

TECHNO-ECONOMIC SUPPORT ON REACH

**Case study on  
“Announcement effect” in the market  
related to the candidate list of  
substances subject to authorisation**

FINAL REPORT

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# 1. Background and objective of the case study

## 1.1. The candidate list of substances subject to authorisation

Substances which will be included on the "candidate list" fulfil the criteria of REACH Art. 57 and will have been identified according to Art. 59. These substances of very high concern (SVHC) include CMRs<sup>1</sup> (Cat. 1+2) and PBTs/vPvBs<sup>2</sup> and other substances which give rise to an equivalent level of concern (e.g. endocrine disrupting chemicals). Classified CMRs (listed in Annex I of Directive 67/548/EEC) and identified PBTs/vPvBs (EU-PBT-List) will be verified and put on the list. The list will be complemented by other SVHC known by industry and by SVHC which will be identified during information collection for registration.

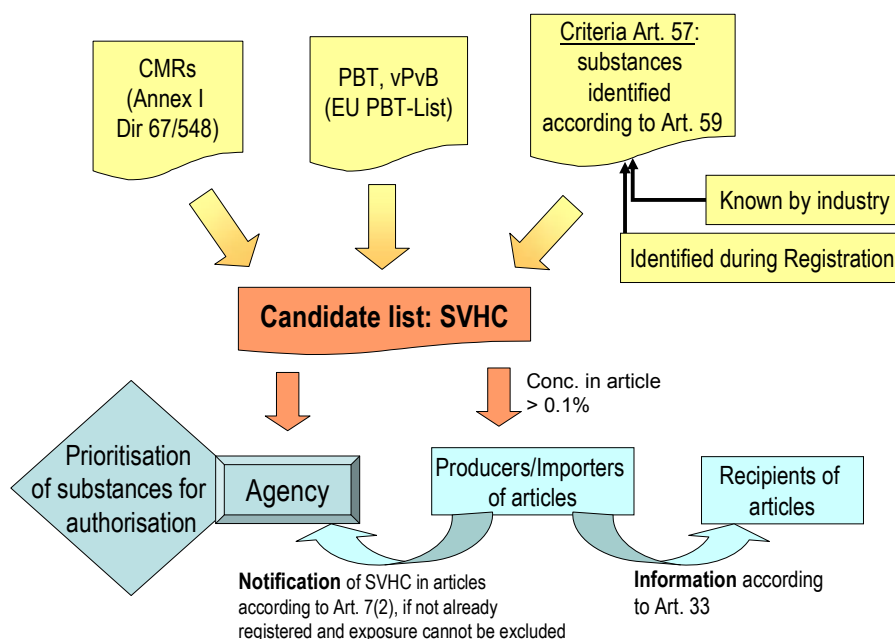


Figure 1: The mechanism of the candidate list

<sup>1</sup> carcinogenic, mutagenic or reproduction toxic substances

<sup>2</sup> persistent, bioaccumulative and toxic substances/very persistent and very bioaccumulative substances

## 1.2. What is the task of the candidate list?

Identified SVHC represent the candidates which may be put on Annex XIV (substances subject to authorisation). Based on the candidate list the Agency recommends, taking into account the opinion of the Member States Committee, priority substances to be included in Annex XIV (Art. 58(3)). Priority shall normally be given to substances with PBT or vPvB-properties, wide dispersive use or high volumes.

Furthermore the candidate list is the basis for notification of substances in articles according to Art. 7(2). Independent of notification, article producers, importers and traders of such articles have to communicate information about SVHC contained in articles and necessary risk management measures to the recipients of the articles and to provide this information to consumers on request (Art. 33).

## 1.3. Objective of the case study

As a risk management measure for substances of very high concern, one aim of authorisation is that the substances "*are eventually replaced by suitable alternative substances or technologies where these are economically and technically viable*" (Article 55). "*An analysis of the alternatives considering their risks and the technical and economic feasibility of substitution*" (Article 62.4(e)) is already to be included in an application for authorisation. To announce the potential subjects for authorisation beforehand on a publicly available candidate list might be an incentive for producers and users of these substances to strive for the substitution goal pro-actively.

The aim of this study is to analyse and describe these potential effects on the market based on existing experiences with comparable legal or voluntary approaches. By analysing industry patterns of reaction in the past, assumptions on the future behaviour of companies with regard to substances on the candidate list under REACH can be derived.

## 2. Working procedure

The activities in these case studies were divided into 4 work packages (= WP):

- WP1: Work Hypotheses
- WP2: Harvesting experience made on substitution
- WP3: Analysis of substitution requirements in existing EU legislation
- WP4: Verification of work hypotheses

The work packages are documented in the respective chapters of the results (chapter 3). However, many overlapping issues are described in depth in the conclusions (chapter 4).

Based on the findings each work hypothesis was revisited and checked to determine whether it is supported or disproved by the findings (WP4). This step is documented in the conclusions.

## **2.1. Work Hypothesis (WP1)**

The starting point of the case study was the generation of a set of work hypotheses on announcement effects that could be expected by introducing a candidate list of substances subject to authorisation (see Annex I). These hypotheses were discussed among experts from Ökopol and RPA and commented by the Commission.

The set of work hypotheses represented the basis for the analysis of existing experiences, legislative requirements and for expert interviews and was continuously compared with the key findings.

## **2.2. Harvesting experiences made on substitution (WP2)**

Several substance lists with different aims exist in Europe and prioritise substances with dangerous properties for further action. In this working paper their effects on the behaviour of market actors regarding substitution have been evaluated. Subjects for deeper analysis were:

1. The Danish "list of undesirable substances" (LOUS)
2. The Swedish observation list (OBS list)
3. The OSPAR list of substance for priority action
4. Lists used by trade
5. Lists used by the electronics industry

Interviews were carried out with experts from authorities, non governmental organisations (NGOs), industry and chemical product service. The focus was on one hand to analyse experiences with specific substance lists and on the other hand to understand how specific industry sectors manage the challenges of product safety with regard to contained chemicals. The contacted industry experts represent downstream users and article producers/importers. A complete list of the persons who have contributed to the study is provided in Annex III.

Experts from manufacturers and importers (M/Is) of chemicals have not been involved and these actors have only been covered by document analysis. This is because M/Is rather tend to defend the use of SVHC they sell as long as they do not have an alternative in their own product portfolio (WWF 2001, SubChem 2006). There is even some evidence that they have not yet informed downstream

users as to whether or not they plan on registering SVHC (RPA 2007). There is also some evidence to suggest that many companies have not yet developed their strategy towards authorisation. Taken together, these factors led to the conclusion that there would be little merit in gathering further statements on to future behaviour from these actors.

Furthermore relevant experiences from other work areas have been evaluated to analyse the mechanisms and results of substitution processes in relation to the work hypotheses. This includes the work on several research projects and impact assessments. Also RPA experiences on risk reduction strategies and the consultation of authorisation provisions have been considered, but the substance cases and actors were made anonymous.

### **2.3. Analysis of existing legal requirements (WP3)**

In this work package substitution requirements in existing EU legislation (e.g. Chemicals Agents Directive (CAD), VOC<sup>3</sup>-directive etc.) and their reported effects have been analysed. Based on this, areas have been identified in which the substitution requirements potentially resulting from the REACH authorisation scheme enhance existing requirements (overlaps) and in which substitution may be an additional/new requirement.

A list of legislation containing substitution requirements is provided in Annex IV.

### **2.4. Verification of work hypotheses (WP4)**

In this work package, the findings from document analysis and expert interviews from WP2 and WP3 are used to challenge, sharpen or disprove the work hypotheses of WP1. Experts were also asked to give their opinion on potential effects on the market and to derive recommendations on how to design the list and to support the desired effects and minimise potential unwanted effects.

The verification of the selected work hypotheses and collected recommendations are described in the conclusions in chapter 4.

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<sup>3</sup> volatile organic compounds

## 3. Results

### 3.1. WP2: How did substance lists influence behaviour of market actors towards substitution?

#### 3.1.1. Roles and behaviour of market actors

##### 3.1.1.1. Manufacturers/Importers of Chemicals

As mentioned above, most M/Is of known or suspected SVHC tend to defend the use of their products. They often argue with benefits of the use and that the known risks can be controlled, while substitutes may lead to unknown or shift of risks (WWF 2001, CEFIC 2006). M/Is may stop supplying a specific SVHC with or without offering a suitable substitute to their clients. Manufacturers may invest in the development of alternatives for substances being subject to existing or upcoming restrictions or for controversially discussed substances if they expect the business risks from introducing an alternative to be compensated by extra (net) revenues. Then they may offer an alternative to their clients to maintain their market or to capture specific segments of markets where they expect a strong demand for non-SVHCs<sup>4</sup>.

A prominent example for this kind of consideration is the development of an alternative for the PVC plasticiser DEHP<sup>5</sup> by one of its manufacturers (BASF). DEHP was classified as toxic for reproduction Cat. 2 and was banned for the use in certain toys for babies and small children. As the new developed non toxic plasticiser DINCH<sup>6</sup> is a high volume new substance, the manufacturer was obliged to notify it under Directive 67/548/EEC including expensive toxicity testing. However, it was not expected that DINCH could compete against the cheap phthalates in the mass markets. The substance was promoted as a non toxic alternative for DEHP in sensitive and rather high priced applications like toys, medical devices and sports wear, where the higher price would be accepted in order to ensure product safety.

Also importers search for different solutions outside the EU to make them available to the EU market (NRW 2004). As importers do not need to invest in production plants the economic barrier to offer substitutes from outside should be lowered compared to EU-manufacturers. However, innovation towards (the import of) new substances is often regarded as too expensive and connected with economic risks under the current system because of the high information requirements for new substances (SubChem 2006). This hindrance should be partly reduced as new and existing substances will be treated equally under REACH.

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<sup>4</sup> e.g. manufacturers of mineral fibers developed bio-soluble fibers as alternatives for carcinogenic mineral fibers in insulation materials (SubChem, 2006).

<sup>5</sup> Diethyl hexyl phthalate

<sup>6</sup> Diisononyl cyclohexane

Where legal requirements and market pressure (existing or anticipated) are missing, the effects of not legally binding lists on substance producers and importers are low. Obviously substance lists are not yet part of the strategies of the chemicals industry like responsible care and product stewardship (WWF 2001).

#### 3.1.1.2. *Formulators*

The most important actor with regard to substitution of SVHC is the formulator. Formulators select substances and combine them to achieve specific technical properties and often they are requested to adapt their products to technical progress and regulatory changes. Representing the link between a substance and a substance in a specific use they are the main addressees for substitution requirements from legislation or customer demands. In many sectors formulators provide chemical products together with comprehending services to their customers. This ranges from consulting on the optimal application of the products to the joint development of product systems adapted to the needs of the user and his clients (e.g. paint industry, electroplating industry, textile finishing, custom-built polymer compounds). Often occupational health aspects, waste disposal or recycling and monitoring are part of this service (RUH 2006, SubChem 2006, NRW 2004). Formulators also invest in research to find new approaches or improve efficiency of the processes in order to maintain the production in the EU and enhance reputation of the sector (especially if central production processes are subject to public debate)<sup>7</sup>.

To avoid repeated reformulation, formulators consider upcoming regulations and anticipate customer demands during an early stage of product development. Observing respective developments and providing an early warning system is often delegated to associations or chemical product service providers (see also chapter 3.1.3). However, anticipated SVHC are not replaced in general. Substitution of these substances is only one aspect in the formulators' product development strategies. Besides the technical performance, the application and the price of the preparation have to be considered. A potential shift of risks<sup>8</sup> has to be excluded, what is often difficult to assess. Customers will only accept a changed performance and/or an increased price of the preparation if they regard an improved product safety as a benefit.

#### 3.1.1.3. *Downstream users of preparations and article producers*

The actors down the supply chain do not directly choose the substances they use but frequently influence the choice of the formulator on which substances are contained in their preparations. To increase legal certainty and become aware of up-

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<sup>7</sup> as an example companies found different ways to reduce risks related to the use of hexavalent chromium in electroplating industry. Some have changed the process and use less toxic trivalent chromium. Others have improved the process, recycling and waste water treatment in a way that almost no waste water is emitted to the environment (RUH 2006).

<sup>8</sup> typical "shift of risks" connected with substitution are the reduction of some (eco-)toxicological impacts while another impact to the same or a different compartment is growing: E. g. substitution of toxic biodegradable substances by less toxic but persistent substances; transfer of burden from atmospheric emissions to aquatic emissions, or increased energy consumption; increased accident risks for workers if (eco)toxic substances are replaced by flammable or explosive substances.

coming substance related requirements, companies or branch associations have implemented own substance lists covering the relevant restrictions and considering other requirements and other existing lists (e.g. automotive industry, electronic industry). This means they restrict the use of the listed substances in their products and in the development of new products, and require compliance with the lists from their suppliers as a condition of supply contracts.

When companies decide to work with a substance list, they often integrate it into their daily routines of supply chain communication, to ensure that the listed substances can be excluded from their input/raw materials, articles or services and can thus be excluded from their products (OBS list, OSPAR). This way, downstream users can decide on the demand for preparations without SVHC. They can either survey the market for alternative products or request their current suppliers to develop alternative preparations with similar performances.

While some downstream users behave pro-active, others seem to be rather observant or ignorant. Pro-active behaviour can be found particularly in companies (formulators for end-use and article producers) that produce or sell consumer products (e.g. household articles, textiles, cosmetics). Awareness is often further increased, if a brand name is involved (cars, branded textiles, branded furniture). Input raw material often needs to pass through complex qualification procedures before it is accepted (automotive industry, aircraft industry). All these enterprises are relatively vulnerable to NGO-campaigns against the use of hazardous substances, even if the substances are not legally restricted (e.g. the WWF requests companies to phase-out OSPAR hazardous substances). They intend to ensure a high product quality with low substance-related risks to raise their reputation and prevent negative publicity.

#### 3.1.1.4. Retailers

While retailers are no REACH actors they play an important role as demanders for products and thus may influence the behaviour of the REACH actors up the supply chain. Many major retailers have adopted lists of substances that should not be used in their own-brand products, whether manufactured outside or inside Europe. The lists are based mainly on lists of substances identified by governmental organizations (e.g. OSPAR) or by NGOs, supported by the company's own research. In the case of electronic equipment, retailers informed their non EU-suppliers beforehand about the upcoming restrictions according to the RoHS<sup>9</sup>-Directive.

In most cases, retailers seek information from suppliers on whether articles contain the listed substances. They also carry out inspections of final products, as there is always a possibility that the products do not conform with the retailer's requirements. One leading retailer spends € 3 million per year in testing the chemical content of products.

Working with suppliers is a major task for retailers, as even a single finished product can have up to 20-25 suppliers. Furthermore, retailers face logistical difficulties

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<sup>9</sup> restriction of the use of certain hazardous substances in electrical and electronic equipment (DIRECTIVE 2002/95/EC)

such as a lack of knowledge amongst their immediate suppliers, the fact that the suppliers of their immediate suppliers are often small and medium enterprises (SMEs) with little experience in safety and environmental issues, the limited information held by such suppliers on the content of their products, etc. Other key difficulties for retailers in relation to substances in articles are that suppliers:

- have difficulty in recognising what the responsible use of chemicals means for their business;
- cannot identify which chemicals substances will or will not reach the consumer;
- have no or very limited information on the chemical content of their product; or
- do not wish to disclose information about certain chemicals within the product for reasons of confidentiality.

For this reason, leading retailers have put in place education programs to bring the suppliers (small and larger) up to European standards in terms of product safety and protection of the environment. However, such training of suppliers takes time and a change in production patterns can take years, even when suppliers improve their standards each year. It should also be noted that retailers have both a stable supply chain base, where they can invest in a relationship with suppliers, and a volatile supply chain (fashion based) where investment cannot be as high.

Faced with these practical difficulties, retailers have developed lists of chemicals of concern that should not be used in particular products. If a chemical of concern is in a product, the retailer works with the supplier to agree on an appropriate strategy using, for example, a toolkit approach based on a timeframe appropriate to the product characteristics and substance issues to be addressed. Those tools include substitution of chemicals with viable lower risk alternatives and discontinuation of the affected product.

If a supplier does not wish to comply with the retailer's chemical policy, the retailer is forced to cease doing business with that supplier. Implementing policies to address chemical substances in articles therefore requires retailers to:

- investigate what substances are contained in articles to ensure that they are used in a safe way;
- develop standardised exposure models applicable to product categories;
- understand which substances are dangerous and whether the alternatives are viable – this requires greater transparency and co-operation in the supply chain<sup>10</sup>;
- raise awareness amongst suppliers about the chemical content of their products;

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<sup>10</sup> this is a broad claim for retailers and only some bigger enterprises might meet it

- train the supplier through a step-by-step approach; and
- invest time and money in product inspection.

**Conclusions:** *Downstream users, article producers and retailers use substance lists to exclude specific substances from their products and thus exert pressure on the supply chain. Formulators taking the central role with regard to substitution consider substance lists and information on upcoming restrictions during product development. For M/Is substance lists can indicate for which substances alternatives might be in demand in the future.*

### 3.1.2. Substance lists are used as black lists

The most basic observation in the interviews and document analysis with regard to the substances lists is that – regardless of whether the substances are legally restricted, subject to voluntary agreements or just declarable - the substances on the list are considered unwanted (OSPAR, LOUS, OBS-List). If a company uses a list then it regards it as a "black list", which means that the company attempts to phase out the listed substances. Especially retailers have gained experiences with the implementation of such lists and know to work with them. During the regular revision of LOUS seven substances (of 80-100) have been withdrawn from the list up to now due to lower volume. So, in general it can be shown that substance lists have the effect of promoting a phase-out of the listed substances in the enterprises using the list. However, authorities got the feedback from industry that it is difficult to consider all the different national lists on the European market and that one harmonised EU-List would be appreciated.

**Conclusion:** *The candidate list will be appreciated as an EU-wide agreed list and implemented as a black list by many companies. This way substitution of identified SVHC will be promoted.*

In this context also the classification of substances according to Annex I of Directive 67/548/EEC is relevant. The EU-wide harmonised classification provides a definite and agreed classification and downstream users seem to be quite aware of this. As the classification of a substance can have strong implications on downstream regulations especially formulators aim at producing preparations with low or no classification. Special attention is given by M/Is and downstream users to the discussion on higher classification of CMRs. Since an increased classification from category 3 to category 2 implies labelling with a T and a skull and cross-bones which requires higher risk management and often triggers DUs to replace the preparation if non classified alternatives are available<sup>11</sup>.

**Conclusion:** *If SVHC are identified by classification under current legislation, downstream legislation triggers substitution*

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<sup>11</sup> an example is given by the harmonised classification of DEHP as reprotoxic cat. 2 in 2001 (see SubChem 2006)

### 3.1.3. Enterprises use substance lists as early warning system

Companies providing product services in the fields of chemical safety offer service contracts for safety data sheets, where they check the ingredients of the concerned preparations regularly to identify those subject to current and upcoming regulation (e.g. amendments to the Directive on marketing and use restrictions and Annex I of Directive 67/548/EEC) and – if requested – whether they are listed on specific substance lists (e.g. lists of occupational exposure limits, GADLS<sup>12</sup>, LOUS). This way companies not having access to all relevant information sources, or being overtaxed by the control of all relevant processes, externalise the task to a professional warning system. They get time to consider the information provided as part of their own decision making, which often results in the phase-out of critical substances. With regard to the development of new preparations, companies use these services as a filter to detect critical substances at an early stage.

**Conclusion:** *To ensure legal compliance and satisfy customer requirements many substance lists have to be observed by companies. This is important enough to pay for the provided service.*

### 3.1.4. What substance lists don't do

The way how substance lists are easily accepted as blacklists indicates that companies often lack the competence to make risk based decisions. Black lists say 'no', but do not give guidance on which risks have to be reduced and how to come to a better solution; a reasonable approach would be to accept the fact of a used substance being 'unwanted' and to take a rational decision on which is the best reaction based on risk considerations. The success of substance lists with regard to risk reduction is questionable due to the lack of risk considerations and in particular due to the lack of a structured assessment of alternatives to the listed substance. Consequently it is possible that companies having reacted on a substance list by substituting will face the same situation again when the substitute turns out to be as dangerous as the original one (CEFIC 2006).

This effect was frequently observed by the Swedish Chemicals Inspectorate (KEMI) with the Swedish Observation list and the reason for KEMI to provide more information and guidelines with the successor, the PRIO-tool. It has also arisen under the Existing Substance Regulation (ESR), with restrictions placed on one set of substances leading to the adoption of other substances within the same overall family of chemicals.

With PRIO of KEMI, companies do not get a list but a tool supporting them in systematic and sustainable safety work. A PRIO substance list is part of the guidance, but less prominent and not exclusively foreseen as the basis for decision making. This tool provides a step by step priority setting guide where substances are at first identified and then assessed with regard to potential risks. The substance list supports the assessment by giving examples at two levels: substances to be phased-out (these criteria are similar to some of the SVHC-criteria) and sub-

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<sup>12</sup> Global Automotive Declarable Substance List

stances with elevated or high risks (including allergenic and high acute and chronic toxic substances and potential PBT/vPvBs).

KEMI has promoted the tool and tried to motivate companies to use it and they now observe that inventories have been analysed and companies are ready to take the next steps of prioritisation and risk reduction. This way the companies not only screen their inventory for specific substances but increase their own competence with regard to chemicals risks and can thus improve their overall chemicals management. KEMI states that this will be also necessary under REACH since many substances which do not completely fulfil the criteria of substances of very high concern have to be regarded nevertheless as very dangerous.

PRIO allows companies purchasing articles to narrow down which substances are likely to be contained in a given material. This way they can limit the number of substances to be considered in purchase contracts for a specific article. Also the Danish EPA offers supporting projects to industry sectors to provide guidance and assist in decision making.

However, against the background of REACH, information on risk management is not restricted to the identification of the SVHC. A kind of guidance on safe handling and a learning system on risk management will be given with the REACH instruments safety data sheet and the exposure scenario<sup>13</sup>.

**Conclusion:** *A substance list should be complemented by guidance to promote risk based substitution. REACH provides some instruments for risk based decision making by the actors in the supply chain.*

### 3.1.5. Industry influences the testing of substances

Industry is often invited to take part in the prioritisation of substances for risk reduction measures and the development of publicly available lists. They may contribute with hazard information, use information and scientific expertise. The mechanisms of the OSPAR prioritisation also give an opportunity for companies and associations to apply for de-selection of substances from the list by providing additional data on substance properties. This was widely used by industry (although some suppliers to retailers claimed that, even when a substance had been investigated under ESR and found not to pose a risk, it was not de-selected by retailers because of continuing pressures from NGOs).

**Conclusion:** *Industry needs to be involved in the selection of SVHC. As belated de-selection is not feasible the identification procedure needs to be transparent and reliable.*

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<sup>13</sup> if an SVHC has already been registered above 10 t/a exposure scenarios will be available for identified uses

### 3.1.6. Companies behave differently: Experiences on the development of risk reduction strategies

Risk reduction strategies (RRS) are developed in response to identified substance related risks. As industry is involved in the consideration of alternatives companies may anticipate the results and replace the substances before legal requirements enter into force. However, companies act differently and pro-active behaviour has not always taken place. Indeed, if a substance is phased-out by its main manufacturers, downstream users need to replace it. If the substance is still available before a decision on the RRS is taken, downstream-user often continue 'business as usual' as long as possible.

As discussed for the substance lists, substances with similar properties as the prioritised substance are often the first choice for a substitute since technical adaptation efforts are expected to be low. In some cases the risk reduction strategy addressed a group of substances belonging to the same family and this way other substances with lower concern or completely different approaches became more relevant as alternatives. However, in other cases even a substance group with positive risk assessment (i.e. conclusions of no unacceptable risks) was banned by manufacturers of branded cosmetics as a result of NGO campaigning.

Companies with qualitatively<sup>14</sup> different solutions have often difficulties to penetrate the market. With the risk reduction strategy they get a platform for their products to be more prominently known. The REACH authorisation procedure provides similar opportunities for companies to promote their alternatives if they contribute with statements on substitution possibilities to the proposals made by the Agency. When applying for an authorisation an assessment of alternatives has to be included. In contrast, the candidate list does not imply such a platform for alternatives.

In one case an "unwanted announcement effect" was observed where within regulatory and voluntary activity aiming at risk reduction, the consumption of the prioritised substance temporarily increased until the proposals were converted into a formal agreement. While a number of uses were restricted, companies consume significant quantities for non-restricted applications, especially in the manufacture of formulations which are exported to countries outside the EU. In the years before the introduction of the marketing and use restrictions, there were notable increases in sales – downstream users of the substances are believed to have been stockpiling the substance before the restrictions came into force.

At least in some industry sectors the 'imaginary pressure' on a substance plays an important role. Confirmation that a substance fulfils the SVHC-criteria alone gives not enough reason to take action if no drastic measures are expected. From this the question arises how high companies or sectors will rank the probability of authorisation requirement for a listed substance within a relevant timeframe and what might influence this ranking. However, even if the probability is low, a high level of uncertainty may trigger long-term planning companies to apply for substitution.

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<sup>14</sup> change of the path

Very often companies try to demonstrate during the process that a suspected risk is low so that drastic risk management measures are not necessary. However, as long as they were not willing to support improved risk assessments by transparency, this behaviour only delayed the decision process.

**Conclusion:** *Companies act differently and pro-active behaviour does not always take place. Where alternatives to SVHC are available at reasonable costs, enterprises may consider switching to alternatives prior to regulatory action taking place; however, where such a change is not convenient for industry and or their customers, action may be postponed until it is practically unavoidable.*

## 3.2. WP3: Substitution in current legislation

### 3.2.1. How is substitution addressed in current legislation?

Legislation is found to be one of the most powerful drivers of substitution. In many cases substitution results as a side-effect even where it is not explicitly addressed as the main goal (Lohse et al. 2003). Thus, the concept of substitution is addressed in many legislative approaches at EU and Member State level, but often not directly. Different strategies to promote substitution of hazardous substances can be found.

The most stringent promotion is the restricted marketing and use of specific substances. Laid down in chemicals legislation M/Is and downstream users (formulators rather than users of preparations) are directly affected and forced to search for alternatives. In these cases authorities take the responsibility for risk reduction and the measures to be implemented. The legislative procedure is complex and often time consuming. Two general mechanisms are used for such restrictions:

- 1) Very hazardous substances are banned for use in those applications where they pose an unacceptable risk.
- 2) Active substances in plant protection products, pharmaceuticals or biocides may only be marketed and used after authorisation. For biocides, authorisation already includes socioeconomic analysis with regard to the societal need for the substance and available alternatives<sup>15</sup>.

Compared to restriction other legislative approaches show much lower incentives for substitution. Substitution of hazardous substances by less hazardous substances is often only required "if technically and economically feasible", which gives room for interpretation. This way responsibility for risk management is partly transferred to industry, where various factors may influence decision making and the behaviour of the actors concerned.

Frequently indirect restrictions are set by "down-stream legislation" related to environmental protection or occupational health (e.g. VOC Directive, carcinogens at

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<sup>15</sup> It needs to be considered that for active substances a high diversity is wanted to maintain the possibility to react on resistant organisms. Thus phase-out of active substances is not generally aspired.

work). Without prohibiting specific substances in general, the use of substances with certain intrinsic properties identified by risk phrases is limited or connected with a high level of risk management. In addressing the users of chemicals by regulatory measures authorities promote the use of less dangerous chemicals and may thus trigger a pull towards the development of less hazardous chemicals by the chemical manufacturers. However, this approach is rather hazard based and may result in shifts of risk, which conflict with an overall target of risk reduction. For certain product groups or applications, the national authorities take the lead to work out detailed requirements and recommendation on the available substitutes, like for example in the German TRGS 600 series<sup>16</sup>.

In some legislation, substitution of hazardous substances is introduced as a general rule or a duty to consider alternatives (e.g. Swedish Chemicals Act, German Dangerous Substance Ordinance, IPPC), but to make good choices remains at company level. In a way these rules give room for risk based considerations, however, experiences showed that SME often lack competence to identify alternatives, to carry out comparative assessment of substance or to develop and implement risk based substitution strategies. Therefore authorities and associations put effort into the development of easy applicable instruments for industry (e.g. TRGS 440 and the column model<sup>17</sup>, COSSH essentials<sup>18</sup>).

### **3.2.2. Overlaps with existing legislation and newly introduced requirements by REACH with regard to SVHC**

The general principle of differentiation between a restriction/authorisation approach by authorities (safety net) and a risk management approach at company level (CSR and DU CSR) for non restricted substances is included in REACH. However, the responsibility of industry is emphasised and better defined in REACH through communication duties in the supply chain.

The REACH authorisation scheme potentially includes substances which have been hardly regulated yet (many PBTs, vPvB and substances with equivalent level of concern) or where risks may be not adequately controlled yet (e.g. CMRs in wide dispersive uses).

The candidate list will represent an indicative list, which is only based on intrinsic properties of substances (hazard approach), but without legal consequences if companies continue the use of the substances listed (as long as they comply with existing legislation and REACH requirements: to notify to the Agency the presence of SVHC in articles (Art. 7.2) and to inform the recipients of the article about the safe use of SVHC (Art. 33), see below). This is quite similar to the current Annex I of Directive 67/548/EEC, which lists the CMRs agreed at EU level, but does not directly restrict their use. However, other criteria of very high concern like PBT, vPvB and endocrine disrupting properties cannot be assigned to definite risk

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<sup>16</sup> TRGS: German technical rules for hazardous substances: The TRGS 600 series restrict the use of various dangerous substances in specific applications and suggest alternatives (see Annex IV)

<sup>17</sup> the TRGS 440 and the column model give advice on how to compare dangerous properties of alternatives and support this way companies in decision making (see Annex IV)

<sup>18</sup> COSSH –Control of Substances Hazardous to Health Regulations (United Kingdom)

phrases and thus the approach of classification and labelling is not suitable for an indicative list including these SVHC. The candidate list thus provides the opportunity to make these substances accessible to downstream legislation. In addition it can be also expected that under REACH the possibility that substances on the candidate list become subject to authorisation is regarded as quite concrete compared to current procedures on risk assessment and risk reduction for existing substances. And this is an aspect relevant for the whole supply chain.

From a legal aspect the candidate list is linked with the introduction of new communication requirements for articles (Art. 33). This means article producers have to indicate to the recipient if an SVHC is contained above 0.1% (including necessary risk management measures) and the article users get the opportunity to compare articles with regard to the content of SVHC.

Currently substance related risks resulting from the use in articles are no general subjects to chemicals legislation, the marketing and use restrictions cover only a few specific cases. However, under the General Product Safety Directive industry is already responsible to ensure that the use of products may cause no risks for health and/or the environment. Thus, the newly introduced requirements together with potential authorisation duties might close the communication gap between the producers of (consumer) end products and the producers of preparations and article components up in the supply chain.

**Conclusion:** *With the candidate list identified PBTs, vPvB and endocrine disruptors, which cannot be identified by a set of risk phrases, may also become accessible to downstream legislation. Connected with the candidate list is a new communication requirement for SVHC in articles which may support substitution efforts in this area. The possibility that listed substances become subject to authorisation may exert additional pressure on the whole supply chain.*

## 4. Conclusions

Based on the results each work hypothesis has been verified to what extent they were supported or disproved.

### 4.1. Hypotheses supported

#### 4.1.1. Hypothesis 1: State of play

As described in this hypothesis the market actors in the EU are quite aware of CMRs, but less aware of PBTs, vPvBs and substances with equivalent level of concern. A number of indicative lists exists referring not only to legal requirements, but indicate also upcoming requirements or substances of which the use

should be limited in order to reduce the risks for people and the environment. These lists are widely used by companies to deal with the challenges of substance related risk reduction. All experts expect that the candidate list will be used in a similar way as the existing indicative lists. Especially companies representing the end of the supply chain are highly interested in an EU wide harmonised list of substances regarded as very problematic.

With regard to the different roles in the supply chain, it seems as if it will be mainly the task of formulators to substitute SVHC in their preparations and that they will often react to a strong demand by their customers. It is yet not clear to what extent M/I of chemicals will invest in the development of alternatives.

#### **4.1.2. Hypothesis 2: Companies will look at the candidate list and consider it in their product development**

Most of the interviewed experts expect that many companies will deal with the candidate list as they do now with the existing lists like OSPAR, LOUS and PRIO. This includes companies providing branded consumer articles (textiles, cars, toys, etc.). It is questionable whether they will replace their current lists, as these cover many more substances, at least during the phase-in period of REACH and current legal and voluntary requirements with regard to articles go partly beyond REACH (e.g. limit concentrations for textiles in voluntary labels are in the range of ppms). Since the candidate list will be publicly available, companies in proximity to the consumer in particular will react in the same way as they did with regard to OSPAR and PRIO-substances. However, the criteria are overlapping and these companies have to anticipate a need for additional action predominantly for newly identified SVHC based on new testing results<sup>19</sup>. Furthermore it can be expected that branch-specific instruments will transfer the relevant substances from the candidate list to their own list. As many of these lists already include CMRs, which are covered by downstream legislation and can be easily recognised by risk phrases, additional announcement effects will be limited to PBT/vPvB-substances and substances with an equivalent level of concern.

It should be stressed that companies will often not behave pro-actively if they see no incentives (like a strong customer demand or the potential to capture new markets) to invest in risk reduction as long as it is not legally required. The incentives might not exist or the companies might not be aware of them. They will rather sit and wait until they are forced to react, because they rank the risk of ineffective substitution efforts higher than loss of business due to delayed activity. This is especially the case if companies fear to lose their business due to high prices or low performance of the substitute. Therefore companies often state that they would prefer a substance ban over an indicative list or voluntary action to ensure a level playing field.

It is questionable whether additional companies and branches will make efforts to implement the candidate list into their daily routines if consumers are not affected directly, as it is not legally binding. This could happen if the potential for authorisa-

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<sup>19</sup> the retailers interviewed expected the number of newly identified SVHC to be low and thus the additional announcement effect to be limited. However, no reasoning was given.

tion is regarded as a strong incentive for existing products and especially for products under development. From the findings in WP 2 it seems that the level of risk management in the company triggers the probability that a company is capable and willing to consider the information from the candidate list in decision making.

#### **4.1.3. Hypothesis 4: Importers, producers and professional recipients of articles will prefer articles without SVHC**

This hypothesis was at least confirmed for consumer articles. As mentioned before retailers and owners of consumer brands may demand SVHC-free products from their suppliers to ensure product safety and give NGOs no reason for criticism. In addition for suppliers the pressure increases to provide respective information on SVHC contained in articles (according to Art. 33) at least for the supply of article parts which are further processed inside EU. Thus, companies might be notified of SVHC they did not yet expect in their products (this is especially expected for PBTs and vPvBs) and they will have to decide how to deal with it.

Some retailers were worried that the candidate list could be too large to be manageable for supply chain communication and in particular for checking compliance through product and supplier inspection. With regard to this problem, the KEMI expert proposed to include information on uses in the candidate list to enable companies to focus on substances relevant for their specific applications and some retailers identified the need to group their products according to the probability of the presence of specific substances. It is not clear, though, whether this would be of much assistance to retailers dealing with very large numbers of product lines to be checked.

On the other hand some interview partners were doubtful whether the article requirements can be implemented for imported articles. Retailers experienced that many Asian suppliers normally agree to the supply commitments regarding substances and concentration limits, but often do not take them serious and the provided products do not comply. For example, the limitations for Cadmium are often exceeded in imported articles<sup>20</sup>. As enforcement is difficult, retailers without sensitive brands or reputation issues might continue their business without making additional efforts and this would remain undetected.

## **4.2. Hypotheses disproved**

### **4.2.1. Hypothesis 3: Industry will try to demonstrate adequate control of identified threshold SVHC during registration**

This hypothesis was not supported and some examples from risk reduction strategies, risk assessment of existing substance and other substitution cases describe rather the opposite effect. Information provided by industry is often not transparent and not sufficient to disprove concerns and thus only delays the process. It re-

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<sup>20</sup> If this is detected by customs the goods are restrained at the border and may not be marketed

mains questionable whether an imminent authorisation will represent stronger incentives than the other legal options. This will be most relevant for the procedure of the selection of substances subject to authorisation, where the Agency has to invite all interested parties to submit comments on its recommendation in particular on uses which should be exempt from the authorisation requirement (Article 58(4)).

### **4.3. Hypotheses with mixed results**

#### **4.3.1. Hypothesis 5: Innovative alternatives not using identified SVHC will be promoted**

This hypothesis is indeed supported to a certain degree as substitution will be promoted in the way described above. However, besides the general incentives to substitute, the candidate list implies no standard mechanism to make alternatives known beyond what is already known. It also does not influence the direction of substitution. DUs need to enquire pro-actively about alternatives if they decide to stay away from a listed substance (see 3.1.1.3) and it remains up to them to compare solutions based on the risk information provided with the safety data sheets and exposure scenarios by the suppliers. The candidate list does not provide recommendations or platforms to promote alternatives.

#### **4.3.2. Hypothesis 6: The candidate list provides a harmonised tool for prioritisation of substances**

While NGOs and authorities expect that the candidate list will harmonise identification and handling of very hazardous substances, many companies and associations remain sceptical. Advocates stated that the substances will be selected scientifically, based on a systematic process and there will be no doubts about their status. The potential authorisation should be incentive enough to aim at phase-out of the substances where possible. Finally the candidate list provides a priority list which should be acceptable by all stakeholders. Opponents fear that the candidate list will represent just an additional list of mixed legal and non legal approaches to be considered. The uncertainty with regard to the probability (and timing) of authorisation will raise additional confusion and make business less predictable. However, the opponents did not explain how the candidate list can cause more confusion than the criteria of Article 57 alone.

#### **4.3.3. Hypothesis 7: With the candidate list the actors in the supply chains get time to identify optimum solutions**

In general it is clear that complex and successful<sup>21</sup> substitution processes take time and authorities and NGOs agree that an indicative list provide the opportunity to behave pro-active and make use of the remaining timeframe. However, it is not

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<sup>21</sup> with regard to risk reduction and economic survival of the providers

clear to what extent industry will invest in pro-active search for alternatives if a substance is put on the candidate list, as long as it is questionable whether or not a substance will be selected for authorisation procedure. If furthermore downstream users do not exert pressure on the supply chain, the incentives for actors to induce supply chain communication aiming at substitution is probably low. An additional supporting or inhibitory factor may be the experience made during the preparation of a registration dossier in a specific supply chain.

#### 4.4. Recommendations

With regard to the candidate list several recommendations were made by the experts interviewed and derived from the findings of the study.

Substitution of an identified SVHC, if not well thought through and through based on comprehensive information, may lead to higher risks if

- a) the alternative is more dangerous than the SVHC;
- b) the alternative has different properties regarding mobility and therefore causes higher exposure levels

Where as case a) should in general be considered in risk assessments and the information should be available, case b) may happen because of lack of data: During the phase-in scheme substance information is generated over time. In general, for low volume substances data gaps may remain due to reduced testing requirements.

It was mentioned that a candidate list based on properties is a hazard based approach not a risk based approach. Changes in processing methods associated with the move to a substitute may result in an increased emission of hazardous substances, which do not fully meet the SVHC criteria. In this context some of the interviewed authorities and NGO experts recommend providing also guidance for actors willing to substitute the listed substances. This includes explanations on how SVHC may pose risks to health or the environment. In addition guidance on comparative risk assessment and information on suitable and maybe non suitable alternatives to specific SVHC should be provided.

Furthermore it was recommended including the following information in the candidate list:

- Besides the classification and labelling of the SVHC additional information on substance properties should be provided. This includes environmental fate and behaviour, PNECs and DNELs and the information whether or not a substance has a quantifiable toxicological threshold. However, NGOs do not support the last aspect, since they are sceptical with regard to the approach of adequate control for SVHC and prefer not to distinguish between SVHC with and SVHC without threshold.
- It was recommended including information on typical uses in order to allow the actors down the supply chain to identify the substances relevant

for their uses and to narrow down their screening for SVHC in their products.

It was a controversial discussion as to how many substances should be listed on the candidate list within a certain timeframe:

- i) *The candidate list should be completed as soon as possible.*  
**Pros:** On a long list many SVHC are identified and published at an early stage and can be considered by all actors including the actors selling SVHC containing articles.  
**Cons:** The assumed legal pressure to substitute a single SVHC would decrease, because only a limited number of substances can be processed by the Agency in the authorisation procedure. However, the pressure increases for substances fulfilling the prioritisation criteria according to Article 58). Thus uncertainty for companies may increase on whether or not investment in substitution will be reasonable.
- ii) *Substances should be put on the candidate list in a way that the number of substances is not much higher than the number that can be processed for authorisation within the next period.*  
**Pros:** With a short list the probability would increase that the substance listed becomes subject to authorisation. This gives a clearer signal to the market and thus the legal pressure toward substitution would increase.  
**Cons:** Many SVHC remain unconsidered for a long time and are not part of the communication requirements for articles. In addition uncertainty for companies may increase with regard to substances not yet identified as SVHC: The risk is increased that misleading information or a prioritisation based on insufficient analysis could trigger unjustified and potentially negative market effects, before the substance is analysed in a careful manner and together with its (potential) alternatives.

The process of the selection of SVHC for the candidate list needs to be transparent and comprehensible. As it was shown in many cases that substances which have been selected cannot be easily de-selected if new data disprove a suspected hazard, decision making should be carried out carefully and based on reliable data. However, a transparent and comprehensive selection should enhance acceptance of the candidate list by industry and improve opportunities to pre-estimate future requirements.

Furthermore a communication gap was identified with regard to communication requirements for preparations where a safety data sheet is not required (Article 32). While information on substances subject to authorization or restriction need to be submitted even without an SDS, SVHCs do not need to be identified to the downstream user of the preparation. Including information on SVHC above 0.1% (w/w) in the communication requirements for preparations would improve communication about SVHC in the supply chain and enable downstream users to compare and decide for SVHC-free products.

## 5. Summary of findings

How fast and how complete substitution takes place after a substance is prioritised by an indicative list is influenced by different factors. While some companies replace the substance in question immediately, others try to use them as long as possible before legislation or industrial agreements come into force. Substitution of SVHC is supported for example by the following factors:

- **Market pressure towards substitution:** Especially downstream users and retailers producing and selling consumer products are sensitive to hazardous substances and require their suppliers to exclude them from their products. However, others may not be aware of the substance in the products they use or are not involved because they are outside EU.
- **NGOs campaigns** may influence consumer behaviour. Thus companies selling consumer products and brands show increasing openness for communication and willingness to exclude hazardous substances from their products. By publishing company policy statements and product policies they demonstrate awareness and responsibility.
- **Companies want to prevent damage to reputation.** This is a strong incentive for all actors in the supply chain to ensure product safety and to cooperate with NGOs in the context of substance related risks. This is most relevant for owners of consumer brands and for enterprises, which demonstrate in their policy a high level of awareness with regard to environmental, health and social issues.
- **Suitable alternatives are available.** This implies a good performance of the resulting products and low additional costs for the substitutes and/or connected risk reduction measures and is of particular relevance for the formulators.
- **Acceptance of the identified risks in the sector:** e. g. companies may not agree with the risk conclusion or cannot understand the meaning of it. Thus, assumed disadvantages of the alternatives are not accepted.
- **Enterprises aim at increased company reputation and brand recognition** if they provide ideal solutions for substance related risks. This is also an incentive for substance manufacturers to search for alternatives.
- **A high level of risk management in the company/supply chain:** If risk reduction is already part of the management system and/or supply chain communication risk based decision making and non voluntary commitments are often more easy to implement.
- **As legislative pressure** is found to be one of the most powerful in driving the companies, the probability of actual drastic measures like restrictions or authorisation will push companies towards substitution.

We found several examples that putting a substance on a hazard based list is not sufficient to raise awareness amongst users and to support demand for risk management. Indeed also the downstream users with low expertise will get the infor-

mation that the substance is not wanted. However, but without further explanation they might not make the best decisions with regard to risk reduction.

Finally the extent of the announcement effect will depend on what the mass-markets of downstream users and recipients of articles and retailers will request from their suppliers with regard to SVHC.

## Annex I: Work hypotheses

### HYPOTHESES 1: STATE OF PLAY

#### SUBSTANCES

Substances that will be on the candidate list of substances subject to authorisation are CMR 1+2, PBT/vPvB and other substances of equivalent concern. However, prior to a decision to include substances in Annex XIV, the Agency shall recommend substances from the candidate list prioritised according to Article 58(3):

- (a) PBT or vPvB properties; or
- (b) wide dispersive use; or
- (c) high volumes.

#### CMRs Cat 1+2

CMRs Cat 1+2 are already highly regulated, e.g. through worker protection legislation as well as chemicals legislation (no use in consumer products, further restriction for certain products). Classified CMRs are to be declared in preparations even in low concentrations.

Current legislation on CMRs is in place already and enforced by Member States. The effect of the candidate list can only be regarded as either a) further enhancing the need to take action and opening windows of opportunities for manufacturers of alternatives or b) no effect, as current legislation has already led to optimal control and substitution efforts have been unsuccessfully made.

#### PBTs/vPvBs

Only very few substances are acknowledged PBTs/vPvBs at the moment. In addition, awareness about that group of substances is low. Potential PBTs/vPvBs currently fall under environmental legislation, if they are classified as N, R50/53; only a few are addressed in the Water Framework Directive or the POP-Regulation. Under REACH, PBTs/vPvBs will be a priority for moving from the candidate list to Annex XV (Article 57(3)).

The effect of the candidate list could be a) further enhancing the need to take action on substance which are already regulated under existing legislation or b) awareness rising and improved risk management for PBTs/vPvBs which are not already regulated; c) ceasing of supply (M/Is) or d) cessation of demand (DUs) due to fear of losing markets; e) no effect or a partial effect (amount used may be reduced, some uses may stop while other continue), as substances are regarded essential and risk management measures already applied are regarded as sufficient. As an accompanying effect in the cases a) to d) manufacturers of alternatives may have better business opportunities.

### **Substances of equivalent concern**

At present, it is not clear which types of substances, apart from EDCs, would be of "equivalent concern". Respiratory sensitizers, classified as R42, are one group of substances which might be considered. In the case of EDCs, they might be classified already for other endpoints and, in this case, they are already regulated by existing legislation. It is likely that companies will be following the debate on EDCs and thus aware of those which are not also CMRs Cat. 1+2 but may believe that evidence is too weak to justify the inclusion of the substance on Annex XIV. However, in the absence of a clear pathway for regulatory action, and/or customer pressure, they may be doing nothing as yet. With the candidate list and the authorisation procedure REACH may provide the clear pathway, and thus encourage earlier action.

The effect of the candidate list for substances of equivalent concern may be a) enhancing the need to take action under existing legislation or b) awareness rising and improved risk management for EDCs which are not already regulated; c) ceasing of supply or d) cessation of demand due to fear of losing markets; e) no effect or a partial effect (amount used maybe reduced, some uses may stop while other continue) as substances are regarded essential and risk management measures already applied are regarded as sufficient. As an accompanying effect in the cases a) to d) manufacturers of alternatives may have better business opportunities.

### **EXISTING SUBSTANCE LISTS AND THE CANDIDATE LIST**

Substance lists are already part of European Legislation. For example substances classified as dangerous are listed in Annex I of Directive 67/548/EEC and classified CMRs Cat. 1+2 are also listed in the Directive on marketing and use restrictions (76/769/EC). The Water Framework Directive contains a list of priority substances and the POP Regulation (850/2004) transfers the list of persistent organic pollutants into European legislation. However, the legislative consequences of these lists are different. The Annex I of Directive 67/548/EEC affects mainly DU legislation and the effect on the market is rather driven by the demand. Directive 76/769/EC and the POP Regulation ban substances from all or specific uses. The Water Framework Directive aims at phase-out of priority hazardous substances and at emission reduction of priority substances to achieve specified environmental quality standards.

Besides this, various lists which are not legally binding indicate substances of concern which are part of regional, national or global working programs and thus may be regulated in the future. This includes the priority lists in the Existing Chemicals Work Area (Council Regulation 793/93), the EU-PBT-list, lists of marine conventions (OSPAR and HELCOM) as well as national lists (e.g. Swedish OBS list, UK Defra list of active substances, Danish list of undesirable substances).

In addition, some industry sectors and retailers use lists as part of their trade contracts in order to comply with legislation, to ensure that specific quality standards can be achieved and to avoid unwanted hazardous substances in their products and processes.

Indeed the criteria for SVHC are well known and do not represent a new approach. But the various existing legislative and non-legislative approaches did not yet succeed to identify and communicate all SVHC in use and ensure their safe handling. With the new candidate list and the obligation to generate information on substance properties, SVHC will be identified systematically and based on verified intrinsic properties (dossier). Moreover, they will be collected in one single list and made accessible to everybody.

For M/Is, formulators and industrial users the candidate list for authorisation is comparable to the legally non-binding lists. If a substance is included in the candidate list, it may become part of a working program and may have to be authorised for use in the future. Many of the future candidate substances are currently regulated under different legislation. This will complicate the assessment of the reactions to of industry actors to the candidate list. For producers and importers of articles, the candidate list is a more legislative instrument, indicating substances for which there are notification and communication duties with regard to articles.

There will be a time and 'magnitude' dynamic depending on the number of substances that are placed on the candidate list, the number of substances that are placed on the Agency's work programme per annum and thus the real threat that authorisation is imminent. If 1000 substances are placed on the candidate list, then a weak response has to be expected. The threat may be regarded as too far off in the future to worry about. If only 100 substances are placed on the list, then the threat is more real and imminent (e.g. within 5-6 years if between eight and 25 substances are added to Annex XIV in a given year). This effect would impact on manufacturers/importers, formulators and industrial users, albeit in potentially different ways.

## **MARKET ACTORS**

M/I, formulators and end-users as well as chemicals distributors and producer/importers of articles may have different reactions to the candidate list.

### **Manufacturers/Importers (M/Is)**

M/I may manufacture/import substances of which they already know fulfil the criteria for SVHC. In addition, they may identify substances as being SVHCs in the process of collecting hazard data for registration. When carrying out a hazard assessment, they will generate information on whether or not these substances do or do not have an effect threshold for which adequate control can in principle be shown. When registering in low volume bands, they may identify their own substances as SVHC (in particular PBT/vPvB and substances of equivalent concern) through the candidate list.

Even applications of well known SVHC are often not well understood. Under REACH, M/Is preparing a CSR for an identified SVHC will have to analyse their customers' uses and define conditions to ensure adequate control for threshold substances. For non threshold substances, they may pre-estimate whether socio economic benefits can be brought forward, in case the substance is prioritised for authorisation.

For M/I, the candidate list will have a limited information effect, as they mostly identify SVHC themselves in the registration process. The decision on their registration strategy, however, will be influenced by the candidate list, as M/I will anticipate the reaction of their clients to that list. The options M/I has are a) not to register SVHCs; b) register SVHCs where substitutes within own product portfolio are not available (if appropriate only for certain uses like industrial but not professional use or exclude the use in consumer articles) and provide a complete service to the customers; c) register SVHCs for those uses that may be exempted from authorisation (due to other regulation etc.); d) register SVHCs for any use and wait to see how the market will develop; e) register SVHCs and wait to see Agency's work programme. With option a) a manufacturer or importer may decide to no longer supply the SVHC in question also without offering (nearly) the same functionality to its customers. They may do so because of the (anticipated) registration costs, the (anticipated) outcomes of the tests (specifically for a substance which had not been suspected to be a SVHC) and the (anticipated) reactions of their customers on the new information and or on any price increase. This would mean that the number of suppliers falls or that the SVHC will not be supplied to the EU market any longer

### **Formulators**

Formulators will be aware if they use already classified substances fulfilling the criteria of an SVHC in the case of CMRs cat 1+2. Other substances fulfilling the criteria of Article 57 will be made known to them indirectly via the (eco)toxicological information in the safety data sheet of their suppliers, if they are obtained as single substances. (Eco-)toxicological information may not be provided for components of a preparation used as raw material. In these cases, formulators can identify SVHC by name or registration number if they are included in the candidate list. A specific substance on the candidate list will normally enter the candidate list after the formulator receives the first REACH safety data sheet, as the formal identification procedure may cause a short delay.

For formulators, the candidate list may have an informative effect, in particular with regard to preparations used as raw material. The decision on whether or not formulators will consider taking action will be influenced by the candidate list, as formulators will anticipate the reaction of their clients and their suppliers to that list. The options the formulator has are to a) assess possibilities to substitute the SVHC and decide on reformulation; b) re-design their preparations with the aim of reducing the concentration of SVHCs c) do nothing as SVHCs are already used in very low concentrations only; d) find out whether the own uses may be exempted from authorisation (due to other regulation etc.); e) await the decision on actual inclusion of the substance in Annex XIV. A formulator may notify the use of a substance with or without a CSA depending on volume (and also apply for authorisation when the time comes).

### **Industrial end-users**

Industrial end-users, including producers of articles, may frequently not know whether they are using SVHC. They also most likely lack the expertise to judge if a substance fulfils the criteria of Article 57 or not based on (eco)toxicological information. In addition, they may not know whether substances contained in the preparations they use have to be considered as SVHC. Thus, for industrial end-

users, the candidate list will be an important information source to identify SVHC by name or registration number.

The decision on whether or not they will consider taking action will be influenced by the candidate list, as they will anticipate the reaction of their clients and suppliers to that list. The options the industrial end-user has are to a) assess possibilities to substitute the SVHC or the SVHC containing preparation and decide on redesigning products or processes; b) do nothing as SVHCs are already used in very low concentrations only; c) await the decision on actual inclusion of the substance in Annex XIV. A DU may notify the use of a substance with or without a CSA depending on volume (and also apply for authorisation when the time comes).

### **Importers/producers of articles**

Importers generally do not even get information on the identity of substances contained in their imported articles, because their suppliers are not obliged to provide this information. For both article producers and importers, the candidate list is needed to identify notification duties according to Art. 7(2) and communication duties according to Art.33. It would not be manageable for them to identify these duties without the candidate list, based only on the criteria of Art. 57.

Importers and producers of articles are obliged to consider the substances on the candidate list. They have the option to a) request suppliers through their contracts to declare SVHC contained in articles based on the candidate list and b) decide to notify and communicate them as required and/or c) assess possibilities to replace the SVHC or the SVHC containing (part of the) article; d) do nothing as substances is below concentration limits of concern; e) ask for product re-design to reduce concentration, etc.

## **HYPOTHESES 2: COMPANIES WILL LOOK AT THE CANDIDATE LIST AND CONSIDER IT IN THEIR PRODUCT DEVELOPMENT**

The candidate list can be seen as an easy assessment tool for prioritisation of substitution and risk management efforts before legal requirements come into force. Companies will avoid selling or using substances identified as SVHC. For research and development, the list will function as an additional (maybe priority) criterion for the choice of substances with a specific function. Connected with the potential for authorisation and the notification and communication duties for articles, the candidate list will increase the pressure on companies, especially DUs, to look for alternatives.

In general, alternatives may cover the whole spectrum of risk management measures including improved end-off-pipe measures, integrated measures or closed systems/automatic processes, in which the SVHC is still in use with a minimum level of exposure. However, many DUs will have difficulties in predicting if they are able to fulfil the technical and organisational conditions for authorisation. Therefore they will prefer substitution of substances or processes so as to become independent of the identified SVHC.

Otherwise for products with a high level of standardization (e.g. automotive, aircraft, medical devices) substitution is a complex process of reengineering and new qualification of products. In such cases the costs of alternatives can exceed the costs of authorisation by far.

In both cases the candidate list indicates the possibility of enhanced requirements, but allows a much longer period for preparing and balancing between different solutions than the authorisation procedure.

### **HYPOTHESES 3: INDUSTRY WILL TRY TO DEMONSTRATE ADEQUATE CONTROL OF IDENTIFIED THRESHOLD SVHC DURING REGISTRATION**

Since authorisation aims at limiting remaining risk due to the use of SVHC, M/Is will make efforts to demonstrate adequate control of identified threshold SVHC when preparing the CSR and the exposure scenarios supported by DUs. Although there is no formal mechanism for it, they may aim to show that authorisation requirement can be dispensed with for specific uses, or the SVHC in general, and the Agency may prioritise SVHC for authorisation of which uses are not already adequately controlled. However, it is not yet clear whether the candidate list will include information on whether a substance has a quantifiable toxicological threshold or not.

### **HYPOTHESES 4: IMPORTERS, PRODUCERS AND PROFESSIONAL RECIPIENTS OF ARTICLES WILL PREFER ARTICLES WITHOUT SVHC**

If SVHC are contained in articles ( $\geq 0.1\%$  w/w), notification requirements according to Art. 7(2) may become relevant. Importers and producers of articles will work with the candidate list to exclude SVHC from their products and to avoid notification duties. Importers may request their non-EU suppliers to exclude SVHC from articles purchased, while EU article producers may choose raw materials not containing SVHC.

Another incentive for producers/importers of articles to avoid these substances is the duty to communicate the presence of SVHC and necessary RMM to the professional recipients of the article (Art. 33). Distributors may exclude those substances from their goods by including the candidate list in their trade contracts. Especially importers of consumer products will refuse to buy and trade such products, if they fear damage to their corporate image. Retailers of consumer products will have the same interest but, however, would not receive such information if they were not included in the definition of article recipients.

The authorisation process alone will not have such an effect because communication requirements do not cover articles.

### **HYPOTHESES 5: INNOVATIVE ALTERNATIVES NOT USING IDENTIFIED SVHC WILL BE PROMOTED.**

In general all actors will think about replacing SVHC. Thus, products without the stigma of SVHC and potential authorisation should get better chances on future markets. By introducing the candidate list, many more substances will be covered than by authorisation alone. However, as pointed out before in hypothesis 0, for products with a high level of standardization implementation of alternatives remains complex. The candidate list may support companies in their search for business opportunities.

### **HYPOTHESES 6: THE CANDIDATE LIST PROVIDES A HARMONISED TOOL FOR PRIORITISATION OF SUBSTANCES**

As described in hypothesis 1 many "black lists" or "grey lists" of substances are published and in use within the EU. Companies often have great difficulty in deciding which of the criteria are justifiable and/or fulfilled and how to focus on the most relevant substances. The candidate list provides a prioritisation tool based on EU-wide agreed criteria for health and environment. However, if the number of candidates is high, then companies will still have great difficulty in deciding where to focus their efforts, particularly if they rely on several/many listed SVHC.

After the registration of phase-in substances is completed, the candidate list will document a standard of knowledge about SVHC. However, further amendments can occur by newly registered substances, newly generated information or substances manufactured or imported below 1t/a, which can still undergo the identification procedure (Art. 59) and thus be placed on the candidate list.

### **HYPOTHESES 7: WITH THE CANDIDATE LIST THE ACTORS IN THE SUPPLY CHAINS GET TIME TO IDENTIFY OPTIMUM SOLUTIONS**

If a substance in use becomes subject to authorisation, the best solution will be influenced by several factors. Not only economic aspects, but also aspects such as transfer of risks, efficiency of the processes, availability of the substances, timeframe, competences of the users, demand for the product etc. have to be taken into account to decide between authorisation of the SVHC and the potential alternatives. Since the various interests and information are distributed over the whole supply chain, sound solutions will be facilitated if companies along the supply chain co-operate. Through the candidate list, the actors in the supply chain will get a signal to start necessary data collection, negotiation and consideration. This way they get the chance to develop a strategy and to have optimum solutions prepared when the authorisation procedure starts.

## Annex II: Substance lists

List	Content of the list
OSPAR's list of substances of possible concern by the OSPAR Commission. The Commission is made up of representatives of the Governments of 15 Contracting Parties and the European Commission, representing the European Community.	Contains about 390 substances suspected to be persistent, toxic and liable to bioaccumulate or suspected to have endocrine disrupting properties. The list was set up based on intrinsic properties only.
OSPAR list of substances for priority action (OSPAR Strategy with regard to hazardous substances)	36 substances or groups of substances have been selected from the list of substances of possible concern on a risk based approach. For these substances measures have been worked out under OSPAR, aiming at cessation of emission, discharges and losses. Substitution is regarded as one suitable measure among others.
Guidance Document on the Appliance of Substances under special attention in Electric & Electronic – Products This guidance document composed in close collaboration of European organizations (CEFIC, EECA, EICTA and EU-ROMETAUX = Chemistry for Electronics) aims to give users and companies comprehensive and practical information about chemicals. Nov 2000	Certain chemical substances in electric and electronic products (E&E) could be the subject of special attention about their possible impact on human health and/or the environment. This guidance document covers both established properties and the status of assessments currently underway. It should thus raise the awareness of those involved in the various stages of the product-life-cycle, through providing appropriate advice about efficient risk management, pass on to them in a responsible way the information which they need. 14 substances are named
List of undesirable substances LOUS (2000, revised 2004), The Danish Environmental Protection Agency	The basis for the selection of undesirable substances was the "effect list" including chemicals with possible future risks, independent of the production figures (ca. 6400 substances). In LOUS have been selected due to their very hazardous properties (based on R-phrases): CMRs, CMRs Cat 3, substances very toxic to the environment, PBT, vPvB, endocrine disruptors, priority substances under the Water Framework Directive (80-100 substances). Both lists are indicative and show the supplier and the user which substances might become more strictly regulated in near future. The lists provide an information tool that enables e.g. enterprises or authorities to get aware of substances of concern which are not yet or not sufficiently regulated or which are subject to further investigations.
Observation List (1998), Swedish Chemicals Inspectorate [KEMI] Publication from the National Chemicals Inspectorate that contains criteria for substances requiring special attention and a list of examples of substances that meet these criteria.	250 particular hazardous chemicals KEMI recommends to seriously reconsider the use in products and processes.
PRIO is a development of the Observation List and replaces it.	

## Annex III: Interview partners

Can be provided on request

## Annex IV: List of legal substitution requirements in the European Union

Legislation	Short description	Substances/criteria	conditions	Reported effects +/-
Stockholm Convention Persistent Organic Pollutants	The Stockholm Convention is a global treaty to protect human health and the environment from persistent organic pollutants (POPs).	aldrin, chlordane, DDT, dieldrin, endrin, heptachlor, mirex, toxaphene, polychlorinated biphenols or PCBs, hexachlorobenzene, dioxins and furans	Substances are prohibited with some exemptions	Included in REACH
Directive on classification and labelling of dangerous substances 67/548/EC, Annex I	Substitution is not addressed, however, the harmonised classification has impacts on the relevance for other legislations	Annex I to Directive 67/548/EEC contains a list of some 8000 "existing" and "new" dangerous substances for which classification and labelling have been agreed at Community level	Indirect substitution effects through other legislation especially downstream	
EU Existing Substance Program Regulation 793/93	The Regulation sets up a program designed to identify and control the risks posed by some of the existing chemical substances listed in EINECS (European Inventory of Existing Commercial Chemical Substances).	Risk assessment and – if necessary risk reduction – of prioritised substances requiring immediate attention because of their potential effects on man or the environment.	Assessment carried out by the Competent Authorities of the Member States. Industry is required to provide necessary information.	Results of the assessment process are several restrictions under Directive 76/769/EEC. However, less than 150 substances have been assessed yet.
Directive 90/394/EEC on the protection of workers from the risks related to the exposure to carcinogens at work	Protection of workers from the risks related to the exposure to carcinogens at work	Substances and preparations which "may cause cancer" R 45	The employer shall reduce the use of a carcinogen at the place of work, in particular by replacing it, in so far as is technically possible, by a substance, preparation or process which, under its conditions of use, is not dangerous or is less dangerous to workers' health or safety, as the case may be.	
Directive 76/769/EEC on marketing and use restriction	Restricts the use and marketing of certain chemicals			The restrictions will be incorporated in the REACH Regulation as Annex XVII
EU Chemical Agent Directive (98/24/EC), Article 6	The general rule of substitution applies for workplaces in all EU Member States	Dangerous substances	<ul style="list-style-type: none"> <li>- substitution of hazardous substances by non hazardous or less hazardous agents or processes</li> <li>- minimise releases by engineering control including closed systems</li> <li>- take collective protection measures, like general ventilation</li> <li>- take individual protection measures</li> </ul>	

Legislation	Short description	Substances/criteria	conditions	Reported effects +/-
Directive 99/13/EEC (VOC)	Legislative instrument with obligation to substitute substances with specified toxicological properties.	Solvents, carcinogenic, mutagenic or toxic to reproduction according to 67/548/EC	Solvents in preparations that exhibit the CMR-properties have to be substituted.	
Directive 98/8/EEC on placing biocidal products on the market	Regulative instrument containing an obligation for comparative assessment within the procedure of uptake of an active substance in the list of allowed active substances within the authorisation process	Active substances in biocidal products	The criteria for substitution are evaluated in a comparative assessment which is focused on the question, whether a less hazardous substance with the same function and which does not lead to economic and practical disadvantages exists. The aspects to be considered for evaluation are described under Article 5(II) (1-4).	
Water framework directive (WFD) 2000/60/EC	Establishment of a <b>priority substance list in the field of water policy</b> . The substances of EU-wide concern were selected in a monitoring and modelling based risk ranking procedure and decided upon separately in Decision 2455/2001/EC.	Presently 33 substances (substance groups) are on the priority list (among the 10 pesticides). For a number of priority hazardous substances the Directive aims at cessation of emission until 2025	Environmental quality standards will be adopted for priority substances. Risk reduction measures have to be identified and implemented by the Commission to achieve the EQS and the cessation goal.	The current proposal for a Daughter Directive contains the EQS and delegates the responsibility for risk reduction to the Member States
Directive 96/61/EC on the integrated pollution prevention and control (IPPC)	the IPPC Directive is about minimising pollution from various industrial sources throughout the European Union. Best Available Techniques (BAT) are established for the most common industrial processes in Europe. Definition of BAT includes options to prevent pollution by "the use of less hazardous substances" in the processes.	Chemical substances	No hard criteria for substitution are described. The IPPC Directive refers to the emission control principle. Replacement of hazardous substances is mentioned among 12 other aspects to be considered when Best Available Techniques (BAT) are determined. Thus, substitution is not directly addressed.	During 2005, the Commission continued infringement proceedings against several Member States because of non-conformity of their national legislation with the IPPC Directive. The Commission sent reasoned opinions to Luxembourg and the Czech Republic and decided to refer France to the Court of Justice.

Legislation	Short description	Substances/criteria	conditions	Reported effects +/-
Directive 75/442/EEC	Establishes the "Polluter Pays Principle" and the possibility for Member States to develop market restrictions for products leading to waste problems upon disposal.	products leading to waste problems upon disposal	Restrictions for marketing of products are formulated, if release of hazardous substances can not be prevented during their disposal. Additionally, the Directive formulates the obligation for manufacturer to be responsible for their products also in the end-of life stage.	The Directive might force indirectly the substitution of products i.e. ingredients in products, with which an environmentally sound disposal is not possible.
Directive 2000/53/EEC End of life vehicles (ELV)	includes prohibition of certain heavy metals in cars imported to or produced in Europe with the aim to reduce risks related to the waste management of end of life vehicles	lead, cadmium, mercury and hexavalent chromium. Although other risks are mentioned the Directive does not contain other substances or specified criteria.	For some applications temporary exemptions are made. This Annex has to be amended on a regular basis according to technical and scientific progress. This makes the process towards substitution of the four elements lead, cadmium, mercury and hexavalent chromium rather dynamic	Car manufacturers in Europe have substituted the substances or changed the process to comply with the Directive.
RoHS (restrictions of hazardous substances in electrical equipment)	Prohibition of certain heavy metals and brominated flame retardants in electric and electronic equipment	Lead, cadmium, mercury, hexavalent chromium, penta- and octabromodiphenylether and brominated biphenyls		
Austrian Water Protection Act (Wasserrechtsgesetz + Verordnungen)	Legislation which restricts discharge of certain hazardous substances. Certain substances from specific industrial sectors are prohibited. Regulation that describes options how to prevent discharge of hazardous substances.	Includes e.g. halogenated compound in the production of paper, EDTA-containing waste water from metal surface treatment...)	(Best Available Technique). In this context specific substances from processes are not allowed to be discharged. Criteria applied for the prohibitions are not specified but might be arisen from pollution problems within water treatment plants. Substitution is regarded as a measure, but not obligatory	
German Dangerous Substances Ordinance (Gefahrstoffverordnung)	Applies a "substitution principle" as it mentions an obligation to substitute hazardous substances	Substitution of hazardous substances (based on classification) where this is necessary for preventing harm to workers health, provided that the less harmful alternative can be applied with reasonable (economic and practical) efforts. Additionally, the processes which are emitting hazardous substances should be substituted by processes from which no or less hazardous substances are emitted, where such measure is regarded as reasonable.	Several instruments exist to support the implementation of the substitution principle: Among them the technical rules TRGS 440 and the column model give advice on how to compare dangerous properties of alternatives and support this way companies in decision making. The 600er TRGS name substances to be substituted and how (see below)	Many companies make use of the provided instruments and have implemented the search for substitutes in their chemicals management. However, substitution is often hindered by lack of data for the alternatives. The criteria for the comparison of environmental risks are less developed (Subchem 2006, UBA 2003)

Legislation	Short description	Substances/criteria	conditions	Reported effects +/-
TRGS 600 Germany	The "technical rules for hazardous substances" regulate the placing on the market and the handling of dangerous substances. The TRGS 600 series restrict the use of various dangerous substances in specific applications and suggest alternatives.	e.g.: - Zinc chromates and strontium chromates as pigments for corrosion protection coatings - Hydrazin in water- und steam systems - strong solvent based pre-coats and alternative proceedings and glues for floors - dichlormethan (DCM) containing paint remover - chromate containing cements and chromate containing preparations - Azo-dyes, which can be split into carcinogenic aromatic amines - strong solvent based surface treatment agents for parquet and other timber floorings - Chrome(VI)-containing wood protection agents	- Check if less hazardous substitutes are suitable and available - use substitutes if reasonable - checking has to be documented and presented on demand - Substance can be prohibited if its use is not necessary	While some substitutions are regarded as successful (e.g. Cr(VI) in wood preservation) many substitution processes were hindered. Partly substitutes were not recommended due to lack of toxicological data (hydrazine). No change in the use of DCM containing paint remover was observed till 2001 because substitutes are less effective. Chromate reduced cement was only hesitantly implemented in Germany.
COSHH –Control of Substances Hazardous to Health Regulations United Kingdom	Supports compliance with the Control of Substances Hazardous to Health Regulations 2002. Companies get easy applicable instruments and rules to control exposure of employees and others who may be exposed to hazardous substances to prevent health damage	Substances or mixtures of substances classified as dangerous to health under Chemicals Legislation (Hazard Information and Packaging for Supply) 2002 (CHIP) Substances with occupational exposure limits are listed in the HSE publication EH40/2005 Workplace exposure limits.	The COSHH Regulation requires to prevent exposure to hazardous substances, if it is reasonably practicable to do so. You might: - change the process or activity so that the hazardous substance is not needed or generated; - replace it with a safer alternative; - use it in a safer form, e.g. pellets instead of powder. The HSE guidance booklet "Seven steps to successful substitution of hazardous substances" advises on how to replace hazardous substances with safer alternatives.	
Chemical Products Act Sweden	The principle of substitution was added to the Swedish Act on Chemical Products in 1990 by a clarifying amendment			

Legislation	Short description	Substances/criteria	conditions	Reported effects +/-
Swedish Guidelines on Chemicals Policy	Contains an obligation for companies to (continuously) check whether less hazardous substitutes exist	chemical products that might entail risks to human health or the environment	"...anyone conducting an operation or taking measures must avoid using or selling chemical products that might entail risks to human health or the environment if they can be replaced with such chemical products as may be assumed to be less hazardous."	
"Action Plan for reducing and phasing out phthalates in soft plastics", the Danish Ministry of the Environment, 1999, Denmark	substance related taxation system	phthalates	The tax shall apply to phthalates in a number of selected product groups for which the tax system was applicable. Another instrument mentioned in the action plan is to support the development of alternatives to phthalate plasticisers by subsidies. From this the availability of alternative materials / plasticisers can be enhanced and might at the same time motivate manufacturers to start development of substitutes.	
Guidance Document for Risk Assessment of Industrial Waste Water (EPA Dk 95), Denmark	a guidance for local authorities who decide about permits for dischargers. focuses on substances with eco-toxicological relevance.	discharging of "list I and II" substances should be prevented (Directive 76/464/EEC)	If an applicant uses listed substances (qualitative criteria) or the toxicity of the effluent exceeds certain limits a detailed analysis or hazard reduction measures have to be carried out which can be avoided by substituting the respective substances. In this respect this legislation builds up pressure towards substitution.	
Strategy on Management of Substances (SOMS), The Netherlands	allows a pragmatic answer to the question on how to assess the risk of chemicals used and sold in the Netherlands in categories according to 5 levels of concern. The industrial community is provided with a tool to enable the assessment on the practical level.	Quick scan of substances: Assessment of hazardous properties of the substance Classification of properties in categories of concern Classification of substances in categories of (in-principle) measures Balancing hazard risks versus social costs and benefits.	The Quick Scan provides a tool for achieving results on a risk assessment of substances in a pragmatic way and gives a basis for risk reduction measures from which one of the most important is the ban i.e. substitution of a substance.	

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