary step towards assuring safety, October 2011. *CIEL: The Center for International Environmental Law*. Official webpage. Retrieved November 11, 2012, from http://www.ciel.org

Azoulay, D. (2012). *Just out of reach*. Geneva: The Center for International Environmental Law (CIEL).

Badaracco, J. (1985). *Loading the dice: a five-country study of vinyl chloride regulation*. Boston, MA: Harvard Business School Press.

Barden, D., Fisher, E., Selin, C., & Guston, D. (2008). Anticipatory governance of nanotechnology: foresight, engagement, and integration. In E. Hackett, O.

Amsterdamska, M. Lynch, & J. Wajcman (Eds.), *The handbook of science and technology studies*. Cambridge, MA: The MIT Press.

Bergeson, L. (2012a, February 17). EPA regulatory agenda includes notices concerning nanoscale materials. *Nano and other emerging chemical technologies blog*. Retrieved March 21, 2012, from http://nanotech.lawbc.com

Bergeson, L. (2012b, June 23). Recent developments in NRDC's case concerning EPA's conditional registration of nanosilver. *Nano and Other Emerging Technologies Blog*. Retrieved March 21, 2012, from http://nanotech.lawbc.com

Bergeson, L. (n.d.-a). EPA issues final SNURs for carbon nanotubes. *Nanotechnology Law Blog*. Retrieved September 15, 2012, from http://nanotech.lawbc.com

Bergeson, L. (n.d.-b). EPA promulgates SNUR for infused carbon nanostructures. *Nano and Other Emerging Chemical Technologies Blog*. Retrieved March 20, 2012 from http://nanotech.lawbc.com

Bergeson, L. (n.d.-c). Potassium titanium oxide SNUR bans manufacture of particle size less than 100 nm. *Nano and Other Emerging Chemical Technologies Blog*. Retrieved April 15, 2012 from http://nanotech.lawbc.com

Bergeson, L. (n.d.-d). ECHA revising REACH guidance documents to include nanomaterials. *Nanotechnology Law Blog*. Retrieved September 26, 2012, from http://nanotech.lawbc.com

Bergeson, L., & Goulden, K. (2010, September). *Nanotechnology and REACH readiness*.

Berry, J. (1999). *New liberalism: The rising power of citizen groups* (First Edition.). Washington, DC: Brookings Institution Press.

BEUC. (2011). BEUC welcomes adoption of "nano-definition" but calls for proper regulation of safety risks. BEUC: The European Consumer's Organization.

Biswas, P., & Chang-Yu Wu. (2005). Nanoparticles and the environment. *Journal of the*

Air & Waste Management Association (1995), *55*(6), 708–746.

Borm, P., & Kreyling, W. (2004). Toxicological hazards of inhaled nanoparticles: Potential implications for drug delivery. *Journal of Nanoscience and Nanotechnology*, *4*(5), 521–531.

Bosley, B. H.R. 5820, the Toxic Chemicals Safety Act of 2010 (2010).

Bowman, D., & Hodge, G. (2007). A small matter of regulation: an international review of nanotechnology regulation. *Columbia Science and Technology Law Review*, *8*, 1–32.

Bowman, D. M., & Hodge, G. A. (2006). Nanotechnology: Mapping the wild regulatory frontier. *Futures*, *38*(9), 1060–1073.

Bowman, D. M., & Hodge, G. A. (2008). "Governing" nanotechnology without government? *Science and Public Policy*, *35*(7), 475–487.

Breggin, L., Falkner, R., Jaspers, N., Pendergrass, J., & Porter, R. (2009). *Securing the promise of nanotechnologies: Towards transatlantic regulatory cooperation. Report*. London, UK: Chatman House.

Brickman, R., Jasanoff, S., & Ilgen, T. (1985). *Controlling chemicals: The politics of regulation in Europe and the United States*. Ithaca, NY: Cornell University Press.

Brown, P. (2007). *Toxic exposures: Contested illnesses and the environmental health movement* (1st ed.). New York, NY: Columbia University Press.

Brumfiel, G. (2003). Nanotechnology: A little knowledge... *Nature*, *424*(6946), 246–248.

BUND. (n.d.). BUND.net - BUND für umwelt und naturschutz Deutschland. *BUND: Friends of the Earth Germany*. Official webpage. Retrieved November 21, 2012, from http://www.bund.net/

Buonsante, V. (2011, March 24). *Reshaping REACH*. Presented at the REACH in Practice ERA Conference, Brussels.

Burstein, P., & Freudenburg, W. (1978). Changing public policy: The impact of public opinion, antiwar demonstrations, and war costs on senate voting on Vietnam war motions. *American Journal of Sociology*, *84*(1), 99–122.

Caporaso, J., & Jupille, J. (2001). The Europeanization of gender equality policy and domestic structural change. In M., Cowles, J., Caporaso, & T., Risse, (Eds.). *Transforming Europe: Europeanization and domestic change*. Ithaca, NY: Cornell University Press.

CEFIC. (n.d.). European Commission communication confirms EU regulatory framework works for nanomaterials. *CEFIC: The European Chemical Industry Council*. Official webpage. Retrieved November 11, 2012, from http://www.cefic.org

Center of Responsive Politics. (n.d.-a). Chemical & related manufacturing. *OpenSecrets.org: Center for Responsive Politics*. Official webpage. Retrieved December 25, 2012, from http://www.opensecrets.org

Center of Responsive Politics. (n.d.-b). Top interest groups giving to members of congress, 2012 cycle. *OpenSecrets.org: Center for Responsive Politics*. Official webpage. Retrieved December 27, 2012, from http://www.opensecrets.org

Commission of the European Communities. (2001, July 25). European governance: A white paper. Retrieved September 10, 2012, from http://eur-lex.europa.eu

Commission of the European Communities. (2008, June 17). Communication from the Commission to the European Parliament, the Council, and the European and Social Committee: Regulatory aspects of nanomaterials. Commission of the European Communities. Retrieved October 27, 2011, from http://ec.europa.eu

Council. (2011, March 29). Conciliation on novel foods failed. Council of the European Union.

Daemmrich, A., & Krücken, G. (2000). Risk versus risk: Decision-making dilemmas of

drug regulation in the United States and Germany. *Science as Culture*, *9*(4), 505–534.

Danish Board of Technology. (1996). *The non assessed chemicals in EU: Report and recommendations from an interdisciplinary group of Danish experts*. Danish Board of Technology.

Davies, C. Developments in nanotechnology (2006). Washington DC.

Davies, C. (2007). *EPA and nanotechnology: Oversight for the 21st Century*. Woodrow Wilson Center for Scholars, Project for Emerging Technologies.

Davies, C. (2008). *Nanotechnology oversight: An agenda for the next administration*. Woodrow Wilson Center for Scholars, Project for Emerging Technologies.

Davies, C. Revisiting the Toxic Substances Control Act of 1976 (2009). Washington DC.

Davies, C. (2009b). *Oversight of Next Generation Nanotechnology*. Woodrow Wilson Center for Scholars, Project for Emerging Technologies.

Decaillon, J. (2009, April 2). *ETUC resolution on nanotechnologies and nanomaterials*. Presented at the Working and Living with Nanotechnologies. Retrieved November 15, 2011, from http://www.nanocap.eu

Delmas, M., & Terlaak, A. (2002). Regulatory commitment to negotiated agreements: Evidence from the United States, Germany, the Netherlands, and France. *Journal of Comparative Policy Analysis*, *4*(1), 5–29.

Denison, R. (2007a). *Comments on EPA's "concept paper for the nanoscale materials stewardship program under TSCA" and "TSCA inventory status of nanoscale substances - General approach," in response to the US Environmental Protection Agency's request for comments published in the federal register on 12 Jul. 2007 (72 FR 38083)*. Environmental Defense Fund.

Denison, R. Research on environmental and safety impacts of nanotechnology: Current

status of planning and implementation under the National Nanotechnology Initiative (2007).

Denison, R. (2008a, May 27). EPA nano authority under TSCA, part 2: "New" isn't necessarily all that better. *Chemicals & Nanomaterials*. Retrieved July 5, 2009, from http://blogs.edf.org/nanotechnology

Denison, R. (2008b, June 27). EPA nano authority under TSCA, part 3: Can EPA track "existing" nanomaterials? *Chemicals & Nanomaterials*. Retrieved July 5, 2009, from http://blogs.edf.org/nanotechnology

Denison, R. (2008c, July 1). EPA nano authority under TSCA, part 4: Can EPA get industry data on "existing" nanomaterials? *Chemicals & Nanomaterials*. Retrieved July 5, 2009, from http://blogs.edf.org/nanotechnology

Denison, R. (2008d, July 2). EPA nano authority under TSCA, part 5: Can EPA regulate "existing" nanomaterials? *Chemicals & Nanomaterials*. Retrieved July 5, 2009, from http://blogs.edf.org/nanotechnology

Denison, R. (2008e, July 28). Fixing TSCA for nano: Don't forget all the other chemicals! *Chemicals & Nanomaterials*. Retrieved July 5, 2009, from http://blogs.edf.org/nanotechnology

Denison, R. Revisiting the Toxic Substances Control Act of 1976 (2009). Washington DC.

Denison, R. H.R. 5820, the Toxic Chemicals Safety Act of 2010 (2010).

DG Enterprise and Industry. (n.d.-a). Thematic studies for review of REACH 2012 - Chemicals - Enterprise and Industry. *European Commission: Enterprise and Industry*. Official webpage. Retrieved November 11, 2012, from http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/

DG Enterprise and Industry. (n.d.-b). Contributions to the public consultation on REACH

- Chemicals - Enterprise and Industry. *European Commission: Enterprise and Industry.* Retrieved June 1, 2012, from http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/archives/consultation/contributions/index

Dinan, D. (2005). *Ever closer union: An introduction to European integration*. Hampshire, UK: Palgrave MacMillan.

Dooley, C. Revisiting the Toxic Substances Control Act of 1976 (2009). Washington DC.

Dooley, C. H.R. 5820 - The Toxic Chemicals Safety Act of 2010 (2010). Washington DC.

Doreen Fedrigo, & Rye Senjen. (2010). *Shaping innovation: Policy approaches on innovation governance: issue 4*. EEB. Retrieved September 20, 2012, from http://www.eeb.org

Dreher, K. L. (2004). Health and environmental impact of nanotechnology: Toxicological assessment of manufactured nanoparticles. *Toxicological. Sciences.*, *77*(1), 3–5.

Drori, G. S. (2003). *Science in the modern world polity: Institutionalization and globalization*. Stanford, CA: Stanford University Press.

Drori, G. S., & Meyer, J. W. (2006). Global scientization: An environment for expanded organization. In G. Drori, J. Meyer, & H. Hwang (Eds.), *Globalization and organization: World society and organizational change*. Oxford, UK: Oxford University Press.

Duprez, L. (2011, October 18). Nano definition too narrow says EEB - EEB. *European Environment Bureau*. Press Release. Retrieved November 8, 2012, from http://www.eeb.org/index.cfm

Duvall, M., & Wyatt, A. (2011). *Regulation of nanotechnology and nanomaterials at EPA and around the world: Recent developments and context*. Washington DC: Beveridge & Diamond, P.C.

EC DG Enterprise. (n.d.). REACH and nanomaterials - Chemicals - Enterprise and Industry. *European Commission*. Retrieved November 7, 2012, from http://ec.europa.eu/enterprise/sectors/chemicals/reach/nanomaterials/index

EC DG Environment. (n.d.). Consultation - Environment - European Commission. Retrieved November 9, 2012, from http://ec.europa.eu/environment/consultations/newprg.htm

ECHA. (2010). *Evaluation under REACH* (Progress Report). European Chemical Agency. Retrieved May 8, 2012, from http://echa.europa.eu

ECHA. (n.d.-a). Guidance on REACH and CLP implementation - ECHA. *ECHA: European Chemicals Agency*. Retrieved November 7, 2012, from http://echa.europa.eu

ECHA. (n.d.-b). Candidate list table - ECHA. *ECHA: European Chemicals Agency*. Retrieved November 7, 2012, from http://echa.europa.eu

ECHA. (n.d.-c). Committee for socio-economic analysis - ECHA. *ECHA: European Chemicals Agency*. Retrieved November 13, 2012, from http://echa.europa.eu

EDF. (2007). Environmental Defense's activities on nanotechnology. Environmental Defense Fund.

EDF. (n.d.). Home: Environmental Defense Fund. *Environmental Defense Fund.* Retrieved September 17, 2012, from http://www.edf.org/

EEA. (1998). *Chemicals in the European environment: Low doses, high stakes?* The European Environment Agency.

EEB. (2009). *EEB position paper on nanotechnologies annd nanomaterials: Small scale, big promises, divisive messages*.

EEB. (n.d.). Welcome to the European Environmental Bureau - EEB. *European Environment Bureau*. Official webpage. Retrieved November 21, 2012, from

http://www.eeb.org/

EEB, ETUC, CIEL, ClientEarth, WECF, BEUC, ANEC. (2012, October 23). Stakeholders' Response to the Communication on the Second Regulatory Review on Nanomaterials. Retrieved September 21, 2012, from http://www.eeb.org/

Einsiedel, E. F., & Goldenberg, L. (2004). Dwarfing the social? Nanotechnology lessons from the biotechnology front. *Bulletin of Science, Technology & Society*, *24*(1), 28–33.

Einsiedel, E., Jelsøe, E., & Breck, T. (2001). Publics at the technology table: The consensus conference in Denmark, Canada, and Australia. *Public Understanding of Science*, *10*(1), 83–98.

EPA. (n.d.-a). Science Advisory Board (SAB) and the SAB staff office. *EPA: United States Environmental Protection Agency*. Official webpage. Retrieved November 13, 2012, from http://www.epa.gov/aboutepa/sab.html

EPA. (n.d.-b). Office of congressional and intergovernmental relations (OCIR). *EPA: United States Environmental Protection Agency*. Official webpage. Retrieved November 13, 2012, from http://www.epa.gov/aboutepa/ocir.html

Epstien, S. (2007). Patient groups and health movements. In E. J. Hackett, O. Amsterdamska, M. Lynch, J. Wajcman, & W. Bijker (Eds.), *The handbook of science and technology studies* (third edition.). Cambridge, MA: The MIT Press.

ETC Group. (2003). *The big down: Atomtech - technologies converging at the nano-scale*. ETC Group.

ETUC. (2008, June 24). ETUC resolution on nanotechnologies and nanomaterials. *ETUC.* Retrieved May 18, 2012, from http://www.etuc.org

ETUC. (2010, December 1). ETUC 2nd resolution on nanotechnologies and nanomaterials. *ETUC*. Retrieved May 18, 2012, from http://www.etuc.org

ETUC. (n.d.). ETUC concept of a regulatory definition of a substance in the nanoform. European Trade Union Confederation.

European Commission. (2001). *White Paper: Strategy for a future Chemicals Policy*. Brussels: Commission of the European Communities.

European Commission. (2002). Science and society action plan. European Communities. Retrieved March 13, 2012, from http://www.cordis.lu

European Commission. (2004). *Towards a European strategy for nanotechnology*. Brussels: European Commission

European Commission. (2007). *FP7: Tomorrow's answers start today*. Brussels: European Commission.

European Commission. (2008, December 15). Follow-up to the 6th meeting of the REACH competent authorities for the implementation of regulation (EC) 1907/2006 (REACH).

European Commission. (2009). *Nanosciences and nanotechnologies: An action plan for Europe 2005-2009. Second implementation report 2007-2009. COM(2009)607* (Communication from the Commission to the Council, the European Parliament, and the European Economic and Social Committee). Brussels: European Commission.

European Commission. (2011). Commission recommendation of 18 October 2011 on the definition of nanomaterial. *Official Journal of the European Union*, (275).

European Commission. (2012). *Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee: Second regulatory review on nanomaterials*. Brussels: European Commission.

European Commission. (n.d.-a). EUROPA - Register of Expert Groups and Other Similar Entities - Group Details Commission Expert Group. Retrieved April 10, 2012,

from http://ec.europa.eu

European Commission. (n.d.-b). *Initial IA screening & planning of further work* (Roadmap Communication on regulatory aspects of nanomaterials - Progress report). European Commission.

European Commission DG Environment. (2007). *Reach in brief*. Brussels: European Commission.

European Parliament. (2008). *Draft report on the proposal for a regulation of the European Parliament and of the Council on novel foods and amending regulation (EC) No XXX/XXXX [common procedure] (COM(2007)0872 – C6-0027/2008 – 2008/0002(COD))* (Draft Report). Brussels: European Parliament: Committee on the Environment, Public Health and Food Safety.

European Parliament. (2009). *Report on the regulatory aspects of nanomaterials: (2008/2208(INI))*. Brussels: European Parliament.

European Parliament. (n.d.). European Parliament. Official webpage. Retrieved November 8, 2012, from http://www.europarl.europa.eu/portal/en

European Parliament, & Council. (2008). Regulation (EC) No 1333/2008 of the European Parliament and the Council of 16 December 2008 on food additives. *Official Journal of the European Union*, (354), 16–33.

European Parliament, & Council. (2009). Regulation (EC) No 1223/2009 of the European Parliament and the Council of 30 November 2009 on Cosmetic Products. *Official Journal of the European Union*, (342), 59–209.

European Parliament, & Council. (2012). Directive 2012/19/EU of the UEropean Parliament and the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE). *Official Journal of the European Union*, (197), 38–71.

EWG. (n.d.). EWG Home. *Environmental Working Group.* Retrieved September 17,

2012, from http://www.ewg.org/

Falkner, R., Breggin, L., Jaspers, N., Pendergrass, J., & Porter, R. (2009). *Consumer labelling of nanomaterials in the EU and US: Convergence or divergence?* London, UK: Chatman House.

Falkner, R., Breggin, L., Jaspers, N., Pendergrass, J., & Porter, R. (2010). International coordination and cooperation: the next agenda in nanomaterials regulation. In G. Hodge, D. Bowman, & A. Maynard (Eds.), *International handbook on regulating nanotechnologies*. Cheltenham, UK: Edward Elgar Publishing Limited.

Falkner, Robert, & Jaspers, N. (2012). Regulating nanotechnologies: Risk, uncertainty and the global governance gap. *Global Environmental Politics*, *12*(1), 30–55.

FDA. (n.d.). 2007 FDA nanotechnology report outlines scientific, regulatory challenges. *FDA: U.S. Food and Drug Administration*. Retrieved November 13, 2012, from http://www.fda.gov

Ferin, J., & Oberdörster, G. (1992). Translocation of particles from pulmonary alveoli into the interstitium. *Journal of Aerosol Medicine*, *5*(3), 179–187.

Ferin, J., Oberdörster, G., Penney, D., Soderholm, S., Gelein, R., & Piper, H. (1990). Increased pulmonary toxicity of ultrafine particles. Particle clearance, translocation, morphology. *Journal of Aerosol Science*, *21*(3), 381–384.

Filipponi, L. (n.d.). Applications of nanotechnology: Catalysis. NanoCap. Retrieved February 15, 2011, from http://www.nanocap.eu

Filipponi, L., & Sutherland, D. (2007a, November). Nanotechnology - A brief introduction. NanoCap. Retrieved February 15, 2012, from http://www.nanocap.eu

Filipponi, L., & Sutherland, D. (2007b, November). Applications of nanotechnology: Energy. Part 1: Solar energy and energy aaving. NanoCap. Retrieved February 16,

2012, from http://www.nanocap.eu

Filipponi, L., & Sutherland, D. (2007c, November). Applications of nanotechnology: energy. Part 2: Hydrogen conversion and energy storage. NanoCap. Retrieved February 16, 2012, from http://www.nanocap.eu

Filipponi, L., & Sutherland, D. (2007d, November). Applications of nanotechnology: Environment. NanoCap. Retrieved February 16, 2012, from http://www.nanocap.eu

Filipponi, L., & Sutherland, D. (2007e, November). Applications of nanotechnology: Medicine. Part 1: Diagnosis and imaging. NanoCap. Retrieved February 18, 2012, from http://www.nanocap.eu

Filipponi, L., & Sutherland, D. (2007f, November). Applications of nanotechnology: Medicine. Part 2: Treatment. NanoCap. Retrieved February 18, 2012, from http://www.nanocap.eu

FoE. (2008). *Out of the laboratory and onto our plates: Nanotechnology in food and agriculture*. Friends of the Earth.

FoE. (n.d.-a). Nanosunscreens threaten your health. *Friends of the Earth.* Retrieved June 19, 2010, from http://www.foe.org

FoE. (n.d.-b). Friends of the Earth. *Friends of the Earth.* Retrieved September 17, 2012, from http://www.foe.org

Fraser, N. (1996). *Justice interruptus: Critical reflections on the "postsocialist" condition* (First Edition.). New York, NY: Routledge.

Frickel, S. (2008). On missing New Orleans: Lost knowledge and knowledge gaps in an urban hazardscape. *Environmental History*, *13*(4), 643–650.

Frickel, Scott. (2004). *Chemical consequences: Environmental mutagens, scientist activism, and the rise of genetic toxicology*. Newark, NJ: Rutgers University

Press.

Frickel, Scott, Gibbon, S., Howard, J., Kempner, J., Ottinger, G., & Hess, D. J. (2010). Undone science: Charting social movement and civil society challenges to research agenda setting. *Science, Technology & Human Values*, *35*(4), 444–473.

Gaude, A. (2006, October 13). BUND warnt vor Waschmaschine mit Nanopartikeln - BUND für Umwelt und Naturschutz Deutschland. *BUND.* Retrieved June 20, 2012, from http://www.bund.net

Georgia Miller. (2006). *Nanomaterials, sunscreens and cosmetics: Small ingredients, big risks*. FoE.

Gillespie, B., Eva, D., & Johnston, R. (1979). Carcinogenic risk assessment in the United States and Great Britain: The case of aldrin/dieldrin. *Social Studies of Science*, *9*(3), 265–301.

Greenpeace. (1997). *Genetic engineering: Too good to go wrong?* Retrieved March, 13 2012, from http://archive.greenpeace.org

Greenpeace. (1999). *An alternative, precautionary approach to the regulation of the manufacturing, marketing and use of chemicals in Europe*. Greenpeace.

Guston, D. (2011). Participating despite questions: Toward a more confident participatory technology assessment. *Science and Engineering Ethics*, *17*(4), 691–697.

Guston, D. H., & Sarewitz, D. (2002). Real-time technology assessment. *Technology in Society*, *24*(1–2), 93–109.

Habermas, J. R. (1991). *The structural transformation of the public sphere: An inquiry into a category of bourgois society*. Cambridge, MA: MIT Press.

Hagendijk, R., & Irwin, A. (2006). Public deliberation and governance: Engaging with science and technology in contemporary Europe. *Minerva*, *44*(2), 167–184.

Hagendijk, R., & Kallerud, E. (2003). Changing conceptions and practices of governance

in science and technology in Europe: A framework for analysis. In *STAGE (Science, Technology and Governance in Europe) Discussion Paper 2*. Presented at the European STAGE network.

Hallstrom, L. K. (2004). Eurocratising enlargement? EU elites and NGO participation in European environmental policy. *Environmental Politics*, *13*(1), 175–193.

Halperin, A. (2010, February 25). Obama's EPA poised to crack down on nanotech. *New Haven Independent*. Retrieved February 9, 2013, from http://www.newhavenindependent.org

Hamlett, P., Cobb, M. D., & Guston, D. H. (2013). National citizens' technology forum: nanotechnologies and human enhancement. In S. A. Hays, J. S. Robert, C. A. Miller, & I. Bennett (Eds.), *Nanotechnology, the brain, and the future* (pp. 265–283). Dordrecht, The Netherlands: Springer.

Hankin, S. M., Peters, S. A. K., Poland, C. A., Foss Hansen, S., Holmqvist, J., Ross, B. L., Aitken, R. J. (2011). *Specific advice on fulfilling information requirements for nanomaterials under REACH (RIP-oN 2)* (Final Project Report). NIA, SAFE NANO, CEFIC.

Hanson, N., Harris, J., Joseph, L., Ramakrishnan, K., & Thompson, T. (2011). *EPA needs to manage nanomaterial risks more effectively* (No. 12-P-0162). Washington DC: US EPA.

Harper, K. (2004). The genius of a nation versus the gene‐tech of a nation: Science, identity, and genetically modified food in Hungary. *Science as Culture*, *13*(4), 471–492.

Helfferich, B., & Kolb, F. (2001). Multilever action coordination in European contentious politics: The case of the European women's lobby. In D. Imig & S. Tarrow (Eds.), *Contentious Europeans*. Rowman & Littlefield Publishers.

Herbst, S. (2002). How state-level policy managers "read" public opinion. In J. Manza, L. Cook, & B. Page (Eds.), *Navigating public opinion: Polls, policy, and the future of American democracy* (pp. 171–183). New York, NY: Oxford University Press.

Hess, D., Breyman, S., Campbell, N., & Martin, B. (2008). Science, technology, and social movements. In E. Hackett (ed.), *The handbook of science and technology studies*. Cambridge, MA: MIT Press.

Hess, D. J. (2007). *Alternative pathways in sience and industry: Activism, innovation, and the environment in an era of globalization*. Cambridge, MA: MIT Press.

Hess, D. J. (2009). Localist movements in a global economy: Sustainability, justice, and urban development in the United States. Cambridge, MA: MIT Press.

Hess, D. J. (2010). Environmental reform organizations and undone science in the United States: Exploring the environmental, health, and safety implications of nanotechnology. *Science as Culture*, *19*(2), 181–214.

Hess, D. J. (2011). To tell the truth: On scientific counterpublics. *Public Understanding of Science*, *20*(5), 627–641.

Hess, D. J. (2012). *Good green jobs in a global economy: Making and keeping new industries in the United States*. Cambridge, MA: MIT Press.

Hodge, G. A., Bowman, D., & Ludlow, K. (Eds.). (2007). *New global frontiers in regulation: The age of nanotechnology*. Cheltenham, UK: Edward Elgar Publishing.

Hontelez, J. (2009, April 2). *Positions and perspectives of environmental NGOs nanotechnologies and nanomaterials*. Presented at the Working and Living with Nanotechnologies. Retrieved September 29, 2010, from http://www.nanocap.eu

Horst, M., & Irwin, A. (2010). Nations at ease with radical knowledge on consensus, consensusing and false consensusness. *Social Studies of Science*, *40*(1), 105–126.

Hoskyns, C. (1991). The European women's lobby. *Feminist Review*, *38*(1), 67–70.

Huff, J. (2002). IARC monographs, industry influence, and upgrading, downgrading and under grading chemicals. *International Journal of Occupational and Environmental Health*, *8*(3), 249–355.

Huff, James. (2007). Industry influence on occupational and environmental public health. *International Journal of Occupational and Environmental Health*, *13*(1), 107–117.

Hullmann, A. (2006). *The economic development of nanotechnology - An indicators based analysis*. European Commission, DG Research.

ICTA. (2006, May 16). Citizen petition to the United States Food and Drug Administration. The International Center for Technology Assessment. Retrieved September 17, 2012, from http://www.icta.org/

ICTA. (2007). *Principles for the oversight of nanotechnologies and Nanomaterials*. Washington DC.

ICTA. (2008, May 1). Citizen petition for rulemaking to the United States Environmental Protection Agency. International Center for Technology Assessment. Retrieved September 17, 2012, from http://www.icta.org/

ICTA. (2011, December 21). Consumer safety groups file first lawsuit on risks of nanotechnology. International Center for Technology Assessment. Retrieved September 17, 2012, from http://www.icta.org/

ICTA. (2012, April 23). Brief of amici curiae. International Center for Technology Assessment, Center for Food Safety, Friends of the Earth, Beyond Pesticides, center for Environmental Health, Institute for Agriculture and Trade Pollicy in Support of Petitioners Seeking Review. Center for Food Safety.Retrieved September 17, 2012, from http://www.icta.org/

ICTA. (n.d.). International Center for Technology Assessment. Retrieved September 17, 2012, from http://www.icta.org/

Imig, D., & Tarrow, S. (2001). *Contentious Europeans*. Lanham, MD: Rowman & Littlefield Publishers.

International Center for Technology Assessment and Friends of the Earth (ICTA–FoE). (2007, July 12). Joint ICTA-FoE "Comments on EPA's "concept paper for nanoscale materials stewardship program (NMSP) under TSCA" and 'TSCA inventory status of nanoscale substances—General approach. International Center for Technology Assessment and Friends of the Earth (ICTA–FoE).

Irwin, A. (1995). *Citizen science: A study of people, expertise and sustainable development*. London, UK: Routledge.

Jacobson, H. K. (2000). International institutions and system transformation. *Annual Review of Political Science*, *3*(1), 149–166.

Jamison, A. (2001). *The making of green knowledge: Environmental Politics and Cultural Transformation* (1st ed.). Cambridge, MA: Cambridge University Press.

Jamison, A. (2006). Social movements and science: Cultural appropriations of cognitive praxis. *Science as Culture*, *15*(1), 45–59.

Jasanoff, S. (1986). *Risk management and political culture: A comparative study of science in the policy context*. New York, NY: Russell Sage Foundation.

Jasanoff, S. (1997). Product, process, or programme: three cultures and the regulation of biotechnology. In M. Bauer (Ed.), *Resistance to new technology: Nuclear power, information technology and biotechnology*. Cambridge, MA: Cambridge University Press.

Jasanoff, S. (2007). *Designs on nature: science and democracy in Europe and the United States*. Princeton, NJ: Princeton University Press.

Jaspers, N. (2010a). How to avoid international trade conflicts. *European Journal of Risk Regulation*, *2010*, 167.

Jaspers, N. (2010b). Nanomaterial safety: The regulators' dilemma. *European Journal of Risk Regulation*, *2010*, 270.

Joint Research Center. (2011). *REACH implementation project substance identification of Nanomaterials (RIP-oN 1)* (Advisory Report). Brussels: European Commission.

Joss, S. (2005). Between policy and politics or whatever do weapons of mass destruction have to do with GM crops? The UK's GM nation public debate as an example of participatory governance. In S. Maasen & P. Weingart (Eds.), *Democratization of expertise?: Exploring novel forms of scientific advice in political decision-making*. Dordrecht, The Netherlands: Springer Science & Business.

Kearnes, M., Grove-White, R., Macnaghten, P., Wilsdon, J., & Wynne, B. (2006). From bio to nano: Learning lessons from the UK agricultural biotechnology Controversy. *Science as Culture*, *15*(4), 291–307.

Kelman, S. (1981). *Regulating America, regulating Sweden: A comparative study of occupational safety and health policy*. Cambridge, MA: The MIT Press.

Kinchy, A. (2012). *Seeds, science, and struggle: The global politics of transgenic crops*. Cambridge, MA: The MIT Press.

Kinchy, A. J., Kleinman, D. L., & Autry, R. (2008). Against free markets, against science? Regulating the socio-economic effects of biotechnology. *Rural Sociology*, *73*(2), 147–179.

Kleinman, D., & Kinchy, A. (2007). Against the neoliberal steamroller? The biosafety protocol and the social regulation of agricultural biotechnologies. *Agriculture and Human Values*, *24*(2), 195–206.

Kleinman, D. L. (2000). *Science, technology, and democracy*. Albany, NY: SUNY Press.

Kleinman, D. L., & Kinchy, A. J. (2003). Why ban bovine growth hormone? Science, social welfare, and the divergent biotech policy landscapes in Europe and the United States. *Science as Culture*, *12*(3), 375–414.

Kleinman, D., Powell, M., Grice, J., Adrian, J., & Lobes, C. (2007). A toolkit for democratizing science and technology policy: The practical mechanics of organizing a consensus conference. *Bulletin of Science, Technology & Society*, *27*(2), 154–169.

Lamprou, A. (2010). *Nanotechnology regulation: Policies proposed by three organizations for the reform of the Toxic Substances Control Act*. Studies in Sustainability. Chemical Heritage Foundation.

Lautenberg. Safe Chemicals Act., Pub. L. No. S.847 (2011). Retrieved June 4, 2009, from http://www.gpo.gov

Lautenberg, Menendez, Whitehouse, Clinton, & Kerry. Kid-Safe Chemicals Act of 2008., S. 3040 (2008).

Lehmbruch, G., & Schmitter, P. C. (1982). *Patterns of corporatist policy-making*. Thousand Oaks, CA: SAGE Publications.

Levidow, L. (1998). Democratizing technology—or technologizing democracy? Regulating agricultural biotechnology in Europe. *Technology in Society*, *20*(2), 211–226.

Levidow, L. (2005). Governing conflicts over sustainability: Agricultural biotechnology in Europe. In V. Higgins & Geoffrey (Eds.), *Agricultural governance: globalization and the new politics of regulation*. London, UK: Psychology Press.

Levidow, L. (2009). Making Europe unsafe for agbiotech. In P. Atkinson, P. Glasner, & M. Lock (Eds.), *The handbook of genetics and society: Mapping the new genomic era. Genetics and Society*. London, UK: Routledge.

Levidow, L., & Carr, S. (2007). GM crops on trial: Technological development as a real-world experiment. *Futures*, *39*(4), 408–431.

Levidow, L., & Carr, S. (2009). *GM food on trial: Testing European democracy* (1st ed.). London, UK: Routledge.

Levidow, L., Carr, S., & Wield, D. (2005). European Union regulation of agri-biotechnology: Precautionary links between science, expertise and policy. *Science and Public Policy*, *32*(4), 261–276.

Levidow, L., & Marris, C. (2001). Science and governance in Europe: Lessons from the case of agricultural biotechnology. *Science and Public Policy*, *28*(5), 345–360.

Levidow, L., Murphy, J., & Carr, S. (2007). Recasting "substantial equivalence":Transatlantic governance of GM food. *Science, Technology & Human Values*, *32*(1), 26–64.

Los Alamos National Laboratory. (2002, June 25). What is nanotechnology? *Nanotechnology at Los Alamos National Laboratory*. Retrieved December 21, 2012, from http://www.lanl.gov/mst/nano/definition.html

Maasen, S., & Weingart, P. (Eds.). (2005). *Democratization of expertise?: Exploring novel forms of scientific advice in political decision-making*. Dordrecht, The Netherlands: Springer Science & Business.

Majone, G. (1996). *Regulating Europe*. London, UK: Routledge.

Management Board Members - ECHA. (n.d.). *ECHA*. Official webpage. Retrieved November 11, 2012, from http://echa.europa.eu

Manley, J. F. (1983). Neo-pluralism: a class analysis of pluralism I and pluralism II. *The American Political Science Review*, *77*(2), 368–383.

Marchant, G. E., & Sylvester, D. J. (2006). Transnational models for regulation of nanotechnology. *The Journal of Law, Medicine & Ethics*, *34*(4), 714–725.

Maxim, L., & Spangenberg, J. H. (2009). Driving forces of chemical risks for the European biodiversity. *Ecological Economics*, *69*(1), 43–54.

Maynard, A., & Rejeski, D. (2009). Too small to overlook. *Nature*, *460*(7252), 174–174.

McAdam, D., & Su, Y. (2002). The war at home: Antiwar protests and congressional voting, 1965 to 1973. *American Sociological Review*, *67*(5), 696–721.

McFarland, A. S. (2007). Neopluralism. *Annual Review of Political Science*, *10*(1), 45–66.

Mehta, M. D. (2004). From biotechnology to nanotechnology: What can we learn from earlier technologies? *Bulletin of Science, Technology & Society*, *24*(1), 34–39.

Monica, J. (2010, November 1). Chemical regulation overhaul may hit roadblock. *Nanotechnology Law Report*.

Moore, K. (2006). Powered by the people: Scientific authority in participatory science. In S. Frickel & K. Moore (Eds.), *The new political sociology of science: Institutions, networks, and power* (1st ed.). Madison, WI: University of Wisconsin Press.

Moore, K. (2008). *Disrupting science: Social movements, American scientists, and the politics of the military, 1945-1975*. Princeton, NJ: Princeton University Press.

Moore, K., Kleinman, D. L., Hess, D., & Frickel, S. (2011). Science and neoliberal globalization: a political sociological approach. *Theory and Society*, *40*(5), 505–532.

Morris, J. T. (2012). *Risk, language, and power: The nanotechnology environmental policy case*. Lanham, MD: Lexington Books.

NanoCap. (2009). *European conference: Working and living with nanotechnologies. trade union and NGO positions*. Retrieved February 26, 2012, from http://www.nanocap.eu

NANOCAP NanoCap. (n.d.). Retrieved April 11, 2012, from http://www.nanocap.eu

National Science and Technology Council. (2008). *Strategy for nanotechnology-related environmental, health, and safety research*. The National Nanotechnology Initiative.

NNI. (n.d.-a). Nanotechnology timeline. *Nano.gov: National Nanotechnology Initiative*. Official webpage. Retrieved August 7, 2012, from http://www.nano.gov/timeline

NNI. (n.d.-b). Nano.gov: National Nanotechnology Initiative. *Nano.gov: National Nanotechnology Initiative*. Official webpage. Retrieved December 22, 2012, from http://www.nano.gov/

NNI. (n.d.-c). Environmental, health, and safety issues. *Nano.gov: National Nanotechnology Initiative*. Official webpage. Retrieved December 21, 2012, from http://www.nano.gov

NPPTAC. (2005, November 22). Overview document on nanoscale materials. National Pollution Prevention and Toxics Advisory Committee.

NRDC. (n.d.). Natural Resources Defense Council (NRDC) – The earth's best defense. *NRDC.* Retrieved September 17, 2012, from http://www.nrdc.org/

Oberdörster, E. (2004). Manufactured nanomaterials (fullerenes, C60) induce oxidative stress in brain of juvenile largemouth bass. *Environmental Health Perspectives*. *112*(10): 1058-1062.

Oberdorster, G. (1996). Significance of particle parameters in the evaluation of exposure-dose-response relationships of inhaled particles. *Particulate Science and Technology 14*(2), 73–89.

Oberdörster, G., Oberdörster, E., & Oberdörster, J. (2005). Nanotoxicology: an emerging discipline evolving from studies of ultrafine particles. *Environmental Health Perspectives*, *113*(7), 823–839.

Ong, E. K., & Glantz, S. A. (2000). Tobacco industry efforts subverting international

agency for research on cancer's second-hand smoke study. *Lancet*, *355*, 1253–9.

PEN. (n.d.-a). Nanotechnology - Project on Emerging Nanotechnologies (PEN). *PEN.* Retrieved September 17, 2012, from http://www.nanotechproject.org/

PEN. (n.d.-b). Nanotechnology publications from the Project on Emerging Nanotechnologies (PEN). *PEN.* Retrieved April 12, 2012, from http://www.nanotechproject.org/publications/

Perin, C. (2006). *Shouldering risks: The culture of control in the nuclear power industry*. Princeton, NJ: Princeton University Press.

Poland, C. A., Duffin, R., Kinloch, I., Maynard, A., Wallace, W. A. H., Seaton, A., Donaldson, K. (2008). Carbon nanotubes introduced into the abdominal cavity of mice show asbestos-like pathogenicity in a pilot study. *Nature Nanotechnology*, *3*(7), 423–428.

Powell, M., & Keinman, D. L. (2008). Building citizen capacities for participation in nanotechnology decision-making: The democratic virtues of the consensus conference model. *Public Understanding of Science*, *17*(3), 329–348.

Purdue, D. A. (2000). *Anti-genetiX: the emergence of the anti-GM movement*. Ashgate.

Renn, O., & Roco, M. (2006). Nanotechnology and the need for risk governance. *Journal of Nanoparticle Research*, *8*(2), 153–191.

Rip, A. (2005, January 13). *Technology assessment as part of the co-evolution of nanotechnology and society: the thrust of the TA Program in nanoned*. Presented at the Nanotechnology in Science, Economy and Society, Marburg. Retrieved October 17, 2012, from http://www.nanoandsociety.org

Rip, A. (2008). Nanoscience and nanotechnologies: Bridging gaps through constructive technology assessment. In G. H. Hadorn, H. Hoffmann-Riem, S. Biber-Klemm, W. Grossenbacher-Mansuy, D. Joye, C. Pohl, E. Zemp (Eds.), *Handbook of*

transdisciplinary research (pp. 145–157). Dordrecht, The Netherlands: Springer.

Rip, A., & Kulve, H. (2008). Constructive technology assessment and socio-technical scenarios. In E. Fisher, C. Selin, & J. M. Wetmore (Eds.), *The yearbook of nanotechnology in society, volume I: Presenting futures* (pp. 49–70). Dordrecht, The Netherlands: Springer.

Rizzuto, P. (2012, March 26). Unions, other groups say new use rules for nanotubes lack necessary protections. *Bloomberg BNA Daily Environment Report*.

Roco, M. C., Harthorn, B., Guston, D., & Shapira, P. (2011). Innovative and responsible governance of nanotechnology for societal development. In M., Roco, C., Chad, & M.,Hersam (Eds.), *Nanotechnology research directions for societal needs in 2020* (pp. 561–617). Dordrecht, The Netherlands: Springer.

Rogers-Hayden, T., & Pidgeon, N. (2007). Moving engagement "upstream"? Nanotechnologies and the Royal Society and Royal Academy of Engineering's inquiry. *Public Understanding of Science*, *16*(3), 345–364.

Rootes, C. A. (1999). The transformation of environmental activism: Activists, organizations and policy‐making. *Innovation: The European Journal of Social Science Research*, *12*(2), 155–173.

Rucht, D. (2001). Lobbying or protest? Strategies to influence EU environmental policies. In D. Imig & S. Tarrow (Eds.), *Contentious Europeans*. Lanham, MD: Rowman & Littlefield Publishers.

Ruzza, C. (2007). Frame bridging and the new politics of persuasion, advocacy and influence. In J. Fairbrass & A. Warleigh (Eds.), *Influence and interests in the European Union*. Oxford, UK: Taylor & Francis.

Rye Senjen. (2009a). *Challenges and opportunities to green nanotechnologies: Issue 1*. EEB. Retrieved March 12, 2012, from http://www.eeb.org

Rye Senjen. (2009b). *Nanomaterials - health and environmental concerns: Issue 2*. EEB. Retrieved March 12, 2012, from http://www.eeb.org

Rye Senjen. (2009c). *A critical review of governance issues in Europe and elsewhere: Issue 3*. EEB. Retrieved March 12, 2012, from http://www.eeb.org

Sanchez, V. C., Pietruska, J. R., Miselis, N. R., Hurt, R. H., & Kane, A. B. (2009). Biopersistence and potential adverse health impacts of fibrous nanomaterials: what have we learned from asbestos? *Wiley Interdisciplinary Reviews: Nanomedicine and Nanobiotechnology*, *1*(5), 511–529.

Sandler, R., & Kay, W. D. (2006). The GMO-nanotech (dis)analogy? *Bulletin of Science, Technology & Society*, *26*(1), 57–62.

Sarewitz, D. (1996). *Frontiers of illusion: Science, technology, and the politics of progress*. Philadelphia, PA: Temple University Press.

Sarewitz, D., & Guston, D. (2004). *Real-time assessment of nanotechnology: Theory, practice, prospects*. Presented at the Nanotechnology in Science, Economy, and Society, Marburg, Germany. Retrieved November, 12, 2012, from http://cgi-host.uni-marburg.de

Sass, J. (2007). *Nanotechnology's invisible threat: Small science, big consequences*. NRDC.

Sass, J. (n.d.). NRDC files lawsuit blocking untested nanosilver pesticide from clothing. *Jennifer Sass's Blog*. Retrieved April, 19, 2012 from http://switchboard.nrdc.org/blogs/jsass

Schot, J., & Rip, A. (1997). The past and future of constructive technology assessment. *Technological Forecasting and Social Change*, *54*(2–3), 251–268.

Sclove, R. (1995). *Democracy and technology*. New York: NY: Guilford Press.

Selin, C. (2011). Negotiating plausibility: intervening in the future of nanotechnology.

Science and Engineering Ethics, *17*(4), 723–737.

Selin, H. (2007). Coalition politics and chemicals management in a regulatory ambitious Europe. *Global Environmental Politics*, *7*(3), 63–93.

Senjen, R., & Illuminato, I. (2009). *Nano and biocidal silver: Extreme germ killers present a growing threat to public health*. FoE Australia and United States.

Singhofen, A. (2011, March 25). *REACH 2012 review: to REACH or not to REACH*. Presented at the ERA Conference on REACH in practice, Brussels.

Smith, R. (1995). Interest group influence in the US Congress. *Legislative Studies Quarterly*, *20*(1), 89–139.

Soule, S. A., McAdam, D., McCarthy, J., & Su, Y. (1999). Protest events: cause or consequence of state action? The US women's movement and federal Congressional activities, 1956-1979. *Mobilization: An International Quarterly*, *4*(2), 239–256.

Spires, S. (2010, December). Chemical & Related Manufacturing: Background. *OpenSecrets.org: Center for Responsive Politics*. Retrieved December 25, 2012, from http://www.opensecrets.org

Tesh, S. N. (2000). *Uncertain hazards* (1st ed.). Ithaca, NY: Cornell University Press.

The Royal Society. (2004). *Nanoscience and nanotechnologies: opportunities and uncertainties*. The Royal Society. Retrieved December, 10, 2010, from http://www.nanotec.org.uk

Toke, D. (2004). *The politics of GM food: a comparative study of the UK, USA, and EU*. London, UK: Psychology Press.

Tony Musu. (n.d.). *REACH, sufficient for nanomaterials?* Retrieved April 18, 2012, from http://www.nanocap.eu

Toumey, C., Reynalds, J. R., & Aggegelopoulou, A. (2006). Dialogue on nanotech: The

south Carolina citizens' school of nanotechnology. *Journal of Business Chemistry*, *3*(3), 3–8.

United States Congress. (2012, December 14). In *Wikipedia, the Free Encyclopedia*. Retrieved August 18, 2012, from http://en.wikipedia.org

US EPA. (2005). Instruction manual for reporting under the TSCA new chemical program (PMN). Retrieved from www.epa.gov

US EPA. (2008a). Summary of the Toxic Substances Control Act. Retrieved from www.epa.gov/lawsregs/laws/tsca.html

US EPA. (2008b, January 23). TSCA Inventory status of nanoscale substances-General approach.

US EPA. (2012a). *Nanomaterial case study: Nanoscale silver in disinfectant spray* (No. EPA/600/R-10/081F). National Center for Environmental Assessment Office of Research and Development US Environmental Protection Agency.

US EPA. (2012b, July 9). EPA opens the registration review docket for nanosilver. *US Environmental Protection Agency: About Pesticides*. Official webpage. Retrieved December 8, 2012, from http://www.epa.gov

US EPA. (n.d.-a). Consent orders and significant new use rules (SNURS). *New Chemicals Program US EPA*. Retrieved November 7, 2012, from http://www.epa.gov/oppt/newchems/pubs/cnosnurs.htm

US EPA. (n.d.-b). New chemicals program. *US Environmental Protection Agency: New Chemicals*. Official webpage. Retrieved December 8, 2012, from http://www.epa.gov/oppt/newchems/

US EPA. (n.d.-c). Nanoscale materials stewardship program. *US Environmental Protection Agency*. Official webpage. Retrieved December 14, 2012, from http://epa.gov/oppt/nano/stewardship.htm

US EPA. (n.d.-d). Control of nanoscale materials under the Toxic Substances Control Act. *US Environmental Protection Agency*. Official webpage. Retrieved December 14, 2012, from http://www.epa.gov/oppt/nano/

US EPA OPPT. (2009). *Nanoscale materials stewardship program* (Interim Report).

US FDA. (2011, June). Guidances considering whether an FDA-regulated product involves the application of nanotechnology. Retrieved September 17, 2012, from http://www.fda.gov

US FDA. (2012, April). Food ingredients and packaging draft guidance for industry: Assessing the effects of significant manufacturing process changes, including emerging technologies, on the safety and regulatory status of food ingredients and food contact substances, including food ingredients that are color additives. Retrieved September 17, 2012, from http://www.fda.gov

Van Oudheusden, M. (2011). Questioning "participation": A critical appraisal of its conceptualization in a flemish participatory technology assessment. *Science and Engineering Ethics*, *17*(4), 673–690.

Vogel, D. (1986). *National styles of regulation: Environmental policy in Great Britain and the United States*. Ithaca, NY: Cornell University Press.

Ward, S., & Lowe, P. (1998). National environmental groups and Europeanization: A survey of the British environmental lobby. *Environmental Politics*, *7*(4), 155–165.

Williams, E. S., Panko, J., & Paustenbach, D. J. (2009). The European Union's REACH regulation: a review of its history and requirements. *Critical reviews in toxicology*, *39*(7), 553–575.

Wilson, G. K. (1985). *The politics of safety and health: Occupational safety and health in the United States and Britain*. Oxford, UK: Oxford University Press.

Wilson, J. Q. (1995). *Political organizations*. Princeton, MJ: Princeton University Press.

Wynne, B. (1996). Misunderstood misunderstandings: social identities and public uptake of science. In A. Irwin & B. Wynne (Eds.), *Misunderstanding science?: The public reconstruction of science and technology*. Cambridge, MA: Cambridge University Press.

Wynne, B. (2002). Risk and environment as legitimatory discourses of technology: Reflexivity inside out? *Current Sociology*, *50*(3), 459–477.

Wynne, B. (2005). Risk as globalizing "democratic" discourse? Framing subjects and citizens. In M. Leach, I. Scoons, & B. Wynne (Eds.), *Science and citizens: globalization and the challenge of engagement*. London, UK: Zed Books.

Yearley, S. (1992). Green ambivalence about science: Legal-rational authority and the scientific legitimation of a social movement. *The British Journal of Sociology*, *43*(4), 511–532.