Norwegian University of Life Sciences
Department of International
Environment and Development Studies,
Noragric

Master Thesis 2015
60 credits

The regulation of bisphenol A in Denmark and Norway: How the problem of chemical safety is framed and addressed amidst scientific uncertainty.

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To my family

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Frequently used abbreviations

BPA	Bisphenol A
Danish EPA	Danish Environmental Protection Agency
DTU-Food	Technical University of Denmark, National Food Institute
DVFA	Danish Veterinary and Food Administration
ED	Endocrine disruptor
EFSA	European Food Safety Authority
EU RAR	European Union Risk Assessment Report
FCM	Food contact materials
FHI	Norwegian Institute of Public Health (Folkehelseinstituttet)
GLP	Good Laboratory Practice
Klif	Climate and Pollution agency (Klima- og forurensningsdirektoratet), predecessor to NEA
NEA	Norwegian Environment Agency (Miljødirektoratet)
NFSA	Norwegian Food Safety Authority (Mattilsynet)
NOAEL	No Observed Adverse Effect Level
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SFT	Norwegian Pollution Control Authority (Statens forurensningstilsyn), predecessor to NEA
TDI	Tolerable Daily Intake
VKM	Norwegian Scientific Committee for Food Safety (Vitenskapskomiteen for mattrygghet)

1. Introduction

Governments worldwide have regulated the production and use of specific chemicals since the beginning of the 20th century. In regulating chemicals, policy makers and regulators have attempted to balance between two conflicting interests, namely maintaining a socially acceptable level of environmental and human health protection while harvesting all the benefits of modern chemistry. Traditionally, science has been the instrument that has shaped our perception and advanced our understanding of environmental threats, and as a consequence, it has also played a vital role in the mediation between environmental risks and policy making. This has led to very specific modes of "chemical governance" that are intimately linked to a history of techno-scientific practices and questions of knowledge production.

The purpose of this thesis is to analyze and compare the regulation of a chemical known as bisphenol A (BPA) in Denmark and Norway. BPA is a widely used ingredient in modern plastics with countless commercial applications such as food packaging, toys and water pipes. Around 4 million tons are produced worldwide each year which makes BPA one of the highest production volume chemicals in the world. It has been found that it migrates from plastic under normal conditions of use and such leaching is believed to be the main source of human exposure. Survey programs worldwide have confirmed that this chemical is widespread in the general population, at remarkably higher concentrations in young children. BPA can act like a synthetic estrogen in living organisms and numerous studies have reported endocrine disrupting effects linked to neurobehavioral problems, cancer onset, diabetes, obesity, cardiovascular disease, ailment of reproductive organs and their functions (EEA, 2013; Vandenberg, Hauser, Marcus, Olea, & Welshons, 2007).

Several health risk assessments of BPA have been conducted in the last decade by different regulatory authorities and expert groups in Europe and internationally. In all cases, the potential adverse health effects of BPA have been identified and evaluated, and in many cases, exposure levels have also been calculated in order to draw conclusions about possible health risks at current levels of exposure. The conclusions on whether or not BPA poses a risk to human health vary greatly between assessments - even among those were the scientific evidence was identical (Beronius, Ruden, Hakansson, & Hanberg, 2010; EEA, 2013).

After 15 years of intense scientific research, there is no consensus on how big is the health risk posed by BPA under current levels of exposure. It is a heated debate where high scientific, political and economic stakes are at work. The risk assessment of BPA has divided scientists, industry and regulatory agencies. One side attempts to undermine the studies claiming a negative effect on health and the other side argues that those same studies represent enough evidence to question the safety of BPA. The division in opinion has resulted in different countries' regulatory agencies deciding on different risk-management strategies for BPA.

In Europe, it is the European Food Safety Authority (EFSA) who has had the main role in assessing BPA's risk for the European Union. In 2006, this agency concluded that under current conditions of usage, BPA was safe and in 2008, 2010 and 2011, it has reaffirmed that initial opinion. However, continuing discrepancies among member states and scientists have forced the agency to conduct a complete re-evaluation of the safety of this chemical. The new assessment has tried to address previous criticisms and has made an effort to address the remaining uncertainties. After three years of work, the agency concluded in January 2015 that the dietary exposure to the chemical was safe (EFSA, 2015d). At the national level, Denmark was the first European country to ban the use of BPA in baby bottles and food containers for children under the age of three in April 2010 based on the precautionary principle. Danish Parliament members have followed BPA's case very actively and in February 2015, Danish experts were asked to evaluate EFSA's latest assessment. The latter concluded that EFSA's recommendation was not sufficiently protective for highly exposed individuals (DTU-Food, 2015c). In Norway the discussion about the safety of BPA has mainly taken place at the agency level - where the Norwegian food and health authorities strictly adhere to EFSA's recommendation even when this goes against (national environmental objectives) and the recommendations of the Norwegian Environment Agency.

1.1 What is bisphenol A?

The exploration of the commercial uses of the synthetic chemical bisphenol A (BPA) dates back to 1934, when a group of British scientists - working on the production of synthetic hormones for pharmaceutical purposes - identified its estrogenic properties (Dodds & Lawson, 1936). Failing to make a career as a drug, BPA instead began to be used by the chemical industry in manufacture of plastics in the 1950's. Since then, it has been used as an essential raw material in

the production of polycarbonate plastic and epoxy resins. Today BPA has numerous and very diverse applications and is one of the world's bestselling chemicals with one of the highest volume production rates world-wide and a steady annual increase of consumption (EEA, 2013).

It is recognized that under regular conditions of use, BPA can leach in very small amounts from its plastic applications. Consumers are thought to be primarily exposed via food in contact with BPA, such as drinks and foodstuff stored in metallic cans and plastic containers made out of polycarbonate . However, during the last years, it has been shown that other types of exposure can also contribute to the total exposure (EFSA, 2015). The regulation of this chemical has mainly fallen under the jurisdiction of food and environmental authorities.

1.2 The dose makes the poison

BPA's safety and that of most chemicals in use today has historically been defined according to the assumption that one can always establish a "safe" threshold value of exposure to which a person can be exposed for a lifetime without developing adverse health effects. This basic scientific principle that lies at the heart of our regulatory toxicity testing paradigm, dates back to the sixteenth century statement of Paracelsus "All things are poison and nothing is without poison, only the dose permits something not to be poisonous" (Paracelsus, 1539). However, this central assumption only holds true when the dose-response curve for the chemical under study is monotonic. That is, when the relation between the exposure dose and its corresponding response effect increases with increasing dose until a maximum response is reached. Based on this rationale high doses are expected to produce serious effects and low doses are expected to produce only small or no effects (Vandenberg, Maffini, Sonnenschein, Rubin, & Soto, 2009). These two assumptions, namely the existence of a threshold and a monotonic dose-response curve have important consequences for chemical regulation. Based on those assumptions, regulatory agencies such as EFSA, can derive a health-based guidance value on which to base conclusions regarding safe levels of human exposure[1] (Beronius, 2013).

For regulatory purposes, it is generally recommended that all relevant data should be considered in the risk assessment process. However, toxicological studies conducted in accordance with

[1] The reference standard, also known as tolerable daily intake (TDI) for BPA it has been set by EFSA and is of 50 μg/kg body weight/day (EFSA 2006, 2008, 2010) and 4 μg/kg body weight/day (EFSA, 2015)

standardized and internationally validated test guidelines such as The Organization for Economic Co-operation and Development (OECD) test guidelines and Good Laboratory Practices (GLP) are usually given extra weight during risk assessment. Standardized studies are considered to be reliable by default as they comply with quality standards for the conduct of protocols and reporting of data. This is thought to promote reliability since experiments can then be easily replicated if needed (Molander, 2015).

1.3 Endocrine disruption and Low-dose theory

The accidental re-discovery of BPA as a *hormonally-active* substance in 1993 came to challenge the long-held validity of the basic assumptions of toxicology. That year, a team of endocrinologists at Stanford University discovered that BPA leaching from the plastic equipment used in their laboratory was responsible for altering the results of their hormone-sensitive experiments (Krishnan, Stathis, Permuth, Tokes, & Feldman, 1993). Promptly after that, BPA became one of the most debated chemicals in the field of endocrine disruption

Unlike the typical regulatory toxicity tests, the endocrine approach investigates the effects of exposure to very small levels of endocrine disruptors that have historically been deemed as "not toxic". The rationale is that the physiological processes depending on hormone action are very efficient and responses usually take place at very low hormone concentrations. So, chemicals that behave like hormones should also be physiologically active at low doses - that not only fall below the reference standard but that also are within the range of what people are regularly exposed to (Vandenberg et al., 2013).

Endocrine scientist use available evidence in this field to show that low doses of BPA can actually be more dangerous than bigger ones, in particular during sensitive periods of exposure such as fetal development. These contra-intuitive findings have been referred to as the "low-dose theory", and studies on low-dose effects have indicated that for some endpoints, the experimental dose-response curve for BPA is rather non-monotonic or u-shaped[2] (F. S. vom Saal & Hughes, 2005). This is to illustrate that effects observed at high concentrations cannot always be used to

[2] Since instead of being linear or monotonic, the dose-response curve resemble an U (when it is said to have an U-shape) or an upside-down U (when it is said to have an inverted U-shaped) depending on which end point is being studied (Vandenberg, 2009).

predict what could happen at intermediate and very low doses. BPA then, as many natural hormones is seen to produce a non-traditional dose-response curve[3] (Vandenberg et al., 2009).

Within the Endocrine Society[4], there is widespread consensus on these results and concepts. Endocrine scientists claim that taken together, the low-dose studies challenge the safety assumptions made by regulatory agencies concerning BPA and call for a new regulatory testing paradigm based on low-dose endocrinology principles (Diamanti-Kandarakis et al., 2009).

Most low-dose studies are non-standard. They are usually carried out at universities and research institutes and their quality control is based on the peer-review mechanism. They usually use sensitive testing approaches to investigate particular endpoints, usually represent cutting-edge areas and are designed to uncover and explore biological mechanism (Myers, vom Saal, et al., 2009). However, in order to be included in health risk assessment they need to be thoroughly evaluated as to their adequacy (reliability and relevance). They are frequently found to have "methodological limitations and being poorly reported" and are thus only seldom used for regulatory purposes (Molander, 2015).

1.4 BPA's scientific controversy

It is of course the widespread use of BPA in commercial products and the fact that it is in contact with food that has stirred much concern on the issue. Measured concentrations of BPA in human urine and blood confirm that exposure is prevalent in the human population (F. S. vom Saal & Hughes, 2005). Public and private money are constantly used to fund new research, making BPA one of the most studied chemicals in the world. In the interim, some countries – like Denmark - have taken precautionary steps and have already enacted total or partial bans for the use of BPA[5] (EEA, 2013). Others, like Norway, keep maintaining that the current exposure to BPA poses no health risk. Not surprisingly, this chemical has received considerable media and public attention over the last twenty years. However, one can say that the debate on exactly how dangerous BPA is; is still unresolved.

[3] It has even been documented that the occurrence of u-shaped dose-response curves is rather frequent.
[4] The largest and most active medical organization in the field of basic and clinical hormone research and treatment of endocrine disorders. It is composed by a large diversity of sub-especialities.
[5] Such as France, Denmark, Sweden, Belgium, Canada and some of the US States.

1.5 BPA regulation

In this thesis it will be shown that the risk assessment of BPA involves uncertainties of many sorts, not all of which can be adequately be accounted for. In contrast to the situation in the laboratory, in real life chemical exposures, there are a multitude of factors that influence the health and environmental outcomes – most of which are beyond control and even identification. These problems are further complicated by: administrative cultures having competing perspectives on the management of chemical risk , the value-laden aspects of risk assessment, the presence of enduring uncertainties and indeterminacies, the politicization of risk, the prevalence of scientific controversies and strong economic interests. I will analyze how the Danish and the Norwegian authorities have dealt with the regulation of BPA.

1.6 Objectives and research questions

Objectives:

First, study the processes that lead Denmark and Norway, which have access to the same scientific information, to different policy outcomes concerning bisphenol A. Second, analyze some of the limitations of the resulting policy outcomes.

Research questions and sub-questions:

1. **How is the bisphenol A problem understood and framed in Denmark and in Norway?**

This question is related to the larger frame of how are the environmental and health problems concerning endocrine disruptors defined in each country. I will argue that this overarching frame has important consequences for how the "risk" of BPA is understood nationally and what is seen as a relevant in the policy process.

2. **What are the processes in each country, that lead to different outcomes in the regulation of bisphenol A?**

Based on the definition of the problem, I will identify the political and administrative processes, and describe how they have been played out in each country. Which processes took place in each country? Who was involved in those processes? How were the decisions taken?

3. **How is scientific uncertainty addressed in each policy solution?**

This is based on the realization that different policy solutions address scientific uncertainties in different ways. I will analyze the policy process in light of ideal models of science-policy interactions and I will point to possible limitations in the way the uncertainties have been treated.

1.7 Structure of the thesis

Chapter 2 and chapter 3 will address the theoretical framework for the analysis of BPA's case study and the methodological approach, respectively. Chapter 4 will present the necessary technical background to be able to understand the bisphenol A debate and I will summarize the main health risk assessments that have taken place in the European Union.

The analysis will be presented in chapters 5-8 and will be divided in two sections – one analyzing the case in Denmark (chapters 5 and 6) and the other analyzing the case in Norway (chapters 7 and 8). The analysis will be chronological and will present the main arguments and actors involved in each case. Chapters 5 and 7 will deal with the problem definition in Denmark and in Norway respectively, while chapters 6 and 8 will present the development of the BPA case in each country and how the particular policy decisions were taken.

The discussion and conclusion will be in chapter 9, where I will summarize the main points of the thesis and review the research questions.

2. Theoretical framework

The traditional way of dealing with chemical decision-making is that, in a first step, scientists are assigned the task of evaluating the possible risk of a given substance under fairly defined circumstances[6] and of giving advice to policy-makers. In a second step, it is the political responsibility of policy-makers to sort out the diverse values and preferences at stake and decide whether the risk is acceptable or not. At the national level, policy-making usually takes place at the ministry level and this work is closely related to the advice given by the corresponding regulatory agencies. The ministries and the agencies are usually the main authorities when it comes to chemical regulation. These actors, in particular agency staff, depend on institutional thinking and practice to sort out, in a predictable way, which preferences and values should guide policy. But final policy outcomes also rely on more than professional (and scientific) advice and institutional thinking – chemical policy-making is increasingly dependent on its broader socio-political context. This is composed of a wide variety of institutions and individuals that interact in several ways to influence problem framing and policy decisions to different extents and at different levels. Such interaction can take place at the national, the European and, to some extent, at the international level. Moreover, we see that current environmental and health issues are increasingly complex and uncertain. This not only challenges the traditional ways of evaluating chemical risk, but at the same time it affects decisions about policy. The latter is due to the fact that different actors disagree on how uncertainty should be dealt with in decision-making. The current debate concerning the safety of BPA illustrates all the above mentioned points. In order to analyze how this chemical is regulated differently in Denmark and in Norway, I will be looking at three different dimensions:

- Institutional aspects: how the different regulatory agencies (and their associated ministries and scientific committees) understand and deal with chemical safety, based on their different administrative cultures.
- The broader socio-political context and risk governance: how the problem is defined, whether actors participating in policy-decisions disagree or collaborate, and how European policy context and broader political decisions influence the debate.

[6] For example, when a substance is present in the diet, or, when workers are exposed as a result of their professional activities, or, when a substance is released into the environment, and so on.

- Complexity and scientific uncertainty at the science-policy interphase – examining the strengths and limitations of current practices and possible alternatives.

In order to examine these dimensions, I will use, respectively, concepts from the literature on institutional theory, on governance and on post-normal science.

I will argue that these three dimensions are in constant communication during a policy decision and that, in order to understand a policy outcome, we need to look at all three simultaneously.

2.1 Institutional theory

2.1.1 Institutions and rules of appropriate behavior

The definition of an institution varies to some extent within and across the different social sciences. However, I propose Vatn's (2005) broad definition as a starting point in order to explain the reasons behind the existence of institutions, and to show which type of situations or problems that institutions attempt to solve.

"Institutions are the conventions, norms and formally sanctioned rules of a society. They provide expectations, stability and meaning essential to human existence and coordination. Institutions regularize life, support values and produce and protect interests" (Vatn, 2005, p. 60).

From this definition, we see that institutions can take the form of conventions, norms and sanctioned rules depending on which type of human problem they are related to. *Conventions* relate to the cognitive dimension of institutions. They tell us how something is to be done by combining specific situations with specific solutions. *Norms* and *formally sanctioned rules* relate to the normative dimension of institutions. They tell us what the appropriate or right behavior is.

The second part of Vatn's definition illustrates the different motivations behind the existence of institutions: institutions help us to understand what kind of situation we are in and to classify relevant behavior. They simplify complexity and create a common framework for action. And most importantly, institutions convey meaning since they are created to produce and protect

particular values and interests. This is significant in policy-making, where the conflict often concerns whose interests should be protected or given weight.

I will furthermore argue that institutions are not only embedded in structures of meaning, but also in structures of resources. This refers to the material and human resources that different institutional settings can mobilize for regulatory purposes. Resources can be financial means, staff competence, or benefits from a specific way of organizing resources. Available resources are important in ultimately defining what is doable. In this respect, the definition of an institution by March and Olsen (2008) complements Vatn's broader definition:

"An institution is a relatively stable collection of rules and practices, embedded in structures of resources that make action possible – organizational, financial and staff capabilities, and structures of meaning that explain and justify behavior – roles, identities and belongings, common purposes, and causal and normative beliefs" (March & Olsen, 2008, p. 2).

Finally I want to introduce the concept of the 'logic of appropriateness' also developed by March and Olsen (2008) to illustrate how policy-making is intimately dependent on its institutional setting.

"The logic of appropriateness is a perspective on how human action is to be interpreted. Action, policy making included, is seen as driven by rules of appropriate or exemplary behavior, organized into institutions. The appropriateness of rules includes both cognitive and normative components. Rules are followed because they are seen as natural, rightful, expected, and legitimate. Actors seek to fulfill the obligation encapsulated in a role, an identity, a membership in a political community or group, and the ethos, practices, and expectations of its institutions. Embedded in a social collectivity, they do what they see as appropriate for themselves in a specific type of situation" (March & Olsen, 2008, p. 1)

According to the logic of appropriateness, decision-making is based on a socialization process where agents (e.g. policy-makers) follow rules of appropriate behavior that depend on the association of a particular identity to a specific situation. Rules of appropriateness are based, for

example, on specific ways of processing information, best practices, key interpretative traditions and previous experience. Those institutionalized rules facilitate interpretation of ambiguous situations and prescribe what the appropriate thing to do is. "To act appropriately is to proceed according to the institutionalized practices of a collectivity, based on mutual and tacit understandings of that is true, reasonable, natural, right and good" (March & Olsen, 2008, p. 2).

It follows that legitimate, stable and well-defined institutions, can provide clear prescriptions (structure of meaning) and adequate resources (structure of resources) that allow individuals to follow appropriate and doable action in an unambiguous way[7].

2.1.2 Implications for BPA policy-making

The institutionalist view thus encompasses the idea that behavior depends on institutions. *Action*, policy-making included, is then more often based on identifying the appropriate "institutional" behavior rather than on calculating the return, or consequences, expected from alternative choices. From this perspective, meaning, values and what is considered appropriate, will depend upon the given institutional setting (March & Olsen, 1989).

When it comes to chemical policy-making, the legislation is usually divided between several segments, or sectors, of the public administration, where each part belongs to a defined institutional setting. For example, we have the environmental authorities dealing with chemicals in products and emissions to the environment, the food authorities dealing with chemicals in food contact materials and contamination, the work authorities dealing with chemical exposure in the working environment, and so on. I will argue that each of these defined institutional settings have developed their own *administrative culture* and follow their own rules of appropriate behavior when regulating chemicals. By this I mean that each public agency[8] has a common understanding and definition of the problem at hand, a common tradition for evaluating and interpreting scientific evidence, a common way of dealing with scientific uncertainty and a common set of

[7] In March and Olsen's definition, the fact that a rule of action is defined as appropriate, does not guarantee its moral acceptability. It can neither be assumed that rules always dictate or guide behaviors. They just make some actions more likely than others (March & Olsen, 2008)

[8] I mainly refer to public agencies since they are going to be the key actors in my analysis. However, we will see that the same administrative culture might also be shared with the relevant ministry and/or the scientific institutions in charge of regulating a particular sector.

acceptable solutions. Alongside this cognitive dimension, there is also a common normative standpoint that relates to shared goals and values.

Each actor (in this case, administrative culture) develops their own rules of appropriateness based on the harmonization of their cognitive and normative dimensions[9]. Those institutional rules will define what is true, reasonable, good and right concerning chemical regulation and will provide clear prescriptions to policy-makers. Whereas the available resources make action possible or restrain it, it is these particular institutional settings that facilitate interpretation of ambiguous worlds and help maintain consistency in the pattern of action (March & Olsen, 2008).

Such an institutionalization of knowledge, meaning and procedures might give the impression that public agencies are self-contained structures. However, as we will see in the next section on governance, we must also see a little further than individual administrative cultures and rules of appropriate behavior (i.e. individual actors and procedures) to fully explain policy-making. During the development of a specific policy, regulators have to relate to even larger institutionalized processes such as for example: national regulatory priorities, compliance with detailed legal frameworks, outcomes of superior political processes at the national and international level. But, most importantly, regulators must interact with several other actors (e.g. economic, political and civil society actors) that contribute with different perspectives to the same problem. Exposure to different actors and processes influence the context and the premises in which decisions are taken.

2.2 The governance of risk

I shall use the concept of *governance* as an angle to describe the totality of different actors, objectives and forms of interaction that are involved in policy-making. And even narrower, I look at *risk governance*, since this delimitation is naturally determined by the field of chemical legislation.

[9] The specific cognitive dimension in policy-making is then *how the problem is perceived*, whereas the normative is what is thought to be the best solution for society.

The term governance can have a variety of meanings, however I will base my analysis on an understanding of governance as "steering" (Vatn, 2015, p. 133).[10] This notion of governance encompasses the multitude of structures and processes which lead to collectively binding decisions. By structures one can understand both the different actor constellations (e.g. experts, administrators, politicians, NGOs) and decision-making procedures (e.g. risk assessments, parliamentary debates). And, by processes, it refers to broader activities such as defining regulatory objectives, framing policy problems and possible solutions and, particularly, coordinating action among actors (Vatn, 2015).

2.2.1 Risk governance: a descriptive and a normative concept

In its *descriptive* dimension, risk governance can be seen as the "[…] increasingly multilayered and diversified socio-political landscape in which a multitude of actors, their perceptions and evaluations draw on a diversity of knowledge and evidence claims, value commitments and political interests in order to influence processes of risk analysis, decision-making, and risk management [...]" (Renn, Klinke, & van Asselt, 2011, p. 231).

The multitude of actors refers here as well to the classical governmental actors such as: public agencies, ministries, politicians and to non-governmental actors such as NGOs, industry, experts, consumers, and think tanks - each of which contribute with their particular knowledge and values to the policy process. I will argue that these actors interact in various formal and informal ways that can lead to the establishment of: joint projects, common forums, alliances, collaborations, deliberative and learning exercises, and many more. Authority, power and the capacity to act will be distributed, at varying degrees, among the different actors and networks. Together, these actors and processes will influence how risks are perceived, defined, evaluated, communicated and ultimately managed.

Amidst this complex web of actors and processes, the concept of risk governance also calls for the consideration of contextual factors, such as for example: the distribution of responsibilities

[10] There seems to be a baseline understanding that governance mainly refers to changing governing styles that blur the traditional boundaries between government and non-government actors - in particular referring to a decreased authoritative role of the State (Stoker, 1998). In Vatn's (2015) definition it is recognized that there is an element of authority involved.

among actors, the legal framework, the economical context, the political culture, and many more: Risk governance "[…] requires consideration of the legal, institutional, social and economic contexts in which risk is evaluated, as well as consideration of the interests and perspectives of different actors and stakeholders."(Hermans, Fox, & van Asselt, 2012, p. 1094)

We can see that there are many similarities between Vatn's (2015) definition of governance (used mainly in the environmental field) and that used by risk scholars such as van Asselt, et al. (2011, 2012), in particular in relation to their analytical and descriptive dimensions. Yet the main contribution of risk governance for my analysis lies in its *normative* dimension. In this respect, a prominent feature of risk governance is the recognition that uncertain, complex and ambiguous risks should not be dealt with in the same way as we usually deal with simple risks[11]. A failure to do so could lead to severe problems for a policy, such as: loss of legitimacy, lengthy controversies and policy deadlock. Risk scholar Ulrich Beck (1992) has even introduced a term for those cases in which risk is inadequately addressed or managed, this has been called "organized irresponsibility". To address this problem, the risk governance perspective encourages the development of more inclusive and deliberative governance models to deal with non-simple risks (those that are uncertain, complex and/or ambiguous), in order to foster robust policy decisions (Hermans et al., 2012; Renn et al., 2011)

2.2.2 Implications for BPA governance

The current debate on endocrine disrupting chemicals regulation is characterized by a tension of stability and change. On the one hand there are those who desire regulatory stability (both in terms of how risk is defined and acted upon). I will argue that they are most often incarnated by the industry and by institutionalized thinking within bureaucracy and public administration. On

11 Simple risks refer to situations where knowledge of the nature of the risk and its likelihood are well understood (Renn et al., 2011). Classical examples include: traffic accidents, routine pathogens, seasonal flooding. In these cases usually the causes are well understood, uncertainty is low and the interpretation of the risk is not ambiguous. Complexity refers to "the difficulty of identifying and quantifying causal links between a multitude of potential candidates and specific adverse effects" (Renn et al., 2011, p. 234). Scientific uncertainty refers to "the limitedness or even absence of scientific knowledge (data, information) that makes it difficult to exactly assess the probability and possible outcomes of undesired effects" (Renn et al., 2011, p. 234). Ambiguity refers to situations when "there are different legitimate viewpoints from which to evaluate whether there are or could be adverse effects and whether these risks are tolerable or even acceptable"(Renn et al., 2011, p. 235)

the other there are often academics, organizations of interests or to some degree politicians that call for a change. I will argue that this tension can only be captured, in all its extent, when we look at policy decisions from a governance perspective, and not only at single actors or institutions. The governance perspective serves particularly well to highlight certain features of the processes involved in policy-making: 1) Chemicals are used in almost all material production in today's society. Hence, chemical policy-making is a field that spans over many sectors, each of which has its own understanding of risk and stable regulatory traditions. 2) Chemical policy is also dependent on very specific legal frameworks, international trade obligations and broader political processes. 3) We see that an increasing number of non-governmental actors are willing to participate in chemical decision making, such as: influential experts, NGOs, industry and consumers.

The governance perspective offers the possibility to capture, integrate and analyze the contribution of all these multiple processes and divergent perspectives. Likewise, in its more normative dimension, it also helps to assess whether or not policy outcomes are socially robust, and whether or not risks have been dealt with in an adequate and responsible manner. This implicit aspect of governance will be further explored in the next section, on how uncertainty and complexity are handled in the science-policy interface.

2.3 Conceptual models of the interface between science and policy – *complexity and uncertainty in policy-making*

In order to analyze how complexity and uncertainty are dealt with during policy decisions, I will make use of theoretical models of science-policy interaction.

These ideal[12] models are inspired on the work of Funtowicz and Strand (2007) whose research has stressed some of the problems of current practices in the interface between science and policy of complex and uncertain environmental and health issues. There is in fact a growing literature calling for a rethinking of our current use of science for policy (Funtowicz & Ravetz, 1993; Funtowicz & Strand, 2007; Renn et al., 2011; Stirling, 2013; Wynne, 2014). What is common to

[12] Here used in the Weberian sense, as a theoretical model – not as it is played out in reality or in practical politics ("realpolitik").

this literature is a call to develop alternative science-policy interfaces, in which uncertainty and complexity are fully acknowledged and science consciously democratized.

2.3.1 The modern model

The modern model is based on the idea that science produces objective, valid and reliable knowledge that can inform policy. It is assumed that science gives – or can give – perfect knowledge and can determine correct policy. Under this technocratic view, the most important thing for good policy-making is to get the scientific facts right.[13] It is usually referred as Science "speaking truth to power", where the power exercised is assumed to be effective and legitimate since it is based on unambiguous facts (Funtowicz, 2006; Funtowicz & Strand, 2007).

Funtowicz and Strand (2007) note there is much more at stake in the formulation of the modern model than the call for an efficient policy-making strategy. In particular, Funtowicz (2006) highlights that this model implicitly assumes that "there are no limits to the progress of our control over our environment, and no limits to the material and moral progress of human kind" (Funtowicz, 2006, p. 139).[14]

The modern model has been very successful in managing simple risks (those that are no complex and uncertain). However, it meets its limitations when exposed to complex environmental and health problems because uncertainties cannot be controlled (quantified) or reduced, complexities abound and experts disagree. In the following I will present four additional models which have

[13] There are several accounts of what a technocratic model is. For example, Millstone's (2004) description of a technocratic model is one in which regulatory decisions about risk are exclusively based on scientific judgements. Under these premises policy decision-making is a unidirectional linear process where scientific experts inform policy-makers. For Millstone (2004), a technocratic perspective is one that does not include other "legitimate factors" in the policy process (these factors are only included in a subsequent model known as the decisionist model) (Millstone, van Zwanenberg, Marris, Levidow, & Torgersen, 2004). However, the technocratic perspective on policy-making that is presented in the modern model is one in which: "to develop a policy is a matter of becoming informed by science and then, in a second step, sorting out values and preferences in order to formulate the correct and rational policy." (Funtowicz & Strand, 2007, p. 5)

[14] Funtowicz and Strand (2007) also argue that the central idea of the modern model is that of mutual legitimation: where the decisions of the modern state are justified and legitimized by the use of the privileged status of scientific rationality. And, at the same time, the institutions of modern science are continuously acclaimed and supported by the modern state - to the extent that they have achieved an influential and dominant position as official knowledge producers. These scholars conclude that: "The modern model has played a crucial part in the legitimation and consolidation of science, governance and political institutions in modern societies. It has also worked at a deeper cultural level in the modern state, securing the belief in the Enlightenment, progress and the superiority of the secular, Western scientific-economic rationality expressed quantitatively." (Funtowicz & Strand, 2007, p. 5).

been developed as an attempt to answer respectively to the limitations of the modern model: inconclusive information, possible conflicts of interests in scientific advice (abuse of science), diverging scientific advice (there is indeterminacy, multiple framing) and all of the above.

2.3.2 The precautionary model

The main idea of the precautionary model is that in case of scientific "imperfection", policy-decisions can be complemented with precaution. This model can be seen as a reaction to the uncertain and inconclusive scientific evidence that more and more often seem to characterize the science-policy interface of many complex risk issues. In many such cases, a call for more research does not ultimately resolve uncertainty. All on the contrary, uncertainties can increase over time due to unforeseen complexities of the systems studied (van der Sluijs, 2005). The basic normative spirit of precaution is that "where there are threats to human health or environment, scientific uncertainty is not a reason for inaction" (Stirling, 2013, p. 1).

In the policy context, we are however more familiar with two more pragmatic and influential accounts of precaution. Namely that of the Rio Declaration and that of the EU communication on the precautionary principle: "Lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation" (UN, 1992, p. 1). On the same line, the EU legal version of the precautionary principle demands, among other things: proportionality between the measures taken and the chosen level of protection and the examination of the benefits and costs of action or lack of action[15] (EC, 2000). What is common to these two versions is their strong emphasis on cost-effectiveness and on the proportionality between costs and benefits. This has led some critics to imply that these versions of the precautionary principle are not more than an extended cost-benefit analysis. For Funtowicz and Strand (2007), for example, these versions are based on the idea that one can ultimately calculate the truth and the good. This is due to the fact that precaution is framed and expressed in terms of *certain* quantitative science and the economic rationality of objective cost-benefit analysis.

[15] For full details please consult the EU communication on the precautionary principle at http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52000DC0001

All things included, the precautionary model still makes a decisive difference when compared to a technocratic position. However, the model meets its limits when confronted with unquantifiable uncertainty of the type 'Can we be precautious and ban a well-studied, problematic chemical when we know it is going to be substituted by much less studied substances that might turn out to be as risky?', since in these cases it is clear that we cannot weight known costs (of prohibition) against unknown benefits.

2.3.3 The demarcation model

The main idea of the demarcation model is that of a clear separation between facts (the domain of science) and values (the domain of politics).

This model can be seen as an attempt to protect science from political interference and thus from the possibility of abuse of science (Funtowicz & Strand, 2007). It can be argued that this model has its origins in the aftermath of the Bovine Spongiform Encephalopathy (BSE) crisis (or mad cow disease crisis) in the late 1990s. As a result to this crisis, the level of public trust in both food safety and food safety institutions in Europe was seriously compromised. The BSE crisis revealed that powerful economic and political interests had been advanced at the expense of consumer protection and that scientific committees had been operating under political pressure (Vos, 2000). After this case, many European food safety institutions were subjected to review and reform in order to restore public confidence in expert advice and in European risk management. The main feature of the reform was the strict separation of risk assessment and risk management activities and responsibilities[16].

Risk assessment is the scientific activity in charge of evaluating the existence of a risk and assessing the likelihood and magnitude of specific effects under specified conditions of exposure. This scientific process should be understood as independent of the broader socio-political context. In this way, the resulting scientific advice is assumed to be based on facts and to give objective and neutral evidence to policy-making (Millstone et al., 2004).

[16] This division of responsibilities was also codified in the "General Food Law" (European Parliament and Council Regulation 178/2002). http://ec.europa.eu/food/safety/general_food_law/principles/index_en.htm

Risk management is an activity in charge of the discussion of values. Risk managers are in charge of evaluating and incorporating other legitimate factors into policy decisions – which might include social, economic, cultural, political, moral or ethical concerns. It is here that scientific advice and other concerns are brought together. In particular, risk managers need to judge the social acceptability of the risk in question (and its associated uncertainties) in exchange for some foreseen benefits (social or economic). These trade-offs are understood as value dependent and thus impossible to be decided only based on scientific considerations (Millstone et al., 2004).

The risk assessment/risk management demarcation is seen as a means of "protecting science from the 'political' interference that would threaten its integrity". At the same time, it is also meant "to ensure that political accountability rests with policy makers and is not shifted, inappropriately, to the scientists" (Funtowicz, 2006, p. 140). [17]

Yet, it seems often to be an inherent interlinkage between the scientific and the political aspects of any policy-decision dealing with complex risk (Renn et al., 2011). In these situations, scientific activities can barely be performed in complete isolation and in a political vacuum. In that sense, it can be said that complexity, uncertainty and indeterminacy challenge the possibility of value free science (Funtowicz & Strand, 2007).

2.3.4 The framing model (link with administrative cultures)

The main idea of the framing model is that in case of scientific indeterminacy – that is, when there are conflicting scientific advices – values need to be made explicit and problems need to be co-framed by all involved stakeholders (scientists in this case). This model can be seen as an attempt to solve policy situations where there are different expert groups reaching differing risk assessments conclusions concerning the same problem. That is, this model deals with the problem when science speaks not one, but many conflicting truths to policy (van der Sluijs, 2005).

[17] However, designing the right level of demarcation between science and policy is not easy. Too little separation can compromise the different responsibilities of those dealing with "understanding risk" and those dealing with "acting" on risks. On the other hand, too much separation can render scientific advice insensible to policy needs.

In this model, scientific deliberations are seen as framed within different and divergent sets of assumptions and questions. Such sets of assumptions and questions can be aligned both with the administrative cultures in institutional thinking or even with paradigms in the Kuhnian sense, and have a profound effect on the scope, content and conclusion of risk assessments. Judgmental values – implicit in the framing – are seen as necessary part without which it would be impossible to undertake a risk assessment.[18] However, when a particular framing is not shared among involved stakeholders, the outcome of the risk assessment can be seen as invalid or/and illegitimate. In order to solve this, it is necessary to call for debate and consensus among experts (and ideally also among all involved stakeholders).

Among the variables that depend on the framing of the scientific problem, we have:

- the establishment of the overall policy goal or the intended end-use
- the scope of the assessment: what is to be included and what is outside (vulnerable groups/general population, one source of exposure/several sources of exposure)
- the selection of what is deemed and what is not deemed as an 'adverse effect'
- the selection of who is best suited for evaluating the evidence
- the selection of what counts as relevant evidence
- the selection of methodology to evaluate and interpret the evidence
- the way to deal with uncertainties during the assessment

The main limitation of the framing model is that it assumes that the systems studied are not *complex*. The ideal that consensual and robust science will be able to speak again with one truth to policy is challenged by empirical research on complex risk issues. This research has shown that in the absence of conclusive scientific basis to favor a particular framing over another there will always be several legitimate scientific descriptions of the same problem (van der Sluijs, 2005).

[18] Even the influential Codex Alimentarius' Committee on General Principles has explicitly articulated the importance of such framing in what they refer to as "risk assessment policy". Codex acknowledges that framing assumptions play a decisive role in setting the agendas of scientific deliberations and in explaining why risk assessment conclusions can differ. In order to deal with this, they also encourage the establishment of a consensual framing (Millstone et al., 2004, p. 28).

2.3.5 The model of extended participation

The main idea of the model of extended participation is that working deliberatively in order to cope with uncertainty and complexity. This model can be seen as an alternative model which was developed as a response to the limitations of the other models when facing scientific uncertainty and complexity in policy-issues. It is based on the concepts and the theory of post-normal science.

Post-normal science situations can be defined as those where "facts are uncertain, values are in dispute, stakes are high, and decisions are urgent" (Ravetz, 2005, p. 349). Under these circumstances, scientific truth is not achievable due to the inherent uncertainty, complexity and indeterminacy of the problems.[19] Post-normal science scholars propose that, in these cases, scientific certainty has to be replaced by scientific quality for policy: "to be sure, good scientific work has a product, which should be intended by its makers to correspond to Nature as closely as possible, and also to be public knowledge. But the working judgements of the product are of its quality, and not of its logical truth" (Funtowicz & Ravetz, 1990, p. 30).

In order to assure scientific quality, the model advocates for participatory approaches where open public dialogue can take place. Quantitative scientific evidence should not be the sole provider of relevant knowledge in complex, uncertain policy decisions. Instead, all involved stakeholders – scientists included – should engage in a deliberative process to evaluate the strength and the relevance for policy of a given body of scientific evidence. In this way, the "extended peer community" – which includes a plurality of legitimate perspectives and forms of knowing – can contribute to a democratic decision-making process. The goal of which will be to answer, in a socially robust manner, what the best solution to a given problem is, and which ideally will complement the technical (scientific) answer to the same question (Funtowicz, 2006).

Today the post-normal paradigm is still in an early stage. However, some challenges might be anticipated. Say, if scientific uncertainty becomes so central that we actually forget or undermine how much we already know about the problem at hand (Udovyk, 2014). Who is to be the judge of what is a legitimate form of knowing, and what rationale do we have for saying that some

[19] The name post-normal science is meant to differentiate this kind of science from "normal" science. The latter can be described as science that aims at achieving ultimate truth.

choice is better than the other. There is a danger both of falling into relativism when action is called for, and of the so called "tyranny of the majority" against rightful expertise.

2.3.6 Implications for our case study

Risk assessment of endocrine disrupting chemicals, BPA included, involves uncertainties of many sorts, not all of which can be adequately be accounted for. We cannot, on ethical grounds, perform experiments to test the toxicity of these chemicals in developing fetuses in statistically significant numbers to have a clear verdict on their safety. Neither can we assess the risk of every conceivable combination of chemical cocktails. In contrast to the situation in the laboratory, in real life chemical exposures, there are a multitude of factors that influence the health and environmental outcomes – most of which are beyond control and even identification.

These problems are further complicated by: administrative cultures having competing perspectives concerning the adequate regulatory course of action, the value-laden aspects of risk assessment, the presence of enduring uncertainties and indeterminacies, the politicization of risk, the prevalence of scientific controversies and strong economic interests.

I will use the introduced ideal models to analyze how the Danish and the Norwegian authorities have, in particular, dealt with questions of scientific uncertainty concerning BPA.

As described in this last section, each model comes with their particular underlying assumptions, strengths and limitations, and no single model can be said to offer a universal solution to the challenges ahead. But I hope that by making evident their limitations, some of the technical questions concerning BPA's safety can be opened for public debate and contribute to the ongoing discussion on the future regulation of endocrine disruptors in Europe.

3. Methods

3.1 The choice of method and epistemological reflections

A qualitative method

The objective of this thesis is to analyze the way in which two seemingly similar countries, with similar administrative structures and with access to the same scientific information end up with two different policy processes and consequently two different policy outcomes concerning the same chemical. For this purpose, I have used a qualitative research strategy. This refers to research that is conducted with the aim of understanding and describing social phenomenon (in my case, policy-making) in depth, and from a closer perspective (as opposed to quantitative research which aims at measuring specific aspects of social phenomenon in order to test causal hypothesis or draw general tendencies) (Bryman, 2008). The rationale behind choosing a qualitative approach is due to the nature of the case I study. Precisely because I aim at finding differences of study objects that are apparently alike, it is necessary to analyze the important documents, look at language and meaning and use interviews as a source of entering deeper in to the contexts of understanding in Norway and Denmark.

As my paper is based on a qualitative method, it means, in its most general form, that I have looked for concepts, words and meanings that were related to my research questions. For my third research question on scientific uncertainty, it was more given what I was looking for, and I was gathering information on how different actors used and dealt with scientific uncertainty. At some points such uncertainty had to be unmasked through a deeper analysis – and a thorough scientific understanding of the problems has been necessary, both for my investigations and to present to the reader. For the two first research questions, on the framing and the legislative processes on BPA it was a more formative process, both to define the problem precisely and to know what to look for. Through reading on the subject as a formative process I eventually saw some explanatory models that fitted best with the data. That is to say, I looked for models that could best explain the state of affairs in the contexts of BPA that I was looking at. These are the ones mentioned in the theory-part.

Along with the theoretical approach, I have also looked at language itself as an approach to the texts that I have studied. I think that it would be possible to analyze parts of my problem

formulation – in particular how the problem of BPA is framed – through the concept of discourse. However, both the scope of the thesis, and the fact that Norwegian is not my mother tongue (and even less so Danish), has impeded such an attempt. I believe that it is also difficult to remain consequent to such an approach, if one is to use it as reductive to the omnipresent concept of power, as it is introduced by Foucault. While both concepts of power and language are indeed relevant to my case study, the particular constellation between them is not as interlinked as in a discourse analysis. A fundamental guideline, however, that is also central to discourse analysis, is that language has a pivotal role in the constitution and ordering of how we think about reality. For example, it does matter whether you call something either "miljøgift" (hazardous chemical) or "kjemikalie" (chemical), and it does matter whether a substance is "hormon-forstyrrende" (endocrine disruptor) or "hormon-hermende" (hormone active substance). An important part of my methodological approach is then to look at how language is used, and which conceptualizations set the agenda.

Ontological and epistemological considerations

I take no pride in declaring oaths to particular ontological or epistemological positions, however I will briefly address the issue here, in relevance to uncertainty in science. One could say, along the lines of Kant, that the thing itself we cannot know. We do not have certain knowledge of what the substance that we call bisphenol A is. We know it by detections on animals, human beings and nature, which allows us to bestow certain its characteristics upon it. We know it by how these characteristics are displayed in the laboratory, and we know it by how we talk about it. Our knowledge of BPA is delimited to our specific interest as human beings. BPA is interesting for us to the extent that it is affecting our lives and particular interests. You may call this an instrumentalist view (Okasha, 2002).

We cannot directly observe BPA, we can merely observe detections of it. We are far from knowing the full extent of its interactions with nature and living organisms. Perhaps all the uncertainties that give shape to the case of BPA say something about the scientific enterprise itself. I will argue that scientific uncertainty is pivotal to operationalizing the debate on BPA.

Uncertainty in science is something that we must acknowledge and take in account, both in how we interpret the world, and when we make decisions on how to deal with potentially harmful substances. In such an "instrumentalist" view, our interest in science should be about saving lives

and preventing diseases. Our concern with science should be to reveal the ways in which it is interpreted – whether it is to serve a particular interest or in the lens of certain sociological or ideological structures.

3.2 Research design

Why a case study?

There are several ways of conducting research in the social sciences. I decided to use a so-called case study research design. A case study approach can be used when the aim is to explore in detail the particularities and complexities of a particular case, and possibly to find some explanations that could be relevant for the study of other similar cases (Bryman, 2008). It helps to narrow down a field of study while at the same time, through its detailed and intensive empirical examination, allows for an in-depth understanding of the context of the particular case and how different factors interact. (Baxter & Jack, 2008)

"The case study method allows investigators to retain the holistic and meaningful characteristics of real-life events"(Yin, 2009, p. 4). I have used the case study research design because my aim was to focus on a very specific real-life case, namely the processes surrounding the regulation of BPA and *how they were played out*. One could say that the regulation of BPA is the case, and the Norwegian and Danish situation specify the context for the case. Only by looking at the debates and the documents that formed part in each debate, could I compare the two cases of Denmark and Norway, and answer the question on how the problem of BPA has been framed and addressed. And through having each specific case as delimitation, it was possible case narrow down the scope of scientific uncertainty – by looking more at how it was dealt with in the regulation processes in each case. Such a research design also gave me flexibility to explore my research questions freely and be open for new or unexpected results.

In the literature on case studies it has been noted that there can be different types of cases, such as a *critical*, *unique*, *exemplifying* or *revelatory* (Bryman, 2008, pp. 55-56). While I think that the case of the regulation of BPA is not a clear-cut typical case, it contains some elements of such types. A *critical* case is defined as a theory placed in a certain circumstance to see whether or not it will hold. The interesting dimension of such a typological approach must be to see *why* the theory holds or not. While I did not have a well-developed theory beforehand, other than a sense

that the regulation of BPA was problematic and perhaps insufficient – it can be useful to see my approach as analyzing the conditions under which regulation has been successful or unsuccessful. It can also be said the phenomenon of the BPA case in *unique*, as it has been one of very few chemicals that have been so extensively studied and debated in the last decades. The phenomenon of the BPA-case creates a space in the interplay between scientific and political debates. In this sense it has perhaps an intrinsic interest and opens a problematic field that needs to be addressed. At the same time it can be said to be *examplifying*, in that it – as science advances – addresses the increasingly common situation of having to make regulatory decision in the face of uncertainty. And it could serve to enlighten certain patterns of how such decisions are made.

Why a comparative analysis?

My paper is also a comparative analysis with the goal to investigate the differences in the regulation of BPA in Norway and in Denmark. A comparative analysis is broadly defined as "the research approach in which two or more cases are explicitly contrasted to each other with regards to a specific phenomenon or along a certain dimension, in order to explore parallels and differences among the cases." (Azarian, 2011, p. 113)

The motivation to conduct a comparative study was that there were two different policy outcomes in two countries that otherwise seems to have many things in common when it comes to chemical policy. They both follow the common European chemical legislation and are bounded by the rules of the internal market, they have a similar organization in their public administration with respect to chemical management, they are both countries known for strong environmental and chemical policies, they share a common understanding and collaboration in the chemical field through the work of the Nordic Council of Ministries, they share a common lifestyle and deal with similar public health problems, none of which have a national BPA-industry, to mention some. One big difference is of course their affiliations with the EU – Denmark being a member state, and Norway only as affiliated through the European Economic Area Agreement. However their mediations between the strong-armed EU-regulations and the prospects of a national regulation are much the same.

Another motivation for comparing the two different policy outcomes was the opportunity to reveal the room in which to maneuver, so to say. What different alternatives are there when it comes to policy making, and is it possible to challenge the customary ways of dealing with

chemical risk? "[C]omparative analysis is worthwhile because, by taking into consideration social actions and events belonging to other contexts, it enables us to see better the implicit and often taken-for-granted basis of our own practices and phenomena." (Azarian, 2011, p. 117)

The policy process in each country is, however, distinctive. We might say that in Denmark the process and outcomes were much driven by a political context, whereas in Norway it took place in a technocratic context. Consequently, it is not a point by point analysis – as in Denmark I mainly follow the case in Parliament, and in Norway at the public administration level. However this is in itself one important finding in the comparison, and I have mainly tried to describe them, and understand what made two such different processes possible in the first place. One very important common point is of course that of scientific uncertainty. I have aimed to show how scientific uncertainty was dealt with in each process – also with the objective to point at possible shortcomings of the relevant authorities.

Some of the limitations of conducting a comparative analysis are that there might be relevant variables that affect the final outcomes, which might have not been taken into consideration during the analysis – such as for example, cultural differences in the understanding of risk. Besides, there is also the issue of the "uniqueness in the process". This idea is borrowed from the History field and refers to the difficulty of generalizing outcomes of historical processes (Azarian, 2011). For my case study this means that: even if I would identify some possible factors that can explain the different policy-outcomes in Denmark and Norway (i.e. the different ways of dealing with uncertainty) – this will not necessarily mean that we, if those factors are in place again, can expect the same policy outcome. It is true that a particular policy-outcome is a unique event that depends on many different factors, such as the amount of evidence that is available, the degree of politization of the problem and the level of participation of influential stakeholders, among others. However we could expect some regularity in the policy process itself, that is, that regulatory decisions will take place in a predicted manner – in particular when decisions are taken at the public administration level.

3.3 Data collection

Documents

For this study I have used very diverse types of documents. I have used academic articles on different theoretical perspectives, such as risk theory, post-normal science and institutional theory. I have also used many natural science articles to understand the hallmarks of the explicit scientific debate on BPA. At the same time I also looked at more technical aspects such as scientific opinions and risk assessment reports. And in order to analyze the case in each country I have studied many policy documents – like white papers, parliamentary records, information published in the different websites of the public administration, as well as newspaper articles. For the study of the Norwegian case I also requested several documents from the electronic public records (Offentlig elektronisk postjournal) to reconstruct the policy debate between the agencies. I also participated in different seminars and conferences related to the topic in order to get a better understanding of what was a stake and who were the main actors.

One limitation to fully access the quality of the data, has been language – as Norwegian and Danish are not my first languages. Another limitation is that the scientific field on BPA is at times highly technical.

Given that a big part of the documents were on either Danish or Norwegian, I felt the necessity to check the same information from several sources to make sure that I had understood everything correctly. This was often done through the interviews (see the next section on semi-structured interviews). The same is true for the more technical part of the thesis: the science and the legislation. Most of that information was in English but given that 'toxicology' and 'endocrine science' represent very specialized academic areas, I felt the necessity to check if I had understood the concepts properly. The same was also the case when it comes to the legislation (for example, understanding the chemical legislation REACH).

Semi-structured interviews

The written material was complemented by information obtained through semi-structured interviews. I conducted a total of 10 semi-structured interviews, using the interview guide included in Appendix 1. I decided to conduct semi-structured interviews in order to cover the specific issues that I had identified as relevant, but particularly to be able to compare information. However, I also conducted several unstructured interviews beforehand in order to acquire a better

understanding of the topic and obtain the necessary information to develop my semi-structured questions. This guide contains a list of open-ended questions on the topics that I wanted to explore with my informants (Bryman, 2008). Yet the interviews were rather flexible, and were slightly modified from case to case in order to clarify particular doubts that I had, or to get more in-depth information about something in particular. I was also flexible with the follow-up questions when I received an unexpected answer, or when an interesting topic came up.

Most importantly I used my interviews as a "triangulation" mechanism, that is, as a second method of data collection on the same information, in order to in order to increase the reliability of my findings (in particular due to language constraints and the high technicality of many of the documents). This is also why I have not made that much use of referring explicitly to each interviewee, as they have often contributed more to the background knowledge, than to specific points that stand alone.

The informants were chosen due to their knowledge on the issue that I wanted to explore – such as to explain policy making in the food sector or the environmental sector, and also in order to hear the opinion of some of the main factors and actors intervening in the policy processes.

Quality of the data

During my interviews I sometimes encountered the problem that it was not always possible to get a hold of the most relevant person for the topic (some other times, it was not possible to get an interview at all, in particular at the ministerial and political level). Likewise, within one agency, different staff might have a very specialized expertise, and at times the person interviewed did not always have full control of what happened at the agency's broader level, that is as an actor in an ongoing debate. Or the activities within the public administration are so diverse that the public servants are skeptic to give comments on other fields of activity within the same institution. But the main limitation of the interviews is that in general the informants were 'careful' when talking about BPA, given that it is still a controversial topic. Many informants asked if they could take the interviews together with a colleague, and many others were interested in the final usage

possible of literal citations. In order to make them feel more comfortable, I also offered them anonymity, and this is also a reason why they are not always referred to directly.[20]

In order to more systematically evaluate the quality of the data in qualitative research, the concept of trustworthiness has been advanced (Bryman, 2008). It is composed of four criteria:

a) Credibility, dealing with how credible your findings are: In this respect I would say that the fact that I tried to triangulate all my data ensures a certain credibility.

b) Dependability, referring to the extent to which your findings can be relevant to another time period: Here I would say that my findings are specific to the time when I was studying them. Actually given the actuality of the topic and the many activities going on, many times I was confronted with changing information from one month to another. As scientific research was advancing (as well as EU-level policy processes), the perspectives of the different actors that I was studying were also being modified accordingly.

c) Transferability, dealing with the question of whether your finding can be generalized: Here I would comment, as stated above, that BPA case cannot be really called a typical case and it cannot be assumed that the same policy-outcome would the same for a different endocrine disruptor. However, as I mentioned, I would expect that the policy processes themselves would be similar.

d) Confirmability, dealing with how much the researcher's analysis was influenced by theoretical inclinations or personal values: To this I must answer that it is very hard to study a controversy without taking a stand, in particular when using a theoretical approach. I would claim that already the selection of the theoretical lens that will be used has a normative dimension. I have used theories that are known to be critical to the current state of affairs when dealing with scientific uncertainty, and thereby, I am most likely influenced by those thoughts. However, I have tried as much as possible to remain objective and open in my approach to all arguments. I do believe that the current regulation on BPA is insufficient, but I have tried to account for the arguments and counterarguments for this as thoroughly as I can.

[20] Again, this is often the case with contributions to background knowledge. When specific ideas are formulated I refer to the interviews.

3.4 Data analysis

Data analysis

In order to analyze the data, I have used a so-called issue-centered analysis, so that I could compare the information about a particular ‘issue’ in all documents and interview transcripts. In order to do that I selected an issue relevant to the research question that I was investigating (e.g. how to deal with uncertainty?) and compared the information given on that particular ‘issue’ in the documents. I used the same approach to compare the answers (on the same issue) given by the different informants during the interviews. The objective of such an approach is to gain an overview of the different perspectives on the issue and to find general tendencies (Thagaard, 2009). To operationalize this approach, I used a color coding method. This involves establishing conceptual categories, assigning colors to them, and then going into the texts and transcripts to use those same colors to identify statements or ideas that are related to those concepts (Bryman, 2008). In this way one can identify the specific data that is relevant for the research questions. However one has to be careful when removing the data from its context in order to analyze it.

4. Background

The purpose of this background chapter is to set the stage for some of the major arguments that take places during the debate about the safety of BPA. As I will explain, the debate over the safety of BPA takes place in the context of a larger debate, namely that of the future regulation of endocrine disruptors

4.1 Endocrine disruptors

4.1.1 What are endocrine disruptors?

Endocrine disruptors (EDs), also known as Endocrine Disrupting Chemicals (EDCs), refer to chemicals that are hormonally active. This means that they can interact with the endocrine (hormonal) system in one way or another (Beronius, 2013).

The endocrine system consists of many interacting organs and tissues that talk to each other, and the rest of the body, using complex signaling pathways mediated by hormones.[21] The body's natural hormones can be seen as messengers that carry vital information across the body and between organs and tissues. There are over 50 different hormones in humans, among which estrogens ("female" hormones) and androgens ("male" hormones). The endocrine system is in charge of releasing and suppressing hormones, which serve as signals that control essential body functions, such as: cell differentiation and organ formation during fetal development, metabolic functions, brain and sexual development, reproduction, growth and many other. These represent complex physiological processes that are not completely understood in all cases (Gore et al., 2014; WHO/UNEP, 2013).

EDs include a large variety of compounds. Some are naturally occurring (like phytoestrogens)[22] and a large majority is man-made (such as synthetic chemicals). They are present in many different chemical groups, such as persistent organic pollutants (POPs), metals, pesticides, food additives, cosmetics and personal care products, pharmaceuticals, chemicals in consumer products, building materials and by-products formed during industrial activities and combustion

[21] These are produced by: the pituitary gland, the pineal gland, the hypothalamus, the thyroid, the thymus, the adrenal cortex, the adrenal medulla, the gastrointestinal tract, the testes, the ovaries, the adipose tissue, the pancreas, the kidney, the heart and the skin.

[22] Phytoestrogens are a naturally occurring group of chemicals found in plants that can act like the hormone estrogen, for example soy and alfalfa.

of waste. Exposures are widespread. Humans and wildlife are daily exposed to complex mixtures of EDs through food consumption, breathing in air, and through skin absorption.[23] Developing organisms are additionally exposed to their mother's chemical load via the placenta and when breastfeeding (WHO/UNEP, 2013).

Among the different groups of EDs, persistent organic pollutants (POPs) have received particular regulatory attention. These chemicals are very persistent and can be transported by air and water currents to distant locations. Consequently, they can be broadly dispersed in the environment and many can also build up in the food chain to high levels in top predators, including humans. During the last decade, it has been increasingly recognized that exposures to less persistent and less bioaccumulative, but equally ubiquitous, EDs – such as phthalates and bisphenol A – are also a matter of concern. In particular when exposures take place during sensitive periods (WHO/UNEP, 2013).[24]

A 2013 study by the World Health Organization (WHO) and the United Nations Environment Programme (UNEP) estimated that there are about 800 known or suspected EDs in the consumer market. Yet, it was concluded that this number was likely to represent only "the tip of the iceberg", given that most chemicals in current commercial use have never been tested for hormonal activity. Neither is there a commonly agreed upon definition nor scientific criteria to systematically identify them (WHO/UNEP, 2013).

4.1.2 Why are EDs a human health concern?

Several recent reports and scientific statements have summarized the growing evidence suggesting that exposure to EDs plays – and has played – a significant role in the increase of many hormone-related diseases and disorders in humans over the last few decades. The converging lines of evidence collectively indicate that many of the hormonally-active chemicals that humans are continuously exposed to, contribute in disease causation, progression and susceptibility.[25] For example, studies conducted in laboratory animals show that low-level

[23] Just in food, for example, EDs can be found as natural constituents, pesticides and pharmaceutical residues, environmental pollutants, food additives and chemicals migrating from food packaging. In the air, they can be present as dust, particles and gases.
[24] Phthalates are plasticizers that are added to plastics to make them more flexible and durable. Bisphenol A is a monomer used in the manufacture of polycarbonate plastic and epoxy resins.
[25] It is important to note that the strength of evidence between ED-exposure and the different health effects is not equally strong in all cases. Even if there is strong evidence for causation for some conditions and exposures, it is a

exposures to certain EDs during development can lead to permanent changes in the endocrine system. This toxicological data is supplemented by varying levels of epidemiological evidence that show similar associations between ED-exposures and a variety of endocrine-related diseases in humans. At the same time, the rapid and significant increase in those diseases in human populations, further supports that environmental factors are contributing in disease etiology – since such changes cannot be solely explained by genetic factors (Diamanti-Kandarakis et al., 2009; Gore et al., 2015; WHO/UNEP, 2013).

Among the endocrine-related diseases, it has been reported an increased incidence of hormone-sensitive cancers (e.g. breast, testicular, prostate, thyroid), neurobehavioral disorders associated with thyroid disruption in children, alarming trends in metabolic disorders like obesity and type 2 diabetes, suppression of the immune system, genital malformations in baby boys, earlier onset of puberty in young girls, fertility problems linked to low semen quality and many more (WHO/UNEP, 2013).

challenge to prove causality. On the one hand there is the complexity of the disease etiology across the lifespan – the fact that diseases are multifactorial with several intervening genetic and environmental factors. On the other hand, there is the complexity of the exposures: low-dose, chronic, in mixtures and the fact that exposures usually take place many years before the development of the disease (WHO/UNEP, 2013). For these reasons, it is important to use different lines of evidence simultaneously, such as: biological plausibility, observations in wildlife, effects observed in cell cultures and laboratory animals, human epidemiological studies and information coming from occupational exposures or chemical accidents (Olsson, 2014). For a detailed discussion on the strength of the evidence, see the State of the science of endocrine disrupting chemicals (WHO/UNEP, 2013), State of the art assessment of endocrine disruptors ((Kortenkamp et al., 2012), Endocrine society two position statements (Diamanti-Kandarakis et al., 2009; Gore et al., 2014).

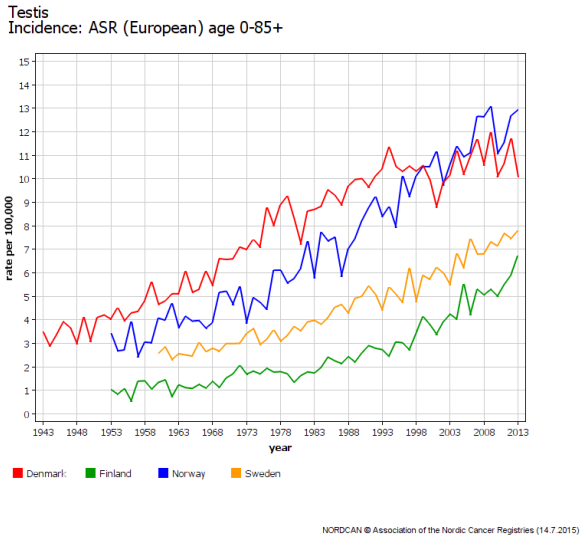

Figure 1: Incidence of testicular cancer in the Nordic Countries[26]. A rise in the incidence of testicular cancer is the most evident of the male reproductive disorders. The incidence of testicular cancer has increased twofold to fourfold over the past 50 years in Denmark.

Moreover, there is a growing concern that exposure to EDs during sensitive periods, such as early childhood, plays a bigger role in the development of endocrine disease than previously anticipated. At the same time, it is commonly young children that have the highest levels of exposure to these chemicals due to their hand-to-mouth activity and higher metabolic rate (Gore et al., 2014).

4.1.3 Call for regulatory action

The mounting concern about the negative effects of EDs on human health and the environment, have motivated diverse calls for regulatory action. On the scientific side, different professional groups – including the Endocrine Society (references), pediatric organizations (Skakkebaek et al., 2011) and the influential update of the WHO/ UNEP (2013) report on Eds – conclude that EDs are a "threat that needs to be solved". On the political side, several NGOs, civil society organizations, governments and even the EU Parliament, are calling to reduce exposures to EDs.

Recent publications have also stressed the opportunity to improve public health and obtain economic benefits by adopting preventive measures. A study released by the Endocrine Society

[26] The graph was made using the software of the Nordic Cancer Registries: Engholm G, Ferlay J, Christensen N, Kejs AMT, Johannesen TB, Khan S, Leinonen M, Milter MC, Ólafsdóttir E, Petersen T, Stenz F, Storm HH. NORDCAN: Cancer Incidence, Mortality, Prevalence and Survival in the Nordic Countries, Version 7.1 (09.07.2015). Association of the Nordic Cancer Registries. Danish Cancer Society. Available from http://www.ancr.nu, accessed on 14/07/2015

in 2015, predicted that exposure to EDs was costing the EU €157 billion per year in health care expenses and lost earning potential (Trasande et al., 2015). While estimations from the Nordic Council of Ministers concluded that the socio-economic costs related only to male reproductive problems linked to ED-exposures could range between €59 million to €1,184 million per year (Olsson, 2014).[27] In both cases the estimations represented only a fraction of the potentially ED-related diseases, which suggests that the real costs might indeed be much higher.

4.2 Legislation of endocrine disruptors in Europe

The European Union has been engaged in policy-related work on EDs since the late 1990s.[28] During the last decade, new chemical regulations have been proposed in Europe, where EDs are specifically identified as problematic compounds that should be subjected to strict authorization processes, or phased out (Stolzenberg et al., 2013). These new pieces of legislation, their economic consequences, together with a growing public concern and the rapidly advancing scientific understanding on endocrine disruption, are at the heart of the ongoing debate concerning the regulation of EDs in Europe.

4.2.1 REACH chemical regulation

In 2007, after intense negotiations and compromises between health and environmental concerns and business interests, the new European chemical legislation REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) entered into force (Fisher, 2008). The intention behind this piece of legislation was to address the general dissatisfaction with the severe lack of safety information of the vast majority of chemicals in the European market,[29] and also to reverse the historical burden of proof in the regulation of chemicals. Namely, that chemical

[27] The costs included: cost of treatment, absence to work, loss of life years and life quality. They were estimated on the assumption that ED-exposures constituted either 2%, 20% or 40% of the total cost, corresponding to €59 million, €592 million and €1,184 million per year respectively (Olsson, 2014)

[28] The EU strategy on EDs dates back to 1999. It focuses on research, international cooperation, public information and political action. The strategy started with the establishment of a list of EDs (documented and suspected), development of test methods and criteria for the identification of substances as EDs, with the objective to – in the long run – cover EDs in the different pieces of chemical legislation in the EU, such as the plant protection products regulation, the biocidal products regulation and REACH (EC, 2015a).

[29] Before REACH, all so-called "existing" chemicals (those which had been introduced into the market before 1981) could be used freely unless an authority had shown a risk and proposed specific regulations. While "new" chemicals (those introduced in the market after 1981) required safety testing. The "existing"/"new" chemical distinction was problematic because it worked as an incentive to keep using old unregulated chemicals and at the same time, maintained the problem concerning the lack of information – with regard to health and the environment – for almost all "existing" chemicals (which represented more than 90% by volume of all chemicals in the market) (Massey, 2005)

manufacturers and importers were made responsible, for the first time, to prove that chemicals were safe *before* placing them in the market (Massey, 2005).[30]

In REACH, endocrine disruptors are considered of similar regulatory concern as substances of very high concern (SVHC) according to REACH article 57(f).[31] This implies that EDs might need to require a special authorization to be used in consumer products in Europe. However, at present, the standard information requirements of REACH are not sufficient to detect substances with ED-properties, meaning that the information required for applying article 57(f) is usually not available. And, for those substances where ED-properties are documented, no specific regulatory criteria are provided for the legal regulation of EDs, according to article 57(f) (as opposed to the other SVHC for which there are detailed criteria) (Stolzenberg et al., 2013).

In order to systematically cover EDs through REACH, it would be necessary to 1) have regulatory criteria for the identification of EDs as substances of very high concern, 2) improve the standard information requirements (in particular covering sensitive ED-effects), 3) clarify whether or not safe regulatory *thresholds* can be determined for EDs (Olsson, 2014; Stolzenberg et al., 2013) .[32]

4.2.2 Plant Protection Products Regulation (PPPR) and Biocidal Products Regulation (BPR)

The new pesticide regulation from 2009 and the new biocide regulation from 2012, introduced ED-properties as a hazard-based "cut-off criterion" for the approval of active substances as pesticides and biocides In practice this means that pesticides and biocides with ED-properties

[30] Before REACH, the authorities had the responsibility to prove that chemicals were dangerous before proposing regulation.

[31] REACH is composed of three stages. In the *registration* phase, producers and importers of chemicals must provide safety information on chemicals produced at or above one tonne per year. During the *evaluation* phase, member states assess the information provided in the registration phase and can request additional information if needed. Substances of very high concern (SVHC substances) can be included in the so-called candidate list according to article 57 (a-e). This includes substances that are classified as CMR (carcinogenic (a), mutagenic (b) and toxic to reproduction(c)), PBT (persistent, bioaccumulative and toxic (d)), vPvB (very persistent and very bioaccumulative (e)) and substances which give rise to an equivalent level of concern such as those having endocrine disrupting properties (f). SVHC substances included in the candidate list can then be recommended to be subject to the *authorization* process, meaning that they will need to be granted special permission to be used. Alternatively, SVHC substances and other problematic chemicals can also be regulated via restrictions if an unacceptable risk is documented (Stolzenberg et al., 2013).

[32] The issue of whether it is possible to determine a *safe level* of exposure to EDs or not (commonly referred to as a *threshold*) is very relevant for the authorization procedure. For substances without a threshold, authorization will be granted only when the socioeconomic benefits outweigh the risks (or if there are no suitable alternatives). For substances with a threshold, authorization will be granted if exposures are below regulatory toxic thresholds.

would no longer be authorized in the EU market unless it is proven that exposure is negligible. This hazard-based approach represents a big change from the traditional risk-based regulation of EDs. Yet, the final implementation of these two pieces of legislation also requires the establishment of regulatory criteria for the identification of EDs (Stolzenberg et al., 2013).

4.2.3 Scientific criteria for the identification of endocrine disruptors

From 2009 to 2013, there was an intense scientific and regulatory activity at EU level, to develop an approach and establish scientific criteria – based on the most recent scientific knowledge – for the regulation of EDs, as demanded by the PPPR, BPR and REACH. With a deadline set by the end of 2013, the EU Commission put that responsibility on the Directorate-General for the Environment (DG Environment). Several scientific reports were commanded to this end, among which the state-of-the-art assessment by Kortenkamp et al. (2012), EFSA's opinion on ED (2013) and the EC's Joint Research Centre report (2013). At the same time, EDs were also high on the political agenda. In 2013, the EU Parliament adopted a resolution on the protection of public health from EDs, and the same year, the 7th Environmental Action Programme also called for minimizing exposures to EDs (Horel, 2015).[33]

Yet the development of the scientific criteria turned out to be more complicated than previously anticipated. For example, different definitions of what an ED is, rely on whether or not there is a clear causal link between a chemical's endocrine activity and the onset of an adverse health effect.

In their 2013 opinion, EFSA adopted the WHO/IPCS definition from 2002, namely that an ED is "an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub) populations" (WHO/IPCS, 2002, p. 1). Adhering to this definition implies two things: First, that it is possible to make a clear distinction between adverse effects of endocrine disruption and normal physiological modulations of the endocrine system. Second, that adverse health effects are caused by a chemical's endocrinal activity. However, it can be said that for the time being there is no enough knowledge to universally define what constitutes an adverse endocrine effect. Nor there are adequate standardized test methods to identify such possible effects. Meaning that

[33] The environmental action programs represent a general policy framework for the EU's environment policy.

adversity, and thus the identification of EDs, would have to rely on weight-of-evidence approaches, relying on expert judgment and done on a case-by-case basis (Beronius, 2013).

Other definitions, in particular the one proposed by the Endocrine Society in 2012, state that an EDC is "an exogenous (non-natural) chemical, or mixture of chemicals, that interferes with any aspect of hormone action" (Zoeller et al., 2012, p. 2) – implying that a chemical's capacity to interact with the endocrine system in itself can be considered as endocrine disruption. In this definition, a causal link is not required, implying that a significant amount of chemicals would potentially be identified as EDs. This would lead to a situation where risk managers would require additional guidelines to prioritize regulatory decisions (Beronius, 2013). Today WHO/IPCS definition is the most agreed upon, however there are still discrepancies on how to operationalize it for regulatory purposes.

Despite these and other complexities, in the summer of 2013, DG Environment had a proposal ready for the definition, identification and categorization of EDs, based on the Kortenkamp's report (2012) and EFSA's opinion (2013).[34] However, before its official release, DG environment's draft proposal was leaked. This led to its ultimately rejection by the EU Commission - who under the pressure of the "informed" chemical industry, put in place less stringent options along with a plan to conduct an impact assessment with regard to the pesticide and biocide legislation.[35] The 2013 deadline was not met, and the Commission embarked on the preparation of an impact assessment to evaluate a range of options for the regulation of EDs which in practice has meant a delay in the implementation of the regulations for at least four additional years (Horel, 2015).

4.2.4 The impact assessment on endocrine disruptors

Even if the delay was initially attributed to scientific disagreements and differences of opinion inside the Commission's Directorate Generals, it was later acknowledged that industry lobbying

[34] Although DG Environment's proposal was intended to be applied first to the PPP regulation, if implemented, it would have later also applied to the BPR and REACH.

[35] Broadly speaking, an impact assessment refers to the evaluation of the potential economic, social and environmental consequences of a policy initiative. Among the critiques of such cost-benefit exercises is that they are biased in favor of economic aspects rather than on public health and environmental aspects. In the sense that it is easier to put numbers on the costs of immediate regulations than on the diverse range of benefits to society that extends much farther into the future than the costs. Furthermore, such lengthy assessments often delay regulation (Ackerman, 2008).

and an open letter written to Anne Glover (the Chief Scientific Adviser to the President of the European Commission) were decisive factors in the Commission's final decision (EU-Monitoring, 2014).

The industry lobbying refers to a coordinated effort of major chemical, plastic and pesticides companies to express their worries among top EU officials. These companies insisted on the need to conduct an impact assessment, and highlighted that the proposed criteria would have significant impacts in economic and agricultural terms, and in relation to trade. A recent article by "The Guardian" has revealed that DG Environment's criteria would have led to the banning of 31 pesticides worth billions of euros (Neslen, 2015). At the same time, the negotiation of the Transatlantic Trade and Investment Partnership (TTIP) between the EU and the US has also been a target for lobbying against ED regulation. The main goal of the TTIP is to promote free trade by removing barriers to commerce, including regulatory barriers. In this respect, a stringent European ED-regulation – based on hazard criteria – would represent a major technical barrier to trade between the European and the American block. Industry and trade lobby groups on both sides of the Atlantic, together with their political allies, have been aiming at achieving some sort of regulatory harmonization where ED regulation is solely risk-based and dependent on thresholds (Horel, 2015; Nielsen, 2015).[36]

The letter directed to Anne Glover also echoed and reinforced the need for an impact assessment. This letter, signed by 71 toxicologists, urged the Commission to reconsider its regulatory approach to EDs. According to the authors there were neither scientific grounds nor broad support in the field to assume that there were no safe thresholds for EDs, as suggested by the hazard-based cut-off criteria for the regulation of pesticides and biocides. This was followed by the publication of an editorial in 14 different toxicology journals under the title: 'Scientifically

[36] Yet the public concerns related to the TTIP cut deeper. Besides the generalized critique that the negotiations have suffered from a lack of transparency and democratic accountability, where only a very few members of the EU Parliament and EU Member States had access to the documents being negotiated by the EU and US trade officials and their industry advisors. Several politicians, scholars and civil organizations are also concerned about the so-called investor-state dispute resolution (ISDR), which would allow any US-based company to sue governments for compensation over rules that affect their expected profits. ISDR would threaten both EU-wide regulatory measures and any more protective measures approved by member states – such as the Danish national ban on bisphenol A. At the same time, it is also feared that in order to minimize the regulatory differences between the two blocks, the EU chemical regulatory framework would have to be downgraded towards regulations and standards that are less protective for health and the environment (as the ones prescribed by the weak American Toxic Substances Control Act (TSCA) from 1976). Consequently, several NGOs have been campaigning at EU level to demand the exclusion of the chemical sector from the TTIP negotiations (CHEMTrust, 2015; Hansen-Kuhn & Suppan, 2013; Horel, 2015).

Unfounded Precaution Drives European Commission's Recommendations on EDC Regulation, While Defying Common Sense, Well-Established Science and Risk Assessment Principles' (the editorial was written by 18 of the undersigned toxicologists)(Dietrich et al., 2013). Yet these claims did not go unanswered. Shortly after, several rebuttals were published, where over 100 endocrine scientists aimed to pick apart the statements put forward by the editorial, and concluded that such publications "does the European Commission, science, including the field of toxicology, and most importantly, public health, a profound disservice"(Gore et al., 2013, p. 3959). In order to address the ongoing discrepancies, Anne Glover convened a meeting with representatives from both sides – toxicologists and endocrine scientists.

The outcome was a surprising consensus on issues that the editorial had originally critiqued; in particular the point that thresholds might not always exist (EC, 2013).[37]

Even when the main doubts concerning the scientific work performed by DG Environment were brought to an end, the Commission supported the continuation of the impact assessment, based on: the complexity of the issue, the diverging views among scientists and stakeholders and the significant potential economic impacts for the chemical industry and international trade.

As of today, the Commission has proposed four options to define possible criteria and three approaches to regulatory decision making.[38] These have been subjected to a public consultation

[37] In the time that followed, an investigation conducted by Environmental Health News (which was awarded a laurel from Columbia Journalism Review) revealed that at least 40 of the 71 signees (including 17 of the 18 authors of the editorial) had failed to disclose ties to the regulated industries including funding, patenting, consultancy and advisory services. Among them, there were three tobacco industry veterans and three members of EFSA's working group on EDs (Horel & Bienkowski, 2013) – a group which had also been heavily criticized due to conflict of interests (Benkimoun & Foucart, 2012). It has been suggested that the actions of this group of toxicologists has many similarities with the tactics used by the tobacco industry in the 1950s, in their fight against the science linking cigarettes to cancer. This strategy – consisting of discrediting scientific consensus, spreading confusion and ultimately promoting doubts – has been well documented in the book of historians Oreskes and Conway, *Merchants of Doubt* (2010). Over the last years, additional journalistic pieces have reported that such a tactic is gaining popularity in the field of chemical regulation (Brown & Grossman, 2015). Given that science is at the heart of many political decisions, sowing scientific doubt can be seen as an effective way of delaying or diluting regulation, by making it harder for policy makers to make decisions.

[38] Four different options to define possible criteria to identify EDs: Option 1 (baseline): keep using the interim criteria in the PPPR and BPR (no policy change). Option 2: use the WHO/IPCS definition to identify ED (proving adversity and endocrine disrupting mode of action and causality). This is similar to EFSA's proposal (2013). Option 3: use the WHO/IPCS definition to identify ED and establish additional categories based on the different strength of evidence (three categories: ED, suspected ED and endocrine active substance). This is similar to Denmark's proposal (ref) and supported by endocrine scientists. Option 4: use the WHO/IPCS definition to identify ED and include potency (the amount of substance necessary to produce a certain effect). Similar to the joint German/British proposal (ref) and supported by the industry.

that confirmed the wide variety of stakeholders and the very diverging views on the topic. At present, two studies are being conducted where 700 potential EDs are being assessed using the four different options for criteria and their corresponding socio-economic impact are being calculated(EC, 2015b) .

Yet, not all actors are equally patient with such delays and stagnation in the regulation. In 2014 Sweden (followed by Denmark, France and the Netherlands) decided to sue the European Commission for delaying the establishment of criteria to identify EDs, and thus hampering the implementation of several pieces of legislation in the EU. By January 2015, both the EU Council of Ministers and the European Parliament, in an unprecedented move, decided to back up Sweden in taking the Commission to the European Court of Justice for failure to act, and fulfil its legal obligations regarding EDs (HEAL, 2015; NexReg, 2015).

What was originally meant to be exclusively science-based criteria for EDs, has become a mix of scientific and socio-economic considerations – where science, values and politics are in tension. This is particularly accentuated by the high stakes of the debate, in terms of public health consequences, economic implications, far-reaching ramifications for trade and not least, given that the EU will be the first authority in the world to regulate EDs, setting a precedent for what is seen as appropriate scientific evidence and regulatory practice. Yet, as of today, it is still not clear how evidence, values and political judgments will be combined to produce the awaited final regulatory decision.

4.3 The scientific debate on endocrine disruptors

Over the last decade, many publications reflect an intense scientific debate concerning the issue of ED. The debate has mainly taken the form of two very distinct perspectives, namely that of toxicologists and endocrine scientists.[39] In what follows the most relevant points of each perspective will be presented.

Three approaches to regulatory decision making: Option A (baseline): no policy change (meaning hazard-based decision making). Mainly supported by NGOs, civil society organizations and citizens. Option B: introduce risk assessment considerations. Mainly supported by the industry. Option C: introduce socio-economic (risk benefit) considerations (EC, 2015b).

[39] Endocrine scientists belong to several disciplines, first and foremost (experimental) endocrinology, but also reproductive and developmental toxicology, biology, epidemiology, environmental epigenetics and many more. I

4.3.1 Toxicology

According to environmental historian Linda Nash, the consolidation of modern toxicology as a scientific discipline took place in the late 1950s when toxicologists became responsible for assessing the risk posed by synthetic chemicals present in consumer products, food chains and the environment (Nash, 2008).[40]

However, the central tenet in toxicology dates back to the sixteenth century scientist Paracelsus' statement "All things are poison and nothing is without poison, only the dose permits something not to be poisonous"(Paracelsus, 1539). This is known as toxicology's "founding sentence" and implies two main assumptions concerning the relationship between the dose and the exposure. First, it is expected that the response (the physiological effect) of an organism to a chemical increases proportionally with the level of exposure (the dose) until a maximum response is reached (beyond which increasing chemical dose will not increase the effect), generating an S-shaped monotonic dose-response (Lagarde et al., 2015). Second, it is assumed that there is a threshold dose for effect. This means that one can always identify a level of exposure (or threshold) below which a chemical is not expected to induce adverse effects (Myers, Zoeller, & vom Saal, 2009).[41]

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will refer to all of them as endocrine scientists given that they share the same understandings concerning how EDs act and their effects, and because they have expertise in hormone research.

[40] According to Nash, toxicology has its roots in the set of techniques developed by industrial hygienists in the early 20th century addressing the problem of chemical exposures in the workplace. Industrial hygienists believed that bodies had the ability to self-regulate and achieve equilibrium again after exposure to low levels of pollutants. Drawing on this idea, they developed the concept of *threshold limit values* – referring to the explicit level of chemical exposure below which the organism (man or animal) had the ability to re-adjust without suffering any harmful biological effects. Such a concept was very welcomed in the industrial context since it offered a middle ground between the workers' rising health concerns and the corporations' interests (Nash, 2008). When it became evident that synthetic chemicals could also migrate out of the occupational realm and into everyday life, toxicology became the applied science in charge of assessing chemical risk.

[41] The exception to this is mutagenic (or genotoxic) carcinogens. For these chemicals it is assumed that there is no threshold for effect (represented by a linear dose-response curve at low doses). This is based on the theoretical understanding of their mode of action. That is, that exposure to one single molecule can induce genetic damage that can ultimately result in tumor formation and cancer (Beronius, 2013).

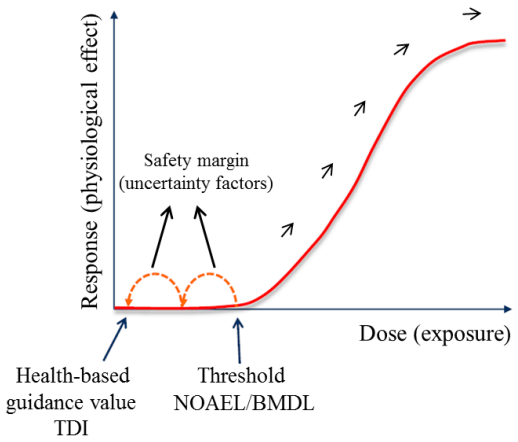

Figure 2: A monotonic dose-response curve with a sigmoidal shape (S-shape) indicating a threshold below which no adverse effects are expected and a health-based guidance value used for regulatory purposes. The dashed orange arrows represent the safety margin – that is, the uncertainty factors that are applied to the NOAEL/BMDL in order to calculate the TDI. Adapted from Beronius (2013)

Determined by these particular assumptions, regulatory toxicology developed to become an experimental science where controlled animal-based experiments are used to predict the toxic effects of chemical exposure. Typically in a toxicological study, adult animals are exposed to *high doses* of a chemical to determine the *no observed adverse effect level* (NOAEL) - which is the concentration of a chemical at which no toxic effect is seen. A health-based guidance value (or safety reference dose) for a chemical is then established by adding a generous safety margin to the NOAEL (Vogel, 2008). The safety margin can account for variability of effects among individuals, vulnerable populations, extrapolation of animal-based results to humans, and many more (Vandenberg et al., 2009). The toxicology model then suggests that chemical exposures below the safety reference dose are, in general, safe for humans. However, toxicologists do not engage in the empirical study of physiological effects below the NOAEL. Instead, the assessment of harm below the safety threshold (or NOAEL) exclusively relies on the assumptions made concerning the dose-response relationship (Vogel, 2008).

Yet, it is important to highlight that the presence or absence of a threshold can never be experimentally proven. The reason is that all methods for measuring effects have a limit of detection below which effects cannot be observed (Hass, Christiansen, Axelstad, Dreisig Sørensen, & Boberg, 2013; Kortenkamp et al., 2012) – and no conclusion regarding the shape of the dose-response curve can be made below this detection limit. In order to produce dose-response curves as accurate as possible, one would require an infinite number of doses and

infinitely precise measures (Hass et al., 2013). However, common toxicity studies often include only three dose groups or less (and a unexposed control group)(Beronius, 2013). This implies two things: First, that the NOAEL does not really represent the dose where there is an absence of effect, but rather, the dose at which it was not possible to observe a an adverse effect (when compared to the control group), which in turn relies on the statistical power of the study (Beronius, 2013). Second, that the conclusions regarding the shape of the dose-response curve cannot be made only by experimental observations but heavily depend on the theoretical assumptions made and their biological plausibility (Hass et al., 2013) .

Typically, toxicology studies examine specific adverse events such as changes in body weight, development of cancer and mortality. Consequently, the methods employed are mainly based on the detection of gross changes in morphology and development. Other more sensitive endpoints and subtle effects are usually not addressed – such as perturbations that change the predisposition to develop a disease, which require more sophisticated analytical tools (Myers, vom Saal, et al., 2009; Vandenberg et al., 2009).

The institutionalization of the regulatory risk assessment paradigm in the 1950s was both based on, and served to sustain, the scientific discipline of toxicology. Environmental historians (such as Nash (2008) and Vogel (2008, 2009) have claimed that this was the result of the simultaneous attempts of policymakers and industry representatives to legitimize chemical exposure – and the corresponding chemical risk – as the necessary trade-off for economic progress. As well as a reaction to the growing evidence that chemical pollution was indeed inevitable (Nash, 2008; Vogel, 2008, 2009).[42] The introduction and acceptance of the toxicology principles and the institutionalization of risk assessment approaches normalized the problem of chemical safety – where the focus did not lie on questioning the hazard per se but in controlling the exposure. Assuming that one can always determine a safe level of exposure, the most relevant question becomes what that level is. This narrative of chemical safety is still very tangible, in particular in the field of food safety where the prevailing assumption is that safety can be achieved by meeting health-based guidance values – that is, by controlling the amount of exposure (Vogel, 2008, 2009).

[42] DDT was the typical example of how chemicals were at the same time "necessary" and impossible to keep out of the food chain.

4.3.2 Risk assessment approach

A risk assessment is a conceptual framework that deals with the structured review and evaluation of toxicological data in order to estimate possible health or environmental outcomes in relation to exposure to chemicals (Molander, 2015).[43] Health risk assessments are commonly based on animal toxicity studies which provide the basis to identify potential adverse effects and dose-response relationships. It usually consists of three main steps: a hazard assessment, an exposure assessment and the risk characterization (Beronius, 2013).

The *hazard assessment* consists of two parts: 1) the hazard identification, where any potential adverse health effects caused by exposure to the substances in question are identified, and 2) the hazard characterization, where the chemical's toxicity is evaluated.[44] The outcome of the hazard assessment is: 1) the identification of the critical effect (i.e. the most sensitive adverse effect relevant to human health), and 2) the characterization of its dose-response relationship with the aim of determining the no observed adverse effect level (NOAEL) (i.e. the highest experimentally determined dose considered not to have resulted in statistically or biological significant adverse effect in laboratory animals) (Beronius, 2013).[45]

The NOAEL for the most sensitive adverse effect is then used to establish an acceptable health-base guidance value which is considered safe for humans – such as the tolerable daily intake (TDI). The TDI represents the estimated quantity of a chemical that can be ingested over a lifetime without posing a significant risk to health (it is usually expressed in milligrams (mg) or micrograms (µg) of the chemical in question per kilogram (kg) of body weight, and per day in the case of repeated exposure) (Beronius, 2013).[46]

To extrapolate the results coming from animal experiments to human conditions, uncertainty factors are applied to account for e.g. possible differences between and within animals and humans, uncertainties due to lack of data, conflicting results, differences between acute and

[43] Both health and environmental risk assessment follow the same steps, although with some differences in the practice of each step. However, the major difference regards their objectives - while human health risk assessment aims at protecting the most sensitive individual, environmental risk assessment aims at preventing harm at the population-level (in order to ensure the proper functioning of the ecosystem).
[44] Including the possible effects on the body, the mechanisms by which it leads to those effects, how the chemical is absorbed, distributed, metabolized and finally eliminated from the body.
[45] Or alternatively, the benchmark dose lower-confidence limit (BMDL) (i.e. the minimum dose of a substance that produces a clear, low level health risk).
[46] Where 1 mg corresponds to 1 000 µg. For the TDI, it is usually assumed standard body mass of 60 kg.

chronic exposure, and many more. The traditional default uncertainty factor for health risk assessment has been 100, consisting of a factor of 10 for extrapolating from test animals to humans and a factor of 10 for differences between individuals (Beronius et al., 2010).[47]

The second step in the risk assessment process is the *exposure assessment*, which, broadly speaking, deals with estimating the likelihood and quantifying the magnitude, frequency and duration of human exposure to the chemical in question. Finally, the last step is known as *risk characterization*, which is an estimation of the potential health impact posed by the current exposure to the chemical in question. In practice, the outcome of the hazard assessment – often the established TDI – is compared to the outcome of the exposure assessment. If the levels of exposure are below the TDI, it is generally considered that there is no health risk (Beronius, 2013).

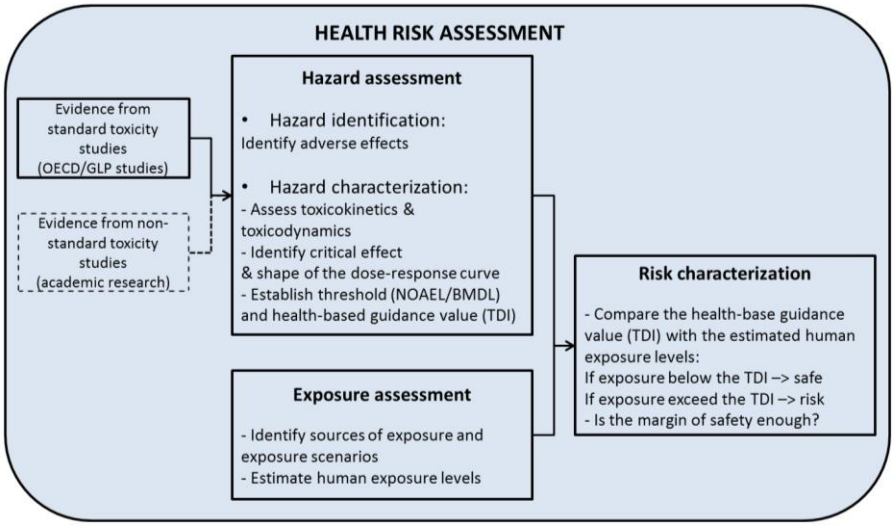

Figure 3: Health risk assessment's main steps: hazard assessment, exposure assessment and risk characterization. Adapted from Molander (2015)

Evaluation of the scientific evidence for risk assessment

In order to conduct a risk assessment, it is necessary to evaluate the reliability and relevance of the available scientific evidence. The reliability of a study relates to "the study's inherent scientific quality, including, for example, the robustness of the methods used and reproducibility of the results." While its relevance relates to "the appropriateness of the experimental model for

[47] The TDI is derived by dividing the NOAEL (or the BMDL) by the chosen uncertainty factors.

investigating the chosen endpoints as well as for evaluating the human health or environmental risk of interest" (Molander, Agerstrand, Beronius, Hanberg, & Ruden, 2015, p. 754) . Risk assessment guidance documents in Europe often recommend that all relevant toxicity data is taken into consideration in the risk assessment process. However, in practice, regulatory risk assessments are predominantly based on so-called standard studies (Molander, 2015).

These are studies that are conducted and reported according to internationally standardized test guidelines, such as the Organization for Economic Cooperation and Development (OECD) tests guidelines and following the principles of Good Laboratory Practice (GLP). The standardized OECD test guidelines provide uniform requirements as well as recommendations for experimental design, execution and reporting of toxicity studies (Beronius, Molander, Rudén, & Hanberg, 2014). GLP is a separate set of requirements that promotes the quality of the laboratory practices by specifying operational laboratory procedures and requirements for data reporting – such as: calibration and maintenance of the equipment, protocols for laboratory animal care and procedures to keep records of raw-data (Tweedale, 2011).[48] Standard studies have traditionally been considered to provide the most adequate data for regulatory purposes given that they promote the reliability of results – that is, they facilitate the replication of experiments if necessary . The major advantages of conducting standard studies are that their results are accepted across jurisdictions and are comparable across substances (Molander, 2015). These type of studies are usually required to authorize the introduction of new chemicals into the market and are thus mainly funded by the industry and performed by commercial laboratories (Beronius, 2013).

However, a frequent critique of standard studies is that their methods do not always represent the most relevant testing approach, neither can they cover all relevant adverse endpoints for a given substance (Beronius, 2013; Myers, Saal, et al., 2009). This has led some critics to claim that "Their objective is not to reflect the best scientific knowledge, but to offer a science-based political compromise among OECD member states. For this reason, there is significant potential for a gap between some OECD guidelines and rapidly advancing scientific knowledge" (Maxim

[48] It has been reported that GLP were originally mandated by the American Environmental Protection Agency in the 70s after the discovery of gross laboratory frauds (intentional manipulation of data) by private research companies. GLPs were established to ensure that basic guidelines were followed when conducting scientific research for regulatory purposes (Tweedale, 2011).

& van der Sluijs, 2014, p. 14). This applies particularly to the case of EDs, given that current standardized test guidelines do not cover: sensitive "windows" (short periods at specific stages of development of the body) of exposure, the most sensitive endpoints and all possible endocrine pathways (Hass et al., 2013).

Weight of evidence (WOE)

Risk assessors often use a so called weight of evidence (WOE) approach to evaluate the available evidence and give an overall conclusion of the hazard of the chemical in question.[49] WOE refers to the way in which a body of scientific evidence is summarized, interpreted and concluded upon. However, most of the times it is not clearly defined which methods and criteria are specifically used, and often, the conclusions are based on the results of one or a few key standard toxicity studies (Beronius, 2013).

Adversity

Adversity relates to what exactly is considered to constitute an adverse health effect during the risk assessment. At present, the most used definition for adversity is that of the WHO/IPCS (2002).[50] Yet, identifying harmful effects also implies that it is possible to differentiate adverse effects from so-called modulatory not-adverse effects. This is based on the idea that organisms may physiologically respond to chemical exposures in ways that do not necessarily impair their functions. Modulatory effects are regarded as adaptive or compensatory effects not leading to harmful effects (EFSA, 2015b). Currently there are no generally accepted criteria, nor transparency in the ways, to determine when an adaptive or compensatory effect becomes adverse, and the distinction between adverse and not-adverse (adaptive) effects heavily depends on expert judgment (Beronius, 2013).

Expert judgment

As mentioned before, there are several aspects in a risk assessment process that are inevitably reliant on expert judgment. These include among other things the evaluation of the reliability and relevance of the available studies, the identification of adverse effects, the assessment of

[49] In the context of the risk assessment, a *hazard* relates to the possible adverse health effects caused by the intrinsic properties of a chemical, for example, its capacity to damage the kidney. This is different from a *risk* in that, the *risk* that that chemical could cause kidney damage must take into consideration: how much of the chemical humans are exposed to, the length of the exposure and when the exposure takes place (fetal life, childhood, adulthood).
[50] "Change in the morphology, physiology, growth, development, reproduction, or, life span of an organism, system, or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress, or an increase in susceptibility to other influences." (EFSA, 2015b).

remaining scientific uncertainties and the determination of uncertainty factors. Expert judgment has been shown to be partly dependent on the knowledge, views and experiences of the risk assessors (Beronius et al., 2010), their disciplinary backgrounds and their institutional affiliations (Maxim & van der Sluijs, 2014).[51]

The flexibility introduced by expert judgment is particularly desirable in face of the complexity and the different levels of uncertainty that typically characterize the assessment of chemical risk. Yet, it can also introduce value-based assumptions to the process, that need to be described and justified (Beronius, 2013; Maxim & van der Sluijs, 2014).

4.3.3 Endocrine science

The origin of the endocrine disrupting hypothesis dates back to a meeting in the early 1990s, when an interdisciplinary group of researchers – including wildlife biologists, experimental endocrinologists and molecular biologists – got together to discuss the emerging body of scientific evidence on the developmental and reproductive effects of chemicals capable of interacting with the endocrine system. The outcome of the meeting was the so-called Wingspread consensus statement declaring that: "Many compounds introduced into the environment by human activity are capable of disrupting the endocrine system of animals, including fish, wildlife, and humans. Endocrine disruption can be profound because of the crucial role hormones play in controlling development" (Hotchkiss et al., 2008, p. 235).

During the last 20 years, the scientific knowledge about EDs has been rapidly increasing– leading to new areas of interest and new concerns. For example, the initial focus on environmental estrogens has been broadened to include several other mechanisms of endocrine toxicity.[52] It is also acknowledged that EDs can affect all hormonal systems and that a single ED can interact with multiple hormonal pathways, leading to several different effects (Gore et al., 2015). At the same time, the field is so complex that even the continuous accumulation of information about effects and mechanisms cannot cover all remaining knowledge gaps. However, there is a broad

[51] This includes whether the expert has prior experience with the chemical to be assessed, by means of own research and publications, what the nature of her/his knowledge is (e.g. experimental or theoretical), her/his institutional affiliation (e.g. regulatory agency, university) and links with industry (affiliation bias, or conflict of interest, can also influence expert judgment, highlighting the importance of establishing appropriate disclosure mechanisms when conducting risk assessments).

[52] Such as androgen, thyroid, corticosteroids, growth hormones, vitamin a and vitamin d hormones pathways – some of which are today considered to be of equal or greater concern than environmental estrogens (Hotchkiss et al., 2008).

consensus among endocrine scientists concerning the main characteristics of endocrine disruptors – such as the fact that EDs exhibit the same characteristics as endogenous hormones (that is, the hormones produced by the body) (Gore et al., 2015). These ED-hallmarks will be summarized in what follows.

Low-dose effects and thresholds

Endocrinological research has shown that natural hormones act at extremely low concentrations, typically in the part-per-trillion to part-per-billion range.[53] EDs, like endogenous hormones, can also induce effects at extremely low concentrations, in the range of typical human exposures (that is, at doses below the NOAEL and the TDI, and also below the doses typically used in standard testing protocols). At the same time, EDs act by the same mechanisms and against a background of natural hormones which means that their activity can add to and increase the response of already ongoing biological processes. Based on these arguments and on experimental observations, many experts claim that it cannot be assumed that there is a threshold for effects induced by EDs. Especially during sensitive and critical periods of development (Gore et al., 2014).

Timing of exposure

The concept of sensitive windows of exposure comes from the realization that developmental processes dependent on precise hormonal signals. During early development, for example, endogenous hormones guide and control the development of tissues and organs from the fertilized egg to the fully developed fetus. During this sensitive period, exposures to EDs can affect this delicate programming, which can lead to irreversible effects.[54] These include physical malformations and functional defects, but also permanent changes that influence the propensity of the exposed organism to develop a disease later in life or the manifestation of a dysfunction in a subsequent generation. Depending on when, how and to which ED(s) the fetus was exposed, the effects can be evident relatively fast, but in general there is a long lag phase between the time of

[53] Respectively, one part in one trillion (1 in 1,000,000,000,000) and one part in one billion (1 in 1,000,000,000).
[54] As an example, the "male" fetus has to be exposed during the precise developmental window to fetal androgens (or male hormones) to trigger the masculinization of the external genitalia. If this does not happen, different signs of de-masculinization can be observed at birth such as a misplaced opening of the urethra, known as a hypospadias.

exposure and the actual manifestation of the effect (Diamanti-Kandarakis et al., 2009; Gore et al., 2014). [55]

Given that some tissues continue to develop after birth (e.g. in the brain and the reproductive system), these sensitive periods can cover many years. Fetal development, infancy, childhood and puberty are periods when developing tissues are sensitive to the action of hormones and thus particularly vulnerable for ED-exposures. Timing of exposure is thus fundamental in order to understand which tissues and organs might be affected. However, exposures to EDs during adult life may have very different consequences, since, in general, the effects are often temporary and usually disappear when the exposure has ceased (Diamanti-Kandarakis et al., 2009; WHO/UNEP, 2013).

Non-monotonicity

Research in the field of endocrinology and clinical medicine has shown that endogenous hormones display non-monotonicity dose-response (NMDR) relationships.[56] Non-monotonicity refers to dose-response curves where the slope of the curve changes sign somewhere within the range of the doses examined (Figure 4).[57] This type of dose-response relationships have also been reported for several EDs (N et al., 2012). Non-monotonicity implies that adverse effects can occur at low dose levels irrespective of effects seen at high doses – and consequently, that the extrapolation from high-dose effects to low-dose effects (as suggested by the toxicology model) is not always possible (Vandenberg et al., 2009).

[55] Based on this understanding, a concept named the developmental origins of health and disease (DOHaD) has been advanced with the aim of investigating developmental exposures to EDs and disease outcomes later in life.
[56] For example, non-monotonicity has been used in human endocrinology as a basic principle behind the pharmaceutical treatment of severe diseases (Hass et al., 2013).
[57] NMDR curves are often U-shaped with maximal responses of the measured effect observed at low and high doses (Figure 4, b), or inverted U-shaped with maximal responses observed at intermediate doses

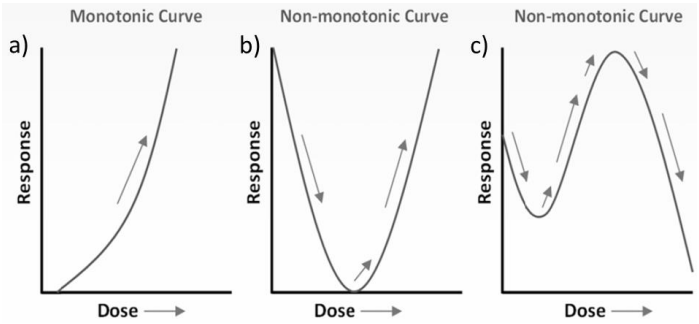

Figure 4: Examples of monotonic (a) and non-monotonic (b,c) dose-response curves. Non-monotonic curves are characterized by a change in the sign of their slope, whereas monotonic curves do not change sign. They may be U-shaped (b) (or inverted U-shaped) when there is one inflection point, or bi-phasic (c) when there are two inflection points . Adapted from Review of the environmental protection agency's state-of-the-science evaluation of non-monotonic dose-response relationships as they apply to endocrine disruptors (2014)

Transgenerational effects

In addition to the well-known transfer of persistent ED from mother to child, it is also recognized today that some EDs can also induce so-called transgenerational effects in subsequent generations. These effects are transmitted through epigenetic changes that modify the way the DNA is expressed and can affect several organ systems. The implication of transgenerational effects is that even when there is no further exposure, the epigenetic changes (imprinted on the organism's DNA) may persist for several generations (Gore et al., 2015).[58]

Combination effects

Endocrine science also recognizes that organisms are exposed to complex mixtures of EDs. In particular, it is highlighted that the simultaneous exposure to a combination of EDs can produce additive effects – even when each chemical is present at low doses and do not cause adverse effects when given alone.[59] Endocrine scientists have stressed that ignoring the effects of simultaneous exposures can lead to wrong risk estimations (Gore et al., 2014).

Academic research on endocrine disruptors

As mentioned, through the last decades, research on EDs has advanced rapidly. The field has grown to include many different scientific specialties that have addressed a large and diverse range of dysfunctions and diseases – reproductive, neurological, behavioral, metabolic,

[58] These effects do not involve DNA mutations but rather changes in DNA methylation and histone acetylation, which are molecular mechanisms that regulate gene expression. When these epigenetic changes take place during development – affecting for example the germ cells of the developing fetus (the egg or the sperm cells) – the effects will not only affect the particular individual, but also subsequent generations (Gore et al., 2014)

[59] Besides dose additivity, mixtures of EDs can also interact multiplicatively (or synergistically) or antagonistically

immunological and several other. Academic research on endocrine disruption often enters new areas of research, and make use of the latest developments in methods. Experimental studies habitually include novel endpoints that are particularly sensitive and relevant to the investigation of endocrine-related effects (Gore et al., 2015).[60] However, this type of academic studies is seldom conducted according to any internationally standardized test guidelines. This has hampered the use of such academic research studies in the regulatory setting, where it is usually concluded that non-standard studies suffer from methodological limitations and have low reliability. Risk assessors point to the fact that many non-standard academic studies only investigate a single dose, are not statistically robust (some failing to control for litter effects and using inappropriate statistical methods), are poorly reported, and often contradict the results reported in standard studies (Molander, 2015).[61]

Yet, several recent investigations have emphasized the need to enhance the use of non-standard studies for regulatory purposes. Today, it is acknowledged that academic research studies can contribute with critical data to fill information gaps in the risk assessment of EDs – and complement the information provided by standard studies (Beronius et al., 2014; Maxim & van der Sluijs, 2014; Molander, 2015; Myers, vom Saal, et al., 2009). In connection to this, several initiatives have been proposed to "bridge the gap" between academic research and regulatory risk assessment, including guidance on how to report research to meet regulatory requirements (Beronius et al., 2014), and to develop a common framework to assess the quality of non-standard studies in a transparent way (Maxim & van der Sluijs, 2014).

4.3.4 Call for a change in risk assessment practices

As summarized in the previous section, the specific characteristics of EDs challenge many of the traditional toxicological assumptions concerning chemical risk and the conventional risk assessment approach. Endocrine scientists have been arguing that the accumulated evidence and

[60] Academic research on endocrine disruption is often conducted at universities and research institutions. They are usually sponsored by public funds and are subjected to publication-related peer-review processes

[61] Independent scientists have, however, highlighted that underreporting is linked to the publishing demands from scientific journals, namely the need to write concise papers and limit the amount of information reported. Similarly, concerning the statistical robustness, it has been explained that most academic studies use only small amounts of animals, to comply with research guidelines in public institutions (Beronius et al., 2014). Finally, concerning the lack of replication of the results, it has been noted that it is impossible to identically reproduce the particular conditions of a specific experiment, and that in academia there is no incentive to repeat previous results given that funding and publications depend on originality (Maxim & van der Sluijs, 2014).

the rising number of many endocrine-related disorders in humans (which are also observed in laboratory animals) warrant a paradigm shift in how risk assessment is conducted and EDs are regulated (Gore et al., 2014; Myers, vom Saal, et al., 2009; Myers, Zoeller, et al., 2009; Zoeller et al., 2012).

An improved risk assessment method would fully incorporate the basic principles of endocrine science, such as: taking into consideration exposures during sensitive windows of development – including the manifestation of delayed and transgenerational effects; considering that effects may occur at very low doses – similar to current levels of human exposure, and below the doses traditionally used in toxicity testing; recognizing that the potential occurrence of non-monotonic dose-response relationships, implying that one cannot always extrapolate the effects observed at high doses to the low doses – and that effects in the low range can take place independently of what is observed at high doses;[62] to not systematically assume the existence of a safety threshold – in particular for exposures during sensitive periods; and lastly, to move beyond the customary chemical-by-chemical approach to incorporate cumulative and mixture effects. At the same time, non-standard academic studies should be included in regulatory assessments to complement the information coming from standard studies – since current standard test guidelines do not represent the most sensitive or relevant endpoints to test, nor do they cover all the specter of possible ED-effects. And finally, endocrine scientists ought to be included in panels that review EDs, given their expertise in hormonal action and effects (Gore et al., 2014; Myers, vom Saal, et al., 2009; Myers, Zoeller, et al., 2009; Zoeller et al., 2012).

Many of these recommendations have been elaborated and published in connection to the controversial risk assessment of one particular endocrine disruptor: bisphenol A.

4.4 The case of bisphenol A

4.4.1 What is bisphenol A?

The invention and synthesis of bisphenol A (BPA) dates back to 1891, but it was not until forty years later that this chemical attracted commercial interest. In the 1930s, medical researcher Edward Charles Dodds, was searching for synthetic chemicals that could be used as estrogen in

[62] This means that effects seen at low doses, but not at higher, should be carefully interpreted, since non-monotonicity challenges the classical assumption, that a chemical must show evidence of an adverse effect that increases proportionally with the dose, in order to be considered dangerous.

pharmaceutical applications. Although BPA's estrogenic activity was confirmed at that time, it was never used as a drug because a more potent and promising estrogen –diethylstilbestrol (DES) became available (Dodds & Lawson, 1936).[63]

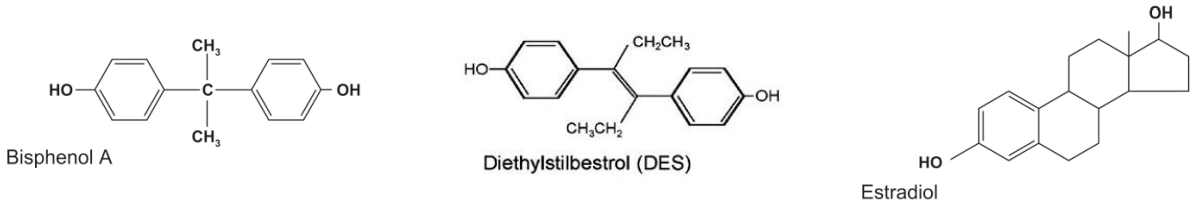

Figure 5: The chemical structures of BPA, DES and Estradiol. Where BPA is a synthetic chemical used in the production of plastic, DES is a pharmaceutical agent and Estradiol is one of the three most important forms of the endogenous female sex hormone – estrogen. Structurally, BPA and DES are more similar to each other than they are to estradiol but all chemicals can bind to estrogen receptors in human cells. Exposure to synthetic estrogen-like substances during critical stages of development has been reported to interfere with normal hormonal signaling, leading to irreversible adverse effects (Vandenberg et al., 2009).

4.4.2 A growing problem

By the 1950s, BPA found new commercial opportunities in the expanding plastic industry. Today, BPA is mostly used in the production of polycarbonate plastic, which is a transparent plastic used in CDs, DVDs, computers, spectacles, but also in food and drink plastic containers, tableware and water pipes. BPA is also widely used in the manufacture of epoxy resins which make the inner coating of metallic cans in order to prevent rusting and corrosion. In the last decades, BPA applications have expanded dramatically and today it is also commonly found in thermal paper (receipts)[64], children toys, medical and laboratory equipment, dental sealants[65], printing inks, flame retardants (tetrabromobisphenol A) and several other products (EU-RAR, 2008b).[66] It has been shown that BPA is released from many consumer products under regular conditions of use and also when these products are disposed. Consequently, BPA is also regularly found in the indoor and outdoor environment – in water bodies, air and dust. Ingestion is considered to be the

[63] DES became a commonly used pharmaceutical drug given to pregnant women in the 50s with the intention of preventing miscarriage and premature births. However, prenatal exposure to this potent estrogen proved to induce different types of reproductive cancers in the daughters and sons of the women who took it during pregnancy (whereas the mother did not suffer any effect). It was finally removed from the market in the 70s (Rubin, 2007). Studies on people exposed to DES during fetal development, together with the study of mouse models of early DES exposure, have provided essential evidence for the development of the developmental origins of health and disease (DOHaD) concept (Rubin, 2007).

[64] Paper used in receipts and tickets where BPA is used as a developing agent.

[65] These are type of dental treatment where BPA is applied to the tooth in order to prevent dental caries.

[66] For a complete review, consult the website of the European Information Centre on Bisphenol A http://www.bisphenol-a-europe.org/uploads/EN_BPA%20applications.pdf

main route of exposure, but over the years, additional sources of exposure have been identified. Today, exposure to skin (from thermal paper and cosmetics) and inhalation are known contributors to total exposures, but precise estimations are uncertain (EFSA, 2015d)

BPA is currently one of the highest production volume chemicals in the world, with a steadily increasing demand. European estimations revealed that the EU consumed about 1.15 million tons of BPA in 2005 and 2006, and that there was an increase in consumption of 69% over a seven year period (late lessons). Even though BPA is not a persistent chemical, it is produced in such large quantities and used in so many products that this chemical is widespread in the environment, and exposure to humans is prevalent (EEA, 2013). Biomonitoring studies reveal that BPA is repeatedly found in human tissues and body fluids of over 90% of all people tested in developed countries. This chemical has also been continually measured in pregnancy associated fluids at concentrations that have been reported to induce harmful effects in laboratory animals (Vandenberg et al., 2009)[67] The highest exposed groups in the population include infants, children and adolescents (EFSA, 2015d).

BPA is believed to have a rapid metabolic clearance, which means that it finds its way out of the system relatively fast. This means that reducing exposure can rapidly reduce body burden. Studies have shown that reducing the consumption of canned foods and usage of plastic containers can rapidly reduce BPA levels in body fluids (Gore et al., 2014).

4.4.3 BPA's estrogenic activity

The origin of the massive scientific interest in the possible risks related to BPA's estrogenic activity was not related to any particular regulatory processes, but to an accident, so to say. In 1993, a team of endocrinologists at Stanford University discovered that BPA leaching from the plastic equipment used in their laboratory was responsible for altering the results of their hormone-sensitive experiments. This incident and its subsequent publication revealed that tiny amounts of BPA leaching from polycarbonate plastic could mimic important functions of the natural female hormone estrogen (Krishnan et al., 1993). Promptly after that, BPA became a study candidate in the emerging field of endocrine disruption and by 1995, BPA became the most prominent example of an ED in the scientific and the public debate.

[67] Such as amniotic fluid, umbilical cord blood and fetal blood and breast milk.

Today, BPA is one of the most extensively studied and well-known EDs. Yet, scientists and regulators still disagree about the nature and extent of the health risks posed by this chemical. The list of adverse health effects associated with BPA exposure has grown to include: adverse impacts on neurological and behavioral development, mammary gland changes related to the development of breast cancer, immune system dysfunctions, cardiovascular disease, perturbation of fertility, modification of insulin regulation and obesity (EEA, 2013).[68]

At present, there are several hundreds of papers on the low-dose effects of BPA. Many of these show significant effects on laboratory animals that are exposed during development, to doses similar to the doses of current human intake. At the same time, these studies show that both the selection of sensitive endpoints, and following up the exposed individuals later in life (when effects usually take place), is crucial. Some of these results also support the observation of non-monotonic dose-response curves for BPA (EEA, 2013; Vandenberg et al., 2009). Within the field of endocrine science there is broad agreement on these concepts and findings. Yet, the BPA-related industry claim that the evidence is questionable, since no study that reports low-dose effects, has been replicated by a second lab.

4.4.4 Industrial sphere of influence on the BPA controversy

In 2005, a literature review on BPA revealed that the source that funded each study was highly correlated with either positive or negative health effect findings. This publication pointed out that from 115 available animal studies published on BPA (looking into low-dose effects), 90% of those that were government-funded (94 out of 104) reported significant effects, while none of the industry-funded studies found an effect (11 studies) at the same exposure doses (F. S. vom Saal & Hughes, 2005). It has also been reported that some years later, the well-known consulting company Weinberg group (known for their renowned work for the tobacco industry) was hired by actors within the BPA industry to "soften" European classification proposals for the regulation of this chemical.[69] Other than this, there have also been references to conflict of interests among

[68] The latest assessment by EFSA (2015) provides a comprehensive account of the possible risks associated to BPA exposure.

[69] For a full account, consult Chapter 10 of the 2013 edition of *Late lessons from early warnings: science, precaution, innovation* (European Environment Agency Report No 1/2013). Some years later, the same consultancy group was subjected to a congressional investigation in the US in connection to their work for the chemical giant DuPont on PFOA (a chemical used in Teflon). The investigation was broadened to also include the consultancy's work on BPA. According to members of the The House Energy and Commerce Committee at the US House of Representatives, Weinberg's work raised the question about whether science was for sale at these consulting firms (Layton, 2008).

the members of the EFSA's panel, who worked on the assessment of BPA (Horel, 2013; Horel & Bienkowski, 2013)

At the same time, in response to the growing public concerns over the safety of BPA, the chemical and plastic industries have also actively tried to get their side of the story out. To this end, they have launched both international and European websites with the intent to educate the public on BPA matters. The European Information Centre on Bisphenol-A and the BPA Coalition's website "let's talk about bpa" have, through specialists in communication and public affairs, been providing "informed industry views on Bisphenol-A (BPA) and its uses" which "validate what international regulatory bodies and scientific research continues to clearly state – that the safe use of BPA poses no known health risk to people".[70] This coalition represents European manufacturers and users of BPA and big industries and corporations like PlasticsEurope, Bayer, Dow Chemical and Momentive (BPA-Coalition, 2015).

4.4.5 BPA regulation in Europe

At the EU level, BPA has been regulated in connection to food safety since 2002, when it was authorized to be used in plastic materials that are in contact with foodstuff (with a specific migration limit of 0.6 mg per kilogram food) (SCF, 2002). In 2011, an amendment prohibited the use of BPA in baby bottles in the EU, based on the precautionary principle. In the environmental sector there are ongoing efforts to restrict the use of BPA in cash register receipts (thermal paper) and tighten the regulation of BPA in toys (Miljødirektoratet, 2015a).

At the member state level, Denmark and Belgium have national bans on BPA in food contact materials for infants and young children, Sweden has a ban in coatings and varnishes for food contact materials for infants and young children, Austria has a ban on pacifiers and teats and France has banned BPA in all food packaging (which recently has been modified to exclude packaging of export products) (BPA-Coalition, 2015).

[70] Through a careful selection of scientific articles and pieces of the controversy, the industry has used videos, graphs, twitter messages and fact sheets in several languages to support their claims. In February 2015, the American Chemistry Council (ACC) launched its latest communication and advertising campaign "Listen to the Science: Experts Say BPA is Safe", to amplify EFSA's latest conclusions on the safety of BPA. The ads were placed in major newspapers and consumer and health websites. For further information on the European websites, consult: http://www.bisphenol-a-europe.org/ and http://www.bpa-coalition.org/ and for the International ones: http://www.bisphenol-a.org/index.html and http://www.factsaboutbpa.org/about-us

4.4.6 The risk assessment of BPA in Europe

Since 2002, BPA has been subject to several panel evaluations in the EU. Some have been in connection to food safety, others in connection to environmental regulations; some have been conducted at EU level and many others at the member state level. These assessments have been based on different assumptions, key studies, weigh-of-evidence approaches, ways of evaluating the quality of the studies and different ways of interpreting the remaining uncertainties. Consequently, different panels have reached different conclusions on the safety of BPA. Even though BPA research has expanded dramatically, and improved methods have improved the risk assessment, the uncertainties have not decreased. Actually the opposite seems to have happened. In 2015, EFSA reiterated that current exposures to BPA were safe, while regulatory agencies at the member state level have reached different conclusions.

Historically, the safety of BPA at the EU level has been assessed according to classical toxicology principles (section 4.3.1.) and using standard studies. In the past thirteen years, the safety of BPA had been based on two key standard studies, investigating reproductive and developmental toxicity. Based on either one of those studies, a NOAEL for BPA of 5 mg/kg body weight (bw) per day has been identified. In 2002, this NOAEL was used to establish a tolerable daily intake (TDI) of 10 µg BPA/kg bw/day, using an uncertainty factor of 500, to cover low-dose uncertainties with respect to reproductive and developmental effects. Four years later, the uncertainty factor was reduced to 100, giving a new TDI of 50 µg BPA/kg bw/day, which was valid until January 2015. During those years, a large number of non-standard research studies reporting developmental effects at very low doses (below the NOAEL of 5 mg/kg bw/day and down to just a few µg/kg bw/day) had continuously been disregarded, since they did not comply with the quality criteria used by the regulatory agencies. The elimination of hundreds of low-dose studies from policy considerations has been one of the main drivers of the BPA controversy in Europe – where regulators have been confronted with the critical question of defining which scientific evidence should be used to assess BPA's safety, and how.

In the meantime, at the member state level, different regulatory agencies have reached different conclusions concerning the safety of BPA. In 2008, the environmental agencies of the Nordic countries wanted to include several non-standard studies (reporting low-dose neurodevelopmental effects) in the ongoing assessment of BPA, conducted by the European Chemical Bureau (EU-

RAR, 2008b). That same year, the Norwegian Scientific Committee for Food Safety (VKM) also expressed some concern about potential neurotoxic effects at low-doses (VKM, 2008), which were expanded by the Danish National Food Institute in 2010 (DTU-Food, 2010), to include possible effects on learning ability. In 2013, the French Agency ANSES went one step further to declare that exposures to BPA during pregnancy posed a risk for the developing fetus (ANSES, 2013).

In an effort to terminate this lengthy debate, EFSA decided to conduct a full re-evaluation of BPA in 2012. This assessment, published in 2015, can be seen as a milestone in EFSA's work with BPA. Besides improving the methodology, it also tried to address common critiques, such as to include both standard and non-standard studies, to take into account several routes of exposure, more transparency in the assumptions made during the assessment, and better treatment of the remaining uncertainties. In this assessment, EFSA established a new temporary TDI of 4 µg/kg bw/day (twelve and a half times lower than the previous one). Yet, dietary exposures were also much lower than previously estimated, which led the agency to conclude that there was no risk for any segment of the population (EFSA, 2015d). However, only weeks after EFSA's release, the Danish National Food Institute released a scientific opinion related to EFSA's latest assessment, that starkly contradicted the agency's conclusions. Danish experts proposed a TDI of 0.7 µg/kg bw/day or lower, in order to protect highly exposed groups against the endocrine disrupting effects of BPA (DTU-Food, 2015b). A more detailed account of the different assessments will be given in the next section.

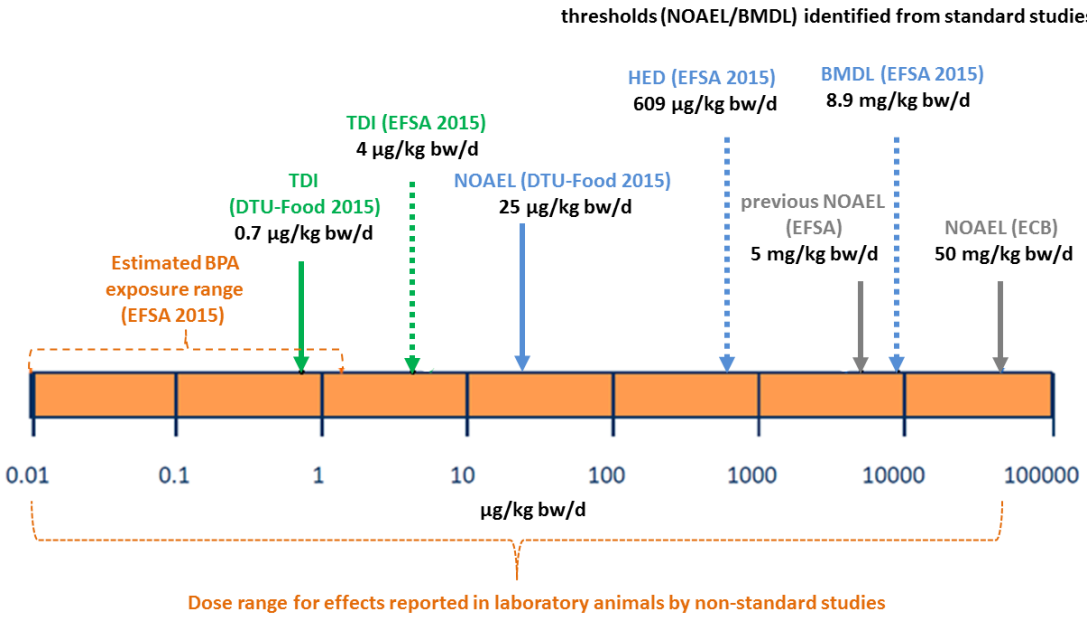

Figure 6: Health based guidance values for BPA in Europe (logarithm scale). The blue and grey arrows represent the regulatory thresholds identified from standard studies in 2015. The continuous blue arrow represents the Danish DTU-Food's NOAEL, and the dashed arrows represent EFSA's BMDL (where the BMDL is an alternative to the NOAEL, and the HED represents the BMDL corrected for differences in kinetics between mice and humans). The grey arrows represent the "historic" threshold values for BPA in Europe in the food sector (EFSA) and in environmental regulation (ECB). Finally, the continuous green arrow represents DTU-Food's TDI calculation and the dashed green arrow corresponds to EFSA's calculation – where the TDI is the estimated amount of BPA that can be ingested daily over a lifetime without posing a significant health risk. Adapted from Beronius (2014) .

4.4.7 The different risk assessments of BPA in Europe and North America

The European Scientific Committee on Food (SCF, 2002)

In 2002, the SCF evaluated the possible risk of BPA migration from in food contact materials (SCF, 2002). The Committee used the standard study by Tyl (2002) to derive a NOAEL for BPA of 5 mg/kg bw/day for effects on reproduction. Based on that NOAEL, the SCF derived a *temporary* TDI of 10 µg BPA/kg bw/day by applying an uncertainty factor of 500, comprising of: the default factor of 100, plus an uncertainty factor of 5 to account for uncertainties related to possible effects on reproduction and development (SCF, 2002).

The European Union Risk Assessment Report of BPA 2003 (EU RAR, 2003)

The former European Chemicals Bureau (ECB) conducted, in 2003, a broader risk assessment for the purpose of chemical legislation. This covered all sources of exposure and assessed effects on human health and on the environment. The health risk assessment was also based on Tyl et al.

(2002). ECB identified a NOAEL of 50 mg/kg bw/day for effects on reproduction, which was used for the risk characterization of BPA (EU-RAR, 2003).

According to the assessors, there was no solid evidence of BPA's effects on developmental toxicity at low levels of exposure – as it was noted that the majority of the low-dose studies reporting such effects used experimental protocols that were not internationally validated. Yet, it was recognized that the conflicting results warranted further attention[71]:

"Overall, in standard developmental studies in rodents, there is no convincing evidence that bisphenol-A is a developmental toxicant. However, the available and apparently conflicting data from studies conducted using low doses (in the μg/kg range) do raise uncertainties. Overall, the majority of EU member states felt that the studies reporting effects at low doses could not be dismissed. However, the member states disagreed on how these studies should be used, if at all, in the risk characterization for this endpoint. The disagreements were based on differing views about the uncertainties surrounding the reproducibility of the findings and their biological significance, if any, to human health." (EU-RAR, 2003, p. 233).

ECB concluded that further testing was required to resolve the remaining uncertainties on developmental toxicity, in particular a new standard reproductive study following test guidelines OECD 416 (EU-RAR, 2003).

The European Food Safety Authority 2006 (EFSA, 2006)

In 2006, EFSA conducted a full health risk assessment of BPA in connection to food safety. The aim was to estimate the exposure of BPA through the diet, to establish a TDI, and to look into the controversial effects on reproduction. Only studies where animals were exposed to BPA through the diet were taken into consideration (EFSA, 2006) .

The panel noted that several non-standard studies reported effects on behavior and reproduction at dose levels below the regulatory NOAEL of 5 mg/kg bw/day. However, the panel expressed "considerable reservations" (p.3) concerning the relevance of the reported adverse effects and the overall reliability of non-standard studies. This because many used a single dose, it was not possible to identify a clear dose-response relationship and most studies used a small number of

[71] The database refers to all the available studies concerning a specific effect at a specific time point.

laboratory animals (EFSA, 2006).[72] It was emphasized that the studies reporting low-dose effects and non-monotonic dose-response curves had not been taken into consideration in the risk assessment, because their results diverged from the results coming from standard studies: "The Panel considers that while low-dose effects and non-monotonic dose-response curves may be theoretically possible (Conolly and Lutz, 2004), low dose effects of BPA in rodents have not been demonstrated with the sufficient certainty to serve as pivotal studies for risk assessment." (EFSA, 2006, p. 46).[73]

It was also concluded that humans could rapidly eliminate BPA from the body after dietary exposure while rodents' elimination was much slower – something that raised further doubts about the relevance of reported low-dose effects of BPA in rodents, to assess human health (EFSA, 2006).

In the panel's view, the results from Tyl (2002) had been further sustained by a new standard study by Tyl (2006)(Tyl et al., 2008).[74] Given that none of these two standard studies reported effects on reproduction or development at low doses, the panel concluded that the new Tyl et al. (2008) study resolved the uncertainties related to possible low-dose effect on reproduction and development. The panel thus decided to remove the extra uncertainty factor of 5 used by the SCF in 2002 to account for such uncertainties. Instead, a default uncertainty factor of 100 was used to derive a new TDI of 50 µg BPA/kg bw/day based on a NOAEL of 5 mg/kg bw/day this time for liver effects identified in Tyl et al. (2008). Based on the new TDI, it was concluded that BPA dietary exposure was safe for all population groups considered (EFSA, 2006).[75]

US Chapel hill assessment 2007

[72] The adverse effects referred to: behavioral effects, changes in tissue architecture, organ weight and time of puberty onset, among others. The panel also noted that some of the changes were present just at particular points of life, and not sustained through adulthood

[73] The panel identified possible confounding factors that could partially explain some of the differences between standard and non-standard studies, such as: the influence of the diet of the animals, the route of BPA exposure during the experiment (leading to different clearing mechanisms in the body), the possible contamination of samples due to the ubiquity of BPA in the environment (such as in housing facilities) leading to increased exposures, and the selection of the animal strain (some animal strains being more sensitive to the effects of oestrogens than others).

[74] The difference between Tyl (2006) and Tyl (2008) is merely that the 2006 version represents the unpublished version and the 2008 the official per reviewed publication of the results. This study is also referred to as Tyl (2007)

[75] Yet, it is interesting to mention that had the additional uncertainty factor of 5 been kept to account for possible low-dose effects in development and reproduction (as in the previous SCF 2002 assessment), the new TDI would have remained at 10 µg BPA/kg bw per day (instead of being changed to 50 µg BPA/kg bw per day). In this case, the highest exposure scenario, estimated at 13 µg/kg bw/day for infants, would have exceeded the new European TDI and challenged the overall conclusion that current BPA exposure was safe for all population groups.

In 2007, the American National Institutes of Health sponsored a meeting in Chapel Hill where 38 endocrine scientists and experts on BPA released a consensus statement that concluded with certainty that current levels of exposure to BPA in humans, have been shown to induce adverse health effects in laboratory animals, and BPA must thus be considered a potential risk to human health. This conclusion was based on a literature review of 700 non-standard studies on BPA up until the end of 2006, and focused on the exposure of the general population to BPA via food and the environment (Chapel Hill, 2007).[76]

The European Union Risk Assessment Report of BPA 2008 (EU RAR, 2008)

In April 2008, the EU-RAR of BPA was updated after an evaluation of the awaited new standard study by Tyl (2008), along with new data on human exposure and newer studies that had become available since 2003.[77] The environmental assessment concluded that there were still uncertainties related to the low-dose effects of BPA on snails (EU-RAR, 2008a) while the health risk assessment concluded that there were no risks for any segment of the population and that no further information or testing was needed(EU-RAR, 2008b).

In the EU-RAR (2008) it is mentioned that a large number of non-standard studies had investigated, among other things, the same developmental and reproductive endpoints examined by Tyl et al. (2008). These non-standard studies had used different animal species and strains, covered a broad array of doses, a variety of exposure routes, different life stages, varying exposure durations, and included a wider selection of endpoints(EU-RAR, 2008b). Yet they were not taken into consideration in the assessment, since the reviewers found that the results were not consistent: "[…] the results from these studies have been in contrast to the results of investigations conducted according to internationally recognized guidelines and in compliance with GLP, including the recent 2-generation study in the mouse by Tyl *et al*. (2007). As we consider this investigation by Tyl *et al*. (2007) as the gold-standard, definitive study of the reproductive toxicity of BPA (for the endpoints examined), all the other recent publications

[76] The results and conclusions from the meeting have been presented in a number of published articles Frederick S. vom Saal et al. (2007), Vandenberg et al. (2007), Richter et al. (2007), Wetherill et al. (2007), Crain et al. (2007) and Keri et al. (2007). For sake of clarity, the collective results of these articles are referred to as (Chapel Hill, 2007).
[77] Tyl et al. (2008) is a standard two-generation reproductive study in mice conducted in accordance with test guideline OECD 416 and GLP compliance. It uses many doses (from the low µg/kg bw/day range and the high mg/kg bw/day range), a large number of animals, and exposure takes place through the diet. The study investigates possible effects of BPA on reproduction, in particular the effects on the development of the male reproductive tract at low doses in mice (EU-RAR, 2008b).

investigating the same standard reproductive and developmental endpoints have not been evaluated in detail in this report." (EU-RAR, 2008b, p. 87).

The uncertainties related to possible BPA effects on development at low doses were put to rest, because Tyl's new study gave no evidence of this type of effects. Based on this study, a NOAEL of 50 mg/kg/day was identified, grounded on effects on bodyweight, kidney and liver(EU-RAR, 2008b).

Moreover, there were also a large number of non-standard studies reporting developmental neurotoxicity effects at low-dose BPA exposures. Since these effects were not examined by Tyl et al. (2008), these studies were evaluated in detail using a weight of evidence approach that focused on the reliability and consistency of the evidence. The overall conclusion was that there was a low level of confidence in the reliability of the studies and a lack of consistency in the results, so that no firm conclusions about developmental neurotoxicity could be drawn. However the representatives of the environmental agencies in Denmark, Sweden and Norway did not agree with this conclusion. These countries considered that the results from four neurodevelopmental studies at low doses (Adriani et al., 2003; Carr et al., 2003; Negishi et al., 2004; Ryan and Vandenbergh, 2006) were sufficiently reliable for regulatory use, or at least warranted further investigation. Their comments were included as a minority opinion in the final report (EU-RAR, 2008b).

US National Toxicology Program (NTP-CERHR, 2008)

This two-year-long literature review on BPA concluded that it could not be dismissed that current levels of BPA exposure could alter human development: "The NTP has *some concern* for effects on the brain, behavior, and prostate gland in fetuses, infants, and children […]" and "[…] *minimal concern* for effects on the mammary gland and an earlier age for puberty for females in fetuses, infants, and children […]" (Beronius et al., 2010, p. 135).

Health Canada 2008

The overall conclusion from the expert group of Health Canada was that BPA "[…] may be entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health."(Beronius et al., 2010, p. 135).

Norwegian Scientific Committe for Food Safety 2008 (VKM, 2008)

In 2008, the Norwegian Food Safety Authority (NFSA) requested the Norwegian Scientific Committee for Food Safety (VKM) to assess whether the four non-standard neurotoxicology studies (Adriani et al., 2003; Carr et al., 2003; Negishi et al., 2004; Ryan and Vandenbergh, 2006), identified by the Norwegian Environmental Authorities during the EU-RAR (2008) assessment, provided sufficient evidence to set a lower NOAEL in the hazard characterization of BPA (VKM, 2008).

The Committee concluded that the four studies had several deficiencies and did not support a change in the current NOAEL of 5 mg/kg bw/day established by EFSA in 2006. Yet, the panel expressed some concern about the potential neurotoxic effects of BPA at low doses and recommended to conduct a standard study according to test guideline OECD 426 and GLP-compliance to clarify remaining doubts on developmental neurotoxicity (VKM, 2008).

European Food Safety Authority 2008 (EFSA, 2008)

In July 2008, EFSA released an updated opinion concluding that after oral exposure, humans rapidly metabolized and eliminated BPA. The panel concluded that EFSA's 2006 conclusion was still valid – exposure to BPA was well below the TDI of 50 µg/kg bw/d, and that was sufficient margin of safety for all segments of the population (EFSA, 2008).

Danish National Food Institute evaluation 2010 (DTU-Food, 2010)

In Mars 2010, the Danish minister of Food asked the Danish National Food Institute (DTU-Food) to evaluate the new developmental neurotoxicity standard study of Stump (2009), provided by the industry (performed according to test guideline OECD 426 and in compliance with GLP). This standard study was specifically conducted to resolve the ongoing uncertainties regarding developmental neurotoxicity effects of BPA at low doses (DTU-Food, 2010).

DTU-Food concluded that even if the study did not provide clear evidence that BPA had harmful effects on the types of behavior that were examined, it gave rise to some uncertainty with respect to effects on learning ability. It was noted that the learning effect was observed at low-dose exposure to BPA, but was not seen at high dose exposures – which suggested a non-monotonic dose-response relationship. The Danish report noted that there was an ongoing discussion on whether BPA could exhibit different effects at low and at high doses. It was concluded that the

effect on impaired learning ability could be a sign of a low-dose effect of BPA, but it could also be an incidental finding (DTU-Food, 2010).

DTU-Food found that the standard study by Stump (2009) was weak in that it had not been designed to address the previously reported adverse low-dose effects of BPA on the development of the nervous system and on behavior. The overall conclusion was thus that even if the Stump (2009) study did not justify a change in the current NOAEL for BPA, it could neither clarify nor change the ongoing uncertainties with respect to BPA's effects on neurotoxicity (DTU-Food, 2010). The conclusions of the DTU-Food's evaluation were used by the Danish government to introduce a BPA ban on food-related products for children younger than three years of age.

European Food Safety Authority 2010 (EFSA, 2010)

In 2010, EFSA noted that recent low-dose studies on developing animals had reported effects on the immune system, biochemical changes in the brain and enhanced susceptibility to breast cancer. Yet, the panel highlighted that these studies had several shortcomings in their methods, experimental design and reporting; and as a result of this, it could not be used to derive a new TDI. It was also concluded that there was no convincing evidence of the possible neurobehavioral toxicity of BPA and no conclusions could be drawn from Stump (2009) with respect to low-dose effects on learning and memory (as suggested by DTU-Food 2009) due to large variability in the experimental data (EFSA, 2010b). A panel member expressed a minority opinion concerning the uncertainties raised by the recent low-dose studies, and recommended to see the TDI as temporary until further clarification (EFSA, 2010a). EFSA's 2006 conclusion was reaffirmed.

The French Agency for Food, Environmental and Occupational Health and Safety 2013 (ANSES, 2013)

In 2011, ANSES published a report on BPA where it was concluded that, based on the available scientific literature and all exposure routes, BPA indicated proven effects in animals (on reproduction, mammary gland, metabolism and brain) and suspected effects in humans (on reproduction, diabetes and cardiovascular diseases), at levels of exposure below the current regulatory thresholds (ANSES, 2011). As a result of this, a full risk assessment was conducted by the French Agency in 2013. In this later assessment, it was concluded that there were situations for the fetus, associated with maternal exposure to BPA during pregnancy, that lead to a moderate risk of enhanced susceptibility to tumor transformation in the mammary gland of the unborn baby.

It was also noted that pregnant women that handled thermal paper and consumed water from refillable polycarbonate containers represented a specific risk situation, where, in addition to the effect on the mammary gland, other health risks were also identified (ANSES, 2013).

European Food Safety Authority 2015 (EFSA, 2015)

In 2012, EFSA conducted a full re-evaluation of BPA, that covered, for the first time, exposures through dietary and non-dietary sources, and included standard and non-standard studies. The assessment lasted for almost three years and included two public consultations. The agency received 503 comments from national agencies, governmental bodies, industry and trade associations, NGOs and academia (EFSA, 2015c).

The final assessment was released in January 2015, and revealed that diet continues to be the main source of exposure to BPA, with canned food as one of largest contributors. Yet, the overall dietary exposure was found to be 4 to 15 times lower than previous EFSA estimations (EFSA, 2015d). Thermal paper was identified as the second largest source of exposure, but there were uncertainties concerning levels of exposure through the skin and what happens to BPA inside the body when it has been dermally absorbed (EFSA, 2015d).

For this re-evaluation, the panel developed a structured weight of evidence approach, based on expert judgment – where the strengths, weaknesses and reliability of each line of evidence, in each study, were evaluated. This approach was developed to treat the evidence more consistently, to make the weighing more transparent and to better describe the uncertainties – in order to determine the hazard that BPA might represent. (EFSA, 2015e). The panel found that effects on the mammary gland (related to carcinogenicity), kidney and liver were "likely", while reproductive, neurobehavioral, immune and metabolic system effects were "as likely as not".[78] Only the effects that were "likely" were taken onward to the hazard characterization (EFSA, 2015e).

For the hazard characterization, EFSA used a new methodology to refine their estimations. The standard study by Tyl, et al. 2008 was used to establish a dose-response curve for effects on the kidney, which in turn was used to identify a Benchmark Dose Lower-confidence Limit (BMDL)

[78] The likelihood was expressed using a seven degree scale of verbal terms (very likely, likely, from as likely as not to likely, as likely as not, from unlikely to as likely as not, unlikely and very unlikely). Where "as likely as not" refers to a level of likelihood between "unlikely" and "likely", which means that "it is equally likely that BPA causes, or does not cause, the effect" (EFSA, 2015e, p. 14).

(or threshold). This was in turn used to derive an oral human equivalent dose (HED) - which is a predictive threshold level where no harmful effects in humans are expected (EFSA, 2015e). [79] With respect to the effects on the mammary gland, it was concluded that there was too big of a variation in the data and no BMDL could be established. Instead it was decided to account for this effect in the overall uncertainty analysis (EFSA, 2015e).

A new TDI of 4 μg/kg bw/d was established based on the calculated HED for effects on the kidney and applying an uncertainty factor of 150. This was composed of a factor of 25 for remaining inter-species differences and inter-individual differences (instead of the default factor of 100) and an extra factor of 6 to account for the uncertainty in the database related to mammary gland, reproductive, neurobehavioral, immune and metabolic system effects (EFSA, 2015e). The extra uncertainty factor came from an assessment of the overall evaluation of the uncertainty - a process dependent on probabilistic estimations and expert judgment, whose objective was the quantification of the remaining uncertainties in the assessment: "EFSA's experts used new methodologies to take account of the uncertainties regarding potential health effects, exposure estimates and evaluation of risks for humans. By analyzing each uncertainty one by one and combining expert judgement, the experts were able to quantify these uncertainties and to factor them in to the risk assessment and derivation of the t-TDI" (EFSA, 2015a, p. 1).[80]

By comparing the TDI with the exposure estimates, the Panel concluded that BPA's exposure from the diet and from a combination of sources (dust, cosmetics and thermal paper) posed no health risk to consumers of any age group at current exposure levels (EFSA, 2015e). It was however noted that the TDI was temporary (t-TDI) pending on the outcome of on-going studies that were expected to reduce remaining uncertainties (EFSA, 2015e).

Danish National Food Institute 2015 (DTU-Food, 2015)

In February 2015, the Danish National Food Institute (DTU-Food) was asked to examine EFSA's (2015) assessment of BPA and to determine whether the agency's new TDI was sufficiently protective according to the Institute. DTU-Food's main conclusion was that "the safe level

[79] The HED was calculated by multiplying the identified BMDL by a calculated factor that takes into consideration the quantitative difference in toxicokinetics between the animals species used in the study and humans
[80] For a detail description please refer to EFSA (2015) assessment, Appendix D - Uncertainty analysis.

recently recommended by EFSA does not adequately protect consumers against endocrine disrupting effects of bisphenol A" (DTU-Food, 2015c, p. 1).

DTU-Food did not support the uncertainty assessment conducted by EFSA, and noted that the new temporary t-TDI of 4 µg/kg bw/day gave insufficient protection to consumers (DTU-Food, 2015b). DTU-Food welcomed the calculation of a BMDL for regulatory purposes, but was critical to the way the "likely" mammary gland effects were dealt with in EFSA's assessment. The Danish Institute proposed instead to conduct a "classical" hazard characterization for this endpoint. DTU-Food looked into the same database as EFSA, and identified a NOAEL of 25 µg/kg bw/day for effects on mammary gland. Using the same uncertainty factors, they established a TDI of 0.7 µg/kg bw/day. The Danish assessment also noted that highly exposed humans belonging to vulnerable groups, such as children and pregnant women (according to EFSA's exposure estimates) were exposed to around 1.4-2 times more than 0.7 µg/kg bw/day BPA – which gave rise to concern. It was also noted that neither EFSA's nor DTU's assessment have taken into account potential mixture effects due to exposure to other chemicals with similar types of effects as BPA, meaning that the overall risk might have been underestimated (DTU-Food, 2015b).

The overall conclusion was that the TDI for BPA should be 0.7 µg/kg bw/day or lower to be sufficiently protective with regards to endocrine disrupting effects of BPA on mammary gland development and other endocrine disrupting effect (such as developmental neurotoxicity and male sexual development, which in the Institute's opinion warranted further attention) (DTU-Food, 2015b).

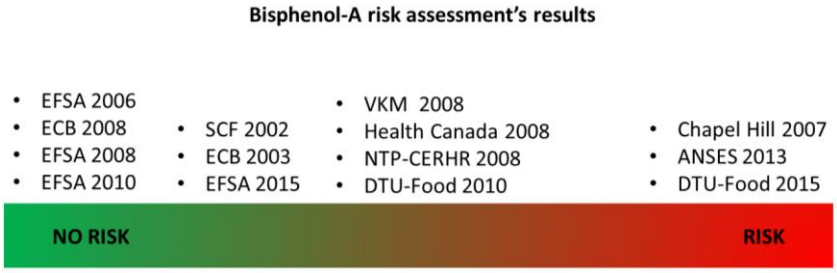

Figure 7: Table summarizing the conclusions of the different risk assessments of BPA in Europe. The results are presented on a traffic light color code: where green is used for those assessments that concluded that there was no health risk and red to those that concluded the opposite, with several other results in between. Abbreviations: EFSA (European Food Safety Agency), ECB (European Chemicals Bureau), SCF (European Scientific Committee on Food, EFSA's predecessor), VKM (Norwegian Scientific Committee for Food Safety), DTU-Food (Danish National Food Institute), ANSES (The French Agency for Food,

Environmental and Occupational Health and Safety). The results of three international assessments were also included since they are mentioned during the analysis chapter. These are: Health Canada, the US National Toxicology Program (NTP-CERHR) and an assessment by endocrine-scientists under the name Chapel Hill. Adapted from Beronius (2014).

5. Endocrine Disruptors in Denmark

In this chapter I will present the main characteristics of how Denmark has defined and addressed the ED-issue, and I will point to examples of what has this meant for the regulation of BPA in this country. One could maybe use the expression "snow ball effect" to describe how the ED-issue has developed in Denmark over the years – from its origin in the laboratories of Copenhagen's University Hospital to its influential position at the European Commission in Brussels. I will argue that the national "framework on EDs" has had a crucial role in supporting common regulatory objectives with respect to EDs and also in coordinating the activities of a broad variety of actors and processes. I will claim that the resulting, predominant understanding of the ED-situation, can help to contextualize and explain how the BPA problem was perceived and dealt with in Denmark – which I will account for in the following chapter.

5.1 Endocrine Disruption – a public health concern

The interest in EDs in Denmark dates back to the beginning of the 1990s and has a medical origin. In particular, it refers to research on male reproductive problems conducted at the University Hospital in Copenhagen (Rigshospitalet). A group of researchers form the hospital, headed by pediatric endocrinologist Niels Skakkebæk, published in 1992 an article revealing that sperm quality in healthy men had been decreasing over the last 50 years, and that during the same period there was a rapid and significant increase in the incidence of testicular cancer (Carlsen, Giwercman, Keiding, & Skakkebaek, 1992) (See Figure 1). One year later, Professor Skakkebæk elaborated the so-called "Oestrogen hypothesis", suggesting that increased exposure to estrogens during fetal life could contribute to the observed falling sperm counts and the rise of disorders in the male reproductive tract. Suspicion was mainly directed towards chemicals in the environment, which could either act as estrogen in the body (the female sex hormone) or affect the estrogen balance(Sharpe & Skakkebaek, 1993). At the same time, there was also increasing evidence that some of these reproductive effects in men were also observed in wildlife populations, and in laboratory animals exposed to potent synthetic estrogens during development (Miljøstyrelsen, 1995).[81]

[81] Human reproductive effects refer to: rise in testicular cancer incidence, decreased fertility due to poor sperm quality, deformed genitals in men and undescended testicles in young boys. The observed effects in wildlife refer to:

These findings caught the attention of the Danish Environmental Protection Agency (Danish EPA), who in 1995 requested Professor Skakkebæk to prepare a report to summarize the evidence. The report concluded that there was insufficient data to either prove or disprove that the growing incidence of male reproductive disorders, partially or completely, were a consequence of the exposure to chemicals with estrogenic effects in the environment (Miljøstyrelsen, 1995). In order to investigate this further, a four-year grant from the Danish EPA was used to establish the Research Centre for Oestrogenic Substances, with the objective to gather more knowledge on chemicals displaying hormonal activity, coordinate Danish research in the area, communicate scientific results and provide tools for regulation(FØS, 2000). The field of enquiry was particularly complex and multifactorial, and called for a multidisciplinary research strategy (Miljøstyrelsen, 1995).

The activities of the center attracted a lot of interest from a broad circle of users, including: industry, NGOs, researchers, educational institutions, regulators, journalists and other individuals. Public interest was high and there was a periodical coverage of the center's achievements in the media. And even if there were still many unanswered scientific questions, Danish research on EDs kept attracting public and political interest, which lead to further initiatives and more research (FØS, 2000).

It can be said that ED-research in Denmark has had a particular focus on health implications, and in particular on male reproductive problems. This can be explained by the national expertise on the topic but it has also been motivated by worrisome trends that have been observed in male reproductive problems in the country. For example, the results from the long term monitoring of sperm quality among young Danish men, have for many years been a cause of concern.[82] At the same time, Danish men have one of the highest incidences of testicular cancer in the world, and there seems to be more boys born with genital irregularities in Denmark than in other comparable countries, such as Finland (Miljøministeriet, 2003, 2004, 2007).

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reproductive defects in Florida panthers, alligators with changes in hormone balance and genital abnormalities (due to pollution in their habitats), feminization of male fish in Britain, and more (Miljøstyrelsen, 1995; Wright, 1996).

[82] The monitoring of sperm quality in Denmark over the last years has revealed that: around 20% of the men tested had sperm concentrations below the World Health Organization reference level, and around 42% of them were at high risk of having fertility problems in the future. It was also calculated that only about 10% of Danish men had optimal sperm quality in terms of sperm count and sperm morphology (shape and appearance) and that semen's quality did not seem to improve over time (Miljøministeriet, 2003, 2004, 2007).

In 2001, Danish researchers came out with yet a new hypothesis, suggesting that the observed male reproductive disorders might have a common cause, that was to be found in the disruption of embryonal programming and gonadal development during fetal life.[83] This hypothesis, the Testicular Dysgenesis Syndrome (TDS), proposed that fetal disruption could be caused by a combination of environmental influences such as exposure to EDs, lifestyle factors and susceptible genetic backgrounds (Skakkebaek, Rajpert-De Meyts, & Main, 2001). This hypothesis has been investigated for many years and in some areas, the link between exposure to EDs and the development of adverse effects has become stronger - for example in animal studies reporting similar effects as those described by the TDS hypothesis. However, at present, conclusive evidence in humans remains elusive for most chemicals (Miljøministeriet, 2007) .

Although the initial interest on male reproductive problems has been expanding over the years, to include many other areas of research and a to cover a wide variety of effects (Miljøministeriet, 2007), male reproduction is still at the core of the Danish work on EDs. In 2014, a new center – the International Center for Research and Research Training in Endocrine Disrupting Effects on Male Reproduction and Child Health (EDMaRC) – was established, with the objective of becoming a world leading research center on male reproductive health and children's health (Politiken, 2015; Rigshospitalet, 2014). Besides male reproduction, EDMaRC would also look into the causes of the observed national trends in premature puberty in girls, which in the last years have also become a cause of concern (EDMaRC, 2015) .

It can be concluded that the origin and a significant part of Danish research in the field of EDs has been related to human health – many times conducted at hospitals by endocrinologist or researchers familiar with hormonal functioning. One can thus argue that the Danish framing of the ED problem is based on an "endocrine science" perspective (see background section 4.3.3), and has a strong public health component.

5.2 Danish endocrine disruptor science

All from the beginning in Denmark, it has been very important to keep developing the knowledge base on EDs (Planlægningsudvalget, 2002; Regeringen, 2005, 2010, 2013). Much of the research

[83] Where the male reproductive disorders refer to: poor semen quality, testicular cancer, undescended testis and hypospadias (an abnormally placed urinary hole).

has been coordinated or carried out by the different national research centers on EDs, and in close collaboration with the Danish EPA.[84]

The constant development of the knowledge base has led Denmark to become an internationally recognized forerunner in ED research. Danish research teams have for example looked into the relation between exposure to EDs and hormone-related diseases, combination effects of EDs, ED effects in the aquatic environment, ED exposure during fetal life and possible effects later in life, research on specific EDs such as BPA, among other areas (Regeringen, 2010, 2013). At the same time, Danish ED research has also been sensitive to real regulatory needs.

From basic research to evidence-based policy

What started as the standard hypothesis-driven investigations in the laboratories of the University Hospital in Copenhagen, has today developed into research with a long-term view on regulation. This is particularly the case for the projects conducted at the Centre on Endocrine Disrupters, which was established in 2008 with the objective of researching on EDs and providing advice to the authorities (CeHoS, 2015). Ever since its foundation, the results of the Centre's investigations have been actively used to update regulatory authorities on new knowledge, provide them with scientific counselling and also answering specific policy-related questions in relation to EDs (Miljøstyrelsen, 2015b).

One example of this well-coordinated interplay between the latest science and regulation is evident in a Danish EPA project from 2009, dealing with combination effects. In this project, the typical daily ED-exposure of a two-year-old in Denmark was assessed, taking into consideration some of the possible combined effects resulting from the simultaneous exposure to several EDs. The results revealed that combined exposures to certain EDs needed to be reduced (Miljøstyrelsen, 2009b). This led to the set up an information campaign for parents to reduce children's exposures (Miljøstyrelsen, 2009a) and to proposing regulation for the combination effects of these EDs in Denmark and at EU level (Miljøministeriet, 2011; Miljøstyrelsen, 2015d).[85] Based on the same evidence, Denmark raised the issue of combination effects at EU

[84] Most often at the Centre for Oestrogenic Substances and the Centre for Endocrine Disruptors.

[85] The information campaign – "65,000 reasons for better chemistry" – was prepared with the intent to reduce toddlers' exposure to EDs, in particular phthalates and parabens (Miljøstyrelsen, 2009a). It was advised, for example to avoid children's cosmetics that contained propyl and butyl parabens (preservative agents used in cosmetics). At the same time, a national ban on these substances was implemented and an EU regulation proposal was initiated to lower the concentrations of these substances in children's products. Concerning the phthalates, a regulation proposal

level, which led to the ongoing EU Commissions work on how to take combination effects into account in future legislation (Miljøstyrelsen, 2015c).

At the same time, I would argue that the close relation between the Danish EPA and the Danish ED research environment has not only resulted in an active use of the latest research for regulatory purposes, but that it also has promoted a common understanding and a common frame for action between experts and regulators. On one hand Danish regulators have been exposed to an "endocrine scientific understanding" of the problem, while on the other hand, Danish researchers have been exposed to the particular needs and limitations of the present chemical regulatory system.[86] Over the years, both Danish experts and regulators have been trying to improve regulation. This has particularly been the case for the environmental sector where the Danish EPA and the Danish ED researchers have been: developing and improving standardized test guidelines for the detection and future regulation of EDs (Miljøministeriet, 2003, 2004, 2007; Regeringen, 2010), preparing the Danish criteria proposal for the identification of EDs (Miljøstyrelsen, 2011)[87] and more recently contributing to improve the regulation of EDs through REACH (Hass et al., 2013). This has also been seen in the food sector. For example, in Spring 2015, researchers at the Danish National Food Institute developed a toolbox to be used for the prediction of combination effects when conducting risk assessments in the food sector (to

for the combination effects of four phthalates (DEHP, DBP, DIBP, BBP) was initiated nationally and at EU level (Miljøministeriet, 2011). Phthalates are a group of chemicals that are used to soften plastics. They can easily be released from the plastics they have been added to, since they are not chemically bound to them.

[86] Examples of these limitations include: shortcomings of the commonly used toxicology model to assess the risk of EDs, limitations of the available standard test guidelines to cover EDs' properties, the potential underestimation of real risk when not taking into consideration combination effects, and many other (see section 4.3).

[87] The Danish proposal has been a very important contribution to the ongoing EU work on the development of common scientific criteria for the regulation of EDs in Europe. Denmark's proposal suggests three regulatory categories: 1) confirmed ED, 2) suspected ED and 3) indication of ED properties. EDs belonging to the "confirmed" category would not be authorized under the pesticide regulation, and would be treated as a substance of very high concern under REACH. The Danish proposal is very similar to the present EU Commission's option 3, which is the option supported by endocrine scientists and NGOs. Denmark's proposal is heavily contrasted by the joint German/UK proposal, which is based on the traditional risk assessment of chemicals and that proposes a potency-based cut-off criteria – meaning that only the most "potent" ED will be subject to regulation. This proposal corresponds to EU Commission's option 4, the one supported by the industry. Regulation based on potency has been heavily criticized as being largely arbitrary and not scientifically justifiable. It is also claimed that it will not offer much protection since it would lead to the regulation of just the few worst offenders (ChemicalWatch, 2012).

complement the conventional one-substance-at-the-time evaluation) (DTU-Food, 2015a, 2015d).[88]

5.3 The Danish framework for EDs

As described in the previous section, the early research on EDs - in particular the work of professor Skakkebæk - and the early intervention of the Danish EPA directed focus and resources on the ED topic. This was followed by a broad interest from the media, the public and, in particular, from politicians.

5.3.1 National Strategy on ED and the Chemical Action Plans

In 2002, the Danish Board of Technology organized a hearing on EDs at the Environment and Regional Planning Committee of the Danish Parliament with the aim of gathering different perspectives on the ED topic (Teknologirådet, 2002b). [89] The concluding advice was, among other things, to establish a multidisciplinary research center for EDs, to regulate based on a precautionary thinking without waiting for full scientific evidence and to strengthen information to the public (Teknologirådet, 2002a).

That same year, the Ministry of Environment and the Ministry of the Interior and Health presented a report (beretning) on EDs to the Danish Parliament which led to the establishment of the national strategy on endocrine disruptors (Folketinget, 2002). After five years, this national strategy was replaced by a broader chemical framework namely, that of the chemical action plans which have been going on for the last ten years (Regeringen, 2005, 2010, 2013). In this respect, it can be said that Denmark has had a long tradition of a common political wish to address the problems related to EDs and to increase the level of protection of Danish citizens.[90]

[88] This team of researchers looked into the combination effects of chemicals in food – and concluded that the combined exposure to low-doses of chemicals (with similar effects) could add to significant adverse effects. This information was used to develop a toolbox to be used for the prediction of combination effects when conducting risk assessments in the food sector. Even though ED were not particularly assessed, it was mentioned that when assessed they also represented a problem (DTU-Food, 2015a, 2015d).

[89] In general, the role of the Danish Board of Technology has been giving advice to policy makers on techno-scientific issues of public concern (such as cloning and genetically modified organism)(Teknologirådet, 2015). The advice on EDs was based on the input from a wide range of stakeholders, including: researchers from several disciplines, authorities from different governmental agencies, organizations (consumer organizations, environmental NGOs, industry and business representatives) and politicians (Teknologirådet, 2002b).

[90] Since 2006, all political parties in the Danish Parliament have agreed on three different four-year-term action plans (from 2006-2009, 2010-2013 and the last 2014-2017).

The national strategy and the action plans have in great measure outlined Denmark's long-term work with respect to EDs. In practical terms these action frames have guided national efforts in the field such as: funding research in EDs, working towards tightening EU chemical legislation; raising awareness among the general public, companies and politicians, and working on initiatives for safer consumer products among others (Planlægningsudvalget, 2002; Regeringen, 2005, 2010, 2013).

I will argue that these action frames (namely the national strategy on EDs and the different chemical action plans) have led to the emergence of what I will call a "Danish framework on EDs". This framework has in turned encouraged the establishment of networks of actors and processes that interact at different levels and in different ways towards the same goal – achieving a better regulation of EDs. In particular I will claim that the Danish framework on EDs and the resulting networks have contributed to the development of a common understanding of the problem at hand and to a better coordination of initiatives in Denmark and abroad. This will be the topic of the following section.

5.3.2 A common scientific voice

In the Danish framework on EDs, knowledge building has always been a priority. This interest has permitted a steady economic support for research in the field and the establishment of several research centers on the topic (Regeringen, 2010, 2013). I will argue that these Centers have played a very important role in gathering resources in one same place, in terms of expertise, funding and regulatory and political attention.[91] But most importantly, they have promoted the development of a common understanding of the ED issue in Denmark where they have functioned as brokers of this unified perspective and as a reference point for all stakeholders. A clear example of this unified understanding is that in Denmark, the scientific controversy around EDs is not nearly as polarized as it is in other places such as the EU and the US (personal communication with representative of the Centre on Endocrine Disrupters).

Looking in particular at the Centre for Endocrine Disrupters, one can see that this center has played an important role not only in coordinating research on ED among different disciplines

[91] This is not to say that all ED-related research in Denmark takes place at those ED- research Centers, but rather that the latter function as national reference points.

(including basic science, human toxicology, ecotoxicology, epidemiology, human hormone related pathologies, and many more), but also among different institutions - referring to the Center's three partner institutions: the Department of Growth and Reproduction at Copenhagen University Hospital, the Division of Toxicology and Risk Assessment at the National Food Institute (the Technical University of Denmark) and the Institute of Biology at the University of Southern Denmark (CeHoS, 2015). At the same time, the Center's annual working program is established by a steering committee chaired by the Danish EPA and including representatives from the National Board of Health, the Danish Veterinary and Food Administration and the Danish Working Environment Authority (Miljøstyrelsen, 2015b). In this respect, one could claim that the work conducted at the center is a reference not only across academic disciplines but also across different sectors (e.g. the environmental sector, the food sector, the health sector and the occupational sector).

Besides, given that the national expertise is gather in one place, it is not unusual that different regulatory agencies receive a common scientific advice on specific questions in relation to EDs. A clear example of this is the scientific opinion given on the toxicity of BPA (DTU-Food, 2010, 2015b). In this case, the National Food Institute, division of Toxicology and Risk Assessment, has been in charge of giving advice to the food agency on scientific matters concerning EDs, and in particular concerning the toxicity of BPA. And, at the same time, this same group of researchers is part of the Centre for Endocrine Disruptors and hence also a main advisor for the environmental agency (CeHoS, 2015). This means that both agencies have been receiving the same scientific input concerning the toxicity of BPA.

Dissemination of information to the external world

Besides its knowledge building and advisory activities, the Center on Endocrine Disrupters has also played an important communication role beyond the standard dialogue between scientists and regulators. Over the years, the Center's research and activities have attracted the interest of a broad spectrum of actors, including: international researchers, the general public, the media, politicians and civil organizations.

The Centre has for example contributed to the steady dissemination of knowledge by means of international scientific conferences and workshops (e.g. the International Copenhagen Workshops on Endocrine Disrupters) and through annual information days for the general public (CeHoS,

2015). Besides, its scientific achievements have continuous been covered by the media leading to a further dissemination of information.

At the same time, it has also been the case that researchers belonging to the Center have been called to present the results of their research to politicians, in particular to members of the Danish Parliament. In November 2014 for example, the Danish Parliament Committees on Health and Prevention and on the Environment arranged a hearing to get an update on EDs research from the Centre. In this occasion, the group working on BPA a the National Food Institute (DTU-Food) had the opportunity of giving a direct and clear message to the politicians, namely this scientific team did not agree with the preliminary conclusions reached by EFSA in their latest risk assessment of BPA and that the recommended European safe level did not adequately protect consumers against the endocrine disrupting effect of BPA (Folketinget, 2014a). Concerning the particular case of BPA, other more informal forms of communication have been witnessed. In 2009, for example, Professor Skakkebæk himself sent a letter to the Danish Parliament concerning the debate on the regulation of BPA where he advise politicians to use the precautionary principle when deciding on the regulation of this chemical.[92] However, in general most politicians are updated on the latest EDs news by the media and the work of some NGOs (personal communication with representative of the Red-Green alliance political party).

Last but not least, it can also be mentioned that researchers belonging to the Centre have also spread their knowledge through projects conducted in collaboration with NGOs. In Denmark there are two NGOs that are very active on the topic of EDs, these are The Danish Consumer Council (dealing mainly with consumer's interests) and The Ecological Council (dealing mainly with broader environmental and health related questions) (personal communication with representatives of both NGOs). In the last years, The Ecological Council has been working with scientists on a project named "better regulation of chemicals" dealing with EDs and cocktail effects. The objective of the project is to prepare "call-for-action" documents to inform Danish and European politicians on the latest scientific advice, to prepare teaching material, to organize seminars and give to advice on substitution of harmful chemicals (Økologiske-råd, 2013) .

[92] The letter can be consulted in the website of the Danish Parliament at: http://www.ft.dk/samling/20091/almdel/flf/bilag/82/772546.pdf

5.3.2 Coordination at the administrative level

During my interviews, it was brought to my attention that the Danish EPA has been the main actor when it comes to ED related work in Denmark (personal communication with representative of the DVFA). Yet, there is also a continuous effort to pull other agencies on board to promote collaboration across ministries and authorities on ED issues - with the ultimate intention of ensuring a better coordination throughout legislative areas. In particular, I was informed that there are two cross-ministerial meetings a year involving representatives from the Danish EPA, the Danish Veterinary and Food Administration (DVFA), the Danish Medicines Agency, the Danish Working Environment Authority, the National Board of Health and the Danish Enterprise and Construction Authority (personal communication with representatives of the DVFA and Danish EPA). [93] Although it was out of the scope of my work to investigate into the precise content and outcome of such meetings, I will argue that an example of such administrative coordination is evident in some national risk reduction strategies, in particular the ones dealing with soft-policy measures.

National risk reduction strategies for EDs.

In Denmark, both hard regulatory measures and soft regulatory measures have been used for managing health and environmental risks posed by EDs.

Hard regulatory measures refer to mandatory rules such as bans or restrictions on certain substances. These measures should preferably take place at EU level and should be mainly used when a *potential* risk has been identified (based on documented adverse effects and worrisome exposure levels). On important point here is that most regulations that concern EDs are harmonized within the EU (e.g. the legislation on chemicals (REACH), food contact materials, pesticides, toys, cosmetics, and many more). It is therefore difficult for member states to introduce national rules. However, in Denmark this has happened now and then, both in the environmental and the food sector, when the risks associated with certain EDs were assessed as unacceptable and not sufficiently managed by existing EU legislations (Dobel, 2011).

[93] Where the Danish EPA is in charge of industrial chemicals, consumer products, cosmetics, indoor climate, pesticides and biocides; the Danish Veterinary and Food Administration (DVFA) is in charge of food contact materials, and pollutants and additives in food; the Danish Medicines Agency is in charge of medical equipment and pharmaceuticals; the Danish Working Environment Authority is in charge of the working environment; the National Board of Health is in charge of semen quality monitoring and the general health of the population and the Danish Enterprise and Construction Authority is in charge of construction materials (personal communication with representative of the DVFA and the Danish EPA).

Examples of national regulations include: a Danish ban in 2010 for the use of BPA in all food contact material for children aged 0-3; followed in 2011 by a national ban on parabens (propyl- and butylparaben) in cosmetic products intended for children under 3 years. More recently, in 2012, Denmark decided to ban four phthalates (DEHP, DBP, DIBP and BBP) from consumer products. All of these regulations have been based on these chemicals' ED-properties and, in the last two cases, also based on potential for combination effects (Dobel, 2011).

Soft regulatory measures, on the other hand, refer to "alternative ways of protecting the consumer without resorting to regulation" (Sørensen, 2011, p. 7). This strategy is preferred when substances are *suspected* of having ED-effects or when the exposures are deemed unnecessary (Dobel, 2011). Soft regulatory measures are particular relevant for the regulation of EDs, since it is often the case that available evidence is insufficient to draw firm conclusions that allow the implementation of hard regulatory measures. Yet, it is also often the case that the evidence raises doubt and warrants caution. In cases of scientific uncertainty, contradictory evidence and inconclusiveness, Danish authorities have opted for the implementation of soft regulatory measures, while waiting for final answers. Targeted information campaigns, is a widely used soft regulatory measure in Denmark. The objective of these campaigns is to increase the chemical knowledge of selected consumer groups where it is particularly important to be careful. This is done by giving them advice on how to reduce exposures and on safer products.[94] The campaigns are based on the assumption that informed consumers might modify their behavior and consumption patterns leading to a risk reduction while waiting for hard regulation (Sørensen, 2011).

Several information campaigns have been launched in the last decade based on: the latest scientific evidence, typical Danish exposure patterns for vulnerable groups and on information coming from inspection activities on consumer products.[95] Even though most campaigns are prepared by the Danish EPA, other agencies have also been involved.[96] At the same time, the

[94] Additionally, I will add that such campaigns can also contribute to a more sustainable production where producers and suppliers have an incentive to apply for environmentally friendly ecolabels, such as the Nordic ecolabel (which certifies that labelled products are among the safer alternatives in the market when it comes to chemical content).
[95] The later refers to the inspection of the content of chemicals in consumer products and the assessment of their related risk (Regeringen, 2005, 2010).
[96] Examples are the 2002 campaign on "Stof til eftertanke – fakta om hormonforstyrrende stoffer". A booklet giving information to pregnant and parents of small children on what EDs are, which effects they have, and how to avoid them(Miljøministeriet, 2003). And the 2015 campaign "Gravid?, Kend kemien", giving advice to pregnant women

food agency DVFA has also set up its own information website: "Food with less chemistry" to give advice to consumers on food safety issues and chemicals in food.[97]

Since 2006, for example, the Danish EPA has been giving advice to soon-to-be-parents on how to minimize chemical exposure during pregnancy and infancy. In addition to the online information, some of the material has also been distributed through a network of midwives, general practitioners and maternity nurses – making Denmark one of the few countries (if not the only) where pregnant women are informed about the possible risk of EDs at the most crucial time. These campaigns have aroused much interest and have been repeated and expanded several times between 2005 and 2015 (Miljøstyrelsen, 2012).[98] The most important though, is that a later evaluation of one of these campaigns revealed that a large majority of the target group had indeed modified their behavior according to the authority's advice (Miljøministeriet, 2007; Miljøstyrelsen, 2015a).

Even though these campaigns in general concentrate in giving a general and easy to follow advice, they can also provide information on specific substances, such as BPA. In the 2015 campaign for pregnant, it is for example recommended to take extra care of the unborn child given their vulnerability to even small amounts of chemicals. Concerning BPA, it is mentioned that there is an ongoing debate concerning BPA's low-dose effects and recommend to stay away from handling thermal paper during pregnancy (Miljøstyrelsen, 2015e). The campaign's website also includes a link to the food agency's information website, where it is advised to avoid food packing made out of polycarbonate plastic and canned food during pregnancy and infancy on precautionary grounds: "Bisphenol-A is an endocrine disruptor. Infants and pregnant women especially, should therefore, as a preventive measure, choose a wrapping that does not contain bisphenol-A, when possible"(Fødevarestyrelsen, 2015).

5.3.3 Collaborations among stakeholders

At the same time, one can argue that the Danish framework on EDs has also encouraged collaboration and network-building of otherwise more distant stakeholders. The particular context

on how to minimize chemical exposures. Available at: http://mst.dk/borger/kemikalier-i-hverdagen/kampagne-gravid-kend-kemien/

[97] Available at: http://www.foedevarestyrelsen.dk/kampagner/madmedmindrekemi/Sider/default.aspx

[98] The three campaigns have been "Nine good habits for pregnant and nursing mothers" (9 gode vaner) from 2006, "Ready for the stork" (klar til storken) from 2012 and "Pregnant, know the chemistry" (Gravid? Kend kemien" from 2015

in Denmark (perhaps together with this country's deliberative culture) has contributed to pull more actors into the debate concerning the regulation of EDs (and BPA). As an example of how these different actors have been interacting at different levels and in different ways in the regulatory processes (be it hard policy or soft policy measures) will be presented below:

The Danish EPA has, for example, been experimenting with new types of consumer information through collaborations with NGOs. Such an example is the joint project with the consumer organization the Danish Consumer Council - dealing with consumers' right to be informed about the chemical content of products (Miljøstyrelsen, 2014c).[99] Another example is the financial support and collaboration with chemical watchdogs, such as Chemistry Watch ("Kemiwatch") - whose objective is to give advice to consumers and put extra pressure in the industry: "The Danes will have a new watchdog, who shall help consumers to find their way in the jungle of chemicals, and simultaneously keep a firm grip on the industry"(Miljøstyrelsen, 2014b).[100] These chemical watchdogs usually used a wider safety margin than the authorities – thinking on those consumers that want to be extra careful (IMS, 2009). Chemistry Watch conducts chemical analyses of different consumer products and publishes tests that help consumers to avoid problematic chemicals. They also give advice and spread information on chemicals through their website, social media and via a hotline (Forbrugerrådet, 2015).

At the same time, the Danish Consumer Council and the Ecological Council (the other Danish NGO working on EDs) are also good at bridging what is going on at the national level and at the European level with respect to EDs. They have for example been following the different European processes with respect to the development of criteria for the identification of EDs and

[99] The campaign refers in particular to chemicals listed in the so-called Candidate List (See REACH section for more information). REACH regulation article 33 which states that suppliers of articles that contain candidate list substances in a concentration above 0.1% weight/weight have the obligation to inform their customers about the content and safe use of the article in case of request. The answer must come within 45 days. Through an app, consumers are able to scan the barcode of an article and send a request to the manufacturers. A database compiles the answers so that the information is available to other consumers. The database also allows searching for articles that do not contain Candidate List substances, making it easier to identify and select this type of products. For more information on the campaign, see http://www.tjekkemien.dk/

[100] Denmark has had a "chemical watchdog" since 2003: the Information center for Environment and Health (Informationscenter for Miljø & Sundhed – IMS). This center provided independent information and advice to consumers concerning chemicals in products (Regeringen, 2010). Its work complemented the general information from the authorities with specific product surveys and to identifying and naming the good and the less good products in the market (IMS, 2009). After, 10 years in operation, it closed in 2013 due to lack of funding (which came from the CAPs. The intense critique that this caused led to a new allocation of fund for Chemistry Watch in 2014) (Politiken, 2013).

have been active in the debate through their European sister organizations (personal communication with representatives of both NGOs). The Danish Consumer Council has for example encouraged Danish citizens to participate in the public hearing related to the impact assessment on EDs going on at the EU Commission.[101] These two NGO's have also been active in raising Danish awareness on broader processes that affect European (and thus Danish) chemical legislation such as the Transatlantic Trade and Investment Partnership (TTIP) (Økologiske-råd, 2015). [102] They have also been working to strengthen consumer and political awareness in the EU through dissemination of the latest Danish research. In this respect, one can argue that the work of these actors has been supplementing the efforts of the Danish Government with respect to ED legislation at the EU level (Forbrugerrådet, 2015; Miljøstyrelsen, 2014b).

Other types of collaborations among a broader range of stakeholders have also been proposed. In 2013 a chemical forum (composed of authorities, industry, trade associations, retailers, consumer organizations and NGOs) was established to soften different perceptions among stakeholders concerning problematic chemicals, including EDs. The objective of the chemical forum is to promote communication and collaboration among stakeholders to find common solutions to the problem of hazardous chemicals in consumer products (Regeringen, 2013).[103]

One can also argue that the Danish framework on EDs has been an incentive for business enthusiast to be frontrunners. In Denmark, as opposed to many other countries, the national context has enabled the development of a big market for health and environmentally friendly products. For some companies, the development of such products has been a great commercial success. For example, Denmark's biggest retailer COOP has had for several years an internal policy to remove all EDs from its brand products, which in practice means that COOP's requirements go many times further than current legislation (EurActiv, 2013).[104]

[101] Through common European campaigns such as: https://www.no2hormonedisruptingchemicals.org/da
[102] The ongoing debate has been that American and European chemical regulation are very different and that acceptance of the TTIP (that is, the avoidance of trade barriers) might imply that Europe will have to adopt the weaker chemical safety standards of the US.
[103] For example by facilitating the coupling of consumer's demand for environmentally friendly products to the industry's motivations for innovation, promoting voluntary phasing-outs and substitutions, etc. Even though there has been skepticisms from both NGOs and the industry on what can really be achieved by such forum (personal communication with representative of the Danish Consumer Council), it seems that the forum has finally found some common concrete demands.
[104] "COOP's policy is that we really want to make use of the precautionary principle when we believe the legislation is imprecise or not strong enough and if we know that alternatives, that can be used, exist. Why wait for the

Finally, it should also be highlighted that occasionally the direct participation of the public has also taken place. In 2009 for example, Danish citizens were invited to participate in the public event "What do you think is good chemistry?", organized by the then minister of environment Troels Lund Poulsen (from Venstre). During this event, the public could directly talk to the minister or simply vote for the chemical themes that they believed should be covered or solved by the chemical action plans (Miljøministeriet, 2009).[105]

5.3.4 A unified Danish position towards the EU

In Denmark, as in any other country following the rules of the European single market, there is a big focus on EU level rules. The vast majority of chemical regulations in Denmark are the result of EU legislation, and at the same time, a large amount of chemicals come into the country from abroad (by trade or via the environment). As a result of this, it has for a long time been acknowledged that the best way of promoting Danish interests in the chemical field, is through an active participation at EU level. Besides, it is also recognized that European solutions promote longer environmental and health protection and a more efficient use of resources. This European focus is particularly evident in the work of the different Danish agencies, which are particularly reluctant in proposing national Danish rules (referring to hard regulatory measures). Instead, Danish authorities are commonly instructed to tackle chemical issues at EU level (Regeringen, 2005, 2010, 2013).

What is distinctive of the Danish contribution to the EU work is that, as explained in previous sections, the governance context in Denmark has promoted a rather common, unified and I would add, more influential Danish position. Danes are often seen as front runners, that come to Brussels with strong scientific arguments, expertise and motivation to influence and guide action at EU level (ChemicalWatch, 2014).

As mention somewhere else, Denmark has been very active on ED-related work at the EU level including: the Danish criteria proposal for the identification of EDs, their work towards the inclusion of combination effects in future legislation, their efforts to improve REACH and more

endocrine-disrupting substances to have an effect if we have the opportunity to use other substances?" (EurActiv, 2013)

[105] For those that could not attend to the event, it was possible to participate and vote through the social media, EPA's website or by meeting with the minister whose door was open for citizens on the last Friday of every month (Miljøministeriet, 2009).

recently, even a national expert has been sent to the EU Commission to contribute on the ongoing EU legislative work on EDs (Regeringen, 2013). Given the current evidence-based policy focus in the EU, it is easy to understand that the most valuable currency when negotiating policy issues at the EU Commission is "scientific evidence". In this respect, Denmark's interests have gotten an upper hand in Brussels.

At the same time, Denmark has also used other political means to influence EU work on EDs such as the implementation of stricter national rules that challenge harmonized EU legislation (Dobel, 2011), suing the EU commission for delaying the establishment of ED criteria (HEAL, 2015), through collaborations and joint initiatives with other equally minded countries to put collective pressure on the commission (including Norway)(ChemSec, 2014), through the work of Danish members of the European Parliament, and so on (Dagens, 2012).

Danish influence, is however not limited to the traditionally official channels. As explained before, Danish NGOs (and Danish citizens) have also been calling for a stronger regulation of EDs at EU level (Økologiske-råd, 2013). For example, through the work of Danish NGOs, Danish citizens were able to participate in the EU Commission's public consultation on defining criteria for identifying EDs (EC, 2015b).[106] At the same time, Danish researches have also participated in different publications calling for action and highlighting the public health relevance of the regulation of EDs (Skakkebaek et al., 2011; Trasande et al., 2015).

5.4 Conclusions

In this chapter I have argued that the Danish framing of the ED-issue has a strong public health component, related to its medical origin and the work of Professor Skakkebæk. It is for example remarkable that in Denmark, very often, EDs are discussed in connection with well-known negative health trends in the country such as: bad semen quality (linked to decreased fertility), increase in the incidence of testicular cancer and more recently, Danish girls reaching puberty earlier (parliament and newspaper). This is not to say that the environmental dimension is

[106] A report summarizing the results of the public consultation reveal that "Individual responses (as opposed to responses of behalf of organizations) accounted for more than 90% of the responses received. Of these individual responses, 88% came from seven Member States (Austria, Denmark, France, Germany, Spain, Sweden and the United Kingdom)" (EC, 2015b, p. 1)

forgotten, yet it seems that most of the research conducted in Denmark and most of the regulations proposed by Denmark have to do with human health implications.[107] At the same time, an analysis of the different documents released by the center on endocrine disrupters and the Danish EPA, reveal that the ED-issue in Denmark is mainly based on what I have called an "endocrine-perspective".

At the same time I have claimed that the early political interest on EDs, in particular the establishment of the national strategy on EDs and the different chemical action plans has promoted the establishment of what I have called the "Danish framework on ED". This refers to the country's long-term strategy and objectives with respect to EDs. I argued that this action framework has also directly and indirectly, encouraged the development of different networks of actors and processes that have been interacting at different levels and in different ways towards the same overall goal – the better regulation of EDs.

In this respect, the governance of EDs in Denmark is characterized by a multitude of processes and structures (actors and institutionalized procedures) which interact 'to steer' the national management of EDs (and many times also the international management of EDs). The processes refer mainly to how the problem is understood (and possibly solved), setting national priorities and coordinating action. I have for example highlighted the importance of the knowledge-building process in Denmark. In particular, I have claimed that the national focus on ED-research has contributed to a common understanding of the problem and as a reference point for action. Such action (or initiatives) have in turned been 'administered' and organized through a variety of actors and different sets of established procedures.

The actors - such as regulatory agencies, experts, NGOs, industry, politicians and the public - represent different perspectives and have different capacities to act. Most of the time, these actors act in accordance to institutionalized procedures - such as proposing regulation, publication and dissemination of scientific findings, raising awareness among the population, promoting political discussions at the parliament and participating in deliberative exercises, respectively. One can see

[107] For an overview one can visit the website of the Centre for Endocrine Disrupters at: http://cend.dk/index.html

that the degree of formalization within the different institutionalized procedures varies a lot, with the action taken place at the public administration level being perhaps the most formal. In practice, it is difficult to accurately describe the governance mechanism given that the different processes and procedures are messy and often, the rules-in-paper differ from the rules-in-use, in particular when working towards trying to influence decisions at the EU level.

At the same time, as explained in the theory chapter, the governance concept (and in particular risk governance) provides more than a descriptive model. With respect to tis normative dimension, risk governance calls for the development of more inclusive and deliberative governance models to deal with uncertain risk. In this respect, I will argue that in Denmark, the participation of a variety of actors and the development of a variety of processes has led to a more robust and resilience management of EDs. The diversity of actors has for example contributed with a variety of sources of information, logics of action, different normative standpoints, variety of perspectives and interests. This has promoted the development of different initiatives to manage ED-risk at different levels and based on different motivations. As illustrated throughout this chapter, several of these initiatives overlap in certain ways and create redundancy. I will claim that this redundancy results in less ED-vulnerability and consequently more resilience. For example, the "Danish framework on EDs" helps to coordinate initiatives at the administrative level, where regulatory agencies convey clear and consistent messages. This information is in turn complemented through the coordinated initiatives of other stakeholders. NGOs give consumers advice on specific questions (via hotlines and social media), help consumers find safer products, promote consumer participation in broader EU initiatives (dealing with ED-regulation). Danish experts, on its part, disseminate information on EDs and sometimes participate in call for regulatory action initiatives. Business forerunners are also seizing market opportunities with respect to the development of safer (certified) products. Several members of the Danish Parliament are engaged in the political debate on how to best regulate EDs. And, at the same time, there are coordinated and unified efforts towards influencing regulation at the EU-level.

I will finally claim that the particular way EDs are 'governed' in Denmark has reinforced its political salience. In this respect is not surprising that these chemicals are many times discussed

in the Danish Parliament and that policy-decisions are taken at the political level. In the next chapter, I will explain how such political debates have dealt with questions of scientific uncertainty and acceptable level of risk, in particular when it comes to regulation of BPA.

6. The BPA-case in Denmark

In this section I will look at the BPA policy process in Denmark. In particular, I will present the different proposals for regulation that have been introduced and debated at the Danish Parliament in the last six years. This gives a unique insight into how scientific uncertainty is dealt with in the political context. My analysis will be mainly based on "the precautionary model" as outlined in theory section (2.3.2.). The main idea of this model as presented by Funtowicz (2006) , is that in cases of scientific uncertainty and inconclusiveness, policy-decisions can be complemented with precaution. I will in particular explore two questions:

1) Under which circumstances, and on which grounds should the precautionary principle be used?, and 2) How to weight the proportionality between the cost of regulation and the benefits of precaution?

6.1 The political interest in EDs

6.1.1. Danish politics and endocrine disruptors

Political parties

Denmark has a multi-party system with many political parties represented in the parliament. Broadly speaking the parties can be divided into two main blocs: a red bloc on the center-left of the political spectrum, and a blue bloc on the center-right.

The main parties in the red bloc are:

- The Social Democrats – Socialdemokraterne (S)
- The Danish Social Liberal party – Radikale Venstre (RV)
- The Socialist People's party – Socialistisk Folkeparti (SF)
- The Red-Green Alliance – Enhedslisten (EL)

And in the blue bloc:

- The Liberal party of Denmark, Venstre – Venstre (V)
- The Danish People's party – Dansk Folkeparti (DF)
- The Conservative People's party – Det Konservative Folkeparti (DKF)
- The Liberal Alliance – Liberal Alliance (LA)

Endocrine disruptors on the Danish political agenda

One can say that in general there is a high political interest in the area of chemicals among Danish politicians – in particular when it comes to EDs. As can be seem from the continuous and unanimous support in the Danish Parliament – the "Folketing" – for the establishment of the national strategy on EDs and the renewal of the different chemical action plans (Planlægningsudvalget, 2002; Regeringen, 2005, 2010, 2013) .

At the same time, several political parties, in particular those in the red block, seem to have an even stronger interest on EDs. For example, all red-block parties have explicit policy goals for EDs in their overall environmental policy objectives – even if their corresponding policy goals vary somehow among parties. For the social democrats safe products are important (Socialdemokraterne, 2015), while, for the social liberals the focus should be on more research (since regulation only moves forward with scientific evidence)(RadikaleB, 2014). For the Socialist People's party, it is absolutely necessary to improve European legislation on EDs (SF, 2015) and the more radical Red-Green Alliance supports the prohibition of all EDs (when safer alternative are available). This small leftwing socialist party encourage the use of the precautionary principle in cases of scientific doubts and warns against compromising public health vis-à-vis the interests of the European single market. Not surprisingly, it is mainly the Red-Green Alliance (and the Socialist party), sometimes with the support of other red-block parties, that has played the most active role in keeping EDs high on the political agenda of the Danish Parliament (Enhedslisten, 2015). This has been done through its work in the Parliamentary Committees, namely by constantly questioning the ministers on smaller and larger issues related to EDs and by regularly putting forward rather ambitious proposals for the regulation of EDs.[108]

Another important difference among the red-block parties concerns their overall European policy, namely that they have different opinions concerning whether regulations should take place at national or at EU level. For the EU-friendly parties (the Social Democrats, the Social Liberals and the Socialist People's party), regulatory processes should preferably take place at EU level by contributing with scientific evidence, proposing stricter EU regulations and applying political pressure. For the Red-Green Alliance, a known European skeptic, regulatory processes should start at the national level (Folketinget, 2009b, 2009c).

[108] For an overview one can consult the website of the Danish Parliament: http://www.ft.dk/

For the blue block parties on the other hand, there seems to be less concrete interest on the topic, except maybe for the Danish People's party (another known EU-skeptic) which, in general is positive to stricter regulations for children's products (Folketinget, 2009b, 2009c). For the remaining parties in the blue-block, regulation should unequivocally take place at the EU and should be as industry-friendly as possible (Folketinget, 2015).

Some of the above-mentioned general positions with respect to ED and EU policies have been reflected since the beginning of the ED-issue in Denmark. Namely, that the red-block parties have been more eager to go further when it comes to EDs. A quick analysis of the "political input to the national strategy on EDs", reveals that the center-right government and supporting parties (the blue-block, which represented a majority) wanted to focus on research and EU work, while the opposition (the red-block, which represented a minority) saw a need to complement knowledge building activities with efforts on regulation based on the precautionary principle (Folketinget, 2002). For example, the Government demanded BPA to be included in the Danish EPA's List Of Undesirable Substances (LOUS) – given the available evidence on its ED-properties and the fact that has not been previously regulated (The LOUS is a signal list that signals which chemicals are in the scope of future regulation). The opposition on the other hand, wanted a BPA ban given that BPA was a "documented" ED according to the European list of EDs and that the available EU risk assessment had concluded that there were ongoing uncertainties (referring to the (SCF, 2002) assessment)(Folketinget, 2002).

The Danish Parliament – the Folketing

To understand the BPA case, it is necessary to understand some of the main traits of the Danish parliamentary situation. Denmark has a parliamentary tradition of minority government. This means that governments do not control a majority of seats in parliament (Andersen, 1997). This means that sometimes, when EDs have been discussed in the Parliament, it has been possible to experience a so-called parliamentary "alternative majorities" – that is, a majority in the Parliament which has pressured the ruling government into introducing more ambitious policy goals that they would not otherwise have pursued. This has many times resulted in "top-down" national ED policies that have been decided at the Parliament (sometimes out winning the corresponding administration and challenging common European rules). One such example is the

ban on BPA (but it has been seen for other EDs such as parabens). These top-down decisions usually start with a proposal for parliamentary resolution.

Proposal for Parliamentary resolution

A proposal for a parliamentary resolution is a request to the Government to take action, such as introducing rules or preparing bills with a specific content. The proposals are prepared by one or several members of the Danish Parliament (MPs). They are usually subject to two readings in the Chamber (two political debates) with a stage in between where the work is further referred to the corresponding standing Committee (Folketinget, 2014b). [109]

In the committee, MPs keep working on the proposals and at the end of their work they issue a report which includes possible amendments and collects the positions of each political party. The committee can submit questions to the corresponding Minister and it can also receive visits from other interested stakeholders on the topic(Folketinget, 2014b). For BPA's case, the Committee working on the different proposals has been that of Food, Agriculture and Fisheries (Folketinget, 2009b).[110]

Some proposals for parliamentary resolutions do not make it to a second reading at the Chamber and the case is either discarded or worked only at the committee level. For those proposals that do make it to a second reading, the political debate at the Chamber is based on the Committee's report. Usually at this stage most details have fallen into place and the proposal for parliamentary resolution can proceed to a vote. If a majority of the Parliament supports the proposal for resolution, then the latter is officially adopted by Parliament. A large majority of the parliamentary resolutions are put forward by the opposition parties, which means that most of them are not adopted by the Parliament at the end (Folketinget, 2014b). Bisphenol A has been debated four times in the Danish Parliament in connection to four different proposals for parliamentary resolutions in a period spanning from 2009 to 2015 (Folketinget, 2009a, 2009b, 2010a, 2015).

[109] The Danish Parliament has 23 different standing (or permanent) committees, each working on specific areas of competence (e.g. The Committee on Environment and Planning; The Committee on Food, Agriculture and Fisheries, and so on, with one committee for each ministry). The Chamber of the Danish Parliament is where MPs debate political issues and vote on bills and proposal for parliamentary resolution (Folketinget, 2014b)

[110] In the Committee, each political party is represented. The Food, Agriculture and Fisheries Committee's areas of competence and responsibility correspond to that of the Ministry of Food, Agriculture and Fisheries (Folketinget, 2014b)

6.2 Bisphenol A in the Danish Parliament

Bisphenol A's proposals for parliamentary resolution:

B101: Proposal to ban BPA in baby bottles
B42: Proposal to ban BPA in food contact material for children aged 0-3
B17: Proposal to ban BPA in all food contact material
B68: Proposal to follow the recommendation from DTU-Food's 2015 assessment on the safety of BPA

During proposals B101 (2009), B42 (2009-2010) and B17 (2010), a blue bloc coalition between Venstre (V) and the Conservative People's party (DKF) was in power, supported by the Danish People's party (DF). For the most recent proposal, B68 (2015), a red bloc coalition between the Social Democrats (S) and the Danish Social Liberal party (RV) was in power, supported by the Socialist People's party (SF) and the Red-Green Alliance (EL).

6.2.1. Under which circumstances, and on which grounds should the precautionary principle be used?

Proposal for parliamentary resolution B101 (2009)

In February 2009, the Red-Green Alliance (EL) put forward the proposal for parliamentary resolution B101, where it is demanded: to stop the use and sale of products containing BPA by means of implementation of national regulation (Folketinget, 2009d).

The proponents of B101 justified the proposal based on the results from recent scientific assessments that had concluded either that: BPA posed a health risk to humans at current levels of exposure (Chapel Hill, 2007), or that there was "some concern" related to possible low-dose BPA effects (See NTP-CERHR, 2008 and Health Canada, 2008) (Figure 7). It was further noted that BPA was widely used and that babies and small children were particularly at risk. The proponents also mentioned that the American State of Chicago and Canada had banned the use of BPA in baby bottles, and that Nordic members of the EU Parliament had also started a petition to ban BPA in Europe. In particular, the Red-Green Alliance was of the idea that EU regulatory decisions (based on EFSA's recommendations) should not prevent Denmark from having stricter environmental and health regulations. Instead, Denmark should use the opportunities that were in the EU system to protect its citizens, in particular by the use of the safeguard clauses in the EEA agreement (Folketinget, 2009d).

During the first reading of proposal B101 in the Chamber (in May 2009), the Red-Green Alliance proposal was welcomed and supported by the opposition (red-block parties), which also considered that there was enough evidence to support regulatory action on BPA (Folketinget, 2009b).

In particular, the Red-Green Alliance member of the Parliament (MP) highlighted that there was enough scientific evidence about the negative health effects of BPA at low doses. Consequently, this party wanted to make use of the precautionary principle and introduce special national regulation in this area. In their opinion, the reasoning of the precautionary principle prescribed that: when there were suspicions that a chemical was dangerous one could, on precautionary grounds, prohibit it until this was clarified – solving the problem of having to wait to have conclusive scientific evidence before acting (Folketinget, 2009b).

This position was supported by the Social Democrats (S) who were willing to support a national BPA ban on food contact material (FCM) and to demand the Government to work towards strengthening EU regulation in this field. For the social democrat MP, the decision was based on the conclusions from a recent BPA workshop, organized by the German environmental authorities and including leading international experts on the field. Namely, that there was *disagreement* among scientists concerning the amount of BPA that was necessary to induce negative effects and as a results of this, it had been recommended to take a precautionary stance with respect to products that were in direct contact with people (such as FCM). At the same time, this MP also mentioned that he has been notified of the fact that BPA's current tolerable daily intake (TDI) had been based on only two industry funded studies – while a big number of studies, done at independent university laboratories reporting effects at low doses have not been taken into consideration. This MP was also of the opinion that Denmark should not worry to get into troubles with the EU (if introducing national regulation on BPA) since there was enough evidence to invoke the precautionary principle to safeguard children's health (Folketinget, 2009b).

The Socialist People's Party (SF) added that Denmark had precedent in introducing special national regulation to manage chemicals of concern to ensure high environmental and health standards. When this had happened, it was stressed, Danish national regulations ended up being

adopted by the rest of the EU. This party believed that the same would happen this time with BPA (Folketinget, 2009b).[111]

For the ruling Government and their collaborators, on the other hand, there was not enough scientific evidence of the possible risks posed by BPA, and at the same time, this was a problem that needed to be dealt with at EU level (Folketinget, 2009b).

The Minister of Food, Agriculture and Fisheries, Eva Kjer Hansen (from Venstre) highlighted that EFSA's 2008 scientific opinion on BPA had concluded that the current BPA exposure for babies and children was well below established safety limits and therefore safe. She acknowledged that uncertainties concerning the effects of BPA at very low exposures had been rising recently. Yet, she stressed that this problem had to be solved at the EU level. In this respect, she had already approached the EU Commission to demand more research to clarify the ongoing uncertainties. She noted that such investigations were under way and that EFSA would come with a new opinion in the beginning of 2010 (Folketinget, 2009b).

The minister stressed that the introduction of special national regulation required that *proper and well documented scientific evidence* was available, showing a health risk at current levels of exposure. For the time being, she highlighted, such evidence did not exist and consequently, no BPA regulation could be considered. She argued that at present, there were only *suspicions* based on the fact that different studies had concluded differently with respect to the safety of BPA. Her position and that of the Government was to wait for EFSA's coming opinion in order to have proper scientific documentation, and then work on a common European regulatory decision based on that. It was particularly emphasized that working at the EU level was part of Denmark's EU agreement – namely, to respect common EU regulation and to comply with the rules of the internal market (Folketinget, 2009b).

The MP from the Conservative people's party (DKF) emphasized that it was particularly problematic that "EU-friendly parties" (such as the socialist people's party , the social liberals but in particular, the social democrats) wanted to introduce national special rules – knowing that these were against EU cooperation principles and that Denmark could risk ending up with a dispute in the European Court of Justice. For this MP efforts should be directed towards more

[111] In particular, the socialist people's party referred to a ban on phthalates in toys for toddlers from 1998 introduced by the Social Democrat Minister of Environment Svend Auken.

developing the scientific basis for deliberation instead of looking into national regulation (Folketinget, 2009b).

However, the MP from Venstre noted that the Government wanted to address the *uncertainties* that had been reported in the media concerning BPA in baby bottles and was going to look into a voluntary agreement with the industry to reduce the use of BPA in such a product (Folketinget, 2009b).

Given that the opposition (S, SF, RV and EL) was supporting the proposal and the Government coalition (V, DKF) was against the proposal, the position of the remaining Danish People's Party (DF) – a known skeptic of the EU system – became very important (since this party's votes would define the majority in the Parliament) (Folketinget, 2009b).

The Danish People's party MP expressed that his party was very concerned about small children's exposure to BPA, which were the most affected by the possible negative health effects of BPA. As a result of this, they were positive to remove BPA from baby bottles as soon as possible. They saw that parts of the proposal were very close to the party's vision (namely that Denmark should not depend on EU-based decisions to protect small children from BPA), but could not support the resolution the way it was formulated at that moment (i.e. a total stop of the use and sale of products containing BPA)(Folketinget, 2009b).

After the political debate, the proposal for resolution B101 was referred to the Food, Agriculture and Fisheries Committee where two amendments were proposed. The first, proposed by the social democrats, was to limit the ban to FCM (i.e. the ban should only cover food-related products, including plastic bottles). The second amendment, proposed by the Danish People party, was to restrict the proposal even more, just to cover a ban in baby bottles. After the amendments, the new proposal from the Parliament was: to introduce a national ban against the use of BPA in baby bottles and at the same time work at EU level to ensure a stricter regulation of BPA. This new version was submitted to a vote and was supported by a majority of the Parliament. The opposition was particularly pleased to see that there was a majority in the Parliament willing to act on BPA by taking preventive political decisions related to public health (Folketinget, 2009c, 2009e).

Proposal for parliamentary resolution B42 (2009-2010)

Just some months after the adoption of B101 by the Parliament, a united opposition (EL, S, SF and RV) presented a new proposal for parliamentary resolution concerning a BPA ban in all food contact materials in Denmark (the B42 proposal). This proposal also stipulated to work together with other member states and the Commission to promote a BPA ban on FCM at the EU level (Folketinget, 2009a).

During the first reading of B42 in the Chamber, the minister of Food explained that in order to introduce special national regulations, a number of very clear requirements – which were specified in the environmental safeguard clause – needed to be fulfilled. Among those requirements, was the need to provide new scientific *evidence documenting a health risk*. Yet, the minister noted, in the case of BPA the available scientific evidence *did not prove that BPA was dangerous* and neither was there new scientific information proving the possible harmful effects of BPA (Folketinget, 2009a).

Consequently, the Government had decided not to follow parliamentary resolution B101 concerning the national BPA ban on baby bottles, as this was seen to go against Denmark's binding obligations under EU law. The same applied to the new proposal for resolution B42 related to a national BPA ban on FCMs. The MP from Venstre added that B101 and B42 would injure the Government's responsibilities by imposing resolutions that would bring Denmark in conflict with EU rules related to the internal market (Folketinget, 2009a).

The opposition on the other hand, considered again that there was enough scientific evidence to call for the implementation of the precautionary principle.

The Red-Green Alliance stressed that one should not expect to have one scientific truth concerning the safety of BPA. And that, the EU system opened for the invocation of the precautionary principle in situations where there was *scientific disagreement* and *the risk was substantial*. It was also pointed to the political dimension of the problem, namely that politicians could have a saying concerning the level of risk that was socially desirable: "[T]here is also the political reality, that we sometimes say, that we are not willing to accept any risks, that we believe are too big" (Per Clausen) (Folketinget, 2009a)

For the Social Democrats the conditions to use the precautionary principle were also met. They noted that there were many assessments and many ways to evaluate BPA. There was information showing that there was a problem and also information showing the opposite. They acknowledged that there was always going to be disagreement between experts and thus, it was a political decision to decide whether the precautionary principle should be invoked (Folketinget, 2009a). Likewise, for the Social Liberal party, precaution should be invoked in cases of doubt, and particularly, when there is so much at stake in terms of public health (Folketinget, 2009a). The opposition also questioned the implicit understanding among the parties in the Government that only EFSA's scientific evidence could be used as the basis to decide on BPA's regulation, and for this sake to decide on whether or not one could invoke the precautionary principle. Some members of the opposition were also very critical to EFSA's conclusions, pointing to the particular political-economic context in which this institution operated and to the fact that the majority of the studies showing low-dose effects were not accounted for in EFSA's risk assessment of BPA: "[W]e must simply acknowledge, that when the European Food Safety Authority rejects 698 studies of bisphenol A – they will not even look at it, because they do not comply with the demands, that EFSA places on studies – we have indeed a real problem. We should perhaps look at the way, in which studies are assessed in the European Food Safety Authority, so that minor studies will also have an effect. Studies from The Centre on Endocrine Disruptors, located at Copenhagen University Hospital, who have a broad knowledge in this field, has time and again said, that bisphenol A is a big problem." (Pia Olsen Dyhr) (Folketinget, 2009a).

The opposition's EU-friendly parties noted that their parties in general want to follow EU rules but that in BPA's they could not afford ignoring the warnings. Plus, they noted that it would be hard for the EU to file a court case against a member state for protecting the health of its population (Folketinget, 2009a).

The position of The Danish People's party (DF) was again crucial for the future of proposal B42 (as it had been for the previous B101), namely that the votes of this party were decisive to gather a majority in Parliament. This party kept noting that they were still very nervous with respect to small children and BPA. Therefore they were willing to use the precautionary principle for products that were intended for children between 0-3 years of age. However, they would not

consider a general ban on FCM until EFSA's 2010 opinion was published. Since they were afraid of using the precautionary principle too much: "[T]here are unfortunately many different answers in this area [...] I am therefore becoming a little nervous that we might end up using this precautionary principle too much if we remove entirely in an entire field, that is – also in the adult field, to put it that way, because we might suddenly use this in many products." (Rene Christensen)(Folketinget, 2009a).

The proposal for resolution B42 was referred to the Food, Agriculture and Fisheries Committee where one amendment proposed by the Danish People's party was included. During the second reading in the Chamber, the proposal was modified one more time to narrow the scope from all products for children to just FCM for children. After these amendments, the new proposal from the Parliament was: to ban BPA in FCM for children between 0 and 3 years of age (Folketinget, 2010c).

In the time between the two readings at the Parliament, the opposition raised the question to the Commission via a member of the EU parliament, of whether or not Denmark could use the precautionary principle in BPA's case. The answer was that Denmark could use it if they had new scientific evidence to justify its use. Hence much of the discussion in the second reading of B42 was about which scientific evidence counted to justify the usage of the precautionary principle. For the government, there was no hesitation, it was only EFSA's or DTU-Food's documentation that were valid (Folketinget, 2010c).

During the second reading of the new version of B42 in the Chamber, the minister stressed that the implementation of the precautionary principle demanded more than just emotions. She argued that scientific documentation concerning the health risk of BPA was required in order to call for a ban based on precautionary grounds: "[…] according to the rules we play by in the EU, there must be some particular precise reasons, for us to apply the environmental clause, and if we are to use the environmental guarantee there are clear demands, as to what must be fulfilled with regards to documentation[…]"(Eva Kjer Hansen)(Folketinget, 2010c).

However, one can note a change of attitude in the Government's and the minister's position. There is in general less emphasis on common EU regulatory decisions and more emphasis in getting a hold of such required documentation to justify the use of the precautionary principle:

"Let me end by saying, that we in Venstre would very much like to take part in in effectuating a ban and to stand alone on that [in the EU], but it requires that we have the necessary documentation." (Henrik Høegh)(Folketinget, 2010c)

This change in attitude can be explained by the fact that the government is confronted with a clear majority in Parliament who support the new version of B42 – and also to the fact that it would be hard to ignore, for a second time, the demands of a parliamentary resolution concerning BPA.[112]

The MP from Venstre noted that the government had succeeded in establishing a voluntary agreement with the industry to remove baby bottles containing BPA from the Danish market. And that the European metallic can association was working to find substitutes for BPA in metallic cans (which was one the main sources of exposure to BPA in FCM) (Folketinget, 2009a).

The minister added that she had been putting pressure on EFSA to make sure that all relevant evidence is taken into consideration in the ongoing European evaluation (including research conducted in Denmark). Yet, she noted that the Danish government was not happy with the long response period of EFSA and that it has been decided to ask the Danish experts at the National Food Institute (DTU-Food) to make a rapid evaluation of BPA that was expected to be ready just within some weeks. If this Danish evaluation concluded that there was a risk, the minister would then introduce special national regulation: "If the Danish analysis, that will come in the end of March, shows that there is a risk, then I will on those grounds seize the precautionary principle and use it to create a special rule for Denmark." (Eva Kjer Hansen)(Folketinget, 2010c).

The opposition on the other hand, could not understand why the government wanted to wait for more evidence before deciding on the regulation of BPA. They even saw this as a tactic to delay preventive action. Some parties even accused the Government for prioritizing industry's interests over consumer's interests. For the opposition there was enough evidence to back up the usage of

[112] The Red-Green Alliance (EL) was also very critical to the fact that the Government has decided not to follow the resolution that has been previously adopted by the Parliament (B101). It was argued that the government could not just ignore a majority in the Parliament, even in situations when the government disagreed with the resolutions. This was against the principles of the parliamentary and democratic system in Denmark. The opposition was going to keep an eye on the Government to make sure that parliamentary resolution B42 was followed up.

the precautionary principle, and that evidence was mainly based in the ongoing disagreement between experts and the resulting doubts concerning the safety of BPA (Folketinget, 2010c).

For the Red-Green Alliance, for example, the need for more proof of harm in order to invoke the precautionary principle rendered the whole principle useless, since it could not be used in its intended preventive way anymore: ”But the reality is however, that if one should use the precautionary principle for anything at all, it should then precisely be used in those situations, where one does not have grounds for instating a ban with reference to, that it has been proved, that something is hazardous, because then it only needs to be banned. It is precisely when there is a number of scientific studies, that show, that it is hazardous, and there is also a number of scientific studies, that claim, that it is doubtful, whether or not it is hazardous, that the precautionary principle ought to be applied.” (Per Clausen)(Folketinget, 2010c).

For the Social Democrats the use of the precautionary principle was a political decision. Scientists will always disagree, that is why they are scientists, they said. However, the EU system gives the possibility of making political decisions based on those disagreements by means of the precautionary principle and the safeguard clauses: ”[S]hould it be the case, that one politically considers, that there is a problem, we do have the means of action, which is stated through, among other things, replies from the European commission, that we indeed can challenge the matters at hand and instate special rules for Denmark.” (Benny Engelbrecht)(Folketinget, 2010c).

At the same time, the Social Democrat MP was also very receptive to the comments of Danish experts on the topic: “Much has been said about scientific basis. When one of the world’s leading professors, professor Niels Erik Skakkebæk contacts the Committee on Food , Agriculture and Fisheries, and points out the risks connected with bisphenol A, then this has a vast significance for the social democratic position. We speak not of any given professor, but of the second most quoted researcher in the world, when it comes to endocrine disruptors. That counts.” (Benny Engelbrecht)(Folketinget, 2010c).

At the end of the political debate, the majority of the Parliament supported the new version of B42, showing again that there was majority in the Danish Parliament that meant that BPA was a health problem. The final resolution adopted by the Parliament was that the government should introduce a national ban against the use of BPA in FCM for children between 0-3 years of age.

However, the opposition noted that a major disadvantage to the new adopted B42 version (ban on FCM for small children) - as opposed to the original B42 version (ban on all FCM) – was that the new version did not cover yet an equally vulnerable group, namely unborn babies and their mothers (Folketinget, 2010c).

DTU-Food March 2010 evaluation

On March 2010, DTU-Food's awaited assessment on BPA was released (See Danish National Food Institute evaluation 2010 in the Background chapter). DTU-Food assessed a new industry study which was expected to resolve the ongoing uncertainties regarding potential low dose effect of BPA in the nervous system (namely, Stump (2009)) (DTU-Food, 2010; Miljøstyrelsen, 2014a). DTU-Food noted that this standard study by Stump (2009) had a "very significant weaknesses", in particular that it has not been designed taking into consideration the previously reported observations of possible low-dose BPA effect on neurotoxicity (Miljøstyrelsen, 2014a, p. 29). It was also noted that even if the study did not provide clear evidence that BPA had harmful effects on the types of behavior examined, it raised some uncertainty with respect to effects on learning ability.[113] DTU-Food's overall conclusions were that the study did not clarify or change the uncertainties related to BPA's neurotoxicity at low doses (DTU-Food, 2010).

This evaluation was used in by Denmark as the scientific basis to justify the temporary national ban on BPA in food contact materials for the 0 to 3 years-old (covering: infant feeding bottles, feeding cups and packaging for baby food) (Miljøstyrelsen, 2014a). After this decision, Denmark became the first member state in the EU to regulate BPA.

In the Danish EU notification message one can read that the justification to implement a national BPA ban is based on the uncertainty found in a *hazard* evaluation of the substance, however the actual *risk* was not assessed (i.e. a quantitative risk assessment taking into consideration current levels of exposure): "The regulations prohibiting Bisphenol A in all products specifically for 0-3 year olds are issued as a result of new, extensive rat experiments on the substance. The experiments have been assessed by The Ministry of Food's adviser on risk evaluations, The

[113] DTU-Food identified impaired learning ability in male offspring at low dose exposure to BPA. However, this effect was just seen at the lowest dose and not on animals exposed to higher doses of BPA. That meant that there was not a "normal" dose-response relationship. The assessor noted that since the mechanisms behind BPA's potential effect on brain development remained unknown, it was not possible to predict how the dose-response curve should look like. It was thus concluded that the found impaired learning ability in male offspring, might be a sign of a low-dose effect of BPA, but it could also be an incidental finding (DTU-Food, 2010).

National Food Institute, The Technical University of Denmark. The Institute considers that findings of impaired learning capacity in young males at low dosages can be an indication of a low dosage effect, but can also be an incidental finding. The new investigations are therefore considered to raise uncertainties with respect to the harmful effects in particular on children. Ensuring acceptable safety levels is very important, in particular for the section of the population that is as vulnerable as small children. A prohibition of the use of the substance Bisphenol A in materials which come into contact with food which are marketed in particular for 0-3 year olds, or which are already in contact with food particularly destined for babies and small children has therefore been prepared. Evaluations show that other substances will be able to replace Bisphenol A in materials which come into contact with food"(Miljøstyrelsen, 2014a, pp. 29-30).

EFSA's 2010 opinion

Just some months later, the also awaited EFSA opinion from 2010 was released. This updated opinion was the results of a request from the EU Commission where the agency was asked to review all new scientific evidence (including low-dose studies) and assess whether the later affected previous opinions on the safety of BPA. EFSA reviewed approximately 800 studies and concluded that they could not identify any new evidence which would lead to modify the current TDI established by EFSA in 2006. The panel noted that recent studies have reported adverse effects on animals exposed to BPA during fetal development at doses below the current TDI – such as changes in the central nervous system, effects on the immune system and enhanced susceptibility to breast cancer. However the panel considered that these studies had many limitations and their relevance for human health could not be assessed. A panel member expressed a minority opinion stressing the uncertainties related to low-dose effects and suggested to see the TDI as temporary until new studies could clarify the uncertainties. EFSA also concluded that it was not possible to assess whether or not there was a possible effect on learning ability at low-dose exposure to BPA (as DTU-Food had expressed) – given that these effects could not be statistically confirmed nor excluded (EFSA, 2010a).

EU ban on baby bottles

By November 2010 the Commission was also considering whether or not to prohibit the use of BPA in baby bottles through an amendment in the FCM Directive (Folketinget, 2010a). This was a difficult policy decision given that EFSA's 2010 opinion had clearly concluded that there were

no scientific grounds to worry about the safety of BPA (EFSA 2010). By that time, Denmark and France had already taken national measures to restrict the use of BPA and Belgium was under way. In January 2011, the EU Commission finally adopted Directive 2011/8/EU prohibiting the manufacture in the EU of baby bottles containing BPA and banning the placing on the market and importing into the EU of such products. "June 1 (2011) is a milestone in our efforts to better protect the health of EU citizens, in particular the health of our children. Due to the fact that there are uncertainties concerning the effect of the exposure of infants to Bisphenol A, the Commission deemed it both necessary and appropriate to take action. The aim is to further reduce the exposure of the most vulnerable part of our population – i.e. infants." (Health and Consumer Policy Commissioner, John Dalli) (EC, 2011)

Yet this ban did not encounter much opposition given that most producers had already phased out BPA due to consumer's concerns.

6.2.2. On proportionality and how to weight the benefits of precaution against the costs of regulation

Proposal for parliamentary resolution B17 (2010)

Meanwhile, in the Danish Parliament, the Red-Green Alliance, the Socialist People's party and the Social liberals put forward proposal resolution B17 (which is a reintroduction of B42), demanding a BPA ban on all FCM in Denmark. It was also demanded that the Danish government should work together with member states and the Commission in order to ban BPA from FCMs in Europe (Folketinget, 2010b).

For the proponents of B17, EFSA's latest opinion (2010) could resolve the remaining uncertainties concerning the safety of BPA – such as possible low-dose, non-monotonic dose-response relationships and combination effects (Folketinget, 2010b). At the same time, the proponents argued that the study used as basis for the Danish ban (Stump, 2009) was a study that exposed rats while they were in the womb and nursing, which meant that the real risk was not for only for the 0-3 year old children (as suggested by the scope of the Danish ban) but for the unborn babies. Yet, the current ban did not cover that vulnerable group, the fetuses. The proponents thus claimed that further regulatory action was needed to protect pregnant women and their unborn babies from BPA exposures through the diet (Folketinget, 2010a). The proponents were of the idea that the government should thus support a broader BPA ban based on the still

ongoing uncertainties instead of instead of waiting until conclusive scientific evidence was available to regulate. The precautionary principle again be invoke to reduce the pregnant women's exposure to BPA (Folketinget, 2010b).

During the first reading of B17 in the Chamber, the new Minister of Food (Henrik Høegh from Venstre) explained that the current BPA ban on FCM aimed at 0-3 year olds was based on the conclusions of DTU-Food's assessment of a new BPA study. Namely, that DTU-Food had concluded that the study raised uncertainties as to effects on learning ability following low doses exposure to BPA. Based on those conclusions, the Danish Veterinary and Food Agency (DVFA) invoked the use of the precautionary principle as a protective measure for small children until new studies could clarify whether low doses of BPA had effects on the development of the nervous system and/or behavior (Folketinget, 2010a).

In particular, the Minister stressed, that DVFA had assessed that the ban was *proportional* to the degree of uncertainty that was found in connection with BPA's possible effects on the development of the nervous system and behavior in rats. Denmark's temporary ban was considered to be sensible as it covered a well-defined range of products: baby bottles, sippy cups and glass jars with baby food (Folketinget, 2010a): "I abide by those researchers, who claim – and the The Danish Veterinary and Food Administration, who recommend – that the ban we have today, in foodstuff material for 0-3-years old, is proportional with what, we have found from the results of research, it has been." (Henrik Høegh)(Folketinget, 2010a).

The Minister also noted that EFSA's awaited 2010 opinion concluded that there was no new data that justified a change in the current TDI of BPA. He stressed that there was not enough scientific evidence to support a broader ban covering all FCM. Such a ban would include all food in cans and glass, soft drinks, beers, water containers, kitchen utensils and food equipment, tanks to store food, and many more. The minister argued that such a broad ban would be *disproportionate* with respect to the current degree of uncertainty. The impact on the food industry would be substantial and it would also represent a problem for consumers since their food choices would be restricted without evidence of increased health protection. The government proposed instead to keep encouraging the work on the development of substitutes, so that BPA could be replaced by safe alternatives in the future. In the meantime, the minister was going to follow the scientific

developments in the area and would if necessary consider regulatory measures that were in proportion to the level of uncertainty (Folketinget, 2010a).

At the same time, the MP from Venstre all noted that it was mainly DTU-Food and EFSA's opinions that should be taken into consideration for regulation: "Of course there will be different studies from different places, but then again we do have our institutes, that we base our work on here in the Parliament, and I believe that we should hold on to that." "Selvfølgelig kan der komme forskellige undersøgelser fra forskellige steder, men så har vi jo lige præcis vores institutter, som vi baserer vores arbejde på her i Folketinget, og det synes jeg vi skal fastholde." (Erling Bonnesen)(Folketinget, 2010a).

Even if the Social Democrats and the Danish people's party supported the intention of the proposal and considered that pregnant women's exposure was something that required attention. These two parties were not really willing to introduce another ban for the time being. Yet, the opposition (S, SF, RV and EL) and the Danish people's party agreed that one should continue to challenge the EU system (when it came to public health) and that the strategy that had led to the EU BPA ban on baby bottles could be used again in the future. Proposal resolution B17 was not supported by a majority in the Parliament (Folketinget, 2010a).

In the meantime there was a change of government in Denmark and from February 2014 to June 2015, it was the red block that was in government. The cabinet was a coalition between the Social Democrats (S) and the Social Liberal Party (RV), supported by the Red-Green Alliance (EL) and the Socialist People's party (SF).

EFSA's reevaluation of BPA safety (January 2015)

In 2012, EFSA decided to conduct a full re-evaluation of the safety of BPA. This was motivated by the significant amount of new publications that had become available in recent years (and I will add the still ongoing scientific uncertainties). In 2015, EFSA concluded that the TDI need to be lower to 4µg/kg bw/day (twelve and a half times lower than the previous one) and that total exposures estimates were also very low (lower than previously calculated). This meant that exposures were still 3 to 5 times below the new TDI. The overall conclusion was thus that BPA poses no health risk to consumers (including babies and children). Yet the new TDI is only

temporary and depends on the results of an ongoing long-term study that will help reduce remaining uncertainties (EFSA 2015).

Danish National Food Institute's recommendation concerning BPA safety (February 2015)

Shortly after EFSA's release, DTU-Food was asked to examine EFSA's assessment to determine whether the agency's new t-TDI was sufficiently protective. DTU-Food's main conclusion was that the TDI should be 0.7 µg/kg bw/day or lower to adequately protect consumers against ED-effects of BPA (DTU-Food, 2015).

Proposal for parliamentary resolution B68 (2015)

In the winter 2015, the Red-Green Alliance put forward proposal for parliamentary resolution, B68, demanding the Government to follow DTU-Food's recommendation concerning how much BPA exposure should be regarded as safe (i.e. DTU-Food's TDI) - instead of following EFSA's recommendation. It was noted that even if the proposal did not concerned a ban per se, it was understood that in order to conform with the TDI proposed by DTU-Food, BPA would need to be phased out from some products. The proponents also noted that some of brightest researchers in EDs were Danish and worked at DTU-Food, and if they recommended a lower TDI, on precautionary grounds, one should follow their recommendations - at the same time, the Red-Green Alliance did not see why EFSA's assessment should be more trustworthy.[114] (Folketinget, 2015)

During the first read of B68 in the Chamber, the then minister of Food - Dan Jørgensen (from the Social Democrats) - and the government, agreed with the Red-Green Alliance in that consumers' BPA intake should be lowered so that no one was exposed to more BPA than what DTU-Food deemed safe. However they did not think that additional national regulation on BPA was the best solution. In particular they were concerned that such a measure would promote the substitution of BPA with chemicals that were less studied and perhaps even more problematic.

"The problem with this solution is, that there are not always safe alternatives to bisphenol A. We then risk moving out of the frying pan and into the fire, because other chemicals will be used

[114] The red-green alliance MP in particular pointed to discussions in the EU Parliament where EFSA's potential conflicts of interest had been discussed. It was also suggested that EFSA's previous rejection of studies indicating negative effects on human health at low dose exposures suggested that the agency was more busy protecting industry interests than public health (Folketinget, 2015).

instead, that can turn out to be even more harmful for the Danes." (Karin Gaardsted) (Folketinget, 2015)

For them, the best and fastest way to reduce the population's BPA exposure was by means of a voluntary agreement with the industry to phase out the use of BPA in FCM in those areas were safe alternatives were available. However, there were no safe alternatives for all FCMs where BPA was used, in particular when it came to conserves.[115] In case the government failed to establish an agreement with the industry to reach their goal (reducing the population's exposure to BPA), the minister would reconsider further legislation in the area. It was however noted that this could take some time since alternatives needed to be thoroughly tested before being placed in the market (Folketinget, 2015).[116]

For the other party in the government, the Social Liberal Party (RV), the solution was to invest more in research on BPA to press for stricter EU regulations, since it was only this type of common European regulations that could drive businesses to invest in safer alternatives. At the same time, the social liberal MP noted that there were no safe alternatives for a big number of products and that in those cases it was better to take a pragmatic approach to the problem: "[W]e devout attention to trying to make something, that works out in the real world, not to make something, meaning, that there will be a worse alternative in the real world. Thereby we must say, that this is something we must live with for some time, and which we all think is problematic. But if we create a bigger problem by going the wrong way, we think, that it is wrong to choose this solution." (Ida Auken)(Folketinget, 2015)

The Danish People's party noted that they have become more skeptical about bans given that alternatives could be more problematic than the substances that were regulated. This MP in particular mentioned that BPA has over the years been replaced by bisphenol S which had almost the same properties: "I have up until today spoken of our last resolution proposal (B42) as a big success, but I have become somewhat uncertain, whether it has been the success that we set up

[115] It was in particular mentioned that BPA was used for sour and salty foods, such as: pickled cucumbers and tomatoes both in cans and in glass, soft-drinks and alcoholic drinks in cans, etc, and that there were no safe alternatives in these areas.

[116] At the end of the debate the Red-Green Alliance and the Socialist People's party agreed to join the work on a voluntary phase-out strategy together with the industry, but both parties stressed that they wanted to put clear political pressure on the industry and do not depend only on the industry's good will (Folketinget, 2015).

for. So I am really expressing gratitude, that this resolution proposal has been advanced. I think that it might make quite a few of us wiser, with regards to what we have done." (Rene Christensen)(Folketinget, 2015). For DF it was time to work at EU level and in cooperation with the industry.

The opposition – this time represented by the blue block: Venstre (V), the Conservatives (DKF) and the Liberal Alliance (LA) – did not support DTU-Food's recommendation and preferred to base their decisions on EFSA's 2015 assessment (Folketinget, 2015). According to which all segments of the population were adequately protected against BPA. Besides, EFSA's assessment was based on a thorough review of many scientific studies and the final assessment had also taken into consideration DTU-Foods comments and criticisms (raised during EFSA's public hearing). But in particular, they acknowledged that adhering to EU science and decisions offered a more fair playing ground for the Danish industry: "It is after all strange with the EU, because we have from the side of the Liberal Alliance a skeptical approach to the EU and believe, that the EU interfere in much more, than the EU ought to interfere with. But sometimes the EU is actually good to lean on, in the sense that EU makes some assessments, which enforces, if we abide by them, that we can ensure that we also from the Danish side have reasonable competitive terms, with regards whatever trade that might take place within the borders of the EU." (Mette Bock) (Folketinget, 2015).

On the other hand, these parties stressed that the Department of Food and Resource Economics at the University of Copenhagen had calculated that DTU-Food's recommendation would cost the Danish industry 350 million Danish crowns. It was claimed that further regulation would injure the competitiveness of the Danish industry and its possibilities to find safer solutions. Additionally, they also commented the problem with the lack of safe alternatives for BPA and the risk of creating the opposite effect, namely exposing the population to nastier substances. So, all in all, it was better to keep things as they were (Folketinget, 2015).

At the end of the debate, the majority of the Parliament agreed to continue working on the case at the Committee level where more details concerning the voluntary agreement with the industry could be clarified – in particular the situation concerning BPA's possible alternatives:

”I thought that the minister of Food, Fisheries and Agriculture referred to, that there at least in France was a common understanding, that there were safe alternatives on a great part of those products, that used bisphenol A, while other speakers today have nearly expressed, there there was no such alternatives in any place, and that it was all one big armageddon, where the only consequence, that there could be of passing the proposal of the Red-Green Alliance, would be, that people would live a more uncertain and dangerous life.” (Per Clausen)(Folketinget, 2015)

The proposal resolution B68 was then sent for further work at the Committee.

6.3 Conclusions

In this chapter I have argued that EDs have been a politically relevant topic in Denmark for a long period. It seems that a generous media coverage together with other channels of information dissemination (e.g. such as expert hearings, scientific opinions and NGO-related work) have contributed to keep politicians interested and informed (personal communication with representative of the Red-Green Alliance party in the Parliament). At the same time, there seems to be a genuine public interest in the topic. According to a survey conducted by the Danish Consumer Council, 80% of the public wants to prohibit EDs (if there is only suspicion that they are EDs) and more recent survey by the consulting company Gallup revealed that 90% of the population supported national regulations even when if that means going against EU legislation.[117]

One could hypothesize that the high public interest, together with the unstable parliamentary situation in Denmark has had a strong impact on ED-policy - by promoting competition among the political parties which are trying to appear most ‘consumer-friendly’. At the same time, it has been experienced in several occasions that there is a real possibility of gathering an ‘alternative majority’ in Parliament in support of stricter ED-policies.

In the particular case of BPA, this chapter has shown that the Danish Parliament has played the most important role in policy-decisions. I have argued that some political parties have been particularly eager to impose more ambitious targets concerning the regulation of this chemical, that would the ruling government. The chapter also describes how in two occasions an

[117] https://enhedslisten.dk/miljoe-klima-og-energi/uoenskede-kemikalier

'alternative majority' in Parliament passed two different parliamentary resolutions (B101 and B42) calling for a stricter national regulation of BPA (even if one of them, B101, was never implemented). Such policy-decisions were justified based on the ongoing scientific uncertainties and on the invocation of the precautionary principle and resulted in a national BPA ban in food contact materials for children aged between 0 and 3 years of age.

During the political debates, much of the discussions revolved around the question of: on which grounds and under which circumstances should the precautionary principle be used. In proposals for parliamentary resolution B101 and B42, it can be observed that for the supporters of the proposals (all the red-bloc parties plus the Danish People's party), the ongoing scientific disagreements and the high public health stakes were enough ground to act precautionary. In their opinion scientific uncertainty represented an early warning that should not be ignored. At the same time, their understanding of the application of precautionary principle solved the problem of having to wait for more evidence and could be enacted through the EU safeguard clauses. Besides, some MPs supporting these proposals highlighted that the deliberation about whether and when to exercise precaution was not only a scientific question. It also involved value judgments concerning the 'acceptable' level of risk and this, in their opinion, was an intrinsically political decision.

For the opponents of proposals B101 and B42 on the other hand, the invocation of the precautionary principle required proper, well-documented scientific evidence of BPA's risk (e.g. in the form of a quantifiable risk assessment) and that precautionary measures were cost-effective. They saw the call for precaution as emotional and based on suspicions. For the opponents, the preferred way of addressing the ongoing scientific uncertainties was through a call for more research. They saw the situation as one in which there was a lack of evidence of harm (and I would add, one in which final scientific certainty could be reached).

One can also observe that political decisions are further complicated by the EU-policy dimension. That is, whether is best to go for an immediate domestic regulation or to wait for a regulatory processes at the EU level. The answer to this question seemed to depend on several aspects. For those against national regulation, the arguments were: that Denmark could risk ending up with a court case in the European Court of Justice for not complying with EU law, that regulation at EU

level gave a better incentive to the industry to replace BPA, that common regulation offered a more fair competition to the Danish industry, but particularly that complying with the rules of the single marker was a binding obligation for all member states. On the other hand, for those supporting a national BPA ban, the arguments were: that Brussels should not always decide on the level of protection of Danish citizens, that national regulation could work as an incentive for the EU Commission to propose stricter common regulations and that the threat of the European Court of Justice was not actual when acting in the promotion of public health.

In the following proposals for parliamentary resolution B17 and B68, one can observe that it becomes much harder to act precautionary when confronted with questions of proportionality between the cost of regulation and the benefits of precautionary regulatory measures. In B17, it is stressed that the proposed broader BPA ban covering all food contact materials would be disproportionate with the level of uncertainty. And, at the same time, it would have a significant economic impact on the food industry without clear evidence of increased health protection. In B68, it is further highlighted that there are no available alternatives to substitute BPA in several food contact applications and that one could risk substituting with equally or more problematic chemicals. Here again, the excessive documented cost of regulation does not seem to be proportional to the 'unknown' (questionable) health benefits. At the end, both proposal B17 and B68 were discarded.

Overall, it can be concluded that in order to gather a majority to pass a proposal in the Parliament, policy-decisions need to accommodate a mix of symbolic politics (willingness to meet society's concerns), real politics (pragmatic solutions) and other political compromises. And, that in order to act precautionary, a defined set of requirements need to be met. For proposals B101 and B42, one can observe that it was possible to gather a majority in the Parliament to act against BPA. In those occasions, the proposed regulations seemed to be proportional to the level of uncertainty and a political compromise was reached to protect those aged between 0 and 3 years. Yet, the fact that Parliamentary policy-decisions depend on political compromises and in a definition of precaution framed in terms of cost-benefit evaluations, means that policy solutions are not always coherent. Namely, if that if the aim was to protect the most vulnerable in the population, then regulation to protect pregnant women and their unborn babies should have also been implemented.

7. Endocrine Disruptors in Norway

In Norway, as opposed to Denmark, there is at present no overarching national strategy to systematically tackle human health and environmental risks in relation to chemicals (although the Government is currently working on an action plan for a toxic free environment (Energi- og miljøkomiteen, 2015)). In Norway (as in Denmark) most of the work in the chemical sector (EDs included) is conducted by the environmental authorities and follows a sector-based approach. The overall objectives of Norway's chemical policy are outlined in a white paper from 2006 entitled "Norwegian chemical policy for a non-toxic future". The aim of this section is firstly to analyze this document (and more recent updates from the Norwegian Environment Agency) to explain how the ED problem is understood and addressed by the environmental authorities. Secondly, to briefly present some of the main actors that participate in the management of chemicals in Norway.

7.1 Endocrine Disruption – an environmental concern

7.1.1 White paper no. 14 - Norwegian chemical policy for a non-toxic future

In December 2006, the Ministry of Environment in cooperation with the political leadership (Stoltenberg II's Government) presented the white paper no.14 – entitled "Working together towards a non-toxic environment and a safer future – Norway's chemicals policy" – to the Norwegian Parliament. This document presented by the red-green government outlined a very ambitious policy for a non-toxic environment, both in terms of its grounding principles and its goals – which received broad support from the parliament (Norwegian Ministry of the Environment, 2006). In what follows I will describe the most relevant points of Norway's chemical policy with respect to EDs (and to the posterior analysis of the BPA policy case in Norway).

The precautionary principle

According to the white paper, Norwegian chemical policy would be based on the precautionary principle, meaning that action will be taken when threats are identified, even if scientific facts are uncertain. This was particularly motivated by the realization that often, the knowledge basis on the hazardous properties, the effects and the exposure to dangerous chemicals is uncertain:

"When a specific threat to health or the environment from chemicals is identified, the precautionary principle calls for action to be taken to reduce or eliminate this threat, even if there are uncertainties in the knowledge base. Thus, application of the precautionary principle does not mean that scientific facts are ignored, nor that we fail to make scientific risk assessments. On the contrary, it provides a guideline for the situations where we lack full scientific certainty. Since there is often uncertainty about the risks associated with chemicals, the precautionary principle is particularly relevant in chemical policy" (Norwegian Ministry of the Environment, 2006, p. 15).

It is especially noted that in order to achieve the objectives introduced by the white paper, regulatory action has to take place when the precautionary principle applies. Even though the way the precautionary principle is formulated in the white paper is quite general, it is stressed that any Norwegian regulation based on the precautionary principle will have to follow the guideline of the EU's Communication on the precautionary principle. This means that the measures have to be proportional (between the measure and the chosen level of protection), non-discriminatory, based on a cost-benefit analysis and reviewed in light of scientific developments (Norwegian Ministry of the Environment, 2006).

National regulatory goals for hazardous substances (including EDs)

The white paper points to "miljøgifter" (hazardous substances) as the greatest long-term threat for the environment and for human health. Hazardous substances are referred to as substances that are persistent (take very long time to degrade in the environment), bio-accumulative (can accumulate in organisms, the food chain and the environment) and/or toxic (for example harmful to reproduction). These substances are seen as a particular threat to the health of future generations, to the environment and to food safety. They can accumulate in organisms and be passed on to their offspring, they can pollute the environment and they can have (or promote) unknown long term consequences (Norwegian Ministry of the Environment, 2006).[118]

In order to address the problems posed by hazardous substances, the government put forward a very specific goal for these types of chemicals: The emission and use of hazardous substances

[118] For example, a well-known group of hazardous substances for the Government are PCBs (polychlorinated biphenyls) which were heavily used before the 80's when they were banned. These chemicals have many negative health and environmental effects, are very persistent and bioaccumulative. They have polluted many aquatic environments such as fjords and lakes, which had led to strict dietary recommendations for fish coming from these places. Places polluted with PCBs, such as sediments, have also been very difficult, lengthy and costly to remediate.

will be continuously reduced with the goal of eliminating them by 2020. This goal is usually referred to as the *generation goal*.[119] It is based on the reasoning that since hazardous substances have the capacity to accumulate in the environment, even low environmental emissions can pose a threat to health and the environment. It is also argued that it is difficult to estimate acceptable emission levels – given that they can accumulate and reach high concentrations in food chains and living organisms over time (Norwegian Ministry of the Environment, 2006).

In the white paper, it is clarified that the specific substances that will be covered by the generation goal are those which are included in the national priority list of hazardous substances. These are identified by means of specific predefined criteria, namely:

1. Substances that are persistent and bioaccumulative, and that either: a) have serious long-term health effects, or b) show high ecotoxicity.
2. Substances that are very persistent and very bioaccumulative (no requirement for known toxic effects).
3. Substances found in the food chain in levels that give rise to an equivalent level of concern.
4. Other substances that give rise to an equivalent level of concern, such as *endocrine disruptors* and heavy metals.

In addition, the Government proposed an adjustment to the criteria that had been used before. Namely, that hazardous substances could now be included in the priority list if they were found in the environment at levels that gave cause for concern – without the need to document that they posed a risk to health and the environment. This change, based on a precautionary thinking, was thought to help to identify substance at an early, more manageable, stage (Norwegian Ministry of

[119] The generation goal is based on The Convention for the Protection of the marine Environment of the North-East Atlantic (the 'OSPAR Convention'). This convention from 1992 was ratified by 15 countries, including Norway and the European Commission. The parties are committed to work on stopping the emissions of a number of specific pollutants by 2020 – that is, one generation after the Convention was signed (NOU, 2010). A similar goal was also formulated in the World Summit for Sustainable Development in Johannesburg in 2002 – namely, that the adverse effects on human health and the environment from the use and production of chemicals was going to be minimized by 2020 (Norwegian Ministry of the Environment, 2006).

the Environment, 2006, p. 18 box 13.15). It can be defined as a *hazard approach*, and it is in line with the ambitious goals set for hazardous substances in the white paper.[120]

On the basis of new information and the above mentioned new criteria, five new hazardous substances were identified at that time and added to the national priority list (and thus became subject to the generation goal). Among these new substances was bisphenol A.

BPA fulfills criteria No. 4, namely that it is an endocrine disruptor and at the same time, it is found in the outer environment at levels of concern. Based on the new adjustment to the criteria, one can also deduce that it was not necessary to conduct a quantitative risk assessment – rather, it was included based on its intrinsic hazard evaluation and the fact that it was widespread in the environment (Norwegian Ministry of the Environment, 2006).

Reflections on the expression "miljøgifter"

It is interesting to note that the white paper makes a distinction between: "Helse- og miljøfarlige kjemikalier" and "miljøgifter". The distinction being that "miljøgifter" are a subcategory of particularly problematic "helse- og miljøfarlige kjemikalier" and as mentioned, it is only "miljøgifter" that are covered by the concrete objectives of the generation goal.

During my interviews, it was brought to my attention that the English translation for "miljøgifter" (translated as ecological toxins in the white paper) was not adequate and that the term should be translated as hazardous substances (personal communication with professor in biology). During my analysis, I will thus translate "miljøgifter" as "hazardous substances" and otherwise keep similar expressions closer to its direct translation.

[120] It indeed signals that the government considers these substances so problematic that it is justified be as precautious as possible. Because in general, the white paper notes that the fact that a chemical is found in people or the environment does not necessarily implied that there was a risk to health of the environment, and specifies that "[…] whether a substance poses a risk depends not only on its hazardous properties but also on how much is released and the degree of exposure" (Norwegian Ministry of the Environment, 2006, p. 9) This is more in line with a quantitative risk assessment, rather than a hazard approach.

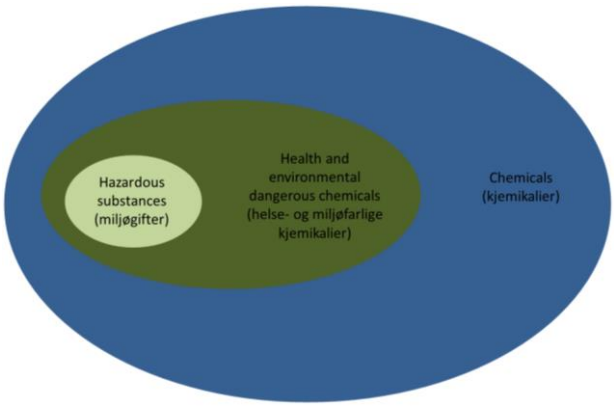

Figure 8: Classification of chemicals according to the Norwegian Environmental Authorities. Adapted from www.miljostatus.no

Moreover, it is important to note that these "discursive" refinements are more than just a technical clarification. The expression "miljøgifter" has strong implications for Norwegian chemical policy as these substances seem to be usually conceptualized in a very specific way – namely, persistent, bioaccumulative, long-transported chemicals. Yet, according to the white paper's identification criteria for hazardous substances, EDs should also be considered a "miljøgift" (hazardous substance), given that they give rise to an "equivalent level of concern" as persistent and bioaccumulative chemicals.[121] However, in the white paper the term endocrine disruptor is almost not used at all, EDs are included in the hazardous substances category and are referred to as "miljøgifter" (Norwegian Ministry of the Environment, 2006). For those EDs that happened to be persistent, bioaccumulative and also toxic (based on their effects on the endocrine system) this is unproblematic (such as for most persistent organic pollutants). However, I will claim that for those EDs that are only toxic but not persistent and not bioaccumulative (such as BPA), this could be problematic since they might not be seen as the typical "miljøgift" (hazardous substance) and at the same time there would be no other "discursive" category to classify them. This would be particularly so for people outside the technical and scientific world (such as the media, politicians, NGOs). At the same time, given that at present there is no universally agreed criteria for the identification of EDs (see background section 4.2.3-4.2.4), even experts, scientists and regulators might have problems defining whether BPA is an ED and thus

[121] This is similar to article 57(f) in REACH, were EDs are also seen as substances of "equivalent level of concern" due to their effects to human health (and/or) the environment. Yet in the lack of generally agreed upon criteria for the identification of EDs, it is difficult to operationalize this article.

whether it can in turn be classified as a "miljøgift". This is illustrated in the different terms used by the environmental authorities in Norway (who refer to BPA as an endocrine disruptor) (Miljødirektoratet, 2015a), and the food and health authorities (who refer to BPA as an endocrine active substance)(Folkehelseinstituttet, 2015).

At the same time, on the discourse level, one can claim that a "miljøgift" – literally translated, an environmental poison (miljø: environmental, gift: poison) – is understood as a substance that has the potential to harm the environment. The fact that only the environmental dimension is captured by this expression, might also contribute to blurring the direct implications of "miljøgifter" for human health in the perception of the "everyday" people (this will be further discussed in the political debate on the white paper). As opposed to in Denmark, where the term 'endocrine disruptor' is exclusively used, it can be argued that both framing BPA as a "miljøgift" and attempting to rule it out of such a definition, can function to obscure its human health effects.

Pollution does not stop at national borders

Another main characteristic of the white paper, and somehow related to the above, is that this document emphasizes the significance of international efforts to secure a safer management of chemicals in Norway.

In several occasions it is stressed that many hazardous substances, such as POPs and heavy metals, can be transported over long distances and end up concentrating in the Norwegian Arctic. Dominant patterns of air and ocean currents make Norway particularly prone to transboundary pollution.[122] As a response to this, the Government proposes to concentrate efforts on the implementation of stricter international regulations (by means of global legally binding agreements) in order to decrease the pollution burden of Norway. This would mean that research and monitoring activities in the High North would to be prioritized given the necessity of developing the scientific basis for establishing strict international regulations of hazardous substances (Norwegian Ministry of the Environment, 2006).[123]

[122] As an example, the white paper notes than more than half of the lead and mercury pollution in Norway comes from abroad. And, in the case of mercury, it is believed that the largest source of pollution is coal-fired power plants in Asia.

[123] The Arctic is often referred to as "a barometer of global chemical pollution" where one can follow time trends of existing hazardous substances and can also identify new substances of concern (Norwegian Ministry of the Environment, 2006, p. 25)

Yet, one can claim that Norway's interests in developing international agreements to counteract the degradation of the Norwegian environment caused by long-range pollution are much older. According to Organisation for Economic Co-operation and Development (OECD) data from 1993, Norway might have been the OECD member country most exposed to transboundary pollution – explained by its downwind and downstream position with respect to Europe (OECD, 1993, p. 111). Andersen (1997) reports that already at that time, Norway was seen both as a pusher and a forerunner Norway in international environmental cooperation .

Moreover, the white paper proposed not only to actively work at the international level but also at the European level. The white paper notes that everyday products have become a major source of emissions of hazardous substances and that trade contributes to the global dispersal of these substances. Importers and retailers often had very limited knowledge concerning the chemical content of the products they put in the market. And, the rising consumption patterns in Norway meant that there was an ever increasing number of (unknown) chemicals in circulation. At the same time, most products in Norway come from abroad and the EEA agreement limited Norway's freedom to implement more restrictive national regulations - in particular for areas that are fully harmonized. In these respects, working towards a strong common European legislation was an important move to ensure safer products and less emission of hazardous substances in Norway. The government expects in particular that REACH would solve many of the ongoing problems concerning the deficit of information on chemicals and that would promote a better regulation for the most hazardous substances. It was thus proposed that the environmental authorities should focus on making REACH as ambitious as possible (Norwegian Ministry of the Environment, 2006). [124]

Regulatory measures to achieve the generation goal

a) Ban on hazardous substances in consumer products

Even if the white paper notes in several occasions that it might be difficult to introduce stricter regulations in Norway than in the rest of Europe. This document also notes that the Government was considering a broad ban on the most hazardous substances in ordinary consumer products. It

[124] When the white paper was being written, the European Parliament and the Council were still negotiating the final version of REACH. The latter was adopted two days after the white paper no.14 was presented to the Norwegian Parliament. REACH finally entered into force on June 2007

is mentioned that the release of dangerous chemicals from products had been rising in comparison to more traditional sources of pollution such as industrial processes. And that a large amount of consumer products contained hazardous substances that had the potential to spread quite widely since these were released during manufacture, under usage and when products were discarded as waste. A broad ban on consumer products was being considered in order to achieve the objectives of the generation goal (i.e. that the hazardous substances that were included in the national priority list would be eliminated by 2020), to decrease hazardous waste and to ensure that safer products were placed in the market (Norwegian Ministry of the Environment, 2006).

Shortly after the white paper was released, the Ministry of Environment commissioned the Norwegian Pollution control Authority (SFT) to work on such a possible ban.[125] SFT proposed a ban on 21 hazardous substances from the national priority list which have been detected in the environment in appreciable concentrations (including BPA). This chemical had only recently been included in the national priority list and its use had not previously been regulated in products in Norway (SFT, 2006b).[126]

One year later, the ban proposal has already been reduced to 18 substances (but BPA was still on the list) (Miljøverndepartementet, 2007). From an analysis of the impact assessment submitted by the Norwegian environmental authorities to the EFTA Surveillance Authority[127] it is easy to see what is the standing point of the environmental authorities with respect to hazardous substances (EFTA, 2007).

[125] In connection to the ban, it was noted that exemptions would be consider for those products where no adequate alternatives were available; where the use of the substances posed no risk to health or the environment; or when the regulation introduced costly barriers to trade. Concerning this last point, it was specifically noted that regulatory measures would had to be consistent with Norway's international obligations concerning trade. In particular, it was specified that "Under the EEA Agreement, Norwegian and EU chemicals legislation is harmonized. This means that as a general rule, the same requirements apply in both Norway and the EU, but there is some room for national regulation of a number of specific substances and areas of use. Norway has most room for maneuver in areas where the legislation is not fully harmonized. It is more difficult for Norway to lay down stricter rules than the EU for substances and areas of use that are specifically regulated in fully harmonized regulations and directives, although there are possibilities for doing so" (Norwegian Ministry of the Environment, 2006, p. 73)

[126] In 2006 there were two European regulations concerning BPA. One was related to the food contact materials and the other, to the Cosmetics regulation. In Norway, these regulations were administered by the food agency

[127] The European Economic Area (EEA) is composed of the Member States of the European Union and three European Free Trade Associations (EFTA) States: Norway, Iceland and Liechtenstein. The EFTA Surveillance Authority's role is to ensure that EFTA States respect their obligations under the EEA Agreement, in particular with relation to the functioning of the internal market.

The Norwegian environmental authorities stressed that it was extremely important to reduce the emissions of prioritized hazardous substances. These were substances that were persistent, bioaccumulative and/or toxic (for example harmful to reproduction) and which could have irreversible effects. At the same time, it was noted that the properties of these substances made it difficult to intervene before damage had already arisen. It was mentioned that hazardous substances could accumulate in nature and in food chains and were thus a serious threat to food security, the health of future generations and the environment. Besides, monitoring data from Norway had shown a substantial spread of the proposed hazardous substances in the environment (Note in particular that the description is the same as the typical "miljøgift" (hazardous substance) and that there is no reference to hormonal properties) (EFTA, 2007).

It was further noted that consumer products were an important source of emissions and consumers lacked the necessary knowledge to protect themselves or the environment against these substances. Besides, the entire population (including the most vulnerable) was exposed to the emission of hazardous substances through the usage of consumer products or via the environment (EFTA, 2007).

SFT also stressed that in order to achieve Norway's objectives in the chemical area, namely to achieve the generation goal, it was needed to have a reduction in the emission of hazardous substances from products. It also stressed that it was important to act precautionary even if the uncertainties were large and it was impossible to quantify the possible health and environmental damage using the available knowledge. At the same time it was also difficult to predict the exact costs of such a regulation. It was estimated that an extremely long time would be required to get sufficiently reliable evidence of the long-term effect of these substances and given the possible serious consequences. The authorities did not want to wait for that and proposed instead that, based on the precautionary principle; the ban ought to be carried out as soon as possible based on existing information (EFTA, 2007).[128]

[128] SFT had estimated that for most application areas there were alternative products on the market that satisfied the proposed requirement. Besides, a number of application areas were also exempted from the regulation when: 1) there were no present alternatives or the costs were too high, 2) when the areas of application were already subjected to total harmonization regulations at EU level or 3) when the application areas belonged to regulatory areas which were not administered by the environmental authorities (EFTA, 2007).

The prohibition proposal was sent out for consultation to stakeholders at the national and international level on May 2007. After the consultation process, the agency received a very large number of consultative statements, the large majority of which were objections (including strong criticism from the surveillance organ of EFTA). After the consultation, it was decided to shorten the list of proposed substances to 10 candidates, including BPA (SFT, 2008b). [129] In the coming years, the original ban proposal was further reduced to only four substances (Miljøverndepartementet, 2010b) . Finally, eight years after, in the summer of 2014, the only national ban based on this regulatory initiative entered into force concerning the substance PFOA (Perfluorooctanoic acid) (Miljødirektoratet, 2013) - the regulation of which is currently being challenged by EFTA surveillance authority.[130]

b) Information on hazardous substances

The white paper also highlighted that it was very hard to make safe, informed purchases since there was scare information on the chemical content of products and consumers have limited knowledge about chemicals. The Government was thus considering improving the information of the content and the properties of chemicals used in consumer products. So that consumers could choose safer products, and in that way, protect their health and the environment (Norwegian Ministry of the Environment, 2006).

It was noted that vulnerable groups, such as children, would benefit from such information so that their parents could make safe choices to protect their health: "Children, like adults, are exposed to hazardous substances in products. They are particularly vulnerable group because they are still developing and are therefore even more susceptible to the harmful effects of hazardous substances. Some substances can cause permanent damage or serious illnesses later in the life of an individual who has been exposed to high concentrations of these substances in childhood or before birth" (Norwegian Ministry of the Environment, 2006, p. 71). As a response to this, the Government was considering launching information campaigns and establishing a website to give

[129] The agency also decided to make some changes to the original proposal concerning the proposed limit values and the areas of use that were subjected to exemptions. Some of the substances that SFT removed from the list were being subjected to different EU regulation processes at the time and it was decided that it was better to wait for those results. Still SFT wanted to maintain the ban proposal for the remaining 10 substances but that depended on the endorsement from the Ministry of Environment (SFT, 2008b).

[130] The regulation of PFOA has a transitional period lasting until January 2018 – allowing the import and sale of products manufactured before 1 June 2014.

advice to consumers. In connection to this, the Government saw it desirable to enhance the cooperation between the environmental, health and consumer authorities (Note that the environmental authorities mention that it is high concentrations that are harmful) (Norwegian Ministry of the Environment, 2006).

In 2006, Klif prepared a campaign on "Children's chemical daily lives" (Barns kjemiske hverdag), which gave advice to parents and others working with children on how to minimize unnecessary exposures to everyday chemicals. The brochure was going to be distributed at the health centers and was available in several languages. The campaign was based on the Danish campaign "Chemistry in children's daily lives" from 2001 (SFT, 2006a). The Norwegian brochure was updated and re-printed in 2012. This is the only information campaign on chemicals in Norway that I am aware of. During my interviews I was notified that this work has not been expanded due to a lack of economic resources (personal communication with a representative of NEA).

In 2010 the website "Erdetfarlig.no" was launched by the environmental agency to inform consumers on chemicals and give advice on safer products. This was done after the release of an study that concluded that "Six out of ten Norwegians feel that the information they receive on hazardous substances to humans and environment is to poor." (Jørgensen, 2010, p. 1) The site was the result of a collaboration between the environmental, the food agency and the Nordic ecolabel (with support of two consumer NGOs).

At the same time, both the Norwegian Food Safety Authority and the Norwegian Institute of Public Health have also their own website where they inform about general food safety and health issues (including chemicals in food) and public-health related topics (such as chemical safety).[131]

Possible Health connection

Most of the document is discussed in terms of hazardous substances and dangerous chemicals, and although many EDs form part of the hazardous substances category - according to the proposed official criteria (see section: *Goals for hazardous substances*) – little reference is made to endocrine disruptors as a category of chemical on itself. It is important to mention that many

[131] http://www.matportalen.no/ (Food and Health authorities)
http://www.fhi.no/ (Health authorities)

endocrine disruptors can also be very persistent and bioaccumulative such as, the well-known PCBs and DDT (and many other pops). It is however their persistence and bioaccumulation that are stressed in the white paper and not so much the fact that they have endocrine activity (Norwegian Ministry of the Environment, 2006).

There is one small subsection in the white paper that refers to some of the health problems related to endocrine disruptors. In here, it is noted that Norway has the highest prevalence of testicular cancer in the world and that there has been an increase in the incidence of baby boys born with undescended testicles and the document points to EDs as a one of the several possible causes behind these rising numbers.

"Exposure to chemicals that are hazardous to health and environment, such as substances that can disrupt the hormonal balance, is one of many factors suspected of having significance for the increase of cancer, for example could exposure at the embryonic stage have significance for the development of testicular cancer." (Norwegian Ministry of the Environment, 2006, p. 10).

However, it also noted that there is not a clear link between exposure to endocrine disruptors and health effects yet:

"There are no clearly established links between disruption of the hormonal system and exposure to chemicals in humans, but the question has been asked on whether reduced sperm quality, disruptions in sexual development and the increasing frequency of testicular cancer could be related to exposure to chemicals." (Norwegian Ministry of the Environment, 2006, p. 10).

This is interesting because, as will be seen in the rest of the analysis, it is very seldom that EDs are connected to these possible effects in the public discourse in Norway (as opposed to Denmark). Actually, in the same year that the white paper was release, the influential Norwegian Academy of Science and Letters published a volume on endocrine disruptors where the possible implications for male reproductive health from EDs were further challenged:

"It should be emphasized that there is no evidence for a decrease in male fertility, and that the decrease in fertility rates is mainly due to socioeconomic factors. Furthermore, no evidence for a uniform temporal increase in hypospadias, cryptorchidism, or a decline in sperm quality has been found. Although studies have shown effect of EDs on male reproductive health, the hypothesis

that EDs represent a threat to male reproduction still remains controversial. Other factors, including diet and lifestyle, should also be considered as risk factors" (Haugen, 2006, p. 154)

However, four years later, in 2010, the same author (the leader of a research group on male reproductive health in the Oslo and Akershus University College of applied sciences), noted that although it was still debate whether environmental chemicals were a real threat for male reproductive health, it was advised to use a precautionary approach when dealing with this chemicals (Haugen, 2010, p. 52).

On the website of her research group one can read today:

"There are indications that male reproductive problems have increased world-wide during the last decades. Furthermore, it seems that Norway is especially subjected to this, as it has among the highest occurrences of testicular cancer in the world and the lowest sperm quality of the Nordic countries, along with Denmark. Embryonic life is assumed to be a critical period for the formation of testicular cancer, malformations in male reproductive organs such as hypospadias (an abnormally placed urinary hole), cryptorchidism (undescended testis) and some cases of lowered sperm quality. Disruptions in the balance between male and female sex hormones, androgens and estrogens, can contribute to an irregular development of male reproductive organs, and a genetic predisposition is probably decisive for the development of disease." (HIOA, 2015)

7.1.2 Update on the environmental authorities' work on endocrine disruptors

In September 2014, following a demand from the allocation letter of the Ministry of Climate and Environment, The Norwegian Environment Agency (NEA) prepared an assessment on how best to reduce the use of EDs in relation to the ongoing EU work (Miljødirektoratet, 2014f). In their assessment, the environmental agency noted that humans and animals were exposed to many different EDs and other harmful chemicals on a daily base and expressed concern about the possible long term effect of such combined exposures (large on EDS). They explained that Norway has had focus on EDs identification and regulation in particular in relation to *environmental effects* (Miljødirektoratet, 2014d). In this more recent document we see that the environmental agency now refers to EDs as such an not as 'hazardous substances' (miljøgifter).

"Norway has for a long time been concerned identifying and regulating the use of endocrine disruptors with a main focus on endocrine disruptors in the environment. Endocrine disruptors

constitute a serious threat to health and environment and have been placed on the Norwegian priority list."(Miljødirektoratet, 2014d, p. 2)

It is further explained that even very small quantities of EDs can cause serious and long term effects in animals and humans exposed during early development. But perhaps most interesting is that the agency makes it clear now that well-known long-transported persistent hazardous substances (such as DDT, PCB, endosulfan, dieldrin) have endocrine disrupting properties. It is however still emphasized that the environmental authorities' focus is on environmental effects (Miljødirektoratet, 2014d).

The agency also mentions that current standard test guidelines (OECD) to identify environmental and health effects of EDs have limitations and therefore it is necessary to complement the information required for regulatory work with non-standard research-based studies:

"It is supposed […] when using standard test methods that there is a threshold for effects also for endocrine disrupting qualities. Such threshold values are however scientifically difficult to determine. This places a limit to the validated OECD test methods that are available to study endocrine disruptive qualities. It is therefore important to include information from research based studies […] when assessing a substance' endocrine disruptive qualitites."(Miljødirektoratet, 2014d, p. 15).

It is also explained that the national work on EDs is split among several authorities and that under such circumstances it is important to have a tighter coordination across the different ministries and agencies to have a coherent regulatory work: "In Norway, several ministries and their underlying agencies have responsibility for chemical regulation that covers endocrine disruptors, for example agricultural and food administration (pesticides, cosmetics, food contact material) and human- and veterinary medical products. In the effort to reduce usage of endocrine disruptors, it is important that we nationally ensure a closer dialogue across ministries and agencies to sustain expert assessments that are coordinated and build on similar principles for regulation." (Miljødirektoratet, 2014d, p. 14)

There is also need for further national research on the topic and is mentioned that the Norwegian research council does not have special programs for this type of research in the council's portfolio at present (Miljødirektoratet, 2014d).

With respect to regulation, the agency notes that they can influence EU work on EDs by working on expert and working groups at EU level. It is stressed that it would be very hard for Norway to introduce national regulation on the use or sale of EDs that come under the scope of REACH, given that this is a harmonized legislation. However, it is also noted that what is exactly harmonized though REACH is open to discussion, yet it would become very costly to prove that a new national regulation is in accordance to the EEA agreement (Miljødirektoratet, 2014f).

"Norway was early with a strict regulation of many hazardous substances, but we now have very small prospects to make national bans. This is limited by EEA-regulations. […] In order to reduce use and emissions of endocrine disruptors, we must strengthen Norwegian efforts in the EU in this area."(Miljødirektoratet, 2014c, p. 1)

We can see then that the regulation of EDs will most likely take place at EU level. However, it is also well-known that in order to participate in chemical policy at this level, Norway has to work at the early stages of policy proposals at the expert's group and committee level. But most importantly is that, in order to have some influence, one must have "high level of expertise, sound scientific arguments and agreed Norwegian positions"(Norwegian Ministry of the Environment, 2006, p. 108).

7.2 Main actors in the management of chemical in Norway

7.2.1. Norwegian public chemical administration

Chemicals are used extensively in many sectors of society and the Norwegian chemical administration/management involves many different authorities.[132] Chemical policy is relevant within environmental policy, health policy, food safety policy, working environment policy and many more.

This means that several ministries and their underlying agencies have responsibilities concerning chemical use and regulation. However, in many cases, these chemical-related tasks often comprise just a small part of their workload and are just one among other major responsibilities – except maybe for the Ministry of Environment.

[132] In lack of a good translation for the more precise term "kjemikalieforvaltning" in Norwegian and Danish, I shall use the term "public chemical administration/management". That is to say how the public sector regulates, informs, advises and exert the political decisions on chemicals.

In several official documents such as the white paper n°14 it is noted that as a result of this split organization, it has happened that different regulatory agencies have conducted different risk evaluations and have reached different conclusions concerning chemical safety depending on whether the study was related to risk for: the environment, patients, ordinary consumer or workers. This fragmentation has thus led to situations where the same substance has been regulated differently in different products. It also meant that usually health and environmental considerations were not fully integrated in the final assessments, leading to inconsistent health and environmental risk reduction measures, particularly when it came to cosmetics and medicines.

In 2001, Statskonsult[133] also published a review concerning the distribution of responsibilities and the level of cooperation between the different agencies involved in chemicals management. An important conclusion was that at the time there was not a satisfactory "unified" policy on chemicals (Statskonsult, 2001)(and we might add: little has changed).

The Statskonsult document explains that the different ministries and agencies that are in charge of chemical management have been set up to safeguard different public interests such as for example: protecting the natural environment, the health of consumers or that of workers, facilitating commercial activity, wealth creation and profitability for different industries. As a result of this, they work with different types of chemical "risk" and prioritize their work on chemicals differently (Statskonsult, 2001).

At the same time, the different authorities (and their related knowledge organizations), are different in terms of knowledge and expertise, access to resources and in their administrative and regulatory traditions. This division of responsibilities in several "policy" sectors presents special challenges in terms of coordination, in particular when it comes to balancing the various social interests against each other and achieving a coherent and unified Norwegian chemical policy (Statskonsult, 2001).

As an example, it was noted that the environmental authorities and the working authorities ended sometimes in situations where there are difficult tradeoffs to be made, given that what is good for the working environment will not always be the best for the natural environment, making it

[133] Statskonsult, or its administrative field, lies today under the Agency for Public Management and eGovernment (Difi) (www.difi.no)

especially important to have a good level of understanding and cooperation between the different agencies (Statskonsult, 2001).

Among the general advices of the Statskonsult were to establish more formalized and binding cooperation arrangements between the agencies and their knowledge organizations, and pointing out that this work should be prioritized highly and that the ministries should have the responsibility for such cooperation (Statskonsult, 2001).

It was also advised to define the responsibilities between the authorities unambiguously and to gather more responsibility for the basic chemical legislation on the Norwegian environmental agency – similar to the Danish system where the Danish EPA is the main actor in chemical policy (Statskonsult, 2001).[134]

But perhaps the most important message from the Statskonsult document and the white paper when it comes to chemical management in Norway was the need for a unified Norwegian position towards the EU. This is very relevant because it is at the expert level and working group level (refereeing to both the scientific and agency level) and during the initial stages of the regulatory work on chemicals that Norway has an opportunity to influence EU chemical regulations - regulations that will later on be incorporated into Norwegian law. In this respect, Norwegian agencies working with chemicals should be able to cooperate well with a view of being able to speak with one voice to the EU (Norwegian Ministry of the Environment, 2006; Statskonsult, 2001). This will ensure that "Norway provides well-founded input and puts forward consistent views in initiatives for the development of effective rules in various forums" (Norwegian Ministry of the Environment, 2006, p. 105).

The Norwegian Food Authorities

The case of food control in Norway is quite particular given than, as opposed to the environmental sector, the responsibility is divided between three ministries and one agency.

[134] As an example, it was recommended to shift the responsibility for the pesticide regulation to the environmental authorities instead of being placed under the agricultural authorities, given that the environmental authorities had already the responsibility for biocides (a closely related field) and to avoid the danger of conflict of interests (Statskonsult, 2001)

Several authors Elvbakken and Rykkja (2006) have claimed that traditionally food safety in Norway has been seen as a health issue under the responsibility of the health authorities but that gradually, the ministry of agriculture has gained more influence in food safety – at the expense of the ministry of health.

"The interest and influence of the agricultural state administration in food control has increased, and the agricultural administration, with the Ministry of Food and Agriculture in front, has taken over the main responsibility. The Ministries of Health and Fisheries are still there as professional ministries (that cover the field), but the Ministry of Food and Agriculture must be understood as leading, both administratively and professionally." (Elvbakken & Rykkja, 2006, p. 133)

Since 1988, the "professional" and political responsibility for food control in Norway has been shared between the Ministry of health, the Ministry of agriculture and the Ministry of fisheries. In his paper on "coordination and regulation of food safety in Norway" (Lie, 2006), Lie notes that in 1996 a public commission was charged with analyzing food safety regulation in Norway (NOU 1996:10). The commission's final report advised to establish one law, one ministry and one regulatory agency to take care of food safety in Norway, and also suggested that the natural ministerial affiliation for such a task would be with the Ministry of Health and Social Affairs (as it was called back then). The commission also acknowledge that the ministries of Agriculture and Fisheries had legitimate interests in the field of food safety and it was thus important to establish good professional cooperation between the three ministries however, they concluded that food safety regulation should be separated from business interests (that were found to be more prevalent in these other two ministries)(Lie, 2006).

"In order not to weaken the legitimacy and trust of the controls, the commission made clear that the responsibility should not be handed to any of the industry-based ministries." (Elvbakken & Rykkja, 2006, p. 127).

In 2003, a new Food Law covering the entire food production chain from "earth/sea to table" was introduced (Lie, 2011, p. 407). This, together with an ongoing reorganization in the public administration, led in 2004 to the establishment of the Norwegian Food Safety Authority

(NFSA)[135] and the Norwegian Scientific Committee for Food Safety (VKM)(Lie, 2006). At the same time - and similar to the new European model on food safety – the food safety reform in Norway also called for a separation between risk assessment and risk management, and allocated the two roles to different organizations. VKM, which was an independent organ under the Ministry of Health, was going to be in charge of the scientific risk assessment tasks. Concerning the risk management, Lie notes that "NFSA has operational and professional responsibility for risk management, while the three ministries have overall political responsibility" (Lie, 2011, p. 408).

The literature also notes that at the time there were lively discussions concerning which would be the best ministerial affiliation for the new food agency: the ministry of health (as advised by the public commission) or the ministry of agriculture.[136] According to Lie "whether food is primary related to health or related to agriculture has been a dilemma in the debate" (Lie, 2006, p. 3). According to Elvbakken and Hellebø Rykkja in this discussion, it seemed to be equally important to ensure consumer's health and to create favorable conditions for the industry (Elvbakken & Rykkja, 2006).

At the end, it was decided that the professional responsibility would continue to be shared by the three ministries and that the administrative responsibility[137] would be with the Ministry of agriculture. NFSA's tasks were going to be preparing draft legislation, making inspections, informing about legislation and giving advice to the ministries (Elvbakken & Rykkja, 2006).

In Lie's work it is also mentioned that the agency's professionals would be in charge of day-to-day issues and that the ministries would pay more attention to the political leadership: such as frame steering, broader policy questions and general guidelines – rather than being involved in individual cases (Lie, 2006).

In a recent publication by Lie (2011) dealing with the effects of the reorganization of food safety in Norway, this author concludes that even though the division of labor between the three ministries is not very clear and the "three ministries have different agendas" (in particular that the

[135] Which was formed after merging the former: Norwegian animal health authority, the department of seafood of the directorate of fisheries, the Norwegian food control authority, the municipal food control authorities and the Norwegian agricultural inspection service, into a bigger agency (Lie, 2006).
[136] The ministry of fisheries has been the third player but has had a less prominent role in the debate.
[137] Understood as steering dialog between the ministries and NFSA and managing the budget

ministry of agriculture and the ministry of fisheries have focus on business interests in addition to food safety; and the ministry of health focuses on health in addition to food safety), conflicts are rare. The author explains that there is good coordination between the three ministries and that "the ministries discuss questions and disagreements at their meetings, and conflicts are therefore rare" (Lie, 2011, p. 409).

When exploring this topic during my interviews, I receive a similar answer to what Lie (2011) reports. I was in particular wondering whether there were situations where the interests and position of the Ministry of Health and Care Services diverged from the interests and positions of the other two Ministries – especially when formulating a national position concerning the legislation on food contact materials vis-a-vis the EU. To what I was told, that unified Norwegian positions with respect to the legislation on FCMs were unproblematic (personal communication with representative of NFSA).

With this short introduction in mind, I will now present the main authorities in charge of food policy in Norway (including the regulation of chemical in food): the Ministry of Agriculture and Food, Ministry of Trade, Industry and Fisheries, the Ministry of Health and Care Services, the Norwegian Food Safety Authority (NFSA) and the Norwegian Scientific Committee for Food Safety (VKM).

Ministry of Agriculture and Food

This ministry is responsible for food and agricultural policy.[138] It has been noted that food safety has become one of the main political objectives for the ministry, together with setting up the right conditions for the agricultural industry:

"The Ministry of Agriculture has the responsibility for food and agricultural policy […]: Safe and healthy food with good quality and satisfied customers, an internationally obligating cooperation, an emphasis on quality all along the chain of food articles and transparency for and participation from consumers based on the best available knowledge." (Statskonsult, 2001, p. 10) "The principle objectives of the ministry are then connected to food safety for the Norwegian population, but also to the conditions for the industry actors in the agricultural industry." (Statskonsult, 2001, p. 16).

[138] When I speak of the ministries here I will use their current names corresponding to their administrative areas. When spoken of historically, or in quotes, I use the names they had at the time.

With respect to its work on chemicals, it has been noted that "The Ministry of Agriculture and Food has the responsibility to minimize health- and environmental risk by using pesticides" (NOU, 2010, p. 58)

Ministry of Trade, Industry and Fisheries

This ministry is responsible for industrial and seafood policy: "The collective value creation nationwide is what determines prosperity and well-being in Norway. The objective of the Government's industrial and seafood policy, therefore, is to maximise value creation in the Norwegian economy." (Regjeringen, 2014b).

With respect to their work on chemicals:

"The Ministry of Fisheries and Costal Affairs has through The Norwegian Coastal Administration responsibility for public security in cases of acute contamination." (NOU, 2010, p. 58).

Ministry of Health and Care Services

This ministry has several chief responsibilities among which health policy, public health, health services, and health legislation (Regjeringen, 2014a).

As previously explained, it has been noted that, when it comes to food safety, the influence of the health authorities has retrieved at the expense of other interests in the field and also due to other bigger responsibilities to take care of. But most importantly for my analysis, is the prioritization of chemical work in this ministry, which seems neither to be on the top list. The ministry of health's role in chemicals management lies in its responsibility for safeguarding public health, particularly from a preventive perspective. Yet, chemicals do not seem to figure among its key policy objectives (Statskonsult, 2001).

"The role of the Ministry of Health and Social Affairs in chemical administration lies in their responsibility to ensure that the population's health is taken care of. The focus will then be towards how it is possible to limit harm to the population's health as a consequence of the use of chemicals. […] Chemicals that are hazardous to health and environment seems however not to have a central place in political propositions of objectives and policy documents from the Ministry of Health and Social Affairs" (Statskonsult, 2001, p. 15)

The Norwegian Food Safety Authority (NFSA)

The Norwegian Food Safety Authority is the subordinate agency under the Ministry of Agriculture and Food. This agency works both on the development and the implementation of legislation in the food sector, and supervises and monitors a whole range of activities along the chain of food production. It also provides advice to the Ministry of Fisheries and Coastal Affairs, the Ministry of Agriculture and Food and the Ministry of Health and Care Services (Norwegian Ministry of the Environment, 2006, p. 80).

The agency's objectives are "(…) to ensure that food and drinking water are as safe and healthy as possible for consumers (…)" and " (…) to contribute to value creation in the food sector" (slide 15) (Mattilsynet, 2015a).

NFSA administers several chemical-related legislations, among other things, the legislation on pesticides, the legislation on food contact materials (FCM) and the legislation on cosmetic products. These legislations are administered by NFSA but they are under the responsibility of the Ministry of Health and Care Services. The legislation on FCM and cosmetics are included, and harmonized, in the EEA Agreement to which Norway is bound (Mattilsynet, 2015a).

The Norwegian Scientific Committee for Food Safety (VKM)

The Norwegian Food Safety Authority in turn depends on the scientific input from the Norwegian Scientific Committee for Food Safety (VKM) to give advice to the relevant ministries and for its regulatory responsibilities (e.g. policy proposals). VKM conducts risk assessments for NFSA across the agency's field of responsibility. These assessments are conducted following "(…) current international standards and methodology in the respective fields of responsibility for VKMs panels." As mentioned before, VKM was established in 2004 following the European frame of risk analysis, namely that scientific risk assessments needed to be separated from risk management activities: "Neither the Ministry of Health and Care Services, other ministries, NFSA, the Norwegian Environment Agency or others may interfere in the scientific work of the committee" (VKM, 2015a, p. 1).

7.2.1.2 The Norwegian Environmental Authorities

Ministry of Climate and Environment

This ministry has the main responsibility for ensuring integrated governmental climate and environmental policies (Regjeringen, 2015).

When it comes to chemicals: **"**The Ministry of Environment has a responsibility to ensure that the natural environment is looked after in chemical policy. In addition, the ministry is the responsible authority on consumer policy." (Statskonsult, 2001, p. 13)

In the white paper it is specified that the Ministry of Environment is responsible for "all regulation relating to both health and environmental effects of chemicals where no separate regulatory measures have been laid down. Medicines, cosmetics, plant protection products and chemicals for occupational use are some types of uses or products that are separately regulated" (Norwegian Ministry of the Environment, 2006, p. 105). The same applies to food contact materials which are regulated by the NFSA.

However, in the case of cosmetics for example, the Ministry of Climate and Environment is responsible for chemicals in cosmetics that are hazardous to the environment but it is the Ministry of Health and Care Services that has the responsibility for chemicals in cosmetics that are hazardous to health. This is due to the fact that the "legislation administered by the health authorities contains provisions designed to prevent direct injury to health" (Norwegian Ministry of the Environment, 2006, p. 106).

In the case of Food Contact Materials, which is of most relevance for the study of the regulation of BPA, the responsibility boundaries are less evident (as will be revealed in the analysis of BPA regulation in Norway). The legislation on FCM is administered by the NFSA and this agency has the responsibility for chemicals in FCM that are hazardous to health. However, FCMs (and the chemicals included in these diverse food packaging) also end up as waste, which is an area of responsibility of the environmental authorities. At the same time, these same chemicals can also be used in other consumer products, which are then regulated by the environmental authorities (both in terms of environmental and health effects). This means that in some cases there can be two different assessment of the health effect of one chemical.

The Norwegian Environment Agency (NEA)

The "new" agency was created in 2013 when the former Directorate for Nature Management and the Climate and Pollution Agency were merged.[139] The agency is subordinate to the Ministry of Climate and Environment. It is in charge of the implementation of chemical policy and on advising on the development of chemical policy goals - with the objective of limiting the usage and spread of dangerous chemicals (Miljødirektoratet, 2015c). Besides preventing pollution, the agency has also other important tasks such as taking care of the Norwegian climate policy, managing Norwegian nature and coordinating the integration of environmental considerations across sectors (Miljødirektoratet, 2015c).

The framework for the agency's activities are set up by the annual letter of allocation, white papers, parliamentary bills, legislation and other political instructions, which determine among other things expenditure budgets and prioritization: "It is the Stortinget and the government that determine the level of ambition and instruments of climate and environmental policy (…)" (Miljødirektoratet, 2015c, p. 2).

The environmental agency has the responsibility of the administration of the REACH legislation in Norway and the biocide legislation, among others (Norwegian Ministry of the Environment, 2006).

Scientific advisors for the environmental authorities

The NEA also depends on the expert input of different scientific bodies to conduct its regulatory activities. During my interviews I was informed that among the scientific bodies that provide such scientific input are: the Norwegian Institute of Public Health (FHI), The Norwegian Institute for Water Research (NIVA) and Norwegian Institute for Air Research (NILU) (personal communication with representative of NEA).

7.2.2. Political actors

During the discussion of the white paper in the Parliament, we can note that in general there was a broad agreement concerning the goals of the white paper and its initiatives. It can also be noted that "hazardous substances" (miljøgifter) were of concern, in particular, the fact that these chemicals were persistent in nature and that they could readily accumulate in the ecosystem and

[139] As with the ministries, I will use their current names, but when spoken of historically, or in quotes, I use the names they had at the time.

in organisms (Stortinget, 2007). The different interventions emphasized that there was need for international solutions and that the Norwegian Arctic was particularly vulnerable:

"Hazardous substances know no territorial boundaries and actually constitute a not so insignificant global problem. Norway and 'The High North' are especially at risk for hazardous substances that come with ocean currents and wind from other countries and continents. Again there is little help in strict bans here at home, as long as our vulnerable Arctic region functions as the world's disposal for poisonous substances. This is in other words also an important global challenge." (Stortinget, 2007, p. 2997)

"I would like to say a few words about the polar bear […] it has been measured steadily increasing levels of chemicals in polar bears in The High North. These poisonous chemicals come up through the food chain, generally through fish to seal and to polar bear. […] The consequence of the high level of chemicals is that the polar bear will have problems with its ability to reproduce. But even though the polar bear is found in areas that are considered as Norwegian, most of the chemicals come from other parts of the world. This shows that it is important to have a significant dedication in international negotiations, because this challenge cannot be solved in Norway alone." (Stortinget, 2007, p. 2999).

It might be that the emphasis on effects for arctic organisms was related to the fact that the Committee had been on a study trip to Svalbard where politicians could "experience" the effects of these chemical on the polar environment. In either case, it is important to mention that although a link to human health was always present, this was not as emphasized or described. Concerning one of the concrete interventions on human health concerning the presence of hazardous substances in breastmilk, it was pointed that:

"We still know very little about how the tiny amounts of these dangerous substances impact our bodies and health, but it is important to be attentive to it and try to avoid having them around. I am therefore content with the measures that the Government now takes to get more information out, so that people can choose not to choose hazardous substances" (p. 3001) (Stortinget, 2007, p. 3001)

Another dominant topic during the discussion was that of remediation action plans to "remediate old sins committed to the environment" (Stortinget, 2007, p. 2998). It was noted that once

persistent hazardous substances are released into the environment, it is very difficult and expensive to remove them. Many members pointed that the negative long term consequences of pollution and the elevated costs of remediation justified an active use of the precautionary principle to ensure that the same mistakes were not committed again (Stortinget, 2007).

7.2.3. On expertise and research

One of the main remarks of the white paper was the serious lack of basic knowledge concerning the health and environmental effects of most chemicals in the market (and those being constantly introduced). "We lack adequate information on 65 % of all substances that are produced in or imported to Norway in amounts of more than one tone every year, and have no information on 21 % of them" (Norwegian Ministry of the Environment, 2006, p. 39). This lack of information concerned the chemicals' properties, hazardousness, short and long-term effects on health and ecosystems, their usage in everyday products, their level of spread in the environment and the effects of combined exposures and the existence of possible substitutes.

That means that there was (and maybe there still is) inadequate information on 86% of the substances in the Norwegian market (produced or imported over a tone per year). The Government was aware that this lack of information made it difficult to inform consumers, challenged the development of regulations both nationally and internationally and was an important for public health:

"To prevent injury to health and damage to the environment we must have adequate knowledge about the effects of chemicals on health and the environment. Building up this type of knowledge is one important aspect of public health work"(Norwegian Ministry of the Environment, 2006, p. 81).

In connection to this, the white paper proposes to build up expertise "(…) both by expanding research activities in this field and by building up the research institutions and public bodies that are involved in evaluating documentation and information on hazardous substances" (Norwegian Ministry of the Environment, 2006, p. 41); to promote cooperation between institutions dealing with health, environmental and occupational concerns "Cooperation between different disciplines and between experts in different sectors will be very valuable in further research on chemicals" (Norwegian Ministry of the Environment, 2006, p. 42), and to strengthen research and monitoring

programs on dangerous chemicals – in particular hazardous substances. Priority will be given to research about the Arctic environment given its strategic importance in the promotion of stricter international regulation (Norwegian Ministry of the Environment, 2006).

7.3 Conclusions

In this chapter we have seen that most of the work done on EDs is conducted by the environmental authorities. One can mention that 1) the particular definition of EDs as hazardous substances (miljøgifter) has had visible consequences, 2) that most of the political attention has been on persistent, bioaccumulative, long-transported EDs, 3) that the stressed focus on the environment has gone at the expense of health effects, 4) that the specific category "endocrine disruptor" has not been an explicit part of the 'discourse' when it comes to chemical policy. 5) the efforts in research have largely been in research on nature, and much of this in the arctic region.

I have argued that in the absence of a national action plan on chemicals, white paper no.14 has been the document guiding Norway's chemical policy in the last decade. An analysis of this document reveals that Norwegian chemical policy is based on a precautionary thinking – particularly so when it comes to hazardous substances. At the same time, the white paper specifies clear regulatory objectives for the environmental authorities with respect to hazardous substances (including EDs) – namely that their use is going to be reduced as much as possible by 2020, according to the generation goal. It is further specified that the risk associated with this particular type of chemicals calls for a hazard (precautionary) approach, where risk does not have to be quantified but is instead based on the intrinsic properties of these chemicals. This is justified given that it would be hard to establish safe limits for chemicals that keep accumulating in the environment, which at the same time can have substantial and irreversible effects and where the posterior costs of remediation can be very high. It is also specified that these national chemical policy objectives should apply to all sectors. In order to achieve the objectives of the white paper, the environmental authorities propose stricter national regulation for those substances listed in the national priority list, among which is BPA.

One can also see that there is not much emphasis on ED's health effects. When it comes to male reproductive disorders for example, this connection is challenged at the time when the white

paper was released, even if one can see a change of attitude in the following years. This is also evident at the political level, where most of the discussions have to do with the environmental consequences and the need to remediate locations that have previously been contaminated with hazardous substances. Here again one could claim that recently, in particular in connection with the ongoing work on an action plan for a toxic free every day, there has been more emphasis on the health implications. However, in recent updates, the environmental agency has clarified that the agency's emphasis when it comes to EDs is on their environmental effects.

But in particular at the administrative level one can see that chemical policy is fragmented between several public bodies. The report from the Statskonsult especially mentions that each of these public bodies have a particular way of defining chemical risk that depends on their particular expertise, their particular regulatory traditions, the interest that they are meant to protect and the resources they have to act on it. As a result of this, they can end up having different management preferences when it comes to chemicals. When it comes to bisphenol A, the main actors are the health, the food and the environmental authorities (this will be analyzed more in detail in next chapter).

It is interesting to mention the particular situation of the food agency, when it comes to chemical management. As mentioned in this chapter, the NFSA is the subordinate agency of three different ministries and is in charge of administrating several pieces of legislation for the Ministry of Health and Care Services in connection to chemicals. Among these pieces of legislation we have the ones related to cosmetics and food contact materials. From the way it is formulated in the different documents that were analyzed, one can understand that the food agency is in charge of taking care of the human health dimension, whereas the environmental agency looks into the environmental effects. However, as explained in this chapter, the environmental agency is also in charge of assessing the human health implications of chemicals in consumer products. Given that many of the chemicals that are used in cosmetic and food contact materials, are also used in consumer products (which are the responsibility of the environmental agency), it becomes ambiguous who has the ultimate responsibility of such health-evaluation. At the same time, it has also been mentioned that chemicals do not rank very high in the list of priorities of the Ministry of Health and Care Services, which adds to the ambiguity of who is accountable for the health dimension when it comes to chemicals used in cosmetics, food contact materials (and that are

also found in other consumer products). Furthermore, and as will be seen in next chapter, each agency has its own group of experts. This means that the scientific input may be different from one agency to the other, which again might add to the differences between the agencies.

Finally it is worth to mention that, until very recently, there has not been much political attention on the topic, and in general, political parties have not included chemicals (even less so endocrine disruptors) in their overall environmental policy objectives (with the exception of Venstre and the Green Party). On the NGO side, there is a current effort to put chemicals back into the environmental agenda, but the work is rather limited in economic and manpower resources (personal communication with representative of Bellona). The Norwegian Consumer council has maybe been one of the most active players when it comes to chemicals, but has received constant critics and even been sued from the cosmetic industry for developing an app to identify EDs in cosmetics. In general it can be said that there is little public awareness on the topic in Norway.

8. The BPA-case in Norway

As explained in the previous chapter, Norway's chemical policy is divided between several administrative bodies. When it comes to the regulation of BPA, it is in particular the environmental, the health and the food authorities that have responsibility for the legislation concerning this chemical. In particular, the Norwegian Food Safety Authority (NFSA) administers the legislation for food contact materials (FCM) – which is the area of responsibility of the Ministry of Health and Care Services. And, the Norwegian Environment Agency (NEA) administers the much broader REACH chemical legislation (covering consumer products) - which is the area of responsibility of the Ministry of Climate and Environment. In this chapter I will start by presenting the initial regulatory interest on BPA from the part of the environmental authorities. In the second part I will chronologically present the debate that took place between the three above-mentioned administrative bodies concerning the posterior regulation of BPA in Norway.

8.1 Environmental authorities interest in regulating BPA

BPA was included in the national priority list of hazardous substances in 2006. It was included because it fulfilled the criteria proposed for the identification of substances of concern. Namely, the criterion of "equivalent level of concern" based on its endocrine disrupting effects and the fact that it was found in the Norwegian environment and biota. BPA's listing meant that this chemical came under the generation goal, namely that: BPA emissions were going to be continuously reduced with the view to eliminating them by 2020 (Norwegian Ministry of the Environment, 2006).

At the time of inclusion little consumption and emission data was available. It was known that BPA was not – and is still not – produced in Norway. It was imported as raw material and in finished products and had a widespread commercial use. BPA is mainly used in the manufacture of polycarbonate plastic but it is also used in paints, adhesives and varnishes (Klif, 2010). The registered consumption of BPA in 2013 was estimated to be 15 tons.[140] However, the real

[140] This estimation comes from the product register which is the official register for chemical products in Norway. One of the limitations of the product register is that it does not adequately cover the content of hazardous substances in imported finished products. This can lead to an underestimation of the emissions when finished products represent the dominant source of emissions (Klif 2012)

consumption of BPA in Norway is expected to be significantly larger. This is due to the fact that the available estimations do not include imported finished products, which are believe to represent the largest share of BPA in the country (Miljødirektoratet, 2015b). It is also mentioned that consumption in the EU is likely to increase in the next years, which could lead to a national increase in the consumption of BPA, again, in the form of imported finished products (Miljødirektoratet, 2014g). Concerning the national emissions of BPA, there is still very limited data. This makes it hard to estimate how far the authorities are from achieving the generation goal (Miljødirektoratet, 2015b). However, it has been noted that BPA emissions in Norway are significant and that plastic waste is likely the main culprit (Miljødirektoratet, 2014g).

The environmental authorities have described BPA as an endocrine disruptor with estrogenic activity. BPA can affect growth, reproduction and development in aquatic organisms (Miljødirektoratet, 2014a) and may also have endocrine disrupting effects on snails at very low concentrations (Miljødirektoratet, 2015b). They also point to the fact that a number of mammal studies have shown that low dose exposure to BPA during pregnancy can affect fetal development and learning ability. BPA is classified as harmful to eyes, irritating to the respiratory tract, allergenic by skin contact and suspected of damaging fertility. It degrades relatively easy and does not bioaccumulates (Miljødirektoratet, 2015b).

For over a decade, BPA has been included in several monitoring programs to estimate the prevalence of this substance in the Norwegian aquatic environment. BPA has constantly been found in effluents and sewage sludge from water treatment plants, and in landfill leachates in relatively large amounts[141] (Klif, 2012). It has also been found in lake sediments and sediments along the coast – as far as the southern and eastern Barents Sea.[142] At the same time, BPA has been found in fish, mussels and cod liver in Norwegian waters. The monitoring programs reveal that the concentration of BPA in the aquatic environment can be very high in the proximity of local sources of emission where the chemical might cause adverse effects to the environment (Miljødirektoratet, 2015b). It has recently been suggested that additional measures might be needed to prevent unwanted spreading from landfills' leachates (Miljødirektoratet, 2014g).

[141] The sewage sludge is usually further used for agricultural purposes, where BPA can also be dispersed to the terrestrial compartment (Klif 2012)

[142] Yet, for the time being, BPA has not been detected in sediment, fish or seabirds analysed in the Artic region. However, since it is produced in so large quantities it is a good idea to keep monitoring it

More recently, other bisphenols such as bisphenol F, bisphenol S, bisphenol BP and bisphenol AF have also been monitored in the environment. Bisphenols are a group of chemicals that are structurally similar to BPA. They are also used in the manufacturing of plastic, in particular, as a replacement for BPA. Some of them have also been found to possess estrogenic activity - similar to that of BPA. For others, there is no ecotoxicological data available. BPA is still the dominant bisphenol when it comes to environmental occurrence in Norway. However, at the time being, it is hard to estimate the combined risk to the environment from this group of chemicals (Miljødirektoratet, 2014e).

Concerning BPA's regulation, this chemical is regulated in the national legislation for food contact materials (Forskrift om materialer og gjenstander i kontakt med næringsmidler, 1993-12-21 nr 1381) with a specific migration limit (SML) of 0.6 mg/kg food (VKM, 2008). As a result of the implementation of European directive (2011/8/EU), BPA has also been banned in baby bottles since summer 2011. It is the NFSA that is responsible for all regulations related to food.

With respect to products, from summer 2015, the limit values of BPA in toys for children under 3 will be reduced and there is ongoing work on a restriction on thermal paper at EU level (a stricter regulation). Other than that, BPA is monitored by the environmental authorities in leachates.

The NEA communicates with NFSA concerning the regulation of BPA (Miljødirektoratet, 2014g).

8.1.1 Environmental authorities' ban proposal for 21 substances (part I, December 2006)

At the end of 2006 and in connection to the environmental objectives put forward by the white paper no.14, the Ministry of Environment commissioned SFT to work on a possible ban on hazardous substances in consumer products. SFT proposed a ban[143] on 21 hazardous substances – among which BPA. The chemical had only recently been included in the national priority list and its use had not previously been regulated in products in Norway[144] (SFT, 2006b).

[143] The ban covered manufacture, import, export and sale of consumer products containing selected hazardous substances

[144] In 2006 there were two European regulations concerning BPA. One was related to the food contact materials and the other, to the Cosmetics regulation. In Norway, these regulations were administered by the food agency (EFTA, 2007)

By 2007 the ban proposal has been reduced to 18 hazardous substances but BPA was still on the list (Miljøverndepartementet, 2007). In the impact assessment available at the EFTA Surveillance Authority website[145], the Norwegian environmental authorities stressed that it was extremely important to reduce the emissions of prioritized hazardous substances. These were substances that were persistent, bioaccumulative and/or toxic (for example harmful to reproduction) and the proponents of the ban saw their effects as irreversible. The properties of these substances made it difficult to intervene before damage had already arisen. It was mentioned that hazardous substances could accumulate in nature and in food chains and were thus a serious threat to food security, the health of future generations and the environment. At the same time, monitoring data from Norway had shown a substantial spread of the proposed hazardous substances in the environment (EFTA, 2007).

Consumer products were an important source of emissions and consumers lacked the necessary knowledge to protect themselves or the environment against these substances. The entire population, including the most vulnerable groups were exposed to the emission of hazardous substances either directly through usage of consumer products or indirectly via the environment. The regulation was also going to contribute to reduce the quantity of hazardous waste in Norway (EFTA, 2007).

It was further argued that in order to achieve Norway's objectives in the chemical area, namely to achieve the generation goal, it was needed to have a reduction in the emission of hazardous substances from products (EFTA, 2007).

The Norwegian Pollution Control Authority (SFT) also stressed that it was important to act precautionary. They were aware that for all the substances the uncertainties were large and it was impossible to quantify the possible health and environmental damage using the available knowledge. At the same time it was also difficult to predict the exact costs of such a regulation. It was estimated that an extremely long time would be required to get sufficiently reliable evidence of the long-term effect of these substances and given the possible serious consequences,

[145] The European Economic Area (EEA) is composed of the Member States of the European Union and three European Free Trade Associations (EFTA) States: Norway, Iceland and Liechtenstein. The EFTA Surveillance Authority's role is to ensure that EFTA States respect their obligations under the EEA Agreement, in particular with relation to the functioning of the internal market. (http://www.eftasurv.int/about-the-authority/the-authority-at-a-glance-/)

the authorities did not want to wait for that. Instead, they proposed that, based on the precautionary principle, the ban ought to be carried out as soon as possible based on existing information (EFTA, 2007).

SFT had estimated that for most application areas there were alternative products on the market that satisfied the proposed requirement. Besides, a number of application areas were also exempted from the regulation when there were no present alternatives or the costs were too high, when the areas of application were already subjected to total harmonization regulations at EU level or when the application areas belonged to regulatory areas which were not administered by the environmental authorities (EFTA, 2007).

With respect to BPA it was stressed that this chemical was included in the priority list due to its endocrine disrupting properties, and that it can be found at levels of concern in the Norwegian environment. The ban was intended to cover, among others, polycarbonate plastics, epoxy resins, paint, varnish, glue and PVC. The proposal for regulation was based on limit values, where products exceeding the proposed limits were going to be prohibited. Other products such as thermal paper and tooth filling were exempted due the apparent lack of alternatives and related high costs and BPA's applications in the area of food contact materials were not included in the proposal given that this area was not regulated by the environmental authorities (EFTA, 2007)

The prohibition proposal was sent out for consultation to stakeholders at the national and international level on May 2007

8.1.2 Risk assessment of bisphenol A in Norway

Updated European Risk Assessment of BPA and effects on developmental neurotoxicity (April 2008)

In the meantime, the European Chemicals Bureau (ECB) updated the European Union Risk Assessment Report (RAR) of BPA, in accordance with Council Regulation (EEC) 793/93.[146] The assessment concluded, with regards to the environmental risk, that there remained uncertainties related to the potential effects of BPA on freshwater snails (EU-RAR, 2008a). Concerning the human health assessment, it was concluded that: there were no risk for consumers with regards to

[146] This regulation relates to the European Union's program for the evaluation and control of the risks of existing substances.

all effects considered and all exposure scenarios, and that no further information or testing was needed. ECB proposed a NOAEL of 50 mg/kg bw/day for regulatory purposes (EU-RAR, 2008b). However, the Norwegian Pollution Control Authority (Statens forurensningstilsyn, SFT) together with the other Nordic environmental authorities disagreed with this conclusion - in particular with the fact that the proposed NOAEL also covered developmental neurotoxicity effects at low levels of BPA exposure (EU-RAR, 2008b)..

In recent years, several scientific groups had been studying the effects of BPA on neurological development. The authors of the EU RAR (2008) report used a weight of evidence approach to assess the reliability and consistency of the available evidence in the hazard assessment of BPA. With respect to developmental neurotoxicity, the panel noted that the area was "relatively new and not fully established area in regulatory toxicity […] and therefore experience in the conduct and interpretation of the studies is limited" (EU-RAR, 2008b, p. 116). The OECD guideline for developmental neurotoxicity testing – OECD Guideline 426 – was under development.

When the rapporteurs evaluated the DNT (developmental neurotoxicity) database for BPA,[147] they concluded that there was on overall low level of confidence in the reliability of the studies and a lack of consistency in the results. Some studies have used tests similar to those recommended by the draft of guideline OECD 426, but others have used techniques that according to the reviewers had no established role in regulatory toxicity. Consequently, no firm conclusion could be drawn concerning the possible developmental neurotoxicity effects of BPA at low levels of exposure (EU-RAR, 2008b).

"Confidence in the reliability of the developmental neurotoxicity database is low because of limitations in the design and reporting in all of the available studies. These limitations include small group size, inappropriate statistical analysis, brief reporting of methods and results, lack of compliance with GLP and use of one BPA dose level. […]. The consistency assessment shows that there is no discernable and reproducible pattern to the behavioural testing results. […] Overall, taking together the low confidence in the reliability of the developmental neurotoxicity studies and the lack of consistency in the results of behavioural testing, no conclusions can be drawn from these studies. This opinion is very similar to that of EFSA (2006), who reviewed nine of the developmental neurotoxicity studies" (EU-RAR, 2008b, p. 120).

[147] That is, all the available studies looking into developmental neurotoxicity effects.

However, this conclusion was challenged by the representatives of the Nordic Environmental Agencies (Sweden, Denmark and Norway). In particular, these members strongly disagreed with the conclusion that a NOAEL of 50 mg/kg bw/day covered developmental neurotoxicity effect at low-dose exposures. In their opinion four of the studies in the DNT database could and should be use for regulatory purposes. These studies indicated a possible risk for developmental neurotoxicity at low levels of exposure that warranted concern. Instead, the Nordic members advocated for a conclusion where either: the identified four studies were included in the risk assessment, or that the conclusion included a demand for extra information to clarify the ongoing uncertainties. However, this position was not supported by the majority of the European Member States and the Nordic position was only included as a footnote in the final report:

"Denmark, Sweden and Norway do not agree with this conclusion. These countries find that some of the studies in the DNT database are sufficiently reliable for regulatory use: Negishi 2004, Carr 2003, Ryan and Vandenberg 2006 and Adriani 2003. The reliability of these studies is judged to be adequate because the behavioural testing has been conducted according to acceptable methods, the group sizes are quite close or equal to those recommended in the OECD TG 426, and the litter has been used as the statistical unit. The effects found in these studies indicate that there is a possible risk for developmental neurotoxicity of BPA at very low exposure levels (0.1-0.25 mg/kg/d). These effects cannot be dismissed based on the other unreliable studies in the DNT database. The above mentioned countries would therefore prefer one of two possible conclusions: 1) the available, but limited data are used for the risk assessment or 2) there is a need for further information (the countries certainly evaluate the database as sufficient to justify a concern warranting further investigation of developmental neurotoxicity), similarly to the proposed conclusion in the final expert panel report on the reproductive and developmental toxicity of BPA performed by NTP, US in November 2007." (EU-RAR, 2008b, pp. 120-121 (footnote))

VKM's assessment of four studies on developmental neurotoxicity of BPA (June 2008)

After the release of the EU RAR 2008, the NFSA requested to the Norwegian Scientific Committee for Food Safety (Vitenskapskomitéen for mattrygghet, VKM) to assess whether the four above mentioned studies on developmental neurotoxicity at low doses provided sufficient evidence to set a lower NOAEL in the hazard characterization of BPA. VKM was further

requested to evaluate a Norwegian exposure scenario based on available dietary and environmental data. The assessment was performed by the Scientific Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics (Panel 4) and released in June 2008 (VKM, 2008).

In the assessment it was mentioned that this scientific request was related to the ongoing BPA ban proposal in Norway (i.e. the environmental authorities' ban proposal for 18 hazardous substances in consumer products) and the recent disagreement concerning the safety of BPA during the EU RAR (2008) assessment: "The request from the NFSA to VKM is categorized as an urgent matter due to the situation that the Norwegian Ministry of the Environment at the moment are considering a ban on BPA in consumer products and the fact that the SFT has disagreed upon the NOAEL for developmental toxicity in the revised EU RAR" (VKM, 2008)

The NFSA asked VKM to include the environmental exposure data proposed by SFT during the EU RAR assessment in order to derive a Norwegian exposure scenario. In relation to children's exposure, SFT had identified that some plastic mittens in the Norwegian market contained high levels of residual BPA (VKM, 2008).

SFT was of the opinion that if small children placed in their mouths such mittens, this could lead to an additional exposure of BPA. This information had been submitted during the update work of the EU RAR (2008) but was not included in the final assessment since the use of mittens was not considered to be representative across the Member States in the European Union (VKM, 2008). According to VKM's assessment, BPA exposure via the mittens resulted in an additional exposure of 3.3 μg/kg bw/day[148] for children between 1.5 and 4.5 years – considering a conservative worst case scenario (VKM, 2008).

In relation to the general population, SFT had analyzed the content of BPA in fish from several Norwegian lakes, rivers and fjords. In some cases, the levels found in Norwegian fish were 10 times higher than the average levels of BPA in fish used in the EU RAR (2008) assessment. These additional conservative estimates were also included in VKM's assessment (VKM, 2008).

[148] The estimation is based on a value of 98.2 μg residual BPA/g mittens and the assumption that the complete amount of residual BPA from 50 g mittens is ingested over a period of 100 days per year.

With respect to the evaluation of the four developmental neurotoxicity studies, the panel concluded that they did not provide enough evidence to change the current NOAEL of 5 mg/kg bw/day established by EFSA in 2006[149] given that the studies had important design and reporting shortcomings. Yet the panel expressed *some concern* about the potential neurotoxic effects of BPA at low doses and recommended to conduct a standardized study to clarify the doubts – namely, a GLP compliant study according to OECD test guideline 426) (VKM, 2008).

With respect to the Norwegian exposure scenario, it was noted, as usual, that infants and children were exposed to higher levels of BPA per kg body weight than the rest of the population. However, it was concluded that, in general, exposure levels to BPA in Norway were low and that estimated exposure for children and adults were well below EFSA's current TDI at 50 μg/kg bw/day (VKM, 2008).

Even though it is clearly stated that VKM's evaluation was not going to address recent international assessments on BPA in their report, one could always wonder if the conclusions reached from VKM's panel were not influenced by the results of such international evaluations, in particular those carried out in Canada and the USA. Scientific panels in these countries have recently expressed "concern" for certain BPA's effects and Canada was even considering regulatory measures (FIND REF: NTP-CERHR 2008, Health Canada 2008). On the other hand, in Europe, both EFSA and the ECB, have concluded without reservations, that BPA was safe. VKM's conclusions were in between these two, they found that the assessed evidence had several deficiencies and did not support a change in the current TDI (i.e. EFSA's TDI) and at the same time the population's exposure was low, meaning that there was no health risk. Yet the panel expressed *some concern* concerning neurodevelopmental toxicity effects at low dose exposure to BPA (VKM, 2008).

Moreover, in the report it is also noted that it was the Norwegian Institute of Public Health (FHI) that was in charge of giving scientific advice to the SFT concerning the toxicity of BPA, and that it is VKM who gave the corresponding scientific advice to the NFSA. And that it is possible that the assessments from these two different bodies might be at variance.

[149] ECB identified and used a NOAEL of 50 mg/kg bw/day for reproductive and general toxicity (based on effects on body weight, liver and kidney) in their assessment, while EFSA based the 2006 TDI on a NOAEL of 5 mg/kg bw/day based on increased incidence of centrilobular hepatocyte hypertrophy, identified during their assessment

"The NFSA assumes that VKM will coordinate their work with the department of the Norwegian Institute of Public Health giving scientific advice to the Norwegian Pollution Control Authority on this matter, in such a way that the risk management in Norway could be as uniform as possible, independent of the source of exposure."(VKM, 2008, p. 10)

One can also notice a good collaboration between the two agencies. For example, the fact that the NFSA asked VKM to conduct a risk assessment of BPA taking into consideration the Norwegian exposure data and the concerns coming from the SFT (taking into consideration both environmental and dietary exposures). Additionally, Norwegian experts (from FHI and VKM) should cooperate on a "common" scientific evaluation of the ongoing uncertainties. But most importantly, it was mentioned that if the assessment concluded that there was a risk, the NFSA would modify national regulation accordingly.

"The assessment should make the NFSA able to establish a new risk-based migration limit for bisphenol A in the national legislation on food contact materials. The NFSA will, until the opinion from VKM is finished, act in accordance with the EFSA opinion from 2006" (VKM, 2008, p. 10).

Given that the panel did not recommend any regulatory changes, it is assumed that the NFSA decided to adhere to EFSA's recommendation on BPA.

8.1.3 Environmental authorities' ban proposal for 21 substances (part II, July 2008)

During the consultation process of SFT's proposal (to regulate hazardous substances in consumer products), the agency received a very large number of consultative statements, the large majority of which were objections (including strong criticism from the surveillance organ of EFTA). It was reported that most of the comments concerned six substances, among which BPA. Many of the comments came from the plastic industry. During the interviews at NEA, it was mentioned that a big number of lawyers from the plastic industry came to Norway concerning the ban proposal for BPA which demonstrates the high stakes in the regulation of this chemical (personal communication with representative of NEA).

After the consultation, it was decided to shorten the list of proposed substances to 10 candidates, including BPA. The agency also decided to make some changes to the original proposal concerning the proposed limit values and the areas of use that were subjected to exemptions.

Some of the substances that SFT removed from the list were being subjected to different EU regulation processes at the time and it was decided that it was better to wait for those results. Still SFT wanted to maintain the ban proposal for the remaining 10 substances which was depended on the Ministry of Environment endorsement (SFT, 2008b).

Concerning the legal criticisms, it was question that Norway had the right to introduce national prohibitions in the context of the EEA Agreement and the WTO regulations – these issues were going to be evaluated by the Ministry of Environment (SFT, 2008a).

With respect to the technical evaluation conducted by SFT, the opponents pointed to the fact that the different European risk assessments have concluded that there were no risks for human health or the environment concerning BPA – meaning that there was no need to prohibit or restrict the use of BPA in consumer products. Some of them meant that SFT was ignoring the existing scientific data and that Norway had no proof of health risk for consumers at current exposure levels. They also stressed that the proposed regulation would have large financial and social consequences for the Norwegian industry and for Norwegian consumers (SFT, 2008a).

SFT, on the other hand, saw BPA as a substance whose production and consumption in the EU was extremely high. The agency clarify that they were not proposing a total ban on BPA in consumer products but a regulation based on limit values – so that residual BPA (BPA that was not bound to the product) did not exceed specified acceptable levels. SFT's analyses had shown that consumer products could have a wide range of residual BPA, with some products presenting rather high levels. The agency argued that these products have not been taken into consideration in the different EU risk assessments available at the moment and that was the reason why they were maintaining the proposed regulation (SFT, 2008a).

It was also highlighted that there were uncertainties with respect to neurotoxic effects on humans at low-doses and also uncertainties with respect to possible effects on snails at low-dose exposure in the environment. The Nordic environmental authorities were of the idea that low-dose effects should not be ignored. In addition, Norway was of the opinion that "the lower limit values from applicable studies that show effects on learning and memory in offspring at extremely low doses must be used until possible new, adequate studies of neurotoxic effects are available" (SFT, 2008a, p. 6). This was in contrast to what the recent EU RAR (2008) assessment had concluded,

namely that there was no health risk and no need for further testing (EU-RAR, 2008b). Additionally, there was also the question of combined effects following the simultaneous exposure to multiple EDs which was not capture in any of the available European risk assessments (SFT, 2008a).

SFT was of the opinion that current safety margins were too low in the different risk assessments (the margin between the TDI – or other reference dose – and the actual exposure). In particular with respect to children's exposure and the ongoing uncertainties concerning effects at low-doses (SFT, 2008a).

It was also noted that VKM had concluded that the results of some of the available studies on neurotoxicity gave reasons for concern. The scientific panel proposed to conduct a new study to clarify the ongoing uncertainties but it was going to take at least 2-3 years before the results were ready. SFT was of the opinion that this was too long and, based on a precautionary thinking concerning BPA's endocrine disruptive effects, wanted to maintaining the proposal to limit the content of BPA in consumer products (SFT, 2008a).

In the next years, what can be seen is that the original list of hazardous substances was further reduced to four substances and BPA was removed from the proposal (Miljøverndepartementet, 2010b). Finally, eight years after the original proposal, in the summer of 2014, the only national ban based on this regulatory initiative entered into force concerning the substance PFOA (Perfluorooctanoic acid) (Miljødirektoratet, 2013), the regulation of which is currently being challenged by EFTA surveillance authority[150]

8.2 Chronological outline of the debate on regulation of BPA in Norway

8.2.1 BPA in baby bottles (fall 2009)

In the fall 2009, the national TV show on NRK, "Consumer Inspectors" (Forbrukerinspektørene, (FBI)), broadcasted a show dealing with BPA in baby bottles. Around the same time and under the initiative of FBI, the Norwegian NGO "Grønn Hverdag" sampled baby bottles and pacifiers in the Norwegian market in order to check the occurrence of this chemical. The random sampling revealed that two thirds of the pacifiers and almost half of the bottles contained BPA

[150] The regulation of PFOA has a transitional period lasting until January 2018 – allowing the import and sale of products manufactured before 1 June 2014.

(Risberg, Hødnebø, & Sommerset, 2009). As a consequence of the show and the media attention, more than 4000 Norwegian food stores voluntarily decided to stop the sale of baby bottles that contained BPA (Hødnebø & Laustsen, 2010).

At that time, the NFSA noted that although BPA was a controversial substance, the current exposure was so small that the Food authorities did not consider it a health threat to small children. The Health authorities also believed that a ban was not necessary:

"Assistant Director Jan Alexander of the FHI, who also lead the risk assessment of bisphenol A for VKM, believes that there is not enough evidence to ban the baby bottles with BPA, even if the research is controversial and show different results." (Risberg et al., 2009, p. 1)

After all the media attention, the NFSA also stated that they were going to look closer into the case and evaluate if there was need for regulation. Specifically, the agency was to send an assessment and a recommendation to the Ministry of Health and Care Services concerning how best to follow up the BPA case (Sommerset, 2009). I was unfortunately denied access to this document by the Ministry, based on the Freedom of Information Act (Offentleglova) § 15. 3.

Yet, the media coverage also revealed that the SFT wanted to ban BPA on consumer products, since it was on the national priority list of hazardous substances that were to be phased out by 2020 – something which increased the confusion around this chemical:

"They create confusion. Everyone who in Norway has a responsibility for people's health should take a clear stance on this substance. The precautionary principle is the only solution, who is a doctor and researcher on hazardous substances among children. […] The Ministry of Health and Care Services should have taken control and banned this substance in baby bottles until there is sufficient knowledge. […] It is irresponsible of the NFSA to approve of a substance that SFT wants to ban, says Odland, who sees an obvious conflict between the two agencies." (Risberg et al., 2009, p. 1)

It is interesting to note that many VKM panel members on food additives (Faggruppen for tilsetningsstoffer, aroma, matemballasje og kosmetikk) – dealing with food contact materials – are also working at the Department of Food, Water and Cosmetics (division of environmental medicine) at FHI. Some of these people have also been working on the same issues with EFSA.

For BPA for example, Professor Jan Alexander was the leader of the group assessing the safety of BPA at VKM and also the assistant director of FHI – which might imply that both in the food sector and in the health sector there is the same understanding of the safety of this chemical – based in a quantitative risk assessment and a particular way of looking at the evidence and the uncertainties.

We can see the same in the latest BPA risk assessment in 2015, where one of the panel members at VKM, Dr Trine Husøy, was also leading the working group on BPA at EFSA and is also working at the department of Food, Water and Cosmetics at FHI. In a way ensuring the same understanding of BPA's safety in these three contexts: EFSA, VKM (and thus also NFSA) and in the health context (FHI).

Remark on cocktail effects

Something similar can also be seen for a slightly different, but much related topic, namely that of cocktail effects. VKM has assessed this topic in Norway two times and has come to the conclusion that the risk of cocktail effect is "small" or "not worrisome" (Mattilsynet, 2014; VKM, 2013). This was based on the assumption that the likelihood of combined toxic effects of multiple exposures, at dose levels below the thresholds for effect, was low:

"Even though VKM only to a limited extent have had cocktail effects in consideration in their risk assessments up to now, VKM does not see this as a cause for concern. VKM concludes that synergetic effects in practice is a minor problem in Norway today, and that it is normally not to be expected that hazardous synergetic effects will occur if the substances are ingested in small doses and at levels beneath their respectively acceptable values. The reason is that these values for chemical substances have a big safety margin, and that many substances do not have a greater effect when they appear together than when they appear alone." (Mattilsynet, 2014, p. 1)

Yet, VKM notes that the exception is substances exhibiting similar modes of action (substances that have the same effect in the body). In these cases, multiple exposures can lead to dose addition effects even if the exposure to individual substances in the mixture is below their respective accepted or tolerable daily intakes (TDIs). In these cases, the risk assessment should take this into account (Mattilsynet, 2014).

Based on VKM's scientific advice, the Norwegian Food authorities (and one could also claim Health authorities) have interpreted this to mean that there is no risk of cocktail effects if the exposures are below the accepted safety values for each individual substance:

"NFSA interprets this to say that if the threshold values in our regulation are kept, there is little cause for concern. If we are exposed to higher doses of xenobiotic [foreign] substances, that is to say doses that surpass the threshold values, the situation is different. According to VKM, such instances must be considered case by case." (Mattilsynet, 2014, p. 1)

A problem that should be noted here is that for the vast majority of chemicals in the market, their specific modes of action are not known, so that their contribution to possible cocktail effects has not been operationalized in this argument. At the same time, there is no procedure commonly agreed upon to group chemicals together to potentially take their combined effects into consideration.

Yet, over the last years, research on cocktail effects has revealed that the health risk of certain individual chemicals (in particular EDs) can be underestimated when combination effects are not taken into consideration (even when exposures are below the accepted safety values). In response to this, practical ways to account for combination effects have started to be used, both in assessing the risk and proposing regulation, specifically in Denmark (DTU-Food, 2015a).

The stand point of the Health authorities

Some weeks later, in an article published in the Government's website by the Ministry of Health and Care Services, it is stated that although BPA's safety has been questioned recently, there are no reasons for concern:

"NFSA did some years ago a study on bisphenol A in pacifiers and came, together with VKM, to the conclusion that there could not be detected amounts of the substances that gave cause for concern, at normal use." (Helse- og omsorgsdepartementet, 2009, p. 1)

VKM's "concerns" about the potential neurotoxic effect of BPA at low doses, does not really seem to challenge the "official" safety of this chemical.

In the article, the Health authorities also tried to clarify the differences between SFT and NFSA with respect to BPA. It is noted that BPA in baby bottles is regulated by the Food authorities and

thus not part of SFT's BPA proposal for regulation in consumer products. It is noted with regards to this:

"According to the Ministry of Environment the government has an elevated focus on the hazardous substance bisphenol A. It is a national goal to stop the emissions and applications of bisphenol A by 2020. Bisphenol A is a prioritized hazardous substance because it is an endocrine disruptor. Hormonal effects have been shown in fish and snails in the environment, and there is a concern that the substance may affect the human reproductive ability." (Helse- og omsorgsdepartementet, 2009)

The fact that it refers to the generation goal's objectives as "according to the Ministry of Environment" can be interpreted to mean that the Ministry of Health does not feel a binding obligation to the government's white paper on chemical policy, even when this document states that its objectives apply to all sectors and when these are precisely aiming at better protecting human health.

8.2.2 Collaboration between Klif and NFSA on BPA (2010)

In June 2010, in a letter from the Ministry of Environment to Klif, it is stated that there has been contact between the Ministry of Environment, the Ministry of Health and Care Services, Klif and NFSA concerning BPA and other hazardous substances (Miljøverndepartementet, 2010a).

It is mentioned that Klif and NFSA should strengthen their collaboration on their work with chemicals of concern, and come up with a plan for future cooperation within the next 3 months, in particular with respect to BPA. In particular, the environmental authorities found that it would be beneficial to make a new gathered assessment on how BPA should be followed up. It is stressed that both the environmental and health authorities have a responsibility for BPA since the chemical is used in products belonging to the areas of responsibility of both authorities (Miljøverndepartementet, 2010a).

By the end of August 2010, an email from Klif shows that the cooperation plan between NFSA and Klif with respect to BPA has been postponed. This was due to the fact that NFSA wanted to wait for EFSA's latest assessment before formulating NFSA's opinion to the following work (OEP, 2015c).

In August 2010 a new piece on BPA hit the media, this time concerning the presence of BPA in screw caps (lids) for glass jars, used in commercial baby food. In the NRK (FBI) article it is stressed that Norway allows products for children with BPA, while Denmark has decided to withdraw them from the market. When interviewed, the spokesperson from NFSA confirmed that:

"When it comes to safety of using BPA in products under NFSA's area of responsibility, the NFSA await the conclusion of the EU's scientific committee EFSA." (Hødnebø & Laustsen, 2010, p. 1)

He also mentioned that after the voluntary withdrawal of baby bottles with BPA, the potential risk was also eliminated:

"As is known, the baby bottles with BPA were withdrawn from the market, and thereby any possible risk for harming the undeveloped nervous system in infants was also removed. The NFSA did therefore not see a reason to take action, neither towards these products nor the other that contributed much less to exposure."(Hødnebø & Laustsen, 2010, p. 1)

At the end of this piece, Klif comments that they wish to phase out the use of BPA in consumer products, and in the meantime they have created a website to give advice to consumers on how to avoid exposure to this, and other chemicals. It is however noted that when it comes to FCM, the responsibility for regulation is with NFSA (OEP, 2015a).

Around this time, organizations such as the Norwegian Consumer Council (Forbrukerrådet) and the NGO Grønn Hverdag state that they cannot understand why member states can regulate BPA, while Norway which is outside of the EU, must comply with EU regulation (Forbrukerrådet, 2010; Hødnebø & Laustsen, 2010).

They further find the attitude of NFSA too passive, referring to the fact that the agency prefers to follow EU regulations instead of taking a more precautionary stance, as other member states (particularly Denmark) (Hødnebø & Laustsen, 2010).

By the end of September 2010, EFSA's awaited opinion is finally released. The European Agency concluded that the panel could not identify any new evidence to modify the current TDI of 50 µg/kg body weight (EFSA, 2010a).

In November 2010, in a communication between NFSA and Klif concerning a meeting in Brussels, it is mentioned that there is much discussion at the Commission concerning BPA and a possible BPA ban on baby bottles – but that the outcome of such discussions was not sure. In particular, the discussion related to the fact that there were no scientific grounds to invoke the precautionary principle, based on EFSA's latest assessment (which had reaffirm that BPA was safe for all the population). It is mentioned that the Commission finds the case difficult and that in case they propose a ban, this will be limited only to baby bottles (and no other food contact materials) (OEP, 2015b).

Most importantly, it is stated that "Norway will not take any independent initiative in this case but will wait to see what happens at the Commission. This position has been agreed with the Ministry of Health and Care Services and the Ministry of food, agriculture and Fisheries"(OEP, 2015b, p. Merethe Steen).

The position of the Ministry of Health and Care Services is further explained in an "official response" from the health minister, Anne-Grethe Strøm-Erichsen (Ap), to a question in the Norwegian Parliament on November 17th 2010, by the Christian Party (KrF), concerning small children's exposure to BPA (Helse- og omsorgsdepartementet, 2010).

The minister explained that BPA is discussed both in a health and an environmental context. The latter being the responsibility of the Ministry of Environment.

"There has been attention around possible health effects from the fact that food contact material, for example baby bottles and lids for children's food containers, can emit traces of BPA. There has also been attention around environmental effects of BPA in water and sediments […]" (Helse- og omsorgsdepartementet, 2010, p. 1).

With respect to potential health effects, the minister notes that most Norwegian retailers have stopped selling baby bottles containing BPA, after the TV show "Forbrukerinspektørene (FBI)" in the fall of 2009. Additionally, EFSA had recently concluded that there were no health hazards related to exposure to BPA and no scientific grounds to revise the current TDI of BPA. Yet there were ongoing discussions at the Commission with respect to a potential ban on baby bottles, where the legal grounds and the health considerations were being discussed. The minister concludes that Norway will wait for the recommendations at EU level, given that the Food

Contact Material legislation is part of the EEA agreement and is an area that is harmonized (Helse- og omsorgsdepartementet, 2010).[151]

From this answer one can understand that the Health authorities are committed to follow the requirements of European legislation, and that they will not try to influence decision-making at EU level (which anyway would be hard since Norway's affiliation to the EU does not allow to participate in the final voting of EU legislations) – even when this would go against Norway chemical's policy goals.

8.2.3 EU ban on baby bottles (2011)

In January 2011, the commission finally decides to put forward a BPA ban on baby bottles, entering into force in June 2011 (EC, 2011).

In March 2011, Klif reports to the Ministry of Environment on the assignment of putting forward a cooperation plan with NFSA concerning the regulation of BPA.

Klif reports that the two agencies have had several meetings concerning BPA, but have come to different assessments for the need of a more extensive regulation of BPA (Klif, 2011a). Specifically, Klif expresses concern for possible adverse health effects on children, and therefore wants to have a common and wide BPA ban on products for small children (in order to keep their exposure as low as possible):

"It has been shown that BPA has serious effects, and that children are particularly exposed. There are also studies that indicate serious effects at very low doses. There is uncertainty concerning the levels where BPA have effect, and whether today's threshold values give sufficient protection. Furthermore it is uncertain when a satisfactory set of data will be available. Klif therefore

[151] With respect to the obligations towards the EEA agreement and the harmonization of regulations, it is interesting to note that in December 2012 Sweden also passed a ban on the use of BPA in varnishes and coatings in the packaging of food for children between 0 and 3 years of age. The Swedish ban was less extensive than the Danish ban, which covers all food contact materials for children 0-3 years old. Concerning the legal scope of the regulation, Sweden recognizes that it is necessary to comply with the harmonized plastic food contact material regulation (10/2011/EU), but notes that: "…in the field of varnish and coating there is a lack of detailed EU legislation, and *consequently this field is not regarded as being fully harmonised. This means that there is legal scope for taking national measures if the prerequisite conditions for this are judged to be in place"* (p. 32-33) The Danish Environmental Protection Agency (2014) Background for national legislation on bisphenol A (BPA) in EU and EFTA countries, available at http://www2.mst.dk/Udgiv/publications/2014/03/978-87-93178-18-2.pdf

considers that the precautionary principle should be applied, even though there is so far no certain scientific evidence that there is a risk for harm." (Klif, 2011a, p. 1).

Such a wide ban should ideally cover products regulated by Klif (the product regulation i.e. toys, pacifiers, biting rings, mittens and other textiles for children) and also products regulated by NFSA (the FCM regulation i.e. baby bottles, packaging for baby food and plastic cups). It is reported that NFSA, on the other hand, does not to agree with the need for a wide food contact material ban for children's products and wants to restricts its proposal to the implementation in Norway of the newly EU ban on baby bottles (Klif, 2011a).[152]

Klif concludes that: "Klif considers, based on a precautionary line of thought, that in order to better protect children, there is a need for a more comprehensive regulation of BPA than the ban that NFSA has suggested." (Klif, 2011a, p. 2). Klif will still consider a ban in products for small children in the regulations that are administered by the agency, even if such measures would have a limited effect compared to the protection offered from a wider ban. At this point, we see a shift to a greater emphasis on human health consequences of the use of BPA, rather than on its environmental implications (Klif, 2011a).

In March 2011, in connection to NFSA's public hearing on the implementation of the EU ban of BPA in baby bottles, Klif sent a comment discussing the same topics as before (and arguing for a broader ban). They emphasize the ongoing scientific uncertainties, such as possible additive effects coming from the simultaneous exposure to different estrogenic chemicals. They reaffirmed their position that a precautionary thinking should apply even if the actual risk could not be proven (Klif, 2011b). Yet, NFSA decided that it was enough to implement the EU ban on baby bottles without any further modification covering other FCM for small children.

And in May 2011, we see a change of strategy from the environmental authorities to focus more on EU work, at the expense of the prospect of a national regulation. The Ministry of environment asked Klif for an assessment of the possibilities to strengthen the regulation of BPA at EU level and a proposal of how Norway can contribute to that work (Klif, 2011d).

[152] The EU ban prohibits the manufacture of baby bottles containing BPA, as well as placing it on the market and importing it into the EU. It refers to EU directive (2011/8/EU) adopted in late January 2001 and entered into force in March 2011 (EC, 2011).

Klif reports that the agency has already proposed a stronger threshold value for BPA in the toy directive and that there were some ongoing EU processes where the agency could participate (Klif, 2011d).

Namely, BPA could be subject to substance evaluation given that it was produced in large volumes and there was uncertainty concerning risk – this could provide the opportunity to demand more evidence and propose risk reduction measures. The agency also suggests trying to get BPA on the Candidate List of REACH due to its endocrine disruptor properties – however this was dependent on having common EU criteria for EDs. And they suggested working on a restriction proposal for BPA under REACH (i.e. children's products, other consumer products such as thermal paper). This procedure would however demand thorough documentation on exposure and risk (Klif, 2011d).

Collaboration between Klif and NFSA on chemical-related work (2011)

In the "minutes" from a meeting between NFSA and Klif concerning their collaboration in the area of chemicals – in particular related to BPA and other chemicals in cosmetics – Klif explains the environmental authorities' work on the generation goal and the role of the National priority list of hazardous substances. They emphasize that these national objectives apply to all sectors. With respect to their work on BPA, Klif informed that they had sent suggestions for further regulation to the Ministry of Environment (Klif, 2011c).

On their side, NFSA noted that EFSA has carried out several evaluations of BPA and has consistently concluded that BPA is not harmful for small children, and that there is no basis for a more stringent FCM regulation. NFSA affirmed that the agency was going to follow development of the case at EU level and act accordingly:

"NFSA deals exclusively with EU's scientific committees (EFSA for food safety and SCCS for cosmetics) and follows their recommendations. If special and distinctive Norwegian conditions calls for it, this will be taken to the Norwegian scientific committee (VKM) for consideration." (Klif, 2011c, p. "case nr.3") .

Concerning the future collaboration between the two agencies, it was highlighted that the agencies had different perspectives on the substances listed on the national priority list. For NFSA, the work on chemicals needed to be based on risk assessment. Yet the agency was aware

that different risk assessments could come to different conclusions, and therefore NFSA preferred to base their work on the overall assessments conducted at EFSA or VKM – given that these scientific committees had a good way of assessing the quality of the available evidence (Klif, 2011c).

“NFSA builds on results from VKM and the scientific committees in EU who conduct independent, scientific risk assessments. NFSA pointed out that, because toxicology is far from an exact science, using independent scientific committees is beneficial to further develop health-related regulations. Different scientific environments and researchers can have broadly diverging views on the risks connected with the different use of various substances. The committees can in a good way assess the quality of the results of new research.” (Klif, 2011c, p. "case nr.10") .

For Klif, on the other hand, it was important to act precautionary if chemicals gave rise to health concerns. These concerns were not always sufficiently accounted for in EFSA’s and VKM’s assessments and this could lead to divergent safety evaluations and regulatory actions. Klif suggested to keep working on those differences:

“Klif puts great emphasis on using the “precautionary” principle when there are concerns that a compound might lead to harm, and wishes in several areas to apply this to a greater extent than the premises laid down by the scientific committees. This can result in different risk assessments and needs for action, which is both hard to communicate, and hard to understand for the world outside us. This is an important subject that we must discuss further.”(Klif, 2011c, p. "case nr.10").

It was concluded that an annual meeting was needed between the two agencies to keep working on chemicals of concern (Klif, 2011c).

8.2.4 BPA in canned food (April 2013)

BPA was again in the news, this time in connection to canned food. Two members of the TV show FBI submitted themselves to a hermetic food diet for two days to show the increase of BPA levels in the body after consumption of diverse canned food. In connection to this, the Consumer Council asked for a BPA ban on food contact materials, based on the unclarified uncertainties. They pointing to the fact that Denmark, and now Sweden and France had put in place stronger regulations for this chemical (Høye, 2013).

On that occasion NFSA commented that the amount of BPA found in hermetic food is so low that it does not represent any problem for human health or food safety.

"BPA is perhaps among the worst in class from an environmental concern, but we take it that it is both legal and safe within the current regulation" (Høye, 2013, p. 1)

At the same time, it was pointed out that the regulation on FCM was quite strict and based on sound scientific assessments. The minister of Health, Jonas Gahr Støre (Ap), also confirmed that the authorities in Norway would wait for results at the EU level before any changes in the current FCM regulation are considered (Høye, 2013).

8.2.5 EFSA newest risk assessment on BPA (January 2015)

One day after EFSA's press release on the new risk assessment of BPA, the websites of NFSA, Matportalen[153], FHI and VKM were updated with the new information to the public, namely that BPA poses no health risk to any segment of the population at current levels of exposure.

This might be connected to the fact that FHI's and VKM's articles were redacted by Dr. Trine Husøy, scientist at FHI, panel member of VKM's Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics and that also chair of EFSA's working group on BPA. These linkages also suggest that the official Norwegian perspective on the safety of BPA – in relation to human health – is the same as that of EFSA.[154]

NFSA and Matportalen

With respect to the information itself, it is striking that in the press release of NFSA, none of the uncertainties expressed in EFSA's opinion are mentioned, such as uncertainties related to the safety assessment of the aggregated exposure. And more importantly, it was not mentioned that the TDI was temporary until further studies can clarify the remaining scientific uncertainties (Mattilsynet, 2015b).

[153] Containing information about food and health from public authorities.

[154] It was however not possible to clarify this point during the interviews since Norway's national expert on BPA, Dr. Husøy, after several attempts, could not talk to me about BPA. The head of communication at VKM wrote me: "I have talked to Trine, and in order to interview her about the Bisphenol-A case you will need to contact EFSA. According to her, the work is sensitive and she feels that she cannot give an interview without having clarified it with EFSA. In other words, I have to ask you to contact EFSA directly. I am sorry for not being able to help you". It should be noted that at a later point, they changed their minds – it was however too late for me at this point to include their opinion in this paper.

Instead NFSA highlights that there is no risk to any segment of the population, that consideration of possible low-dose effects has already been included in the uncertainty factor and that consumer's exposure is below the new TDI (Mattilsynet, 2015b). The same applies to the information on the Matportalen website.

VKM

On VKM's blog, Dr. Husøy gives a slightly more technical explanation, were she explains that BPA is a so called "hormonhermende stoff" (that is literally translated as hormone mimicking), which means that this chemical can imitate the functioning of a natural hormone, but only if you are exposed to high concentrations: (VKM, 2015b).

"BPA is a so-called hormone-mimicking substance. That means that it can have the same effect as the hormones that exist in humans and animals, but BPA would only be able to have a hormonal effect when you get high concentrations of the substance into your body." (VKM, 2015b)

This is similar to what EFSA has stated with respect to BPA, namely that BPA is a "hormone active" substance and not an endocrine disruptor, given that, to date, there is no single clear explanation for the effects of BPA in humans. In order to be considered an endocrine disruptor, BPA should fulfill the following criteria: 1. the presence of an adverse effect, 2 .the presence of endocrine activity and most importantly, 3. a causal relationship between the two. It is particularly the third criterion that, according to EFSA, has not been sufficiently proven.

So, BPA is then defined by the agency that gives scientific advice to both the food and the health authorities, as a hormone-mimicking substance, or "hormon*hermende* stoff" (a hormone active substance, in EFSA's terminology) and not a "hormon*forstyrrende* stoff" (an endocrine disruptor). And this could have significant policy implications in Norway. Firstly, it could mean that BPA no longer fulfills the national criteria to be included in the national priority list of hazardous substances (given that it is not an endocrine disruptor). Secondly, the fact that it is expressed that only high concentrations are dangerous also challenges one of the main debated properties of EDs, namely that EDs can be active at low concentrations and that there might not even be possible to establish safety thresholds for these substances. It is timely to note how an area of scientific uncertainty gives room for such slight changes in terminology, that can have a

tremendous impact both in the regulatory context, and on how the concept of BPA is understood and regarded in the public debate.

Norwegian Institute of Public Health (FHI)

The information on the FHI article is more balanced, as it explains the uncertainties related to dermal exposure (leading to more active BPA in the body, as opposed to oral exposures) and its possible implications for human health. It also mentions that there is a health risk for newborn babies that make use of medical equipment containing BPA in the hospital. It still describes BPA as a hormone active substance that for the time being, poses not health risk to the population through the diet (FHI, 2015).

An interesting point though is that when the article refers to the other risk assessments that have been conducted on BPA – in particular the assessment conducted by the French agency ANSES – it fails to report that other scientific committees have reached different conclusions than those of EFSA. The author rather points to the fact the American food agency (FDA) still affirms that the previous European TDI of 50 µg/kg of bw/day is safe (which is 12 times higher than the current European proposal):

"Other national and international agencies have also assessed the risk of bisphenol A. For example Health Canada, ECHA, French Agency for Food, Environmental and Occupational Health & Safety (ANSES). Among other, the FDA (Food and drug administration) in USA published a new risk assessment in the end of 2014 where the kept the old threshold value of 50 µg per kg of bodyweight. The EU commission, however, base their handling of bisphenol A on the advice from the EU's food safety agency EFSA." (FHI, 2015, p. 1)

The lack of scientific consensus on BPA can here again seen to be used as a tool in public information. It is easy to choose evidence for a message to be conveyed, and it is easy to leave out conflicting views.

Norwegian Environment Agency (NEA)

With respect to EFSA's ongoing re-evaluation of BPA, it is mentioned that NEA has been in touch with EFSA to express their concern about the effects of BPA, including environmental effects. However, from the formulation it is not clear whether NEA's comments were related to health and environmental concerns or just to environmental concerns (It was not possible to find

NEA's comments in the document published by EFSA concerning the public consultation on BPA). It is also mentioned that NEA and NFSA "communicate" on the BPA case, also with respect to precautionary assessments, though it is not really clear what is mean by that (Miljødirektoratet, 2014g).

"In Norway it is the NFSA that has the responsibility for regulation on food, and we have a dialog with NFSA in connection with effects of bisphenol A and precautionary considerations. NFSA have given comments to EFSA's risk assessment where we also raise a concern about the environmental effects of bisphenol A" (Miljødirektoratet, 2014g, p. 17).

In the NEA's consumer site "Erdetfarlig", the information concerning BPA has not been updated six months after EFSA's 2015 press release. They still refer to the preliminary results from EFSA and report that consumers get less BPA than previously assumed and that exposure is well below the tentative new TDI. The final outcome (after the public hearing) was however not reported. Neither is there much information with respect to the environmental effects of this chemical, other than that it can be harmful to aquatic life. And even if the aim of the website is to advise consumers on how to avoid chemicals of concern and select more environmentally friendly products, no explicit advice is given to avoid exposure to BPA (Miljødirektoratet, 2014b).

So, overall, no "official information channel for consumers" provides balanced enough information on the current scientific situation with BPA. No one refers to the fact that experts still do not agree on the safety of this chemical – even after 10 or more years of intense scientific research and multiple evaluations. It is not well described which could be the most vulnerable groups and how could they avoid exposure, if wanted.

NEA suggest to limit the intake of hermetic food and to choose glass instead of plastic, but we do not find for example information on one of the biggest sources of exposure – thermal paper – nor do we read about important situations to be precautious (i.e. during pregnancy and childhood)

The Norwegian Consumer Council (Forbrukerrådet)

The only one that gives a different picture of the situation is the Norwegian Consumer Council. In an article from February 2015, they explain that while EFSA gives green light to BPA, the Danish National Food Institute says that EFSA's BPA tolerable daily intake is too high, based on the same scientific evidence (Forbrukerrådet, 2015).

“The researchers from DTU have, based on the same studies, come to a quite different conclusion. They say straight out that the consumers with EFSA's recommendations are not sufficiently protected against the hormone disruptive effects of bisphenol A.” (Forbrukerrådet, 2015)

They further explain that Danish Food authorities are looking into a voluntary agreement with the industry to reduce the population’s exposure to BPA and thereof follow the recommendations of the Danish experts. At the same time, the food authorities are actively advising that children and pregnant, on precautionary grounds, try to avoid food packaging containing BPA when possible (Forbrukerrådet, 2015).

The Consumer Council finally notes that for such a controversial substance like BPA, the information from the Norwegian authorities should have better reflected the ongoing uncertainties and scientific disagreements (Forbrukerrådet, 2015).

8.3 Conclusions

Chapter 8 describes the discrepancies between the food agency and the environmental agency concerning the assessment of the safety and the regulation of BPA in Norway. Namely, that the environmental authorities have wanted for a long time a stricter national regulation of BPA, whereas the food and health authorities has seems more satisfied with the regulatory standards set at EU level. It is the food agency who administrates the legislation on food contact materials, which is under the responsibility of the Ministry of Health and Care Services).

One could argue that these discrepancies can be explained using an Institutional theory perspective. Much in line with the work of March and Olsen (2008) and Vatn (2005), these two agencies can be said to belong to two very well defined and different institutional settings. They represent two distinct administrative cultures based on different rules of appropriate behavior. These rules are based on particular understandings of the problem at hand, specific traditions for evaluating and interpreting scientific evidence, preferred ways of dealing with scientific uncertainty and what is considered to be an acceptable solution. At the same time, appropriate behavior also depends on the harmonization of cognitive and the (implicit) normative elements, namely: which interests are these agencies serving and defending? It is also important to remember that these agencies have different resources at their disposition (in terms of expertise,

money and influence), and at the end of the day these resources play a critical role in determining which actions are possible and which are not.

We can recall from last chapter that chemical policy in Norway is based on a precautionary thinking, in particular when it comes to hazardous substances (such as EDs). At the same time, the white paper also establishes clear regulatory objectives for the environmental authorities with respect to EDs – namely that its use will be heavily reduced by 2020 (the generation goal). In this respect, I would claim that the white paper no.14 determines the frame for how the environmental authorities should understand the problem related to BPA, and that is that: 1) BPA is a hazardous substance that is listed in the national priority list, it is used in big amounts and is widespread in the Norwegian environment, 2) BPA is a substance covered by the generation goal and thus emissions need to be halted or significantly decreased by 2020, 3) A hazard based approach should be used to manage the risk posed by this substance.

In accordance with this particular understanding of BPA, the Norwegian environmental agency proposed, in 2006, a broad national ban on BPA in consumer products which was finally abandoned due to severe criticisms from the plastic industry and the EFTA surveillance authority.[155]

By analyzing the different proposals for regulation that the environmental agency has put forward in the last decade, one can get a clear picture of what was the agency's stand point with respect to this chemical. Environmental regulators have noted that the production and consumption of BPA was high, and likely to increase in the coming years. At the same time, there were uncertainties with respect to low-dose effects, possible combination effects had not been accounted for in any of the available risk assessments, and safety margins were in general low (in particular for children). The agency also expressed in different occasions that they supported the consideration of results coming from non-standard studies in the risk assessment of BPA, and that they wanted to take a precautionary approach instead of waiting for definite scientific answers.

In 2011, the environmental agency was still considering a stricter national regulation on BPA. At that time they proposed a broad ban on children's products, which ideally would also cover the

[155] In particular it was mentioned that there was no scientific evidence proving that BPA was dangerous (i.e. at that time the available risk assessments at EU level had concluded that BPA was safe) and that such a regulation would have significant economic consequences for the industry.

legislation administered by the food agency. Here again, the environmental agency's arguments were that there were still ongoing uncertainties with respect to low dose effects, and that these effects could be significant. The environmental agency wanted to take a precautionary stand, but this proposal was not supported by the food agency and was ultimately abandoned. In the last years, one can observe that the environmental agency has finally dropped any further plans for national regulation, and has instead focused on work at EU level – where a stricter regulation for BPA in the toy directive is proposed.

The above illustrates the environmental agency's logic of appropriateness at play. At the cognitive level, BPA is seen as an endocrine disruptor of regulatory significance (it is included in the national priority list and covered by the national generation goal) and has to be regulated using a hazard-based approach without the need to conduct a quantitative risk assessment. At the same time, low-dose effects, non-standard studies and combination effects should be taken into consideration when deciding on the safety of this chemical. At the normative level, the interests of the consumers (and the environment) are actively protected, and in case of scientific uncertainty, the precautionary principle should be used. There is more ambiguity with respect to whether regulations should take place at the national or at the European level, but it seems that the latest decision is to take it at EU level.

When it comes to the food authorities, there was some promising cooperation between the two agencies at the beginning. For example, when in 2008 VKM assessed the four BPA non-standard studies identified by the environmental agency. In this occasion, the food agency noted that in case a risk was identified, the agency would modify national regulation according to the recommendations of VKM. Yet, at the time, the overall conclusion was that there was no enough evidence to propose any new regulatory measure (even if the panel also concluded with 'some concern' for low-dose effects on neurotoxicity).

However, this initial 'concern' disappeared rather fast, in particular due to the fact that EFSA's advice has consistently been that BPA poses no risk for the population. From the documents analyzed, argue that NFSA adheres to EFSA's scientific assessments and advice when it comes to the regulation of BPA. This means that NFSA will also base its regulatory decisions on the results of the quantifiable risk assessments conducted at EU level.

In the last years, one can also observe that some VKM experts have also been working at EFSA on issues related to EDs, and in particular to BPA. The chair of EFSA's panel on the risk assessment of BPA was a Norwegian expert that also works at VKM (and the FHI). This common work ensures a common understanding of the problem. This is evident when it comes to the classification of BPA as an endocrine active substance (which is a classification that has been proposed by EFSA). As a result of this, during the last year, the food and the health authorities in Norway have been refereeing to BPA as endocrine active substance, while the environmental authorities keep refereeing to it as an endocrine disruptor.

From the analysis presented in chapter 8, I argue that the food authority's logic of appropriateness is very much based on EFSA's scientific understanding of the problem. Namely 1) that BPA regulation has to be based on the results of a risk assessment, 2) that standard studies are still the most reliable evidence to assess the safety of this chemical, 3) that for the time being it is sufficient to assess the safety of one chemical at the time, without taking into consideration possible combination effects and that scientific uncertainties could be addressed through the traditional risk approach (by adequately quantifying them). At the same time, and based on EFSA's latest assessment, BPA has to be classified as an endocrine active substance (and not an ED). At the normative level it is hard to say how the opposing interests that NFSA is supposed to protect are weighted (namely, to ensure that food is safe for consumers and to contribute to value creation in the food sector), in particular in situations when the agency has to take a stance – such as when participating in regulatory processes at the EU level.

I will conclude that given that these two authorities have very different ways of conceiving the safety of BPA. The overall decision of who has the main responsibility for the health effects of this chemical can be seen as a decision of regulatory policy on its own – since it would be expected that these two agencies would arrive at very different policy recommendations.

9. Discussion and conclusions

9.1 Denmark

In chapter 5, I have argued that the Danish framing of the ED-issue has a strong public health component and that in Denmark EDs are often discussed in connection with well-known negative health trends in the country (bad semen quality, increase in the incidence of testicular cancer and more recently, girls reaching puberty earlier). At the same time, I mentioned that the ED-issue in Denmark is mainly based on what I have called an "endocrine-perspective".

I also mentioned that the early political interest on EDs, in particular the establishment of the national strategy on EDs and the different chemical action plans has promoted the establishment of what I have called the "Danish framework on ED". This refers to the country's long-term strategy and objectives with respect to EDs. I argued that this action framework has also directly and indirectly, encouraged the development of different networks of actors and processes that have been interacting at different levels and in different ways towards the same overall goal – the better regulation of EDs.

The governance of ED in Denmark is characterized by a multitude of processes and structures which interact in several ways to steer the national and international management of EDs. The processes refer mainly to how the problem is understood and possibly solved, setting national priorities and coordinating action. I have for example highlighted the importance of the knowledge-building process in Denmark. In particular, I have claimed that the national focus on ED-research has contributed to a common understanding of the problem and as a reference point for action. Such action (or initiatives) have in turned been organized and 'administered' through a variety of actors and different sets of established procedures. In section (5.4) some examples have been advanced.

I have also argued that the inclusion of such a variety of actors and processes has given more resilience to the management of EDs, given that initiatives often overlap and create redundancy. And at the same time, this broader inclusion of interested parties has also contributed to a better

integration of relevant knowledge and relevant concern (related to the different perception of the potential risk), leading to more socially robust results.

When it comes to the safety of BPA, I have claimed that this overarching frame has encouraged the development of a common understanding of the problem. All from the beginning, research on EDs has been high on the agenda and most of these knowledge building activities have been closely followed by the Danish EPA. I have argued that this close and long relationship between the national ED-research environment and the Danish EPA has promoted a common understanding and a common framing for action between experts and regulators. Where regulators have adopted an endocrine-science perspective on the issue, experts are particularly aware of the current limitations of the regulatory system, and where both experts and regulators work on projects with a long-sight view on regulation.

From an institutional perspective one can claim that this particular socialization processes between scientists and regulators have promoted the establishment of mutually agreed (or institutionalized) rules that have been prescribing what is the appropriate way of dealing with EDs. They have developed common set of rules that prescribe which aspects have to be taken into account when assessing the safety of these chemicals, for example: assess one chemical at the time or a combination?, with exposures during infancy or adulthood?, relying on only on standardized studies or also in academic ones?. It has also contributed to particular ways of evaluating and interpreting the evidence, for example: are there safety threshold for EDs?, are non-monotonic dose-response curves and low-dose effects possible?. And, to common ways of dealing with the remaining uncertainties, for example the need for a larger safety margin, reduce possible risks by informing vulnerable groups, among others. At the same time, and also as explained by March and Olsen, institutions depend on resources, so the fact that scientific expertise and financial means are available, have also played a significant role in sustaining these rules and promoting the development of new ones.

Taking the above into consideration, one could partially explain why Danish assessments on the safety of BPA have sometimes been at odds with more conventional (status quo) evaluations based on a different set of 'appropriate rules' (besides the natural scientific disagreement). At the

same time and in line with the thoughts of March and Olsen (2008) and Vatn (2005), such an institutionalization of knowledge and procedures has also a normative dimension to it. The latter is based on what is conceived to be the best solution for society, or as Vatn (2005) has described it, depends on which interests such 'institutionalization' is to protect. I will give two brief examples of how the particular institutional setting in Denmark has influence how the BPA problem is understood and framed. I will in particular look at some aspects of the risk assessment conclusions concerning the safety of BPA.

In 2010 the Danish National Food Institute was asked to give a scientific opinion on a study that was meant to resolve the uncertainties related to possible low-dose BPA effects on developmental neurotoxicity. In their evaluation of the Stump (2009) study, the experts at DTU-Food concluded that the study could not resolve the uncertainties related to neurotoxic effects, but that the study raised additional uncertainties with respect to possible impaired learning ability.

When the authors of the Danish report were interviewed by the Danish newspaper Ingeniøren concerning the divergent scientific opinions between EFSA and DTU-Food, they mentioned that they "[…] perhaps look at the data with a different perspective and consider, whether it can be ruled out, that bisphenol A is dangerous, whereas EFSA focuses on, whether it is proven, that it is dangerous." (Bredsdorff, 2010, p. 1)

This example shows that – given the many uncertainties in the risk assessment of BPA – shifting the burden of proof can lead to different conclusions regarding the safety of BPA. This is linked to the fact that it is not the same to assume that BPA could be dangerous until proving that it is safe, as DTU-Food suggests. Than the other way around, assume that BPA is presumably safe until ultimately proving that it is dangerous, as EFSA suggests. Since, as has been witnessed in the last 15 years of intense research on BPA, final evidence for either way might never come. From an institutional theory perspective, the allocation of the burden of proof depends on the normative dimension of the institutional setting. In this example the normative dimension refers to determining which party should benefit from the uncertainties: the consumers or the food industry?

The second example deals with the cognitive dimension of the institutional setting and is taken from DTU-Food's 2015 opinion on the safety of BPA. In this opinion one can observe that the differences between DTU-Food and EFSA are also fundamentally rooted at the cognitive level, starting at the definition level.

What is an endocrine disruptor? while DTU-Food sees BPA as an ED, EFSA describes BPA as endocrine active substance

What is an adverse ED effect? while DTU-Food sees changes in anogenital distances (AGD) as an indication of reproductive problems, EFSA sees fertility as the adequate indication for reproductive problems

What counts as evidence? while DTU-Food sees non-standard studies as reliable evidence (some of which are even authored by themselves), EFSA keeps relying on standard studies to derive safety guideline values

Which safety margin should be used to account for remaining uncertainties? while DTU-Food considers that the real risk might be underestimated by not taking possible combination effects into consideration, EFSA stills relies on assessing the safety of one chemical at the time.

From an institutional theory perspective, one can argue that such cognitive differences depend on what each actor considers being the appropriate thing to do when assessing the risk of BPA. These internalized rules depend on particular epistemological stand points, established guidelines, and common practices but could also be related to aspects of role and identity). In this respect, it should not be surprising that when two scientific organizations belonging to different institutional setting (thus having different set of rules of appropriate behavior) evaluate the safety of the same chemical, they can reach different conclusions. In the post-normal science school, this situation - where different expert groups reach diverging risk assessment conclusions concerning the same problem - has been referred to as one where science speaking not one, but many conflicting truths to policy (Funtowicz & Strand, 2007).

Funtowicz (2006) explains (as suggested by institutional theory) that these situations arise because scientific deliberations are framed with different set of assumptions (cognitive dimension) and implicit judgmental values (normative dimension). He notes that the framing model (Section 2.3.4) has been advanced to deal precisely with these problems, where the main idea is to try to

reach consensus between the different groups of experts. Yet, as explained by the framing model, both DTU-Food's conclusions and EFSA's conclusions are equally legitimate, in that such a framing (I will say, such a set of rules of appropriate behavior) is an absolute necessity to be able to conduct a risk assessment. And, in the absence of conclusive scientific evidence to favor a particular framing over another, there will always be several legitimate descriptions of the same problem. However, policy-problems can arise when the particular conclusion of one of these actors are seen as invalid by the others.

However, it is important to highlight that the fact that most actors in Denmark have a common scientific understanding does not mean that they also agree on what is the most appropriate way of regulating BPA. In this respect it can be expected that the Food agency in Denmark will agree more with EFSA that with the Danish EPA. However the fact that in Denmark many final regulatory decisions concerning BPA are taken at the political level renders the processes at the administrative level not that relevant for my analysis.

In Chapter 6, I have concluded that EDs are a politically relevant topic in Denmark and that several members of the Danish Parliament have been particularly eager to impose more ambitious targets concerning the regulation of this chemical. This has been done through the introduction of proposal for Parliamentary resolutions.

In particular I mentioned that in two occasions it has been possible to gather an 'alternative majority' in Parliament to impose stricter national regulations (namely in proposal for parliamentary resolution B101 and B42). This decision made Denmark the first country in the EU to pass regulation on BPA (linked to baby bottles). In particular we see that such policy-decisions have been based on the full acknowledgement of ongoing scientific uncertainties and thus based on the invocation of the precautionary principle. One can conclude that in Denmark, the Danish Parliament has played the most important role in policy-decisions concerning BPA. This has often been described as a top-down approach, where policies have been decided at the Parliament and then communicated to the subordinate agency level which is then in charge of the technical and administrative tasks of putting such policy into practice.

What can be observed during the different parliamentary debates is that there are several ways of interpreting when the precautionary principle should be invoked and on which grounds. I will look into the question of how specifically has scientific uncertainty been dealt with in the political context. But first some few words about the precautionary principle. In Europe, precaution is understood as an extra element in policy decisions that can be used once a scientific evaluation has been conducted and concluded that there are residual uncertainties (Millstone et al., 2004). Yet, as pointed by Stirling (2013), precaution is probably one of the most misunderstood concepts in the politics of risk – many times even being referred to as 'unscientific'. The basic normative spirit of precaution is that "where there are threats to human health or the environment scientific uncertainty is not a reason for inaction" (Stirling, 2013, p. 1). However, on a more pragmatic level, the EU communication on the precautionary principle and the rules of the EEA Agreement (NOU, 2010) specify that precaution should only be used when a risk has been scientifically documented and when the proposed measure to deal with that risk meet the requirement of proportionality between the costs and the benefits.

I will now turn again to the BPA case to illustrate some of point made above, namely that, what is precisely meant by precaution and when should it be used, is still a highly debatable topic. In particular, one can see that during the first two proposals (B101 and B429), the main discussion revolves around on which grounds and under which circumstances should the precautionary principle used?

In section (5.4) I have pointed that for the supporters of the precautionary principle the ongoing scientific disagreements and the high public health stakes were enough ground to act precautionary (without the need to wait for more evidence). At the same time, the supporters of the precautionary principle highlighted that the deliberation about whether and when to exercise precaution was not only a scientific question. It also involved value judgments concerning the 'acceptable' level of risk and this, that is, an intrinsically political decision.

For the opponents of the precautionary principle on the other hand, it was required that well-documented scientific evidence of BPA risk (preferably in the form of a quantifiable risk assessment) was available and at the same time, that precautionary measures were cost-effective.

At the end, one can observe that in order to get a majority in the Parliament, final policy-decisions become a mix of symbolic politics (willingness to meet society's concerns), real politics (pragmatic solutions) and all other sorts of political strategies and compromises. For proposals B101 and B42, one can observe that it is possible to gather a majority in the Parliament to act against BPA, the political compromise being to protect only those aged between 0 and 3 years. Yet, the fact that Parliamentary decision depend on political compromises means that, as suggested by proposal B17, policy solutions are not always coherent. Namely, if that if the aim was to protect the most vulnerable, then policies to protect pregnant women and their unborn babies should have also been implemented.

Yet, vis-à-vis scientific uncertainty, the precautionary approach reaches its true limits when confronted with questions of proportionality and cost-efficiency. As explained in Funtowicz (2006), precautionary model (theory 3.3.2.). This is evident during proposals B17 and B68. In proposal B17, the proponents of a BPA ban on all food contact materials, point to the need to protect pregnant women and their fetuses from BPA exposures. They point to the many unresolved scientific questions concerning the safety of BPA and argue that a more extensive (and expensive) ban would needs to be introduced. Although some political parties agreed with the need to protect this vulnerable group, most of them are not willing to support the proposal.

For the opponent of the proposal, the decision is much easier, such a broad ban was impossible because it would be disproportionate to the level of uncertainty. The opponents argue that the impact on the food industry would substantial and at the same time there would be no evidence of increased health protection for the population. As opposed to the more limited ban that was implemented for food contact material for the 0-3 years old, which they stressed, covered a well-defined range of products and was proportional to the level of uncertainty.

However, it is not until the debate on proposal B68, that we see the limitations of the precautionary principle in its full extent. In this proposal (concerning following the recommendations of DTU-Food's 2015 assessment on the safety of BPA) some regulations would have to be introduced to reduce the dietary BPA intake of the population. Even if this time there is 'scientific evidence' of a potential risk (namely, DTU-Food's recommendation), the

precautionary principle cannot be used because there are no available alternatives to substitute BPA in several products and one could risk using replacements that turn out to be more dangerous. When faced with this type of 'unknown' future risk, Danish politicians have argued, it is unsuitable to use the precautionary model because one might end up with an equally problematic situation. At the same time, it was highlighted the excessive price of such a precautionary measure (which had already been quantified). The majority in the Parliament is thus more supportive for working together with the industry to find 'suitable' substitutes in the future.

As noted by Funtowicz and Strand (2007), in order to overcome such a limitation, a new reformulation of the principle would be needed where precaution "would not be contingent upon what will happen in the future, because this cannot be known. It would have to be framed by what is at stake today." (Funtowicz & Strand, 2007, p. 7). This means that when the precautionary principle is contingent to proportionality between the cost and the benefits, it is unable to provide a real alternative in the face of uncertainty. The last Danish proposal for parliamentary resolution (B68) shows precisely that there are many BPA-policy questions that involve uncertain outcomes – like, how toxic will a new BPA-substitute turn out to be? The uncertainty here is related to the fact that we don't know the answer for that question yet. When faced with such uncertainties, it is impossible to estimate the potential health benefits of BPA's regulation (to be able to compared them to the already quantified cost of regulation). A precautionary approach would have to be detached from this, to provide a real alternative approach for decision-making under uncertainty.

9.2 Norway

In the Norwegian case I have argued that the ED-issue has mainly been the responsibility of the environmental authorities. In Norway, EDs have historically been referred to as hazardous substances (miljøgifter) and the specific term EDs has not be used so much until very recently. This emphasis can be understandable given Norway's position as a clear importer of transboundary pollution (in particular in the Arctic regions) where traditional hazardous substances are an environmental problem. In chapter 7, I argued that using the term 'hazardous

substance' instead of ED has had several significant implications among which that more emphasis has been placed in chemical properties such as persistency and that the problem has been mainly understood as an environmental problem rather than a health-related problem like in Denmark. This has also meant that regulatory efforts (in terms of research and expertise) have been focused on typical hazardous substances in the High North which means that research on non-persistence chemicals like BPA have not been prioritized.

I have argued that in the absence of a national action plan on chemicals, white paper no.14 has been the document guiding Norway's chemical policy in the last decade. National chemical policy in Norway has been based on a precautionary thinking – particularly so when it comes to hazardous substances. At the same time, the white paper specifies clear regulatory objectives for all sectors with respect to hazardous substances listed in the national priority list (including EDs) – namely that their use is going to be reduced as much as possible by 2020, according to the generation goal. It is further specified that the risk associated with this particular type of chemicals calls for a hazard (precautionary) approach, where risk does not have to be quantified but is instead based on the intrinsic properties of these chemicals. This is justified given that it would be hard to establish safe limits for chemicals that keep accumulating in the environment, which at the same time can have substantial and irreversible effects and where the posterior costs of remediation can be very high.

I have also pointed to the fact that there has not been much political attention on the topic, and that in general, political parties have not included chemicals (even less so endocrine disruptors) in their overall environmental policy objectives (with the exception of the Liberal Party of Norway and the Green Party which have some policy objectives for hazardous substances)[156]. On the NGO side, there is a current effort to put chemicals back into the environmental agenda, but the work is rather limited in economic and manpower resources (personal communication with representative of Bellona). The Norwegian Consumer council has maybe been one of the most active players when it comes to chemicals in the last years. In general it can be said that there is little public awareness and political interests on the topic in Norway.

[156] Venstre being the only one that used the word EDs

This means that, as opposed to Denmark, we cannot really talk about a 'governance' of EDs in Norway (understood as the collective and coordinated common steering of ED-management). In Norway, as reported by several official documents much of the work takes place at a fragmented administrative level. The report from the Statskonsult from 2001 especially mentions that each of these public bodies have developed particular ways of defining chemical risk that depends on their particular expertise, their particular regulatory traditions, the interest that they are meant to protect and the resources they have to act on it. And that as a result of this, it is not uncommon that these public bodies end up having different management preferences when it comes to chemicals. In the case of bisphenol A, the main actors have been the health, the food and the environmental authorities.

In chapter 7 I have also commented on the particular roles of the food agency, when it comes to chemical management. Namely that NFSA is the subordinate agency of three different ministries and that it is in charge of administrating several pieces of legislation for the Ministry of Health and Care Services in connection to chemicals. Among these pieces of legislation we have the legislation on food contact materials which regulates the usage of BPA in food-related products. In particular, the food agency is in charge of taking care of the human health dimension, while the environmental agency regulates those same chemicals in the terms of their possible environmental effects. However, as explained in chapter 7, the environmental agency is also in charge of assessing human health implications of chemicals in consumer products, many of which are also used in food contact materials. Given that the environmental authorities has recently highlighted that, when it comes to EDs, their focus is on environmental effects, it become really ambiguous who has the ultimate responsibility of the health dimension. At the same time, it has also been mentioned that chemicals do not rank very high in the list of priorities of the Ministry of Health and Care Services, which adds to the uncertainty of who is ultimately accountable for the health dimension of those chemicals that are covered at the same time by the legislation administered by the food agency and by the environmental agency (namely cosmetics, food contact materials and pesticides). Furthermore, the fact that each agency has its own group of advising experts, further increases the chances of a diverging health evaluation.[157] It has been

[157] In Denmark for example, the Danish EPA has responsibility for most of the legislation on chemicals (including cosmetics and pesticides), while the DVFA is in charge of the legislation on food contact materials. However, given

impossible for me (with the scope of my thesis) to figure out how much autonomy – or discretion to make more or less independent decisions - these agencies have when it comes to deciding on regulation. The way I understand it from the documents that I have analyzed and my interviews is that the agencies prepare a "technical recommendation" and it is up to the ministry to endorse the recommendations. Yet, the regulation of chemicals, both in the environmental and in the food sector, is a field that requires expert advice (from science) and professional competence (from the agencies), meaning that the ministries are dependent on that technical input, and although it is recognized that the different parental ministries can intervene on professional considerations as well when deciding on regulation, it is unclear what is the threshold to call for such an intervention.

In chapter 8 the different preferences between the food agency and the environmental agency concerning the regulation of BPA were further analyzed using an institutional theory perspective. I concluded that much in line with the work of March and Olsen (2008) and Vatn (2005), these two agencies can be said to belong to two very well defined and different institutional settings - represented by two distinct administrative cultures based on different rules of appropriate behavior. These rules are based on specific ways of processing information, best practices, key interpretative traditions, previous experience and I will add different ways of dealing with scientific uncertainty. As pointed in the theory, those institutionalized rules facilitate interpretation of ambiguous situations and prescribe what the appropriate thing to do. As a result of this, these two agencies understand the problem at hand and its possible solutions very differently. Their main characteristics are presented below.

For the environmental agency, BPA is seen as an endocrine disruptor of regulatory significance (it is included in the national priority list and covered by the national generation goal) and has to be regulated using a hazard-based approach without a need to conduct a quantitative risk assessment. At the same time, low-dose effects, non-standard studies and combination effects should be taken into consideration when deciding on the safety of this chemical. At the normative

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that both agencies get their scientific advice from the same experts, ensures some consistency in their health evaluations.

level, the interests of the consumers (and the environment) are actively protected, and in case of scientific uncertainty, the precautionary principle should be used.

For the food agency on the other hand, BPA regulation has to be based on the results of a quantitative risk assessment – where standard studies are still the most reliable evidence to assess the safety of this chemical. At the same time, it is understood that it is sufficient to assess the safety of one chemical at the time and that scientific uncertainties could ultimately be quantified and addressed through the traditional risk approach.[158] According to this way of evaluating the evidence, BPA is to be classified as an endocrine active substance (and not an ED). At the normative level it is hard to say how the opposing interests that NFSA is supposed to protect are weighted (namely, to ensure that food is safe for consumers and to contribute to value creation in the food sector), in particular in situations when the agency has to take a stance – such as when participating in regulatory processes at the EU level.

These particular preferences can be explained by different factors. In the food field for example (as explained in theory section 2.3.3), after a series of food crises in the late 1990s, many European food safety institutions (including NFSA) were subjected to review and reform in order to restore public confidence in expert advice and in European risk management. The main feature of the reform was the strict separation of risk assessment and risk management activities and responsibilities (something that was codified in the European Food Law). At the same time, EFSA became the eminent scientific risk-assessment authority for food policy issues in Europe (Lofstedt, 2011). In this respect, we can say that risk assessment is the basis for food safety in Europe – and this 'culture' is something that is share among most food agencies in Europe (including NFSA).

The environmental authorities, on the other hand, are more familiar with the concept of precaution (which actually originated in the environmental field) and hazard based approaches which are commonly used in today's environmental regulatory system. In particular when there are considerable scientific uncertainties - such as information gaps, complexity of biological

[158] In case a precautionary measure needs to be taken, this would have to be based on the EU-agreed definition of the precautionary principle, including some sort of risk assessment and respecting the clause for cost effectiveness.

effects, difficulty to estimate exposure scenarios, and many more - and concern about significant effects.

At the same time, these two authorities have different overall responsibilities. While the environmental agency is usually in charge of protecting the environment and consumer from *unnecessary* chemicals (chemicals that one could as well live without), the food agency is in charge of finding the safest way of dealing with chemicals that are unavoidable (given that they are food contaminants and food is something that is needed).

Furthermore, food regulators usually have a narrower mandate than their environmental counterparts in that they just have to assess chemical safety in relation to the diet, while the environmental authorities have to relate to a broader field ranging from assessment of chemicals in consumer products to impacts in whole ecosystems. One could also argue that there are also differences in terms of money and influence, with the food authorities historically having more of these resources (Lofstedt, 2011).

However, perhaps their main difference relates to the much larger debate of whether chemicals should be regulated using a risk or a hazard based approach.[159] In Europe, this is still an unresolved discussion and it has been noted that these two approaches represent the two souls of the EU risk regulation system: the rational, risk and evidence-base technocratic soul and the messier, more human and pluralistic precautionary-oriented soul (Alemanno, 2011).

The fact that in Norway policy-decisions concerning BPA are taken at the administrative level and in particular based on the conclusions of a risk assessment, means that in this country it is the rational, technocratic, evidence-based soul that has been responsible for managing the risk related to BPA. At the same time, the fact that such risk assessment conclusions are challenged by different expert groups complicates the legitimacy of this decision. If we go back to the risk governance literature (section 2.2.1), in particular to it normative dimension, risk scholars warn about this precise type of situations: when uncertain risks are managed as if they were simple

[159] Where regulation based on hazard refers to "the potential for a substance, activity or process to cause harm or adverse effects" and the risk-based approach refers to "a combination of the likelihood and the severity of a substance, activity or process to cause harm".

uncontroversial risk. A failure to take the ongoing uncertainties into consideration could lead to Beck's famous "organized irresponsibility".

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Appendix

Can you explain me what is your work with respect to BPA?

What are the specific guidelines, internal rules, practices that are relevant for your work with BPA? (look for ways of process information, best practices, interpretative traditions, previous experience)

Can you explain me what is the ED-issue about?

Is there a scientific controversy with respect of EDs? Or can we talk about consensus?

How are the regulatory processes at the different levels: agency, ministry, EU, other?

Is the ED issue a national or an international problem?

Are there enough economic means to deal with EDs?

How are the responsibilities organized?

Who has the ultimate decision on BPA regulation in the country?

Are EDs high on the political agenda?

What is the best way of dealing with scientific uncertainty? Who decides?

Who defines the policy-ambitions? Who defines the desired level of protection?

Which factors should drive decision-making: scientific, environmental, social, ethic, economic?

Who are the relevant actors for EDs policy-making?

Is there any established cooperation/collaboration between the different actors?

Are there some stakeholders that are more influential than others?

Which is the best way to influence EDs policy-making at EU level? Is there any room for national regulation?

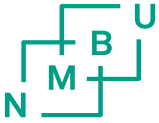
Who gets to disseminate information on EDs? How?

Where do you get your scientific information from? Is there enough research/competence on the topic?

Are EDs a media topic? Are they depicted accurately?

After so 15 years of intense research on BPA, can we say that the main scientific uncertainties are overcome?

What are the responses from the Industry?



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