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National Policies on Substances of Concern

A study of national policies on substances of concern in six selected EU Member States: Belgium, Denmark, France, Germany, Sweden, the Netherlands

Colofon

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Date: 3 March 2017

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1. Introduction

1.1 Background of the study

In the Netherlands, a specific government policy has been developed that aims to keep substances of high concern as much as possible out of the living environment. Substances are deemed to be of high concern, in Dutch 'Zeer Zorgwekkende Stoffen' ('ZZS'), when they are particularly harmful for man and environment, for instance because they are carcinogenic, are harmful for human reproduction or accumulate in the food chain.[1] The Dutch ZZS policy measures include strict emission standards in permits and stimuli for industry to substitute ZZS by less harmful alternatives.

In practice, the implementation of the policy runs into some difficulties. It is not always easy and sometimes even impossible to investigate which ZZS are actually used or emitted in the Netherlands. Sometimes it is only by incidents that this becomes known, in which cases the policy loses it preventive effect. In the Dutch political arena, chemicals policies of neighbouring countries are sometimes highlighted as examples of a more proactive stance. At the same time, however, there is a call (notably by industry) for a European level playing field and a rejection of national policies that are above European standards.

It is for all these reasons that the Dutch Ministry of Infrastructure and the Environment and the governmental expert institute in the field of public health and the environment in the Netherlands, the RIVM (Rijksinstituut voor Volksgezondheid en Milieu) expressed the need to get a more detailed insight into the national policies on substances of concern of neighbouring EU Member States. The Ministry and the RIVM are looking for opportunities to mirror the Dutch ZZS policy to what is happening elsewhere, to exchange lessons learned from experiences in other countries and to see in what instances and aspects Dutch policy can become more efficient and effective. Of particular interest is whether, and if so in which way, other countries address policy issues that are considered as priorities for the actual Dutch policy development process: emission control, promotion of substitution and circular economy (recycle and re-use). Eventually increased cooperation with these countries could be a perspective.

The study that is reported here has been carried out to provide the Ministry and the RIVM with the desired insights.

1.2 Purpose of the study

The purpose of the study that has been carried out is threefold:

1. to explore whether selected EU Member States do indeed have national policies on substances of concern, and if so, what are the main characteristics of these policies;
2. to obtain inspiration and ideas for possible further development and/or fine tuning of effective Dutch ZZS policies; and

[1] Although the English translation of 'Zeer zorgwekkende stoffen' (ZZS) is 'Substances of very high concern', ZZS cover more substances than SVHC under REACH. The definition of ZZS does, however, match with art. 57 of the REACH regulation (EC 1907/2006).

3. to contribute to mutual acquaintance with, and possibly exchange of and cooperation between national policies on substances of concern in 6 selected EU Member States.

In this study 'national policies on substances of concern' are defined as: policy efforts within a country (federal, national or regional) that extend beyond, give concrete interpretation to or get ahead of European and global obligations for reducing (certain categories of) 'substances of concern' in relation to public health and the environment. It should be noted that in this study the term 'substances of concern' does not refer to a predefined group of substances. The term is used to indicate the substances at which national policies aim; which is taken as the sign that – apparently – they cause specific national 'concern'.

The formulation of the purpose makes clear that this is not a comparative study. The study aims to find inspiration and lessons in other EU Member States that can help Dutch policies to become more efficient and effective; not to compare – and judge - policies with and between these countries. In all selected countries national policies have evolved in specific national, historical and political contexts. As such, national policies cannot be seen as more or less developed, as better or preferable, but first and foremost as *different*, originating from distinct national backgrounds. Consequently the findings of this study will be presented this way.

The selection of countries to be included into this study was based on a first exploratory study carried out by RIVM. It showed indications that there were national policies on substances of concern in Belgium, Denmark, Germany, France and Sweden. Most of these countries are also close or direct neighbours to the Netherlands, which adds to the relevance of the study in the light of mutual economic and environmental influences. This is particularly the case for the countries with which the Netherlands shares its rivers: Belgium, France and Germany.

In order to allow for a mutual exchange of information and experiences with the selected countries, the Dutch national policy for substances of concern has been investigated and presented in this report in a similar way as the policies of the other countries.

1.3 Method of the study

The method

The basic methodology followed was the same for all 6 selected countries. In the course of the study the approach diverged somewhat, depending on the preferred method of information exchange of the policy makers in the respective countries.

As a first step of the study contact was made with the counterparts of the Dutch policy makers in the selected countries: the national competent authorities for REACH. Simultaneously an internet search for documentation of national policies on substances of concern was carried out. When contact was established and cooperation was confirmed – which happened successfully in all target countries – further input was asked for and obtained for completing the first internet search.

On the basis of the results of this search, a first version was written of an overview of the national policy for substances of concern in the respective countries. This first version was then presented to the contact person for verification and completion if needed. With almost all countries, the first version was discussed during telephone calls followed by email exchanges.

In some of the countries (Belgium, Denmark, Germany) the policy makers and researchers agreed that more detailed information could be exchanged during face-to-face contacts. Therefore, study visits were arranged in which several policy makers and experts were interviewed about their national policies. With the help of this information a second version of the overview of the national policy for substances of concern was prepared, which again was presented to the national experts for correction and completion.

The activities that were carried out in the interaction with the different countries are listed in table 1 below.

Table 1. Expert interviews in the different countries

Country	Email interviews	Telephone interviews	Face-to-face interviews	Group interviews
Belgium	X	2	1	1
Denmark	X	1	5	1
France	X	2		
Germany	X	2	1	
Sweden	X			
The Netherlands	X	2		

On the basis of all national overviews, the research team looked into the nature of the national policies on substances of concern and into the specific substances that are deemed to be 'of concern' in the different countries. The team selected examples of policies and measures that are particularly instructive, inspiring, innovative or 'different'. The latter are used to provide the reader with a general impression and overview in the next chapter.

Limitations

Given its leading questions, the study has a broad scope. The extent of the data collection has however been limited by its timeframe. The active search for data ended by the end of 2016. Additional incoming information was included in the study until the end of January 2017. If only for that reason, the research team cannot claim completeness of the overviews and information. Moreover, to a certain extent the amount and types of information that were available depended on the level of openness and self-presentation of policies on government websites, on the vantage point of the experts that were interviewed, as well as on how the relevant authorities are organised (e.g. one central agency or an amalgam of federal and regional bodies). It should therefore be noted that if policies are not mentioned, this may be because information on them was lacking, rather than because they don't exist.

1.4 This report

Chapter 2 presents information related to the general questions of this study. What are the national backgrounds of the national policies on substances of concern? What is their nature? What specific substances are deemed to be 'of concern'? And what examples of policies and measures are particularly instructive, inspiring, innovative or 'different'?

Chapter 3 contains a brief reflection on the research process and outcomes by the research team. In particular the question is addressed which of the identified policies and measures in other countries are particularly promising for Dutch policy practice and/or merit further exploration.

The actual descriptions of the national policies of concern in the 6 selected EU Member States are presented in 6 annexes to this report. These presentations are all based on the same standard format:

- First a general description is given of the national policies and measures for substances of concern.
- Next, the substances are described that are considered 'substances of concern.'
- Then a number of characteristics of the policy structure and process are described: their legal and formal basis, their organisational basis, the involvement of stakeholders, the relation with European policies and international agreements and the monitoring and evaluations that take place or have taken place with regard to these policies.
- Separately a description is given as to whether any incidents have taken place with relevance to these policies, and of the relationships of these policies with emission control, inspection and enforcement, circular economy and substitution.

Each annex report contains an own overview of contact persons and information sources.

2. National policies on substances of concern in selected EU Member States; an overview

2.1 Introduction

In this chapter an overview is presented of inspiring and instructive examples of national policies and measures for substances of concern. This overview is preceded by a description of the specific national contexts of these policies and measures. As stated in the previous chapter, these policies originate from specific national backgrounds and respond to specific drives, possibly even incidents. These are described in chapter 2.2.

In paragraph 2.3 the national selections and prioritisations of substances of concern are examined. Which specific (groups of) substances give rise to concern in which country? What are the 'national substances of concern'?

From paragraph 2.4 onwards examples are presented of policies and measures for substances of concern. For presentational purposes these examples are ordered to types of policies or measures. These types are:
- National bans and restrictions (§ 2.4)
- Registration requirements (§ 2.5)
- Obligations and requirements for commercial transactions (§ 2.6)
- Targeted and accelerated research and assessment (§ 2.7)
- Targeted information (for industry and for consumers) (§ 2.8)
- Stakeholder involvement (§ 2.9)
- Emission control (§ 2.10)
- Inspection and enforcement (§ 2.11)
- Substitution and circular economy (§ 2.12)

The examples that are presented are not exhaustive. More examples of policies and measures can be found in the different country studies in the annexes to this report.

2.2 Different national policies from different backgrounds

2.2.1 Different backgrounds

First a brief description is given of the backgrounds of the national policies on substances of concern. Which national institutions are responsible for these policies, what were – according to our contacts – the drives and incidents that prompted them, and what types of policies have resulted?

2.2.2 Belgian backgrounds and policies

- In Belgium, both the federal government as well as the three regional governments have responsibilities with regards to the development of policies and legislation for managing substances of concern. The federal government is responsible for implementation of regulation on the placing on the market of chemical substances (and products) and for labor protection. The regional governments are responsible for the implementation of regulations on the uses of the substances (and products), their related emissions and the aspects of enforcement.

- Belgium's main drive to take action on a substance (or group of substances) is to follow European and international requirements. In anticipation on European legislation, Belgium already implemented a nanoregister. The main reason for this initiative is the uncertainty of the effects of nanomaterials in combination with the fact that nanomaterials are on the market in a large number of products.
- Belgium's federal and regional policies are fully based on the European Directives and Regulations (e.g. REACH/CLP/WFD) and on international conventions (e.g. PIC/POP/SAICM).

2.2.3 Danish backgrounds and policies

- In Denmark, the Environmental Protection Agency (EPA), an agency of the ministry for Environment and Food, is responsible for legislation and is the authority in charge of major tasks with regards to chemicals. Some issues regarding chemicals are dealt with by the Working Environment Authority. There is close cooperation with other Scandinavian countries, notably with the Swedish chemical agency (KEMI).
- In Denmark, there is rather high attention for chemicals by the public, the media and politicians. There is a push for initiatives on a national level. Also scientific findings, for instance on endocrine disruptors, have been a drive for national initiatives.
- The Danish national policy for substances of concern consists of a broad array of different measures, including Danish priority substances, research and surveys, and different information campaigns targeted at either industry or consumers.

2.2.4 French backgrounds and policies

- In France, both the ministry for the environment and the ministry of labour have responsibilities for policies on substances of concern. In chemical matters they are supported by ANSES, the French Agency for Food, Environmental and Occupational Health & Safety, and INERIS, the National competence centre for Industrial Safety and Environmental Protection.
- The main drives of French policies on substances of concern are societal concerns and pressures. The levels of concern over 'bisphenol A' and over pesticides exposure in France are probably unparalleled by any other EU Member State. Also, the parliamentary initiative of the 'Loi Detox' can be seen as an expression of pressure on policy makers to work on the substitution of substances of concern. The policy process itself is quite open for societal input, like via the annual 'Environmental Conference' (formerly known as 'Grenelle') and by taking societal concern as a criterion for substances of concern.
- The French national policy for substances of concern addresses many different specific substances and substance groups, with measures ranging from accelerated assessments and registration requirements to a specific ban.

2.2.5 German backgrounds and policies

- In Germany, a variety of institutions is involved at both federal and state level. At the national level, the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety is responsible for the implementation of legislation related to chemicals, and the Federal Ministry of Labour and Social Affairs is responsible for worker protection.

- As the leading chemical producer in Europe and number four in the world, Germany's drive to take action is based on particular stewardship. The country strictly follows EU/International requirements.
- The German national strategy to manage substances of concern is based on meeting European/international requirements, with a particular focus on the 'SVHC Roadmap'. In addition, Germany still has its own legislative framework in place (incl. a ban of 4 substances). In the rare case that a risk associated with a substance only occurs in Germany, national legislation supersedes EU/international requirements.

2.2.6 Swedish backgrounds and policies

- The responsibility for the management of hazardous chemicals (SVHC as well as others) is mainly placed on the Swedish Chemical Agency (KEMI). KEMI is a supervisory authority under the Ministry of the Environment and Energy, and is responsible for ensuring that companies and society at large deal with chemicals in an acceptable manner. Furthermore, municipalities play an essential role in the local regulation of chemical substances. A network of municipalities is working actively in the area of a non-toxic everyday environment, particularly in pre-schools.
- The environmental objective 'A Non-Toxic Environment' is the main driving force behind Sweden's approach to manage chemicals in the everyday environment. It has a strong focus on the protection of human reproduction and child health. Scientific research and incidents are important impulses for the development of new policies. Sweden furthermore seems to be a pioneer in the development of new and/or strengthening of existing chemicals legislation within the EU.
- EU legislation, mainly REACH and CLP, forms the legislative ground for both the 'Strategy for a non-toxic environment' and the subsequent 'Action plan'. In addition, Sweden implemented a number of measures (e.g. development of an action plan for highly fluorinated substances) and rules (e.g. on reporting to the Product Register and on bans/restrictions of substances), only applicable in Sweden.

2.2.7 Dutch backgrounds and policies

- In the Netherlands, the ministry of Infrastructure and the Environment (IenM) is the first responsible authority for policies on substances of concern. The National Institute for Public Health and the Environment (RIVM) plays a key role in implementation of chemicals policy and advice.
- The Netherlands is a densely populated country. Companies and inhabitants often live close to one another. Political pressure arises from public concerns over the health risks of people living in the vicinity of polluting industries and over the pollution of nature conservation areas.
- An important element of the Dutch national policy for substances of concern is the approach where substances identified as being of very high concern in international legislation are also treated as such in national legislation for emission. Other national policies concern plant protection products and asbestos (outdoor) roofs.

2.3 National substances of concern

What are the substances that the national policies on substances of concern focus on? Which national selections and prioritisations of substances exist? Which specific (groups

of) substances give rise to concerns in which country? What are, in other words, the 'national substances of concern'?

First it should be noted that in several countries (part of) the national policies on substances of concern do not focus on specific national priority substances. Instead, these policies focus on substances that are (already) prioritised in international legislation. The policy's measures, however, go further or are stricter than the international regulations require; therefore they are, within the context of this study, labelled as *national* policies for substances of concern. For example, in Denmark, measures are taken to inform and assist industry and consumers in exercising their rights and duties concerning potential CMR's in REACH registrations and substances on the REACH Candidate list.

Other (parts of) national policies on substances of concern do indeed focus on national priority substances. Three types of 'national substances of concern' can be distinguished:

1. *Substances prioritised in a national classification system*
   Some policies are based on a national classification system that selects and ranks substances according to their properties and attributions. For example, in France a system exists to rank 'substances toxique les plus préoccupantes' and in the Netherlands criteria are in place to identify 'ZZS'. All systems include criteria like CMR, PBT, vPvB and endocrine disrupting effects. But also other types of criteria are employed, like relevance for the domestic market (DK) or societal perception (FR).

2. *Specific categories of substances of concern*
   In all countries some categories of substances are distinguished that are of specific concern and on which specific national policies are developed. Examples of these categories are nanomaterials (BE, DK, FR, SE) and endocrine disruptors (DK, FR, SE).

3. *Specific substances*
   In some countries specific substances are singled out on which specific policy measures concentrate. For example, in France Bisphenol-A is banned from thermal cash receipts while Germany banned several substances (and substance groups).

Table 2 on the next page presents an overview of the different types of substances of concern that are distinguished and addressed with policy measures in the different countries.

(Please note that an empty cell might indicate two options: either that in this country no such (mode of) selection of national substances of concern exists, or that no information is found).

Table 2. (Modes of) selection of national substances of concern

	BE	DE	DK	FR	SE	NL
National classification system			'LOUS' substances	'Substances toxique les plus préoccupantes'	'Särskilt farliga ämnen'	'Zeer zorgwekkende stoffen' (ZZS)
Specific categories of substances: - Endocrine disruptors - Nanomaterials - Pesticides - Asbestos - Medicine discharge - Other	X	– Perfluorinated compounds and phthalates – Dioxins and furans – Bio-persistent fibres	X X	X X X X	X X X – Highly fluorinated substances and allergens – Microplastics – Chlorinated solvents	X X X
Specific substances		– Formaldehyde – Pentachlorophenol		– '6 toxic substances' (Hg, As, PAH, BEN, perchlorine ethylene, PCB's / dioxins) – BPA	- BPA; two-part epoxy containing BPA or BPA diglycidyl ether - Triclosan - Cadmium in fertilisers - Mercury and articles containing mercury - Ammunition containing lead - Detergents containing phosphate - Certain hazardous products/ articles, like drain cleaning products and car care products containing methanol.	

2.4 National bans and restrictions for substances of concern

In this and the following paragraphs we turn to the actual national policies on substances of concern that are in place. We describe the types of policies and measures that are installed, and clarify them by some examples from the country studies. These examples are not exhaustive, more examples of these policies and measures can be found in the different country studies in the annexes to this report.

First of all, in some countries specific substances are banned, either in specific applications or in general. In the latter case these substances are also restricted under REACH.

Examples

- In France, the use of **bisphenol-A in thermal paper** (cash receipts) is restricted.
- In Germany, the Chemical Prohibition Ordinance regulates restrictions for placing hazardous substances on the market and prohibits a few specific substances (**formaldehyde, dioxins and furans, pentachlorophenol as well as bio-persistent fibres**) in order to protect public health and the environment.
- In Sweden, The Chemical Products (Handling, Import and Export Prohibitions) Ordinance contains particular provisions on bans and other restrictions when handling:
  - two-part epoxy containing **bisphenol A** or **bisphenol A diglycidyl ether**;
  - **cadmium** in fertilisers;
  - **chlorinated solvents** (methylene chloride, trichloroethylene or tetrachloroethylene);
  - **mercury** and articles containing mercury;
  - ammunition containing **lead**;
  - detergents containing **phosphate**;
  - certain other products and articles hazardous to health and the environment, such as dry cleaning products and car care products containing **methanol**.
- In the Netherlands, a ban on **asbestos roofs** has been announced, which will come into effect in 2024. This means that owners will need to remove all existing roofs with asbestos.
  Also a national ban has been introduced on the **use of chemical plant protection products in the non-agricultural sectors on hardened surfaces** (from end of 2017 also on non-hardened surfaces).

2.5 Registration requirements for substances of concern

In several countries companies that place substances or products on the domestic market or make use of these products or substances, are required to enter these substances in a national register. These registers serve on the one hand for policy makers to obtain an oversight of the substances and products on the national market and/or in use and to prioritise and fine-tune policy initiatives. On the other hand they serve to inform and create awareness in industry (by reflecting on its substances and products) and among consumers and the general public (that is given access to a public version of the registry).

Examples

- In Belgium and France, an obligation has been created for industry to enter nano materials that are placed on the domestic market into a **Nano Registry.**
- In Denmark and Sweden, companies that manufacture, import or change the trade name of any hazardous chemical substance or material in certain quantities used for commercial purposes, must notify the **Product Registry**. Together the Scandinavian countries maintain a web based database called **SPIN**, that is open to the public.

2.6 Obligations and requirements for commercial transactions

In some instances obligations and requirements are developed at national level to regulate the way commercial transactions of (products containing) chemicals are conducted.

Examples

- In Germany, for certain substances (for instance with pictogram GHS06 or GHS08 and the signal word 'danger' plus certain hazard statements) the **nature of commercial transactions** is regulated. These chemicals can only be sold by persons with specific qualifications ('Sachkunde') that are reliable and at least 18 years old, to customers that declare in writing their legitimate use of the chemicals, with specific administrative requirements.
  Furthermore, an **'over-the-counter'-obligation** (a 'self-service ban') is in place for a number of substances, meaning that substances that are sold by retail may not just be put on a 'shelf', but need to be locked away and may only be handed to the customer by qualified staff members.
- In Sweden, a network of municipalities has been initiated and requirements have been developed (by KEMI) to promote an **environmentally sound procurement of chemicals and products containing chemicals for pre-schools**.

2.7 Targeted and accelerated research and assessment

Concerns about chemicals are sometimes reasons for countries to intensify research to reduce basic uncertainties (for instance with regards to the possible risks of nanomaterials), to accelerate risk assessments of chemicals (for instance concerning endocrine disrupting properties) or to obtain insights into the use and dispersion of chemicals (for instance in consumer products).

Examples

- At federal level in Belgium contributions are made to **scientific research for improving regulations on nanomaterials**, like the projects 'nanopolymer' and 'To²DeNano'.
- In Denmark, national **strategies on LOUS substances** have been developed on the basis of comprehensive reviews (surveys and data collection). Also, for more than a decade the Danish EPA has commissioned **surveys to identify chemical substances in a number of consumer products**, such as toys, cosmetics, clothes, furniture.
- In France, the 'Stratégie Nationale sur les Peturbateurs Endocriens' aims to **drive research, valorisation and surveillance of endocrine disruptors** and to **accelerate and improve the evaluation** of these substances.
- In Germany, responsible use of nanomaterials is promoted at national level through **ministry-funded research in the field of nanotechnology and –materials**; e.g. concerning several widely used nanomaterials such as TiO2, Ag, Au.

2.8 Targeted information on substances of concern

Examples can be found where specific information about substances of concern is provided for industry or consumers.

2.8.1 Targeted information for industry

Substance-specific types of information for industry are either meant to enable companies to properly play their role in the registration and communication process and/or to promote a proactive stance by companies.

Examples

- In Denmark, the **'List of Undesirable Substances' (LOUS)** was drafted to identify substances that had better be substituted, due to their hazardous properties and future banning potential, thus assisting and enabling companies to take a proactive stand.
- In 2013 the Danish EPA carried out a project in which it **screened pre-registered and registered chemicals under REACH with the help of QSAR for potential CMR properties**. The findings were used to flag to industry that there may be a need to obtain more knowledge in order to document a safe use.
- In Sweden, the **web-based tool PRIO** has been launched to assist companies in work on risk reduction. It is developed in order to improve knowledge in companies of chemicals and how they should be handled. Furthermore, several industrial sectors in Sweden have developed their own systems to reduce risks associated with chemicals. '**BASTA**' is an example for the construction sector. It identifies construction products that do not contain SVHC. The tool was developed in cooperation with Swedish government agencies, and the criteria are partly based on the criteria in PRIO.

2.8.2 Targeted information for consumers

Substance-specific information for consumers is mostly developed to assist in making purchase decisions. Sometimes specific types of consumers are addressed, like pregnant women or parents. In some cases there is also an intention to promote the legally sanctioned information exchange between suppliers and consumers (see example "Tjek Kemien") .

Examples

- In Denmark, several information campaigns have been held **targeting pregnant women, to inform them about endocrine disrupters and other chemicals**. The first campaign was launched in 2006. In 2011 another public campaign took place, prompted by a study of pregnant women and exposure to endocrine disrupting chemicals in everyday personal care products, food and domestic chemicals. In April 2015, the government launched a campaign in which General Practitioners advised pregnant women about endocrine disrupting chemicals.
- The Danish EPA and the Danish Consumer Council developed and launched an **app called 'Tjek Kemien – check the chemicals in your products**.' With this app consumers can scan the barcode on a product. This triggers an automatic request for information on the content of Candidate List Substances in the product to the supplier. Suppliers have an art. 33.2 REACH obligation to reply to these requests.
- Both the Swedish 'Action Plan for a non-toxic everyday environment' and the website of the Swedish Chemicals Agency are presented as **information portals for consumers**.

2.9 Stakeholder involvement in national policies on substances of concern

In what way do stakeholders play a role in the development of national policies on substances of concern? In almost all countries in the study stakeholders are consulted during policy development process and in the evaluation process of existing policies. Often there is a general habit of regular consultation of the authorities with stakeholders. In many cases the development of new policies is kicked-off with a discussion with stakeholders, and often also research and assessment processes are carried out with consultation of stakeholders on the side.

In some countries specific arrangements are in place to consult and involve stakeholders in a more general fashion. And in some cases also citizens are directly consulted.

Examples

- Part of Germany's strategy to promote the responsible use of nanomaterials is the '**NanoDialogue'**, a national platform for the exchange of ideas between civil groups and stakeholders about the opportunities and risks of nanotechnologies. More than 200 experts participate on a voluntary base.
- In France, a broad public participation process is organised on an regular basis, in order to identify and prioritise the environmental issues to be addressed. This process is known by the name **'Environmental conference' (formerly known as 'Grenelle').** One example of a policy initiative that was prompted through this process, is the 'Stratégie Nationale sur les Peturbateurs Endocriens'.
- In the Netherlands, voluntary agreements called **'Green deals'** are made **between government and stakeholders**. 'Green deals' are voluntary agreements that are intended to facilitate sustainable initiatives. These initiatives are carried out by stakeholders. The government contributes by facilitating the initiative, e,g, by simplifying regulatory obligations. Examples of green deals for substances of concern can be found in the field of plant protection products.

2.10 National policies on substances of concern and emission control

All countries control industrial emissions by means of permits and inspections. The country studies, notably those concerning France and Germany, describe practices where emission standards in permits are derived from CLP classifications (which in a way also implies some kind of 'national policy for substances of concern'). The clearest connections between 'national policies on substances of concern' and emission control are to be found in Germany and the Netherlands.

Examples

- In Germany, the **Federal Immission Control Act** ensures that substances of concern are directly linked to (local) emission control. The Immission Control Act lists the requirements for emissions of dangerous substances (**classified as such under CLP**) to air, water and soil. The German Bundesländer each have a **permit system** in place that implements this Federal Law.
- In the Netherlands, **the ZZS policy** aims to keep these substances of concern as much as possible out of the environment. The policy **is implemented first of all by means of a permit system**, based on the 'Activities Decree'. Companies are obliged to report to the authorities every 5 years. The report contains information about the emissions of ZZS and the possibilities to reduce this emission. The company has to minimize the emission of ZZS. Subsequently the competent authorities include emissions restrictions and obligations for continuous improvement in the permit that is granted.

2.11 National policies on substances of concern and inspection and enforcement

In the country studies two instances can be found in which inspection and enforcement activities are directly related to national policies on substances of concern. The one instance concerns chemicals in products (by the Danish Chemicals Inspectorate), the other chemicals in emissions (by the Dutch Human Environment and Transport Inspectorate (ILT)). There is no information in the other country studies about inspection and enforcement of national policies on substances of concern.

Examples

- In Denmark, **the Product Registry is used by the Chemical Inspectorate**, both for general planning purposes (for instance for inspections of companies that deal with specific substances of concern) and for ad hoc purposes like following up on complaints about allegedly illegal products.
- **The 'Tjek Kemien' app was used by the Danish Chemical Inspectorate** to look into products with phthalates. Fifty articles of PVC plastic were analysed on the content of phthalates, and their suppliers were sent requests for information through the app. Next, the findings of the analyses could be compared to the suppliers' answers. Suppliers who answered incorrectly were informed of this. Suppliers who failed to reply were summoned to do so after all.
- In the Netherlands, the **ZZS policy** is implemented via the **Activity Decree**. This decree is **enforced by the Human Environment and Transport Inspectorate (ILT).**

2.12 National policies on substances of concern in relation to substitution and circular economy

2.12.1 National policies on substances of concern and substitution

Generally speaking, 'substitution' is one of the underlying objectives of most national policies on substances of concern. Substitution of substances of concern is a measure at source that prevents exposure and risks. In many cases it is seen as either the goal or as a positive side-effect of measures like bans and restrictions, prioritisation systems, registration requirements and information campaigns.

In some countries additional measures are taken to promote substitution of substances of concern. These measures either provide companies with information about substitution opportunities or offer direct assistance to companies to carry out substitution activities.

Examples

- In Denmark, a **substitution centre** has been installed, called **'Kemi i Kredsløb.'** It offers two types of services: general substitution tools and methodology, and direct support to concrete substitution projects.
- In Germany, the initiative is taken to develop the **International Sustainable Chemistry Collaboration Centre (ISC3)**, which aims to support a global breakthrough in Sustainable Chemistry.
- In France and the Netherlands, **substitution guides for industry** have been conceived. In the Netherlands this guide specifically aims at SME's.

2.12.2 National policies on substances of concern and circular economy

The objective to give European economies a more circular character is shared by all countries in this study. The presence of substances of concern in products complicate the realisation of this objective, as they hinder or preclude the re-use or recycling of these products (or their degradation products). As a consequence policies for a circular economy often also aim for substitution of hazardous substances. However, this aim often remains implicit and/or is dealt with on a case-by-case basis. Still, there are examples in which national policies on substances of concern are explicitly connected to the goal of a circular economy. Some of these examples are described below.

Examples

- In Denmark, one of the issues addressed in the LOUS review concerns undesirable **chemistry in construction**. The review established an overview of problematic substances in construction and gave a basis for recommendations addressing both environmental, health and circular economy aspects. Among the Danish surveys on chemicals in consumer products are surveys on **'chemical substances which may prevent recycling'** and on **'the use and potential use of bioplastics in Denmark'**.
- In the Netherlands, the National Institute for Public Health and Environment (RIVM) carries out research on **ZZS substances that may hinder recycling**. For example, at the moment the RIVM is looking into textiles and rubber granulates (the latter also in relation to a public incident). This is a Dutch priority.

3. Conclusions and prospects

3.1 Introduction

In the previous chapter some aspects of the national policies for substances of concern were discussed and illustrated with examples from the different countries.

As indicated in chapter one of this report, the objective of this study was not to compare or rank the policies that were analysed and presented. The key issue was to get inspiration and to learn from the different measures that have been developed throughout these countries and the experiences to which these have led.

For that purpose in this chapter we reflect and draw conclusions with regard to the policy priorities that the Dutch authorities share with most of the authorities in the selected countries, and highlight some ideas and inspirational features that come to the fore. The final paragraph of this chapter presents a short reflection on the research process.

3.2 Policy priorities

3.2.1 Prioritised substances

One of the priorities of (and challenges for) the Dutch authorities is to find a way to focus its national measures on substances of the highest concern within the Dutch context. The Dutch list of ZZS contains around 1400 substances. It is not entirely clear which of these substances are actually on the market and/or are emitted in the Netherlands, nor in which quantities. This complicates a further national prioritisation within this large group of ZZS.

From the overview in this study it shows that several countries have developed further national prioritisation methods. Here is an opportunity to learn and exchange. Interesting features of the Danish and Swedish prioritisation systems are the use of market data (which is possible because in these countries there are product registers in place) and – in Denmark – of QSAR. The French system employs an objectified variable for the amount of societal concern over certain substances. In the Danish prioritisation system the societal and political pressure is part of the equation as well, albeit in a less mathematical way. What also makes the Danish LOUS prioritisation of interest, is its clear goal to come up with an acceptable and workable amount of priority substances (i.e. 40), if necessary through tightening of the criteria that are applied. This is done in order to make it possible for both industry and the authorities to focus their prime efforts on the substances of the highest relevance and concern.

3.2.2 Emission control

All selected countries control emissions by means of permitting systems . In most countries stricter emission standards are used for more hazardous chemicals. In the Dutch case it is clear how this is done. Permits (under the 'Activity Decree') prescribe that emissions of substances of concern ('ZZS') have to be minimized and that companies have an obligation for continuous improvement and for substitution if possible. In the French and German cases particular mention is made of CLP classification as the basis of emission standards. In general it is however not clear in this study in which way standards for emission of

substances of concern are set or derived. The reason for this may be that the authorities in charge of national policies for substances of concern (chemical departments or agencies) have other organisational bases than the authorities in charge of emissions ((elsewhere in) environmental departments or at regional/local level). It may be worthwhile to have a further look into this matter.

3.2.3 Substitution

In all countries the national policies for substances of concern aim to promote substitution. It is seen as either the goal or as a positive side-effect of measures like bans and restrictions, prioritisation systems, registration requirements and information campaigns. In some countries pressure is generated to get specific types of substances substituted (like on LOUS substances in Denmark, on endocrine disruptors and BPA in France and on ZZS in the Netherlands.

Some specific measures are taken in different countries to promote substitution of substances of concern as a business opportunity. Part of these measures focus on information for companies about substitution opportunities (through brochures, handbooks and workshops). It is not always clear whether these measures have effect. In other cases direct assistance is offered to companies to carry out substitution activities. In Denmark this has led to experiences that give some reason to reconsider this type of measure. One experience was that bigger companies are not too keen to participate. For them, substitution is a normal part of ongoing innovation, as an element of their business strategy. Participation in state sponsored projects would put them and their innovations in the limelight and would require public reporting. Innovative SME's are hesitant for the same reason, whereas less innovative SME's are less aware and prone to enter a substitution process.

In the Dutch country study it is noted that in general it is not easy to interest companies for dialogues about substitution. In one particular case in the Netherlands there was an attempt for a voluntary agreement ('green deal') to participate in a substitution process. This attempt was less successful however, because confidentiality issues proved to be a barrier for cooperation.

The overall impression so far seems to be that 'soft' or voluntary measures to effect substitution are not the most effective. The impression is that it is first and foremost pressure – either societal or legal pressure – that prompts companies to look for alternatives for substances of high concern. Such legal pressure is not easy to build up on the national level alone (see the example of the 'Loi Detox' in France). However, examples of productive interplay between the national and the European level are available (see for instance the Danish 'Tjek Kamien' app and the Danish project 'Use of QSAR to identify potential CMR').

3.2.4 Circular economy

The objective to give European economies a more circular character is shared by all countries in this study. In many countries, however, there is no – or only an implicit or case-by-case – connection between the aim of a more circular economy and the need to

avoid and/or substitute substances of concern because they hinder or preclude the re-use or recycling of products (or their degradation products).

There are however examples in which countries look to identify whether substances of concern are present in products that may hinder their recycling or re-use. This is mostly done in surveys, research projects or analyses – either as part of longer running research programmes or as a response to societal incidents. There is no reason why the outcomes of these studies should only be relevant for the domestic market. Therefore active sharing between countries of research results in these areas could improve the use and value of these studies and promote a circular European economy.

3.3 Ideas and inspiration

The country studies also show other points of interest that can serve as inspiration.

3.3.1 Registrations

One of these points is the availability in the Nordic countries (Denmark and Sweden) of a Product register of classified mixtures. Although all countries in this study have product registers at the national poison information centres (following article 45 of CLP regulation (EG 1272/2008), only the Scandinavians have registers that allow policy makers and analysts (and the inspectorate) to get an insight into the substances that are on their national markets and the quantities in which they are supplied, and are even able to connect this to the companies that supply these products. It is this type of information that enables policy makers to assess the relevance of certain substances for their home situations and to prioritise substances on other criteria than their intrinsic properties. Other countries can only turn to the REACH registers for this type of information and hence have to work with data that are not specific for their own country.

There is some indication that a somewhat similar situation exists in France with regards to an emissions database. Further information on this is however required.

3.3.2 Societal concerns

Societal concerns are behind many of the policies and measures on substances of concern, usually because they are taken over and given voice by NGO's and political parties. In some countries there are however measures in place to proactively assemble and translate these concerns and worries into policy priorities (or priorities on substances of concern). The most clear example of this is the 'Environmental conference' in France. Another example might be the German 'NanoDialogue' that serves as a platform for the exchange of opportunities and risks with regards to nanotechnology.

3.3.3 Targeted information

More and more targeted information about substances of concern in products may help consumers in their purchasing decisions. More and more targeted information to companies may help them to get the right knowledge about the substances of concern in their products and on the risk properties of these substances. And more exchange of this type of information in the product chain may help to effect the REACH objectives of better informed decisions throughout the product chain.

Particularly in the Scandinavian countries several inspirational and innovative examples are to be found of this targeted information. Targeting consumers, pregnant women, parents, suppliers, REACH registrants, municipalities (and via them pre-schools). This all happens by means of campaigns, apps, research reports, databases, et cetera. In Sweden, even the pre-school and school-aged children are targeted to learn about sustainable development and 'non-toxic environment' in educational programmes. Moreover, there is a lot of inspiration to be found in the comprehensive, transparent and practical way in which the Swedish policies on substances of concern are presented on the Swedish government website.

3.4 The study process

This study could only be carried out with the cooperation of policy makers in all countries concerned. We did indeed meet with willing and even enthusiastic cooperation from all the policy makers that we addressed. There was a clear interest to discuss national practices with us. Also there is a keen interest to learn from the activities and experiences of colleagues in other countries. In some of the countries there was an interest to participate in this study as a means to further the domestic discussion on policies for substances of concern.

Several countries expressed their interest in further exchange of information and experiences. At the same time, most policy makers point at the existence of coordination mechanisms at the EU and international level. These mechanisms, including the corridors of European and international meetings, could also be used to continue the exchange of experiences with and ideas for national policies of concern, for which the authors hope this study has delivered some contribution and indicated that indeed there is potential.

Annex 1: Belgium

1. Organisations contacted	**Main contact:** Martine Röhl, Advisor Risk Management – Chemicals (REACH) DG Environment |Department of Product Policy and Chemical Substances Federal Public Service (FPS) Health, Food Chain Safety and Environment Place Victor Horta, 40/10 |1060 Brussels |Belgium T. +32(0)25249610 +32(0)25249610 E. Martine.rohl@environnement.belgique.be **Other contacts:** • Simon Cogen – Ministry of Economy, Unit Sustainable Economy, Helpdesk Reach • Chris Lambert – Flemish Region, 'Departement Leefmilieu' • Stanislaw Constant – Brussels Capital Region, Environmental Permits • Philippe Raucq – Walloon Region, Operational Directorate-General of Agriculture, Natural Resources and the Environment, Department of Environment and Water • Alexandra Panis – Walloon Region, Operational Directorate-General of Agriculture, Natural Resources and the Environment, Department of European Policies and International Agreements
2. Relevant literature and websites	**Literature:** • Global Business Briefing (2016), *Nano registers: are they having the desired effect?*, June 2016 • Superior Health Council (2013), *Endocrine disrupters: low dose effects, non-monotonic dose responses and critical windows of sensitivity*, Publication of the Superior Health Council No. 8915, expert opinion on endocrine disrupting chemicals, 3 July 2013 • Coordinatiecommissie Integraal Waterbeleid (2015), *Stroomgebiedplannen voor Schelde en Maas 2016-2021* • MO Mondiaal Nieuws (2015), *Belgische politiek reageert op hormoonverstoorders,* author: Vincent Harmsen, 10 april 2015 (online available at: http://www.mo.be/analyse/hormoonverstoorders-reacties-uit-de-belgische-politiek • Brussels-Capital Regional Government (2016) *Gewestelijk programma voor circulaire economie 2016-2020. De hulpbronnen mobiliseren en de verloren rijkdommen tot een minimum beperken: Voor een vernieuwde gewestelijke economie*, maart 2016 (online available at: http://document.environnement.brussels/opac_css/elecfile/PROG_160308_PREC_DEF_NL) • Verbond van Belgische Ondernemingen (2016), '*Circulaire economie – Federaal plan als aanvulling gewestelijke strategieën*', Competentiecentrum Duurzame Ontwikkeling & Mobiliteit, author: Vanessa Biebel, 8 November 2016 (online available at: http://www.vbo-feb.be/actiedomeinen/energie-mobiliteit--milieu/afval-en-materialen/circulaire-economie--federaal-plan-als-aanvulling-gewestelijke-strategieen_2016-11-08/) • Ministry of Energy, Environment and Sustainable Development (2016), '*Samen de economie doen draaien dankzij de circulaire economie in ons land*', Oktober 2016 • The Eco-Innovation Observatory (2015), 'Eco innovation in Belgium', EIO Country Profile 2014-2015, financed by the European Commission's Directorate-General for the Environment, 2015 (online available at: https://ec.europa.eu/environment/ecoap/sites/ecoap_stayconnected/files/field/field-country-files/belgium_eco-innovation_2015.pdf)

	Websites: • Belgium portal site: http://www.belgium.be/nl • Federale overheidsdienst (FOD) Volksgezondheid, Veiligheid van de Voedselketen en Leefmilieu: http://www.health.belgium.be/nl/milieu • FOD Volksgezondheid, Veiligheid van de Voedselketen en Leefmilieu. Dienst Gewasbeschermingsmiddelen en Meststoffen: http://fytoweb.be/nl • FOD Economie, K.M.O., Middenstand en Energie: http://economie.fgov.be/ • Belgisch Antigifcentrum: www.antigifcentrumbelgie.be • REACH website Belgium: http://www.reachinbelgium.be/index.php?page=home&hl=en_US • Flanders government portal website: https://www.vlaanderen.be/nl • Brussels-Capital government portal website: http://be.brussels/brussels • Walloon government portal website: http://www.wallonie.be/ • L'Institut Scientifique de Service Public ('The Walloon scientific institute for a healthy and safe environment'): http://www.issep.be/ • Leefmilieu Brussel: http://www.leefmilieu.brussels/ • Flanders Environment Agency ('Vlaamse milieumaatschappij'): https://en.vmm.be/ • Coordination Committee on Integrated Water Policy / Integrated Water Policy Flanders: http://www.integraalwaterbeleid.be/en • Wateruitvoeringsprogramma (WUP): http://www.integraalwaterbeleid.be/nl/stroomgebiedbeheerplannen/wateruitvoeringsprogramma-wup ' • Flanders concrete implementation of REACH in Vlarem: https://www.lne.be/milieuvergunningendecreet-vlarem-i-ii-en-iii • The Flanders Environment & Health Support Point ('Steunpunt Milieu & Gezondheid'): http://www.milieu-en-gezondheid.be/
3. General introduction	Since its independence in 1830, 5 state reforms took place in Belgium. As a result, the first Article of the Belgian constitution reads today: "Belgium is a federal state, composed of communities and regions". The power to make decisions is no longer the exclusive preserve of the federal government and the federal parliament. The leadership of the country is now in the hands of various partners, who independently exercise their authority within their domains. The redistribution of power took place along two lines: (1) the establishment of the communities on the basis of language and culture and (2) the establishment of the regions based on economic interests. The community has powers for culture (theatre, libraries, audio-visual media, etc.), education, the use of languages and matters relating to the individual which concern on the one hand health policy (curative and preventive medicine) and on the other hand assistance to individuals (protection of youth, social welfare, aid to families, immigrant assistance services, etc.). They also have powers in the field of scientific research in relation to their powers and international relations associated with their powers. The second line of state reform was historically inspired by economic interests. The regions, which aspired to more economic autonomy, conveyed these interests. The establishment of the three regions was the result. The Belgium regions dispose of a considerable amount of autonomy; they are competent and exclusive in decision-making. The regional governments are among others responsible for the development and implementation of environmental policy in their region. The Federal State nevertheless retains important powers. Broadly speaking, the powers of the Federal State cover everything connected with the public interest (e.g. the public

	finances, the army/national defence, the judicial system, social security, foreign affairs as well as substantial parts of public health and home affairs). Furthermore, the Federal State is responsible for the obligations of Belgium and its federalised institutions towards the EU.
4. National drives	Belgium finds it relevant to take measures against a substance or a substance group if European regulations/decisions or international conventions prescribe to take action. With regards to Belgium's federal policy for nanomaterials the main drive may be uncertainty about the effects of nanomaterials in combination with the fact that nanomaterials are on the market in a lot of products. Nanomaterials include extremely small particles (smaller than 100 nm) and therefore have specific physico-chemical properties that differ from the properties of the same materials without nanoparticles. Nanomaterials are very different; the impact on people and the environment can also be very variable. The nano registry will identify the supply chain of nanomaterials on the Belgian market. This will allow to react efficiently in case problems have been identified with a specific nanomaterial.
5. Policies and measures	**Management of dangerous chemical substances/products** Belgium does not have unique, country-specific legislation for dangerous chemical substances/products at the federal or regional government level. Belgium's federal strategy to manage dangerous chemical substances/products is fully based upon meeting the European/international requirements, laid down in EU regulations/decisions (e.g. on authorisation and restriction) and international conventions (e.g. PIC and POP) or programs (e.g. WHO monitoring of POPs in breastmilk). The following were mentioned by the contacted organisations as relevant in the framework of this investigation: - REACH Regulation - Prior Informed Consent (PIC-procedure) - CLP Regulation - The Strategic Approach to International Chemicals Management (SAICM) - EU Water Framework Directive (WFD) With regards to the management of dangerous chemical substances/products, the federal government is competent for placing on the market of chemical substances/products and worker protection, while the regional governments are competent for the uses and related emissions of those substances, and the related aspects of enforcement. Compliance with EU and international requirements is the common basis of both the federal and the regional governments. **Federal policy on nanomaterials** In addition to the implementation of the EU/international requirements, the Belgium government implemented a federal policy on nanomaterials, including a nanoregister. Belgium requires the registration of nanomaterials from 1 January 2016, and where they occur in mixtures, the requirement will apply from 1 January 2017. Once fully operational, the registration procedure will give a good idea about the nanomaterials, both qualitative and quantitative, on the Belgium market, and provides traceability along the supply chain. The register aims at mapping out nanomaterials so that possible risks can be identified in a more specific way and, in case of problem, to ensure a quicker response. Employers also have the obligation to supply their workers with information about nanomaterials that should be registered.

	With regards to the management of nanomaterials, the Federal Public Service (FPS)[2] Health, Food Chain Safety and Environment acts both at the Belgium federal level and at the European and international levels: • At the federal level, the FPS contributes to scientific research for improving regulations on nanomaterials. The following projects are of particular relevance: ▪ project "nanogenotox": study of the potential of damage caused to genetic material (http://www.nanogenotox.eu/) ▪ project "nanopolymer": study of risks to the health and environment of nanometric polymers (http://www.health.belgium.be/en/nanostudy-toxicity-nanopolymers) ▪ project "To^{2}DeNano": towards a toxicologically relevant definition of nanomaterials) • At the EU level, the FPS promotes an important adaptation of the EU legislation to the specific features of nanomaterials. The Belgium FPS represents the country in various European forums aiming at: ▪ a better integration of the nanomaterials specific features in the legislation, ▪ the implementation of this legislation, ▪ a better understanding of the impact of manufactured nanomaterials on human health and the environment ▪ the improvement of nanomaterials' traceability throughout their life cycle. Furthermore, the FPS maintains particularly close relations with France, Sweden and Denmark in order to maintain a certain consensus concerning the national registry projects of nanomaterials. • At the international level, the FPS represents Belgium in three international organisations: ▪ the Organisation for Economic Cooperation and Development (OECD), where it actively participates in a working group on manufactured nanomaterials aiming at testing many nanomaterials widely available on the world market (http://www.oecd.org/env/ehs/nanosafety/). The goal of this group is to provide medium-term adaptation and standardisation of test methods that would be specific to nanomaterials' characteristics. ▪ the UN Commission on Sustainable Development (CSD), which also focuses on the emerging issue of nanomaterials (https://sustainabledevelopment.un.org/csd.html). ▪ the Strategic Approach to International Chemicals Management (SAICM), where a comprehensive strategy for chemicals is being developed with specific attention to emerging issues such as nanomaterials (http://www.saicm.org/).

[2] As part of the most recent major reforms in Belgium, the word 'ministry' was renamed 'Federal Public Service' (FPS). Only the Ministry of Defence retained its former name. The tasks entrusted to FPSs are the same as those given to the former ministries. This means that FPS's are still under the authority of minister(s), even though the emphasis is on providing services to citizens.

Regional focus: an example of Flanders

As a result of the state reform of 1980, the protection of the environment became a regional responsibility. This included the granting of licenses to “nuisance establishments” ("hinderlijke inrichtingen") and the monitoring of them. Initially in Flanders this was done as before the reform of the State, based on Title I of the ARAB (General Regulations for Labour), which went back to 1947. This regulation was primarily aimed at preventing nuisance (by air emissions, odor, noise, etc.). It however contained little substantive obligations for companies; and the classification list that was used for the classification of "nuisance establishments" was outdated. There were also separate arrangements for other environmental aspects, such as a waste permit and a discharge permit for waste water. Each had its own procedure and was issued by separate bodies.

The Decree of the Flemish Council of 28 June 1985 concerning Environmental Licences and its implementing regulations (**VLAREM**) aimed to modernize outdated and fragmented and integrating into a single scheme. That of the environmental permit. The environmental permit replaced (among others) the former operating license (e.g. the discharge permit), the permit to protect groundwater against pollution and the permit for the disposal of waste. In 1999, the permit for extracting groundwater was also included in the environmental permit. The environmental decree is a framework decree that establishes a number of general principles.

VLAREM is the implementation act (‘uitvoeringsbesluit’) of the Decree on Environmental Licences and consists of three parts: VLAREM I, II and III. Together, they might be considered as the Flemish counterpart of the Dutch Law on General Provisions Environmental Hygiene (‘Wet Algemene Bepalingen Milieuhygiëne’). The REACH Regulation is fully incorporated into the VLAREM. The main objective of VLAREM is to prevent and reduce nuisance, environmental pollution and safety risks.

"VLAREM I", which came into force on September 1, 1991, presents most of the provisions of the Decree. It is based on the classification list for nuisance establishment in **annex I**; a list of (potentially) harmful activities such as storing waste, the production of chemicals, combustion processes, etc.. If you want to start a company in Flanders, you should consider whether you need an environmental permit. That depends on whether your business is a Class 1, 2 or 3 of the VLAREM I:

- A company class 1 or 2 requires an environmental permit.
- A company in class 3 has only notification.

Classes 1, 2 and 3 indicate the degree of possible disruption of your business for people and the environment. The following factors play a role in the classification of a class: size of the storage capacity of the equipment and the use of hazardous products or materials.

- Class 1 means the most annoying activity.
- Class 2: less annoying activity.
- Class 3: the least burdensome activity.

Annex 2 of VLAREM I presents (a) an indicative list of the most relevant polluting substances in waste water, (b) a list of dangerous substances for discharge into groundwater; and (c) a list of dangerous substances for discharge into the aquatic environment.

Furthermore, VLAREM I also contains the various authorization procedures, procedures for monitoring (inspection) and possible coercive measures, and the general principles to which each permit-required establishment must comply with (such as always take the necessary measures to prevent damage and nuisance).

VLAREM II includes the environmental conditions that are applicable to the classified establishments, while VLAREM III includes environmental conditions applicable to GPBV establishments (e.g. companies that have large environmental impact; IPCC). Both, VLAREM II and III include general requirements (e.g. making use of the BAT-principle) and sectoral conditions (e.g. the discharge standards for the textile industry) applicable to establishments of a certain section of the classification list.

6. Substances covered	On the federal level, Belgium does not have a 'list of undesirable substances', since the country focusses on substances that are prioritized through EU and international decisions (e.g. REACH, CLP, POP, PIC). In Belgium there is a strong focus on the federal level on the identification of PBT, reprotoxic and endocrine disrupting substances through, e.g.: (1) substance evaluation under REACH (2) participation in PBT and ED expert groups by ECHA (3) involvement in EU and OECD discussions on per- and polyfluoroalkyl substances (PFASs). On the regional level, there might be a small difference in focus on certain substances. For instance, in Flanders priority is given to PBT substances and biomonitoring (www.lne.be/flemish-human-biomonitoring-program), in Brussels-Capital substances the substances from the REACH Candidate List and POPs are prioritized, while in Wallonia the focus is foremost on the substances from the REACH Candidate List **Nano Register** The registration only applies to the deliberately manufactured nanomaterials with a size between 1 and 100 nm. The difference between "deliberately manufactured" is not always obvious. The fine particles that are present in the air through combustion (for example of motors) or nanomaterials that result from welding can be considered as by-products of human activities and should not be registered. Furthermore, the registration requirement applies when within one calendar year more than 100 grams of the substance is brought on the Belgium market. Although still in its infancy, the Belgian nano registry has received more than 300 registrations.
7. Legal / formal bases	**Nano register** According to the Royal Decree of 27 May 2014, companies have to register the nanomaterials they place on the market. Substances produced in nanoparticular state (such as titanium dioxide, zinc oxide) had to be registered before January 1st, 2016. Mixtures containing such substances (e.g. paints, sun creams), have to be registered before January 1st, 2017.
8. Organisational basis	**Nano register** ▪ The FPS of Health, Food Chain Safety and Environment manages the nano registry. ▪ The FPS of Employment, Labour and Social Dialogue is in charge of the protection of the well-being of workers. This registry will make a well-founded estimate of the types and amounts of nanomaterials used, of the ways in which they are used and of the speed and the extent of the evolution towards more complex nanomaterials. ▪ In order to support companies and laboratories in their quest for quality, the nanometrology department of the FPS for the Economy has set up a working group for the dimensional metrology of nanoparticles. The aim is to create a network of laboratories that are able to perform reliable and comparable dimensional metrology assessments of nanoparticles, and to harmonise these metrology results at national and international level. In a further stage, other nanoparticle properties will be investigated. **REACH Agreement of Cooperation** The implementation of REACH is partly a federal, partly a regional competence (and partly a competence of the communities). The complexity of the application and enforcement of REACH requires a coordinated approach. This is why a REACH agreement of cooperation has been concluded between federal and regional authorities. The agreement is to ensure the coordinated and effective implementation of REACH in

	Belgium. Three committees are set up in the context of the REACH agreement of cooperation. Two committees are responsible for the coordinated approach to the application and enforcement of REACH: the 'Belgian REACH Committee' and the 'National Forum Reach'. A third committee will mainly ensure scientific support: the 'Scientific Reach Committee'. **Federal organisation for the implementation of REACH** On the level of the federal government, the following Federal Public Services (FPS) are relevant authorities with regards to the implementation of REACH: 1. *FPS for Health, Food Chain Safety and the Environment* ▪ The risk management service department of the DG Environment of the FPS for Health, Food Chain Safety and the Environment is the competent Belgian authority responsible for the coordination of the tasks determined in the REACH regulation. The department is accordingly responsible for the evaluation of the substances and attending the various committees meetings of the European Chemicals Agency (ECHA) and taking initiatives for the addition of substances subject to authorisation or to which restrictions apply. ▪ Risk management also plays an important part in informing companies and the population. The department supports companies in the transition to REACH and informs the population about the risks of chemical substances to health and the environment. 2. *FPS Economy, SME, Self-employed and Energy* The national REACH Helpdesk of the FPS Economy, SME, Self-employed and Energy offers advice to manufacturers, importers, buyers and other interested parties on their responsibilities and obligations with respect to the REACH regulation. The department is also a partner in the aforementioned Agreement of Cooperation within Belgium, attends meetings of ECHA's Socio-Economic Analysis Committee (SEAC) and the Commission's REACH Committee for certain subjects. 3. *FPS Employment, Labour and Social Dialogue* The FPS Employment, Labour and Social Dialogue is responsible for the protection of employees against chemical agents in general and against carcinogenic (including asbestos) and mutagenic agents. **Regional management of dangerous chemical substances/products** The regional governments have the authority to develop and implement policies according to EU/international requirements. In general, the regional governments are responsible for the uses of substances, their related emissions, and the related aspects of enforcement. The regions have therefore developed and implemented their own policies to manage dangerous chemical substances/products in the environment. Compliance with EU/international requirements is checked through a regional permitting system, which links the substances to emissions on a local scale. The following regional authorities are the designated Competent Authorities with regards to the environmental permit procedures, including monitoring (inspection) and enforcement in respectively Flanders, Brussels-Capital and Walloon region: **1. Environmental Licences Division of the Environment, Nature and Energy Department (LNE)** With regards to the management of dangerous chemical substances/products, the REACH Regulation is fully implemented in Flanders via the Flemish Decree on Environmental Licences and its implementation act (VLAREM). The Environmental Licences Division of the Environment, Nature and Energy Department is the competent authority for the Flemish legislation according to environmental permitting system VLAREM.

	The Flanders Environmental Agency (VMM) is however also an important authority in charge of the environmental permit and its related procedures, including monitoring/inspection and enforcement. VMM is an agency of the Flemish government part of the Environment, Nature and Energy policy domain. It has a wide range of responsibilities within the domains water, air and the environment. The mission of VMM is to contribute to the realisation of the environmental policy objectives by reporting on the state of the environment and by preventing, limiting and reversing harmful impacts on water systems and pollution of the atmosphere, and to the realisation of the integrated water policy objectives. VMM tasks are established by decree and conducted under a management agreement with the Flemish government, setting strategic and operational goals, but also ensuring a great deal of autonomy concerning how to carry out tasks and how to develop the organisation. VMM works closely together with the Flemish provinces, cities and municipalities, the polders administration, the Flemish Welfare and Health Agency, the Flemish ministry of Transport and Public Works, the Policy Research Centre of Environment and Health ('Steunpunt Milieu & Gezondheid') and the Public Waste Agency of Flanders ('Openbare Vlaamse Afvalstoffenmaatschappij' - OVAM). **2. Leefmilieu Brussel** Leefmilieu Brussel was founded in 1989 and is the government agency for environment and energy of the Brussels-Capital Region. The activities cover the environment in a broad sense, including: ▪ air quality; ▪ energy; ▪ bottom; ▪ noise; ▪ electromagnetic waves; ▪ waste management planning; ▪ sustainable production, sustainable construction and sustainable consumption; ▪ nature and biodiversity; ▪ animal welfare; ▪ management of the Sonian Forest, the green spaces and natural areas ▪ management of navigable waterways; ▪ fight against climate change. With regards to the management of dangerous chemical substances/products, Leefmilieu Brussels strictly follows the REACH Regulation. On 4 October 2010 a new act came into force. The act provides for the obligation to apply for an environmental permit class 1B for certain dangerous substances that are being used alone or as a component of a mixture, and which are included in Annex XIV of the EU REACH Regulation ('stoffen van bijlage XIV'). The production, the use and the storage of these substances now falls under the new Section 173 of the list of classified establishments, e.g. subjected to an environmental permit. Inspectors of Leefmilieu Brussel monitor and inspect establishments in order to make sure that they operate accordingly. If not, they have the power to punish them. **3. Operational Directorate-General for Agriculture, Natural Resources and the Environment (previously: DGARNE, now: DGO3)** The DGO3, the environmental Competent Authority in Wallonia, originated from the mid-2008 merger of two former Directorates-General, namely the DG for Agriculture and the DG for Natural Resources and the Environment. The DGO3 is in charge of policies such as: ▪ nature conservation, environment, agriculture, waste, air, subsoil management, soil protection, and the management and use of two major natural resources: water and Wallonia's forests;

	▪ detection and management of accidents with environmental consequences; ▪ monitoring of observance of sustainable development requirements in the primary, secondary, and tertiary sectors; ▪ preparation, monitoring, and implementation of the Common Agricultural Policy (CAP); ▪ co-ordination of research, with countless popularisation tasks; ▪ management of the region's agricultural lands as part of its spatial planning and the certification of the quality of breeding stock and plant propagation material; ▪ raising awareness of the importance of sustainable development among citizens, politicians and professional decision-makers. With regards to the management of dangerous chemical substances/products, the DGO3 brings together different departments and directorates responsible for the implementation and monitoring of the REACH regulation, Geological and mining authorities, the control department, the management of permits and authorizations and the Walloon Waste Office (Soil and Waste Department). In addition, the Walloon Air and Climate Agency (AWAC), plays an important role in the management of dangerous chemical substances / products. AWAC was created in 2008, from the Air Unit of the former Directorate-General for Natural Resources and Environment. The Agency represents the Region at national level and in international air and climate organizations. It coordinates the monitoring of the negotiations, ensures the transposition of the decisions into Walloon legislation and guarantees their implementation.
9. Involvement of stakeholders	With the exception of its nanopolicy, Belgium does not have an official strategy on dangerous chemical substances/products, in the way as the Netherlands has its ZZS policy. Belgium focusses primarily on the management of substances that are prioritized by the EU and international fora. With regards to its nanopolicy, stakeholders are largely involved in all aspects of the policy. On the regional level, the implementation of the EU/international frameworks is characterized by government-arranged meetings with stakeholders.
10. Relation with European policies / international agreements	The federal government follows the general EU and international guidelines on management of dangerous chemical substances/products as strict as possible. Taking part in the follow-up of the EU policies/international agreements and in the implementation of them is dealt with on an national level (mainly within the cooperation agreement on international environmental policies, or as included in specific cooperation agreements on certain topics, for instance on REACH, SEVESO, …) involving experts of the concerned federal and regional authorities.
11. Monitoring of substances and evaluations of effects	Monitoring of substances is a responsibility of the regional governments. All three regions have their own monitoring systems in place. Monitoring takes place on a continuous base.
12. Incidents with relevance to these policies?	On 4 May 2013 a freight train accident occurred in Wetteren. During the fire toxic fumes of acrylonitrile arose, as well as decomposition products by pyrolysis, including hydrogen cyanide (prussic acid), nitrogen oxides and acetylene (acetylene). As a result one inhabitant of Wetteren died, about 400 people were hospitalized due to poisoning, and almost 2000 persons needed to be evacuated. It is said that a human error caused the accident.

	With the exception of above mentioned accident, no large incidents occurred in Belgium since 1942. (Smaller) incidents with dangerous chemical substances/products did not lead to new policy developments and/or changes in existing policies.
13. Relation with emission control	Emission control is a regional responsibility. Regional policies are aimed at reducing emissions and are in line with the EU substances policies (e.g. Industrial Emission Directive / Water Framework Directive). Within each region a competent authority is assigned to ensure that emissions of dangerous chemical substances are in line with legislation.
14. Relation with inspection and enforcement	Inspections and enforcement take place on both the federal as well as the regional government level. The federal government is responsible for inspection and enforcement with regards to worker protection and placing on the market of substances, while other aspects of inspection and enforcement are the responsibility of the regions. Each region assigns a competent authority for substance monitoring, inspections and enforcement of regional policies and legislation. The Federal Environmental Inspection of the Environment Directorate General has been designated to track and establish violations of the Federal Environment Legislation and Standards. The competences for this are determined by the Law of December 21st, 1998 concerning the product standards for the advancement of sustainable production and consumption patterns and for the protection of the environment, public health and the employees ('the Law Product Standards'). The assignment of the Federal Environmental Inspection is checking the compliance by companies and private individuals with the legal arrangements concerning the bringing of products on the market and in some individual cases concerning their use. The purpose of this check is to avoid the potentially damaging consequences which these products may have for the human health and/or the environment, by taking sanctioning actions. The Federal Environmental Inspection takes action in response to: ▪ a campaign: the inspections which are carried out within the framework of a campaign, relate to specific domains and take place during a predetermined period. These campaigns are recorded in a yearly inspection plan. ▪ a RAPEX report: The Federal Environmental Inspection will also carry out an inspection when they receive a RAPEX report through the Belgian RAPEX point of contact, that is the Central Contact Point for Products of the FPS Economy, SMEs, Self-Employed and Energy. A RAPEX report ("rapid alert") is a report within the framework of the European alarm system, which becomes operative when a hazardous product (except foods, pharmaceuticals and medical devices) is found on the European market. ▪ an incident: the Federal Environmental Inspection also takes action in response to an incident, that is to say an occurrence which may have an immediate harmful effect on the human health and/or the environment. ▪ a complaint: the Federal Environmental Inspection takes the necessary initiatives and inspection measures when it receives a complaint, e.g. through the Contact Centre.
15. Relation with circular economy (re-use and recycle) and substitution	Belgium adopted a federal roadmap to the establishment of circular economy entitled 'Vers une Belgique Pionnière de l'Economie Circulaire' ('België als voortrekker van de circulaire economie') that consists of 21 joint measures to promote the circular economy. All measures will come into effect before 2019. The plan complements the following ambitious regional initiatives: ▪ Flanders Materials Programme (Flanders Region)

- Regional Program for Circular Economy (Brussels-Capital Region)
- Plan wallon des Déchets-Ressources (Walloon Region).

No direct linkage between the management of dangerous chemical substances/products and the 'Vers une Belgique Pionnière de l'Economie Circulaire' were found; e.g. none of the 21 measures defined in the roadmap are aimed at the management of such substances.

On the federal level, the GO4CIRCLE initiative furthermore exists. GO4CIRCLE is the umbrella association for private companies who put the circular economy at the heart of their operations. It represents 220 companies who are helping enterprises across all sectors to fundamentally change their production processes, making the transition towards the circular economy, and also including manufacturing companies who use circular economy principles. Between them, they employ around 8000 people, accounting for an annual turnover of 2.8 billion euros.

Substitution of a dangerous substance or process by a harmless or less dangerous substance or process is at the top of the hierarchy of risk management measures. Both in the context of occupational safety (federal jurisdiction), public health (partly federal jurisdiction), as the manufacturing policy to protect the environment. For carcinogenic and mutagenic substances is substitution, if technically possible, an obligation.

Regional focus on promotion of the circular economy and substitution:

- **Flanders**
  End 2011, the principles of sustainable materials management and circular economy were anchored in the Flemish legislation through the adoption of the Materials Decree. To facilitate the transition towards a circular economy, OVAM launched the Flanders' Materials Programme (FMP) in 2012. This public-private partnership streamlines the multitude of public and private initiatives in a shared and broadly supported programme with co-ownership between knowledge institutes, industry, civil society and the government. FMP combines ambitious long-term vision development (Plan C) and policy-relevant research (SUMMA), with concrete actions:
  - Plan C aims to accelerate breakthroughs in sustainable materials management and circular economy. The three core activities are: shaping a vision, activating a self-learning network and the support and strengthening of transition experiments (www.plan-c.eu/nl).
  - The Policy Research Centre Sustainable Materials Management (SUMMA) brings together researchers from UGent, KU Leuven, UHasselt, University of Antwerp, HUB and VITO, and investigates which economic, policy and social preconditions need to be fulfilled in order to realise the transition to a material-efficient circular economy (www.steunpuntsumma.be).
  - In order to make progress in the evolution towards a circular economy in Flanders, FMP is now implementing 45 concrete projects in cooperation with active partners and with a clear time schedule. Special focus is placed on five sectors or clusters for which roadmaps were developed: critical and valuable metals, construction, raw materials from waste water, food and agriculture, chemistry and plastics (www.vlaamsmaterialenprogramma.be).

  The FMP includes both environmental benefits and economic benefits. On the environmental side, the circular economy has to capacity to lower the pressure on resources and the amount of waste generated. On the economic side, indicative estimates of the economic benefits of the circular economy for Flanders show savings on materials cost of 2 to 3.5% of the Flemish GDP and the creation of 27,000 additional jobs, ranging from high-tech to low-skilled.

- **Brussels-Capital region**
  The Brussels-Capital region's Policy Statement ('gewestelijke beleidsverklaring') attempts to replace the current linear economy model by a circular economy system that is competitive for companies in the markets, but also creates local jobs.

  The Regional Program for Circular Economy (GPCE), was approved by the government on March 10, 2016. Brussels Environment manages this program, together with Impulse, Innoviris and Net Brussels. With the GPCE, the region wants to put itself on the map as a particularly innovative European region; e.g. as a pioneer in the field of public policy supporting the transition to a circular economy.

  GPCE includes 111 measures grouped into four strategic areas: transversal measures, sectoral policies, regional policies and governance measures. The GPCE specifies for each measure the pilot, milestones and objectives, and mobilized partners. Each measure with a budgetary impact was budgeted. In total in 2016 a budget € 12,839,500 was allocated for these measures.

- **Walloon region**
  The Walloon Government has put a clear focus on resource efficiency and circular economy since 2009 through its regional development plan, the 'Marshall Plan 2. Green'. Building on this experience, the smart specialization strategy adopted by the Walloon Government aims at further developing the competitive advantages of the industry in Wallonia, particularly through circular economy. Furthermore, in its Regional Policy Declaration, the Walloon Government identified the Circular Economy as a priority aiming at supporting the development of its. As such, the so-called NEXT programme is fully dedicated to circular economy and is a transversal axis for deepening the Walloon Strategy for smart specialisation, through its linkages with other key sectors and clusters (biotechnology and health, agro-business, mechanical engineering, green chemistry and sustainable materials, transport and logistics, aeronautics and space). The development of the bio-economy, sustainable industrial policy, eco-innovation, environmental technologies are clearly identified as the major factors in the development of sustainable and efficient Walloon economy in the use of resources. This approach is central of the regional development Plan 2015-2019 of the Walloon Government, the 'Marshall Plan 4.0', which intends to refocus the priorities of the economic redeployment around the circular economy, the creative economy and the digital economy to strengthen the economic attractiveness of Wallonia.
  The European Commission has selected Wallonia as one of the six "model demonstrator regions" in Europe to lead the way toward a sustainable chemical industry. The 6 regions have been selected from 28 applicants from EU regions, and will receive advisory support from the 'European Sustainable Chemicals Support Service' (ESCS), led by the European Commission and CIRCE (Center for Intelligent Research in Crystal Engineering). The aim is to encourage investments in sustainable chemicals production in Europe that will contribute to the development of the circular economy, for example by taking advantage of domestically available feedstock such as biomass, waste or CO2.

  Interesting initiatives in Wallonia (*randomly selected, not exhaustive*):

  - Wallonia has launched an operational program called 'NEXT' promoting circular economy as one of the keys for future growth and added value creation. BE.Fin, a subsidiary of SRIW (Walloon Regional Invest Company), leads this program together with the A.E.I. (Agency for Enterprise and Innovation) which can count on many local development agencies on the Walloon territory in order to educate companies on the boosting possibilities of circular economy and in order to detect opportunities to develop concrete initiatives. In the country of beer, existing initiatives concern the re-use of packaging of course, but also the

	use of cleansing, yeast-loaded, waters to accelerate the treatment of sewage of neighbouring companies or the use of brewer's spent grains for animal feed. ▪ The 'Short Cycles Reference Centre' was launched in 2013. It is the contact point for any accompanying structure regarding "short cycles". It has established a catalogue of direct and indirect actors in Wallonia, connects and strengthens actors and fosters the emergence of innovative sustainable "short cycles" projects. This objective is to highlight local producers and to bring them into relationship with consumers to help them develop. ▪ The 'Circular Economy Reference Centre' was created in 2014 and focuses on raising Walloon businesses' awareness about the challenges and opportunities of the circular economy and resource management, coordinates field players on this topic and manages the circular economy fund for the Walloon SMEs to help projects materialize. ▪ 'Le Coq Vert' ("The Green Rooster") is an initiative launched by a few key public and private players in order to stimulate economic developments in bio-based chemistry in Wallonia. The development of a new bio-based chemical sector – where biomass would replace non-renewable fossil resources – makes fully part of the Wallonia strategy for green growth. This initiative is expected to become more significant thanks to the involvement of Wallonia into the EU demonstrator regions programme.

Annex 2: Denmark

1. Organisations contacted	Ministry of Environment and Food of Denmark Danish Environmental Protection Agency l Strandgade 29 l 1401 Copenhagen l Tel +45 72 54 40 00 l mst@mst.dk l www.mst.dk Direct contact: • Magnus Løfstedt: Deputy Head of Division l Chemicals +45 72 54 42 92 l malfs@mst.dk • Finn Pedersen: fiped@mst.dk • Anette Albjerg Ejersted: ae@MST.DK • Flemming Ingerslev: fling@mst.dk • Birte Børgium: Head of Function, The Chemical Inspection Service +45 72 54 42 97; bb@mst.dk Other: • Henrik Søren Larsen: hesla@mst.dk
2. Relevant literature and websites	1. Chemicals Initiatives 2014 – 2017 (Ministry of Environment and Food of Denmark) - http://kemikalieindsatsen.dk/english/ 2. Chemicals Action Plan 2010 – 2013 - http://eng.mst.dk/topics/chemicals/the-chemicals-action-plan-2010---2013/ 3. The Danish List of Undesirable Substances (the LOUS List) - http://eng.mst.dk/topics/chemicals/assessment-of-chemicals/list-of-undesirable-substances/ 4. LOUS project on undesirable chemistry in construction (in Danish with English summary) - http://mst.dk/service/publikationer/publikationsarkiv/2016/okt/uoensket-kemi-i-baeredygtigt-byggeri/ 5. The advisory self-classification list - http://eng.mst.dk/topics/chemicals/assessment-of-chemicals/the-advisory-list-for-selfclassification/ 6. Use of QSAR to identify potential CMR substances of relevance under the REACH regulation - http://www2.mst.dk/Udgiv/publications/2013/09/978-87-93026-48-3.pdf 7. Danish consumer projects - http://eng.mst.dk/topics/chemicals/consumers--consumer-products/danish-surveys-on-consumer-products/ 8. The Danish strategy on endocrine disrupting substances - http://eng.mst.dk/topics/chemicals/endocrine-disruptors/ 9. Campaigns and folders on endocrine disruptors: http://eng.mst.dk/topics/chemicals/endocrine-disruptors/campaigns-and-folders-on-endocrine-disruptors/ 10. WEMOS, WECF and Pesticides Action Network: *Measures against endocrine disrupting chemicals – The examples of Denmark, Sweden and France.* June 2016. 11. The Danish Product Register - http://engelsk.arbejdstilsynet.dk/en/produktregistret 12. The SPIN database website - http://195.215.202.233/DotNetNuke/Home/tabid/58/Default.aspx 13. The Danish nano database - http://eng.mst.dk/topics/chemicals/nanomaterials/the-danish-nanoproduct-register/ 14. List of Endocrine disrupting substances (new project which is not finalized) 15. N. E. Skakkebaek research: http://www.bmj.com/content/305/6854/609 16. Database of substances in consumer products - http://mst.dk/virksomhed-myndighed/kemikalier/fokus-paa-saerlige-produkter/database-over-kemiske-

	stoffer-i-forbrugerprodukter/ 17. Information to companies about article 33 in REACH and 'Tjek Kemien'- https://www.docdroid.net/ER4DMta/tjek-kemien-information-to-companies-2016-eng-version.pdf.html 18. Art. 33.2 REACH: Duty to communicate information on substances in articles; an Enforcement project. Presentation by DK Chemical Inspectorate. 19. Website of Kemi i Kredsløb - http://eng.kemiikredsloeb.com/ 20. Website of Eco-innovation - http://eng.ecoinnovation.dk/
3. General introduction	– In Denmark, the Environmental Protection Agency (EPA), an agency of the ministry for Environment and Food, is responsible for legislation and is the authority in charge of major tasks with regards to chemicals. Some issues regarding chemicals are dealt with by the Working Environment Authority. There is close cooperation with other Scandinavian countries, notably with the Swedish chemical agency (KEMI). – In Denmark, there is rather high attention for chemicals by the public, the media and politicians. There is a push for initiatives on a national level. Also scientific findings, for instance on endocrine disruptors, have been a drive for national initiatives. – The Danish national policy for substances of concern consists of a broad array of different measures, including Danish priority substances, research and surveys, and different information campaigns targeted at either industry or consumers.
4. National drives	Perhaps the most significant Danish circumstance behind the initiatives to develop national policies for substances of concern, is a rather high attention for chemicals by the public, the media and politicians. This is a push for initiatives on a national level. Also, scientific findings can be drives. See below (under 'Incidents with relevance to these policies').
5. Policies and measures	**Chemical action plans** For a longer time already, Danish policies on chemicals are developed within the framework of Chemical Action Plans: comprehensive plans that set out priorities and allocate part of the budget and personnel. The present plan is called *'Chemicals Initiatives 2014-2017 – towards a life without toxins'*. It is the follow-up of the Chemicals Action Plan 2010 - 2013 (*'Safety in Denmark – international collaboration*). Meanwhile, work is going on to develop the new plan for the upcoming period, at present particularly by consulting stakeholders. The present action plan sets out three priorities: 1. International collaboration (REACH, CLP, BPR, Endocrine disruptors, Nano, Arctic Council) 2. Non-toxic products ('consumers must be able to avoid chemicals of concern') 3. Circulating resources ('more alternatives to chemicals of concern; more substitution') As these priorities already demonstrate, the action plans address both supra-national and national policies for substances of concern. In the remainder of this factsheet we will focus mainly on the Danish national policies. The following national policies and measures for substances of concern exist in Denmark. **LOUS – a signal list and a review project** From 1988 onwards, the Danish EPA has been identifying and drafting 4 different versions of a 'List of Undesirable Substances' (LOUS). Originally, the idea was to identify

	substances that had better be substituted, due to their hazardous properties and future banning potential, thus assisting and enabling companies to take a proactive stand. The LOUS list has gradually evolved, with the current list being the 4th. The criteria for the selection of LOUS substances are further explained in section 5 of this annex, about 'substance covered'. In a later stage, a LOUS review *project* was carried out of the 4th list. From 2012-2015 the Danish EPA (hired consultancies that) carried out comprehensive surveys and collected information about 40 selected substances and substance groups on the List of Undesirable Substances. On the basis of the surveys, national strategies for each substance/substance group were prepared. The results are used for various purposes. The Danish EPA uses them to ensure common and ambitious regulation in the chemicals area in the EU. On the national level, LOUS is used to find alternatives to some of the substances of very high concern, to increase supervision, to set threshold values for drinking water and soil, and to inform consumers and industries. Businesses can – still – use LOUS if they want to be one step ahead of regulation and use less, replace or completely phase out substances of concern. From 2016 onward it is possible to see the continuing work in Denmark and in the EU with each of the 40 substances and substance groups, since the status of the work is updated regularly on the Danish EPA's homepage. In the next years the LOUS project is only expected to be continued on a stationary level as a part of the Danish EPA's other work in the chemicals area.. **Product Registry and SPIN** Companies in Denmark that manufacture, import or change the trade name of any hazardous chemical substance in quantities equal to 100 kg up to 1000 kg per year or material in quantities equal to or exceeding 100 kg per year used for commercial purposes, must notify the Product Registry. Registered information is used by, for example, the Danish Working Environment Authority (WEA), the Chemical Inspectorate and the Danish Environmental Protection Agency (EPA) to monitor the use of hazardous chemicals in Denmark. Only four persons in EPA have access to the Product register's database. For publication of its contents, several confidentially clauses apply. It has to be anonymous, on the basis of aggregates of at least three companies and/or three products. Similar product registries exist in the other three Scandinavian countries. Together they maintain a web based database called SPIN. Through SPIN the content of the registers is made publicly available on an anonymous and aggregate basis. The database contains volumes in use for each substance in the four countries, also by industrial branch (NACE) and product type (UCN). Using the information in the Nordic product registers, tools are provided that make it possible to estimate exposure of human beings and the environment from different chemical uses. **Nanoproduct register** The Danish government has agreed on establishing a nanoproduct register. This register concerns certain mixtures and articles that contain and release nanomaterials and that are intended for sale to the general public. **Endocrine disruptors** In Denmark there is a national strategy on endocrine disruptors. This strategy has 3 focus areas: knowledge building and development of test methods, action-orientated investigations and regulation. Denmark is actively contributing to the EU work on endocrine disruptors. Special area of attention is 'combination / cocktail effects'. In 2006, the Danish government launched an information campaign targeting pregnant women, to inform them about endocrine disrupters and other chemicals. In 2011,

	Denmark launched another public campaign, prompted by a study of pregnant women and exposure to endocrine disrupting chemicals in everyday personal care products, food and domestic chemicals. The campaign included an information day in a hospital, television appearances by specialists, and an information flyer. In April 2015, the government launched a campaign in which GPs advised pregnant women about endocrine disrupting chemicals. In Denmark, pregnant women usually visit their GP first, after which the GP refers them to a midwife. **Surveys on chemicals in consumer products** For more than a decade the Danish EPA has commissioned surveys to identify chemical substances in a number of consumer products, such as toys, cosmetics, clothes, furniture etc.. The data on chemicals that have been identified in consumer products, are used to prioritise work on these chemicals, to inform industry and to develop information campaigns for consumers. The reports on these surveys are published on the EPA website. Also, the chemicals that are identified are made public through a web based database on the EPA website. **The advisory self-classification list** The Danish EPA has published a database with advisory hazard classifications for 49,000 substances based on QSAR predictions. The goal of this database (list) is to assist industry in meeting its CLP obligations. Companies are advised to self-classify their hazardous substances in accordance with the predicted classifications in the database unless they have other reliable information (such as test data) that leads to a different conclusion. **'Use of QSAR to identify potential CMR'** In 2013 the Danish EPA carried out a project in which it screened pre-registered and registered chemicals under REACH with the help of QSAR for potential CMR properties. In order to prioritize substances with positive CMR predictions information from the Nordic Product Register SPIN was used to give an indication for exposure potential. In doing so, it found 695 substances that had not been registered, possibly due to unrecognized CMR properties caused by lack of test data. Also, it found 212 registered chemicals that had not been self-classified as CMR. These findings were used as input for further evaluations of the substances, and to flag to industry that there may be a need to obtain more knowledge in order to document a safe use (depending on which available documentation already exists). **"Tjek Kemien"** In 2014 the Danish EPA and the Danish Consumer Council together developed and launched an app called 'Tjek Kemien – check the chemicals in your products.' "The aim of Tjek Kemien is to increase the awareness of Candidate List Substances and to make it easier for both companies and citizens to share information about the content of these chemicals in articles.' With this app consumers can scan the barcode on a product. This triggers an automatic request for information on the content of Candidate List Substances in the product to the supplier. Suppliers have an art. 33.2 REACH obligation to reply to these requests. A company's reply is entered into the app's database. This ensures that a next consumer will immediately receive the reply stored in the database, without the company having to do anything. The "Tjek Kemien" app has been downloaded 13.000 times in 2016. It is used to scan products on average about 2000 times a month (over 100.000 times since it came into existence). There were 237 companies in the database of the previous version of the app, and 47 in the current one. On a Tjek Kemien'-webpage it is mentioned that its development was inspired by "a German example where, in cooperation with an NGO (BUND), environmental protection authorities are carrying out a similar project." Meanwhile a project application has been

	filed under LIFE+ to further develop the app for application in the whole of the EU. **Kemi i Kredsløb** Kemi i Kredsløb is a substitution centre set up and run by consultants and financed by the Danish EPA. It describes itself as 'a partnership that helps Danish enterprises reduce the use of chemicals of concern in their products.' Its advisory board, which consists of people from industry, NGO's, science and the EPA, is in fact chosen by the Danish EPA. Kemi i Kredsløb offers two types of services: - general substitution tools and methodology; - direct support to concrete substitution projects. **Groundwater protection** A special feature of Danish policy is the policy on ground water. A political decision has been made that no pollution whatsoever is acceptable of Danish groundwater. Consequentially, the limit values for substances in ground water are very low. The quality of the groundwater is monitored. When at some place limit values are exceeded, this is followed-up by inspection and enforcement activities.
6. Substances covered	**Substances in LOUS** The 40 substances and substance groups in the LOUS project (in LOUS 2009) were selected on the basis of the following criteria: – because they had undesirable properties with regard to human health or the environment, – and because in 2009 they were being used in Denmark in amounts exceeding 100 tonnes a year, or had specific interest for the Danish market (the latter referring to heightened political attention, expressed by delegates, the media, the Danish consumer organisation; this was for instance the case for allergens in perfume). There is a wide overlap between the criteria for inclusion in LOUS and the criteria for inclusion in the Candidate List under the EU chemicals legislation (REACH). The basis of LOUS 2009 is the Danish EPA's List of Effects. The List of Effects contains all substances which fulfil the criteria set regarding hazardous properties (based on other official lists in the EU and the Danish EPA's advisory list of self-classifications elaborated with the help of QSAR models). This list (that does not consider the substances' use or non-use in Denmark) contains about 19,500 chemical substances. In 2012, the Danish Finance Act earmarked DKK 48 mill. over four years to review and examine all 40 substances and substance groups on the list. All 40 substances and substance groups have been through the same process: – Survey of existing data on use, regulation, waste, environmental and health effects and alternatives – Strategies with measures for managing identified environmental and health risks – Implementation of measures For about 25% of the 40 substances and substance groups, it was concluded that there is no need to take further steps other than sharing knowledge from the surveys with other countries. For the remaining substances and substance groups measures have been implemented in order to address the challenges identified. **Substances in the Product Registry** The requirements of the Product Registry concern any hazardous chemical substance in quantities equal to 100 kg up to 1000 kg per year or material (i.e. mixtures) in quantities equal to or exceeding 100 kg per year used for commercial purposes. (note: REACH sets out the requirements for registration to ECHA of substances manufactured of placed on the market in the EU in quantities of 1000 kg or more per year.) In recent years the data in the Product Register have proven not always to be up-to-

	date. Companies forget to record changes or updates. In April 2017 a new ICT system will be introduced through which companies can (an must) directly update their products' data. **Substances in the Nanoproduct register** The reporting requirement for the Nanoproduct Register concerns mixtures and articles that are intended for sale to the general public and that contain nanomaterials, where the nanomaterial itself is released under normal or reasonably foreseeable use of the mixture or article or where the nanomaterial itself is not released but substances in soluble form that are classified as CMRs or environmentally dangerous substances are released from the nanomaterials. Exceptions are listed, mainly for mixtures and articles that are covered by other regulations (e.g. foodstuffs, feed, medicinal products, etcetera) as well as for pigments only added to paints and inks as colourants. The Danish register differs from the French, as in the latter nanomaterials themselves are registered, whereas the Danish register concerns mixtures and articles, i.e. products. In Denmark the idea was to build on the existing infrastructure of the Product Registry. Besides, in Denmark no actual production of nanomaterials takes place. As a consequence, combination with the French data and/or common upscaling to EU level is hardly possible. So far, it has proven to be difficult to establish whether a product matches the definition of the reporting requirement, i.e. that it is a product that contains and releases materials of nano size (other than by wear and tear) and that it is not exempted by the regulation. All in all, the first 4-year period of the nano register has led to limited (and little useful) data. **Endocrine disruptors** Denmark is keen to exert influence on the establishment of new criteria for endocrine disruptors in the EU. It has submitted a 'Danish proposal for criteria for endocrine disruptors' to the EU. **Surveys on chemicals in consumer products** The surveys are targeted towards products that might contain problematic chemicals, or products that consumers are highly exposed to. Recent examples (among many more) are: allergenic substances in products targeted at children; chemicals that may prevent recycling; toluene and other neurotoxic substances in children's rooms; danger and resource assessment of 3D printers and 3D printed articles.
7. Legal / formal bases	• LOUS, The List of undesirable substances, is a policy document. • The Product Register is based in the Executive Order on the Registry for Substances and Materials • The Nanoproduct register is based on Statutory Order no. 644 of 13/06/2014. • In September 2002 the Danish Parliament approved a report on endocrine disruptors which established the Danish strategy in the field of Endocrine disruptors and combination effects. • The work with chemicals in consumer products is based on a political agreement.
8. Organisational basis	EPA, the Danish Environmental Protection Agency, is an agency of the Ministry of Environment and Food. The Environmental Protection Agency is responsible for legislation and is the authority in charge of major national tasks as well as particularly complex tasks. The Environmental Protection Agency prepares legislation and guidelines and grants authorisations in several areas. Further duties include the monitoring of chemicals and offshore platforms.

	• Both the LOUS list and the LOUS project 2012-2015 are carried out by the Danish EPA. • The Executive Order on the Registry for Substances and Materials is carried out by The Danish Working Environment Authority, which is an agency under the auspices of the Ministry of Employment. • The Nanoproduct register is carried out by the Danish EPA. • The Danish strategy in the field of Endocrine disruptors is carried out by the Danish EPA. Also, there is a 'Centre on Endocrine disruptors': This is an "interdisciplinary scientific network without walls" with the main purpose "to build and gather new knowledge on endocrine disruptors with the focus on providing knowledge relevant for the preventive work of the authorities." • The surveys on chemicals in consumer products are commissioned by the Danish EPA. EPA has a formal cooperation with KEMI, The Swedish chemical agency. Also, cooperation with all Scandinavian countries takes place through the Nordic Council of Ministers.
9. Involvement of stakeholders	In the LOUS project, the Danish EPA worked closely with stakeholders from other agencies, consumer organisations, environmental organisations, sector organisations, interested businesses and a number of other EU Member States. Throughout the project, processes have been transparent and have involved all stakeholders, who have regularly contributed input to the work. In the work with chemicals in consumer products, all reports are established in consultation with distributors, importers or manufacturers of the products. This is to make sure they agree on the methods employed in the surveys. Other stakeholders can from time to time be involved in the project group and are informed before publication of the reports. With regard to the Advisory Self-classification List companies are given the opportunity to post information for specific substances on the webpage. This can be used if companies disagree with the advisory self-classification and want to publish their own information.
10. Relation with European policies / international agreements	• The Danish EPA uses the results of the LOUS project to ensure common and ambitious regulation in the chemicals area in the EU and in an international context (the Montreal Protocol). • The Product register is additional to the registrations that already take place under REACH • The Nanoproduct register was established after close consultation with other interested EU Member States (France, Germany, Netherlands), to make sure that a possible future conversion to one unified EU register can be effected without problems, for both policy makers and industry. However, Denmark chose a different course, for reasons and with effects that have been described before. • Denmark is actively contributing to the EU work on endocrine disruptors. It has submitted a 'Danish proposal for criteria for endocrine disruptors' to the EU. • Results from reports on chemicals in consumer products contribute to restrictions in EU if problematic substances that pose a risk are found. • The Advisory self-classifications can be used for companies to fulfil their requirement under the CLP regulation to self-classify substances that are put on the market. In addition, it can be used by REACH registrants in the tonnage level of 1-10 Tpa to decide if the Annex III requirements are fulfilled (i.e. if they need to submit the standard information requirements in Annex VII).

11. Monitoring of substances and evaluations of effects	Continuous monitoring is taking place of chemicals in the environment (air, drinking water inlets). SVANA (Ministry for Environment and Food) is responsible for this. The monitoring itself is commissioned to the University of Aarhus (formerly the National Research Institute). The monitoring is most of all directed to meet the monitoring requirements that follow from EU regulations (mostly Water Framework Directive) and international agreements (Stockholm convention, Minamata convention on mercury). Next to that, ad hoc monitoring takes place. The findings are published in condensed reports. EPA has no access to the underlying database. Also, groundwater is monitored. This is done by GEUS, the Geological Survey of Denmark and Greenland. Groundwater quality is monitored through a series of special monitoring wells from which samples are taken each year. These samples are examined for substances such as nitrates, pesticides, chlorides, arsenic and organic pollutants. Also monitoring takes place to investigate whether approved pesticides or their degradation products leach into young groundwater in concentrations above the limit value. There is a separate Arctic monitoring system (AMAP), in which Denmark participates through its work in the Arctic Council and in connection with Greenland. This monitoring work does provide EPA with important insights into (accumulation of) substances in the Arctic. For example new types of brominated flame retardants come to the fore. These findings are used in proposals for the Stockholm Convention and the REACH Candidate List. Likewise the data are used to measure effectiveness of the international regulation of substances of concern (REACH, Stockholm Convention, Minamata Convention, LRTAP). The LOUS project was evaluated by the consultancy firm Rambøll in 2015. The conclusions from the evaluation indicate high-quality work, both regarding the technical content and the process-related result. There is no specific monitoring of effects for LOUS, but the progress in the execution of the strategies for each of the 40 substances and substance groups are made public on the Danish EPA's homepage. The status for each entry in the list is updated once a year.
12. Incidents with relevance to these policies?	Most incidents with chemicals in Denmark happened in the working place. One of the more recent incidents concerned exposure to epoxy in Danish windmill factories. An important case that drove the Danish policies in endocrine disruptors, resulted from the research that was carried out in the early 90's by N. E. Skakkebaek, on data on semen quality gathered over a large number of years from Danish soldiers. These data showed a significant decrease of semen quality over the years, to the extent that one third of Danish young men is no longer able to procreate without medical support. Skakkebaek linked this deteriorated semen quality to the presence of certain chemicals in the environment. This has put endocrine disruptors quite firmly on the political agenda in Denmark.
13. Relation with emission control	There is little relation between the Danish national policies for substances of concern and emission control. The granting of permits and emission control are responsibilities of the municipalities and SVANA. EPA has an advisory role in providing emission standards. There are no special emission requirements for LOUS substances. The data of the Product register play no role in the permitting process. Neither do the monitoring data.

14. Relation with inspection and enforcement	There are indeed relations between the Danish national policies for substances of concern and inspection and enforcement. One example is the use of the Product Registry by the Chemical Inspectorate, both for general planning purposes (for instance when companies are to be inspected for their dealing with specific – e.g. authorized – substances of concern) and for ad hoc purposes (for instance following up on complaints about allegedly illegal products). The 'Tjek Kemien' app was used by the Chemical Inspectorate to look into products with phthalates. Fifty articles of PVC plastic were analysed on the content of phthalates, and their suppliers were sent requests for information through the app. Next, the reactions were compared to the result of the analyses: – In 21 articles no phthalates were found; the suppliers replied correctly – In 18 articles no phthalates were found; the suppliers failed to reply – In 1 article phthalates were found; the supplier replied correctly – In 5 articles phthalates were found; the suppliers replied incorrectly – In 5 articles phthalates were found; the suppliers failed to reply
15. Relation with circular economy (re-use and recycle) and substitution	*Circular economy* There are indeed relations between the Danish national policies for substances of concern and the policies aiming at a circular economy. An example in the LOUS review is the implementation of a project on undesirable chemistry in construction (in Danish with English summary). It established an overview of problematic substances in construction and gave a basis for recommendations addressing both environmental, health and circular economy aspects. In the Surveys on chemicals in consumer products issues of recycling and re-use (circular economy) are addressed, for instance in surveys on 'chemical substances which may prevent recycling' and on 'the use and potential use of bioplastics in Denmark'. In all instances the Danish position is that recycling should be improved and enhanced by getting substances of concern out of products right from the beginning. *Anecdote:* *One of the PVC plastic products that was analysed by the Chemical Inspectorate during the 'Tjek Kemien' project, turned out to contain phthalates. They were components of the membral devices that had been recycled into this PVC product (for packaging of medical products these phthalates are authorized). Notwithstanding this origin, the supplier was obliged to mention its content when asked by consumers.* *Substitution* There are also indeed relations between the Danish national policies for substances of concern and efforts aiming for substitution. Examples can be found in the LOUS project, where 'substitution' is one possible (element of a) strategy and in which the surveys are also geared to look for alternatives. The Product register is instrumental in monitoring the phasing out and possible substitution of specific chemicals. Indeed, it has shown that use of for instance allergens in perfume or flame retardants in Danish products has gone down. Some policy measures specifically aim to effect substitution, most notably 'Kemi i Kredsløb' and, broader, the eco-innovation project. The experiences so far, give some reason to reconsider these projects. It looks like bigger companies are not too keen to participate in these projects. For them, substitution is a normal part of ongoing innovation, as an element of their business strategy. Participation in state sponsored projects would put them and their innovations in the limelight and would require public

	reporting. SME's feel largely the same and/or are less aware and prone to enter a substitution process.

Annex 3: France

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2. Relevant literature and websites	1. Plan National Santé Environnement 2, 2009 -2013' (PNSE 2): http://social-sante.gouv.fr/IMG/pdf/PNSE2.pdf 2. INERIS project Définition d'une méthode d'identification et de hiérarchisation de substances préoccupantes: http://www.ineris.com/rapports-etude/risques-chroniques/limpact-pollutions-homme/substances-preoccupantes 3. INERIS report: Définition d'une méthode d'identification et de hiérarchisation de substances préoccupantes – Application au cas particulier de la préparation du troisième Plan National Santé Environnement.: http://www.ineris.fr/centredoc/rapport-phs---aveccouv-1366704410.pdf 4. On the national strategy on endocrine disruptors: http://social-sante.gouv.fr/sante-et-environnement/risques-microbiologiques-physiques-et-chimiques/article/perturbateurs-endocriniens 5. The national strategy on endocrine disruptors: https://www.pnrpe.fr/IMG/pdf/ART_137___2014-04-29_Strategie_Nationale_Perturbateurs_Endocriniens.pdf 6. Plan National Santé Environnement 3, 2015 -2019' (PNSE 3): http://www.developpement-durable.gouv.fr/3e-plan-national-sante,41430.html?onglet=themes 7. Assemblée National, propoed law 'Loi DETOX': http://www.assemblee-nationale.fr/14/dossiers/principe_substitution_produits_chimiques.asp 8. Chemical Industry on the Loi DETOX: http://www.industrie.com/chimie/la-loi-detox-adoptee-a-l-assemblee-nationale,70184
3. General introduction	– In France, both the ministry for the environment and the ministry of labour have responsibilities for policies on substances of concern. In chemical matters they are supported by ANSES, the French Agency for Food, Environmental and Occupational Health & Safety, and INERIS, the National competence centre for Industrial Safety and Environmental Protection. – The main drives of French policies on substances of concern are societal concerns and pressures. The levels of concern over 'bisphenol A' and over pesticides exposure in France are probably unparalleled by any other EU Member State. Also, the parliamentary initiative of the 'Loi Detox' can be seen as an expression of pressure on policy makers to work on the substitution of substances of concern. The policy process itself is quite open for societal input, like via the annual 'Environmental Conference' (formerly known as 'Grenelle') and by taking societal concern as a criterion for substances of concern. – The French national policy for substances of concern addresses many different specific substances and substance groups, with measures ranging from accelerated assessments and registration requirements to a specific ban.

4. National drives	The main driving force behind the French policies for substances of concern are societal concerns and pressures (often also from industry vis-à-vis NGO's). Special concerns arise over hazards and risks of endocrine disruptors and reprotoxic substances, particularly in relation to sensitive groups like pregnant women and children. It was particularly the annual 'Environmental Conference' (previously known as 'Grenelle') that put endocrine Disruptors firmly on the policy agenda. In France the levels of concern over 'bisphenol A' and over pesticides exposure are probably unparalleled by any other EU Member State. Also, the parliamentary initiative of the 'Loi Detox' can be seen as an expression of pressure on policy makers to work on the substitution of substances of concern.
5. Policies and measures	The following national policies for substances of concern exist in France. In the **'Plan National Santé Environnement 2, 2009 -2013' (PNSE 2)** (National Plan for Health and Environment) 12 measures are announced. Measures with particular relevance to substances of concern are: • Effect a reduction by 30% of emissions to air and water of 6 toxic substances: mercury, arsenic, polycyclic aromatic hydrocarbonates, benzene, perchlorine ethylene and PCB's/dioxins. • Ensure the protection of the 500 most endangered drinking water inlet points • Improve knowledge and reduce the risks of medicine discharge into the environment • Reinforce the surveillance of substances placed on the market in France, particularly aimed at children • Reduce exposure to substances of concern in living environments and buildings for children • Identify and regulate environmental 'black spots'; zones in which an overexposure to toxic substances is likely to occur One of the actions related to 'fiche 2' of the PNSE2, is the action ('action 5') to define a **methodology to identify and prioritise toxic substances of the highest concern ('substances toxique les plus préoccupantes).** This is done in order to prepare for an input in different national, European and international policies. Following up on this, INERIS has developed this methodology, based on a multicriteria analysis. It has applied this on substances used in France in order to come up with priority actions for the next national plan (PNSE3). In 2014 the **Stratégie Nationale sur les Peturbateurs Endocriniens** was launched (National Strategy on Endocrine Disruptors). This aims of this strategy are: • to drive research, valorisation and surveillance • to accelerate and improve the evaluation of these substances (at least 15 in 3 years), to be carried out by ANSES • to promote the regulation and substitution of endocrine disruptors (by demanding at EU level: a common definition; an exclusion of their use in pesticides (plant protection products and biocides), a restriction of bisphenol A in thermal paper and re-evaluation of the admission of 21 active substances for pesticides) • to develop an information and education campaign This strategy is incorporated in the PNSE3. The **'Plan National Santé Environnement 3, 2015 -2019' (PNSE 3)** (National Plan for Health and Environment) announced 10 measures. The measures with particular relevance to substances of concern are: • Develop a precautionary approach towards the potential risks of nanomaterials • Reduce exposure of the population to endocrine disruptors • Improve drink water quality

- Control and reduce the use of pesticides

The "PNSE's" are developed by regional authorities into regional plans, called **"PRSE's"**. In these regional plans, national priorities and actions are translated to and made applicable for the specific regional situations.

In order to promote substitution of substances of concern, a working group is drafting a **substitution guide for industry**. This guide is meant to help industry to identify substances of concern in their products and production processes (for instance by looking at the Candidate List) and to search for appropriate alternatives. As such, the guide is an attempt from the Ministry to work *with* French industry and to assist it in looking at the future.
The draft guide will be finalised at the beginning of 2017.

A new law has been proposed in French Parliament, called **'Loi DETOX'.** This law passed first reading in the Assemblée Nationale on January 14, 2016. The Loi DETOX aims to accelerate the substitution of substances of concern, by the following measures:

- A national plan for the substitution of substances of concern
- Yearly publication (by the Ministers of Environment, Health and Labour) of a list of substances of concern that must be substituted by companies
- Obligatory notification of substances of concern to Ineris
- Development of a label for companies that are least pollutant (*'les plus vertueuses'*)
- Installation of a platform for technical, scientific and financial assistance for substitution
- Installation of a fiscal facility for substitution
- A possibility to put a label on consumer products indicating the absence of substances of concern that are on the government list.

The French chemical industry strongly denounces the plan for this new law. It points to the existing legal means of REACH and CLP, and to the competitive disadvantages the new law would entail.
According to our sources, it is not to be expected that the proposed 'Loi Detox' will come to pass (for instance because of the overlap with REACH).

6. Substances covered

- The 'Six' substances that are particularly addressed in the PNSE2 are: mercury, arsenic, polycyclic aromatic hydrocarbonates, benzene, perchlorine ethylene and PCB's/dioxins.
- The 'methodology to identify and prioritise toxic substances of the highest concern' uses a number of criteria, including CMR, PBT, protection of vulnerable groups and risks to individuals. One criterium is the 'Indicateur de Perception societale' (IPS; societal perception indicator), that is based on the attention for a substance in the media. The method applies multicriteria analyses to prioritise substances, resulting in two rankings (G1 and G2). The picture below shows the top 5 substances in both rankings (in the report a top 100 is presented).

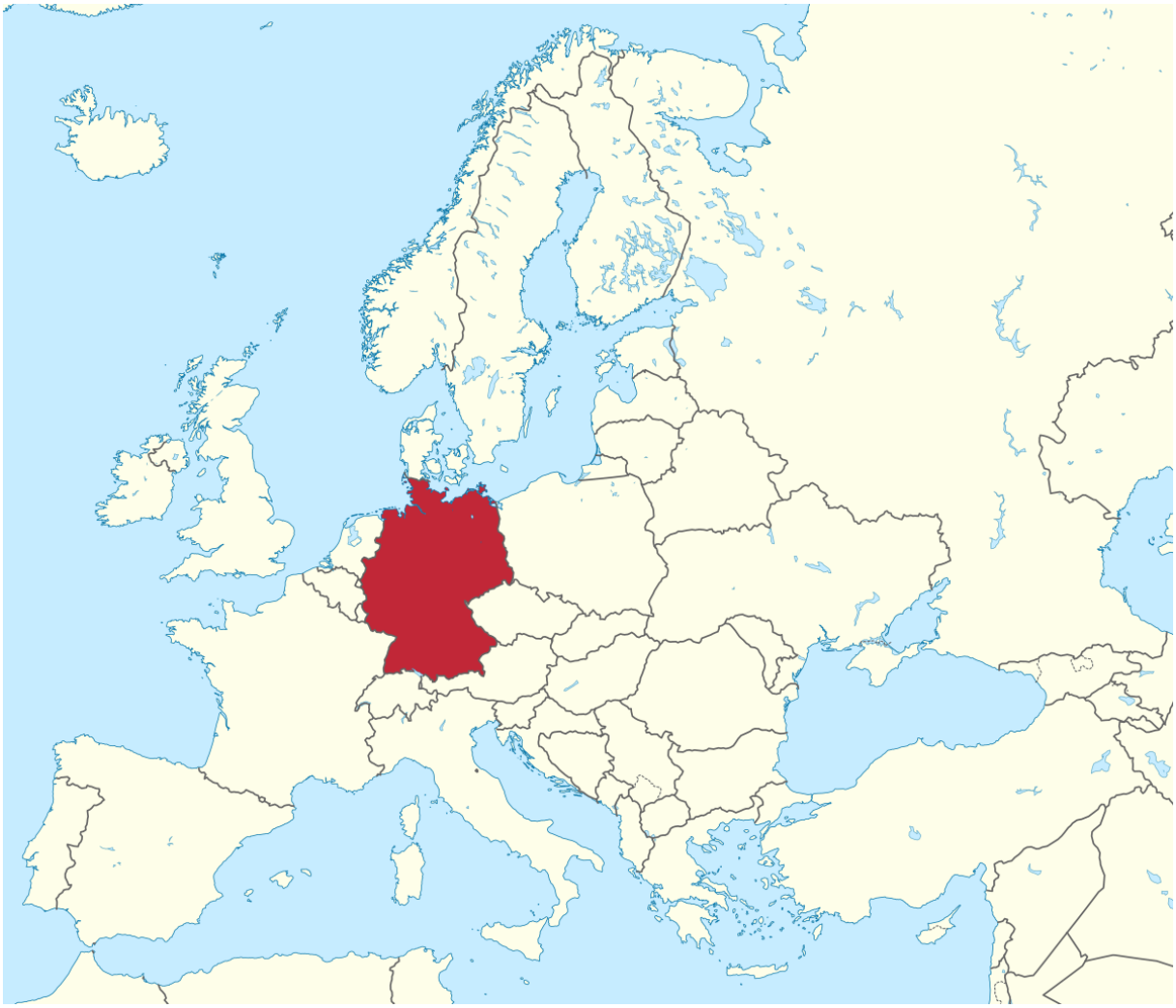
Rang G1	Substances	Rang G2	Substances
1	Benzo(a)pyrene	1	PCDdioxine : 2,3,7,8-tétraCDD
1	Phtalate de bis(2-éthylhexyle) (DEHP)	2	DDT, P,P (4,4Dichlorodiphenyltrichloroethane)
3	Benzène	3	Benzène
4	PCDdioxine : 2,3,7,8-tétraCDD	3	Mercure et ses composés
5	DDT, P,P (4,4Dichlorodiphenyltrichloroethane)	5	Phtalate de bis(2-éthylhexyle) (DEHP)
5	Di-n-butylphthalate (DBP)	5	Trichloroéthylène

	• In the process of 'identification and prioritisation of toxic substances of the highest concern', ANSES uses both REACH data and data on emissions in France. ANSES has access to the REACH database. Also, it has access to a database of emissions in France. The National Strategy on Endocrine Disruptors aims directly at pesticides and bisphenol A in thermal paper, and more in general in more extensive identification and evaluation of substances.
7. Legal / formal bases	The PNSE's and the 'Stratégie Nationale sur les Peturbateurs Endocriniens' are policy documents. They serve as action plans, guiding the designation of financial and personnel resources in order to achieve specific goals.
8. Organisational basis	• Both the Ministry for the Environment and the Ministry of Labour have responsibilities for policies for substances of concern. For example, the Ministry for the Environment is responsible for REACH, whereas the Ministry of Labour is responsible for CLP. They meet and coordinate on a regular basis; in these meeting also the Ministry of Health and ANSES participate. • The PNSE's are drafted and carried out under the responsibility of the minister for the environment (presently: Mme. Ségolène Royal) and the minister of health. • The PRSE's are drafted and carried out under the responsibility of regional authorities (State, regional council, ARS (Regional Health Agency)). • The 'Stratégie Nationale sur les Peturbateurs Endocriniens' was drafted following an initiative of the first 'Environmental Conference' (previously known as 'Grenelle') in 2012. The strategy was developed by a working group consisting of a broad group of parties involved (see below). The actions that were mentioned in the strategy are partly the responsibility of the Ministry for the Environment, and partly of the Ministry of Health. Later on, the strategy was incorporated in the PNSE3. • The proposal for the Loi DETOX was initiated by Mr. Jean-Louis Roumégas, a French politician who is a member of the National Assembly representing the 1st district of Hérault and a member of the ecologists group.
9. Involvement of stakeholders	In general, French policy processes on substances of concern are very transparent, both for industry and NGO's. It is always known which substances are under scrutiny. The 'Stratégie Nationale sur les Peturbateurs Endocriniens' was drafted following an initiative of the 'Environmental Conference', and was developed by a working group consisting of a broad group of parties involved. This working group included national and European MEP's, public research institutes, environmental and consumer NGO's, representatives of industry and of professional groups, and of the Ministries involved. Both the draft 'Stratégie Nationale sur les Peturbateurs Endocriniens' and the draft PNSE's have been subjected to public consultation before becoming final. Stakeholders are also associated in several working groups, such as : - GSE: Health environment group in charge of steering the PNSE - GT SNPE: Working group on SNPE, following the 'Stratégie Nationale sur les Perturbateurs Endocriniens' - GT REACH: Working group on REACH, discussing subjects concerning REACH regulation Another example of stakeholders involvement is the public consultation that is carried

	out before the publication of an RMOA (Risk Management Option Analysis) of a substance in the REACH regulation context.
10. Relation with European policies / international agreements	Both the methodology to identify and prioritise toxic substances of the highest concern, and the 'Stratégie Nationale sur les Peturbateurs Endocriniens', have as one of their objectives to contribute to the formation of European and international policies and regulation of hazardous substances.
11. Monitoring of substances and evaluations of effects	The National Strategy for Endocrine Disruptors dates from 2014. Recently, meetings have taken place with the different parties involved, in order to get an idea whether and how the Strategy can be improved. Monitoring happens in France in cases where this is required by international regulations and agreements (e.g. POP). It is not clear whether additional monitoring takes place of substances in the air, in water or in the soil. As to soil pollution, permits do require industry to carry out monitoring activities; this is however a consequence of the SEVESO Directive.
12. Incidents with relevance to these policies?	There are cases in which substances of concern have given rise to public concerns and debate. • There has been a lot of discussion in France around phytopharmaceutical (plant protection) products. This is a sensitive subject: a plan named 'Ecophyto' was initiated (in 2008) with the objective to decrease the use of pesticides by half (by 2018). • There was and is a lot of pressure in France on bisphenol A. Particularly the NGO's paid a lot of attention to this issue. This has grown to become a major case in France, probably more so than in any other European country. It is not clear to our sources why this is the case.
13. Relation with emission control	Particularly the PNSE 2 has a strong focus on measures to control emissions of substances of concern. The objective is formulated to effect a reduction by 30% of emissions to air and water of 6 toxic substances. The protection of the 500 most endangered drinking water inlet points is to be ensured. Medicine discharge into the environment is seen as a major issue of concern. And the exposure to substances of concern gets a lot of attention: both the exposure to substances of concern in living environments and buildings for children, and so-called environmental 'black spots'; zones in which an overexposure to toxic substances is likely to occur. The planning period of the PNSE2 was 2009-2013. This period was before our contact person came to office. So far we have no further information. There appears to be no direct relation between the French national policies for substances of concern and emission control. Emission standards and monitoring requirements (to air and water) are specified by regional authorities, and depend on the regional configuration. The emission norms are established on the basis of the CLP classification of the substances and are adapted to the physical surroundings, the types of industry in the area and the regional environment.
14. Relation with inspection and enforcement	We have no further information on the relation between the French national policies for substances of concern and inspection and enforcement.

15. Relation with circular economy (re-use and recycle) and substitution	The policy issue of 'circular economy' is a responsibility of the Ministry for the Environment as well (as well as the responsibility for policies of substances of concern). The issues are dealt with by different sections of the Ministry. However, there is ample coordination between these sections and between the policies in both fields, for instance concerning the recovery of material and the re-use of waste. This coordination takes place on a case-by-case basis. There are indeed relations between the French national policies for substances of concern and efforts aiming for substitution. Substitution is one of the aims of the French National Strategy on Endocrine Disruptors (later incorporated in the PNSE3). It is the central aim of the Substitution guide for industry that is being drafted (to be finalised at the beginning of 2017). This guide is meant to help industry to identify substances of concern in their products and production processes (for instance by looking at the Candidate List) and to search for appropriate alternatives. The proposed 'Loi DETOX' (which, according to our sources, will not come to pass) had substitution of substances of concern as its central objective.

Annex 4: Germany



1. Organisations contacted	**Main contact:** Dr. Frauke Averbeck Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA) Fachbereich 5 Bundesstelle für Chemikalien (BfC) T. +49 231 9071 2279 E. averbeck.frauke@baua.bund.de **Other contact:** Dr. Marc Brandt Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB) Chemicals, Risk Assessment and Risk Management T. +49 301 8305 6582 E. marc.brandt@bmub.bund.de
2. Relevant literature and websites	**Literature:** • Federal Office for Chemicals (2013), 'Nationale Risikomanagementstrategie unter REACH und CLP – Ermittlung regulierungsbedürftiger Stoffe und Auswahl des geeigneten Verfahrens', AZ: 721 10/00/2012.0187, 07-03-2013, Dortmund • The Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety / Bundesrat (2016), 'Verordnung zur Neuregelung nationaler Vorschriften über das Inverkehrbringen und die Abgabe von Chemikalien', Verordnung der Bundesregierung, Drucksache 559/16, 29-09-2016. • Bundesinstitut für Risikobewertung (2010), 'Chemie im Alltag – Eine repräsentative Befragung deutscher Verbraucherinnen und Verbraucher', Berlin. • Weinmann, Thomas, Klein (2005), 'Gefahrstoffrecht und Chemikaliensicherheit, Sammlung der chemikalienrechtlichen Gesetze, Verordnungen, EG-Richtlinien und Technischen Regeln mit Erläuterungen'. **Websites:** • The Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety ('Bundesministerium für Umwelt, Naturschutz, Bau und Reaktorsicherheit' - BMUB): http://www.bmub.bund.de/en/topics/health-chemical-safety-nanotechnology/ • The Federal Ministry of Labour and Social Affairs ('Bundesministerium für Arbeit und Soziales' - BMAS): http://www.bmas.de/EN/Home/home.html • The Federal Environment Agency ('Umwelt Bundesambt' - UBA): https://www.umweltbundesamt.de/en/topics/chemicals • Federal Institute for Occupational Safety and Health ('Bundesanstalt für Arbeitsschutz und Arbeitsmedizin' - BAuA): http://www.baua.de/en/Homepage.html • The Federal Institute for Risk assessment ('Bundesinstitut für Risicobewertung' - BfR): http://www.bfr.bund.de/en/home.html • The Federal Institute for Materials Research and Testing ('Bundesanstalt für Materialforschung und –prüfung' - BAM): https://www.bam.de/Navigation/EN/Home/home.html • Institute for Occupational Safety and Health of the German Social Accident Insurance ('Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung - IFA): http://www.dguv.de/ifa/index.jsp • The Federal Office of Consumer Protection and Food Safety ('Bundesamt für

	Verbraucherschutz und Lebensmittelsicherheit' - BVL): http://www.bvl.bund.de/EN/Home/homepage_node.html • Database of the 'Bundesländer': https://www.gefahrstoff-info.de/ • The Hazardous Substances Information System of the Professional Association of the Chemical Industry (GISCHEM): http://www.gischem.de/index.htm • The International Sustainable Chemistry Collective Centre (ISC3) website: https://isc3.org/ • The Substitution Support Portal "SUBSPORT": http://www.subsport.eu/ • The OECD Substitution and Alternatives Assessment Toolbox (SAAT): http://www.oecdsaatoolbox.org/Home/Index
3. General introduction	The Federal Republic of Germany ('Bundesrepublik Deutschland') is a federal parliamentary republic that includes sixteen federal states, which are collectively referred to as 'Bundesländer' (or: 'Länder'). Each state has its own state constitution and is largely autonomous with regard to its internal organisation. This exploratory study focusses on the national level, because it is not possible to look into the policies of each of the 16 states due to the (explorative) nature of this study.
4. National drives	Chemical safety is a major cause for concern nowadays in Europe and around the world. In the interest of strengthening domestic markets and cutting costs, the EU has been gradually replacing national approval and assessment procedures with European ones. But this of course does not absolve the member states from meeting their responsibilities, for they are still required to take on the key assessment, management and monitoring tasks. As the leading chemical producer in Europe and number four worldwide, Germany has a particular stewardship responsibility in this domain. More in particular, Germany finds it relevant to take measures against a substance or a substance group if European Regulations prescribe to take action. National or local indications might however also be an initiator for the development of new policies. It was mentioned that media attention is not so much an initiator for the development of (new) national substances policies.
5. Policies and measures	**Management of dangerous chemicals** The German national policy on dangerous chemicals was developed with a view to fulfil the tasks within the framework of REACH, in particular in the framework of the SVHC Roadmap to 2020. The "Roadmap for SVHC identification and implementation of REACH Risk Management measures from now to 2020" gives an EU-wide commitment for having all relevant currently known substances of very high concern (SVHCs) included in the Candidate List by 2020. How SVHC are identified and how the best risk management option is determined in Germany is described in the policy paper "**Nationale Risikomanagementstrategie unter REACH und CLP – Ermitlung regulierungsbedürftiger Stoffe und Auswahl des geeigneten Verfahrens**". This policy paper basically translates the REACH/CLP guidelines into the German context. It is developed by the German Federal Office for Chemicals. **National policies** With the implementation of the REACH and the CLP Regulation Germany's existing national legislation on dangerous chemicals became (partly) superfluous and its scope was largely reduced, except for cases where there is not yet a comparable EU rule (as e.g. for the bio-persistent fibres which are still in the national Chemical Prohibition Ordinance). For occupational safety and health (OSH) this is different, since there is only an EU Directive. As an EU Regulation is directly applicable in EU Member States, an EU Directive only sets minimum standards and it is each Member State responsibility to

	implement its own OSH-legislation that meets at least the minimum requirements laid down in the Directive. So for industrial chemicals, only in the very rare case that a risk associated with a substance only occurs in Germany, the national legislation is considered. If it is EU-wide considered as a risk or 'problematic' than the EU rules are applicable. The main objective of Germany's national framework for the management of dangerous chemicals is to protect human health and/or the environment by identifying substances of concern, finding the best risk management option to deal with and implement it. The focus of the strategy is equally on protection of the environment, occupational safety and health and consumer safety. The following policies together make up Germany's legislative/institutional framework for the management of dangerous chemicals: • The **German Chemicals Act** ('Chemikaliengesetz' or 'ChemG') is the national policy framework on industrial chemicals. It serves the implementation of several EU legislations in Germany. The Chemicals Act is of organisational nature; it defines the roles and tasks of the different authorities within these frameworks. In particular, regulations are being implemented in accordance with the REACH/CLP regulations. The possibility of national bans and restrictions is laid down in paragraph 17 of the German Chemicals Act, however it needs to be checked whether a national restriction is legally possible or if there is the need to act under EU law. • The **Chemical Prohibition Ordinance** ('Chemikalienverbotsverordnung' or 'ChemVerbotsV') regulates restrictions for bringing hazardous substances on the market and prohibits a few specific substances with a view to protect the general public health and the environment within the Federal Republic of Germany. A number of obligations are imposed on the placing on the market, such as regulatory approvals, notification obligations, recording obligations, and also evidence of a product. A self-service ban was also prescribed for a number of substances. This means that substances that are sold by retail may not just be put on a shelf (e.g. in hardware stores) but need to be locked away and may only be handled to the customer by qualified staff members in order to ensure that the appropriate rules are being followed. • The **Hazardous Substance Ordinance** ('Gefahrstoffverordnung' or 'GefStoffV') deals with substance restrictions and prohibitions, which primarily serve the purpose of occupational health and safety. According to Art. 6 of the German Hazardous Substances Ordinance the employer is obliged to take all necessary measures to protect employees from health hazards during activities with hazardous substances. The central tool of the Ordinance is the risk assessment. Its purpose is to identify and assess risks relating to hazardous substances, e. g. due to inhalation or dermal exposure, and to define and check protective measures. The Technical Rules for Hazardous Substances (TRGS) 400 "Risk assessment for activities involving hazardous substances" and 402 "Identification and assessment of the risks from activities involving hazardous substances: inhalation exposure" define the procedure for risk assessment in detail. • The **Federal Immission Control Act** (´Bundes-Immissionsschutzgesetz' or ´BImSchG´) regulates the protection of humans, animals, plants, soils, water, atmosphere and cultivated animals from immissions and emissions of dangerous subtances (classified as CLP). The German Länder each have a emission control system in place that implements the BImSchG. Emission limitations are included in permits. Monitoring of dangerous substances in relation to the BImSchG is the responsibility of the authorities (enforcement), although companies also have a responsibility to monitor their own emissions.

	Focus on nanomaterials With a view to promote safe and sustainable use of dangerous chemicals, Germany specifically pays attention to nanomaterials. Three years ago Germany submitted a proposal to the EU how nanomaterials could be included into the REACH Regulation. Currently, the country is still waiting the European Commission to take action in this regard. Germany currently does not have an official policy or legislation on nanomaterials, although it has since 2006 a strategy that promotes responsible use of nanomaterials through. The following measures are part of that strategy: ▪ The development of the Federal Government Nanotechnology Action Plans (every five years). The third Nanotechnology Action Plan 2020 was adopted by the Cabinet in autumn 2016. The action plan follows on from the Action Plan Nanotechnology 2015 and the NanoInitiative – Action Plan 2010. ▪ The 'NanoDialogue', a national platform that aims to support an exchange of ideas between civil groups and stakeholders on the opportunities and risks of nanotechnologies. More than 200 experts were thus engaged on a voluntary basis in the discussion on the responsible use of nanomaterials. ▪ Performing research in the field of nanotechnology and nanomaterials. As part of its ministry-funded research, the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB) supports projects on environmental research and regulation: - investigation of two widely used nanomaterials (TiO2, Ag) for ecotoxicological long-term effects - adaptation of the test guidelines; - investigation of widely used nanomaterials and gold nanoparticles in standardized ecotoxicological tests; and - final report by UBA on the fate and behaviour of TiO2 nanomaterials in the environment In addition, BMUB also support German involvement in the following two EU nanoresearch projects: - NANOGENOTOX - The EU NANoREG Project ▪ Participation in the 'International NanoAuthorities Dialogue'. This is an annual event offering a dialogue platform for environmental, health and occupational safety authorities and scientists from German speaking countries (Germany, Austria, Switzerland and Liechtenstein). This year, more than 50 representatives of ministries, authorities, research institutes and companies from Germany, Austria, Switzerland and Liechtenstein addressed the topic "governance and regulation of nanomaterials". Discussions were held on the requirements and the need for future regulation of nanomaterials as well as on the possibilities for the sustainable development of nanotechnologies. ▪ Participation in the OECD Working Party on Manufactured Nanomaterials (WPMN). The BMUB is head of the German delegation. Since 2006 the WPMN has been working on the development of internationally coordinated methods and strategies to identify and manage the potential risks to human health and the environment of nanomaterials. The results are made available to the public and aim to help the countries involved implement measures to ensure the safe use of nanomaterials. ▪ Participation in the CARACAL (the meeting of the Competent Authorities for REACH and CLP) subgroup for nanomaterials (CASG Nano). The Federal Office for Chemicals (BfC) sends the official German member of this group, BMUB is also participating, if possible. ▪ Participation in ECHA's Nanomaterials Working Group (to be renamed into Nanomaterials Expert Group). The BfC send the official German member with auxiliary experts coming from the assessment units.
6. Substances covered	As Germany's dangerous chemical policies are based upon implementation of the EU's SVHC Roadmap 2020, Germany does not have a national list of undesirable substances.

	For identification of SVHC and determination on the best risk management option, Germany developed national criteria in different areas. In addition, there are certain groups of substances which the German authorities are or have been working on, e.g. perfluorinated compounds and phthalates. • The **German Chemicals Act** is the German national policy framework for industrial chemicals, it does not have a focus on individual substances or groups of substances. The 'Chemicals Act' is of organisational nature as it describes the roles and responsibilities of the various authorities involved in the management of industrial chemicals. • The **Chemicals Prohibition Ordinance** regulates the prohibitions and restrictions on the placing on the market of 'hazardous substances in general' and 'particularly hazardous substances'. 'Hazardous substances in general' 'Hazardous substances in general' in terms of the Chemicals Prohibition Ordinance refers to substances that have to be classified according to CLP for certain properties and labelled in a certain way (e.g. with pictogram GHS06, or with pictogram GHS08 and the signal word "danger" plus certain hazard statements). For these substances the placing on the market and use is not prohibited per se but certain obligations apply to the delivery of these chemicals. On the one hand, the person who sells them needs to have a certain qualification ("Sachkunde"), needs to be reliable and at least 18 years old. He has to inform the purchaser about the hazards related to the substance, precautionary measures e.g. in case of spilling and the correct disposal. The vendor also needs to ensure, e.g. by asking for a signed statement of the purchaser that he will only use the substance for allowed uses and that he fulfils the legal requirements to do so. Each sale needs to be documented in a so called "Abgabebuch" including the name and address of the purchaser, the date, the designated purpose, as well as information on the substance and the amount. 'Particularly hazardous substances' The aim of the Chemicals Prohibition Ordinance was originally to transform the EU Directive 76/769/EWG into German Law. The 'particular hazardous substances' listed in EU Directive 76/769/EWG were identified at EU level as being of particular concern; meaning that there is an actual risk when these substances are placed on the market and/or used in certain applications (e.g. asbestos, formaldehyde, dioxins and furans, benzene, aromatic amines, arsenic, mercury and cadmium compounds, polychlorinated biphenyls and polychlorinated terphenyls, pentachlorophenols, vinyl chloride, aliphatic hydrocarbons, tar oils). When the REACH Regulation entered into force, the restrictions contained in Directive 76/769/EWG were transposed into Annex XVII of the REACH Regulation, which directly applies in all EU member states. Therefore, all of these restrictions have become obsolete and will now be removed from the Chemicals Prohibition Ordinance. A new version of the Chemicals Prohibition Ordinance is currently in the process of being adopted. The '**Verordnung zur Neuregelung nationaler Vorschriften über das Inverkehrbringen und die Abgabe von Chemikalien**' is a revision of the Chemical Prohibition Ordinance. It has the status of a Federal Regulation. Paragraph 3 makes reference to the restrictions under REACH and indicates that the four substances listed in Annex 1 shall also not be place on the market in Germany (formaldehyde, dioxins and furans, pentachlorophenol as well as bio-persistent fibres). The focus on these four substances can only be explained from a German national and historic perspective as these substances were not included in Directive 76/769/EWG. Three of the four substances (bio-persistent fibres, dioxins and

	furans, and formaldehyde) were first included in Germany's national Occupational Safety and Health (OSH) legislation (e.g. 'Hazardous Substance Ordinance'). OSH legislation sets rules for manufacture and use whereas the Chemicals Prohibition Ordinance regulates the placing on the market. So for consistency the same substances have been included in the Chemicals Prohibition Ordinance as well, in order to have a complete ban covering manufacture, use and placing on the market. For bio-persistent fibres the reason to include them was that Germany originally wanted to have a stricter classification than what was decided at EU level. So in order to better protect German workers, a national regulation was implemented. The reason to include dioxins and furanes is based on their toxicity and persistency in the environment. For formaldehyde the main reason for inclusion seemed to be consumer protection because of its allergenic characteristics. For pentachlorophenol Germany originally had an own regulation (PCP-Verordnung) which was later on included in the Chemicals Prohibition Ordinance. The protection goal of this regulation was the environment. Pentachlorophenol is also included in REACH Annex XVII but there only the use of the substance as such is regulated whereas Germany's national regulation deals with articles containing PCP. • The **Hazardous Substance Ordinance** comprehensively regulates the protective measures for employees with activities with hazardous substances. It solely focusses on the safety of employees in the workplace. Hazardous substances are those substances, preparations and products which have certain physical or chemical properties, such as highly inflammatory, toxic, corrosive, carcinogenic, to name only the most dangerous. The Hazardous Substances Ordinance does not make reference to specific substances but defines hazardous substances, i.e. mainly substances classified according to the hazard classes of CLP as well as explosives and substances that can form hazardous substances or explosives during manufacture and use. Furthermore substances that could pose a hazard to employees by the way that they are used and substances which have been assigned an occupational exposure limit. • The **Federal Immission Control Act** deals with emissions of dangerous substances classified as CLP.
7. Legal / formal bases	• German Chemicals Act is a federal law for the protection against hazardous substances. • The Chemical Prohibition Ordinance is a federal law that regulates national restrictions for dangerous chemicals. • The Hazardous Substances Ordinance came into force 1 January 2005. In addition to the Chemicals Act, it is now also based on the Occupational Safety Act. • The Federal Immission Control Act is a federal law.
8. Organisational basis	The organisational basis for the management of dangerous chemicals is complex, since a large number of institutions are involved in Germany. In general, the **Federal Ministry for the Environment, Nature Conservation and Nuclear Safety** (BMUB) is the responsible national body for the implementation of legislation related to chemicals in Germany. This ministry is responsible for the implementation of REACH, the Federal Immision Control Act and the Chemical Prohibition Ordinance. The **Federal Ministry of Labour and Social Affairs** (BMAS) is responsible for implementation of CLP and the Hazardous Substances Ordinance (e.g. worker protection). The following governmental

	agencies, institutes and offices are involved in the management of dangerous chemicals: • The **Federal Environment Agency** (UBA) is the scientific environmental authority under the jurisdiction of the BMUB, responsible for the most diverse range of topics. UBA has therefore become the competent body for the assessment of environmental risks associated with chemicals. In addition to evaluating submitted information, UBA is in charge of identifying substances whose manufacture or application requires regulation due to their impact on the environment or certain intrinsic properties. UBA is also involved in the further development of chemical safety evaluation methods. The state of knowledge in science must be integrated whilst doing justice to the precautionary principle. Finally, UBA makes proposals on the further development of the REACH Regulation and introduces them to the discussion process at EU level. The scope of UBA's work also includes commissioning research projects or expert reports to third parties. UBA staff members sit on a number of different REACH committees, including the committee on risk assessment and the socio-economic analysis committee, which drafts statements on planned restrictions, authorisations and classifications. • The **Federal Institute for Occupational Safety and Health** (BAuA) is a research division within the BMAS. It advises the BMAS in all matters of safety and health and of the humane design of working conditions. As a federal institution with R&D functions the Federal Institute operates at the interface between science and politics and renders transfer services from the science system into policy, corporate practice and the broader society and vice versa. BAuA's tasks range from policy advice, the performance of sovereign duties and knowledge transfer into corporate practice through to the educational and instructional work done by the DASA Working World Exhibition. Division 4 and 5 of BAuA are of particular importance with regards to the management of dangerous chemicals. **Division 4** is responsible for improving the protection of employees working with hazardous substances and biological agents (pathogens). It describes their risks, evaluates them and suggests measures to lower the risks for the employees to an acceptable level. Current research and development focuses on the following: ▪ nano materials and innovative materials; ▪ health risks caused by exposure to biological agents and intensive use of antibiotics in animal husbandry ▪ the easy-to-use workplace control scheme for hazardous substances (EMKG) ▪ assessment of exposure to hazardous substances in the workplace and ▪ improvement of the communication of hazard and risk reduction needs in the chemical supply chain The EU ordinance for the regulation of industrial chemicals (REACH), the ordinance for the classification, labelling and packaging of chemicals (CLP) and the Chemicals Act for placing on the market of biocidal products form the basis of the legal tasks of the division. Division 4 includes the '**REACH Assessment Unit OSH**' within the framework of REACH and the 'Biocides Assessment Unit OSH', which is part of the authorization of biocidal products. The most important statutory requirements pertain to the following: ▪ Classification and labelling of hazardous substances and mixtures ▪ Authorisation and restriction of substances of very high concern ▪ Evaluation of selected substances and dossiers as part of the REACH registration ▪ Support of small and medium-sized companies with helpdesks ▪ Risk evaluation of active substances of biocides, and ▪ Authorisation of biocidal products in Germany and mutual recognition of

	authorisation within the EU Division 4 focuses its political consulting on further development of the European legislation on substances and its specific implementation in technical guidance. The division supports the BMAS in the enhancement and implementation of the hazardous substances and biological substances ordinance as well as the ordinance concerning occupational prevention. **Division 5** carries out the tasks as **Federal Office for Chemicals** ('Bundesstelle für Chemikalien' - BfC) in accordance with the Chemicals Act. It is responsible for the implementation of legislation aimed at protecting people and the environment from hazardous substances. It performs statutory tasks with international activities in the field of regulation of industrial chemicals and the authorisation and evaluation of biocidal products. In the process, it acts as a national and international interface. The BfC is supervised by the BMUB and is appointed as the German Competent Authority for coordinating the German activities with regards to the implementation of the REACH/CLP Regulations. According to the Chemicals Act, the BfC has the task to coordinate the national activities within these frameworks. The BfC works in close co-operation with the other federal authorities involved, defining the overall position and presenting it to the ECHA and the EU Commission. For certain aspects, further national authorities can be involved (e.g. the 'Bundesanstalt für Materialforschung und –prüfung' - BAM) for the evaluation of hazardous physical chemical properties. In addition, within the framework of its responsibility for EU Regulation (EC) No. 528/2012 on the making available on the market and use of biocidal products, the BfC evaluates biocidal active substances and processes/decides upon applications for authorisation of biocidal products. In these procedures, Division 5 works in close co-operation with the other federal authorities involved, defining the overall position and presenting it to the ECHA and the EU Commission. The responsibilities of the BfC include the following: ▪ Information centre for REACH, CLP and biocides (REACH-CLP-Biozid Helpdesk), ▪ Evaluation of chemicals and risk management under the terms of REACH, ▪ Evaluation of biocidal active substances and authorisation of biocidal products, ▪ Notification of biocidal products in accordance with the Biocidal Products Notification Ordinance, ▪ Implementation of special procedures relating to CFCs, PIC (Prior Informed Consent) and POPs (Persistent Organic Pollutants), ▪ Implementation of the EU Regulation on Classification, Labelling and Packaging (GHS, *Globally Harmonized System of Classification and Labelling of Chemicals* - CLP, *Classification, Labelling and Packaging*), ▪ Exchange of information with the Commission of European Communities, the European Chemicals Agency (ECHA) and with the competent authorities in other Member States, ▪ Coordination of other Federal Authorities involved in the procedures, and exchange of information with the law enforcement authorities. • The **Federal Institute for Risk Assessment** ('The Bundesinstitut für Risikobewertung' - BfR) assesses risks from many areas of daily life. This includes the large spectrum of chemicals as well as foods of plant or animal origin, cosmetics and toys. The BfR is the authority responsible for consumer protection in Germany, and occupational safety is in the remit of BAuA. The Chemicals and Product Safety Department of the BfR assesses chemical

	substances that fall under the European chemical law (REACH Regulation). The objective is to ensure toxicological assessment, health risk assessment for consumers and the identification and initiation of necessary risk mitigation measures in accordance with the REACH Regulation. Assessments are also carried out with the aim of classifying and labelling of substances in accordance with the CLP Regulation. In addition, the department is involved in the assessment of health risks that might be associated to cosmetic products, tobacco products, commodities (food contact materials, toys, baby bottles, teats, cleaning agents, garments, etc) as well as other consumer products (furniture, mattresses, carpets, DIY products, etc.). It takes in account not only the existing knowledge gaps of science-based risk assessment but also the concerns of the general public in this field. Experimental projects on migration and exposure as well as the toxicity of chemicals present in these articles of daily use are an integral part of these assessment activities. The remit of the department also includes the coordination and overall evaluation of risk assessments, the identification of data gaps and research needs for risk assessment and the initiation and supervision of internal and external research projects to support risk assessments. The department's employees represent the BfR on national and international bodies, such as the OECD, the WHO/IPCS, the European Food Safety Authority (EFSA), the European Chemicals Agency (ECHA), the EU Scientific Committee on Consumer Safety (SCCS), the Committee of Experts on Cosmetic Products of the Council of Europe, and the BfR Committees for Consumer Products and Cosmetics as well as various working groups such as the ALS (Working Group of Experts in Food Chemistry from the German "Bundesländer") and national and international standardisation committees. • The **Federal Office of Consumer Protection and Food Safety** ('Bundesamt für Verbraucherschutz und Lebensmittelsicherheit' - BVL). In the area of health related consumer protection the BVL aims to improve the coordination between the Federal Government and the Federal States (Bundesländer), to make the communication of risks more transparent and to manage risks before they turn into crises. The BVL has a multifaceted role in the cooperation between the federal government and the federal states. An important aim is to achieve uniform standards of control, analysis and surveillance programmes as well as to record data in a uniform way and to generate valuable data for Germany. For this purpose, there are numerous working groups and committees that discuss specialist topics and problems between the federal government and the federal states. The challenging objective of the BVL is to replace reaction with prevention. As the body responsible for the rapid alert system, the coordination of nationwide food monitoring and the approval of plant protection products, veterinary drugs and genetically modified organisms, the BVL meets all the requirements for utilising, expanding and recreating synergies when employing preventative measures. With regards to plant protection products in Germany, the Plant Protection Act, which implements several European laws and ordinances into German legislation, specifies the BVL as Competent Authority and thus responsible for authorising plant protection products in Germany. In this process, the BVL is responsible for risk management, i.e. for authorisation decisions and administrative measures to protect both humans and the environment. Furthermore, the BVL acts as the national coordination point in the European cooperation to evaluate active substances in plant protection products and to determine maximum residue levels. It lists plant resistance improvers and adjuvants which are permitted in Germany.

9. Involvement of stakeholders	The BMUB is committed to improve chemical safety and thus the protection of health and the environment at both national and international level. For this purpose it leads a constructive dialogue with industry and environmental associations and communicates with the enforcement authorities of the Bundesländer. With regards to the implementation of the REACH framework, corresponding policies and legislation have been developed without stakeholder involvement. Germany's implementation strategy however was presented on several occasions to different audiences in order to explain how SVHC are identified and managed by the German authorities under REACH. According to the UBA website; REACH stakeholders have the following obligations: • Manufacturers and importers must assume responsibility and ensure high quality of the information in their registration dossiers. They must carry out appropriate risk assessment; that is, according to state of the art and by taking into account the precautionary principle. • Manufacturers, importers, and merchants must fulfil their duty to provide information on SVHC in articles – both along the supply chain and to users. • All stakeholders in the value added chain ensure safety in the use of chemicals, mixtures and articles through implementation of recommended risk reduction measures. • All stakeholders in the value added chain aim for sustainability in chemicals use, e.g., by taking the initiative to either minimise or not use critical substances at all.
10. Relation with European policies / international agreements	Germany's policies for dangerous chemicals have been developed in the framework of the REACH SVHC Roadmap to 2020. It is possible that some aspects of the policies may differ a bit from the EU guidelines (e.g. more or less stringent). For example: in the field of occupational safety and health where the EU legislation only sets minimum requirements, national policy is in some cases more stringent. The same might apply in the field of environmental legislation.
11. Monitoring of substances and evaluations of effects	• In Germany there a different monitoring programmes for dangerous chemicals on different levels. In some cases, the government makes an agreement with a company to perform monitoring tasks for them. • On the national level, the UBA is responsible for the environmental monitoring of SVHC and/or other dangerous chemicals. Monitoring takes place continuously, as well as on incident-based. • SVHCs from the REACH Candidate List are prioritised for monitoring on a case-by-case basis, so only if it is decided that monitoring of this substance is relevant. They are not per se monitored because they are on the REACH Candidate List. However naturally, substances that are listed on the REACH Candidate List get more attention, as it can be assumed that the specific substance has been selected for SVHC identification for a reason. • On the state level, it is the Bundesländer's responsibility to implement a system for monitoring of emissions and enforcement. Companies furthermore have a responsibility to monitor their own emissions. • The common hazardous substance database of the authorities of all federal states ('Gefahrstoffdatenbank der Länder' - GDL) is responsible for the state monitoring of the hazardous substances legislation in the area of occupational health and safety.

12. Incidents with relevance to these policies?	Industrial accidents involving dangerous chemicals are documented by the Accident Reporting and Assessment Unit ('ZEMA') of the UBA. Incidents are mostly handled at the level of the Bundesländer. At the Federal Government level there is no indication that such incidents have resulted in changes of policies or development of new policies.
13. Relation with emission control	The Federal Immission Control Act ensures that substances of concern are directly linked to (local) emission control. The Immission Control Act lists the requirements for emissions of dangerous substances to air, water and soil. The German Bundesländer each have a permit system in place that implements this Federal Law. Depending on the plant and the substance emitted an environmental permit is required. Emission limitations are included in the environmental permits. In some cases environmental permits are not required. It is then the responsibility of the company to reduce and minimize exposure.
14. Relation with inspection and enforcement	• It is the German Bundesländer's responsibility to implement a system for enforcement of national legislation, which includes a permit system, appointment of local authorities, monitoring and inspection procedures. • The BfC informs the enforcement authorities of the Bundesländer in case a company is non-compliant with the REACH/CLP Regulation.
15. Relation with circular economy (re-use and recycle) and substitution	• The relationship between dangerous chemicals and the circular economy is currently a topic of national discussion at the ministry level in Germany. • Germany has implemented a Federal Law, the Closed Cycle Management Act ('Kreislaufwirtschaftsgesetz' - KrWG), that promotes the recycling of natural resources and ensures the protection of man and the environment in the production and management of waste and, in particular, material recycling and substance recovery. The Closed Cycle Management Act transposes the EU Waste Directive 2008/98/EU into German Law. • German national authorities work together with Competent Authorities at the level of the Bundesländer to promote innovation and substitution. For the Federal government it is sometimes unclear, which initiatives are in place at lower government levels. There are many different programs and activities in Germany to promote innovation and substitution of hazardous chemicals. The UBA is an important institution with regards to the promotion of substitution of dangerous chemicals. The UBA focusses both on substitution of specific substances (e.g. discussion with fire brigades on alternatives for PFCs and participation in research projects on alternatives for outdoor textiles), but also on more general (international) programmes/initiatives, such as the International Sustainable Chemistry Collaboration Centre (ISC_3) and the Substitution Support Portal "SUBSPORT". The **International Sustainable Chemistry Collaboration Centre (ISC_3)** The ISC_3 is an initiative set-up in March 2013 by the UBA and the BMUB. The German project team is completed with: 1. *N^3 Thinking Ahead* (think tank with long-term experience in resource management) 2. *DECHEMA Society for Chemical Engineering and Biotechnology* (scientific society with more than 5900 members, active in all fields of chemical engineering, environmental technologies and biotechnology), and

	3. *The BZL Kommunikation und Projektsteuerung GmbH* (consulting company that supports public-sector customers and companies als well as non-governmental organizations or foundations in issues related to waste management, climate change, chemicals, resource efficiency and sustainability). The ISC_3, which includes a network of worldwide experts, aims to support a global breakthrough in *Sustainable Chemistry*. The main tasks of the ISC_3 are still under discussion (e.g. ISC_3 and its network should become available early 2017), however the following tasks have been proposed by the project team to the Advisory council, which consist of a large number of international chemical experts: ▪ Monitoring of the discussion on how to define and interpret the term "Sustainable Chemistry" ▪ Development of "quality criteria" for processes, materials and resource demand in order to assess different Sustainable Chemistry approaches ▪ Review of main interfaces to resource and health protection as well as product and plant safety ▪ Analysis and dissemination of business models which promise economic success on the basis of Sustainable Chemistry ▪ Positioning of Sustainable Chemistry as a key element of the global agenda for the 21st century ▪ Support for emerging and developing countries in the safe handling of chemicals and disposal of waste from hazardous substances produced or used earlier ▪ Guidance for emerging and developing countries in the implementation of international regulations in the field of Sustainable Chemistry ▪ Exchange of good practice (e.g. advanced synthesis strategies, sustainable material flow management, product design) at global level ▪ Advancement of good professional standards in the manufacture, processing and use of chemicals as well as their utilization and disposal ▪ Dissemination of the current state of knowledge on Sustainable Chemistry at all levels of the educational system The ISC_3 will deploy a wide variety of instruments which will be planned in detail once the centre's tasks have been defined. A key instrument will be an "International Sustainable Chemistry Network", which will be launched by the ISC_3. This will form a platform for a worldwide exchange of information, ideas and projects on this topic. **Substitution Support Portal "SUBSPORT"** The SUBSPORT information portal is intended to constitute a state-of-the-art resource on safer alternatives to the use of hazardous chemicals. It is a source of not just information on alternative substances and technologies, but also of tools and guidance for alternatives assessment and substitution management. The SUBSPORT web portal aims to be the first entry point for anyone interested in substituting hazardous chemicals, to support companies in fulfilling substitution requirements within EU legislation (e.g. REACH, WFD, Chemical Agents Directive), as well as being a resource for other stakeholders such as authorities, environmental and consumer organisations, and scientific institutions. SUBSPORT is currently extended with information specific to the textile industry: SUBSPORT Textile. The SUBSPORT team maintains a network of experts and stakeholders who are active in substitution. The network assists in content development and promotion of the portal as well as ensuring sustainable updates and maintenance. The SUBSPORT portal team consists of: ▪ Kooperationsstelle Hamburg IFE GmbH (Germany, project coordinator)

- ChemSec (Sweden)
- Grontmij (Denmark)
- ISTAS (Spain)

The SUBSPORT portal received financial support from the German Federal Institute for Occupational Safety and Health (BAuA).

iPhone App ToxFox to inform consumers on EDCs in cosmetics

An interesting, consumer-orientated tool that is promoted on the SUBSPORT portal is the German-designed tool to detect Endocrine Disrupting Chemicals (EDCs) in cosmetics: "ToxFox".

The German Bund für Umwelt und Naturschutz Deutschland (BUND) launched an App for consumers to check if their cosmetics contain EDCs, on 24 July 2013. BUND is a German non-governmental organisation (NGO) dedicated to preserving nature and protecting the environment. BUND is a member organisation of the international network Friends of the Earth (FoE).

EDC's can be found in every cosmetic product category such as shower gel, sunscreen, lipstick, shaving foam, hair tinting lotion or deodorant. Because it is complicated for consumers to identify dangerous substances in the long ingredient lists, BUND provides the free iPhone App ToxFox.

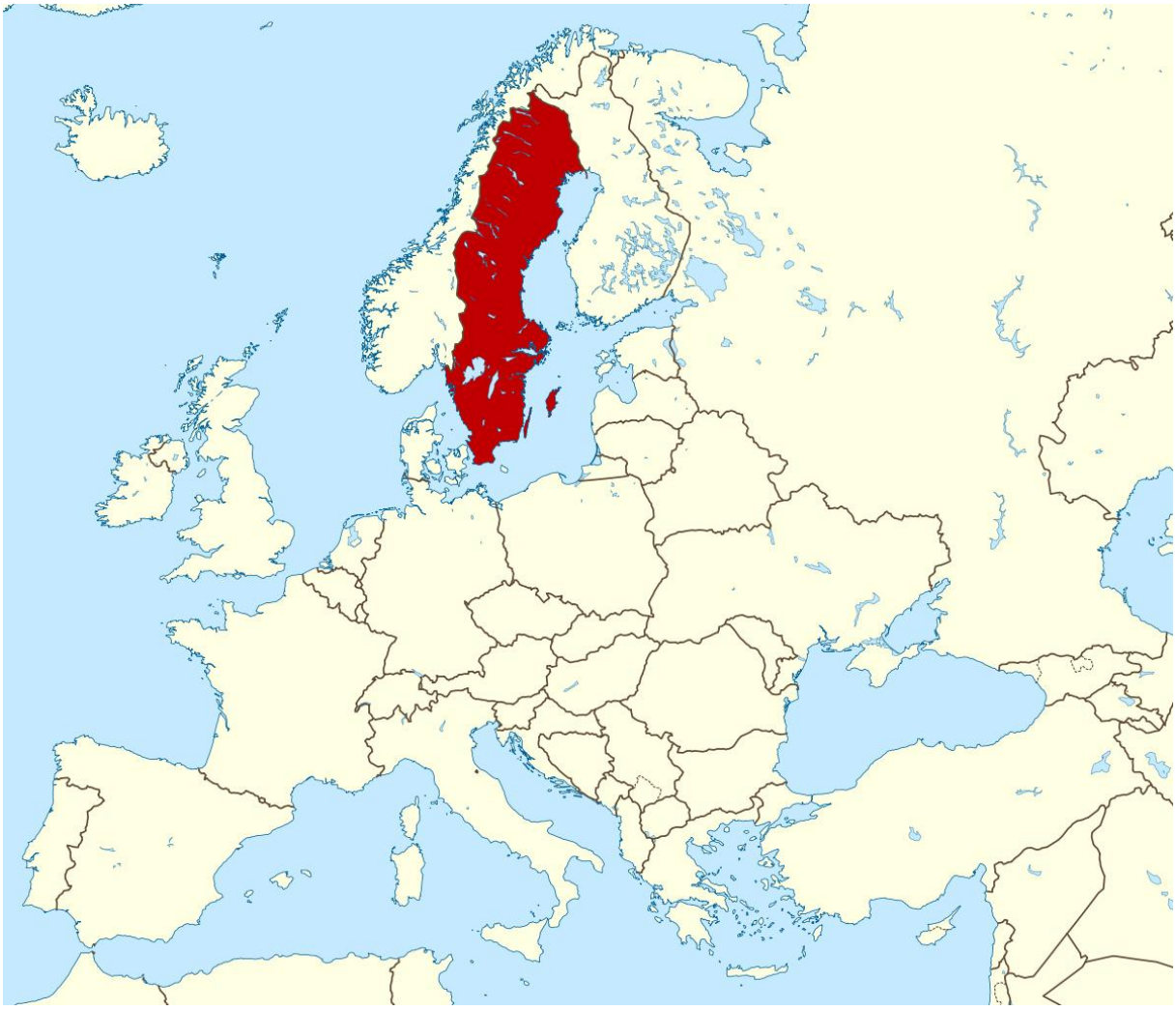
ToxFox enables consumers to scan the barcode of the products right away in the store and get immediate information if the cosmetic contains endocrine disruptors. The system identifies products through their barcode, which can be different from country to country and might not work properly outside Germany, Austria or Switzerland. The service is only available in German. Those without an iPhone or Smart phone can use the tool via BUND's website.

The OECD Substitution and Alternatives Assessment Toolbox (SAAT)

The OECD Ad Hoc Group on Substitution of Harmful Chemicals was established in 2012, with the goal of furthering tools and approaches to support decision making for the substitution of chemicals of concern. The Ad Hoc Group is co-chaired by the U.S. Environmental Protection Agency and the European Chemicals Agency. Its members include a broad range of stakeholders (government agencies, industry, trade associations, NGOs, and others) across OECD member countries. For Germany, the UBA participates as member.

The Work Plan for the Ad Hoc Group calls for a comprehensive review of the current status of substitution and alternatives assessment practices, as well as the development of an online toolbox to support decision-making. The OECD Meta-Review, published in November 2013, captures the number and diversity of alternatives assessment frameworks, tools, and methods; the key drives and audiences of alternatives assessments; and gaps and opportunities to advance the field. The knowledge gained through the meta-review process was the foundation for the development of this OECD Substitution and Alternatives Assessment Toolbox.

Annex 5: Sweden



1. Organisations contacted	Swedish Chemicals Agency (KEMI) Contact: Jan Hammar – Policy Advisor T. +46 8 519 41 198 E. jan.hammar@kemi.se
2. Relevant literature and websites	**Literature:** • KEMI (2010), 'The Products Register', factsheet, September 2010 • KEMI (2011), 'Action plan for a toxic-free everyday environment 2011-2014. English summary of a government assignment', Stockholm, March 2011 • KEMI (2011), 'Handlingsplan för en giftfri vardag 2011-2014', English summary • KEMI (2014), 'Handlingsplan för en giftfri vardag 2015-2020', English summary • KEMI (2014), 'Rules on chemicals in the life-cycle of article – a legal analysis', Report 3/14, ISSN 0284-1185, Article number: 361 121, Stockholm 2014 • KEMI (2015), 'Developing REACH and improving its efficiency – an action plan', Report 2/15, ISSN 0284-1185, Article number: 361 142, Stockholm, 2015 • KEMI (2016), 'The Swedish Chemicals Agency's Analyses in Conjunction with Enforcement 2014-2015', ISSN 1654-2355, Article number: 511 215, Stockholm, 2016 • Ministry of the Environment (2013), 'The Swedish environmental objectives system', information sheet, Article number: M2013.01, Stockholm, January 2013 • Chemical Watch (2014), 'Sweden and Denmark's influence on EU policy', Global Business Briefing, September 2014 • The Swedish Research Council for Environment, Agricultural Sciences and Spatial Planning (2015), 'An analysis of Swedish research and the ability to achieve the Swedish Environmental quality objective A non-toxic environment, Stockholm, October 2015 • Swedish Environmental Protection Agency (2016), 'Sweden's Environmental Objectives – An Introduction, ISBN 978-91-620-8743-2, 2016 • Wemos, WECF and PAN staff (2016), 'Measures against endocrine disrupting chemicals. The example of Denmark, Sweden and France', Doc: EDC2016, June 2016 **Websites:** • Swedish Government Offices: http://www.government.se/ • Swedish Chemicals Agency (KEMI): http://www.kemi.se/en • National Food Agency: http://www.livsmedelsverket.se/en/ • Swedish Environmental Protection Agency (SEPA): http://www.swedishepa.se/ • Swedish Work Environment Authority: https://www.av.se/en/ • United Nations: http://www.un.org/esa/dsd/dsd_aofw_ni/ni_pdfs/NationalReports/sweden/Chemicals.pdf • The Environmental Objectives Portal: http://www.miljomal.se/sv/Environmental-Objectives-Portal/ • National information service coordinated by the Swedish Consumer Agency: http://www.hallakonsument.se/
3. General introduction	Sweden has three levels of government: national, regional and local. In addition, there is the European level which has acquired increasing importance following Sweden's entry into the EU. At the national level, the Swedish people are represented by the Riksdag (Swedish parliament) which has legislative powers. Sweden is divided into 21 counties (or regions) and 290 municipalities. The division of tasks between central government and municipalities has changed over

	the years. Activities have chiefly been transferred from central government to municipal bodies, inter alia for democratic reasons. In municipalities it is easier to maintain continuous contact between decision-makers and the private individual.
4. National drives	The thinking behind Sweden's environmental objectives is that environmental problems should be tackled now, and not pass on to future generations. The overall aim of Swedish environmental policy is to hand over, by 2020, a society in which the major environmental problems facing the country have been solved. This is summed up in a 'generational goal', which describes what is to be protected and what changes need to be made in society. The generational goal and the 16 environmental quality objectives have been adopted by the Riksdag (the Swedish Parliament), and are a promise to future generations of clean air, a healthy living environment, and rich opportunities to enjoy nature. The environmental quality objectives, moreover, are to be achieved without increasing the environmental and health problems of other countries. Sweden hopes to inspire other countries, through its ambitious environmental policy. Within the scope of this research, Swedish environmental objective 'A Non-Toxic Environment' deals with dangerous chemicals. The main driving force for Sweden in this regard is the protection of human reproduction and child health. It has been the starting point of everything from national enforcement and dialogue with Swedish companies to proposals of measures in the EU and internationally aimed at hazardous chemicals. The main drives for the development of new policies in this regard are scientific research (e.g. data on the occurrence of substances in different environmental compartments) and incidents with dangerous chemicals. Media attention and public awareness may also influence policies, however are considered less important for the development of new policies.
5. Policies and measures	The environmental objectives Sweden has adopted are of three different types. One is the generational goal, which defines the overall direction of environmental efforts. To facilitate those efforts, and to make the generational goal more tangible, there are also 16 environmental quality objectives and a number of milestone targets. **Generational goal** The generational goal is intended to guide environmental action at every level in society. It indicates the sorts of changes in society that need to occur within one generation to bring about a clean, healthy environment. It focuses environmental efforts on recovery of ecosystems, conserving biodiversity and the natural and cultural environment, good human health, efficient materials cycles free from dangerous substances, sustainable use of natural resources, efficient energy use, and patterns of consumption. "The overall goal of environmental policy is to hand over to the next generation a society in which the major environmental problems have been solved, without increasing environmental and health problems outside Sweden's borders." The generational goal means that the conditions for solving environmental problems are to be met within one generation and that environmental policy should be directed towards ensuring that: • ecosystems have recovered, or are on the way to recovery, and their long-term capacity to generate ecosystem services is assured; • biodiversity and the natural and cultural environment are preserved, promoted and used sustainably; • human health is exposed to minimal negative environmental impact, while the

positive impact of the environment on human health is promoted;
- ecocycles are resource-efficient and as far as possible free from hazardous substances;
- natural resources are managed well;
- the share of renewable energy increases and use of energy is efficient, with minimal impact on the environment; and
- patterns of consumption of goods and services cause the least possible problems for the environment and human health.

Environmental quality objectives
The environmental quality objectives describe the quality of the environment that Sweden wishes to achieve by 2020. There are 16 of them, covering different areas – from unpolluted air and lakes free from eutrophication and acidification, to functioning forest and farmland ecosystems. For each objective there are a number of 'specifications', making clear the state of the environment to be attained.

Milestone targets
Over the years, the Riksdag has adopted a number of additional and revised interim targets in priority areas. These targets are replaced on an ongoing basis with milestone targets, which define steps on the way to achieving the environmental quality objectives and the generational goal. Decisions on these milestone targets are taken by the Government.

'A Non-Toxic Environment'
One of the 16 environmental quality objectives is called 'A Non-Toxic Environment'. This objective deals with dangerous chemicals: "The occurrence of man-made or extracted substances in the environment must not represent a threat to human health or biological diversity. Concentrations of non-naturally occurring substances will be close to zero and their impacts on human health and on ecosystems will be negligible. Concentrations of naturally occurring substances will be close to background levels."

Strategy for a non-toxic environment
On 26 March 2014, the Riksdag adopted a strategy for how to achieve the environmental quality objective 'A Non-Toxic Environment', which is based on the bill 'Towards a toxin-free everyday environment – a platform for chemicals policy' (Govt Bill 2013/14:39). The bill considers working on groups of dangerous chemicals to accelerate their phase-out. A first group to be addressed are perfluorinated substances. Further, the policy document states that Sweden will push for more stringent information requirements for low production volume substances under REACH. A particular focus is placed on nanomaterials, endocrine disrupting chemicals (EDCs) and mixture effects. Sensitive subpopulations are also be considered. The strategy especially focusses on the protection of children and young people, as they are particularly susceptive to risks associated with toxins in the everyday environment. The text further specifies that consumer information on dangerous substances shall be improved in the future. To support these strategic aims, research, a national systematic environmental monitoring and the discussion of a chemicals tax shall be furthered, clarifies the strategic document.

The strategy and platform for chemicals policy consist of the eight interim targets on hazardous substances previously adopted by the Government, the measures necessary to achieve the interim targets and other measures needed to achieve the environmental quality objective 'A Non-toxic Environment' or the generational goal.

<u>EU focus</u>
The focus of the strategy is on applying and strengthening existing chemicals legislation in the EU with the aim of improving protection for human health and the environment. Application of the substitution principle should be strengthened and endocrine disruptors regulated. Groups of substances with similar properties, structures or areas of use should

	be evaluated and examined together. To begin this work the Swedish Government proposes that an action plan for the group consisting of perfluorinated substances be drawn up at EU level. New EU regulations must be developed, for example concerning regulating hazardous substances in textiles – an area which currently lacks such regulations. The pace of phasing out particularly hazardous substances must be increased and the risk of exposure to other hazardous substances reduced. The Swedish Government's proposals include drawing up a cadmium strategy at EU level and prioritising restriction proposals for mercury in dental amalgam. Information about hazardous substances in products must be improved to enable safe handling and informed choices by consumers. Sweden will work for more stringent information requirements for low volume substances in the REACH Regulation. Priority will be given to work to develop assessment criteria and test methods for nanomaterials, endocrine disruptors and combination effects of chemicals, as well as to work on test methods and assessment criteria that take account of children's special sensitivity. Policy instruments must be developed; for example, financial policy instruments in the form of a chemicals tax need to be considered. The risks involved with pharmaceuticals in the environment must be reduced. EU regulations on medicinal products for human or veterinary use should therefore be refined so that they take greater account of environmental aspects. To reduce emissions of both pharmaceutical residues and other chemicals into the environment, it is also important to develop and test new sewage treatment technologies. <u>Swedish prioritized product groups</u> In order to reduce human – and particularly children and young people's – exposure to hazardous substances in products, the Government of Sweden has highlighted certain product groups that should be prioritised: construction products and fixtures, electrical and electronic products, clothes and shoes, and toys and other products intended for children. Particular attention should be given to measures against exposure to hazardous substances via food and drinking water, as well as cosmetic products. **Action plan for a non-toxic everyday environment 2011-2014** Within the framework of a non-toxic environment the Swedish government in December 2010 assigned the Swedish Chemicals Agency (KEMI) with the task to develop and implement an action plan for a toxic-free everyday environment for the years 2011 – 2014. The Swedish Action Plan for a non-toxic everyday environment 2011-2014 is an important part of the strategy to achieve the environmental quality objective 'A Non-Toxic Environment'. Efforts focus on measures to protect children's and young people's health. About 35 million Swedish kronor are put into the action plan each year. The EU legislation, mainly REACH and CLP, forms the legislative ground for the action plan. Swedish classification criteria and the criteria for identifying SVHC are adopted from the REACH/CLP framework. The focus of the action plan is to protect foetuses and children. The Swedish group of prioritized substances "<u>särskilt farliga ämnen</u>" ("particularly dangerous substances") is basically the same as the SVHCs, but includes more substances for example strong sensitizers and also endocrine disrupting substances. The definition of a "Särskilt farliga ämne" is defined within the environmental goal "a non-toxic environment". The following measures were proposed by KEMI: • The Government allocates special funds for increased investment in research in the field of chemical health and environmental risks. The funding of research should also be of a more long-term nature and better coordinated. Research in the areas of endocrine disruptors, synergies between chemicals and health and environmental

	risks of nanomaterials are examples of areas of concern. Children and chemical hazards should be given special attention. • The Government instructs the Swedish Chemicals Agency, in consultation with the Environmental Protection Agency, the National Food Administration and the Medical Products Agency and other relevant central agencies, to undertake a broad review of EU legislation and identify a strategy for how the rules in a long-term perspective could be developed and enhanced to contribute to a non-toxic environment under the Swedish environmental objectives and to a non-toxic everyday environment. The assignment would include providing comprehensive proposals for how legislation at EU level can be changed and improved. • The Swedish Chemicals Agency prioritises work in the OECD and the EU to help establish, in various EU legislation, scientifically based criteria and guidance documents with a high level of protection for endocrine disruptors, interaction effects of chemicals and considerations on the health and environmental risks of nanomaterials. • The Swedish Chemicals Agency endeavours to further develop the methods of EU risk assessment in order to obtain reasonable assurance that we do not underestimate the risk that chemicals will harm children. • Sweden calls for European legislation to be strengthened so that increased demands are made on companies to develop knowledge about the health and environmental hazards of chemicals that people are exposed to in their everyday lives. • Sweden becomes one of the leading EU member states when it comes to pursuing proposals for bans on hazardous chemicals that people may be exposed to in their everyday lives. • Sweden calls for European legislation to be tightened up to further restrict the presence of hazardous chemicals in products used in such a way that consumers may be exposed to them. This particularly concerns the presence of chemicals that can cause cancer, genetic damage or harm to reproduction. It also applies to chemicals that cause allergy, which are suspected endocrine disruptors or which may accumulate in the environment. • The Swedish Chemicals Agency substantially increases the monitoring of hazardous chemicals in toys and other articles used in such a way that people may be exposed to hazardous substances in their everyday lives. • Sweden calls for tighter EU legislation and international agreements on widely available information on health and environmentally hazardous chemicals in articles. • The Government instructs the Swedish Board of Agriculture, in consultation with the Swedish Chemicals Agency to assess the impact of a national limit for cadmium in mineral fertilisers, based on the level identified as sustainable by the Swedish Chemicals Agency, and to promote a strict limit for cadmium in mineral fertilisers under EU legislation on fertilisers. • The Swedish Chemicals Agency promotes and supports companies in the process of doing more to replace hazardous substances in chemical products and articles. • The Swedish Chemicals Agency analyses how economic instruments can be used to bring about substitution of hazardous substances or otherwise reduce health and environmental risks. • The Swedish Chemicals Agency contributes more, in cooperation with the Swedish Consumer Agency and other agencies, to increasing aware-ness of chemical hazards among purchasers and consumers and thus to their ability to make informed environmental choices. **Extension of the action plan** The action plan initiative is being extended until 2020. The focus on safeguarding the reproduction of human beings and child health has remain. In the new mandate, the Government has placed greater focus on developing national bans when EU legislation is insufficient (e.g. for Bisphenol , Triclosan and microplastics). Measures at global level remain a high priority and strategic national measures are an important complement to

	the work at EU level. The prolonged action plan for the period 2015–2020 has been an opportunity for the Swedish government to increase the number of measures to be taken at national level as part of the action plan. ▪ *Reduce the risks of hazardous chemical substances* The government asked KEMI to investigate the possibility of accomplishing other national measures regarding hazardous chemical substances. The assignment also includes an evaluation of whether national legislation is required for areas where no harmonisation exists and where EU legislation has been proven to provide insufficient protection. KEMI will, for instance, investigate whether more measures are required to reduce the risks connected with bisphenol, triclosan and microplastics. ▪ *Action plan for highly fluorinated substances* Highly fluorinated substances are extremely persistent in the environment, and some of these are bio-accumulative and toxic. The pollutants already found in the soil will continue to leach into lakes and the groundwater for many decades to come. Carrying out forceful measures in this area will require broad cooperation with other authorities, researchers, industry and different interest organisations. KEMI therefore initiated a national action programme regarding highly fluorinated substances. In 2016, KEMI presented proposals for national and EU regulation to reduce the risks associated with highly fluorinated substances. Fire-fighting products were given particular priority. The government recognizes that other national action programmes may be required at a later stage. The action plan for a non-toxic everyday environment stipulates that there is a specific need for national action on: - highly fluorinated substances - endocrine disruptors - allergens Increasing numbers of scientific studies are suggesting that endocrine disrupters in the environment may affect the ability to have children. Foetuses and young children are particularly susceptible to disruption because of the rapid development of various organ systems. There have also been reports in epidemiological studies of statistical correlations between exposure to endocrine disrupters and some of the most widespread diseases, such as diabetes. However, there is scientific uncertainty as to whether the substances contribute to the development of these diseases, and if so to what extent. Allergy is the most widespread disease in the western world. Asthma and allergy often begin early in life and can cause life-long disability. Pollen, furred animals, mites, foodstuffs and many chemicals are examples of allergens. It is common for consumers to be affected by allergic symptoms caused by allergenic substances in chemical products and in articles such as clothing. ▪ *Network of municipalities and requirements regarding procurement of chemicals.* Several municipalities are working actively in the area of a non-toxic everyday environment, particularly in pre-schools. KEMI initiated a network for municipalities to further stimulate and support their work. The combination of the large number of chemical substances used in the production of articles and then used in the articles once they are produced makes it impossible to establish legislation that is capable of regulating all chemical substances in detail. The requirements regarding the procurement of chemicals could form an important complement to legislation. Within the network and in other ways KEMI seeks to ensure that the guidance provided by the Swedish Competition Authority on environmental procurement for pre-schools is made known to and used by county councils and municipalities.

	▪ *Increase pupils' knowledge of sustainable consumption* KEMI considers it important that the action plan for a Non-Toxic Environment (during the period 2015-2020) contributes to an increase in the knowledge of pre-school and school pupils in the area of sustainable development. The 'Keep Sweden Tidy Foundation' has been working for many years within a large network including pre-schools and schools. In cooperation with the Foundation, KEMI will be pressing for A Non-Toxic Environment to be included in the Grön Flagg (Green Flag) system and to become an integral part of the pedagogical work of schools and pre-schools. ▪ *Continued enforcement of banned substances in articles* KEMI's enforcement of the legislation on banned substances in articles has led to many items being withdrawn from the market. The articles published in the local media as well as other forms of information provision have a knock-on effect, meaning that those companies not yet subject to inspection ensure that they comply with the legislation. Enforcement continues to be an important area under the action plan. *The strategy and action plan are both developed within the framework of EU legislation. Sweden however also implemented some rules that are not based on EU harmonised regulations or directives, but are specifically Swedish rules. Examples of such rules are:* • **Rules on reporting to the Products Register** Manufacturing notifiable chemical products in Sweden or import or transfer of these into Sweden, must be reported to the Swedish Chemicals Agency by submitting an activity report. This must be done as soon as possible and no later than when the activity is initiated, regardless of how much of a notifiable product the company manufactures. Notifiable chemical products are those products whose customs tariff numbers are on the list of customs numbers in Annex 1 to the Chemical Products and Biotechnical Organisms Ordinance. Companies must once a year report the quantity for the previous year, de-notify/re-notify products and report changes in product information and chemical composition. All companies that have submitted an activity report are registered in the Swedish Company Register. The Company Register furthermore provides information on companies that have a permit to act as commercial agents and companies that have registered products to the Products Register. A product report must be submitted if the annual volume of each notifiable product is at least 100 kg. A product report relates to each specific chemical product, unlike an activity report. A product report can also be made by a commercial agent, instead of the company with a notification obligation. If so, KEMI must give consent for this to be done. An annual chemical charge must be paid by companies which are responsible for product notification if the aggregate volume of all the company's notifiable products is at least 1,000 kg. This charge consists of two parts: a Register charge and a chemical charge based on quantity. This charge shall be paid in arrears and is based on the annual accounting report of numbers of products and quantities. The chemical charge is coordinated with the pesticide charge. If a company has an authorisation for a pesticide and pays an annual charge for that, it does not have to pay a chemical charge. For commercial agents with a permit who are reporting products on behalf of another party, they must pay the chemical charge to the Products Register. • **Permit requirement for sale and private use of very hazardous chemical products** A permit is required for the sale and private use of very hazardous chemical products. The applicable rules are: Chemical Products and Biotechnical Organisms Ordinance and The Swedish Chemical Agency's Chemical Products and Biotechnical

	Organisms Regulations. • **Certain Swedish restrictions and bans** The Chemical Products (Handling, Import and Export Prohibitions) Ordinance contains particular provisions on bans and other restrictions when handling: - two-part epoxy containing bisphenol A or bisphenol A diglycidyl ether - cadmium in fertilisers - chlorinated solvents (methylene chloride, trichloroethylene or tetrachloroethylene) - mercury and articles containing mercury - ammunition containing lead - detergents containing phosphate - certain other products and articles hazardous to health and the environment, such as dry cleaning products and car care products containing methanol. • **Swedish transitional rules on biocides** The EU Biocidal Products Regulation applies since 1 September 2013 and regulates the making available on the market and use of biocidal products. Many active substances occurring in biocidal products are currently evaluated within the EU Review Programme. As long as the review evaluation is going on, Swedish, national rules apply. Applicable Swedish rules to apply during the transitional period are contained in: - Chapter 14 of the Environmental Code - Chapters 3 and 4 of the Pesticides Ordinance - The Swedish Chemical Agency's Pesticides Regulations • **Rules on biocidal products consisting of nematodes, insects and arachnids** Biological pesticides must be authorised by the Swedish Chemicals Agency before they can be sold or used. Specific Swedish rules apply in the case of biological pesticides consisting of nematodes, insects or arachnids. The applicable rules are contained in: - The Biocidal Products Containing Nematodes, Insects or Arachnids Ordinance - The Swedish Chemical Agency's Pesticides Regulations • **Rules on plant protection products consisting of nematodes, insects and arachnids** Biological pesticides must be authorised by the Swedish Chemicals Agency before they can be sold or used. Specific Swedish rules apply in the case of biological pesticides consisting of nematodes, insects or arachnids. The applicable rules are contained in: - The Plant Protection Products Containing Nematodes, Insects or Arachnids Ordinance - The Swedish Chemical Agency's Pesticides Regulations • **National pesticide fees** Fees for applying for the authorisation of a pesticide and annual charges based on the sales value are regulated at national level. The provisions regarding application fees and annual charges for pesticides are contained in the Pesticide Fees Ordinance. The fees apply to the evaluation of active substances in plant protection products and biocidal products, product authorisation, exemption and change of conditions. Annual charges are based on the value of the sales of pesticides during the previous year. *Within the scope of this research, the following relevant (chemical) substance databases are characteristic for Sweden:* • **Products Register** The Swedish Chemicals Agency uses the Products Register to store information on chemical products and biotechnical organisms that are manufactured in or

	transferred or imported into Sweden and information on the ways in which these are being used. Examples of such information are the product's area of use, its function, composition, volumes, and health and environmental classification. Anyone manufacturing or importing products that have to be reported must provide this information to the Agency. • **The SPIN Database** SPIN (Substances in Preparations in the Nordic countries) is database that contains "non-confidential" information on substances from the Product Registers of Sweden, Norway, Finland and Denmark. SPIN also contains data on the amounts of substances and the products and sectors in which the substances are used. • **Restricted Substances Database** The restricted substances database is a tool for finding out about legislation related to individual substances. The database contains information on whether the restrictions placed on a substance or group of substances are in compliance with the provisions set out in Swedish Government regulations or are in compliance with those set out in the Swedish Chemicals Agency regulations. The information contained in the database is limited to the specific provisions that apply to individual chemical substances or groups of substances. Note that there are further restrictions on the use of chemical substances in addition to the ones contained in the Restricted Substances Database, such as the obligation to obtain permits for toxic or highly corrosive substances. Other government agencies such as the Swedish Work Environment Authority or the Swedish Environmental Protection Agency also have regulations that restrict the use of chemical substances. These are not included in the database. • **PRIO** PRIO is a web-based tool to assist companies in work on risk reduction. It was launched by KEMI in 2004 to improve knowledge of chemicals and how they should be handled. PRIO can be used to search for substances and obtain information about environmental and health hazards, obtain information about those chemicals that must be prioritised for early phase-out, find substances contained in substance groups and various product groups and obtain assistance in developing routines for purchasing, product development and risk management. PRIO can also be used for guidance in risk reduction work and as a database in which to search directly. • **Nano Register** In 2013, the Swedish authorities had already advocated the creation of a Nano register in its "National Action Plan for the safe use and handling of Nanomaterials". In 2015, KEMI was entrusted with the task of designing of a national nanomaterial register in Sweden. Upon the request of the Swedish Ministry of the Environment KEMI drafted a regulation for companies to provide information on nanomaterials in chemical products to the Swedish products register, by 28 February 2019. Nano materials will be registered as a specific category under the Products Register. The first registrations, under KEMI's proposed scheme, would concern manufactured and imported quantities during 2018.
6. Substances covered	• **Products Register** It provides particulars about product type, industrial category, classification, composition and quantity of chemical products and biotechnical organisms imported to or manufactured in Sweden. About 2,200 companies are obliged to provide information to the Products Register. During 2014 these companies reported a total of about 91,000 products. The Register contains information on more than 200,000 chemical products (substances or preparations) and biotechnical organisms.

	• **Restricted Substances Database** KEMI's Restricted Substances Database contains substances that are restricted under Swedish legislation. A small number of substances are completely banned. Many substances are merely regulated in a particular application. There are references here to rules that apply to: - Those substances or substance groups that are restricted by rules within the area of activity of the Swedish Chemicals Agency and are named in statutes in the Swedish Chemicals Agency's statute book. - Those substances that have been allocated the comment "ε" and are assessed as being carcinogenic, mutagenic or toxic to reproduction (CMR substances) in the Swedish Chemical Agency Regulations on the Classification and Labelling of Chemical Products (KIFS 2005:5). These substances must not be used in chemical products that are released onto the market to be sold to the public. - Substances that must not be used or have restricted use in plant-protection or biocidal products in accordance with Annexes 4, 5 and 7, KIFS 2008:3. • **PRIO** PRIO database contains both substances that are regulated and those that are not covered by any legislation. The database contains around 4400 substances, all of which have properties that fulfil certain selection criteria. The criteria are drawn up on the basis of the national environmental objective 'A Non-Toxic Environment' (which resembles the REACH Candidate List criteria) and upon the criteria for the Classification & Labelling inventory (CLP). • **Nano register** The Nano register is not yet operational, however the Swedish Government defined Nano materials in accordance with the recommended definition of the European Commission: "*A natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm. In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %. By derogation from the above, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials."*
7. Legal / formal bases	• The Swedish **Environmental Code**, with its subordinate rules (ordinances and agency regulations), is the primary legislation responsible for implementation of the EU rules (e.g. REACH/CLP) at national level. The Environmental Code is a 'framework law' that covers a wide focus area. The Environmental Code constitutes a modernised, broadened and more stringent environmental legislation aimed at promoting sustainable development. It came into force on 1 January 1999. It replaced fifteen previous environmental acts which were amalgamated into the Code. With regards to the tasks and responsibilities of KEMI, Chapter 13 on Genetic Engineering and Chapter 14 on Chemical Products and Biotechnical Organisms in particular apply. Furthermore, three basic regulations apply to KEMI (published in Code of Statutes of the Swedish Chemicals Agency – KIFS): - KIFS 2005:7 – Classification and Labelling Regulations - KIFS 2008:2 – Chemical Products and Biotechnical Organisms Regulations - KIFS 2008:3 – Pesticides Regulations • The '**strategy for a non-toxic environment**' is based on the bill 'Towards a toxin-free everyday environment – a platform for chemicals policy' (Govt Bill 2013/14:39). The Action Plan for a non-toxic everyday environment is an important part of the strategy

	to achieve the environmental quality objective 'A Non-toxic Environment. • The Environmental Code provides for the legal basis of the **Swedish Products Register**. Pursuant to Chapter 14, Paragraph 12, of the Environmental Code, chemical products which are manufactured in or imported into Sweden in the course of business must be entered in a register ('the Swedish product register') held by the competent national authority. Chapter 14, Paragraph 2(1), of the Environmental Code defines a chemical product as a chemical substance or a preparation of chemical substances which is not a commodity. • **PRIO** PRIO is not based on legislation but is concerned with the intrinsic health properties and environmental properties of substances. In PRIO, the prioritisation of chemical substances for risk reduction measures, follows the recommendations based on the environmental quality objective "A non-toxic environment" - a work towards a sustainable development adopted by the Swedish parliament, and are in line with the objectives in the EU chemicals legislation, Reach. Throughout PRIO, reference is made to Swedish legislation and other Swedish regulations. • **Restricted Substances Database** The database contains the following regulatory instruments: - REACH Regulation - The Chemical Products (Handling, Import, and Export Prohibitions) Ordinance (1998:944) - Council Directive 96/59/EC on the disposal of polychlorinated biphenyls and polychlorinated terphenyls (PCB/PCT). - Ordinance (2007: 19) On Pcbs, Etc. - The Swedish Chemicals Agency's Chemical Products and Biotechnical Organisms Regulations (KIFS 2008:2) - The Swedish Chemicals Agency's Pesticides Regulations (KIFS 2008:3) - Regulation (EC) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals - Regulation (EC) No 782/2003 of the European Parliament and of the Council of 14 April 2003 on the prohibition of organotin compounds on ships - Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC - Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC - Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys - Förordning (2012:861) om ämnen i elekrisk och elektronisk utrustning Directive 2011/65 - (RoHS 2) - Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents • **Nano register** In January 2015 KEMI was commissioned by the government to investigate a way of formulating a reporting requirement to provide information on nanomaterials in chemical products and articles to the Swedish Products Register. KEMI drafted a regulation for companies to provide information on nanomaterials in chemical products to the Swedish products register, by 28 February 2019. Nano materials will be registered as a specific category under the Products Register. The first registrations, under KEMI's proposed scheme, would concern manufactured and imported quantities during 2018.

8. Organisational basis	**Generational goal and quality objectives in general** In order to achieve the environmental quality objectives set out in the Swedish generational goal, the Swedish government calls out all members of society (e.g. government agencies, non-governmental and other organisations, companies, county administrative boards, municipalities, individuals, the Government and the Riksdag) to get involved and assume a share of responsibility: • Sweden's Parliament (the Riksdag), the supreme political decision-making body in the country, has adopted environmental quality objectives and interim targets for sustainable development. • The Swedish Government bears overall responsibility for the environmental quality objectives. • An All Party Committee on Environmental Objectives has been set up to secure broad political consensus on environmental issues. • The Environmental Objectives Council is a platform for the heads of government agencies that are strategically important to achieving the environmental objectives. • The Swedish Environmental Protection Agency (Swedish EPA) coordinates follow-up, provision of information and the use of economic impact assessments within the environmental objectives system. • Eight national (government) agencies have been assigned one or more of the environmental quality objectives, which it is their job to follow up and evaluate. Other agencies work within their respective sectors to promote progress towards the objectives. • In their capacity as regional environmental agencies, the county administrative boards play an overarching, coordinating part in work to achieve the environmental objectives. • The Swedish municipalities play an essential role in the work of achieving the environmental objectives. By translating national and regional objectives into local aims and actions, they can make the objectives effective tools in local politics. • The business sector, in cooperation with other stakeholders, has a substantial role in achieving the environmental quality objectives. Today, many companies are engaged in structured environmental work that has a major bearing on the environment. • The environmental organisations are continuously engaged in a range of issues that are directly linked to the various environmental objectives. **A Non-Toxic Environment** The responsibility for hazardous chemicals (SVHC as well as other substances) is mainly placed on the Swedish Chemicals Agency (KEMI), with some exemptions. The 'Instructions for the Swedish Chemicals Agency Ordinance (2009:947)' provides guidelines for KEMI. The enforcement of hazardous chemicals is divided between different agencies, depending on the use area of the product. • **Swedish Chemicals Agency (KEMI)** KEMI is a supervisory authority under the Ministry of the Environment and Energy, and is responsible for ensuring that companies and society at large conduct controls of chemicals in an acceptable manner. In general, its KEMI's task to improve and strengthen health and environmental legislation concerning chemicals. KEMI checks that the industry complies with applicable rules and handles applications for approval of pesticides before they can be used. KEMI has initiated a national network with regional and local authorities in order to stimulate actions to reduce childhood exposure in areas such as construction and building, public procurement and information to Swedish citizens. Many regional and local authorities are working actively in the area of a non-toxic everyday environment, particularly in pre-schools.

KEMI is organised into three department, each with its own tasks:

1. **Development of Legislation and Other Instruments Department**
   KEMI takes part in work conducted within the EU, carries out assessments of substances, presents proposals for measures, and prepares documentation for the Swedish Government concerning the development of rules at EU and international level. KEMI decides on and issues its own regulations. KEMI collaborates at the international level to achieve chemicals control.

2. **Authorisation and Guidance Department**
   KEMI evaluates applications for the authorisation to sell and use pesticides, and handles applications for derogations. KEMI provides guidance, information and training to companies, authorities, organisations and consumers in order to increase knowledge about the rules applying to chemicals.

3. **Enforcement and Registries Department**
   KEMI carries out inspections of manufacturers and importers of chemical products, articles and pesticides. KEMI provide guidance to municipal authorities and county administrative boards in their enforcement measures relating to chemicals. Chemical products which are manufactured, imported and distributed on the Swedish market are registered in KEMI's Products and Pesticides Registers.

- **Swedish Work Environment Authority**
  The Swedish Work Environment Authority´s goal is to reduce the risk of bad health and accidents and to improve the work environment. Inspectors check compliance with the rules when they inspect working places.

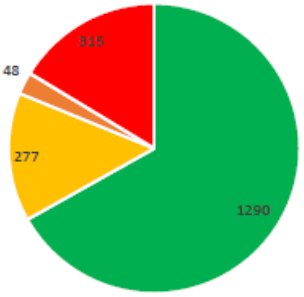
- **Swedish Poisons Information Centre (GiC)**
  The GiC started in 1960 as one of the first in Europe. Relevant tasks of the GiC in relation to the scope of this study are:
  - The GiC is the Swedish National ICE (International Chemical Environment) Centre; e.g. the Swedish part of a European network of emergency response centres for chemical accidents, initiated and financed by the chemical industry. This means that the centre, along with health hazards information and first aid advice, provides information regarding environmental hazards from safety data sheets concerning chemical products from the participating companies.
  - In 2013, GIC was officially appointed to be the body responsible for receiving information about chemical composition of products, according to the CLP Regulation. This information is used for formulating preventative and curative measures, in particular in the event of emergency health response. To be able to make a correct assessment of the acute risk and provide adequate advice in all incidents of poisoning, the Poisons Centre needs accurate information about the composition of chemical products.

- **Swedish Board of Agriculture**
  The Board of Agriculture is the Government's expert authority in matters of agri-food policy, and is responsible for the agricultural and horticultural sectors to the benefit of its consumers. The Board is responsible for providing advice and education to professional users of pesticides.

- **Swedish Consumer Agency**
  The Swedish Consumer Agency is a government agency whose task is to safeguard consumer interests. The agency is responsible for product safety information and service to consumers together with the municipalities. Supervision of the chemical properties of consumer products is carried out in co-operation with the Swedish Chemicals Agency. Consumer guides provide answers to the rights and obligations of

	consumers´ questions on the website Hallå konsument. • **Municipalities** Swedish municipalities have a supervisory authority, such as measuring air and water pollution and checking the labelling of foodstuffs. The inspectors of the municipal environment and health protection boards also carry out the task of inspecting industrial facilities and enforcing environmental permit condition. In general, municipalities and county administrative boards are responsible for: ▪ Supervising the way chemicals are handled for work purposes by professional users, for example, or in operations that are hazardous to the environment. ▪ Checking chemical products, pesticides and articles for placing on the retail market. ▪ Checking the handling of chemicals by those who are not manufacturers and importers into Sweden, and checking that restrictions are applied in accordance with Annex XVII to the REACH Regulation; for example, checking that the use of permits and the conditions thereto are in accordance with REACH, and that companies comply with instructions on managing the risks described in supplier safety data sheets and exposure scenarios. ▪ Checking product reports that have been submitted to the Swedish Chemicals Agency's Products Register by companies manufacturing or importing chemicals to Sweden solely for their own use. • **National Food Agency** The agency works towards ensuring safe food and drinking water. The municipalities, the county administrative boards and the National Food Agency in cooperation check that the manufacturers and distributors of food comply with applicable legislation. • **Medical Products Agency** The agency is responsible for authorising medicinal products for human and veterinary use, including natural remedies. Cosmetic and hygienic products for human use are monitored by the agency. Such products for animal use are chemical products and monitored by the Swedish Chemicals Agency. • **Swedish Civil Contingencies Agency (MSB)** The MSB is responsible to develop, in cooperation with others, the ability of the individual and the civil society to prevent, handle and learn from emergencies and crises. The agency handles issues regarding transport of dangerous goods. On its website (https://www.dinsakerhet.se/) guidance and information on risks is given to consumers. • **Swedish Environmental Protection Agency (EPA)** The agency monitors the state of the environment and is responsible for the follow-up and evaluation of the work on Sweden´s environmental objectives, which engage many authorities in cooperation. The agency is an expert authority for chemicals in the form of waste and is responsible for managing disposal of waste in cooperation with the local municipality.
9. Involvement of stakeholders	The Swedish Action Plan for a toxic-free everyday environment was developed in cooperation with different stakeholders, among which companies. The dialogues between authorities and industry should create increased awareness for information on the chemical content or articles and risk reduction. Such dialogues with (industrial) sectors have largely focused on products that contain SVHC. In addition, several different industrial sectors in Sweden have developed their own systems to reduce risks associated with chemicals. An example of this is BASTA, a

	sector-wide tool developed on the initiative of the construction sector. More than 45,000 different materials are used in the construction sector, many of which contain hazardous substances. BASTA identifies construction products that do not contain substances of very high concern. The tool has been developed in cooperation with Swedish government agencies, and the criteria in BASTA are partly based on the criteria in PRIO. The system makes it easier for purchasers in building companies to buy articles that do not contain substances of very high concern. The idea is that suppliers should be able to have their products registered in BASTA if they fulfil the BASTA requirements, so that the construction companies can then more easily find the "right" products.
10. Relation with European policies / international agreements	The current EU legislation, mainly Reach and CLP, forms the legislative ground for Sweden's Strategy and Action plan for a toxic-free everyday environment (e.g. think about the classification criteria and the criteria for identifying SVHCs). Vice versa Sweden's Action plan has contributed to the European Commission on-going work regarding an EU strategy for a non-toxic environment. The EU's 7th Environment Action Programme (EAP) includes the objective of a non-toxic environment in the EU. Both, Sweden's Strategy and Action plan place large emphasis on developing new, and strengthening current, chemicals legislation in the EU. Sweden has for many years actively pursued and contributed to the establishment of a ban on using a group of active substances with potent endocrine-disrupting properties, as well as substances with persistent and bio-accumulative (PBT) properties in plant protection products for use in the EU. This applies to vinclozolin, procymidone and fenarimol and to lindane, trifluaralin,and endosulphan respectively. In the area of national restrictions there has in certain cases been a need to carefully devise the restriction in order not to be in conflict with the law of the EU. This was the for example the case with Sweden's ban on Bisphenol A (BPA). In July 2010, following the example set by Denmark, the Swedish government decided to ban the use of Bisphenol A (BPA) in feeding bottles for infant formula. The following year, a ban on the use of BPA in baby feeding bottles came into force throughout the European Union. In April 2012, Sweden also introduced a ban on the use of BPA in food packaging materials for children up to three years of age, as a preventive measure and in line with the Action plan for a toxic-free everyday environment. A general national ban on the use of BPA in food packaging materials would not be legally possible within the framework of European regulations. There was, however, a lack of detailed European legislation with regard to the use of BPA in paints and coatings, which allowed sufficient scope for national legislation in this area.
11. Monitoring of substances and evaluations of effects	The idea of the environmental quality objectives is that they should be followed up on a regular basis, with annual reports to the Government and an in-depth evaluation once every parliamentary term. A number of government agencies are responsible for following up and evaluating specific environmental quality objectives. The Swedish EPA, working with all the agencies with responsibilities within the environmental objectives system, prepares an overall report to the Government. The results of this follow-up are presented on the Environmental Objectives Portal. In 2016 the Swedish EPA assessed that the environmental quality objective A Non-Toxic Environment has not yet been achieved and cannot be achieved by 2020 with existing and approved instruments and measures. No clear trend in the state of the environment can be seen. Some toxic pollutants are declining in the environment. For many other substances, not enough is known about their effects on humans and the environment. Growing global consumption results in increased production of chemicals and goods, and with this the diffuse dispersal of dangerous substances. In the EU, restrictions are beginning to be imposed on substances of very high concern. In many sectors, interest is

	on the rise in voluntary substitution of hazardous substances. Legislation must be developed in certain cases in order to bring about toxin-free life-cycles.
12. Incidents with relevance to these policies?	One of the challenges identified in the Action plan for a non-toxic everyday environment 2015-2020 is that Swedish foods and drinking water need to be better protected. Cadmium is probably already a public health problem. Fish from many Swedish lakes, watercourses and coasts have in practice long been unusable as food by children and women of childbearing age because of high levels of PCBs, dioxins and mercury. Incidents can be a driving force for policy development. An important example is the discovery of relatively high levels of highly fluorinated substances in some ground- and drinking water in Sweden. This is one important reason for the stringent Swedish view on fluorinated substances. The development of an action plan for highly fluorinated substances is a direct reaction to the fact that drinking water sources in several Swedish municipalities are polluted with such substances.
13. Relation with emission control	There is little (known about the) relation between the Swedish national policies for substances of concern and emission control.
14. Relation with inspection and enforcement	KEMI is the central enforcement authority for regulations within the field of chemicals. One aspect of the agency's supervisory activities consists of conducting chemical analyses of products in order to check that they do not contain hazardous chemical substances and substances to which legal restrictions apply. KEMI's Enforcement and Registries Department inspects companies that manufacture and import chemical products (the term also includes pesticides), biotechnical organisms and articles that are treated with or contain chemical substances. In the case of articles, KEMI's enforcement responsibilities also encompass distributors and resellers. The inspections are conducted with the support of the Environmental Code and the Safety of Toys Act. Enforcement activities are one aspect of Swedish market supervision, which checks that articles on the market are safe. As one aspect of its enforcement activities, KEMI has checked the chemical substances content of articles and chemical products using analyses. During 2014 and 2015 Kemi tested 1930 products, belonging to one of the following categories: toys and childcare articles, clothing, shoes and accessories, electrical products, building materials and furnishings, sports and leisure equipment, and chemical products. The category with the highest percentage of non-compliance was 'electrical products'. With regards to the category 'chemical products', (49 products were analysed) the following prohibited concentrations were found: chloroform in nail adhesive and hexachlorobenzene in fireworks. ***Figure: Distribution of all products analysed (2014 and 2015) that contained restricted substances in excessive concentrations (red), substances on the Candidate List (orange), low concentrations or unrestricted substances (yellow) or did not contain any of the substances sought (green).***  In the cases where restricted substances are found at levels above the limit values, the companies are informed about the result and KEMI may request a ban on sales and a withdrawal of the product from the market. Authorities in other member states of the EU are also informed about these results. In addition, the analytical findings may also be used as background information when new legislation is

	being developed or when existing rules are reviewed. Other companies and consumers may also make use of these results to avoid use of dangerous chemicals in similar products. In the future, KEMI will continue to prioritise chemical analyses of products as a part of the enforcement. Especially articles within the appointed categories will be prioritised in these analyses. The Agency will also be testing chemical products and pesticides as a complement to control of warning and safety information. The Enforcement and Registries Department furthermore provides guidance to municipal authorities and county administrative boards in their enforcement measures relating to chemicals. Chemical products which are manufactured, imported and distributed on the Swedish market are registered in the Products and Pesticides Registers.
15. Relation with circular economy (re-use and recycle) and substitution	• The circular economy is of increasing importance in Sweden. Both the Swedish Environmental protection Agency and KEMI are working on issues related to the circular economy. KEMIs does this through increasing the possibilities to reduce the number of "särskilt farliga ämnen" ("particular dangerous substances") in chemical products and in articles. • Sweden has recently adopted (2016) a new government action plan called "Handlingsplan Smart industry en nyindustraliseringsstrategi för Sverige" (roughly translated: "Action plan for a smart industry – a strategy for a new industry"). An important aspect of this action plan is to increase environmentally sound innovation and production methods. The action plan highlights the need for increased knowledge, information and substitution of dangerous substances. A governmental commission is now working on a proposal for a new organisation, a centrum to stimulate substitution of dangerous substances, to support industry in their work to reduce chemical risks. This commission will publish its report in April 2017. • In order to reduce the risks associated with chemicals and to phase out the most hazardous substances, Sweden continuously works on a number of different policy instruments: ▪ development of requirements for companies to replace SVHC as far as possible with less hazardous alternatives capable of fulfilling the same function or need; ▪ development of rules on restriction (regulatory frameworks); ▪ monitoring and enforcement of rules; ▪ the provision of information; and ▪ dialogue with particular industries and civil society

Annex 6: The Netherlands

1. Organisations contacted	Dr. Jochem F.M. van der Waals Ministry of Infrastructure and the Environment; Directorate-General for Environmental Protection and International Affairs; Directorate for Safety and Risk Management Plesmanweg 1-6; PO box 20901; 2500 EX The Hague, The Netherlands Telephone + 31 (0)6 52595749 Jochem.vanderwaals@minienm.nl Lindeijer-Schoof, H.B. (Heddy) – DGMI Ministry of Infrastructure and the Environment; Directorate-General for Environmental Protection and International Affairs; Directorate for Safety and Risk Management Plesmanweg 1-6; PO box 20901; 2500 EX The Hague, The Netherlands Telephone: +31 – (0)70 456 1575 GSM: +31 – (0)6 467 48886 Heddy.LINDEIJER@minienm.nl
2. Relevant literature and websites	1. Green Deal with sector organizations about reduction of the use of plant protection products at sports and recreation fields, such as golf courses: http://www.greendeals.nl/gd-189-sport 2. Leeuwen, L.C., C. Smit en A. Schuur: *Verkenning Indicatoren voor Zeer Zorgwekkende Stoffen.* RIVM, Bilthoven, 2014. (Click here). 3. Le Blansch, C.G.: *Informatie-uitwisseling over ZZS; advies op basis van een verkenning.* Bureau KLB, Den Haag, 2015. 4. Letters from the Ministry of Infrastructure and Environment to Dutch Parliament about the emission of GenX by Chemours, dated 25 August 2016. 5. InfoMil about ZZS: http://www.infomil.nl/onderwerpen/klimaat-lucht/zeer-zorgwekkende/ 6. RIVM about ZZS: http://www.rivm.nl/rvs/Stoffenlijsten/Zeer_Zorgwekkende_Stoffen 7. Royal Haskoning: *Vervangen van zeer zorgwekkende stoffen; wanneer vervangen en hoe dat te doen? Handreiking voor het MKB.* Amersfoort, 2013: https://www.royalhaskoningdhv.com/nl-nl/nederland/specials/zzs-handreiking 8. About subsidies for the removal of asbestos roofs: http://www.rvo.nl/subsidies-regelingen/subsidieregeling-verwijderen-asbestdaken 9. About risk policy in nanomaterials: Le Blansch, 2012; *Procesevaluatie risicobeleid nanotechnologie*: https://www.rijksoverheid.nl/documenten/rapporten/2012/11/09/rapport-procesevaluatie-risicobeleid-nanotechnologie 10. Commissie Maatschappelijke Dialoog Nanotechnologie, 2011: *Verantwoord verder met nanotechnologie*. 11. Verschoor et al., 2016: *Emission of microplastics and potential mitigation measures; abrasive cleaning agents, paints and tyre wear.* RIVM Report 2016-0026 12. About prenatal exposure: https://www.gezondheidsraad.nl/nl/taak-werkwijze/werkterrein/gezonde-leefomgeving/risicos-van-prenatale-blootstelling-aan-stoffen 13. About the Wageningen University study about possibilities for substitution of hazardous substances by biobased alternatives: http://www.wur.nl/upload_mm/d/a/d/027cf799-0ba9-4496-85bf-d53bd6cd6d64_WUR-FBR%20report%201506%20RIVM%20ZZS-2-BIO%20project_v2.pdf. 14. About the study on possible exposure to plant protection products of residents living nearby flower bulb fields and fruit orchards: http://www.bestrijdingsmiddelen-omwonenden.nl/en 15. Presentations of a recent workshop with stakeholders about substitution can be found here: https://www.chemischestoffengoedgeregeld.nl/content/presentaties. 16. The report “Initial inventory of alternatives to biocidal products containing

	formaldehyde or formaldehyde releasers": http://www.rivm.nl/dsresource?objectid=60d1e447-9332-4525-a5fe-65b6aedf80d5&type=org&disposition=inline
3. General introduction	– In the Netherlands, the ministry of Infrastructure and the Environment (IenM) is the first responsible authority for policies on substances of concern. The National Institute for Public Health and the Environment (RIVM) plays a key role in implementation of chemicals policy and advice. – The Netherlands is a densely populated country. Companies and inhabitants often live close to one another. Political pressure arises from public concerns over the health risks of people living in the vicinity of polluting industries and over the pollution of nature conservation areas. – An important element of the Dutch national policy for substances of concern is the approach where substances identified as being of very high concern in international legislation are also treated as such in national legislation for emission. Other national policies concern plant protection products and asbestos (outdoor) roofs.
4. National drives	The Netherlands has had a policy to limit industrial emissions of hazardous substances for a long time, focusing on ' prioritary substances' for emissions to air. In 2011 this policy was transformed into the current ZZS policy in view of the international legislation, and the desire for a consistent approach, where substances identified as being of very high concern in international legislation are also treated as such in national legislation for emissions. This approach takes into account new developments in – for instance – the REACH regulation and the list of prioritary substances in the Water Framework Directive. The list of ZZS (see below) serves to combine substances lists of different frameworks in a single set, thus providing a unitary overview. The policy recently gained more attention because of political pressure arising from public concern and/or outrage of people living in the vicinity of polluting industries. Holland is a densely populated country. Companies and inhabitants often live close to one another.
5. Policies and measures	The following national policy for substances of concern exists in the Netherlands. **National Policy for 'Zeer zorgwekkende Stoffen'** The Dutch government has a policy to address 'Zeer zorgwekkende Stoffen' (ZZS) with priority (literally: Substances of Very High Concern). The objective of this policy is to keep these substances as much as possible out of the environment. Specific aims are: • Reduction of emissions of ZZS • A shift to different production methods that preclude the use and/or emissions of ZZS (substitution of methods) • A shift towards the application of non-ZZS substances (substitution of substances) • Improvement of methods to prevent emissions The policy is implemented first of all by means of a permit system, based on the 'Activities Decree'. Companies are obliged to report to the authorities every 5 years. The report contains information about the emissions and the possibilities to reduce this emission. The company has to minimize the emission of substances of very high concern (article 2.4 of the Activity decree). Subsequently the competent authorities include emissions restrictions and obligations for continuous improvement in the permit that is granted. Also research is being commissioned (at Wageningen university) and promoted to explore substitution opportunities. Workshops are held with industry in order to raise

consciousness on the risks of and constraints on ZZS, and to stimulate companies to change and improve methods. A brochure has been developed by Royal Haskoning, commissioned by the Ministry for the Environment, to serve as a guideline for SME's in finding and applying substitutes for substances of concern ('Vervangen van zeer zorgwekkende stoffen; wanneer vervangen en hoe dat te doen? Handreiking voor het MKB').

In addition to this legislation the Netherlands has some specific activities aimed at substitution and safe use of harmful substances:

- **Policy to ensure the quality of drinking water**
  In the policy document 'Drinking Water' ('Beleidsnota Drinkwater') of 2014, reference is made to the Water Framework Directive, policies on pesticides and on soil pollution. Concerning 'new chemicals', reference is made to existing policies on medicine discharge. Also, research into the possible added value of a 'signal value' is announced.
- **Activities concerning plant protection products**
  - In 2013, the government published the policy plan "Gezonde groei, duurzame oogst" (Healthy growth, sustainable harvest). The plan is written in consultation with the relevant stakeholders and formulates the ambitions, goals and measures for sustainable agriculture in 2013-2023. Key items are further development of integrated pest management, safety of workers, consumers and bystanders, protection of biodiversity, reduction of non-agricultual pesticide use, and improvement of water quality. To reduce emissions of pesticides from greenhouses, waste water treatment will become obligatory as from 2018. The ultimate aim is to have almost no exceedance of the water quality standards for drinking water and surface waters by 2023. For active substance that exceed environmental quality standards, the registration holders agreed to draft emission reduction plans. The evaluation of water quality in relation to pesticide use is done by means of a national monitoring network and a centralised database. All monitoring data are published in an on-line atlas (http://www.bestrijdingsmiddelenatlas.nl/).
  - A national ban on the use of chemical plant protection products in the non-agricultural sectors on hardened surfaces (from end of 2017 also on non-hardened surfaces).
  - A Green Deal with sector organizations about reduction of the use of plant protection products at sports and recreation fields, such as golf courses.[3]
  - A Green Deal aimed at accelerating introduction of plant protection products with low risks by facilitating procedures for their admission on the market.
  - A Green Deal with retail and sector organizations about communication to consumers about alternatives to hazardous plant protection products.
  - A large study about possible exposure to plant protection products of residents living nearby flower bulb fields and fruit orchards. The background of this study is the advice from the Health Council in 2014, which concluded that risk assessments do not explicitly take into account these effects, as well as media attention and public concern on the subject. The study will run from 2015 to 2021 and includes environmental monitoring and biomonitoring. There is a Sounding Board with stakeholders involved (residents, agricultural organizations, NGO's, Area Health Authorities)

- **Innovation, science and research policy**
  Innovation Policy is organized in 'topsectoren', one of which is the Topsector Chemistry. There are funding possibilities in the context of public-private

[3] http://www.greendeals.nl/gd-189-sport/

partnerships, and some recent projects have a (possible) link with substitution. However, no projects thus far had substitution as the main objective. Wageningen University has been commissioned a small research project about possibilities for substitution of hazardous substances by biobased alternatives.[4]

- **Risk assessment**
  The RIVM works on the integration of toxicity aspect in integrated assessment methods for substances. An example is the report "Initial inventory of alternatives to biocidal products containing formaldehyde or formaldehyde releasers" in which the characteristics of the alternatives were assessed.

- **Asbestos**
  Recently, the Netherlands announced a ban on asbestos (outdoor) roofs, which will come into effect in 2024. This means that the owners will need to remove all existing roofs with asbestos. This measure addresses possible risks from the weathering of roofs. In the period 2016-2019 € 75 mln is available to make a quick start with the operation; this subsidy is already widely used. The clean-up operation is managed in cooperation with provinces, municipalities, agricultural organisations, removal companies, insurance companies and inspections.**Nanomaterials**
  Since 2008 the Dutch policy on the risks of nanomaterials consists of three types of activities, respectively aiming to increase knowledge, to engage in dialogue with stakeholders and society at large and to bring about EU regulation (Le Blansch, 2012). Several national research projects have taken place (concerning nano silver, consumer products, nano reference values and more). Also, the Netherlands plays an active role in European research projects like NanoReg I and II and NanoNext. At the RIVM a Knowledge and Information point on the Risks of nanotechnologie (KIR-nano) is installed, that serves as an intermediary between the worlds of science and government policy. Dutch policy makers consult on regular basis about nano risk policies with a sounding board of stakeholders from industry, NGO's and expert institutes. Between 2009 and 2011 a 'national dialogue on nanotechnology' has taken place (Nanopodium). One of the conclusions of the committee that organised this societal discussion was that Dutch citizens support a ; responsible' further development of nanotechnology (Commissie Maatschappelijke Dialoog Nanotechnologie, 2011).

- **Microplastics**
  In order to push for an active policy on microplastics within OSPAR, the Netherlands had research carried out by RIVM (Verschoor et al., 2016) and Ecorys (Briene and Zwart, 2016). The ministry of Infrastructure and the Environment organised an international conference in 2015 to discuss reduction and mitigation measures with stakeholders and policy makers.

- **Prenatal exposure**
  In 2014 the Health Council produced an advice about prenatal exposure. It concluded that the assessment for admission of substances on the market does not take effects on the unborn child sufficiently into account. This has lead to increased work of the RIVM to adjust test methods of the OECD .

- **Information for consumers**
  The Ministry of Health, Welfare and Sports recently started the initiative for an online platform to inform consumers about chemicals in products. This platform aims to inform about the presence of chemicals and safe use of products, based on scientific insights. The platform will evolve gradually, starting with paint and toys,

[4] This project is a follow up to this report: http://www.wur.nl/upload_mm/d/a/d/027cf799-0ba9-4496-85bf-d53bd6cd6d64_WUR-FBR%20report%201506%20RIVM%20ZZS-2-BIO%20project_v2.pdf.

	followed by other product types such as cosmetics, detergents and biocides. The website will go live in the course of 2017.
6. Substances covered	Although the English translation of ZZS is 'Substances of Very High Concern', ZZS cover more substances than 'SVHC' under REACH. The definition of ZZS does, however, match with art. 57 of the REACH regulation (EC 1907/2006). Substances are deemed ZZS when they match one or more of the following criteria: • Carcinogenic (C) • Mutagenic (M) • Toxic for reproduction (R) • Persistent, bio-accumulative and toxic (PBT) • Very persistent and very bio-accumulative (vPvB) • Substances — such as those having endocrine disrupting properties — for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern All substances that match these criteria are deemed ZZS (but are not necessarily SVHC, e.g. pesticides, which are not covered by REACH). ZZS can in any case be identified on the basis of the following European Acts and Treaties: • Substances classified as C, M or R under CLP (EG 1272 / 2008) • Substances on the REACH Candidate List (Annex XIV) (EC 1907/2006) • Similar substances of concern in the POP Regulation (EG 850 / 2004) • Prioritary hazardous substances in the Water Framework Directive (200/60/EG) • Substances on the OSPAR List of Chemicals for Priority action As a means of assistance the RIVM publishes a non-exhaustive list of ZZS on its website, which is updated every half year. Neither the existence of this list nor that of the other guidelines to identify ZZS relieve companies of their responsibility to self-classify the substances they use and/or emit, and to act in accordance with the outcome of this self-classification and the requirements of the ZZS policy.
7. Legal / formal bases	The government policy for ZZS is codified in the Activities Decree. The Activities Decree contains environmental regulations, especially for companies. The Decree is applicable to all companies in the Netherlands unless they have little or no impact on the environment. The requirements are particularly important for companies in scope of the Industrial Emissions Directive (IED). The Decree orders companies to prevent emissions of ZZS to air and water. If this is not attainable, emissions must be limited to the lowest attainable level (minimisation obligation). The requirements for emissions to the air are elaborated in the Handboek ZZS Lucht (Manual ZZS Air). Those for water in the Algemene Beoordelings Methodiek 2016 (ABM; General Assessment Method) and the Manual Discharge Test 2016 (Handboek Immissietoets).
8. Organisational basis	The Activity Decree is implemented by various competent authorities. Depending on the type / risk class of the company, this can either be the local authorities, the provincial authorities, the national authorities (either the Minister for Infrastructure and Environment or the Minister for Economic Affairs) or the water authorities. It is enforced by the Human Environment and Transport Inspectorate (ILT).

	Information and expertise on ZZS policy is obtained from InfoMil, on ZZS substances from the RIVM (National Institute for Public Health and the Environment). In terms of the science-policy interface, an important feature is the prominent role of two institutions: • the National Institute for Public Health and the Environment (RIVM) which plays a key advisory role in the development and implementation of chemicals policy • the Health Council of the Netherlands, an independent body with legal status which advises the government on health-related issues, based on thorough scientific evaluations.
9. Involvement of stakeholders	In the preparation of the ZZS policy and legislation, there have been intensive discussions with companies affected and their sector organisations, with much attention to the practical implementation. In a more general sense, the Netherlands has close contacts with stakeholders from both industry and NGOs. In addition to regular meetings of a sounding board of stakeholders, the Ministry of Infrastructure and Environment organises twice a year, together with sector organisations and NGOs, a seminar about a topic in chemicals policy. Stakeholders are informed and involved in the ZZS policy via these existing stakeholder meetings. Other examples where this cooperative approach can be seen are the 'Green Deals' about plant protection products (voluntary agreements with stakeholders), the programme to remove roofs with asbestos, and the study about possible exposure to plant protection products of residents living nearby flower bulb fields and fruit orchards.
10. Relation with European policies / international agreements	The ZZS policy draws (through its criteria) on several European policies and international agreements (see above). Conversely, through its prioritisation the ZZS policy provides input to these policies and agreements.
11. Monitoring of substances and evaluations of effects	Knowledge on the use and presence of ZZS in the Netherlands is partly scattered over different authorities and sectors and partly absent (source: RIVM) (Le Blansch, 2015). There are attempts to organise for monitoring of the effects of the ZZS policy. However, the proper indicators for such monitoring activities have not yet been established (RIVM, 2014). Up till now the ZZS policy has not been evaluated. An evaluation of experiences with the legislation is expected early 2017.
12. Incidents with relevance to these policies?	In 2016 it was found that the factory of Chemours (formerly known as 'Dupont') had been emitting the substance FRD-903 ('GenX'). This led to unrest under the people living in the vicinity of the factory, coverage by national TV and newspapers and questions in Dutch Parliament addressed to the State Secretary for the Environment. The State Secretary explained that the competent authorities had treated the emissions correctly within the framework of the ZZS policy, and in accordance with what is presently known of the properties of FRD-903. Additional research was commissioned. (Letters from the Ministry of Infrastructure and Environment to Dutch Parliament dated 25 August 2016).

	Previously, the same company had already been found to emit PFOA. PFOA fits the criteria of ZZS. Hence, strict permit requirements would have had to be in place. However, at the time already a discussion on restriction of PFOA under REACH was taking place. Therefore, the Dutch authorities decided not to take pre-emptive action and to wait for the outcome of this discussion. When the emissions became public, questions were raised in Parliament and the authorities were blamed for being lax. Incidents like these have happened more often. They serve as a trigger for more active policies. For example: • Emissions of mercury led to depositions in the 'Waddenzee' (sea nature conservation area in the north of the Netherlands). • International debates on BPA and activity of Member States France and Denmark prompted questions in Dutch parliament about Dutch passiveness on this issue.
13. Relation with emission control	There is a strong relation of the Dutch ZZS policy with emission control. The policy is implemented first of all by means of a permit system, based on the 'Activities Decree'. Companies are obliged to report to the authorities every 5 years. The report contains information about the emissions and the possibilities to reduce this emission. The company has to minimize the emission of substances of very high concern (article 2.4 of the Activity decree). Subsequently the competent authorities include emissions restrictions and obligations for continuous improvement in the permit that is granted.
14. Relation with inspection and enforcement	There is indeed a relation of the Dutch ZZS policy with inspection and enforcement. The Dutch ZZS policy is implemented first of all by means of a permit system, based on the 'Activities Decree'. This Activity Decree is enforced by the Human Environment and Transport Inspectorate (ILT).
15. Relation with circular economy (re-use and recycle) and substitution	*Circular economy* There is indeed a relation of the Dutch ZZS policy with circular economy. The National Institute for Public Health and Environment (RIVM: Rijksinstituut voor Volksgezondheid en Milieu) carries out research on ZZS substances that may hinder recycling. What ZZS ingredients in waste prevent reuse? For example, at the moment the RIVM is looking into textiles and rubber granulates (the latter also in relation to a present public incident). This is a Dutch priority. *Substitution* There is a strong relation of the Dutch ZZS policy with substitution. Substitution is one of its central aims. The minimization obligation of the emission of substances of very high concern (article 2.4 of the Activity decree) forces companies to reflect explicitly on the possibilities of substitution and is deemed to be a driver to look for alternatives. Next to that, research is being commissioned (at Wageningen university) and promoted to explore substitution opportunities. Workshops are held with industry in order to raise consciousness on the risks of and constraints on ZZS, and to stimulate companies to change and improve methods. A brochure has been developed by Royal Haskoning, commissioned by the Ministry for the Environment, to serve as a guideline for SME's in finding and applying substitutes for substances of concern ('Vervangen van zeer zorgwekkende stoffen; wanneer vervangen en hoe dat te doen? Handreiking voor het MKB'). There were also less successful attempts for voluntary agreements, where confidentiality issues proved to be a barrier for cooperation. In general, it is not easy to

	interest companies for dialogues about substitution.