Developing REACH and improving its efficiency

– an action plan
The Swedish Chemicals Agency is supervisory authority under the Government. We work in Sweden, the EU and internationally to develop legislation and other incentives to promote good health and improved environment. We monitor compliance of applicable rules on chemical products, pesticides and substances in articles and carry out inspections. We review and authorise pesticides before they can be used. Our environmental quality objective is A Non-toxic Environment.
Preface

This report presents an account of the Swedish Chemicals Agency's assignment given by the Swedish Government in the appropriation directions for 2013. The assignment was to prepare an in-depth analysis and proposals for an action plan for Sweden's initiatives relating to the development of REACH, the EU chemicals legislation, and to examine how it can be applied more effectively, in order to contribute to the Swedish environmental quality objective "A Non-Toxic Environment."

The EU REACH Regulation is a fundamental piece of chemicals legislation, which is of primary importance in the prevention and reduction of chemical risks. The application of REACH also impacts on other EU provisions, e.g. concerning biocide products, cosmetic products and the work environment legislation.

The aim of this action plan is to present an integrated picture of how the REACH chemicals legislation can be developed and its application strengthened. The Swedish Chemicals Agency hopes that the action plan will result in the REACH Regulation being systematically developed so that the legislation can contribute to achievement of the Swedish environmental quality objective "A Non-Toxic Environment" more effectively.

The assignment has been carried out at the department for Development of Legislation and Other Instruments at the Swedish Chemicals Agency. The work was based on underlying information and views provided by many Swedish Chemicals Agency employees. Consultation concerning the action plan has been carried out with relevant authorities, companies and organisations.

As compared to the Swedish version of this report some changes (deletions, insertions, rewordings and corrections) have been introduced in order to increase clarity. The present report may thus not be regarded as a verbatim translation of its Swedish counterpart, Utveckla och effektivisera Reach – en handleingsplan, Rapport 4/14, Swedish Chemicals Agency, June 2014.
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Summary

In the appropriation directions for 2013, the Swedish Chemicals Agency was tasked by the Government with producing an in-depth analysis and proposals for an action plan for Sweden's initiatives relating to the development of the EU chemicals legislation REACH and examining how it can be applied more effectively in order to contribute to the Swedish environmental quality objective *A Non-Toxic Environment*. When performing this task, the Swedish Chemicals Agency consulted a number of relevant authorities and other stakeholders (section 1.1).

This report identifies key areas for the development of REACH based on analyses of the areas specified by the Government in the assignment, as well as a number of other areas added by the Swedish Chemicals Agency.

The assignment to draw up an action plan for the development of REACH forms part of the Swedish strategy for *A Non-Toxic Environment* described in the 2013 Government Bill on chemicals policy. The report analyses how proposed measures can contribute to attaining the Swedish milestone targets in *A Non-Toxic Environment*.

The Swedish Chemicals Agency considers REACH to be a major step forward in the protection of health and the environment compared with previous EU regulatory frameworks. REACH places clearer responsibility on industry to ensure that chemicals are handled safely. However, there are shortcomings in how REACH is applied and a need to further develop REACH.

We believe there to be a need for initiatives at both technical and political levels to ensure that REACH will contribute effectively to attaining the milestone targets for hazardous substances in the Swedish environmental quality objective *A Non-Toxic Environment*. The Government's commitment on the action plan for *A Non-Toxic Everyday Environment 2015 – 2020* means that the Swedish Chemicals Agency is well placed to act for a more effective REACH at the technical level. The development work that is required at EU level will need to continue for at least ten years into the future. The relatively slow and complex processes involved in this work mean that it will not be possible to achieve the parts of the milestone targets where the target year is 2015. It will also be a major challenge to achieve the other milestone targets by the specified target year.

The Swedish Chemicals Agency takes the view that the chemical policy aspects should be given a greater impact in the implementation and development of REACH. The complexity and highly technical nature of the regulation has meant that certain important issues relating to application and development have largely only been considered as technical issues.

The EU seventh environmental action programme can contribute towards providing the political conditions we deem to be necessary for it to be possible to develop REACH in such a way that the regulation contributes effectively to meeting the milestone targets. This applies in particular to the EU strategy for a Non-Toxic environment which is to be prepared under the EU seventh environmental action programme by 2018.

In addition to the seven areas of development specified in the assignment (groups of substances, substitution in connection with restrictions and authorisation, information requirements for low volume substances, combination effects, endocrine disruptors, children's health, better access to and compilation of information in ECHA databases), the Swedish Chemicals Agency has submitted proposals in another six areas. These are the quality of the

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registrations, nanomaterials, work by companies on substitution, identification and prioritisation of substances of very high concern, information on substances of very high concern in articles and enforcement. For each area of development, we have proposed measures at EU level that apply both to changes in the regulatory framework and to application of the provisions.

In several cases we have identified needs for initiatives at a political level to create the conditions needed to bring about these changes. The proposals have been broadly collated in the Action plan in brief (Chapter 3) with recommendations regarding how the initiatives can be prioritised in the shorter and longer terms. It is also apparent from the action plan whether there is a need to continue with initiatives such as further analyses, in order to formulate proposals for measures in an area of development.

The report contains an overarching, qualitative impact assessment but does not address the issue of resources or financial needs to implement proposed measures.

A summary of the proposals is presented below:

**Measures to improve the implementation and effectiveness of REACH**

**Initiatives at authority level:**
– Take action in working groups and committees for processes in REACH such as restriction and authorisation to become more effective.
– Take part in EU-wide activities on ECHA's review of registration data.
– Provide support making it easier for Swedish companies to fulfil their obligations.
– Take part in working groups at EU level to improve the guidance provided to companies, with the aim of raising the quality of the information transferred in the supply chain.

**Initiatives at political level**
– Act for discussions to take place in the Council of the European Union regarding how work in the various processes of REACH can be made more effective with the aim of achieving a higher level of protection.

**Measures to develop REACH - Enhanced information requirements for low volume substances**

**Initiatives at authority level**
– Participate in the working group(s) the Commission launches in order to address the issue of data requirements for low volume substances.

**Initiatives at political level**
– Take action for the Commission's work on data requirements for low volume substances to be completed in such good time that it can have an impact on the data requirements at the time of registration in 2018.
– Take action for more research to make it possible to raise the test requirements in REACH for low volume chemicals in a cost-effective way without substantially increasing the number of animal experiments.

**Measures to develop REACH – Enhanced principle of substitution**

**Initiatives at authority level**
– Endeavour to ensure that article-producing companies, retailers and consumers will get better access to information about hazardous substances in articles, through amendments to the regulation and also via systems making information more accessible.

**Initiatives at political level**
– Endeavour to ensure that article producing companies, retailers and consumers will have better access to information about hazardous substances in articles, through amendments to the regulation and also via systems making information more accessible.
– Strive for the EU strategy for a Non-Toxic environment to emphasise that the impetus for substitution of hazardous substances should be strengthened.
– Strive for stronger rules on substitution to be introduced into REACH, such as an overarching rule of substitution.

Measures to develop REACH – Endocrine disruptors

Initiatives at authority level
– Act for the EU criteria to establish which substances which are endocrine disruptors to provide for a high level of protection.

Initiatives at political level
– Act for endocrine disruptors and strongly allergenic substances to be regarded as substances of very high concern.

Measures to develop REACH – Combination effects

Initiatives at authority level
– Endeavour to ensure in the EU technical working groups that risk assessments and proposals for restrictions of risk should take account of possible combination effects, for example in the form of an extra assessment factor.

Initiatives at political level
– Initiatives may be needed at political level to ensure that work on combination effects is resumed in the EU technical working groups.
– Strive for the EU strategy for a Non-Toxic environment to facilitate the introduction of rules on combination effects.
– Strive for REACH to require industry to take account of possible combination effects in their registrations.

Measures to develop REACH – Better protection for children

Initiatives at authority level
– Endeavour to ensure better guidance in the EU technical working groups in order to assess how children are exposed to chemicals and promote greater consideration of the particular sensitivity of children in risk assessments.

Initiatives at political level
– Strive for the EU strategy for a Non-Toxic environment to embrace a high level of protection for children and indicate how children can be better protected against substances of very high concern in articles used in everyday life.

Measures to develop REACH – Nanomaterials

Initiatives at authority level
– Develop a basis for the drafting of new provisions, for example regarding appropriate information requirements at different tonnage levels.

Initiatives at political level
– Strive for the Commission to present previously promised proposals for expanded information requirements for registration of nanomaterials.
– Strive for special EU provisions for nanomaterials to be developed as a complement to the REACH Regulation or through amendments to REACH.
**Measures to develop REACH – Group-based assessment of chemicals**

**Initiatives at authority level**
– Propose in the EU working groups that ECHA should launch a project to test the feasibility of targeting groups of substances in the substance evaluation work to obtain experience that can provide the basis for a continued development activity.

**Initiatives at political level**
– Strive for the regulatory framework to be developed so that group assessments do counteract inappropriate or false substitution.

**Measures in the area of data dissemination - Access to and compilation of information**

**Initiatives at authority level**
– Contribute experience from the work of the Swedish Chemicals Agency on databases and, where necessary, propose complementary measures to make the information in ECHA’s databases freely available in a format that allows further comprehensive processing.

**Measures in the area of Enforcement**

**Initiatives at authority level**
– The Swedish Chemicals Agency should plead for the development of appropriate means to enforce conditions for authorisations.
Sammanfattning

Kemikalieinspektionen har i regleringsbrevet för 2013 fått i uppdrag av regeringen att ta fram en fördjupad analys och förslag till handlingsplan för Sveriges insatser i utvecklingen av EU:s kemikalielagstiftning Reach samt hur dess tillämpning kan effektiviseras, i syfte att bidra till miljökvalitetsmålet *Giftfri miljö*. Vid genomförandet av uppdraget har Kemikalieinspektionen samrått med ett antal berörda myndigheter samt andra intressenter (avsnitt 1.1).

Denna rapport pekar ut de viktigaste utvecklingsområdena för Reach utifrån analyser av de områden som regeringen angav i uppdraget, samt ytterligare några områden som Kemikalieinspektionen lagt till.

Uppdraget att ta fram en handlingsplan för arbetet med att utveckla Reach är ett led i den strategi för *Giftfri miljö* som beskrivs i regeringens proposition om kemikaliepolitiken 2013¹. I rapporten analyseras hur föreslagna åtgärder kan bidra till att nå etappmålen i *Giftfri miljö*.

Kemikalieinspektionen anser att Reach är ett stort steg framåt för skyddet av hälsa och miljö jämfört med tidigare EU-regelverk. Reach lägger ett tydligare ansvar på företagen för en säkerhantering av kemikalier. Det finns dock brister i hur Reach tillämpas och ett behov av att ytterligare utveckla Reach.


Kemikalieinspektionen menar att de kemikaliepolitiska aspekterna måste få ett ökat genomslag vid tillämpning och utveckling av Reach. Förordningens komplexitet och starkt tekniska natur har medfört att vissa viktiga tillämpnings- och utvecklingsfrågor hittills i alltför stort utsträckning har behandlats endast som tekniska frågor.

EU:s sjunde miljöhändlingsprogram kan bidra till att ge de politiska förutsättningarna som vi bedömer är nödvändiga för att det ska vara möjligt att utveckla Reach på ett sådant sätt att förordningen effektivt bidrar till att uppfylla etappmålen. Det gäller särskilt den strategi för en giftfri miljö, som ska tas fram inom ramen för EU:s sjunde miljöhändlingsprogram till år 2018.

Utöver de sju utvecklingsområden som specificeras i uppdraget (grupper av ämnen, substitution i samband med begränsningar och tillstånd, informationskrav för lågvolymämnen, kombinationseffekter, hormonestörande ämnen, barns hälsan, bättre tillgång till och anpassning av information i Echas databaser) har Kemikalieinspektionen lämnat förslag inom ytterligare sex områden. Dessa är registreringarnas kvalitet, nanomaterial, företagens arbete med substitution, identifiering och prioritering av särskilt farliga ämnen, information om särskilt farliga ämnen i varor samt tillsyn. Vi har för varje utvecklingsområde föreslagit åtgärder på EU-nivå som gäller både förändringar i regelverket och i reglernas tillämpning.

¹ På väg mot en giftfri vardag – plattform för kemikaliepolitiken (prop. 2013/14:39).
I flera fall har vi identifierat behov av insatser på politisk nivå för att skapa förutsättningar för att få till stånd dessa förändringar. Förslagen har sammanställts övergripande i Handlingsplan i korthet (kapitel 3) med rekommendationer om hur insatserna kan prioriteras på kortare och längre sikt. Av handlingsplanen framgår också om det behövs fortsatta insatser i form av ytterligare analyser, för att utförma förslag till åtgärder inom ett utvecklingsområde.

Rapporten innehåller en övergripande, kvalitativ konsekvensanalys men behandlar inte frågan om resurser eller ekonomiska behov för att genomföra föreslagna åtgärder.

I det följande presenteras förslagen i sammanfattning:

**Åtgärder för att förbättra tillämpningen och effektivisering av Reach**

**Insatser på myndighetsnivå:**
- Verka i arbetsgrupper och kommittéer för att processer i Reach såsom begränsning och tillstånd ska bli effektivare.
- Delta i EU-gemensamma aktiviteter om Echas granskning av registeringsunderlagen.
- Ge stöd som underlättar för svenska företag att uppfylla sina skyldigheter.
- Delta i arbetsgrupper på EU-nivå för att förbättra vägledningen till företagen, i syfte att höja kvalitén på informationen som överförs i leverantörsledet.

**Insatser på politisk nivå**
- Verka för att diskussioner förs i europeiska unionens råd om hur arbetet i Reach olika processer kan effektiviseras med en ökad skyddsnivå som mål.

**Åtgärder för att utveckla Reach - Högre kunskapskrav för lågvolym kemikalier**

**Insatser på myndighetsnivå**
- Delta i de arbetsgrupper som kommissionen startar för att behandla frågan om datakrav för lågvolymämnen.

**Insatser på politisk nivå**
- Verka för att kommissionens arbete med datakrav för lågvolymämnen slutförs i så god tid att det kan påverka datakraven vid registreringstillfället år 2018.
- Verka för ökade forskningsinsatser som gör det möjligt att kostnadseffektivt öka testkraven i Reach för lågvolym kemikalier utan att öka antalet djurförsök.

**Åtgärder för att utveckla Reach – Förstärkt substitutionsprincip**

**Insatser på myndighetsnivå**
- Arbeta för att varutillverkande företag, återförsäljare och konsumenter ska få bättre tillgång till information om farliga ämnen i varor, genom ändringar i förordningen, men även med system för att göra information mer åtkomlig.

**Insatser på politisk nivå**
- Arbeta för att varutillverkande företag, återförsäljare och konsumenter ska få bättre tillgång till information om farliga ämnen i varor, genom ändringar i förordningen, men även med system för att göra information mer åtkomlig.
- Verka för att skrivningar i EU:s strategi för en giftfri miljö tydligt kommer att betona att drivkraften för substitution av farliga ämnen måste förstärkas.
- Verka för att starkare regler om substitution införs i Reach, såsom en övergripande substitutionsregel.
**Åtgärder för att utveckla Reach – Hormonstörande ämnen**

**Insatser på myndighetsnivå**
- Verka för att EU:s kriterier för att fastställa vilka ämnen som är hormonstörande har en hög skyddsnivå.

**Insatser på politisk nivå**
- Verka för att hormonstörande, samt kraftigt allergiframkallande ämnen, ska betraktas som särskilt farliga ämnen.

**Åtgärder för att utveckla Reach - Kombinationseffekter**

**Insatser på myndighetsnivå**
- Arbeta i EU:s tekniska arbetsgrupper för att riskbedömningar och förslag till riskbegränsningar ska ta hänsyn till möjliga kombinationseffekter, till exempel i form av en extra osäkerhetsfaktor.

**Insatser på politisk nivå**
- Det kan behövas insatser på politisk nivå för att arbetet med kombinationseffekter åter ska komma igång i EU:s tekniska arbetsgrupper.
- Verka för att EU:s strategi för en giftfri miljö underlättar att införa regler om kombinationseffekter.
- Verka för att Reach ska kräva att företagen beaktar möjliga kombinationseffekter i sina registreringar.

**Åtgärder för att utveckla Reach – Bättre skydd för barn**

**Insatser på myndighetsnivå**
- Arbeta i EU:s tekniska arbetsgrupper för bättre vägledning för att bedöma hur barn exponeras för kemikalier och för större hänsyn till barns särskilda känslighet i riskbedömningarna.

**Insatser på politisk nivå**
- Verka för att EU:s strategi för en giftfri miljö får en hög skyddsnivå för barn och hur barn bättre kan skyddas från särskilt farliga ämnen i varor som vi använder i vardagen.

**Åtgärder för att utveckla Reach – Nanomaterial**

**Insatser på myndighetsnivå**
- Ta fram underlag för utformning av regler, till exempel avseende lämpliga informationskrav vid olika tonnagenivåer.

**Insatser på politisk nivå**
- Verka för att Kommissionen presenterar tidigare utlovade förslag till utvidgade informationskrav för nanomaterial i samband med registreringen.
- Verka för att särskilda EU-regler för nanomaterial utvecklas som ett komplement till Reach eller genom förändringar av Reach.

**Åtgärder för att utveckla Reach – Gruppvis bedömning av kemikalier**

**Insatser på myndighetsnivå**
- Föreslå i EU:s arbetsgrupper att Echa ska starta ett projekt för att pröva grupper av ämnen i ämnesutvärderingen, för att få erfarenheter som kan ligga till grund för det fortsatta utvecklingsarbetet.

**Insatser på politisk nivå**
- Verka för att utveckla regelverket så att gruppbedömningar kan motverka osund substitution.
Åtgärder inom Tillgång till och anpassning av information
– Bidra med erfarenhet från Kemikalieiinspektionens arbete med databaser och vid behov föreslå kompletterande åtgärder för att tillgängliggöra och bearbeta information i Echas databaser.

Åtgärder inom Tillsyn
– Kemikalieiinspektionen bör verka för att lämpliga former för att följa upp efterlevnaden av tillståndsvillkoren utvecklas.
1 The assignment and its execution

1.1 The Government’s assignment

In the appropriation directions for 2013, the Swedish Chemicals Agency was tasked with investigating and submitting a report on the development and application of REACH. The assignment was worded as follows:

The Swedish Chemicals Agency is tasked with preparing an in-depth analysis and proposals for an action plan for Sweden’s initiatives relating to the development of REACH, the EU chemicals legislation, and examining how it can be applied more effectively in order to contribute to the [Swedish] environmental quality objective "A Non-Toxic Environment". The analysis should identify the key development areas for REACH and shall, among other things:

- consider the opportunities available within the framework of the regulation for assessing, handling and testing groups of substances with certain properties or applications,

- consider the way in which the principle of substitution is applied and can be enhanced in connection with restrictions, authorisation and other aspects of the regulation,

- assess how the information requirements relating to the registration of substances that are manufactured or imported in lower quantities (less than 10 tonnes per manufacturer or importer and year) can be strengthened,

- review how the regulation should be developed in order to improve the management of health and environmental risks from combination effects and endocrine disruptors, and how consideration can be given to the special sensitivity of children towards chemicals, and

- consider the opportunities for improving access to and adapting information that is gathered in accordance with REACH and the CLP Regulation (Classification, Labelling and Packaging of Substances and Mixtures), which has been collated by the European Chemicals Agency (ECHA), with the aim of e.g. facilitating product development, substitution and other risk-mitigating measures.

The assignment includes investigating the possibilities for proposing measures at EU level in the form of changes to the regulation, including the associated annexes and application provisions, as well as with regard to the application of the regulation.

The action plan should set out the continued initiatives in the form of further analyses and the formulation of proposals that are needed, as well as when the initiatives should be prioritised in terms of time.

During this process, the Swedish Chemicals Agency shall consult relevant authorities and other stakeholders. A report on the assignment shall be submitted by 1 June 2014.

During the process, the Swedish Chemicals Agency invited the following stakeholders to consultation meetings. Consultation meetings have been held on three occasions: 15 April 2013, 16 December 2013 and finally 11 April 2014.

Swedish Work Environment Authority
Swedish National Board of Housing, Building and Planning
Animal Rights Sweden
Swedish National Electrical Safety Board
Public Health Agency of Sweden
1.2 Delimitations

The development areas covered by the assignment are in some cases also relevant to other aspects of the EU legislation concerning chemical products (substances and mixtures). For example, this applies to endocrine disruptors and nanomaterials. Despite this, the Swedish Chemicals Agency has decided to limit the proposals in the action plan to the REACH Regulation. In some cases, proposals for measures outside REACH are also included when activities within associated areas are either of importance for or complement the proposals.

1.3 Layout of the report

The structure adopted for Chapter 3 - Action plan for REACH in brief - explains the subdivision of the assignment into proposals for improvements as regards application and efficiency, as well as proposals for the development of REACH.

A number of development areas are highlighted in the report. However, the Swedish Chemicals Agency has decided to structure Chapter 4, which contains a more detailed analysis and associated proposals for measures, so that it follows the processes in the REACH Regulation. This emphasises the fact that the development proposals primarily concern the REACH Regulation.
2 Introduction

2.1 REACH – a fundamental regulation concerning chemicals

In 2001, the Commission presented a white paper setting out a strategy for a future chemicals policy. In this white paper, the Commission expressed its views on how a new system for the control of chemicals ought to be formulated in order to protect human health and the environment. The European Parliament expressed its views in a report on the Commission's thoughts in the white paper, while the Environment Council presented its points of view in the form of Council conclusions. Following discussion of the Commission's proposals and broad negotiations, EU's chemicals regulation REACH was adopted in 2006. It was a strong political will in the area of chemicals in several Member States that made it possible to bring about this by far most ambitious chemicals legislation in the world in the EU.

REACH, like the Regulation on Classification, Labelling and Packaging (CLP), is one of the fundamental acts of Community law governing chemicals. REACH is a very extensive EU regulation which, as well as gathering previous EU rules together in one legal instrument, covers important new rules for example on data requirements and authorisation.

The legal basis for rules applicable to chemical products or articles placed on the market and relating to free circulation is normally Article 114 of the Treaty on the Functioning of the European Union. The requirements are harmonised, which means that individual Member States may not introduce stricter or less stringent requirements. REACH is an example of such a regulation.

| Pre-registration | Industry supplies information and proposes adequate measures for safe handling and use |
| Registration | |
| Exchange of information | |
| Evaluation | ECHA and the competent authorities in the Member States check and can request further information |
| o Documentation/data/safety assessment | |
| o Chemical substance | |
| Authorisation | The Commission applies the Community system for risk management, with support from ECHA and the competent authorities in the Member States |
| Restriction | |
| Classification and labelling | |

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5 Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
Registration

A fundamental principle in REACH is that industry has to take responsibility for the chemicals they place on the market being safe. REACH requires companies to obtain knowledge (e.g. test data), among other things about the hazards posed by their chemicals to health and the environment. Manufacturers and importers have to register substances manufactured or imported in quantities of more than one tonnes per manufacturer or importer per year. The registration is submitted to the European Chemicals Agency (ECHA) and includes test data and, when the quantity exceeds ten tonnes per year, also an assessment of the hazardous properties and intended use of the substance. If the quantity manufactured/imported exceeds ten tonnes per year, a risk assessment (a chemical safety assessment – CSA) shall be carried out by the registrant. For CLP classified substances and PBT/vPvB substances it shall be specified in these chemical safety reports (CSR) how the substances can be used in a safe way for humans and the environment for each identified use (own uses and recommended uses).

Evaluation

The substance registrations may be evaluated, and ECHA evaluates a small proportion of the registration dossiers to check that they contain accurate information, while the Member States’ competent authorities carry out in-depth evaluations of substances that have been placed on a special priority list - CoRAP. The aim of the in-depth evaluation is to clarify whether the manufacturing or use of a substance poses a suspected health or environmental risk and whether the risks are so great that manufacturing or use needs to be restricted or otherwise controlled in the EU.

Knowledge of the hazardous properties of substances and the need for alternatives to animal experiments

Tests on animals and other organisms can be used to predict and assess the hazardous properties of chemicals. It is already established in the introductory article of REACH that one of the purposes of the regulation is to promote alternative methods for assessment of hazards of substances in addition to protection of human health and the environment, free circulation of substances and enhanced competitiveness. Unnecessary animal experiments are to be avoided and experiments on vertebrates are only to be performed as a last resort. Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes also applies to animal experiments performed in order to fulfil the requirements of REACH.

Information that is gathered concerning the hazardous properties of chemicals in order to fulfil applicable safety requirements and to protect human health and the environment must be both reliable and usable. To ensure a high level of protection, it is still not possible to avoid testing of chemicals in vertebrate animals in many cases. But as soon as reliable alternative test methods are available, animal experiments are not to be used. Extensive research and development activities have taken place in the area of alternative testing methods for several decades. Several hundred million euros have been spent on various research projects in the past ten years under EU research programmes. Great efforts are also being made in this area of research in the United States. However, there is a need for continued extensive research.

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7 Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes
8 E.g. SEURAT-1 Towards the Replacement of in vivo Repeated Dose Systemic Toxicity Testing http://www.seurat-1.eu/
activity in Sweden and in the EU. The objective should be for it to be possible to expand the test requirements in REACH, for example concerning low volume substances, while at the same time taking into account both the ethical aspects of animal experiments and cost-effectiveness. For such elevated test requirements to become feasible without a substantial increase in the number of animal experiments, new testing and screening methods based on alternative methods need to be developed and put to use. This applies for example to in vitro methods, methods based on computer modelling and novel test methods based on scientific progress in e.g. molecular biology, system biology and bioinformatics.

**Classification of the hazardous properties of substances for health and the environment**

The Regulation on classification, labelling and packaging of substances and mixtures (CLP) establishes a harmonised classification for the health and environmental hazards of many substances, for example which substances are to be regarded as carcinogenic and toxic to reproduction. The so called Candidate List - kept and regularly updated by ECHA - lists those substances that are to be regarded as substances of very high concern – SVHC substances. These various provisions both directly and indirectly affect a large number of other directives and regulations, for example within various product areas, the work environment, the natural environment and waste.

**Information in the supply chain on the hazardous properties of chemicals**

Suppliers of substances and mixtures that fulfil the criteria for classification as hazardous under the CLP Regulation shall provide professional users of the chemicals with safety data sheets. The safety data sheets have to contain information on classification and on how the substances and mixtures are to be used in a safe way. There is also a limited obligation to inform about substances of very high concern in articles.

**Authorisation**

Substances assessed as being of very high concern may be subject to authorisation before they are allowed to be sold or used. These are substances that are carcinogenic, mutagenic or toxic to reproduction – CMR category 1A & 1B substances, persistent, accumulate in living organisms (bio-accumulating) and toxic – PBT substances, very persistent and very bio-accumulating – vPvB substances, and of an “equivalent level of concern” (ELOC substances) such as endocrine disruptors or highly allergenic substances. Such substances are placed on a special list, known as the Candidate List, and may then gradually be included in an annex of the REACH Regulation, Annex XIV- List of substances subject to authorisation. At that time a timetable for authorisation is fixed. Substances that are in widespread dispersive use, are used in large volumes or have particularly serious hazardous environmental properties are prioritised.

**Restrictions**

Restrictions can also be introduced through REACH as conditions for or prohibition/ban of manufacturing, placing on the market or use of substances on their own, in mixtures, and in articles. Annex XVII of the regulation contains restrictions on around 60 substances and a long list of CMR chemicals which may only be sold for professional use. A very limited number of restrictions in the annex involve a total ban on placing on the market and use of some substances. There are also restrictions on certain uses of some substances.

**Particularly hazardous substances and Substances of Very High Concern (SVHC)**

“Particularly hazardous substances” [in Swedish: “Särskilt farliga ämnen”] means substances that have serious and often irreversible effects on human health and the environment. The
expression is used in various contexts, often in order to distinguish substances that have such hazardous properties that their use should be avoided and phased out as they pose considerable risks for humans and the environment. The term is used as defined here throughout this report. In addition to this definition, the scope of the term can vary to some extent, depending on the context. Where appropriate, the specific scope is indicated in the report and the term is otherwise used as follows:

- In connection with the REACH Candidate List, which is a list of Substances of Very High Concern (SVHC), the term "particularly hazardous substances" is commonly used more or less synonymously with 'SVHC substances'. The Candidate List should however be regarded as a list of substances that have been officially identified in accordance with REACH procedures as being particularly hazardous. In order to be identified as a SVHC and included in the Candidate List, a substance must fulfil at least one of the following conditions:
  - Fulfils the criteria to be classified as carcinogenic, mutagenic or toxic to reproduction (CMR) in category 1A or 1B in the CLP Regulation
  - Fulfils the criteria to be considered as persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) in accordance with Annex XIII of REACH
  - Has other properties which give rise to an equivalent level of concern (Article 57f of Reach). This could for example concern endocrine disruptors.

- The term “particularly hazardous substance” is generally used with a slightly broader scope and also encompasses substances that fulfil the SVHC criteria but have not (yet) been identified as a SVHC and included in the Candidate List.

- In connection with the Swedish environmental quality objective, A Non-Toxic Environment, the scope is somewhat broader still. In this context, a substance that is bio-accumulative and persistent need not have been demonstrated as being toxic in order to be considered to be a particularly hazardous substance. Endocrine disruptors and highly allergenic substances are also covered by the term on the basis of their respective properties, without any assessment on a case-by-case basis as to what extent the substance "gives rise to an equivalent level of concern". The three heavy-metals mercury, cadmium and lead have also been directly identified in the Swedish environmental quality objective as particularly hazardous substances.

**Assessment of risk, adequately controlled use and uncertainty in REACH**

A fundamental principle of REACH is that the use of a substance shall be "adequately controlled". This safe use shall be elaborated by the company registering a substance by presenting appropriate handling instructions and safety measures, based on information on the properties and uses of the substance. If these "exposure scenarios" are followed during use, the use is considered to be “adequately controlled” and thus assessed as safe with regard to human health and the environment. If it is not possible to bring about adequately controlled use through these measures, further risk management measures in the form of authorisation or restrictions may be considered by the authorities.

Below, a general overview is given on methods and tools for risk assessment, the uncertainty that exists in the assessments and why there is a need for additional precautionary thinking as a complement to the risk assessment model applied in REACH.
What is expected to be "adequately controlled" use from an environmental perspective is established in REACH through a standard model. This model is based on a calculated concentration level of a substance in the environment\(^{10}\) being related to the concentration of the substance that is not expected to lead to any toxic/adverse effect on living organisms\(^{11}\). If this risk quotient is less than 1, the use concerned is considered to be “adequately controlled” and safe. In a corresponding way, use is assessed as "adequately controlled" from a human health perspective if the quotient between a calculated exposure in a predicted exposure situation (i.e. an exposure scenario), and the exposure level\(^{12}\) at which no toxic/adverse effects in humans is expected is less than 1.

"Adequately controlled" exposure levels determined using risk quotients for both human health and the environment are established on the basis of available data concerning, for example, harmful/adverse effects. The extent and depth of the available data is determined by the volume-based information requirements in REACH. To compensate for different types of uncertainties in the available data and for unknown variation in sensitivity within groups of exposed humans and among species populations, standard/default assessment factors (safety factors) are normally applied. The type and seriousness of the harmful effects, the scope of the exposure and the quality and extent of the available database also affect the values obtained.

With regard to the estimated exposure of humans and in the environment, it is generally necessary to rely on modelled data to provide a reasonable, but presumed exaggerated exposure ("reasonable worst case").

The standard model described above is applied to substances regarded as having a threshold value for their environmental and human health effects\(^{13}\). Other methods are used for substances without a threshold for human health effects and for certain categories of substances of very high environmental concern (see also section 4.4.1).

Taken together, it can be noted that the calculated exposure levels deemed to be safe (adequately controlled) and the estimated relevant exposure of both humans and the environment are estimates which, even if they are obtained using methodology that should provide a high level of protection, are nevertheless subject to uncertainty. Quotients between these quantities become even more uncertain, and an absolute limit for a risk quotient of less than 1 for when a particular exposure situation is to be regarded as "safe" from the point of view of health and the environment is therefore impossible to justify scientifically. The procedure can be described rather as a scientifically underpinned policy decision. This means that assessments that produce risk quotients of less than 1 may in many cases need to be refined by further information being obtained on harmful effects and exposure. An alternative to this is to tighten the conditions for use, which provides a modified exposure scenario giving lower exposure.

Conditions that shall be fulfilled for a particular use to be regarded as adequately controlled are stated in the exposure scenario. These conditions consist of risk management measures and operating conditions such as requirements for the use of gloves, ventilation, respiratory protection, protective clothing etc. The conditions may also prescribe maximum volumes allowed per day, limitations in time periods with exposure, methods of application etc.

\(^{10}\) Predicted environmental concentration, PEC.
\(^{11}\) Predicted no effect concentration, PNEC.
\(^{12}\) Derived no effect level, DNEL.
\(^{13}\) Substances for which it is possible to establish a maximum level of exposure under which effects do not occur.
It is difficult to decide to what extent the conditions in the exposure scenarios will be followed in practice. To achieve a high degree of compliance, it is reasonable to assume that a significant increase in inspections would be required.

It is also evident that a typical exposure scenario only deals with exposure to a single substance from a single source and do not take account of any combination effects. The concept of “adequate control and safe use exposure scenarios” is therefore inadequate to deal with several important aspects of the total exposure of both humans and the environment. Various aspects of these problems are touched upon in later sections of this report (4.1.8).

Based on knowledge of the deficiencies and limitations in the risk assessment models, the risk management tools, and due to the prevalent uncertainty in our scientifically based knowledge on hazardous effects from exposure to individual or groups of chemicals it may in the individual case be required to apply the precautionary principle to improve the protection of human health and the environment.

The deficiencies and uncertainties that exist in the models described above are part of the background to many of the proposals in the report. It is all about better capturing and taking due account of general scientific uncertainty in chemicals control.

Further uncertainties in the risk assessment may be due to new or less well explored aspects of the problems of chemicals that are presently insufficiently, or not at all, addressed in the regulatory framework. Examples of such areas are risks associated with endocrine disruptors, nanomaterials, combination effects, combined exposure from different sources and via different exposure routes and the special sensitivity of children to chemical exposure.

**Enforcement is important for the effective application of REACH**

Enforcement is carried out to determine whether companies are following applicable legislation and to demand rectification in the event of breaches. Enforcement also helps to counter any distortion of competition between companies. Clear rules help companies to comply with applicable rules and at the same time facilitate the control of compliance with the rules. Enforcement leads to the establishment of a practice concerning interpretation of the rules, and the experience can be valuable, e.g. in connection with the development of guidance documents. Experience gained during the enforcement can be fed back into the development/amendment of regulations, which in turn makes regulatory compliance easier to supervise. In order to achieve these aims, coordinated, integrated and effective enforcement within the EU is essential.

**Timetable for entry into force of the REACH Regulation**

<table>
<thead>
<tr>
<th>Year</th>
<th>Events along the way to full introduction of REACH</th>
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<tbody>
<tr>
<td>2001</td>
<td>The Commission presents a white paper containing a strategy for a future chemicals policy.</td>
</tr>
<tr>
<td>2005</td>
<td>The European Parliament and the Council of Ministers decide on the final text of REACH.</td>
</tr>
<tr>
<td>2007</td>
<td>Some parts of REACH start to apply. The regulation is thereafter implemented in stages.</td>
</tr>
<tr>
<td>2008</td>
<td>Most of REACH starts to apply.</td>
</tr>
<tr>
<td>2009</td>
<td>The annex containing restrictions and prohibitions/bans starts to apply (Annex XVII).</td>
</tr>
</tbody>
</table>
2010 | Registration of substances manufactured in quantities of at least 1000 tonnes per manufacturer/importer per year, and of substances regarded as being of very high concern for health and the environment.

2013 | Registration of substances manufactured or imported in quantities of at least 100 tonnes per manufacturer/importer per year.

2018 | REACH applies in full. Registration of substances manufactured or imported in quantities of at least 1 tonne per manufacturer/importer per year.

As the obligations under the regulation are largely introduced in stages, in practice it has only been fully in force for a few years, it is therefore too early yet to conduct a complete analysis of how well it fulfils the aim of protecting human health and the environment.

### 2.2 Chemical risks – political ambitions in the EU and in Sweden

**EU’s 7th Environmental Action Plan**

EU’s 7th Environmental Action Plan\(^ {14} \) was adopted by the EU Council of Ministers and the European Parliament in November 2013. Under the new environmental action programme, the European Commission is to develop a strategy for a Non-Toxic environment by 2018, which is to minimise exposure of the population to hazardous substances. Four areas are particularly prioritised: 1) nanomaterials and materials with similar priorities, 2) endocrine disruptors, 3) combination effects and 4) hazardous substances in articles, including imported articles, Non-Toxic material cycles and the indoor environment. A database is to be built up focused on measuring levels of hazardous substances in humans and the environment.

**The Swedish environmental quality objective - A Non-Toxic Environment - and milestone targets for hazardous substances**

To provide a clear structure for environmental activity, the Swedish Parliament (Riksdag) took a decision in 1999 on national environmental quality objectives, one of which is A Non-Toxic Environment. In 2010, the Swedish Government and Parliament decided on a number of changes to the former system of environmental objectives. These changes included a revised basis for assessing the prospects of attaining the environmental quality objectives which take account of nature's recovery periods and the fact that the effects of environmental protection measures often occur after some delay. In follow-ups, it has also since been assessed, except in cases where the desired environmental quality is achieved, whether the necessary prerequisites in the form of policy instruments and measures are in place in order to attain the objectives.

A Swedish environmental quality objective is assessed as being attainable either if the state of the environment expressed by the objective and its specifications can be achieved, or if adequate measures, nationally and internationally, are decided upon and expected to be implemented within a generation. A generation is counted from the establishment of the system of environmental objectives until the year 2020.

The structure of environmental objectives has been adapted and now has three levels: a generational goal, 16 environmental quality objectives with associated specification and

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milestone targets for different areas. The generational goal defines the direction of the changes in society that need to occur within one generation if the country’s environmental quality objectives are to be achieved. The environmental quality objectives describe the state of the Swedish environment which environmental action is to result in. The milestone targets define steps along the road and are intended to steer towards the changes in society that are needed to attain the environmental quality objectives and the generational goal. The objectives in the system provide a long-term signal to all actors in society on what the Swedish Government and Parliament wish to achieve with environmental policy and integration into other policy areas.

The Government has adopted eight milestone targets relating to hazardous substances since 2013. There are milestone targets in the following areas: substances of very high concern, knowledge of the hazardous properties of all substances, information on hazardous substances in articles, development and application of EU rules on chemicals, more effective enforcement of chemicals in the EU, Non-Toxic and resource-efficient material cycles, reducing the exposure of children to hazardous chemicals, and greater consideration for the environment in EU pharmaceutical legislation. The milestone targets are mainly focused on change and development of rules in the EU, and on international agreements.

The purpose of this Government assignment is to contribute to the Swedish environmental quality objective A Non-Toxic Environment and to the milestone targets relating to substances of very high concern. Each section with proposals for measures in the report contains a reference to the milestone target(s) that we consider the measures concerned to contribute most clearly. The milestone targets are presented in full in Chapter 5.

2.3 REACH needs to be further developed

The Swedish Chemicals Agency’s general assessment of the effectiveness of REACH and how the legislation should be developed is partly based on REACH fulfilling the original objectives set out in the Commission's white paper and the European Parliament's resolution. We have also taken account of views expressed by the Council of Ministers. The assessment is based in particular on the extent to which REACH contributes to fulfilment of the milestone targets for the Swedish environmental quality objective A Non-Toxic Environment (Chapter 5).

We regard REACH as being a major step forward from the point of view of protection in comparison with previous EU regulatory frameworks. REACH places clearer responsibility on companies for safe handling of chemicals. The requirements for companies to obtain knowledge of the health and environmental hazards posed by their chemicals cover significantly more chemicals than previous rules. In addition to the fact that REACH has an authorisation procedure for certain substances of very high concern, the regulation has generally also created stronger pressure for such substances to be substituted.

However, the Swedish Chemicals Agency's general assessment, considered in relation to the milestone targets in the Swedish environmental quality objective A Non-Toxic Environment and the original thoughts regarding the formulation of REACH, suggests that there are shortcomings in how REACH is applied and also a need to further develop REACH.
3 The action plan for REACH in brief

3.1 Need for continuous prioritisation and updating of the action plan

The Swedish Chemicals Agency believes there is a need for initiatives at both technical and political levels to ensure that REACH contributes effectively to attainment of the milestone targets in the Swedish environmental quality objective A Non-Toxic Environment. The Government's focus on the action plan for A Non-Toxic Everyday Environment 2015 – 2020 means that the Swedish Chemicals Agency is well placed to act for a more effective REACH at the technical level.

We emphasise here at an overarching level what measures are needed in the shorter (one to three year) and longer (three to ten year) terms. More detailed proposals for measures are presented in Chapter 4. For the shorter-term proposals there are opportunities in many cases for the Government and the Swedish Chemicals Agency to be active in EU work already under way. A benchmark for the short-term measures is the review of how REACH is working, which is being started through the report on the implementation of REACH which the Commission is due to submit by 1 June 2017. The long-term development work required will in many cases need to continue for at least ten years. This means it will not be possible to achieve the aspects of the Government's milestone targets for hazardous substances that have 2015 as the target year within the specified time. It will also be a major challenge to achieve the other milestone targets by the specified target year.

Most of the proposals principally concern the Swedish Chemicals Agency. Several other authorities may, however, need to contribute to the work in their particular areas of responsibility. Some of these authorities also have defined responsibilities in relation to REACH.

The action plan contains a large number of proposed measures, which taken together should be regarded as a preliminary list. Sweden and the Swedish Chemicals Agency will not be able to work actively on all the proposed measures or sub-areas at the same time with present-day resources. It is, however, important that there is a collective catalogue of measures through this report for the development of REACH.

The action plan and proposed measures are based on present-day knowledge and the current work situation. However, continuous prioritisation and updating of the action plan will be required. Changed political and scientific conditions may affect the prospects at an overarching level. How the economic climate in the EU and in the world develops will, for example, be of great significance to work on REACH. Depending on how these factors develop, different parts of the action plan will come into focus at the same time as there is a need to adapt the proposed measures. The single question that is probably of greatest significance to prioritisation is whether the Commission decides to open the text of the articles of REACH to changes. If this becomes the case, Sweden's initiatives will be considered with pressing for stronger protection of the environment and health and counteracting weakening of the regulation. If, on the other hand, REACH is not opened up to changes, some of the measures proposed in the long term will fall. The focus will then to a greater extent be on developing annexes and guidance documents. It will then also be a matter of quality, working practices and procedures in the application of rules, both in committee work and in enforcement work.
Many of the proposed measures mean enabling the Commission or ECHA to draw up proposals and carry out analyses. The way in which this is brought about will vary greatly, from taking part in the discussions in existing forums and raising issues at political level to carrying out separate exploratory work and presenting more detailed proposals. It is difficult to predict at present what way of working will be relevant – this will be greatly influenced by what priorities are set by other stakeholders at different levels. However, it is generally the case that the more active Sweden can act, the better the prospects are of influencing the development of REACH. With regard to the proposed measures in both the shorter and longer terms, the work on analyses and knowledge-building should generally start now if Sweden is to be able to build up readiness to act in suitable forums at EU level. Sweden also needs to create alliances and pursue issues together with other Member States with similar points of view. Sweden already does so today, and this way of working should be developed.

It was the strong political will of a number of Member States in the area of chemicals that made it possible to bring about by far the world's most ambitious chemicals legislation in the EU. REACH is scientifically-based legislation. Our assessment is that the complexity and the highly technical nature of the regulation has contributed to rendering some important implementation and development issues being restricted to mainly being dealt with as technical issues, taking insufficient account of the chemicals policy dimension, for example in the form of international and national environmental objectives.

An example where striking a balance between the technical aspects and the chemicals policy aspects is important is the need to develop REACH so that children are better protected. In section 4.1.6, we present a number of technical proposals to reduce the risk of children being harmed. Our assessment is, however, that it will be difficult for several of the proposals to have an impact, as no clear political line has been formulated at EU level on the special sensitivity of children and concerning the need to increase protection. There is a risk that the proposals will therefore be addressed separately and from a technical perspective. In the action plan, we have identified areas where we believe it will be difficult to achieve a breakthrough unless the Government acts for a general raising of the level of ambition in EU chemicals policy.

The EU strategy for a Non-Toxic environment which is to be prepared by 2018 under the EU 7th Environmental Action Programme can help the chemicals policy aspects and objectives to again be accorded greater emphasis in the implementation and development of REACH. The areas emphasised in the Environmental Action Programme are safe management of nanomaterials, minimisation of exposure to endocrine disruptors, enhancing of the legislation to encompass combination effects and minimisation of exposure to hazardous substances in articles. We believe it is important that the EU strategy for a Non-Toxic environment also addresses the special sensitivity of children and the way in which impetus for the substitution of hazardous substances can be generated.

- The Swedish Chemicals Agency will contribute from 2014 with a national expert seconded to the Commission's Directorate-General Environment to work on formulating the EU strategy for a Non-Toxic environment.

3.2 Measures to improve the implementation of REACH

We have identified two areas in the action plan as particularly important with regard to implementation of the REACH Regulation.
• Inadequate effectiveness in the implementation of REACH.
• Inadequate quality in industries’ registration data.

3.2.1 Inadequate effectiveness in the implementation of REACH

We consider the REACH process for restriction of hazardous chemical substances as being more troublesome and more demanding than it was in previous regulatory frameworks. The information that ECHA's Risk Assessment Committee (RAC) and Socio-Economic Analysis Committee (SEAC) regard as necessary to be able to provide an opinion has increased in scope compared with previous legislation. This means that the costs of drawing up proposals for restrictions become unreasonably high for the Member States. Producing data for restriction of a substance under REACH normally costs between SEK 5 and 10 million. A consequence of this is that only a few Member States have submitted proposals for restrictions of substances in the past three years. The total number of proposals from these Member States is only seven, of which Sweden has submitted three. There is a risk of inefficiency and unreasonably high costs to the Member States meaning that restriction in practice does not become a usable approach to risk management.

The substances on what is known as the Candidate List are those regarded as being of very high concern. The substances then transferred to Annex XIV of the regulation are additionally covered by authorisation requirements. The fact that REACH requires authorisation for the use of certain hazardous substances may prove to be a major improvement compared with previous legislation. For this to be the case, however, it is required that the authorisation requirement covers the substances of very high concern whose handling poses unacceptable risks. There is great uncertainty over the future effectiveness of the authorisation process. The uncertainty relates both to increasing resistance to the substances having to be covered by the requirement for authorisation and to the risk of the authorisation process becoming too cumbersome and labour-intensive. Practical experience of the authorisation procedure to date is limited, as no applications for authorisation have yet been finalised.

European industry has argued that the authorisation procedure gives non-European industry a clear competitive advantage over European industry. Discussions are therefore in progress on taking account of economic aspects more systematically in the application of REACH. The Commission and certain Member States have become more hesitant about including the substances recommended by ECHA in Annex XIV. There is also uncertainty over the procedures and the number of applications that will need to be processed. ECHA estimates that between 70 and 245 applications will be received in 2016. It is therefore important that the routines in the authorisation process are efficient so that the workload on ECHA's committees (RAC and SEAC) does not become too high.

15 The process for a competent authority submitting a restriction dossier is as follows: Risk Management Option (RMO) analysis → dossier production → submission to ECHA → ECHA's (RAC/SEAC) Conformity Check → supplements in conjunction with and after Conformity Check → ECHA (RAC/SEAC) processes → follow-up work → approval. The Swedish Chemicals Agency has drawn up a restriction dossier for lead in consumer products that have passed through the entire process and been approved. The total cost for this dossier was just over SEK 7 million, broken down as follows:
RMO analysis: 19%
Dossier production: 53%
Supplementation after Conformity Check: 20%
Public consultation: 3%
Follow-up work: 5%

16 Proposals for restriction of nonylphenol in textiles, of lead and lead compounds in consumer goods and cadmium in artists’ paints.
The ineffectiveness of the restriction process at present reduces the possibility of attaining the milestone target concerning development and implementation of EU rules on chemicals. An effective authorisation process is also needed to improve the prospects of attaining both this target and the milestone target concerning substances of very high concern.

- The Swedish Chemicals Agency proposes that the Government acts in the short term for discussions to take place in the Council of the European Union on how work on the various processes of REACH can be made more effective with the aim of a higher level of protection.
- The Swedish Chemicals Agency intends to act in the short term in various working groups and committees for work on restrictions, authorisation and other processes in REACH to become more effective.

More detailed proposals for measures relating to the inadequate effectiveness of the implementation of REACH are presented in Chapter 4.

### 3.2.2 Inadequate quality in industries´ registration data

The basis for REACH to function as intended is that industry presents adequate data in their registrations. The companies shall set aside resources to develop knowledge on the hazardous properties of their chemical substances, formulate chemical safety reports of good quality and so on. The compliance checks conducted by the European Chemicals Agency (ECHA) on the registration documents show clearly that many companies submit registration data of highly deficient quality. This is one of the reasons why there are also often great shortcomings in the information transferred in the supply chain. The Swedish Chemicals Agency, as the national enforcement authority, will contact the companies for follow-up and possible sanctions or other measures in the event that ECHA finds shortcomings in the registration data of Swedish companies.

These shortcomings contribute to making it difficult for the milestone target relating to knowledge of the hazardous properties of substances for health and the environment to be achieved.

- The Swedish Chemicals Agency will actively take part in the EU-wide activities concerned with the ambition and orientation of ECHA's review of registration data, partly in order to provide support to make it easier for Swedish companies to fulfil their obligations.
- The Swedish Chemicals Agency intends to take part in working groups at EU level to contribute to improved guidance to companies, which in turn can contribute to improved quality of the information which under REACH has to be transferred in the supply chain.

More detailed measures to improve the quality both of the companies' registration documents and the information distributed via the supply chain are discussed in section 4.1.1.

### 3.3 Measures to develop the REACH regulatory framework

We have identified four areas in the action plan that are particularly important with regard to the development of REACH.
3.3.1 Stricter knowledge requirements for low volume substances

It is estimated that around 20,000 chemical substances are handled in low volumes, i.e. between 1 and 10 tonnes per year. For the vast majority of these substances, the requirements for information in registration in REACH are entirely inadequate to allow hazard and risk assessment. With the test methods that are available today, it is not reasonable from either an ethical perspective in relation to animal experiments or a financial perspective to conduct extensive tests on all low volume substances. We therefore believe that Sweden should act for the REACH review to lead the EU to develop an approach based on alternative methods to animal experiments in order to make it possible to target stricter information requirements and prioritise initiatives concerning low volume substances which could pose risks to health and the environment.

The existing inadequate knowledge requirements that apply to low volume substances make it difficult to attain the Swedish milestone target regarding knowledge about the hazardous properties of substances as regards health and the environment.

- The Swedish Chemicals Agency believes that Government initiatives may be needed if the Commission's work concerning information requirements for low volume substances is going to be completed in due time to have any practical impact on the information that will be required when substances in the range of 1–10 tonnes have to be registered in 2018.
- In the short term, the Swedish Chemicals Agency will participate in the working groups that the Commission will probably launch in order to address the issue of data requirements concerning low volume substances.
- The Swedish Chemicals Agency proposes that the Government acts for more research initiatives in both Sweden and the EU with the aim of it becoming possible in the longer term to raise the test requirements in REACH concerning low volume substances in a cost-effective way without substantially increasing the number of animal experiments.

More detailed proposals for measures relating to stricter knowledge requirements for low volume substances can be found in section 4.1.5.

3.3.2 The substitution principle needs to be strengthened

REACH is a highly technical regulation, which is as would be expected give that the criteria for classification, methodology for risk assessment and guidance documents are "scientifically based". The large number of existing substances and the potential to synthesise new ones that are chemically closely related to banned substances make it impossible to handle every imaginable chemical variant through detailed rules. If REACH were to handle the huge number of variants of problematic substances that could potentially be manufactured under the current principle of regulation, it would require an almost infinite number of detailed rules.

Rules stating clearly that industry is responsible for safety during the use of a substance are largely absent in REACH, even if it is not covered by a detailed rule. We therefore consider
that REACH should be supplemented by clear rules highlighting the responsibilities of companies even in the absence of detailed rules. The key principles of such rules are general provisions concerning substitution (the principle of substitution). It is particularly important that the responsibilities of companies for replacing substances are clear in cases where these are suspected as being of very high concern. There are several examples where society has banned harmful chemical substances and where these have been replaced by chemically closely related substances with similar hazardous properties. This has happened, for example, in the groups of brominated flame retardants and highly fluorinated substances. The new substance is often somewhat less hazardous but leads to essentially the same problems. The formulation of the rules is important, as experience shows that rules kept general on responsibility in chemicals legislation often have a limited impact in reality.

A Swedish resource centre for substitution would contribute to building up knowledge on existing alternatives. It might also help Swedish companies to coerce suppliers into replacing hazardous substances. A corresponding resource centre at EU level might improve the implementation of REACH by making it easier for European industry to replace hazardous substances.

More stringent provisions concerning substitution and a greater understanding of possible alternatives to hazardous chemical substances would contribute to the attainment of a number of milestone targets, primarily the target relating to substances of very high concern and that relating to the development and application of the EU rules on chemicals.

- The Swedish Chemicals Agency proposes that the Government acts in the short term for the EU strategy for a Non-Toxic environment to emphasise that the impetus for substitution of hazardous substances should be boosted. We wish to emphasise the importance of discouraging the replacement of banned hazardous substances by chemically closely related substances through the regulatory framework, if there is reason to suspect that they have the same hazardous properties as the prohibited substance.
- There is a need for a number of measures aimed at ensuring that manufacturers, retailers and consumers gain better access to information on hazardous substances in articles. These are both short-term and long-term measures, at both political and technical levels. The measures include amendments to the regulation, for example in Article 33, as well as the development of systems to make information more readily available.
- The Swedish Chemicals Agency proposes that the Government acts in the long term for stricter rules concerning substitution to be introduced into REACH, including a general rule concerning substitution.
- The Swedish Chemicals Agency notes that in Government Bill 2013/14:39 the Government intends to examine the prospects for establishing a national resource centre to promote the substitution of hazardous substances. In this context, we also wish to stress the need to establish a resource centre at EU level in the longer term.

More detailed proposals for measures concerning substitution can be found in section 4.1.9.

3.3.3 Faster adaptation to technical and scientific developments

The pace of technical and scientific development is rapid. It is important that the legislation keeps up with this rapid development in order to respond to new or previously unknown risks.

There is increasing evidence that certain chemical substances, known as endocrine disruptors, can harm human and animal reproduction, affect the unborn child and also affect a
child’s later development. Sweden should continue to strive for a strict view to be taken of endocrine disruptors. This applies both to these substances having to be regarded as being of very high concern and to them becoming the object of risk management measures, for example in the form of authorisation under REACH.

Rapid development of the legislation is necessary, principally to attain the milestone targets on substances of very high concern and on knowledge of the properties of chemical substances hazardous to health and the environment.

- The Swedish Chemicals Agency is to continue to prioritise the work relating to endocrine disruptors. This means, among other things, acting for the future EU criteria to establish which substances are endocrine disruptors to have a high level of protection.
- The Swedish Chemicals Agency proposes that the Government should act in the longer term for endocrine disruptors to be regarded as substances of very high concern in the REACH Regulation. The same should apply to highly allergenic substances.

More detailed proposals for measures concerning endocrine disruptors can be found in section 4.1.3.

We know that in some cases chemical substances can interact in such a way that the risks are greatly increased through exposure to combinations of substances compared with the risks associated with exposure to individual substances. This applies particularly to certain endocrine disruptors. Despite this, in present-day legislation the risk is generally assessed on the basis of one substance at a time, without possible combination effects being considered. REACH and other EU regulatory frameworks need to be developed to take better account of combination effects.

- The Commission's work on combination effects has been delayed. Initiatives may therefore be needed at political level to ensure that work on combination effects is launched in the EU technical working groups.
- The Swedish Chemicals Agency intends to endeavour to ensure in the EU technical working groups that proposals for risk restrictions developed in the Member States and ECHA take account of possible combination effects, for example in the form of an extra uncertainty factor.
- The Swedish Chemicals Agency proposes that the Government in the short term acts for the EU strategy for a Non-Toxic environment to be formulated so that it supports the introduction of rules for combination effects in REACH, with a high level of protection.
- The Swedish Chemicals Agency proposes that the Government acts for REACH in the longer term to require industry to take account of possible combination effects in their registrations.

More detailed proposals for measures concerning combination effects can be found in section 4.1.8.

There is a great need to develop REACH to **protect children better** from being harmed by chemical substances. This applies to all stages from the testing of hazardous substances to how risk assessments are made and what risk-limiting measures are implemented.
• The Swedish Chemicals Agency proposes that the Government in the short term should strive for the EU strategy for a Non-Toxic environment to address the need to protect children better and that this should contribute to a high level of protection for children in REACH and other EU legislation in the area of chemicals. An important issue is how the protection of children can be improved with regard to the presence of substances of very high concern in articles we use in our everyday lives.

• The Swedish Chemicals Agency will endeavour to ensure in the short term in the various EU working groups that among other things better guidance is developed to assess how children are exposed to hazardous chemical substances and how risk assessments are to take account of the special sensitivity of children.

More detailed proposals for measures to better protect children can be found in section 4.1.6.

There is no special legislation at present for nanomaterials. Nor are there any explicit requirements in REACH concerning nanomaterials, either in articles or in annexes. The rules need to be developed, firstly with regard to information on the presence of nanomaterials in chemical products and articles and secondly with regard to test requirements and requirements for information on the hazardous properties of nanomaterials for the environment and health and risks of exposure to these.

• Initiatives may be needed at the political level for the Commission to, as previously promised, as soon as possible present a proposal for extended information requirements for nanomaterials in connection with registration in REACH. These extended requirements are to be introduced through amendments to annexes of REACH.

• The Swedish Chemicals Agency intends in the short term to draw up background material for the Government on how information requirements for nanomaterials can be formulated for different tonnage ranges.

• The Swedish Chemicals Agency proposes that the Government acts in the short term for special EU rules concerning nanomaterials to be developed to complement REACH or for relatively comprehensive amendments to REACH to be implemented.

More detailed proposals for measures concerning nanomaterials can be found in section 4.1.4.

3.3.4 Better opportunities to assess and manage the risks of groups of chemicals

REACH is primarily focused on the assessment of individual substances. In certain cases, however, groups of substances have been dealt with jointly in authorisations and restrictions. We consider that REACH needs to be developed so that assessment of groups of substances is made easier. An example that clearly illustrates this need is that of the highly fluorinated substances. This group consists of hundreds of substances. Dealing with the group of highly fluorinated substances one substance at a time would take many decades, for example in connection with the substance evaluation, and the authorisation and restrictions procedures in REACH. The knowledge that exists on this group of substance suggests that persistence and the ability to harm the liver and reproduction may be common to many of these substances or their break-down products. Dealing with these substances one at a time would therefore, as well as being inefficient, probably also be misleading from the point of view of risk. A combined assessment should instead be made of the risks associated with the whole group of
highly fluorinated substances. The fact that these substances are used together in various combinations and replace each other in many types of articles further suggests combined management of the group of substances.

Better opportunities to carry out group assessments would contribute to a number of the milestone targets on hazardous substances, principally the milestone target concerning the development and implementation of the EU chemicals legislation.

A type of group assessment is often used by industry in their REACH registrations. This means that companies justify their decisions not to test the hazards of a substance to health and the environment by arguing that the substance belongs to the same group as a tested substance and hence have the same (or lack of) properties. However, the groupings are often done incorrectly and therefore entail misuse of the possibility offered in the rules of exemptions from testing. Measures for dealing with problems of this type are described above in section 3.2.2 “Inadequate quality in industries´ registration data, and in section 4.1.7.

- It is important in the short term to explore the possibilities for group-by-group assessments of some selected groups of substances in the framework of substance evaluation in REACH. The Swedish Chemicals Agency will propose in the EU working groups that ECHA starts a project to gather experience that can form the basis for continued development activity.
- Group assessments may be essential to bring about effective chemicals controls with a high level of protection. In the longer term, initiatives are needed at both political and technical level to develop the regulatory framework in this respect. Difficult scientific and legal issues are linked to the development of the regulatory framework that increases the possibility of group assessments and at the same time discourages inappropriate substitution (see the section above on substitution and section 4.1.9).

4 Analysis and proposed measures

4.1 Registration

4.1.1 The quality of registrations needs to be improved

REACH is based on the principle that it is the manufacturers, importers and downstream users who bear the responsibility for ensuring that the substances that they manufacture, place on the market or use do not have any harmful effects on health or the environment. Anyone who wants to manufacture or place a substance on the market within the Community must register the substance and demonstrate that they have collated the information that is required in accordance with REACH. Companies submit their information in the form of a registration dossier. In this dossier, they must also demonstrate that they have evaluated the substance's hazardous properties and risks, and proposed measures that are sufficient to manage any risks associated with the use(s) of the substance.

The content and quality of registrations are of fundamental importance in ensuring that the REACH Regulation and subsequent processes in REACH function as intended. The primary responsibility rests with the registering company. Companies who use the chemicals also have a responsibility in this context. They are encouraged to provide information on their uses of the substances to the company that is responsible for the registration. Responsibility for investigating compliance with the requirements ultimately rests with ECHA, but Member
States are also responsible for distributing information and assisting ECHA with enforcement with respect to the registrants.

REACH places the responsibility for evaluation of the registration dossiers on ECHA. The authority checks that the registration information complies with the legal requirements by compliance checking of at least five percent of the registrations. ECHA also conducts an annual evaluation of the registration information and identifies commonly occurring deficiencies in the registration dossiers. According to ECHA's report from 2013, the quality of two thirds of the dossiers reviewed that far was so deficient that ECHA had to request additional information from the registrants. During 2013, most such requests for information concerned basic data such as the substance's chemical identity and physical-chemical properties.

In February 2013, the Commission presented its first review of REACH, i.e. recommendations concerning improvements to the application. The recommendations highlighted the quality of registrations as an area where industry, ECHA and Member States should step up their efforts. Companies need to improve both their registrations and their safety data sheets. According to the recommendations, registrants should also improve and reinforce their reasoning in cases where they intend not to follow the standard information requirements for submitting a registration for a substance.

**Objectives regarding registration quality**

- Information concerning the health and environmental properties of substances in industries’ registration dossiers is available and adequate to enable risk assessments to be carried out regarding all uses.
- The information submitted is based on accurate and reliable underlying information gathered on the basis of e.g. animal tests or alternative test methods.
- Hazard assessments (including hazard classifications), risk/safety assessments and recommended risk management measures which are based on the registration information fulfil applicable criteria and follow prescribed methods and applicable guidance.

**Prioritisation and need for political initiatives**

We propose that a high priority should be put on enforcement activities towards Swedish registrants who have not provided the supplementary information that ECHA has requested in due time. ECHA's work should be monitored as regards improvement of the quality of the information in registrations, action to maximise the effects of the recommendations concerning safe use in the supply chain and to improvement of the distribution of information. Supplementary initiatives should be carried out as necessary. For example, information initiatives are needed relating to support and information aimed at Swedish companies that are required to register substances in accordance with REACH. Initiatives are also needed to contribute to and follow ECHA's development work on the registrants recommendations on safe use (i.e. the 'exposure scenarios'), which suppliers often need to provide their customers with. The development work concerns methodology and information systems.
Proposed measures concerning the quality of industries’ registration dossiers

The measures that are proposed for improving the quality of registration information provided by industry relate partly to boosting ECHA's work within the area and partly to helping Swedish companies to provide ECHA with the right information and, in the longer term, to consider implementing stricter checks on the underlying information.

Short-term measures

- The Swedish Chemicals Agency should work with ECHA to determine how national authorities can best contribute to the measures and activities that ECHA is planning in order to improve the quality of registrations. This includes participating in workshops and other activities organised by ECHA to discuss the orientation and formulation of the authority's work relating to the review of registrations.
- The Swedish Chemicals Agency should participate in support and information activities targeted at Swedish companies, partly through collaboration with ECHA's HelpNet.

Long-term measures

- The Swedish Chemicals Agency should consider developing ECHA's currently highly automated checks on the completeness of registration information. The aim of this is to ensure that substance identities in the registered information are correct before they are accepted and a registration number issued.

Need for further analyses

- Consideration should be given to revising the regulation so that ECHA will be able to withdraw registration numbers for substances that show serious deviations from the registration requirements. In its annual evaluation report for 2013, ECHA claims that they already have the authority to recall registrations, but have not yet exercised that authority. It is however unclear where in the REACH Regulation ECHA is given such authority.

How the proposals help to ensure achievement of the Swedish milestone targets concerning dangerous substances

(A description of the Swedish environmental target A Non-Toxic Environment and the milestone targets is given in Chapter 5)

The milestone target concerning knowledge of the health and environmental properties means, among other things, that information concerning the health and environmental properties of chemical substances should be sufficient and available to enable a risk assessment to be carried out for all areas of use.

Comments: The proposed measures are expected to contribute to ensuring that the quality of registration information is sufficiently high. This is of pivotal importance for the milestone target.

4.1.2 Access to and adaptation/processing of information from REACH and CLP

ECHA, the EU chemicals authority, receives the information that is prepared in accordance with REACH and with the Regulation on Classification, Labelling and Packaging (CLP). For
anyone wishing to reduce the risks associated with using chemicals, information on the substance, any risks linked to its use and any alternatives that are available is essential for both safe handling and the possibility of selecting or avoiding the substance on an objective and impartial basis. The databases that are being built up by ECHA contain a large quantity of information with a unique link to the regulation, ensuring both reliability and relevance. ECHA has an obligation to make information from the databases available to interested parties.

The information which is submitted to ECHA which the authority then makes available is often technically complicated in terms of content, general and very extensive. Many users find it difficult to retrieve the right information and to interpret the information. ECHA's website has no advanced search or filtering options and downloading and saving the information can also be difficult.

ECHA is currently working to improve the website in order to make data more accessible. The aim is that in the future interested parties will gain access to information via a single portal on the website. This will apply regardless of whether the information has been submitted to ECHA in accordance with REACH, CLP or the Biocide Regulation, which also falls within ECHA's remit. The results of public consultations will also be made available via this single portal. ECHA's development plans contain a number of separate parts. For example, ECHA intends to review the structure of the website in order to integrate data from different sources and facilitate the downloading of data. The interface that greets users and the filtering and search options should also be adapted. During the development process, ECHA will also draw attention to the content and quality of the information. ECHA plans to launch the new website during 2015.

**Objectives for access to information**

- All information held by ECHA which is not confidential can be accessed by interested parties in a structured and manageable way. This has been achieved through the development of advanced search tools for ECHA's website.
- The information has been processed and adapted to meet the needs of various target groups, including companies that use chemicals, both within the EU and internationally.
- Guidance is available on ECHA's website which shows the principles for searching in the databases. The guidance also facilitates interpretation of the information and understanding its limitations.

**Prioritisation and need for political initiatives**

Access to and adaptation of information held by ECHA can be achieved without legislative changes. ECHA is working to improve accessibility and a new information portal is planned for 2015. Until then and also after 2015, the Swedish Chemicals Agency should monitor developments and, if necessary, propose supplementary measures.

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17 Report from advisory group on dissemination MB/48/2013, 20 Sep 2013
Proposed measures concerning access to information

The proposed measures concern monitoring of the work in technical working groups and committees and, if necessary, contributing to this work.

Short-term measures

- The Swedish Chemicals Agency should monitor the work to make available and process the information in ECHA's databases.
- The Swedish Chemicals Agency should contribute with its own relevant experience relating to databases and, if necessary, propose supplementary initiatives.

Long-term measures

- After the launch of ECHA's information portal in 2015, the Swedish Chemicals Agency should also continue to monitor the handling of information and propose supplementary measures if necessary.

Need for further analyses

The opportunities for improving the information in ECHA's databases and adapting it to meet the needs of various user groups need to be analysed further. Access to such customised information would be valuable in connection with product development, as well as substitution and other risk-mitigating measures.

Work is under way to distribute chemical-related information in a number of contexts. Sweden has introduced an Ordinance on an information service for consumers - a consumer portal. Authorities that are responsible for information will contribute to this service within their respective fields. There is also discussion on the need for a resource centre concerning substitution (see section 4.1.9), with collated information which can facilitate the work of companies relating to substitution.

An analysis of Sweden's Consumer Portal, ECHA's Information Portal and a future resource centre relating to substitution should clarify how these can complement each other and interact.

How the proposals help to ensure achievement of the Swedish milestone targets concerning dangerous substances

(A description of the Swedish environmental target A Non-Toxic Environment and the milestone targets is given in Chapter 5)

The milestone target concerning knowledge of the health and environmental properties of substances means, among other things, that information on properties of chemical substances should be sufficient and available to enable a risk assessment to be carried out concerning a particular application.

Information concerning the health and environmental properties of a substance is vital in order to prevent and mitigate risks associated with chemical substances. The availability of information is essential in order to use the information. Fundamental provisions relating to requirements for knowledge and information concerning substances are set out in REACH and
CLP, and the milestone targets are in the first instance aimed at ensuring that these regulations are developed.

Comments: The proposed measures are expected to contribute to attainment of the milestone target. The target year for the milestone target coincides with ECHA’s launch of the new information portal in 2015.

4.1.3 Endocrine disruptors

Hormones control a number of functions in the bodies of humans and animals, including reproduction, the immune defence system and metabolism. Substances with hormone disrupting properties (endocrine disruptors) have the potential to cause harmful effects on the functioning of the hormone systems. They are considered to be particularly problematical because they can cause serious disorders in humans and the environment as a result of exposure during key developmental stages, e.g. during the foetal stage, the growth stage, the teenage years and the menopause. The effects can also be permanent (irreversible) and can appear long time after exposure, or they may not even become noticeable until future generations.

The issue is one of the highest profile aspects of the work relating to chemical safety over the past 15 years. The discussion has partly centred on test methods and criteria for identifying endocrine disruptors, as well as on issues such as the existence of effects at very low exposure levels, non-linear dose response relationships, the possibility of establishing threshold levels for effects and the importance of when during development exposure takes place.

The importance of endocrine disruptors is being discussed in connection with increases in the frequency of cases of certain forms of cancer, earlier puberty development in children, increased frequency of genital malformations, impaired sperm production and sperm quality in men, as well as overweight, diabetes and behavioural disorders. Within the environmental field, there is concern about endocrine disruptors in water causing abnormalities in fish and other animals in wastewater recipients and elsewhere. As yet, REACH neither contains criteria for identifying endocrine disruptors, nor any specific requirement to provide information on endocrine disruptors upon registration or a requirement to test and otherwise investigate whether a substance should be considered as an endocrine disruptor. However, it is already possible to identify certain endocrine disruptors as SVHC in accordance with the provisions concerning substances which "give rise to an equivalent level of concern" (Article 57f).

As of May 2014, no criteria for determining which substances are endocrine disruptors in REACH have yet been adopted. At the time of writing, it is therefore unclear as to what extent such criteria will encompass endocrine disruptors or which of the substances that are identified will be deemed to be a SVHC substance. The endocrine-disrupting potential of the identified substances will probably be graded in some way. A further issue being discussed is whether endocrine disruptors should be considered as substances without a threshold level for when exposure could have harmful effects. If a substance is considered to have a threshold, under REACH, authorisation shall be granted if the risks associated with use of the substance is deemed to be adequately controlled. However, if no threshold applies, authorisation may only be granted if a socio-economic analysis shows that the benefits outweigh the risk.

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19 The threshold level for a substance can be described as the lowest level of exposure at which effects can arise.


21 The expression "adequately controlled" is used in the REACH text and is also used synonymously in this report.
The internationally accepted methods that are currently available only cover certain aspects of the hormone system, i.e. effects on sex hormones, the thyroid hormones and parts of the steroidogenesis. Additional test methods should be developed in order to encompass effects on other parts of the hormone system. Correspondingly, additional test methods should be developed for endocrine-disrupting effects in the environment. Existing test methods concerning environmental effects are largely restricted to effects on fish and amphibians.

According to the Commission, the criteria for endocrine disruptors should be published as a recommendation. Relevant legislation could then refer to the recommendation. However, no decision concerning such a solution has been taken. Other possibilities could for example be that the criteria are incorporated in a separate regulation or in a separate annex to REACH or the Regulation on Classification, Labelling and Packaging (CLP). The advantage of incorporating the criteria in a separate regulation, in REACH or in CLP is that they would be legally binding. However, the consequences of the various alternatives need to be studied in more detail.

**Objectives for endocrine disruptors**

The aim of the envisioned regulation of endocrine disruptors is to achieve a high level of protection for health and the environment. The rules should particularly focus on the safety of children and other sensitive groups and on protecting sensitive groups of organisms. In the case of endocrine disruptors, this is achieved through the establishment of:

- criteria for endocrine disruptors based on the intrinsic properties of the substances,
- requirements on identification of endocrine disruptors in relevant regulations,
- standard information requirements which enable the identification of endocrine disruptors in relevant regulations,
- a testing strategy which includes screening tests and tiered requirements for further testing in cases where screening tests indicates that the substances have a hormonal effect,
- guidance documents concerning the identification and risk assessment of endocrine disruptors,
- test methods, methodology and models which encompass additional parts of the hormone system and additional animal groups in the environment and take into account the fact that endocrine disruptors can have effects during particularly sensitive stages - “time windows” - in an organism's development and that hormonal effects can have impacts which only become apparent later in life or in future generations, and,
- requirements concerning information and, in the longer term, hazard labelling, targeted at downstream users and consumers.

**Prioritisation and need for political initiatives**

Development of the EU provisions concerning endocrine disruptors should be given a high priority in terms of urgency in an action plan to develop REACH. Work has been under way for some time within a number of expert groups and other forums initiated by the Commission. According to the EU regulation concerning biocides and plant protection

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22 The formation of steroid hormones in the body.
products, criteria should have been established by December 2013. This deadline has been brought forward because the Commission intends to carry out an impact analysis and no new date has so far been announced. Further initiatives at political level should be considered in order to accelerate the work at EU level. Suitable forums exist for many of the proposed measures concerning annexes, guidance documents and regulations. These measures are handled at authority/EU level in committees and working groups. To enable endocrine disruptors to be identified as substances of very high concern (SVHC) in accordance with REACH, without applying the special provisions concerning SVHCs in Article 57f, an amendment to the article would be required and therefore consideration by both the Council and Parliament would be necessary.

**Proposed measures concerning endocrine disruptors**

**Short-term measures**
The measures concerning endocrine disruptors that are of relevance in the short term largely concern changes in annexes to REACH and the development of guidance and methodology for testing and risk assessment. This work is normally carried out in committees and technical working groups, in which Sweden is represented by the Swedish Chemicals Agency. In order to keep up the pace and level of ambition, political initiatives may also be necessary within the Council and in other forums for discussion with the Commission and with other Member States. Over the next few years, Sweden should carry out the following initiatives and strive to bring about the following measures and decisions at EU level:

- At their respective levels, the Swedish Government and Swedish Chemicals Agency should promote the establishment of EU criteria for the identification of endocrine disruptors based on the intrinsic properties of substances, as soon as possible.
- The Swedish Chemicals Agency should actively participate in ongoing processes within the EU and OECD in order to develop methodology and guidance for the testing, identification and risk assessment of endocrine disruptors.
- Sweden should actively participate in the ongoing work relating to an EU strategy for endocrine disruptors. Sweden should also actively participate in the work relating to a future EU strategy for a Non-Toxic environment, which according to the EU 7th Environmental Action Programme will be drawn up by 2018 and include the issue of endocrine disruptors. It is anticipated that the work will encompass initiatives both at a political level and in committees and working groups.

**Long-term measures**
The measures relating to hormone disruptors that are being proposed for the longer term include amendments both to articles in REACH and CLP and in annexes and guidance documents. Amendments to articles will require initiatives at Council level and in committees and working groups and will therefore involve both the Swedish Government and the Swedish Chemicals Agency. The third and fourth points below do not concern registration, but are described for the sake of clarity in this section together with other proposals concerning endocrine disruptors. In the longer term, Sweden should strive to bring about the following measures or decisions and contribute to the following processes within the EU:

- separate annex containing criteria for the identification of hormone disruptors should be drawn up under REACH. This would correspond to Annex XIII of REACH, which contains criteria for the identification of persistent, bioaccumulative and toxic

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substances, known as PBTs. An alternative is to incorporate criteria for the classification of endocrine disruptors into CLP. In the long term, a corresponding addendum concerning the classification of endocrine disruptors should be promoted at international level in the globally harmonised system for classification and labelling (GHS).25

- New provisions should be incorporated into Annex I of REACH, requiring the registrants to assess whether a substance is an endocrine-disruptor in their chemical safety assessments on the basis of amended standard information requirements.
- Endocrine disruptors should be considered in a separate category in the provisions for identifying substances of very high concern (Article 57 in REACH) and therefore no longer be dealt with under the category substances of an equivalent level of concern according to Article 57f.
- Information on the occurrence of endocrine disruptors in chemical products and in articles should be made available to professional users and to consumers as such substances are identified. Information on individual endocrine disruptors should as far as possible be made publicly available via an existing or, if necessary, new database managed by ECHA or DG Joint Research Centre. In the long term, labelling of chemical products in the form of hazard phrases and/or hazard symbols should be required.

Need for further analyses

The opportunities that exist for introducing a separate regulation with criteria for identifying endocrine disruptors or for introducing such criteria for the classification of endocrine disruptors in the CLP and, in the longer term, in GHS, should be reviewed. The advantage of incorporating the rules in a regulation is that they would be legally binding. A further possible advantage is that EU would gain practical experience and a basis for future proposals to include criteria for endocrine disruptors in GHS.

How the proposals help to ensure achievement of the Swedish milestone targets concerning dangerous substances

(A description of the Swedish environmental target A Non-Toxic Environment and the milestone targets is given in Chapter 5)

The milestone target concerning particularly dangerous substances means that decisions taken within the EU and internationally concerning such substances will include measures to ensure that endocrine disruptors (and strong allergenic substances) are deemed to be substances of very high concern in all relevant regulations by 2015.

Comments: The proposed measures concerning criteria need to be implemented in order to achieve the specific objective of endocrine disruptors being considered to be substances of very high concern. Whether this objective can be achieved by 2015 is currently uncertain, primarily as a result of the delay to the Commission's proposal for criteria.

4.1.4 Nanomaterials

Nanotechnology is developing rapidly and the occurrence of nanomaterials in chemical products and articles on the market is believed to be increasing at a corresponding rate.

25 The global harmonised system for the classification and labelling of chemicals was originally adopted by the UN in 2002 and has since been revised on five occasions.
Nanotechnology has applications within many fields such as electronics, material technology, chemistry and biology and will probably constitute an important area for innovation and technical development for many years to come.

Nanomaterials are characterised by their extremely small dimensions. Nanotechnology is creating opportunities to design new, previously unknown physical structures. In turn, this means that a substance can have completely different properties when it occurs at a nanoscale, compared with the properties it has in its larger form. Such special properties are much sought-after and form the basis for the considerable potential for innovation and development within the field. However, these properties can also mean that in some cases nanomaterials can impact on human health and the environment in a different way compared with the corresponding conventional material. Nanomaterials can therefore give rise to other or new types of health and environmental risks compared with chemicals in a different form. They could for example be more reactive than other materials and pass through the natural barriers of the body more easily. It is therefore important to develop analysis methods, testing and risk assessment methodology, registration requirements and risk management measures which are appropriate for nanomaterials.

There is no special legislation at present concerning nanomaterials. Nor are there any explicit requirements in REACH concerning nanomaterials, either in articles or in annexes.

As a nanomaterial is a substance, it is in principle covered by REACH. As REACH is currently formulated, however, the rules are not appropriate for these materials. At present, registrations for nanomaterials are often incomplete or even non-existent. It is also unclear whether the test and risk assessment methods that are currently prescribed are applicable to materials on a nanoscale. Validated methods for risk assessment and testing are also not yet available. REACH contains no legally binding definition of nanomaterials.

No information is currently available concerning either the quantities of nanomaterials that are on the market or the chemical products in which they are used. It is however likely that the lenient information requirements laid down in REACH concerning health and environmental properties of low volume substances (substances handled in quantities of 1-10 tonnes per manufacturer or importer and year) constitute a special problem as regards nanomaterials. This is because, in the opinion of the Swedish Chemicals Agency, many materials in the nano category probably belong to the category of low volume substances, or are even handled in quantities of less than one tonne. If this is the case, they will in many cases not be covered by the test requirements concerning health and environmental effects in REACH, or will at least only be covered to a limited extent. An indirect effect of this is that other regulations which are based on information that is prepared in connection with registration in REACH, also do not work satisfactorily as regards nanomaterials. An example of such regulations is EU’s Cosmetic regulation, which is dependent on REACH for information concerning the environmental properties of cosmetic ingredients.

In summary, it is an important task as regards the control of chemicals to create the foundations necessary to facilitate the safe handling of nanomaterials. It is therefore important to rectify the deficiencies regarding analysis, test and risk assessment methods and the deficiency regarding specific provisions in REACH and other regulations.

**Objectives concerning nanomaterials**

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26 Swedish Chemicals Agency report no. 1/10, Säker användning av nanomaterial – behov av reglering och andra åtgärder.
The overarching objective as regards the regulation of nanomaterials is to achieve a high level of protection for human health and the environment. In the case of nanomaterials, this is achieved through the establishment of:

- a binding definition of nanomaterials,
- a common EU reporting system for nanomaterials based on amended provisions in REACH,
- access to clear information for downstream users of nanomaterials, and
- additional registration requirements for nanomaterials in REACH which involve:
  - stricter information requirements in connection with lower tonnage levels.
  - new requirements concerning identification of nanomaterials.
  - expanded standard information requirements (including applicable test methods, dosimetry methods and sample preparation).

**Prioritisation and need for political initiatives**

Development of EU's regulatory framework should be given a high priority in the action plan in terms urgency. The Commission has promised changes to the REACH annexes, and the need to adapt the annexes is also recognised in the EU 7th Environmental Action Programme. Changes to annexes were to be presented before the end of 2013, but has been delayed and a proposal for amendments can be expected no earlier than July 2014. Sweden should act politically to ensure that the work is not delayed further. The work to develop provisions concerning nanomaterials is also continuing in CASG Nano. Sweden should also work with other countries in order to achieve a wider support for its proposals. A first step is the contact that the Swedish Chemicals Agency has made with Denmark and Germany concerning collaboration relating to nano issues, among other things. Prior to the REACH review that is to be carried out in 2017 and prior to the Commission's follow-up of the Second Regulatory Review on Nanomaterials, which is to be carried out in 2015, consideration should be given to whether or not it is possible to gain support for a proposal for changes to REACH regarding nanomaterials.

The proposals and measures presented here are in line with the conclusions of the Swedish study on a national action plan for the safe use and handling of nanomaterials. Implementation of the proposals recommended by the study would contribute to attainment of the objective outlined above.

As regards some of the proposed measures outlined below, it would be sufficient for the annexes to be amended through comitology. Other changes aimed at introducing more stringent information requirements concerning low volume substances, separate registration of nanomaterials and a reporting system would require the text of the regulation to be amended or a separate “Nano Regulation” to be adopted. Even if it is possible to implement changes to the annexes, it would be desirable to introduce a legally binding definition of nanomaterials and a requirement to provide information to downstream users in the form of safety data sheets in the legal text.

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29 An advisory sub-group to the expert group for competent authorities for REACH and CLP (CARACAL).
31 Säker utveckling! Nationell handlingsplan för säker användning och hantering av nanomaterial, SOU 2013:70. [In Swedish with English summary]
Proposed measures concerning nanomaterials

Short-term measures

The measures concerning nanomaterials that are proposed in the short term concern changes to the annexes to REACH and the development of test methods and guidance. This work is being carried out by EU committees and technical working groups within the EU and OECD, in which Sweden is represented by the Swedish Chemicals Agency. However, the development work concerning nanomaterials should also be carried out through political initiatives, e.g. at Council level or with respect to the Commission and other Member States; hence initiatives from the Swedish Government may also be necessary. In the short term, Sweden should carry out the following initiatives, among others, and strive to bring about the following measures and decisions at EU level:

- The Commission should be urged not to delay any further a proposal for expanded information requirements concerning nanomaterials in connection with registration. Such information requirements could be introduced in the form of amendments to annexes to REACH.
- The Swedish Chemicals Agency should actively participate in the development of validated and standardised methods for analysis and testing of nanomaterials within the EU and OECD, as well as the development of guidance for the testing, identification and risk assessment within the field.

Long-term measures

Both the proposed measures concerning nanomaterials in the long term include changes to the text of the REACH Regulation, which involves a process at Council level. Hence, initiatives by the Swedish Government will be required, and the Swedish Chemicals Agency will need to be involved in order to draw up a basis and implement investigatory initiatives. In the longer term, Sweden should carry out the following initiatives, among others, and strive to bring about the following measures and decisions at EU level:

- In the long term, a common EU reporting system should be developed for nanomaterials, including a register which includes articles in addition to chemical products. The Commission has initiated a study to review the consequences of various initiatives in order to improve our understanding of nanomaterials on the market, including a register. The Swedish Chemicals Agency will participate in the work insofar as is possible, partly through submitting remarks. Input to EU's 7th Environmental Action Programme also provides support for considering the establishment of an EU-wide database for nanomaterials.
- Expanded requirements concerning information relating to nanomaterials should be introduced in the long term through amendments to articles in REACH. Amendments to REACH annexes should be seen as a first step, which will be followed up in the long term through amendments to the text of the regulation. An alternative to amending REACH which should be considered is to adopt a separate Nano Regulation.

Need for further analyses

The way in which Sweden can best bring about a common EU reporting system for nanomaterials needs to be analysed further. Consideration should also be given to whether a national reporting system for nanomaterials is appropriate in anticipation of a common EU system.
How the proposals help to ensure achievement of the Swedish milestone targets concerning dangerous substances

(A description of the Swedish environmental target *A Non-Toxic Environment* and the milestone targets is given in Chapter 5)

The milestone target concerning knowledge of the health and environmental properties of substances means that decisions will be taken both within the EU and internationally which will require information concerning such properties of substances to provide an adequate basis for assessing risks relating to all applications. This means that by 2015 relevant legislation will require a knowledge of hazardous properties and occurrences concerning nanomaterials which is sufficient to assess and minimise their health and environmental effects.

*Comment:* The proposed measures contribute to attainment of the milestone target. It is however unlikely that the REACH Regulation will be adapted by 2015. On the other hand, the annexes could be amended, which would be a step in the right direction.

**4.1.5 Stricter information requirements relating to the registration of low volume substances (1-10 tonnes)**

*Information requirements for low volume substances for registration in REACH are inadequate*

The Swedish Chemicals Agency considers that the inadequate information requirements for low volume substances in REACH (1-10 tonnes per year and registrant) represent one of the fundamental deficiencies in the regulatory framework.

REACH requires manufacturers and importers of chemical substances to compile information on the physical-chemical, human health and environmental properties of substances and to submit this information to ECHA when registering the substance. The information requirements are most stringent for substances which are produced or imported in volumes exceeding 1,000 tonnes per manufacturer or importer per year. Gradually less stringent requirements then apply for substances in the range 100-1,000 tonnes and 10-100 tonnes. The least stringent information requirements are imposed on what are known as low volume substances that are produced or imported in quantities of 1-10 tonnes per manufacturer or importer per year. As regards substances that are handled in quantities of less than 1 tonne per year, no registration at all is required.

In most cases, the information requirements that currently apply to low volume substances only concern physical-chemical properties, e.g. boiling point and solubility in water. The information that is provided upon registration is therefore insufficient to carry out an adequate risk assessment of the substance. This also means that there is not normally a basis for assessing what is required for safe handling and use of low volume substances. It is believed that there are around 20,000 substances in the range 1-10 tonnes available on the EU market.

According to REACH, registrations concerning low volume substances shall be submitted to ECHA by 2018. If the information requirements for these substances are not strengthened before then, there is a risk that the information shortfall will persist, with the result that the properties of substances that could be harmful to health and the environment could remain unknown. As a result, no risk management measures would be introduced either.

*How do the information requirements need to be tightened?*

The current information requirements for so-called “phase-in substances” in the range 1-10 tonnes (i.e. substances available on the market which have been pre-registered in connection with the entry into force of REACH) are set out in Annexes III and VII of REACH and are very
inadequate. Annex III of REACH contains special rules triggering the full annex VII information requirements to apply in cases where a phase-in substance has "presumed" hazardous properties and where the use results in consumer exposure. These rules are unclear and it is uncertain to what extent they will result in any further health and environmental information being collected in practice. For “nonphase-in substances” in the range 1-10 tonnes only Annex VII applies.

In order to produce test data sufficient for a basic hazard assessment, hazard classification and risk assessment, even the current information requirements according to Reach Annex VII would need to be supplemented with information on e.g. toxicity after repeated exposure, and the range of tests for mutagenicity needs to be broadened to cover more in vitro screening tests. This information is fundamental in determining what is required in order to handle any substance safely.

According to the Commission’s white paper with a strategy for a future chemicals policy, one of the reasons behind the introduction of REACH was to ensure that the same rules should apply to new and old substances on the EU market. This would make for equal competition conditions for the two substance categories and promote substitution. As long as different rules apply to old (phase-in substances) and new substances (non phase-in substances), this is not fulfilled.

The Commission's report from the first review of REACH was presented in February 2013. It is apparent from the report that data requirements for low volume substances will be analysed further. Within the framework of this work, the Commission will probably consult with Member States and other stakeholders. It is also likely that a special working group will be set up to discuss these issues.

Objectives concerning tightening of the information requirements for the registration of low volume substances

The aim is to strengthen the test data requirements for low volume substances well in advance of 2018, which is the dead-line for the registration of phase-in substances in the range 1-10 tonnes according to the REACH timetable. This would eliminate the unjustified differences in information requirements between new and old substances and should produce test data sufficient for a basic hazard assessment, hazard classification and risk assessment and safe use. This would be achieved through:

- An amendment of Article 12 of REACH so that new and old substances are treated equally as regards information requirements for registration. Annex III will therefore become superfluous and can be annulled.
- Amendments to the information requirements for low volume substances in Annex VII of REACH so that the information that is required will be sufficient to enable basic hazard assessment, hazard classification and risk assessment and safe use, which is in line with the Swedish milestone target concerning substances of very high concern.
- Sweden is working both at national level and within the EU for a substantial strengthening of research and development relating to screening and testing methods and risk assessment methodology. In the opinion of the Swedish Chemicals Agency, the analysis of environmental toxicological research which Formas is to carry out.

32 Tests that are carried out in test tubes or on cultivated cells.
33 In this context, environmental toxicological research includes, but is not limited to, the research fields of toxicology, ecotoxicology, environmental chemistry, epidemiology and regulatory toxicology.
34 Formas is the Swedish research council for, among others, environmental research and sustainable development.
according to the Swedish Government should include an assessment of research needs as regards new screening and testing methods. This could reduce the costs associated with testing and the need for animal experiments, and facilitate screening and testing of the health and environmental properties of e.g. low volume substances.

**Prioritisation and need for political initiatives**

Stricter data requirements concerning low volume substances in REACH are a high priority issue for Sweden, as reflected in the Swedish milestone target concerning information about the health and environmental properties of substances. Pursuant to Article 138 of REACH, the Commission has been tasked with reviewing these data requirements. On the basis of this review, the Commission may present legislative proposals to revise the information requirements applicable to low volume substances, taking into consideration the latest developments, e.g. as regards alternative test and modelling methods, particularly quantitative structure-activity relationship [(Q)SAR].

Further initiatives are required at both authority and the political level in order to accelerate the EU work. The matter should be brought up and promoted in CARACAL and should also be raised within the Council.

**Proposed measures to tighten the information requirements concerning the registration of low volume substances**

**Short-term measures**

The measures being proposed in the short term concern the initiation of a process at EU level which will lead to the adoption of stricter information requirements relating to low volume substances. The process would encompass amendments to both articles and annexes to REACH. In order to take these steps, political initiatives will be necessary in order to raise the issues. Initiatives will also be required within the Council and in committees and working groups. Sweden should carry out the following initiatives, among others, and strive to bring about the following measures and decisions at EU level:

- The issue of information requirements concerning low volume substances should be raised in the Council and in REACH committees in order to persuade the Commission to involve Member States in the process. According to the Commission's report dating from February 2013 on the first review of REACH, the issue will be analysed further. It is desirable and likely that consultations will be carried out with Member States and other stakeholders and that a special working group will be set up.
- The Swedish Chemicals Agency should prioritise the task of initiating a more detailed analysis of the issue of inadequate information requirements for low volume substances and formulate solutions, proposals and strategies for achieving the objectives within the area. The task also includes contact with various stakeholders and possibly also consultant studies within certain areas.
- The Swedish Chemicals Agency should actively participate in the working group which the Commission is expected to set up in 2015 and promote and anchor proposed measures, etc.

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Long-term measures

- The Swedish Government and relevant authorities and research funding agencies should prioritise research and development initiatives concerning screening and testing methods which enable or facilitate the testing of health and environmental properties of e.g. low volume substances. This will be necessary in order to make future stricter information requirements in REACH feasible. The initiatives will be carried out both in Sweden and the EU and internationally and include methods which lower the costs associated with testing and reduce the need for animal experiments and otherwise facilitate screening and testing of chemicals.

Need for further analyses

Areas which may need to be studied further include the way in which research and development initiatives within the field can be supported and promoted, what research is currently available, what future initiatives are of particular importance and which researchers are currently active within the field. A first step will be to bring forward these issues in the analysis of environmental toxicological research which should be carried out according to the Swedish Government (see under Objectives above and in prop. 2013/14:39, p.115). The Swedish Government should therefore commission relevant authorities to initiate the analysis. This analysis should result in a strategy which includes the aforementioned research and development areas and should result in additional resources for such R&D activities.

By June 2014, the Commission shall analyse whether chemical safety assessments are needed for low volume substances (1-10 tonnes) that are carcinogenic, mutagenic and toxic to reproduction (known as CMR substances) and may propose amendments to REACH in this respect. Sweden should develop a position on this issue and also whether chemical safety assessments should be required for low volume substances within other categories of substances of very high concern (e.g. PBT and vPvB substances).

How the proposals help to ensure achievement of the Swedish milestone targets concerning dangerous substances

(A description of the Swedish environmental target A Non-Toxic Environment and the milestone targets is given in Chapter 5)

The milestone target concerning knowledge of the health and environmental properties of substances means that decisions must be taken both within the EU and internationally which will require that information concerning the health and environmental properties of substances should be available and provide an adequate basis for assessing risks relating to all uses. Among other things, this means that the information requirements in REACH concerning the registration of substances produced or imported in quantities of less than 10 tonnes per manufacturer or importer per year must be strengthened by 2018.

Comments: Implementation of the proposed measures sufficiently ahead of 2018 should facilitate attainment of the target.
4.1.6 **Children need to be better protected from exposure to chemicals**

*Development needs relating to REACH in order to better protect children*

There is a strong need to develop the REACH Regulation to ensure that children are better protected from hazardous chemicals. Existing legislation is inadequate as regards identifying, providing information about and to restrict the use of chemicals which can harm children.

Children and adolescents are more vulnerable than adults to the effects of chemicals. This is due to a number of factors. In many cases, biological systems and organs which are in the process of developing can be particularly sensitive to interference by chemicals, including endocrine disruptors. Children have a lower body weight and they also eat, drink and breathe more relative to their body weight and have a larger skin area than adults in relative terms. In many cases, all these factors combine to make children more sensitive and also more vulnerable to chemical exposure. Factors relating to the behaviour of children are also important as regards exposure, e.g. children tend to investigate objects around them by sucking and chewing on them. Children are often on or close to the floor where they are exposed to dust, which has been shown to bind certain chemicals which occur in indoor environments. As a result of their rapid rate of development, foetuses and new-born babies are particularly sensitive to interference. During pregnancy, the unborn child is exposed to extraneous, undesirable substances via the placenta, while after birth new-born babies are exposed to such substances via their mother's milk and other sources. Health effects where the exposure of children to chemicals can be of importance include effects on the reproductive and hormone system, the development of certain forms of cancer, obesity, diabetes, disorders in the development of the nervous system and the development of asthma and allergies.

*Risk assessment principles specific to children are needed*

One of the ways in which the legislation should be developed is by specifying in more detail what effects and effect areas are particularly relevant to the protection of children from exposure to hazardous chemicals. Test methods also need to be identified for the testing of chemicals as regards such effects and effect areas. The standard information requirements laid down in REACH need to be reviewed and strengthened as regards tests of particular relevance to children. The need for and magnitude of children-specific assessment factors in connection with assessments also need to be analysed, and exposure data and exposure scenarios relevant to children need to be defined.

As children have even less opportunity to choose their living environment than adults, society has a special responsibility to protect individuals. REACH currently contains no requirements for clear and readily accessible information concerning the occurrence of chemicals in articles to which children may be exposed. The existence of such requirements would facilitate the identification and handling of exposure sources and enable suppliers, distributors and consumers to adopt a preventive approach and choose better alternatives. However, the primary effect of the information requirements would probably be to reinforce the incentive for manufacturers, distributors and retailers to phase out the use of hazardous substances more rapidly.

In order to achieve a high level of protection for children as regards exposure to chemicals, in the long term, substances of very high concern should not be used in chemical products and articles to which children could be exposed. In this context, the term 'substances of very high concern' includes substances that are carcinogenic, mutagenic, toxic to reproduction, endocrine disruptors and highly allergenic chemicals. Exposure to substances of very high concern represents a particular problem as regards young children who could be exposed
when they suck, lick and bite on objects around them. Adult consumers are generally not subjected to such direct exposure via the mouth.

Allow less scope for interpretation in the legislation

Children need to be highlighted in the legislative texts as a "special" or "specific" vulnerable group. Explicit reference to the protection of children in the legislation will leave less room for interpretation. Authorities will therefore have more scope to impose requirements under the legislation.

From a socio-economic perspective, initiatives aimed at protecting the health of children would in many cases be particularly effective. This is because such initiatives can prevent health problems which in many cases result in socio-economic costs in the form of suffering, higher morbidity with the associated care needs and a long-term reduction in work capacity. Measures to protect children also often contribute to the general protection of human health and, in particular, to the protection of other sensitive groups, such as population groups at greater risk of developing certain types of disease or ill-health.

Objectives for the protection of children

- REACH contains rules concerning exposure assessments, which are formulated so that they give particular attention to the need to protect children. The need to protect children is also reflected in the conditions of use and handling (known as exposure scenarios) in REACH. This is achieved through exposure assessments which:
  - are not limited to exposure which is traditionally considered to be children-specific but include all exposure to which children may be exposed, and
  - encompass all relevant exposure sources and exposure paths, including indirect exposure via the mother during the foetal stage and breastfeeding.

- REACH (Annexes VII-X) has been expanded to include information requirements concerning tests of relevance to children, as a basis for chemical safety assessments. Relevant guidance documents have also been revised accordingly. Amendments to information requirements and guidance documents focus on
  - the information requirements applicable to studies of individuals during the development and growth stage,
  - the way in which data from studies of adults can be transferred to young and growing individuals,
  - information requirements concerning studies of uptake, metabolism, accumulation and elimination of chemicals from the body (toxicokinetics),
  - data that is obtained through mandatory tests is sufficient to identify and reach a decision concerning the classification of SVHCs, including endocrine disruptors and highly allergenic substances.

- Updated guidance has been issued containing clear guidelines for establishing derived no effect levels (DNELs) specific to children. Clear guidance has been established concerning the type of effect that is most important as regards the protection of children and concerning the magnitude of the assessment factors. Both age-related sensitivity and vulnerability during critical periods of development are considered.

- Requirements have been established concerning information that is available to consumers and content lists concerning hazardous substances and substances of very high concern (including allergenic substances and endocrine disruptors) in articles
with which children could come into contact. The information is available without delay and without needing to be requested.

- Substances of very high concern, including endocrine disruptors and highly allergenic substances, may not be used in chemical products or articles with which children may come into contact.
- Children represent a "special"/"specific" exposed group in REACH and are explicitly referred to in relevant articles and annexes.

**Prioritisation and need for political initiatives**

The Swedish Chemicals Agency believes that development of the field of children and chemical safety in REACH and in other EU legislation should be given a high priority. This is also in line with the Swedish Government's strategy for a *Non-Toxic environment* (Government Bill 2013/14:39) and the milestone target to reduce the exposure of children to hazardous chemicals adopted by the Government, and also in line with statements in EU's 7th Environmental Action Programme.

The objective of the 7th Environmental Action Programme is to ensure that the use of hazardous substances in articles is minimised in order to protect the health of children. An overarching strategy for minimising exposure to hazardous substances should therefore be developed. A database on exposure and effects should also be created, particularly with the aim of protecting vulnerable groups, including children and pregnant women. Together with the preparation of guidance and test and risk assessment methods, this will enable better decisions to be made.

*Draw up a strategy for child safety*

The European Commission currently has neither an active forum nor a strategy for considering issues relating to children and chemical safety. It is therefore important that the Commission issues a declaration of intent to draw up a strategy for children and chemical safety. The Swedish Government should therefore take initiatives within the field, e.g. by proposing Council conclusions concerning children and chemical risks for decisions by the Environment Council. Such Council conclusions could for example be that the Commission should prepare an inventory of the need, as well as an associated strategy, for a review of provisions relating to the protection of children's health with regard to exposure to chemicals.

Further studies are also needed within certain fields in order to formulate the initiatives that are required in order to achieve the specified objectives. In recent years, the Swedish Chemicals Agency has carried out many activities and prepared a number of reports within the field of children and chemical safety. An analysis of relevant provisions has for example been carried out. This analysis led to the conclusion that there was a need to develop the provisions, e.g. with regard to information requirements and test and risk assessment methodology. A basis for the development of an EU strategy concerning children and chemical safety therefore already exists.

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36 Increasing children’s protection through Reach, PM 1/14, December 2013.
Proposed measures concerning the protection of children

Short-term measures
Measures proposed in the short term concerning the special sensitivity of children to chemical exposure include initiatives aimed at raising the political profile of the issue within the Council and initiatives in committees and technical working groups. Sweden should pursue the following initiatives, among others, and strive to bring about the following measures and decisions at EU level:

- The Swedish Government should take the initiative to ensure that Council conclusions concerning children and chemical risks are prepared and approved by the Council or that the political profile of the issue is raised within the EU in some other way. The initiative should result in an analysis of the extent to which REACH and other relevant legislation consider the special sensitivity of children and, if necessary, a strategy for implementing the legislative amendments that are needed. Support for such an initiative exists at EU level in statements concerning children and chemicals in the 7th Environmental Action Program and at national level in the Swedish Government's milestone target to reduce the exposure of children to hazardous chemicals and in prop. 2013/14:39.
- The Swedish Chemicals Agency should actively participate in technical working groups within the EU, OECD and WHO which have been set up to develop methods and guidance for exposure assessments concerning children.
- The Swedish Chemicals Agency should actively participate in technical working groups within ECHA which are working to update and clarify the guidance concerning the use of risk assessment factors specific to children.

Long-term measures
The long-term measures include amendments to annexes and articles in REACH. Initiatives will be required within both the Council and within committees and working groups. Sweden should pursue the following initiatives, among others, and strive to bring about the following measures and decisions at EU level:

- Annex I to REACH (concerning risk assessment and chemical safety reports) should be revised so that children are expressly identified as a special/specific vulnerable group and that requirements concerning exposure scenarios specific to children are included.
- Annexes VII-X to REACH (on information requirements in connection with registration) should be supplemented with the addition of information requirements that are relevant to risk assessments concerning children.
- The provisions concerning substances of very high concern in REACH articles (including Articles 7 and 33) should be developed through the inclusion of a requirement for readily accessible information on the presence of hazardous substances in articles to which children are exposed.
- The use of substances of very high concern in articles to which children are exposed should generally be banned or strictly limited, e.g. through amendments to Article 68.2 on general restrictions on uses of substances of very high concern which could lead to consumer exposure.
Need for further analyses

Collaboration with other countries and organisations

The United States Environmental Protection Agency (US EPA) has long been active within the field of children and chemicals and has for example drawn up guidance concerning how consideration should be given to the special sensitivity of children to chemicals, as well as legislative measures. One possible initiative to achieve the Swedish milestone target is to establish collaboration with the US EPA and, in this context, study the US legislation, e.g. the Children’s Safe Product Act (CSPA). This legislation requires industry to phase out hazardous substances and to inform consumers what substances are used in their products. For this purpose, CSPA includes a list of Chemicals of High Concern to Children (CHCC).

Swedish should also actively participate in and influence OECD's work to draw up guidelines concerning test methods and risk assessments regarding children. Test methods that are developed within OECD's test method programme are usually introduced without alteration in EU's test method regulation.

Research and development

Research and development are fundamental to the work to strengthen the legislation as regards the protection of children from exposure to chemicals. Such initiatives are needed in order to establish a basis for exposure data and exposure scenarios, test methods and risk assessment methodology of relevance to children. Research is important in order to investigate the link between early exposure and the development of certain forms of cancer, obesity, diabetes, damage to the nervous system and the development of asthma and allergies. Such studies are needed in order to determine the type of effects where stricter or broader standard information requirements are warranted.

How the proposals help to ensure achievement of the Swedish milestone targets concerning dangerous substances

(A description of the Swedish environmental target A Non-Toxic Environment and the milestone targets is given in Chapter 5).

The milestone target concerning knowledge of the health and environmental properties of substances means that decisions must be taken both within the EU and internationally which will require information concerning such properties of substances in order to provide an adequate basis for assessing risks relating to all applications. The decision should include measures which will ensure that by 2015 the EU legislation takes into account the fact that children are particularly sensitive to the effects of chemicals.

The milestone target to reduce the exposure of children to dangerous chemicals means that by 2018 a decision must be taken concerning existing and, if necessary, new legal provisions and other instruments, which will result in a substantial reduction in the health risks for children from their combined exposure to chemicals. The reduction in risk should be assessed relative to the situation in 2012.

Comments: The measures being proposed concerning the safety of children in this section are in line with the two of the Swedish milestone targets and would result in the revision of the EU rules so that they take into consideration the fact that children are particularly sensitive to chemicals.

However, it is unlikely that the proposed changes in either the main text of REACH or its annexes will be implemented by 2015. It will therefore be difficult to achieve the milestone target of reducing the health risks to which children are exposed by 2018.
4.1.7 Better opportunities to assess and manage the risks of groups of chemicals

More effective chemical control and a higher level of protection with more group-based assessment

It has been predicted that there are around 100,000 substances which either occur or could occur on the market. On the EU market, it is estimated that between 30,000 and 40,000 substances are manufactured or imported in quantities of in excess of one tonne per manufacturer or importer per year. As a consequence, a very large number of substances may need to be handled in different ways in the chemical control system, which is resource-intensive.

The existing EU chemicals control system and the associated legal framework is largely aimed at assessing substances individually. In practice, however, people and the environment are continually exposed to a mixture of chemicals. Some of these substances have a similar chemical structure and impact on living organisms. In some cases, the similarity in chemical structure means that simultaneous exposure to a number of similar substances can give rise to combination effects not accounted for in risk assessment of individual substances. For better handling of the combination effects from exposure to structurally similar substances there are good can reasons to strive for more scope to assess and manage the risks from groups of substances collectively.

Combat false and inappropriate substitution

A greater element of group-based assessment would also help to combat the problem of 'false' and 'inappropriate' substitution. This problem essentially means that when a substance becomes restricted or banned, it tends to be replaced by a substance that is more or less closely related structurally. The substitute substance sometimes has properties that are as undesirable as those of the original substance. The problem has its origins in the possibility of making small changes to the structure of an organic molecule in order to create many variants of a substance which have similar structures and hazardous properties, yet still have different CAS numbers and are considered different substances. This represents a major challenge as regards the control of chemicals, as each such substance is normally to be considered separately, e.g. in connection with restrictions. Examples of groups of substances where this type of problem occurs are phthalates, poly- and perfluorinated substances (see also section 3.3.4), brominated flame retardants, etc. Such problems could to some extent be combated by assessing groups of substances with similar structures collectively to a greater extent than is the case today. It should also be possible to group and treat substances on the basis of certain common types of intrinsic properties collectively. Another possibility would be to group and assess substances with a certain use function or a certain application collectively. Such group-based assessments are applied to certain types of chemicals which are regulated through legal instruments other than REACH. For example, this concerns active substances in pesticides and certain ingredients in cosmetic and hygienic products.

The feasibility of more group-based assessments in REACH

A general view is that the more systematic risk assessment and risk management of groups of substances via REACH would improve chemical control considerably. This would also help to ensure that authorisations, restrictions and other risk management measures have the intended effect in the form of substitution which also gives the desired reduction in risk.

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38 Substance-specific registration numbers issued by the Chemical Abstract Service.
However, REACH is largely based on the hazard and risk assessment of individual substances, in the same way as chemical legislation generally. Risk-mitigating measures such as hazard classification, authorisation requirements, restrictions and bans are also normally aimed at individual substances. The main processes in REACH are registration, evaluation (evaluation of registration dossiers and substance evaluation), authorisations and restrictions. Within these processes there are varying needs and opportunities for group-based approaches.

In connection with the registration of substances in REACH, substance- and company-based information shall be provided by manufacturers and importers. As regards information requirements on health and environmental properties, there are major opportunities to use group-based assessment, e.g. through utilising existing test data for a substance to fulfil the data requirements for one or more other untested substances (see below concerning "read across").

Within the closely related REACH processes of registration and evaluation of registration dossiers, it is necessary in the short term to overcome the problem of the inadequate quality of company registrations (see section 4.1.1) and in particular the unfounded or inadequately justified use of group assessment in the form of "read across" (see below).

For the process substance evaluation, ECHA is carrying out a development project, involving analysis of the structural similarity of registered substances which could be candidates for substance evaluation. In the short term, there are good opportunities to move towards more group assessments on the basis of certain carefully selected substance evaluations, which can also enhance each other.

Developing the process of substance evaluation towards more general assessments of groups of substances as regards similar properties, structures or applications would require a major revision of the REACH Regulation. It would also require more administrative input from ECHA. Such a development of the substance evaluation process in REACH would form the basis for considerably more effective risk management. However, the process would need to be given a wider focus, a revised time frame and more economic resources compared with the existing substance evaluation process.

For the authorisation process, opportunities need to be created for the group-based inclusion of substances of very high concern in the Candidate List and the authorisation list in Annex XIV (see section 4.2.1). This opportunity should be provided for chemically related substances of very high concern with the same properties, e.g. certain metal compounds. Thereby, individual sets of information (known as dossiers) would not need to be prepared by the authorities for the substances in the group before inclusion in the Candidate List. In the same way, a solution is needed to the problematic requirement for individual dossiers for inclusion in the Candidate List of multi-constituent and UVCB substances containing a substance of very high concern as a constituent. As regards mixtures, a concentration threshold of 0.1 percent for a SVHC constituent applies in order for a mixture to come under the authorisation provisions of REACH and the same rules should apply to multi-constituent and UVCB substances.

The restriction provisions in REACH do not present any direct barriers to group based risk assessment and management of substances with certain hazardous properties or applications/uses. However, an important barrier to a more frequent use of such group restrictions is the fact that the already high existing workload and time usage for restriction dossier production and decision-making dramatically increases if a restriction dossier is covering more than one substance.
Read across - Action should be taken to impede the misuse of adaptation possibilities in the test data requirements

One particular aspect of the grouping issue is the frequent misuse of an adaptation possibility provided for by REACH Annex XI allowing “category” and “read across” approaches to be used for fulfilling the test data requirements for substance registration. These approaches provide for the use of test data from one or more structurally similar substances to be used for one or more untested substances. More specifically, this means that the hazardous properties of a substance need not be tested in some cases if the substance is sufficiently structurally similar to another substance for which test data is available. Read across may be applied if the structurally similar substance has low or high toxicity. However, this option for an exception from testing has been utilised frequently without proper justification and by grouping substances erroneously. This type of adaptation has been frequently misused in connection with the registration of around 3,000 high-volume substances (i.e. phase-in substances which are manufactured or imported in quantities exceeding 1,000 tonnes per manufacturer or importer per year), which were registered in 2010 in accordance with the REACH timetable. Such misuse of the provisions counteracts the application of the precautionary and substitution principles in chemical control and should be combated.

In an initial step, ECHA's guidance should be developed and an existing ECHA draft for a “read across framework” should be incorporated into the guidance. At the same time, ECHA's work to evaluate registration information should be streamlined and targeted at the more serious cases of misuse of group assessment based on read across. Given the large number of registrations that are inadequate in this regard, it is not reasonable to solely use the evaluation of the registration information in order to remedy the problem. Suitable measures should be considered which gives registrants an incentive to initiate the updating of existing registrations that are of inadequate quality. One example of such measures is greater scope to impose sanctions.

Objectives concerning group-based assessment

In the short term, the objectives behind the development of group-based assessments are as follows:

- Within the related REACH processes of registration and evaluation of registration information (dossier evaluation), the problem of many company registrations being of inadequate quality has been remedied, and the unfounded or inadequately justified use of group assessment in the form of read across has been impeded.

In the longer term, the objectives behind the development of group-based assessments are as follows:

- ECHA's development work within the process of substance evaluation in REACH has been extended to cover a systematic analysis of structural similarity among substances during the prioritisation phase and has also resulted in specific proposals concerning the way in which groups of substances should be treated during the substance evaluation process.

- In connection with the scheduled review of REACH in 2017-2019, the process for substance evaluation is being developed to encompass opportunities for group based assessment and management of the risks from substances with certain hazardous properties or applications.
The authorisation process has been simplified and streamlined through
- the application of group-based inclusion of chemically related substances such as metal compounds and salts with the same hazard properties of very high concern, and
- the inclusion of multi-constituent and UVCB substances containing a substance of very high concern as a constituent under the same rules that currently apply to mixtures, i.e. considered as covered by the SVHC categorisation of the constituent on the candidate list down to the 0.1 % (or 0.3 % as appropriate) concentration cut off.

Prioritisation and need for political initiatives
In the short term, the above problem areas should be pursued through ECHA's committees (particularly the Member State Committee) and through workshops and the Commission's expert group for competent authorities for REACH and CLP (CARACAL).

Proposed measures concerning group-based assessment

Short-term measures
There is currently no organised process or discussion concerning the group-based assessment of substances within REACH. Political initiatives are needed in order to bring about a process which can lead to specific measures. As a first step, initiatives at political level within the Council, and possibly with respect to the Commission and individual Member States, are therefore required. The Swedish Chemicals Agency also needs to further develop the analysis as regards possible routes for developing the opportunities for group-based assessments and pursuing proposals within the field through committees and working groups. Sweden should implement the following initiatives, among others, and strive to bring about the following measures and decisions at EU level:

- The Swedish Government should initiate a discussion concerning group-based assessments at political level within the Council or another appropriate forum at EU level. For strategic reasons, it may be appropriate to refer to the general discussions concerning the need to streamline chemicals control and simplify the associated legal framework. Given appropriate formulation, greater use of group-based assessments would bring about substantial improvements and also enhance the level of protection for human health and the environment.
- The Swedish Chemicals Agency should work to ensure that ECHA's guidance concerning information requirements and chemical safety assessments are developed to safeguard the correct use of the existing opportunities for group-based handling of substances, e.g. through the incorporation of ECHA's existing draft for a read across framework into the guidance.
- The Swedish Chemicals Agency should strive to ensure that the most serious cases of misuse of group assessments based on read across are better captured through ECHA's work to evaluate registration information. In connection with this, methods should be developed which give registrants a stronger incentive to update existing registrations and to improve the quality of future registrations.
- In the short term, it is urgent to explore the feasibility of group-based assessments of selected groups of substances within the framework of substance evaluation in REACH. The Swedish Chemicals Agency should propose that ECHA initiates such a project to gain specific experience that can form the basis for further development. A basis for such a project has been established through a development project within ECHA (see below).
• Within ECHA, development work is under way within the process substance evaluation. This work concerns a systematic analysis of the structural similarities of substances in connection with the prioritisation of such substances prior to the substance evaluation stage. The Swedish Chemicals Agency should propose that a broader and more wide-ranging concept for the development of the substance evaluation process within REACH should be developed within the framework of substance evaluation. The aim of the concept should be to introduce more scope to assess and manage the risks from groups of substances with certain hazardous properties or applications and could for example be presented in connection with the national reports relating to the review of REACH in 2017.

• The Swedish Chemicals Agency should analyse and propose measures to facilitate the systematic application of group-based restrictions on substances. The restriction provisions in REACH do not pose any direct obstacle to a collective risk assessment and risk management of groups of substances with certain hazardous properties or applications. However, a number of practical hurdles exist, one of which is the cost and additional work involved for a Member State that is preparing a restriction dossier covering a group of substances.

**Long-term measures**

The issue of facilitating group-based assessments is a key strategic issue in the development of REACH and chemicals control in general. In order to promote the issue, political initiatives on the part of the Swedish Government are needed, along with analyses and studies at authority level. In many cases, more far-reaching changes will require amendments to articles in REACH, and therefore consideration by the Council and in the form of discussions in committees and working groups. In the long term, Sweden should promote proposals and strive to bring about decisions within the following areas:

• More comprehensive changes to the substance evaluation process as regards opportunities for assessing groups of substances with certain hazardous properties, structural similarities or similar applications would require major changes and additions to the REACH Regulation. Bringing about a development of the legal provisions will be a long-term task. Alongside the analysis of improvements which can be achieved in the short term, the Swedish Chemicals Agency should begin to consider the opportunities for the long-term development of substance evaluation in a dialogue with other stakeholders.

• The Swedish Chemicals Agency should investigate and propose measures to facilitate the systematic group-based handling of substances in connection with authorisation. As regards the authorisation process, the objective should be to simplify and streamline the work relating to the Candidate List and the Annex XIV authorisation list through group-based inclusion of chemically related substances, such as metal compounds/salts with similar properties of very high concern. For multi-constituent and UVCB substances containing a substance of very high concern as a constituent, the same rules as apply to mixtures should be introduced. This would eliminate much redundant work.

How the proposals help to ensure achievement of the Swedish milestone targets concerning dangerous substances

(A description of the Swedish environmental target A Non-Toxic Environment and the milestone targets is given in Chapter 5)

The milestone target concerning the development and application of EU’s chemicals rules is that by 2020 REACH and other relevant EU provisions should be applied or, if necessary,
revised to facilitate the risk assessment and risk management of groups of substances with similar intrinsic properties, chemical structure or applications.

Comments: A general assessment is that a more systematic handling of groups of substances via REACH would improve chemical controls considerably.

The proposed measures would be a major contribution to attainment of the milestone target by 2020.

4.1.8 Combination effects

Harmful effects may be fortified through mixed exposure to chemicals

Humans and the environment are continuously exposed to mixtures of a number of different chemicals. The combined toxic effect is often greater than the individual toxicity of each of the separate components, even if one considers the most toxic substance. Studies have been conducted which have shown that the combined effects of exposure to mixtures of chemicals at doses/exposure levels which individually would not be expected to cause harmful effects have still caused injury as a result of the chemicals’ joint action in different ways. Even without any appreciable effect after separate exposure, combined-concomitant exposure to low concentrations of some substances can cause a very strong effect, a phenomenon known as “potentiation” or “synergism”.

Despite our increasing understanding of combination effects, risk assessments of chemical substances under the current legislation, including REACH, are normally carried out on one substance at a time.\(^{39}\)

REACH and other legislation also give little or no consideration to what is known as “cumulative exposure”. This term often concerns both simultaneous exposure to a number of similar substances and combined exposure to a single substance from different sources or via different exposure pathways. The latter is also known as “aggregated exposure”.

In order to bring about long-term improvements in the risk assessment and risk management of the many chemicals from different sources to which humans and the environment are exposed, major initiatives are needed to improve our understanding and develop principles for legal solutions. A broad review of both risk assessment methodology and environmental and health-oriented legislation is needed. Issues concerning combination effects are relevant in connection with a broad raft of legislation. In addition to REACH, the legal framework for pesticides, medicines, cosmetic and hygienic products, foods, water, waste, industrial discharges, work environment and also various product legislation are relevant in this respect.

Combination effects are inadequately covered in REACH

Combination effects are not referred to in the REACH text. However, it is apparent from ECHA's guidance concerning information requirements and chemical safety assessments (Part D, Exposure assessment\(^{40}\) and Part E, Risk characterisation\(^{41}\)) that registering companies should take into account exposure to a number of structurally related substances with very similar properties (derivatives and analogues). For the authorities, there is thus an opportunity to carry out an integrated risk assessment of such substances in connection with e.g. substance

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\(^{40}\) Guidance on information requirements and chemical safety assessment, Part D: Exposure scenario building, ECHA, October 2012 (version 1.2).

\(^{41}\) Guidance on information requirements and chemical safety assessment, Part E: Risk Characterisation, ECHA, November 2012 (version 2.0).
evaluations and restriction proposals, provided that a risk at EU level can be argued. The type of combination effects which may become relevant based on the guidance are primarily those which are caused through aggregated exposure, but it is also possible to take into consideration simultaneous exposure to a number of similar substances.

The REACH guidance contains no directions on how to carry out risk assessments taking combination effects into account. There are also no requirements on companies that register a substance to consider the combined exposure to any jointly acting substances or even the aggregated exposure to the registered substance from sources that are not covered by a particular registration.

Objectives concerning combination effects

In the short term, the objectives for the development work on combination effects are as follows:

- A scientific basis has been developed, which provides an adequate basis for new guidance as regards when and how combination effects should be taken into consideration.
- A guidance document has been prepared by ECHA, which describes general methods in connection with the risk assessment of combination effects (by a detailed risk assessment and, in addition, by general/default approaches, e.g. through the use of an additional assessment factor).

In the longer term, the objectives for the work on combination effects are as follows:

- The REACH articles in have been revised so that the regulation requires combination effects to be taken into consideration, particularly by registering companies.
- In addition to the legal responsibility of companies to consider the combination effects of the use of chemicals, a new mindset has become established among companies and authorities including that it is accepted that an integrated approach should be applied and that due consideration should be given to the combined/cumulative and aggregated exposures to chemical substances.

Prioritisation and need for political initiatives

In 2009, the Commission was tasked by the Council with investigating how the EU legislation could take combination effects into consideration42. This measure came about at the initiative of Denmark and was approved in the form of Council conclusions during the Swedish presidency of the Council in 2009. As a result of this task, the Commission presented a Communication43 in 2012 stating that ECHA, the European Food Safety Agency (EFSA), the European Medicines Agency (EMA) and the European Environment Agency (EEA) will jointly chair a working group which will prepare a broad assessment, develop technical guidance and increase our understanding of which typical chemical mixtures humans and the environment are exposed to. The results of this work will be presented in a combined report in June 2015. As the Communication initiatives to be carried out by the agencies have not yet started, political initiatives may be needed in order to remind the Commission of this task.

Many activities are currently under way relating to the field of combination effects. In connection with the Biocide Regulation\textsuperscript{44}, guidance concerning the assessment of combination effects for human health and the environment is currently the under discussion. The DG Joint Research Centre has initiated a project which is aimed at investigating how different risk assessment methods, including mathematical modelling (QSAR), can be used to predict combination effects. At the same time, the EFSA is doing development work to define groups of pesticides (plant protection products) which should be assessed collectively in order to capture combination effects (known as “cumulative assessment groups”). The OECD is also set to begin a project aimed at evaluating combination effects of e.g. phthalates.

**Proposed measures concerning combination effects**

**Short-term measures**

From a toxicological/scientific perspective, the occurrence of combination effects has long been known as a problematic issue. Nevertheless, it presents major challenges as regards methods for testing, risk assessment and risk management. Therefore, a political commitment is needed in order to drive the process forward, along with analyses and knowledge building. Sweden should promote developments within the following areas:

- Within the Council and other appropriate forums, the Swedish Government should call for a start of the work on the action plan pledged by the Commission in the Communication on combination effects from 2012, originating from the Council conclusions adopted during the Swedish EU presidency in 2009.
- The Swedish Chemicals Agency should promote and participate in discussions which lead to a unified view and agreement concerning principles for the risk assessment of combination effects. This should form a basis for incorporating these principles into relevant legal frameworks, including REACH.
- The Swedish Chemicals Agency should promote the initiation of a process at EU level aimed at drafting a guidance document on how to take combination effects into account in connection with the application of relevant provisions. A scientific basis needs to be developed for use as a starting point for this work.

**Long-term measures**

- The Swedish Government and the Swedish Chemicals Agency should strive to ensure that requirements for risk assessment of combination effects are incorporated into REACH and other legal frameworks. This will require substantial changes to the regulatory frameworks and is a relatively long-term process which will involve initiatives at both the political and authority level. An alternative to more comprehensive changes to REACH which might be considered is the incorporation of provisions concerning combination effects in a separate regulation, to which REACH and other relevant legislation can make reference.
- Alongside the regulatory development process, the Swedish Chemicals Agency should promote further methodological development and knowledge building.

**Need for further analyses**

There is a limited number of alternative methods available which can be applied when assessing potential combination effects. The principal alternatives should be developed

\textsuperscript{44} Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.
The development process should include the acquisition of knowledge concerning chemical mixtures to which humans and the environment are frequently exposed and considered to be of particular importance.

One of the methods for taking potential combination effects into account is based on the use of an additional assessment factor (“mixture assessment factor”, MAF) in risk assessments. A deeper understanding of actual common exposure patterns and a better appreciation of the importance of such combination exposures for human health and the environment are key starting points for discussions concerning the magnitude of such an assessment factor.

Consideration should be given to whether Sweden can contribute to the development of the issue of combination effects by drafting basic proposals on how the issue could be dealt with in the main regulatory frameworks, as well as proposals for risk assessment models.

**How the proposals help to ensure achievement of the Swedish milestone targets concerning dangerous substances**

(A description of the Swedish environmental target *A Non-Toxic Environment* and the milestone targets is given in Chapter 5)

The milestone target concerning knowledge of the health and environmental properties means that the preconditions are in place for ensuring that the relevant legal frameworks can take combination effects associated with exposure to chemicals into account by 2015.

The aspect of the milestone target which states that “the preconditions are in place to enable relevant legislation to take combination effects for chemicals into account by 2015” will hopefully be achievable as regards the work of public authorities, but it is unreasonable as regards the registrants' own assessments.

### 4.1.9 Initiatives to promote the work of companies relating to substitution

**Voluntary substitution is needed in addition to legislative requirements in order to achieve the environmental targets**

Substances which are hazardous and/or of very high concern are widely used in chemical products and in articles. However, according to the Swedish environmental target *A Non-Toxic Environment*, the aim is for the use of substances of very high concern to cease insofar as is possible, while total exposure to other substances should not be harmful to humans or biological diversity. We believe that much remains to be done in order to achieve the objectives and that the development of both REACH and other legislation and their application will be necessary in order for it to be possible to achieve the objectives. For example, the regulatory framework must promote voluntary work by companies relating to substitution.

The work concerning risk mitigation and substitution must be based on the voluntary work of companies regarding substitution. This could for example involve a company switching to a substance with better health and environmental properties or a different technical solution, rather than continuing to use a problematic substance which requires various safety measures and precautions to be taken. The majority of the work relating to substitution must be achieved through such initiatives. At the same time, the number of authorisation reviews or restrictions in REACH will always be relatively small compared with the large numbers of substances that are used in society. The risk management measures that follow from the regulatory framework will therefore act rather as a last line of defence in cases where substitution could not be achieved voluntarily. The need to encourage and develop the work of companies relating to substitution will come further into focus as the application of the
Authorisation and restriction processes in REACH are very resource-intensive and also encumbered by important deficiencies (see sections 4.3.1 and 4.4.1).

Existing legislation contains relatively few bans and restrictions concerning the use of chemicals. REACH currently restricts the use of around 60 substances, a few of which are completely banned. There is also a list of around 1,000 hazardous substances which may not be used in chemical products intended for consumers. This can be compared with the several thousand substances of very high concern and the tens of thousands of hazardous substances.

Given the current formulation and application of REACH, there is a risk that many substances of very high concern will continue to be used for many years to come. Even if the work relating to authorisation reviews and restrictions under REACH can progress at a satisfactory rate in the future, this will be insufficient in itself. The provisions and their application therefore need to be developed so that they promote voluntary substitution to a greater extent. An additional problem which must be eliminated is the phenomenon of “false” or inappropriate substitution, i.e. the problem where problematic substances are not infrequently substituted with other substances with similar or different hazardous properties.

**REACH and its application needs to be developed in order to better promote substitution**

The principle of substitution is pivotal to chemicals policy. This principle is set out in Chapter 2 Section 4 of the Swedish Environmental Code and is known as the “produktvalsprincipen”, or “substitution principle”, in this context. As the principle is expressed in the Environmental Code, it involves an obligation not to use or sell chemical products which could harm human health or the environment if they can be substituted with less hazardous products and if it is reasonable to use or sell such products instead. The principle of substitution is also expressed in the global chemical strategy, SAICM45. The principle can also be found in a number of EU documents which have been adopted in recent years. In EU law, the principle of substitution has a broader meaning than in the Swedish Environmental Code, for example. In the context of EU law, it also concerns the substitution of hazardous chemical products with alternative techniques.

In the Swedish version of REACH, “substitution” is translated as “ersättning”. The principle of substitution is most clearly expressed in Article 55 of Title VII on authorisation. In this article, it is stated that the aim of authorisation is “the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. To this end all manufacturers, importers and downstream users applying for authorisations shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution”. Substitution is also referred to in similar terms on a number of occasions in the preamble to REACH (recitals 12, 70, 72, 73 and 74). However, given the way in which the substitution principle is expressed in REACH, in a concrete sense it only applies to authorisation and, in practice, only reactively too, i.e. only once a substance has been formally identified as being of very high concern.

As the substitution principle is currently expressed in REACH, it is probably the indirect incentive that the provisions create for companies to work on voluntary substitution, rather than the direct application of the regulation, that is of greatest importance.

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45 Strategic Approach to International Chemicals Management (SAICM), Dubai Declaration on International Chemicals Management.
Satisfactory compliance with the REACH provisions concerning registration, information in the supply chain and requirements imposed on downstream users would be a major contributor to both the safer handling of hazardous substances and the greater use of substitution. However, the registration information currently being provided by companies is often inadequate as regards hazard and risk assessment, as well as recommendations concerning safety measures. As a result, there are also problems associated with the transfer of information to companies which use chemicals further down the supply chain (known as “downstream users”), and with compliance with the prescribed safety measures. These safety measures are described in REACH in what are known as 'exposure scenarios', which are included in the chemical safety reports drawn up for substances that are manufactured or imported in quantities in excess of 10 tonnes per manufacturer per year. The exposure scenarios indicate how the substance should be handled by the user and the safety measures that are required in order for the use to be deemed adequately controlled.

Better information to downstream users concerning risks and the need for safety measures, better compliance with the prescribed safety measures and more effective supervision would probably promote greater substitution. The incentive for companies to voluntarily substitute chemicals could for example be reduced costs relating to safety measures and waste management, as well as reduced business risk.

The Candidate List promotes substitution

The so-called “Candidate List” encompasses substances of very high concern which could be subject to authorisation (see also sections 2.1 and 4.2.1). The inclusion of substances of very high concern thus gives an indication of impending risk management measures at EU level and has therefore probably been the measure in REACH that has contributed most to encourage companies to substitute chemicals. Inclusion on the Candidate List also involves a requirement (in Article 33) to provide information on the occurrence of the substance in articles to professional use and, on request, consumers. This may also help to promote substitution.

As of May 2014, the Candidate List included 151 substances. To date, only a small proportion of all substances of very high concern have been included in the list. Based on the strong signal that will result from inclusion in the Candidate List, resistance to expanding the list to include more substances appears to be gradually stiffening (see sections 4.2.1 and 4.2.2 Information on hazardous substances in articles).

One strategy which can be used by chemical suppliers in order to avoid or delay identification and listing of a substance of very high concern is to make a minor change to the substance's chemical structure. This will give the substance a new identity and a separate CAS number, yet the substance may still have the properties that are of very high concern. This is a variant of the problem relating to false or inappropriate substitution which could reduce the high level of protection afforded to health and the environment, which is one of the cornerstones of REACH.

Information concerning alternatives and procurement requirements can promote substitution

One of the factors limiting the work of companies relating to substitution is the obvious lack of readily available information concerning alternatives to hazardous substances and experiences of previous work within the field. The lack of information particularly applies to substitution initiatives which are relevant to companies that use chemicals rather than chemical manufacturers. This can apply to the use of different technical solutions or materials as a way of eliminating the need for hazardous substances in order to fulfil a particular purpose. More resources need to be put into systematically collating such information and to
developing and testing technical solutions which can promote substitution. Support for this form of initiative both within the EU and at national level is also considered in section 4.3.1 concerning authorisation. There is also a need to improve the range of alternative technical solutions and chemical substances with good environmental and health properties that are available. This could be promoted through allocating more resources to research and development, e.g. within the field of “green chemistry”.

In the Swedish Government Bill entitled På väg mot en giftfri vardag – plattform för kemikaliepolitiken [On the way to a Non-Toxic everyday life - platform for the chemicals policy (2013/14:39)], the Government refers to the need for a function to support substitution at EU level (section 9.2.1, p. 61). In the same Bill, the Government also notes that the preconditions for establishing a national resource centre to promote the substitution of hazardous substances should be reviewed (section 9.2.2, p. 63). Examples of this type of function and activity can be found in the German and Austrian project entitled SUBSPORT (Substitution Support Portal), which was carried out during the period 2010–2013 with the support of the EU LIFE+ programme, Germany's national institute for health and safety and the Austrian ministry for land and agriculture, environmental and water management. Another example is the Lowell Center for Sustainable Production, University of Massachusetts Lowell in Boston. Consideration should also be given to whether ECHA can systematically make available knowledge and experience to support the work of companies relating to substitution. The European Agency for Safety and Health at Work (EU OSHA) and others have carried out this type of initiative. In summary, the formulation of possible support functions for substitution at EU level should be studied in more detail (see below). In a similar way, issues relating to a national resource centre to promote substitution also need to be studied more closely.

The work of companies concerning substitution should also be promoted through the government, local authorities and county councils imposing stricter requirements relating to chemicals in connection with public sector procurement. Such requirements are currently only imposed to a limited extent and more knowledge is needed concerning how procurement requirements can be used in an effective and strategic manner for this purpose.

**Objectives concerning substitution**

In the short term, the objectives for stimulating the work of companies relating to substitution are as follows:

- Compliance with requirements concerning the information that is to be provided upon registration, the requirement to forward information in the supply chain and to follow prescribed safety measures has considerably improved among companies.
- The number of substances of very high concern included in the Candidate List has increased considerably, as has compliance with the requirement to provide information on the occurrence of such substances in articles (Article 33).
- Improvements in the application of the restriction and authorisation processes in REACH have resulted in an expectation and a readiness among companies for decisions concerning hazardous substances within these processes, which in turn promote companies to substitute hazardous substances.
- Information concerning both chemical and technical alternatives to hazardous substances and experiences of substitution has been collated and made readily available both at EU level and nationally.
- The initiatives relating to research and innovation within the field of “green chemistry” have been strengthened in Sweden and the EU and the supply of
substances with good environmental and health properties can therefore be expected to improve in the long term.

In the longer term, the objectives to incentivise companies to use substitution are as follows:

- A general obligation to strive towards substitution has been incorporated into REACH, which means that:
  - more often than they do today, companies consider the substitution of hazardous substances throughout their operations, alongside other risk management measures, and document their initiatives and deliberations in order to fulfil this obligation;
  - companies will not develop or start using substances of very high concern;
  - in cases where a substance that a company supplies or uses is identified as being of very high concern, the company concerned is obliged to implement measures with the aim of substituting the substances with a less hazardous alternative in the long term.

**Prioritisation and need for political initiatives**

Better support for the work of companies relating to substitution, e.g. in the form of information concerning alternatives, should be accorded a high priority in terms of time. The same applies to stricter supervision of registration information and compliance with safety measures. As regards collaboration regarding enforcement, Sweden can act through the REACH Forum and other fora. As regards support functions for work relating to substitution, some initiatives are in place today, but further initiatives are required both at EU level and nationally (see above Information concerning alternatives and procurement requirements can promote substitution).

There are also a number of initiatives concerning “green chemistry” in place today, but it is important to ensure that these encompass the perspective of identifying good alternatives from a toxicological and ecotoxicological viewpoint, alongside the objective of increasing the use of bio raw materials and low energy consumption and climate impact.

Political initiatives are needed in order to incorporate a general obligation in REACH to strive towards substitution. An obligation for a company always to consider the possibility of substitution can be seen as a variation on the theme of introducing a sort of general duty of care in REACH, which was one of Sweden's aims during the REACH negotiations.

**Proposed measures concerning substitution**

**Short-term measures**

A broad raft of measures is needed to promote the work of companies relating to substitution. These measures include initiatives both at political level and among the public authorities. This applies to the application of REACH and to knowledge acquisition and development work aimed at promoting substitution. In the short term, Sweden should take the following measures, among others:

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46 Remarks: In addition to the proposals in this section, many other measures that are proposed elsewhere in the report can help to incentivise and enhance the work of companies relating to substitution. This applies for example to sections 4.2.2 Information on hazardous substances in articles, 4.2.1 Identification and prioritisation for authorisation, 4.31 Authorisation of substances of very high concern, 4.4.1 Restriction, and 4.5 Supervision.
• The Swedish Chemicals Agency should contribute to the preparation of better guidance in order to support and facilitate the work of companies to carry out chemical safety assessments and exposure scenarios for chemical substances and mixtures. This work has been started under the leadership of ECHA (“Chemical safety assessment/chemical safety report roadmap”).

• The Swedish Chemicals Agency should help to ensure that both the scope and quality of the supervision carried out by Member States is enhanced as regards the quality of chemical safety reports, including exposure scenarios, the mediation of information in the supply chain and compliance with prescribed safety measures. The Swedish Chemicals Agency should pursue the matter in the REACH Forum, which is the collaborative board of the Member States and ECHA for issues concerning the supervision of REACH and CLP.

• At their respective levels, the Swedish Government and the Swedish Chemicals Agency should promote initiatives which systematically build up and make available knowledge which can support the work of companies relating to substitution and enhance application of the substitution principle in REACH generally. Examples of such initiatives are the creation of support functions at EU level and nationally, which systematically collate information concerning alternatives to hazardous substances in the form of safer chemical or technical solutions, as well as good examples of transitions to such solutions.

• The Swedish Chemicals Agency should promote the creation of a database at EU level containing information on restrictions on usage, concentration limits, etc. that apply to chemical substances. The Swedish Chemicals Agency's restriction database contains this type of information and could be used as a starting point in the process.

Long-term measures

In the longer term, a need for changes to articles in REACH is anticipated in order to promote and strengthen the work relating to substitution and introduce a higher degree of prevention. This will help to prevent the manufacture and use of hazardous substances and substances of very high concern. In the short term, Sweden should therefore take the following measures, among others:

• The Swedish Government and the Swedish Chemicals Agency should promote the incorporation of a responsibility in Title VII of REACH (authorisation), based on an analysis, to avoid substituting substances of very high concern with other substances with the same type of properties.

• The Swedish Government and the Swedish Chemicals Agency should work to establish support for, and promote research and development concerning, chemicals with good health and environmental properties, as well as new technical solutions, with the aim of improving the supply of alternatives and thereby facilitating substitution.

Need for further analyses

The formulation of measures aimed at systematically building up knowledge which can help to support the work of companies relating to substitution and strengthen application of the substitution principle in REACH needs to be analysed further. Such an analysis should encompass the orientation, delimitation and organisation of functions to support substitution at EU level and nationally. A further aspect which should be considered is financing and
ownership for such a support function, e.g. whether it should be managed by the private or public sector or as a joint venture between the two sectors.

**How the proposals help to ensure achievement of the Swedish milestone targets concerning dangerous substances**

(A description of the Swedish environmental target *A Non-Toxic Environment* and the milestone targets is given in Chapter 5)

The milestone target concerning the development and application of the EU chemicals rules is that REACH and other relevant EU provisions must, by 2020, be applied or if necessary revised so that the principle of substitution and its application are reinforced in connection with restrictions, authorisation and other relevant aspects in the regulatory framework.

The milestone target concerning particularly dangerous substances means that such substances will be subject to review or a decision concerning phase-out under applicable provisions within all applications by 2018.

*Comments*: The proposed measures should lead to the considerable strengthening of the substitution principle and its application and to hazardous substances being substituted in connection with restrictions, authorisation and other relevant aspects in the regulation.

### 4.2 Substances of Very High Concern

#### 4.2.1 Identification and prioritisation for authorisation

The Candidate List in REACH is a list of *Substances of Very High Concern, SVHC*. The list can therefore be said to be a list of substances which according to REACH have been officially identified as being particularly hazardous substances.

In order for a substance to be identified as being of very high concern, it must fulfil the criteria set out in Article 57 of REACH. This essentially means that the substance must correspond to one or more of the following points:

- fulfils the criteria to be classified as carcinogenic, mutagenic or a reproductive toxicant in category 1A or 1B in the CLP Regulation
- fulfils the criteria to be considered as persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with Annex XIII of the REACH Regulation
- has other properties which give rise to an equivalent level of concern. This could for example concern endocrine disruptors.

An EU Member State or ECHA (at the request of the Commission) can prepare a dossier for identifying substances for the Candidate List. If ECHA's Member States committee unanimously decides that a substance fulfils the criteria, then ECHA will include the substance in the Candidate List. If not, a prescriptive committee under the Commission will reach a decision concerning identification of the substance concerned.

REACH. When a substance is included in Annex XIV, this means that the substance may not be used or placed on the market without authorisation. Annex XIV specifies a deadline for the submission of an application for authorisation to ECHA and a final date after which the substance may no longer be placed on the market or used without authorisation (“sunset date”).

So far, only a small proportion of the substances that actually has properties of very high concern have been included in the Candidate List. In order to rectify this situation, the EU has reached agreement concerning a roadmap for SVHC\(^48\), with the aim of ensuring that all relevant substances of very high concern are included in the Candidate List by 2020. Extensive collaborative work on this has begun. In itself, this is a very positive development, but the process forward is also linked to a number of problems:

- One of the criteria set out in the roadmap for determining whether a substance of very high concern should be considered as relevant risks causing severe delays in the inclusion of certain substances in the Candidate List and Annex XIV. If any use of the substance involves an “unacceptable risk”, a proposal for restriction must first be drawn up and adopted. Several years may pass without any certainty that a restriction will be introduced. The consequence of this will be that, as regards substances for which it should be a matter of relative urgency to apply the pressure to stop the marketing and use of the substance that inclusion in the Candidate List and, to an even greater degree, in Annex XIV entails, such inclusion may instead be heavily delayed.

- Examples of the above include substances which are widely used in imported articles where a particular occurrence which is considered to be associated with risk would necessitate the preparation of a proposal for restrictions. The outcome may then be that the substance will not be included in the Candidate List until much later, or may even not be included at all, and the pressure on other use to cease will be delayed or come to nothing.

- It is doubtful whether the criteria for relevance adequately encompasses substances which are primarily used in imported articles and not otherwise manufactured or used within the EU in sufficient quantities in order to be registered, for example. If they are not included in the Candidate List, no requirements concerning substances of very high concern in articles will be triggered either.

- There is increasing pressure from a number of sources to consider economic consequences in connection with the so-called RMO analyses\(^49\), which are voluntarily carried out by Member States before preparing, for example, a basis for identifying substances in the Candidate List. The problem with this is that it is not possible at such an early stage in the process to have access to the information that is needed in order to perform a balanced socio-economic analysis. Instead, there is a risk that warnings concerning negative consequences from special interests will result in substances being put to one side, when a more thorough assessment could have shown that continuing to use the substance would in reality be more expensive than phasing it out.

- There are no criteria for identifying substances of very high concern within key areas, such as endocrine disruptors and highly allergenic substances. The alternative, to identify them as substances which give rise to an equivalent level of concern, involves both more work and a more uncertain outcome.


\(^{49}\) RMO = Risk Management Options.
A major problem as regards the authorisation process as a whole is that there is strong resistance from industry, many Member States and some parties within the Commission to even include substances in Annex XIV at all. Whenever there are suspicions concerning the level of risk, there is pressure to use the restriction system instead. At the same time, the process relating to restrictions has become so cumbersome that there is a risk that it will grind to a halt (see section 8, Restriction). Overall, this means that there is a risk that chemical controls will be severely hindered and delayed as regards the substances that need to be remedied most.

In connection with the inclusion of substances in Annex XIV, there are also demands for very long transitional periods (i.e. the deadline for the submission of authorisation applications and sunset dates) and to exempt uses from the authorisation process. There is also pressure to take into account economic consequences at this early stage, even though there is no process for doing so in a balanced way. REACH has been formulated so that economic consequences cannot be taken into consideration in a balanced way until the actual application review stage.

Given the Swedish environmental targets system, the target date for the roadmap and the rate at which substances are included in Annex XIV also pose problems. According to the milestone target for substances of very high concern, such substances must be subject to review or a decision concerning phasing out under applicable legal provisions with regard to all applications by 2018, while according to EU’s roadmap for substances of very high concern, the deadline for the inclusion of all relevant substances (i.e. to have identified such substances as being of very high concern) is not until 2020. However, no deadline has been announced by which such substances must also have been subject to review and a decision concerning phasing out, primarily through authorisation and restrictions.

Increased transfer of knowledge between REACH and the EU environmental and work environment provisions

The objective of the phasing out and substitution of hazardous substances is contained not only in REACH and other legislation within the field of chemicals, but also in certain EU provisions within the fields of environment and work environment. There are certain parallels between, on the one hand, processes such as the identification and listing of substances of very high concern, as well as the authorisation and restriction procedure in REACH and, on the other, corresponding processes in the environment and work environment provisions. However, the approach, definitions, criteria and terminology vary between the various provisions, e.g. as regards the selection process for problematic chemicals.

Certain mechanisms which link REACH and EU's environment and work environment provisions are already in place (see below). However, a general view is that an increase in the exchange of information and, where appropriate, inter-sector collaboration as regards the development and application of these provisions, could generate economies of scope and thereby promote substitution.

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50 The EU environmental legislation encompasses a large number of legal documents which are most often aimed at the state of the natural environment or at activities which could cause environmental damage. Unlike the chemical legislation, these legal documents are based on Article 192 of the Treaty and are known as minimum rules, which means that Member States can impose stricter rules. Examples of minimum rules which contain rules concerning chemicals or hazardous substances can be found in the EU provisions concerning waste and water. The EU work environment legislation (Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of works at work) also contains minimum rules concerning chemicals, but in this case using Article 153 of the Treaty as the legal basis.
Within the EU, discharges from industrial plants are regulated through the *Industrial Emissions Directive*\(^{51}\). The provisions impose a requirement that conclusions concerning the *best available technology (BAT)* must be used as a reference in connection with the authorisation of plants in accordance with the Directive. Among the criteria for determining what constitutes the best available technology is that it must reduce the use of hazardous substances. Better transfer and utilisation of such information concerning chemicals which have been developed through the various processes in REACH can better enable the reviewing authority to impose a requirement for the substitution of hazardous substances in connection with the application of the provisions concerning BAT in the Industrial Emissions Directive.

There are also links between REACH and the Industrial Emissions Directive which are more inclined to discourage substitution. An example of this is that someone who applies for authorisation in accordance with REACH can enclose an explanation as to why discharges of the same substance from a plant which has been authorised pursuant to the Industrial Emissions Directive should not be taken into consideration in connection with the authorisation review.

Work is under way within the EU to investigate possible synergy effects between REACH and the Industrial Emissions Directive. This work has been initiated by IMPEL\(^{52}\), on which Sweden is represented by the Swedish Environmental Protection Agency. The REACH Forum is also participating in this work (see also 4.5 Enforcement).

One of the aims of the *Framework Directive for Water*\(^{53}\) (hereinafter the *Water Framework Directive*) is to gradually reduce the contamination of inland surface water, water in transitional zones, coastal waters and groundwater by problematic substances. Annex VIII of the Directive contains an “indicative list of the main pollutants”, while Annex X contains a “list of priority substances in the field of water policy”. Environmental quality standards for priority substances and certain other pollutants are established through the Directive concerning environmental quality standards for priority substances\(^{54}\). The Water Framework Directive itself contains no mechanisms for limiting the use of identified substances. In order to achieve this, specific measures are required with the support of other legislation. Measures can be implemented under national legislation in cases where the problem only concerns an individual Member State or catchment area. In cases where the scope of the problem justifies measures at EU level, they can be based on REACH or other chemicals legislation. One conclusion from this is that the interaction between different sets of legislation is complicated and that there is a significant risk that measures targeted at hazardous substances could 'fall between the two stools'. It is therefore appropriate to analyse how this interaction can be improved in the application and development of the respective legislation.

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\(^{52}\) The European Union Network for the Implementation and Enforcement of Environmental Law (IMPEL) is an informal collaboration between the environmental authorities of the EU Member States, the candidate countries and the EEA countries which is working to ensure the effective application of the EU environmental legislation.


EU provisions concerning protection of the marine environment are set out in the Marine Strategy Framework Directive\(^{55}\), which contains rules concerning contaminants or hazardous substances similar to those of the Water Framework Directive.

Examples of existing links between REACH, the Industrial Emissions Directive and the Water Framework Directive can be found in the provisions concerning authorisation in Articles 61.4-61.5 of REACH. Article 61.4 contains a reference to the so-called IPPC Directive\(^{56}\), which is the predecessor to the Industrial Emissions Directive and the provision means that authorisation that is granted for the use of a substance may be reviewed if an environmental quality standard is not fulfilled. Similarly, Article 61.5 states that authorisation that is granted concerning the use of a substance within a catchment area may be reviewed if the environmental targets in accordance with Article 4.1 of the Water Framework Directive are not achieved.

There are also links between REACH and the environmental legislation, which in some cases may weaken the protection afforded to environment and health. An example of this is the opportunity under certain circumstances not to take into account certain health and environmental risks in connection with authorisation in cases where the same substance has been assessed under the Industrial Emissions Directive or the Water Framework Directive. Applicants applying for authorisation in accordance with REACH may explain in their application why health and environmental risks associated with the use of a substance should not be taken into account if such risks arise as a result of discharges of the substances concerned from a plant that has been issued with authorisation pursuant to the IPPC Directive, which preceded the Industrial Emissions Directive (Article 62.5b I of REACH). Similarly, the application may also explain why risks should not be taken into consideration if they arise through discharges from a point source that is covered by the requirement for advance regulation in accordance with the Water Framework Directive and legislation adopted in accordance with Article 16 thereof (Article 62.5b II of REACH).

The abovementioned references in REACH to the IPPC Directive can still be found in the consolidated version of REACH. They have therefore not been updated to refer to the Industrial Emissions Directive. It is thus unclear at present whether, and if so how, these provisions could be applied.

In summary, an analysis should be carried out concerning how Sweden can promote greater transfer of knowledge and, where appropriate, coordination between processes linked to REACH and other relevant legislation, with the aim of contributing to better protection for the environment and health and increased substitution. Information that is prepared concerning a substance's health and environmental properties, areas of use, etc. in REACH can probably be better used than is currently the case as regards prioritisation and assessment in these regulations. Similarly, underlying information that has been prepared and priorities that have been established within other regulations can in some cases form a basis for priorities in processes such as substance evaluation, authorisation and restrictions in REACH.


Objectives concerning identification and prioritisation for authorisation

- The EU work relating to the roadmap for substances of very high concern is well under way and resulting in the rapid and ongoing development of the Candidate List.
- Increasing numbers of these SVHCs are being regulated step by step through authorisation reviews and/or restrictions.
- The relevance of including substances in the Candidate List is based only on whether the substance has properties of very high concern, without any consideration being given to economic reasons or whether regulation other than via authorisation would be appropriate.
- When substances are included in Annex XIV, the starting point is whether the substance should be prioritised with regard to hazardous properties and use/exposure, without any consideration for economic reasons.

In the long term:

- The work relating to the roadmap has by 2018 already resulted in all known substances of very high concern being included in the Candidate List, or at least being subject to measures which will lead there within two years.
- This applies both to substances which fulfil the roadmap's criteria for relevance and to substances which are included in the Candidate List for other reasons, e.g. substances that are primarily used in imported consumer goods.
- All substances which should be prioritised for phasing out through authorisation are also listed in Annex XIV by 2020.

Prioritisation and need for political initiatives

An appropriate balance is needed between contributing within the framework of the joint work relating to the roadmap for substances of very high concern and, from the Swedish side, working with other like-minded Member States to contribute to the preparation of proposals for substances which we strongly believe should be included in the Candidate List but which others have side-lined, citing economic considerations to justify their claim that a use must first be subject to risk mitigation or that the use cannot be subject to an authorisation review.

Proposed measures concerning identification and prioritisation for authorisation

Short-term measures

In order to maintain the pace and quality of the work to identify and list substances for authorisation, initiatives are needed at political level both in the technically oriented work at authority level and in committees and working groups. Sweden (the Government/the Government Offices and the Swedish Chemicals Agency) should therefore take the following measures:

- Through its respective forums, the Government and the Swedish Chemicals Agency should emphasise the importance of the Candidate List and the authorisation system in REACH for bringing about substitution and the phasing out of substances of very high concern. The Candidate List has become very important in guiding companies as regards substitution, and it gives foresighted companies a chance of planning in advance as regards the phasing-out of substances of very high concern and finding alternatives. It is therefore important to maintain a high pace in the expansion of the Candidate List.
- The Swedish Chemicals Agency should actively contribute to fulfilling the objective in the Commission's “roadmap for SVHC” for all “relevant”
substances of very high concern to be included in the Candidate List by 2020. The Swedish Chemicals Agency should continually submit proposals to the Commission concerning the inclusion of priority substances in the Candidate List and needs sufficient capacity to do this.

- Through their respective forums, the Swedish Government and the Swedish Chemicals Agency should also work to ensure that substances with properties of very high concern are not put to one side as a result of claims concerning economic considerations or that a use should first be subject to a risk assessment. The selection of substances should be based on the criteria for substances of very high concern in REACH and substances which clearly qualify for inclusion in the Candidate List.

- The Swedish Chemicals Agency should be prepared for proposing the identification of substances which should be included in the Candidate List as a matter of urgency, yet which are at risk of being side-lined by other Member States. The Swedish Chemicals Agency should also be prepared for drawing up classification proposals concerning CMR substances when necessary in order to identify substances as being of very high concern in the next stage.

- The Swedish Chemicals Agency should work to ensure that substances on the Candidate List which meet the criteria for being prioritised for authorisation are also included in Annex XIV (authorisations) and thereby allocated a deadline for receipt of an authorisation application and a sunset date by which all use must have ceased unless authorisation is granted.

- The Swedish Environmental Protection Agency and the Swedish Chemicals Agency should participate in the work of IMPEL and REACH Forum to investigate possible synergy effects between REACH and the Industrial Emissions Directive.

**Long-term measures**

- Through their respective fora, the Swedish Government and the Swedish Chemicals Agency should work to ensure that specific criteria are incorporated in REACH for the identification of some of the substance categories which can currently only be identified in accordance with Article 57f ‘substances which give rise to an equivalent level of concern’, e.g. endocrine disruptors and highly allergenic substances.

- The Swedish Chemicals Agency is striving to ensure that all or most of the substances which have been assigned the highest priority for authorisation by 2020 are included in Annex XIV and that a final date for receipt of authorisation applications and a sunset date have been set.

- The Swedish Chemicals Agency is working to ensure that all or most of the substances of very high concern which are known to be widely used in consumer articles are included in the Candidate List by 2020, even in cases where they do not meet the Commission's current criteria for relevance in the Commission's roadmap.

**Need for further analysis**

The opportunity to develop coordination and knowledge transfer between REACH and other relevant provisions of significance to the substitution of hazardous substances and the way in which Sweden can contribute to this should be analysed further. In this context, consideration
should also be given to whether or not there is a need to update references in REACH to the previous IPPC Directive, so that they refer to the legislation currently in force instead - the Industrial Emissions Directive - where applicable.

**How the proposals help to ensure achievement of the Swedish milestone targets concerning dangerous substances**

(A description of the Swedish environmental target *A Non-Toxic Environment* and the milestone targets is given in Chapter 5)

The milestone target concerning particularly dangerous substances means that a decision must be taken within the EU according to which the group **substances of very high concern** must include substances which are endocrine disruptors or highly allergenic.

Substances of very high concern must be subject to review or a decision concerning phase-out under the applicable regulatory framework for all applications by 2018. In order to achieve this, substances of very high concern must be identified.

*Comments:* The proposed measures concerning the identification of substances of very high concern are essential if chemical risks are to be prevented and minimised, and they therefore contribute to attainment of the Swedish milestone target and the Swedish environmental target *A Non-Toxic Environment* in a fundamental way.

**4.2.2 Information concerning substances of very high concern in articles**

When a substance has been identified as being of very high concern and included in the Candidate List, it means that, in addition to the fact that the substance may be subject to authorisation, if the substance is present in articles, ECHA must be notified and information given to customers. The information requirement concerning articles in REACH is thus limited to substances of very high concern in the Candidate List, while the corresponding objective concerning information on articles in the Swedish environmental quality objective *A Non-Toxic Environment*, both the objective specification and the milestone target, encompasses the entire group of 'hazardous substances' (see Chapter 5).

The requirement for ECHA to be notified means that anyone who manufactures or imports an article containing more than 0.1 percent of a substance which is included in the Candidate List, and the total quantity of the substance manufactured or imported exceeds 1 tonne per year, shall notify ECHA in accordance with Article 7.2. The notification shall include limited information compared with a registration, e.g. concerning use of the substance in articles and the uses of the articles. If the substance is suspected of giving rise to health or environmental risks, ECHA may however in principle ask the company to carry out a full registration for the substance (Article 7.5). However, it is unlikely that this rule will be applied to any great extent in practice. However, no notification will be required if the substance has already been registered for the use concerned or if the manufacturer or importer is able to demonstrate that humans and the environment will not be exposed to the substance in question under normal or reasonably foreseeable conditions of use.

The requirement for the provision of information to customers in Article 33 means that anyone who manufactures, imports or sells products containing more than 0.1 percent of the substance must give the recipient sufficient information to which the supplier has access, so that the article can be handled safely. This information must, as a minimum requirement, include the name of the substance. The information must always be given to customers who use the article in their industrial processes or who use the article professionally. Upon request,
consumers are entitled to receive corresponding information from the supplier of the article free of charge within 45 days.

The requirements concerning the occurrence of substances of very high concern in articles are vitally important as a driving force for the work of companies relating to substitution. However, it has become apparent that there are serious deficiencies as regards both the formulation and application of the provisions in REACH at EU level:

- The concentration threshold of 0.1 percent for when information should be provided is not interpreted in the same way by different Member States, ECHA and the Commission. The interpretation that is preferred by the Commission, ECHA and a number of Member States means for example that if a substance of very high concern is present in a bicycle handlebar grip, the concentration threshold must be applied to the entire bicycle and not the grip. This means that if the rest of the bicycle is sufficiently heavy, the information on the substance in the grip need not be disclosed by a bicycle dealer to the recipient regardless of how high the concentration is. For many composite products, this counters the purpose of the provisions concerning both the requirement for notification and the requirement for information. Guidelines have been drawn up jointly by Sweden, Belgium, Denmark, France, Norway and Germany because these countries do not accept this interpretation. These countries believe that if an article (in our case, the bicycle handlebar grip) contains more than 0.1 percent of a substance that is included in the Candidate List, the supplier must always inform its customers of this, regardless of whether they sell the article separately or whether the article forms part of a composite article (the bicycle). The Commission has initiated a process which will result in the European Court of Justice resolving the issue, and a French court has also requested an advance statement from the Court of Justice.

- According to Article 33 the information requirement covers “sufficient information to which the supplier has access, including at least the name of the substance, so that the article can be used in a safe manner”. However, the provisions give no indication of the lengths to which a supplier must go in order to prepare information for the customer. There is also no indication of what information is needed to enable safe use under what conditions or when the name would be sufficient, either in REACH or in ECHA's guidelines.

- According to REACH, the consumer is only entitled to information on request and only after 45 days. This considerably reduces the importance of the information as an incentive for substitution and a basis for safe handling. An example of a step in the right direction can be found in the Construction Products Regulation, which entered into force in 2011. This regulation imposes a requirement according to which information on substances of very high concern must be provided in the article's documents at the sales stage for construction products in the form of what are known as “declarations of performance”, so that all recipients, including consumers, receive the information directly.

- The provisions only apply to substances that are included in the Candidate List and very few substances of very high concern and known usage in articles have so far been included in the Candidate List. The inclusion in the Candidate List of substances of very high concern which are primarily used in articles can also be delayed and counteracted by the relevance criteria that are established in the recently adopted roadmap for substances of very high concern (see section 4.3.1).

- An associated problem is that the requirements do not cover hazardous substances other than those which meet the criteria and which are identified as being of very high
concern, such as allergenic substances. Only in exceptional cases can the very worst of the other hazardous substances be identified as substances which give rise to an equivalent level of concern and be included in the Candidate List. There is therefore a marked absence of provisions which make it possible to know whether articles that are used for everyday purposes by humans contain hazardous chemicals.

- There is also currently a marked absence of awareness of the information requirements that apply amongst article suppliers. Guidance is available from ECHA, but it is difficult to obtain, inadequate and poorly distributed. The problem particularly applies to small enterprises and the retail sector in particular.

- Notifications to ECHA by manufacturers and importers of articles which contain substances of very high concern in accordance with Article 7.2 are submitted all too infrequently. This is partly because the notification requirement has been formulated so that exemptions apply if the substance is already registered for the use in question, and partly because the current system in ECHA's guidelines for specifying the use of articles in connection with registration is too imprecise.

- There is a marked lack of widely available information concerning common uses in articles of substances that are included in the Candidate List, e.g. on ECHA's website. To some extent, this is also linked to the very limited number of notifications submitted to ECHA by producers and importers of articles which contain substances of very high concern. The absence of such a basis prevents suppliers from asking its article suppliers the right questions. In turn, this means that the knowledge concerning the content of substances of very high concern in articles is not being improved to the desired extent.

- There are no rules to ensure that information on substances of very high concern reaches waste processors and recycling organisations, which under the current rules are not considered to be recipients of articles. This makes it difficult for such organisations to avoid risks associated with waste management and prevent substances of very high concern from being distributed further via recycled materials. Waste processing, recycling and other organisations further down the supply chain, e.g. producers of complex articles made from sub-components which are not chemical products, also have no access to safety datasheets and other information from registrations, such as exposure scenarios. This further hampers the much-needed transfer of information and knowledge.

**Objectives concerning information on substances of very high concern in articles**

**Short term:**

- Many more companies than today are aware of the requirements concerning information relating to substances of very high concern in articles. This particularly applies to importers and smaller suppliers of products within the EU.
- In their work to comply with applicable requirements, companies have been supported by appropriate, simple and functional guidance suitable for their needs, as well as a material database managed by ECHA which contains information on which substances are used in which materials.
- The Candidate List contains a considerably higher number of substances with important uses in articles compared with the current situation, which means that the information requirements cover more substances.
It has been established that the concentration threshold in REACH of 0.1 percent must be applied to an article regardless of whether the article is sold separately or forms part of another article.

In the international collaboration that is taking place within SAICM concerning information relating to chemicals in articles, voluntary measures have been agreed to increase the amount of information concerning substances in articles. The implementation of these measures has started for various product groups. These and other voluntary measures support and accelerate the development of appropriate provisions.

Long term:

- The Candidate List in REACH encompasses all known substances of very high concern which are widely used in articles.
- The chemical legislation has been developed, e.g. through REACH, as regards information concerning hazardous substances in articles, resulting in establishment of the following requirements:
  - information must also be provided for hazardous substances other than those which meet the criteria and which are identified as being of very high concern, such as allergenic substances.
  - information accompanies an article throughout its entire lifecycle and therefore also reaches waste processing and recycling organisations
  - consumers receive information directly at the time of purchase, e.g. via the internet
  - suppliers must document how they ensure that the information requirements are fulfilled.
- It is clear from both REACH and guideline documents:
  - what type of information must be provided to professional customers, consumers and waste processing and recycling organisations
  - how and when the information must be provided
  - how and when the requirement to notify ECHA of articles that contain substances of very high concern is to be applied
  - how use in articles must be specified precisely upon registration of the substance.
- There is a binding international agreement which sets out requirements concerning information relating to substances in articles and which has been implemented for a number of important consumer article groups.

In the future, information requirements should ultimately cover all hazardous substances and be available to all stakeholders throughout the lifetime of the article, including the waste stage.

Prioritisation and need for political initiatives

In the short term, all the above mentioned goals are of high priority and there are suitable EU forums through which they can be pursued. In the long term, political initiatives at Council

\[57\] An overarching goal in SAICM, the UN's global chemicals strategy (Strategic Approach to International Chemicals Management), is that all players must have access to information so that they can handle chemicals safely throughout the life cycle. The goal also includes information concerning chemical substances in articles. By 2015, a proposal for a voluntary international programme concerning information relating to substances in articles must be developed.
level will be required in order to open up the REACH Regulation to changes so that Article 33 can be amended and in order to take the proposed changes forward.

**Proposed measures concerning information on substances of very high concern in articles**

**Short-term measures**

Requirements concerning information on hazardous substances in articles in REACH are relatively limited. Yet they are also important, as the legislation currently contains no general information requirements concerning concentrations of chemicals in articles, and the absence of such information represents a major problem in the control of chemicals. The issue of improving the information requirements encompasses both overarching political aspects and more technical aspects. Sweden (the Government/the Government Offices and the Swedish Chemicals Agency) should therefore take the following measures, among others:

- At their respective levels in their communication with EU institutions and other Member States, the Government and the Swedish Chemicals Agency should highlight the issue of hazardous substances in articles generally and the importance of improving the provision on availability of information in particular.

- The Swedish Chemicals Agency should strive to ensure that ECHA and the Member States prepare and disseminate information in order to raise awareness of the requirements in Article 33, particularly to importers, smaller suppliers and retailers of products, and to companies in third countries which export articles to the EU.

- The Swedish Chemicals Agency should strive to ensure that ECHA formulates clear and practically oriented guidance concerning the REACH requirements regarding information on substances of very high concern in articles (Article 33). These should be particularly targeted at importers, smaller suppliers and retailers of articles, and at companies in third countries which export articles to the EU.

- The Swedish Chemicals Agency should strive to ensure that substances of very high concern which are widely used in articles are included in the Candidate List insofar as is possible. The Swedish Chemicals Agency should draw up proposals for the inclusion of priority substances in the Candidate List and therefore needs to have the preparedness necessary to do so (see also section 4.2.1).

- The Swedish Government and the Swedish Chemicals Agency should contribute underlying information to support the interpretation of the requirements concerning information regarding substances of very high concern in articles (Article 33 in REACH) which is practised by Sweden, Belgium, Denmark, France, Norway and Germany and which means that the concentration threshold in REACH of 0.1 percent must be applied to an article regardless of whether it is sold separately or forms part of another article. There is for example a need to update and develop such underlying information ahead of an up-coming ruling by the European Court of Justice.\(^\text{58}\)

- The Swedish Chemicals Agency should promote or propose the creation by ECHA of a database containing information on the occurrence of substances of very high concern in articles.

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\(^{58}\) On 6 March 2014, a French court submitted a request to the Court of Justice for an advance ruling concerning the interpretation. If it wishes to do so, Sweden has until 6 June 2014 to submit a statement to the Court of Justice concerning this case (C-106/14).
concern in different types of materials. An important aim is to make it easier for suppliers to apply Articles 7.2 and 33 to the right substances and articles in the best possible way. Another aim should be to facilitate waste management and recycling.

- The Swedish Government and the Swedish Chemicals Agency should promote or propose a programme coordinated by ECHA aimed at systematising the task of preparing information on the occurrence of substances of very high concern in articles. Possible starting points for the programme are Articles 7 and 33 in REACH. The information should be collated and made available to consumers via ECHA's website.

- Sweden should strive to ensure that the EU continues to support and develop the process for developing voluntary measures for better information concerning hazardous substances in articles which is under way as part of the global chemical strategy (SAICM). This is considered to be an important supplement to the work relating to information on hazardous substances in articles within REACH and can in the long term help companies within the EU to provide such information.

**Long-term measures**

- The Swedish Government and the Swedish Chemicals Agency should work at their respective levels to develop the requirements concerning information on substances of very high concern in articles in Article 33 of REACH, in particular, in the following respects:
  - The requirements are expanded to encompass additional categories of substances, including highly allergenic substances and, in the longer term, at least certain categories of hazardous substances, in addition to substances of very high concern.
  - A requirement is introduced to forward information to the waste stage and to make information directly available to consumers, e.g. via the internet.
  - The legislative requirements imposed on suppliers of articles, including importers, distributors and retailers within the EU, are being clarified and tightened as regards, for example, the type of information and how and when it must be provided.

- The Swedish Government and the Swedish Chemicals Agency are working to ensure that the requirements concerning the notification of substances in articles (Article 7 of REACH) are clarified and tightened as regards the circumstances under which notification must be given, and to ensure that when registering substances manufacturers/importers must specify the uses of substances in articles precisely.

- The Swedish Government and the Swedish Chemicals Agency are working to promote international rules containing a binding requirement for producers and suppliers of articles to provide information on the occurrence of substances of very high concern, at least as regards especially prioritised article groups.

**Need for further analyses**

In connection with the right of consumers to request information concerning substances of very high concern in articles (Article 33 of REACH), the opportunities that exist to systematically prepare, collate and make available such information should be studied in more
The substance groups that should be prioritised in connection with the expansion of the information requirements to include substances other than those of very high concern should also be examined further.

**How the proposals help to ensure achievement of the Swedish milestone targets concerning dangerous substances**

(A description of the Swedish environmental target *A Non-Toxic Environment* and the milestone targets is given in Chapter 5)

The milestone target regarding information about dangerous substances in articles means that rules or agreements within the EU or at international level must be applied so that information concerning harmful substances in articles will be available to everyone concerned by 2020. The rules will be introduced in stages for different article groups. Information concerning hazardous substances in materials and articles shall be available throughout the lifecycle of the article.

Access to information is an important precondition in order to reduce chemical risks in connection with manufacturing and use and during the waste stage. The requirement in REACH for information on the occurrence of substances of very high concern is driving the acquisition of knowledge concerning hazardous substances in materials and articles generally, but it needs to be developed and include more groups of hazardous substances.

*Comments:* The proposed measures should lead to the strengthening of the information requirement in line with the milestone target concerning information on hazardous substances in articles.

### 4.3 Authorisation

#### 4.3.1 Authorisation of substances of very high concern

*The aim is to control and substitute substances of very high concern*

The authorisation process for substances of very high concern is one of the new aspects of REACH compared with the previous chemicals legislation. Certain other chemicals legislation have contained provisions concerning authorisation, including the provisions concerning plant protection products, biocides and medicines. However, the authorisation of industrial and consumer chemicals has not been covered by the provisions in this area which preceded REACH.

A stated aim of the authorisation process is that substances of very high concern will gradually be substituted by safer alternatives or techniques. Article 55 of REACH states that the aim of authorisation is “the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. To this end all manufacturers, importers and downstream users applying for authorisations shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution.”

In the absence of alternatives, substances of very high concern can be granted authorisation. The authorisation is linked to certain conditions which define the application and safety measures. Authorisation may be granted if the use is considered to be adequately controlled. Authorisation may also be granted on the basis of an assessment of the socio-economic benefits, even if the use is not adequately controlled.
ECHA and the Member States are gradually including substances which meet the criteria for authorisation in the so-called Candidate List. From this, certain substances are selected, based on properties and use. Priority substances are included in Annex XIV in accordance with a special procedure where the Commission is the determining body. This process also results in the establishment of a “sunset date”, which is the date from which placing of the substance on the market and use of the substance must be prohibited if authorisation is not granted, and a date by which an application must be received by ECHA. An application for authorisation may be submitted by the manufacturer or importer of the substance, or by a company that uses the substance (known as a 'downstream user').

In the assessment of authorisation, health and environmental risks, the availability of alternatives and socio-economic impacts are taken into consideration to varying degrees. For substances that are carcinogenic, mutagenic or toxic to reproduction (CMR substances) and have a threshold for effect, authorisation must be granted if the applicant is able to demonstrate that the risks are adequately controlled, even if better alternatives are available. If the applicant is unable to demonstrate this, authorisation may only be granted if no alternative substances or techniques are available and the socio-economic benefits of further use outweigh the associated risks. This also applies if the substance is a CMR substance without a threshold for effect, if the substance is persistent, bioaccumulative and toxic (PBT substance) or if it is very persistent and very bioaccumulative (vPvB substance). The Commission decides whether to grant or reject authorisations after a public consultation process concerning alternatives has been carried out, after ECHA's scientific committees have issued statements and after Member States have voted via the prescriptive committee.

According to REACH (Article 60.8), any authorisation will be valid for a particular period of time and will normally be linked to certain conditions, including monitoring arrangements. After expiry of the time-limited review period, the authorisation may be reviewed and renewed. The authorisation concerns use of the substance both separately and as a constituent in a preparation. It also concerns incorporation of substances of very high concern in articles that are produced within the EU. Furthermore, the authorisation requirement does not apply to substances of very high concern used in articles imported from countries outside the EU. It also does not apply to the way in which a substance that is exported from the EU is used in non-EU countries. The occurrence of substances of very high concern in imported articles can however be regulated through restrictions or a ban in accordance with Title VIII of REACH (see section 4.4.1).

So far, limited practical experience of the authorisation process in REACH has been gained. Rules entered into force in 2008 and the first applications were submitted in 2013. To date, no authorisation applications have been fully processed by ECHA's committees for risk assessment (RAC) and for socio-economic analysis (SEAC) and no applications have therefore been approved by the Commission. However, it is already possible to draw certain conclusions concerning up-coming problems and deficiencies in the authorisation process. These are based on an analysis concerning the formulation of the provisions, the guidelines for the work that ECHA has carried out to date and the way in which the first applications have been handled as regards checks on whether they fulfil the requirements (known as “conformity checks”). A review is presented below of some of the key problems that have already been identified or that can be anticipated in connection with the application of the authorisation provisions in REACH.

*Access to alternatives poorly considered in the authorisation process*
As noted previously, it is stated in Article 55 of REACH that the purpose of authorisation is to progressively replace substances of very high concern with suitable alternatives or techniques. However, the provisions do not contain a mechanism for preparing independent information concerning these alternatives and techniques. The Commission and ECHA interpret the REACH provisions as meaning that a party applying for authorisation need only analyse alternatives that are feasible from their own particular perspective. In cases where the application is a chemical producer, it is therefore likely that the analyses will be restricted to substances which the producer itself is able to supply. Alternatives in the form of other materials, techniques or other types of substances, that a chemical user could switch to, will probably be excluded from the analysis in most cases.

As part of the assessment of an authorisation application, ECHA conducts a public consultation process, with the aim of suppliers of alternatives submitting information on possible alternatives. For confidentiality reasons, however, only limited and general information is given out concerning the uses covered by the application. Suppliers of alternatives will therefore have difficulty determining whether their product is suitable for the use in question and therefore whether they should submit information to ECHA. This fear is confirmed by the fact that little information concerning alternatives was provided during the first consultation process which was conducted in autumn 2013. The socio-economic committee has also no opportunity to draw up or order supplementary, independent information concerning alternatives in connection with its processing of authorisation applications.

One conclusion is that, as they are currently worded, the rules provide no broad information on alternatives to substances of very high concern that are subject to an authorisation review. This particularly applies to alternatives in the form of other technical solutions which are normally supplied by companies other than the company which is applying for authorisation for a chemical substance. The alternatives will therefore not be given adequate consideration in connection with the review. Instead, the decision-making process will largely be based on information from the authorisation application itself. In most cases, these are chemical suppliers who have no incentive to provide information concerning alternatives other than those which they are able to provide themselves.

Overall, there is a risk that, as it is currently worded, the authorisation process in REACH will not promote substitution to any great extent and, in certain cases, could even hinder such substitution. Both the authorisation provisions themselves and their application therefore need to be developed if they are to constitute an effective tool for substitution.

Authorisation scope, review period and formulation and follow-up of conditions

In some cases, during the initial checks to determine whether the application fulfils the requirements in REACH, applications have been let through which have specified the intended use of a substance in a broad and imprecise manner. This is contrary to the requirements to describe use with a high level of precision which have been envisaged previously. The handling of authorisation applications also contrasts with the considerably more demanding requirements concerning the precise description of uses which are currently being applied in the restriction process (see section 4.4.1).

One way of stimulating substitution would be to grant authorisations for a relatively short period of time. However, ECHA has worked with the Commission to draw up a recommendation according to which authorisations will normally be valid for a period of seven years, with two optional possibilities by increasing the period to twelve years or reducing it to four. This differs from the REACH text, which indicates that the period of
validity of an authorisation shall be determined on a case-by-case basis. The recommendation indicates a risk that authorisations will often be issued for a long period of time, which would lead to a reduction in the pressure exerted on companies to substitute substances of very high concern.

The appropriate formulation and application of the authorisation system is possibly of particular importance during the early stages of the authorisation system. For example, it is important that ongoing discussions result in authorisations being linked to clear conditions. The condition could concern monitoring and reporting, a maximum quantity which can be manufactured or sold, etc. Furthermore, there is uncertainty as to how conditions shall be followed up and where the responsibility for such follow-up lies. REACH provides no guidance on this matter and also contains no provisions requiring reports to be submitted concerning supervision of the conditions conducted by Member States. There is therefore an obvious risk that the Commission and ECHA will have no basis on which to assess compliance with the authorisation conditions or, consequently, to determine the need to review and revoke the authorisation.

Deficiencies in the provisions concerning substitution plans

Authorisation applicants only need to present a substitution plan if alternatives are available. As the provisions are currently worded, it is likely that substitution plans will only be submitted for substances which have a threshold as regards when exposure will lead to effects on health and where the applicant's own analysis shows that alternatives are available. If the assessment of such an application shows that use of the substance can be controlled adequately, the Commission must grant the authorisation, even if safer alternatives are available. It is open to question whether this was the intention when REACH was being formulated.

As regards substances of very high concern which are considered to have the most serious effects (CMR substances without a threshold for effect and PBT and vPvB substances), the wording of the provisions incentivises applicants to demonstrate that no alternatives are available. This is because the Commission can only grant authorisation if no alternatives are available and the socio-economic benefits of further use are considered to outweigh the risks. In such cases, it is unlikely that any substitution plans will be submitted. There is also no requirement to present plans to develop or consider alternatives. As a temporary solution to this problem, the Commission has supplemented the guidance in order to encourage applicants to present initiatives aimed at developing alternatives. The Commission has also promised that the legislation will be clarified by the time of the REACH review in 2012. The implication of the clarification should be that the aim of both the alternative assessment routes for authorisations is to promote substitution (i.e. both cases where use is considered to be adequately controlled and cases where adequate control cannot be demonstrated, but the socio-economic benefits are considered to outweigh the risks). No such clarification has been forthcoming, however, as the articles in REACH were not brought up for amendment in connection with the review in 2012.

Insufficient consideration given to total exposure

There is a risk that total exposure to a substance from different sources will not be adequately taken into consideration in the assessment of an authorisation application. For legal reasons, each application will normally be processed individually, depending on whether any other applications or authorisations have already been granted concerning the same substance. If a number of applications for authorisation are granted for a particular substance to several applicants, the combined exposure from different uses could become unacceptable for society.
or the environment. Whether, and if so how, this problem will be handled in REACH is as yet unclear.

**Clarification is needed concerning the authorisation of substances in recycled materials**

The Swedish Chemicals Agency's report *Regler om kemikalier i kretsloppet för varor – en juridisk analys* (Rules on chemicals in the life-cycle of articles - a legal analysis) dating from June 2014 presents an analysis of how the authorisation process in REACH should be applied for substances of very high concern in recycled materials. The report concludes that the assessment of whether a use can be considered to be adequately controlled under the REACH provisions must encompass the entire product cycle through to recycling, including exposure from articles and exposure and discharges in connection with waste management. Substances of very high concern that occur in recycled materials must therefore be subject to authorisation assessment in the same way as substances used for virgin materials.

A possible problem associated with recycling is that the recycled materials contain impurities that have not been successfully removed during the recycling process. These impurities may be substances of very high concern, even if the rest of the material intended to be recycled does not have such properties. The definition of 'substance' in REACH and CLP means, however, that impurities are, under certain conditions, not to be regarded as separate substances, even if they occur in high concentrations. According to ECHA's guidance for the area, a substance may contain up to 20 percent of an impurity. If an impurity cannot be considered to originate from or otherwise be related to the substance that is to be recycled, it will however be considered as a substance in a mixture. The substance must then be authorised if it is present in the mixture at levels above 0.1% or at levels which mean that the mixture is characterised as hazardous waste (Article 56.6 of REACH).

A discussion is currently under way within the EU concerning the authorisation of recycled materials and associated problems. Recycled materials may contain many different types of additives which are substances of very high concern but which have previously been allowed to use without authorisation. This could result in different types of problems and uncertainties in connection with recycling. The question has also become topical in connection with a specific case where a recycling organisation applied for authorisation to recycle PVC plastic containing DEHP, a phthalate plasticiser. DEHP is a substance of very high concern that shall be assessed for authorisation under REACH by 2015. Representatives from the industry have also raised the issue of a general exemption from authorisation, citing Article 58.2 of REACH. These provisions state that, under certain conditions, uses or substance categories may be exempted from authorisation. The industry representatives have also pointed to the definition of 'substance' which permits impurities of up to 20 percent in a substance. Member States also have different interpretations as regards whether, and if so how, the authorisation provisions should be applied to recycled materials.

The Swedish Chemicals Agency believes that it is not possible to exempt recycled materials generally from authorisation pursuant to Article 58.2 of REACH. It is also not reasonable or in accordance with the intentions behind REACH to authorise substances of very high concern in recycled materials without assessing the substances in the same way as applies to uses in newly manufactured materials. Authorisation appears to be a suitable process for conducting such an assessment.

59 The term 'substance' is discussed in the ECHA guidance on which this section is based. See "ECHA, Guidance for identification and naming of substances under Reach and CLP, Version 1.2, March 2012".
It is also important to minimise the occurrence and spreading of substances of very high concern in recycled materials. According to the specification of the Swedish environmental quality objective *A Non-Toxic Environment*, the use of substances of very high concern must cease as far as possible. The phasing-out of such substances should apply to both virgin and recycled materials.

ECHA’s guidance should be developed so that, for example, it is clear what applies to the authorisation of substances of very high concern in recycled materials. It is also important that a more detailed analysis is carried out as regards how REACH and the waste legislation interact in respect of these and related issues and, if necessary, that measures to improve coordination are proposed.

According to the Swedish Government’s milestone target concerning a Non-Toxic and resource-efficient ecocycle, a combined strategy of measures within the EU must, by 2018, lead to the EU legislation concerning waste, chemicals and products being largely complementary and coordinated such that they promote a Non-Toxic and resource-efficient ecocycle. Furthermore, the principle of high and uniform requirements concerning the content of hazardous substances in virgin and recycled materials must be established through a decision where appropriate. The Government Bill entitled *På väg mot en gifffri vardag – plattform för kemikaliepolitiken* (On the way to a Non-Toxic everyday life (prop. 2013/14:39)) emphasises the strategy for a Non-Toxic environment and, in particular, Non-Toxic material cycles, which according to the EU 7th Environmental Action Programme must be drawn up by 2018, as being important for achieving the abovementioned milestone target.

**Objectives concerning the authorisation process**

In the short term, the objectives for development of the authorisation process in REACH and its application are as follows:

- The guidance for authorisation applications have been developed and clarified to better explain the fact that applicants can voluntarily draw up a plan for the development and testing of alternatives in cases where no alternatives exist. Applicants have an incentive to draw up such a plan because it can make the granting of authorisation more likely or result in the authorisation being granted for a longer review period.
- Access to independent information concerning alternatives, including alternative materials and techniques, as a basis for the assessment of authorisation applications must have been improved. The Commission, ECHA and Member States contribute to the preparation of such information in order to supplement the information that is produced through the public consultations concerning an authorisation application.
- The authorisations that are granted:
  - describe the use of the substance with a high degree of precision,
  - state clearly how much of the substance concerned the applicant may place on the market or use,
  - specify monitoring arrangements, and
  - have a review period that has been determined taking into account the need to promote the development of, and a transition to, safer alternatives.

In the long term, the following objectives for development of the authorisation process in REACH and its application have been established:

- It has been clarified in REACH that the purpose of authorisation in accordance with Article 55, i.e. the progressive substitution of substances of very high concern with
suitable alternatives when economically and technically feasible, applies to all such substances, regardless of whether or not the use is considered to be adequately controlled.

- The requirements clearly state that authorisation applications must contain a plan for developing and testing alternatives in cases where the applicant's analysis shows that no alternatives are available.
- The provisions state that an independent review of the availability of alternatives shall be carried out if necessary to provide a basis for assessment of the authorisation application by the Socio-Economic Analysis Committee (SEAC).
- For more categories of substances of very high concern than is the case today, authorisations may only be granted if no alternatives are available and the socio-economic benefits outweigh the risks.

Prioritisation and need for political initiatives
The short-term measures can be promoted through existing forums such as the Commission's expert group for competent authorities for REACH and CLP (CARACAL), ECHA's Management Board, RAC and SEAC and through direct communication with the Commission, ECHA and Member States. Political initiatives are needed to bring about changes to articles in REACH in the long term.

Proposed measures concerning authorisation

Short-term measures
A stated aim behind the authorisation process in REACH is to achieve a high level of protection for health and environment through substituting substances of very high concern with substances or technical solutions which constitute safer alternatives. The authorisation process should be developed to make it more effective and so that it promotes the work relating to substitution. Sweden should therefore take the following measures:

- At their respective levels, the Swedish Government and the Swedish Chemicals Agency make use of their contact with EU institutions and authorities to emphasise the importance of a process that is effective and promotes substitution.
- The Swedish Chemicals Agency should strive to ensure that the guidance in authorisation applications makes it clear that, when no alternatives to a substance of very high concern are available, applicants can on their own initiative draw up a plan for the development and assessment of such alternatives. In order to incentivise applicants to draw up such a plan, consideration should be given to whether or not the presentation of a plan could make the issuing of an authorisation more likely or make it more likely that the authorisation is granted for a longer review period.
- Through committees and working groups, the Swedish Chemicals Agency should strive to ensure that the work to acquire knowledge concerning alternatives to hazardous substance is developed and systematised, which could for example involve the following initiatives:
  - ECHA and the Member States ensure the wider distribution of information concerning ongoing public consultations regarding substances for authorisation assessment, with the aim of receiving more information concerning alternatives.
  - Both companies and Member States which have information on alternatives to substances which are subject to an authorisation assessment are encouraged to submit the information they have at their disposal to ECHA.
- The Commission and/or ECHA are examining how alternatives in the form of the application of different technical solutions or the use of different materials can be made more widely known and taken into consideration in authorisation assessments.

- The Commission and/or ECHA are examining the possibility of establishing a function at EU level for systematically searching for and building up information concerning alternatives to hazardous substances, including good examples of transitions to such alternatives (see also section 4.1.9 The work of companies relating to substitution).

- The Swedish Chemicals Agency should strive to ensure that, when assessing authorisation applications, the Commission, ECHA and the socio-economic committee (SEAC) consider alternatives to substances of very high concern, including alternatives in the form of other technical solutions, from a holistic perspective. This means that alternatives which may be relevant for downstream users should be considered, not just alternatives which can be supplied by the authorisation applicant.

- The Swedish Chemicals Agency should strive to ensure that the guidance for authorisation applications is formulated so that, when no alternatives are available, it better incentivises applicants to voluntarily draw up a plan for the development and testing of such alternatives. Such a plan can make the granting of authorisations more likely or in some cases lead to the granting of a longer authorisation period.

- The Swedish Chemicals Agency should strive to ensure that conditions in accordance with Article 60.8 of REACH are normally stipulated in any authorisation decision and that such conditions clearly state the uses that are permitted, the largest quantity of the substance that may be placed on the market or used, and appropriate requirements concerning monitoring measures and reporting. The period of validity of an authorisation should also be set individually and in a way which promotes substitution.

- The Swedish Chemicals Agency should strive to ensure that suitable forms of follow-up concerning compliance with authorisation conditions are developed. For example, some form of systematic reporting from the process to enforce compliance with authorisation conditions needs to be developed in order to enable the Commission to revoke or review authorisations in cases where the conditions are not met.

- The Swedish Chemicals Agency should strive to ensure that ECHA's guidance is clarified as regards authorisation assessments concerning substances in recycled materials.

**Long-term measures**

In the longer term, it is desirable that the ambition of bringing about an effective process which clearly contributes to substitution is also clarified through amendments to articles in REACH where necessary. In the longer term, Sweden should therefore take the following measures:

- The Swedish Government and the Swedish Chemicals Agency should strive to ensure that more categories of substances are covered by assessment in accordance with the provision (Article 60.3) which states that authorisations for certain substances of very high concern must only be granted if no alternatives are available and the socio-economic benefits of further use outweigh the risks. This approach to assessment is currently only applied to CMR substances without a threshold for harmful effects and to PBT and vPvB substances. In future, this approach to assessment should, for example, be applied to certain categories of endocrine disruptors.
The Swedish Government and the Swedish Chemicals Agency should strive to ensure that, in the absence of alternatives to a substance of very high concern, the authorisation application must include a plan for phasing out the production and/or use of the substance and, where relevant, the way in which the substance will be substituted with a safer alternative. This could for example be achieved through the amendment of Article 60.4.

The Swedish Government and the Swedish Chemicals Agency should strive to ensure that the provisions in Article 64.4(b) are developed so that it is made clear that the analysis conducted by the socio-economic committee (SEAC) encompasses alternatives which are technically and economically feasible from a broader perspective. At present, the analysis tends to be limited to alternatives which are considered to be reasonable from the perspective of the applicant. The Swedish Government and the Swedish Chemicals Agency should strive to ensure that, when assessing authorisations, ECHA’s committees (RAC and SEAC) consider the total exposure to a substance from different sources to a greater extent (Art. 60). One way of achieving this would be for authorisation decisions to specify a maximum volume, which takes total exposure into account.

How the proposals help to ensure achievement of the Swedish milestone targets concerning dangerous substances

(A description of the Swedish environmental target A Non-Toxic Environment and the milestone targets is given in Chapter 5)

The milestone target concerning particularly dangerous substances means that a decision must be taken within the EU which means that by 2018 substances of very high concern must be subject to assessment or a decision concerning phasing-out under applicable legislation as regards all applications, and only used in manufacturing processes under strictly regulated conditions.

Comments: The proposed measures concerning the authorisation process provide a better basis for the prevention of chemical risks, and therefore contribute to attainment of the Swedish milestone target and the Swedish environmental target A Non-Toxic Environment in a fundamental way.

4.4 Restriction

4.4.1 Restrictions

The use of chemicals which involve risks can be limited or prohibited

According to REACH (Title VIII, Article 68), a substance must be restricted “when there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis”.

In the restriction system, the occurrence of risk in connection with the manufacture and use of a substance forms the starting point, unlike the authorisation system which is intended to handle substances of very high concern. The restriction system also presents the only way of restricting the use of hazardous substances in articles that are imported into the EU.

Adopted restrictions are set out in REACH in Annex XVII. New or revised restrictions are incorporated in this annex. In June 2014, Annex XVII contained restrictions concerning
around 60 substances. Most of these restrictions came about under the so-called Limitations Directive\textsuperscript{60}, which preceded REACH. The annex also contains a long list of substances which are carcinogenic, mutagenic or toxic to reproduction (CMR substances) and which may not be sold to consumers, either on their own or as a constituent in chemical products. They may only be sold to professional users for professional use.

The Commission and Member States may take the initiative to introduce a ban or restriction procedure. A basis for a restriction decision, known as a “restriction dossier”, is prepared by the Member States themselves or by ECHA on behalf of the Commission.

A list of substances for which proposals for restrictions are either planned or in the process of being implemented is prepared by ECHA. This information is also made available via the authority's website. ECHA also announces the cases for which the Commission or Member States intend to draw up proposals concerning restrictions on a substance and informs the companies that registered the substance concerned. The parties involved are also given the opportunity to submit their views on the restrictions dossier.

A completed restriction proposal that is submitted to ECHA will first be considered by the risk assessment committee (RAC) and the committee for socio-economic analysis (SEAC). The Member States in the prescriptive committee then vote, before the Commission takes the final decision. The decision will normally involve a ban on certain uses and/or requirements concerning specific safety measures. Unlike an authorisation assessment, a restriction decision may also cover use in imported articles. In exceptional cases, a decision may result in a total ban on the manufacture, placing on the market and use of the substance. The restriction provisions in Title VIII and Annex XVII were introduced on 1 June 2009. The first decisions in restriction cases where all background information was prepared and processed in accordance with the REACH provisions were taken in 2011.

Many problems have become apparent during the period of application of the restriction provisions in REACH. In some cases, the problems stem from the formulation of the provisions themselves, while in other cases they relate to interpretation and application of the provisions. In some cases, the problems have been caused by the development of working methods adopted by the committees. An example of this is the requirements of various stakeholders, which often have no basis in the legislation and in some cases may even contradict their stated aim (see also below).

Many of the problems that burden the restriction process have been highlighted within committees, working groups and elsewhere. Discussions concerning appropriate measures are currently under way between the Commission, ECHA and the Member States. It is however unclear whether, and if so how, the discussions will result in specific measures to improve the situation or whether the measures will be sufficient to make the restriction process effective.

\textit{The work relating to restrictions is slow and resource-intensive}

The slow pace of the work relating to restrictions on chemical substances under the previous Limitations Directive was one of the reasons behind the review of the EU chemicals legislation which led to REACH. The need to accelerate and streamline the restriction process is underlined in the Commission's White Paper on a strategy for future chemicals policy\textsuperscript{61} dating from 2001, which outlines the main aspects of REACH. This is also highlighted in the preamble to REACH, most clearly in recital 84.

\textsuperscript{60} The so-called Limitations Directive (76/769/EEC) has been superseded by REACH, as the restrictions procedure in Title VIII in REACH entered into force in 2011.

In practice, the work relating to restrictions under REACH has so far been considerably more work-intensive and ineffective than that under previous legislation. Many of the restrictions that were approved under the Limitations Directive would probably not have come about had they been subject to the requirements and procedures that apply under REACH. During the period 2011-2014, when decisions were taken in many restriction cases which were handled entirely under REACH, the number of restriction decisions per year was lower than during the previous ten-year period. This is despite the fact that a lot of new information concerning health and environmental risks has become available through the REACH registrations.

There is currently considerable uncertainty as regards the application of the authorisation procedure in order to regulate substances of very high concern in accordance with the intentions in REACH (see also section 4.3.1). Restrictions may therefore represent the best opportunity to regulate such substances. Given the cumbersome restriction process, there is however a risk that few decisions will be taken and the pace of work will be slow. This also leads to fears concerning the extent to which REACH will contribute to attainment of the objectives concerning better management of environmental and health risks that are expressed in the White Paper. This particularly applies to risks associated with substances of very high concern.

Before REACH, it was relatively common for Member States who are active within the field of chemicals to develop national restrictions in cases where such restrictions were considered important. In turn, this often led the Commission to draw up proposals for harmonised restrictions. With REACH, this possibility has been sharply reduced or even eliminated altogether. The Commission interprets the harmonised effect of REACH differently from many Member States. According to its interpretation, the Commission claims that Member States must always submit a complete basis for restrictions in accordance with the REACH provisions (known as an "Annex XV dossier") to ECHA. According to the Commission, this also applies if a need for restrictions has only been identified at national level.

According to REACH, the responsibility to draw up proposals for harmonised restrictions largely rests with the Member States, unlike the previous situation where the Commission was responsible for this task assisted by consultants. However, the Commission can still initiate restrictions by asking ECHA to prepare an Annex XV restrictions dossier (Article 69). Alternatively, they can prepare background information themselves as regards CMR substances in consumer articles (Article 68.2).

Demanding and increasingly stringent requirements are being imposed on the restrictions dossiers that are submitted to ECHA. The work relating to these dossiers therefore requires considerable input from the Member States in the form of time, expertise and data acquisition. The task may require several person-years, even just to draw up a proposal for restrictions with a limited scope\(^\text{62}\). The more stringent requirements are partly the result of ECHA's comprehensive guidance, a desire for more background information from members of

\(^\text{62}\) The process for a competent authority submitting a restriction dossier is as follows: Risk Management Option (RMO) analysis $\rightarrow$ dossier production $\rightarrow$ submission to ECHA $\rightarrow$ ECHA's (RAC/SEAC) Conformity Check $\rightarrow$ supplements in conjunction with and after Conformity Check $\rightarrow$ ECHA (RAC/SEAC) processes $\rightarrow$ follow-up work $\rightarrow$ approval. The Swedish Chemicals Agency has drawn up a restriction dossier for lead in consumer products that have passed through the entire process and been approved. The total cost for this dossier was just over SEK 7 million, broken down as follows:

- RMO analysis: 19%
- Dossier production: 53%
- Supplementation after Conformity Check: 20%
- Public consultation: 3%
- Follow-up: 5%
ECHA's scientific committees, and the industry's efforts to reduce restrictions. ECHA's guidance does not set out any appropriate minimum level concerning information requirements. Instead, they point to many details, which collectively lead to a very high level of ambition. When restrictions dossiers are considered by ECHA's committees, additional, demanding and often poorly justified requirements are added. These requirements are not based on the regulatory framework, but are put forward by rapporteurs and individual committee members and involve considerable additional work for the Member State that prepared the dossier.

The main reasons behind the developments in the application of the restriction procedure described above is that the Commission has not been sufficiently clear about what minimum level applies as regards the background information they need to receive from Member States, the risk assessment committee (RAC) and the committee for socio-economic analysis (SEAC) in order to reach a decision. The Commission and ECHA have also not clarified the roles of RAC and SEAC sufficiently. The control that ECHA exerts over the committees, in the form of their chairmanship, is also insufficient.

**Difficult to obtain a factual basis for restriction proposals**

The hope was that REACH would result in better information concerning the health and environmental properties of chemical substances becoming available through the registration procedure. In the next stage, this information should form the basis for risk management measures such as authorisations and restrictions. In practice, however, it has become apparent that the information that is provided during the registration procedure is far too inadequate to provide a basis for a restriction proposal, for example. It is also difficult for individual Member States to prepare information concerning EU levels with regard to issues such as applications, quantities and alternatives, and the associated costs. Furthermore, the companies concerned have no incentive to contribute such information when the proposal for restrictions is drawn up. In addition to this, there is the requirement to carry out analyses of consequences, including socio-economic effects. In practice, this requirement is imposed on Member States and has been considerably tightened up.

**Interpretation of "unacceptable risk" counters a cautious approach to restrictions**

One of the main aims behind REACH is to provide a high level of protection for health and the environment. This is emphasised in Article 1 of the regulation and, for example, in recitals 1, 3, 7 and 9 in the preamble. In order to achieve this high level of protection, the precautionary principle must be applied. That the provisions in REACH are based on the precautionary principle is apparent from Article 1.3 of the regulation.

The way in which the application of the restriction provisions in REACH has developed is tending to reduce the scope to apply the precautionary principle in connection with restriction decisions. A fundamental factor behind this development is the view of what constitutes an "unacceptable risk". According to Article 68 of REACH, a substance must be restricted or prohibited if the substance's manufacture, use or placing on the market involves an

63 The precautionary principle has long been established within environmental and chemical policy. This means that if there is a threat of serious or irreversible damage to the environment, the absence of scientific proof may not be used as an excuse to delay cost-effective measures in order to prevent environmental impact. The precautionary principle has been introduced in rules of consideration in the Swedish Environmental Code (Chapter 2 Section 3), in the Treaty on the Functioning of the European Union (Article 191.2) and at a global level through the Rio Declaration on Environment and Development from the United Nation's Conference on Environment and Development in Rio de Janeiro in 1992 (Principle 15). As in EU law, in the Environmental Code, protection for human health is also included in the precautionary principle (Commission from the Commission on the precautionary principle (COM(2001) 1 final).
unacceptable risk to health or the environment. Yet REACH contains no definition of the specific term “unacceptable risk”. However, it is stated in Annex I of REACH that the risk can be deemed "adequately" (or "sufficiently well") controlled if the exposure does not exceed the maximum dose that is not considered to cause an effect. In practice, the Risk Assessment Committee applies the same reasoning when determining the need for restriction measures at EU level.

The interpretation which follows from ECHA’s guidance concerning risk assessment and which is applied in the restriction procedure is that an unacceptable risk is deemed to exist if the so-called "risk quotient" is greater than 1. This interpretation already existed before REACH. However, decisions were made which imposed broad restrictions on a particular substance, without it having been demonstrated that the risk quotient was greater than 1 for each use. The reason for this was that there was some scope for supplementary deliberations as regards what should be deemed an unacceptable risk, which is one way of applying the precautionary principle.

Through the restriction procedure in REACH, according to which a proposal must be approved by scientific committees, the scope for such deliberations appears to have been reduced or eliminated completely. The current interpretation of what constitutes an "unacceptable risk" makes it almost impossible to completely ban the use of a substance based on its intrinsic properties. This is because, once the uses that involve the greatest and most obvious risks have been restricted, it is virtually always possible to find a use where the risk quotient is below 1.

The current interpretation of "unacceptable risk" makes it difficult to adopt a preventive approach in the restriction procedure. This applies for example to the possibility of intervening as regards a problematic substance before its use becomes widespread or before new applications are developed which in the long term, or by the time they become sufficiently widespread, would result in an unacceptable risk. The difficulty of adopting a preventive approach and the precautionary principle mean that substances with very hazardous characteristics could be used without it being possible to act before the risk has become reality in the form of measurable damage to health and the environment. In addition, the interpretation makes it difficult or even impossible to limit the use of substances of very high concern in articles that are imported into the EU while it has not been demonstrated that a specific use is linked to an unacceptable risk. This also applies in cases where all use of the substance concerned within the EU has been phased out via the authorisation procedure. In addition to the deficient logic as regards chemical safety, this leads to competitive disadvantages for industry within the EU.

The interpretation of the meaning of unacceptable risk and the indirect effects that this has had as regards the application of the restriction procedure in REACH directly conflicts with the precautionary principle. A reasonable application of the precautionary principle in this context would be to impose a restriction, where appropriate, despite some scientific uncertainty as

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64 Annex I, General provisions for assessing substances and preparing chemical safety reports.
65 Whether the use of a substance is “adequately controlled” from an environmental perspective is determined in REACH by dividing the calculated concentration of the substance in the environment (“predicted environmental concentration”, PEC) by the highest concentration at which no toxic effects on living organisms are expected (“predicted no effect concentration”, PNEC). If the quotient of these values is <1, the use is considered to be adequately controlled. Similarly, the use is considered to be “adequately controlled” from a health perspective if the ratio between the measured exposure in a predicted exposure situation, i.e. an exposure scenario, and the exposure at which no toxic effect on humans is expected (“derived no effect level”, DNEL) is less than 1. The interpretation of the term “unacceptable risk” that is applied in connection with decisions concerning restrictions in REACH is that such a risk is deemed to exist if the risk quotients are >1.
regards whether or not the use of a substance is unacceptable. The current scheme concerning restrictions also hinders substitution. This is because the occurrence of lower risk and less economically feasible alternatives to the problematic use of a substance does not justify a restriction while no unacceptable risk has been demonstrated. See also section 2.1, under the heading Assessment of risk, controlled use and uncertainty in REACH.

It should be noted that the above reasoning applies to substances with a threshold for health or environmental effects, i.e. substances for which it is possible to determine a lowest level of exposure at which effects can arise. For substances without an effect threshold, the risk quotient cannot be calculated. The degree of precaution is determined for such substances in different ways instead\textsuperscript{66}. However, as regards these categories of substances, there is also a similar problem regarding the assessment of risk, adequately controlled use and application of the precautionary principle.

Problems and opportunities to restrict the use of chemicals in articles

The scope to effectively and reliably restrict the use of problematic substances in articles is hampered by the fact that the available information is generally deficient as regards which substances are present in articles. As a result, the public authorities that have the right to initiate a restriction are often unaware that such a restriction may be necessary.

As regards substances of very high concern, use in articles which are manufactured within the EU can be prohibited through the authorisation procedure. However, as authorisations only concern the incorporation of substances of very high concern in EU-produced articles, use in imported articles can continue until a restriction is also imposed.

Through Article 68.2 of REACH, the Commission can propose restrictions on substances that are carcinogenic, mutagenic and toxic to reproduction (CMR substances) in consumer products via a simplified procedure. With this procedure, the currently available background information (known as an "Annex XV dossier" or "restriction dossier") need not be prepared. In addition, no unacceptable risk needs to be demonstrated and ECHA's committees need not be involved in the process. However, an initial attempt to apply the simplified procedure in order to limit polycyclic aromatic hydrocarbons in consumer products met with stiff resistance from a number of stakeholders and thus became very time- and work-intensive.

As a result of the very time- and resource-intensive task of preparing a restriction proposal in accordance with the standard procedure, it would be preferable if the simplified procedure as a "shortcut" for the restriction of CMR substances in consumer products could be developed and used as often as possible. This would result in considerable streamlining of the restriction process.

The restriction of groups of substances needs to be developed

The restriction procedure has been formulated to restrict a well-defined substance based on comprehensive background information. In principle, the provisions also enable a group of structurally very closely related substances to be dealt with collectively, provided that a basis for a restriction dossier concerning such a group has been prepared.

It would often be desirable in the assessment of restrictions to be able to group substances according to principles other than structural similarity (see also section 4.1.7 There needs to

\textsuperscript{66} In the case of substances that are carcinogenic, mutagenic and toxic to reproduction (CMR substance) without a threshold, the degree of precaution is determined according to how the "derived minimal effect level" (DMEL) is calculated. In the case of persistent, bioaccumulative and toxic substances (PBT substances) and very persistent and very bioaccumulative substances (vPvB substances), the degree of precaution is instead determined according to what is considered sufficient as regards the minimising of exposure.
be more scope to assess and test groups of substances). The grouping could concern different types of substances which are used in consumer goods, such as textiles, and which result in considerable exposure. However, there is nothing in the current restriction rules to facilitate such an approach.

In order to streamline the restriction process and achieve the sought-after high level of protection for health and the environment within a reasonable period of time, it is clear that the REACH provisions must be developed, e.g. as regards the scope to group substances. Alongside REACH, product-specific provisions (often called "product directives") need to be developed, as these offer an opportunity to collectively regulate many different substances which are used in a particular product group.

**Objectives concerning restrictions**

In the short term, the objectives for the development of the restriction process in REACH and its application are as follows:

- The restriction process has become considerably less work-intensive than it is at present, partly through the fact that the requirements for a restriction dossier have been clarified and are significantly lower than those imposed under present practice and partly through keeping the requirements for supplementation in connection with processing by ECHA’s committees at a reasonable level.
- The clarification and simplification of the restriction process particularly applies to the processing of restriction dossiers for substances of very high concern.
- The assessment of when the restriction of a substance is needed at EU level (i.e. when an "unacceptable risk" exists) is based on a broader assessment than is currently the case. This could for example involve the application of an additional safety factor in order to take account of the need for different types of additional precautionary measures, where necessary.
- The simplified procedure for the restriction of CMR substances in consumer articles (Article 68.2) is widely used.
- The knowledge available concerning substances of very high concern that are used in articles imported into the EU has improved.
- The restriction process considerably helps to promote the work of companies relating to substitution. This takes place through restriction decisions and indirectly through the fact that companies are aware that problematic substances and uses could be limited in the future.

The long-term objectives for the development of the restriction process in REACH and its application are as follows:

- The REACH Regulation and associated annexes have been revised so that the precautionary principle is applied more frequently than is currently the case in connection with the assessment of the need to restrict substances at EU level, particularly as regards substances of very high concern.
- The scope of the simplified procedure for restrictions in Article 68.2 has been expanded to include the restriction of substances of very high concern other than CMR substances and is frequently used for this purpose.
- In respect of many article groups with widespread consumer use, there is scope to regulate relevant hazardous substances via special product-specific legislation (product directives). This applies to textiles, among other things.
Prioritisation and need for political initiatives

Considerable streamlining of the restriction process and a broader interpretation of the term 'unacceptable risk' are key measures and are necessary in order to ensure that the restriction process promotes substitution to a greater extent. It should be possible to promote the short-term measures via existing fora such as the Commission's expert group for competent authorities for REACH and CLP (CARACAL), ECHA's Management Board, RAC and SEAC, and through direct communication with the Commission, ECHA and the Member States. In particular, political initiatives are needed in order to expand the scope of Article 68.2. Political initiatives are also needed to initiate the work relating to the product directives, which supplement REACH and enables the simultaneous regulation of a large number of important substances which are used in a particular product group.

Proposed measures concerning restrictions

Short-term measures

The restriction process needs to be streamlined and simplified so that it contributes to the phasing out of hazardous substances and thereby also to the high level of protection afforded to health and the environment, which is one of the main aims of REACH. In order to achieve this, initiatives are needed at both political and technical level. Sweden should therefore take the following measures:

- At their respective levels, the Swedish Government and the Swedish Chemicals Agency should make use of their contacts with EU institutions and authorities to emphasise the importance of a streamlined and simplified restriction procedure. Unlike the currently prevailing practice, the restriction procedure should be developed to provide a high level of protection and be based on the precautionary and substitution principles.

- The Swedish Chemicals Agency should strive to ensure that the Commission and ECHA take the initiative to clarify the requirements that should be imposed on the background information for Commission decisions concerning restrictions (known as 'restriction dossiers' or 'Annex XV dossiers', which are prepared by Member States and ECHA). The initiatives should result in new guidance concerning restrictions from ECHA, which make it clear that the requirement for a restriction dossier should be lower and require a more reasonable workload than is currently the practice.

- The Swedish Chemicals Agency should strive to ensure that the precautionary principle is applied in connection with decisions concerning restrictions to a greater extent. This should partly take place through a broader assessment in order to determine whether an "unacceptable risk" exists, and therefore whether restriction measures are needed at EU level. Further analysis of how this change could be brought about is needed.
The Swedish Chemicals Agency should strive to ensure that the Commission establishes a working method which means that the simplified restriction procedure in accordance with Article 68.2 can be used as a shortcut for restrictions concerning CMR substances in consumer articles. This could be a major factor in reducing the use of resources compared with what is needed to prepare a restrictions dossier. It may also increase the scope to also bring about restrictions in cases where "unacceptable risk" cannot be demonstrated. Furthermore, CMR substances that are subject to phasing out via authorisation assessment (Annex XIV of REACH) should also automatically be assessed under Article 68.2.

Long-term measures
In the longer term, the restriction procedure should also be developed through measures which require amendments to the articles in REACH, which will require consideration by the Council. Sweden should take the following measures:

- The Swedish Government and the Swedish Chemicals Agency should strive to ensure that the articles and associated annexes in REACH are revised to increase the scope for applying the precautionary principle in the event of an assessment as to whether risk exists which justifies restriction measures at EU level. In the case of substances of very high concern, the level of protection should correspond to that which applies in the authorisation process, i.e. it should be possible to ban the use of substances without a threshold for effect on the environment and health if suitable alternatives exist and the benefits of using the substance do not outweigh the associated risks.
- Where possible, the Swedish Chemicals Agency should promote changes to relevant guidance and policy documents, which will lead to a broadening of the interpretation of "unacceptable risk", particularly as regards the assessment of substances of very high concern.
- The Swedish Government and the Swedish Chemicals Agency should strive to ensure that the application of the alternative restriction procedure in accordance with Article 68.2 is expanded from CMR substances to cover all substances of very high concern in chemical products and articles intended for consumer use.
- The Swedish Government and the Swedish Chemicals Agency should strive to ensure that the use of all relevant hazardous substances and substances of very high concern in certain product groups are regulated. This applies for example to product groups which are widely used by consumers and those which otherwise result in considerable exposure. This will require regulation via other provisions, as a supplement to REACH. This could for example be achieved through product-specific regulations. Consideration should be given to which substances are relevant in this context, partly on the basis of criteria for classification and for substances of very high concern.

Need for further analyses
Further analysis will be necessary to determine how the restriction process can be streamlined and how the application of the precautionary principle in restriction decisions can be made stricter.

How the proposals help to ensure achievement of the Swedish milestone targets concerning dangerous substances
(A description of the Swedish environmental target A Non-Toxic Environment and the milestone targets is given in Chapter 5)
The milestone target concerning particularly dangerous substances means that a decision must be taken within the EU which means that by 2018 substances of very high concern must be subject to assessment or a decision concerning phasing-out under applicable regulations within all applications, and only used in manufacturing processes under strictly regulated circumstances.

*Comments:* The proposed measures concerning the restriction of hazardous substances provide a better basis for the prevention and minimisation of chemical risks, and therefore contribute to attainment of the Swedish milestone target and the Swedish environmental target *A Non-Toxic Environment* in a fundamental way.

### 4.5 Enforcement

This section gives a general presentation of the enforcement process with proposals which can help to make the application of REACH more effective.

**Enforcement of the REACH Regulation**

REACH is enforced at different levels by various authorities in Sweden and elsewhere in the EU. The enforcement process concerning chemical and product rules is national, and decisions concerning supervisory requirements and sanctions are taken at national level.

Inspections relating to REACH in Sweden are carried out pursuant to the Environmental Code, which also sets out the consequences.

The Swedish Chemicals Agency's enforcement concerns primary suppliers which place products on the Swedish market as the first link in the chain. These are companies which manufacture or import chemical products, articles containing chemicals or pesticides into Sweden. Central authorities, including the Swedish Environmental Protection Agency and the Swedish Work Environment Authority, also carry out enforcement relating to REACH.

Municipal authorities and county councils have enforcement responsibility for the handling of chemicals by enterprises, e.g. professional users and environmentally hazardous activity. Municipal authorities also have enforcement authority as regards chemical products, pesticides and products in the retail sector.

**Registration requirements**

The European Chemicals Agency (ECHA) checks registrations against the underlying information requirements in REACH and requests additional information in cases where the requirements are not met.

The content and quality of the registrations are key to ensuring that the regulations and subsequent processes in REACH function as intended. In the first instance, responsibility for registering substances lies with the substance manufacturers, but companies that use chemicals also have a responsibility to inform registering companies of their usage of the substances (see section 4.1.1). If a company fails to fulfil its obligations despite approaches from ECHA, ECHA can contact the supervisory authorities in the Member States. The Swedish Chemicals Agency can then apply provisions in the Environmental Code to require information to be provided.

The Swedish Chemicals Agency should work with ECHA to determine how national authorities can best contribute to the measures and activities that ECHA is planning in order to improve the quality of registrations.
Collaboration between the EU enforcement authorities leads to more effective enforcement

The REACH Regulation states that EU Member States must work together with regard to the enforcement of REACH by participating in the Reach Forum67, which is an ECHA committee. However, the enforcement collaboration does not affect the right of Member States to make decisions concerning, for example, enforcement requirements or sanctions.

The Reach Forum is responsible for drawing up strategies for enforcement, developing enforcement methodology, coordinating and evaluating joint EU enforcement projects and developing a training programme for inspectors. The Reach Forum has developed a fundamental strategy for the REACH enforcement. However, it is not a binding forum, as decisions concerning enforcement are taken at national level.

Another important task for the Reach Forum is to examine and comment on restriction proposals from an enforcement perspective. The Forum also administers an IT system via which the Member State's enforcement authorities can exchange and obtain information.

The enforcement of REACH with regard to provisions concerning chemical substances varies between the Member States as regards both direction and available resources. The joint EU enforcement projects are important for bringing about a more uniform enforcement of REACH within the EU in the longer term and counteracting the distortion of competition between companies.

Within the Reach Forum, the Swedish Chemicals Agency should work to ensure that the enforcement carried out by Member States is reinforced with regard to both scope and quality, as regards the quality of chemical safety reports, including exposure scenarios, the dissemination of information in the supply chain and compliance with prescribed safety measures.

Certain provisions in REACH provide scope for interpretation

Clear provisions form an important basis for a system which results in legal certainty and effective enforcement. Clear provisions also make it easier for the enforcement authorities to interpret the provisions and impose similar requirements on the same breaches.

Companies that register a substance must present different handling instructions and safety measures, based on information concerning the properties and uses of the substance. These exposure scenarios must be followed to ensure that human health or the environment are not harmed. The provisions regarding exposure scenarios in REACH are not entirely clear. Experience gained through a national enforcement project indicates that there is scope for varying interpretations and that a number of often complex models and other tools are used to fulfil the requirements in REACH. ECHA is working with other stakeholders according to an action plan 68 with specific measures to develop and improve the work relating to exposure scenarios and the way in which they are used for communication in the supplier chain.

Enforcement of chemical substances in articles

The REACH provisions are primarily aimed at substances and mixtures of substances, but there are also provisions that apply to substances in articles. The provisions in REACH concerning substances in articles primarily apply to the restricted use of the substances in different

67 Reach Article 76f and Article 77:4.
articles (in accordance with Annex XVII) and the information and notification obligations that exist as regards the Candidate List (Articles 7 and 33).

The provisions in Articles 7 and 33, concerning the obligation to inform and give notice of substances that are included in the Candidate List when they occur in articles, are unclear in important respects (see 4.2.2 Information on substances of very high concern in articles).

REACH restriction provisions (Annex XVII) concerning the restricted use of substances largely concern the use of substances in articles. Many of the provisions contain uncertainties which complicate the enforcement process. Many articles on the EU market are produced outside the EU. Supply chains are long and complex, often involving a number of producers of the parts that make up the finished article. Many articles are seasonal and have a short life-cycle. Checking the concentration of specific substances in an article requires chemical analyses to be carried out. This makes it more resource-intensive to carry out checks on hazardous substances in finished articles compared with the same process at earlier production stages.

A survey conducted by the European Commission\textsuperscript{69} shows that most Member States carry out enforcement of the restrictions in Annex XVII (these also apply to substances and mixtures of substances). A questionnaire conducted by ECHA shows that Member States have generally not prioritised provisions concerning articles in the enforcement of REACH. The reasons put forward include insufficient resources and the prioritisation of other aspects of REACH in the enforcement process, but a lack of clarity of certain provisions is also indicated. Within the Reach Forum, the supervision of article provisions is also not given a high priority in joint enforcement projects, for example. However, it is also clear from notifications in Rapex\textsuperscript{70} that checks are carried out on articles with respect to the restrictions in REACH. One possible explanation for this is that authorities other than those represented in the Reach Forum carry out these checks.

Legislation other than REACH also imposes requirements as regards concentrations in articles. The Restriction of Hazardous Substances in Electrical and Electronic Equipment Directive (RoHS)\textsuperscript{71}, the Toy Safety Directive\textsuperscript{72}, the Persistent Organic Pollutants (POPs) Regulation\textsuperscript{73} and the Packaging Directive\textsuperscript{74} contain provisions concerning substances which must not occur in articles. In Sweden, responsibility for the enforcement of these provisions rests with the Swedish Chemicals Agency, but in other Member States the responsibility can rest with authorities other than those responsible for enforcing the provisions in REACH.

To ensure in a resource-efficient manner that articles placed on the EU market do not contain prohibited substances and that companies fulfil the information obligations in REACH, these requirements must be widely known and be imposed as early as the production stage. This can be achieved through the more coordinated and effective enforcement of articles at EU level. Coordination must be enhanced both between Member States and between the various pieces of legislation. The European Commission has put forward a proposal for a new Market

\textsuperscript{69} Implementation and Enforcement of Restrictions under Title VIII and Annex XVII to REACH in the Member States; Milieu Ltd submitted to the European Commission DG Enterprise and Industry, 7 March 2012.

\textsuperscript{70} The EU warning system for hazardous products.


Surveillance Regulation, as part of the so-called Product Safety Package\textsuperscript{75}. The proposal includes the establishment of a forum for market surveillance. It is intended that such a forum will bring about more effective supervision and better coordination in the supervision of articles, both between Member States and between different legislation. Experience gained through the general archiving and information exchange system which market surveillance authorities must use under the current Market Surveillance Regulation and elsewhere\textsuperscript{76} shows however that initiatives are required among national enforcement authorities in order to make common EU forms of working and tools both objective- and resource-efficient.

There are also other voluntary collaborative forums concerning supervision within the EU (in some cases, non-EU/EEA countries are also members of these forums), e.g. the Chemicals Legislation European Enforcement Network (Cleen) and the Product Safety Enforcement Forum of Europe (ProSafe). Within some EU legislation, such as the Restriction of Hazardous Substances in Electrical and Electronic Equipment Directive (RoHS)\textsuperscript{77}, there are voluntary collaboration groups within which Member States discuss enforcement issues, among other things.

**Prioritisation and need for political initiatives**

In some cases, uncertainties in the provisions can be rectified within the framework relating to guidance, questions and answers and information, and within the Reach Forum. The provisions concerning the information obligation as regards substances of very high concern in articles in REACH need to be clarified, as described in section 4.2.2 Information on substances of very high concern in articles.

As regards enforcement of the provisions concerning exposure scenarios, we believe that, in the first instance, guidance and practice need to be developed within existing structures and that specific political initiatives relating to this issue are not currently a high priority. The Swedish Chemicals Agency should work with ECHA to determine how national authorities can best contribute to the measures and activities that ECHA is planning in order to improve the quality of registrations. Among other things, this could involve participating in workshops and other activities organised by ECHA in order to discuss the orientation and formulation of the authority's work relating to the review of registrations.

Greater coordination as regards the enforcement of articles should take place within the framework of the work concerning the new Market Surveillance Regulation and through development of the work within the Reach Forum in particular. Other measures which are needed within the supervisory process can be handled through the Reach Forum and other ongoing work. Other than this, we do not believe that specific political initiatives are necessary.

\textsuperscript{75} Faktapromemoria 2012/13:FPM74, förordning om marknadskontroll av produkter.
Proposed measures concerning enforcement

- The Swedish Chemicals Agency should strive to ensure that suitable forms of follow-up concerning compliance with authorisation conditions are developed. For example, some form of systematic reporting from the process to verify compliance with authorisation conditions could be developed to enable the Commission to revoke or review authorisations in cases where the conditions are not met. (4.3.1)
- The Swedish Chemicals Agency should continue to work within the Reach Forum to develop a common view of the enforcement process concerning REACH and to increase the level of activity within the Forum as regards article enforcement.
5 The task's background and link to the environmental objective system

5.1.1 Background to the task

In the Government Bill relating to chemicals, *På väg mot en giftfri vardag - plattform för kemikaliepolitiken* (On the Way to a Non-Toxic Everyday Life), the Government presents an integrated strategy for achieving the Swedish environmental quality objective *A Non-Toxic Environment*. The strategy consists of the milestone targets concerning hazardous substances which the Government previously established along with initiatives aimed at reducing exposure to hazardous substances with regard to people and the environment, as described in the Government Bill. The basis for the strategy included the environmental objective committee's report and the approved milestone targets, as well as a proposal for measures under various areas in the action plan for a Non-Toxic everyday life, which the Swedish Chemicals Agency presented to the Government in an interim report in January 2013. The basis also included the Swedish Chemicals Agency's report entitled *Bättre EU-regler för en giftfri miljö* (Improved EU rules for a Non-Toxic Environment), which contains a general analysis of deficiencies and development needs in the EU work and other international work within the field of chemicals, with proposals for the way in which EU and other international provisions can be developed and improved.

The Swedish Government tasked the Swedish Chemicals Agency with preparing a detailed analysis, and a proposal for an action plan for Sweden's work to develop the REACH Regulation forms part of the strategy. The action plan is the next step in the further specification of the initiatives, instruments and measures that are needed in order to contribute to attainment of the applicable milestone targets and the environmental quality objective.

5.1.2 The environmental objective system

In 1999, the Swedish Parliament adopted 15 national environmental quality objectives in order to establish a clear structure for the environmental work, which has since been developed into an environmental objective system with various secondary objectives under the primary environmental quality objectives. In 2002, the Swedish Government established an Environmental Objective Council, which was responsible for follow-up, assessment and reporting to the Government with regard to attainment of the environmental quality objectives.

In 2010, the Swedish Government and Parliament approved certain changes to the system of environmental objectives. Secondary objectives were abolished, and specifications concerning the primary environmental quality objectives were given a central role instead. The Environmental Objective Council was abolished and responsibility for coordinating follow-up and evaluation was delegated to the Swedish Environmental Protection Agency. A new parliamentary committee, the Environmental Objectives Committee, was established with the aim of developing proposals for environmental strategies with milestone targets and measures within areas that were prioritised by the Government. Among other things, a revised basis was introduced for assessing the environmental quality objectives, which takes account of the

78 Regeringens proposition 2013/14:39.
80 Swedish Chemicals Agency report 1/12, En redovisning av ett regeringsuppdrag som Kemikalieinspektionen genomförde i samråd med åtta andra centrala myndigheter.
natural recovery period and the fact that the effects of environmental measures can be delayed. In connection with follow-up, an assessment was then made as to whether the desired environmental quality was being achieved and whether the preconditions were in place in order to achieve the objectives. A Swedish environmental quality objective should thus be assessed as being attainable either if the state of the environment expressed by the objective and its specifications can be achieved, or if adequate measures at both national and international level have been approved and are expected to be implemented within a generation after the establishment of the environmental objective system, which is scheduled to take place in 2020.

The structure of Swedish environmental objectives has been developed and now has three levels: a generational goal, 16 environmental quality objectives and associated specifications and milestone targets, one of which is A Non-Toxic Environment, and milestone targets for a number of areas.

- The generational goal defines the direction of the changes in society that need to occur within one generation if the country’s environmental quality objectives are to be achieved.
- The environmental quality objectives describe the state of the Swedish environment which environmental action is to result in.
- The milestone targets define steps on the way to achieving the environmental quality objectives and the generational goal.

The objectives in the system provide a long-term signal to all actors in society as regards what the Swedish Government and Parliament wish to achieve through environmental policy and integration into other policy areas.

### 5.1.3 The generational goal and its practical implications

The revised environmental objectives structure includes a generational goal, which indicates the sorts of changes that need to occur at every level of society within one generation to bring about a clean, healthy environment. Together with its seven indents, the generational goal is worded as follows: The overall goal of Swedish environmental policy is to hand over to the next generation a society in which the major environmental problems in Sweden have been solved, without increasing environmental and health problems outside Sweden’s borders. This calls for an ambitious environmental policy – in Sweden, within the EU and in international contexts.

The generational goal means that the basic conditions for solving the environmental problems we face are to be achieved within one generation, and that environmental policy should be directed towards ensuring that:

- Ecosystems have recovered, or are on the way to recovery, and their long-term capacity to generate ecosystem services is assured.
- Biodiversity and the natural and cultural environment are conserved, promoted and used sustainably.
- Human health is subject to a minimum of adverse impacts from factors in the environment, at the same time as the positive impact of the environment on human health is promoted.
- Materials cycles are resource-efficient and as far as possible free from dangerous substances.
Natural resources are managed sustainably.
The share of renewable energy increases and use of energy is efficient, with minimal impact on the environment.
Patterns of consumption of goods and services cause the least possible problems for the environment and human health.

5.1.4 The Swedish environmental quality objective "A Non-Toxic Environment" and associated specifications

The environmental quality objectives that have been adopted by the Swedish Parliament form the basis for Swedish environmental policy. Of the 16 environmental quality objectives, it is A Non-Toxic Environment which in the first instance considers the objectives of chemical policy and therefore forms a cornerstone for Swedish chemicals policy and the stances that Sweden has adopted both within the EU and internationally. However, other environmental quality objectives, such as Good Built Environment, A Varied Agricultural Landscape, Clean Air, Good-Quality Groundwater and A Balanced Marine Environment, Flourishing Coastal areas and Archipelagos also encompass chemicals issues.

The environmental quality objectives describe the state of the Swedish environment that environmental action is to result in. The specifications clarify the implications of the objectives and are used in the follow-up work. A Swedish environmental quality objective can be deemed to be attainable if the state expressed by the objective and its specifications can be achieved, or if adequate measures, both nationally and internationally, have been adopted and are expected to be implemented within a generation.

The Swedish environmental quality objective A Non-Toxic environment is worded in accordance with the Swedish Parliament's resolution:

The occurrence of man-made or extracted substances in the environment must not represent a threat to human health or biological diversity. Concentrations of non-naturally occurring substances will be close to zero and their impacts on human health and on ecosystems will be negligible. Concentrations of naturally occurring substances will be close to background levels.

According to the Government's resolution, the environmental quality objective A Non-Toxic Environment is specified to mean that the aim is to ensure that:

- Total exposure to chemical substances via all sources of exposure is not harmful to people or biodiversity.
- As far as possible, particularly dangerous substances are no longer used.
- There is very little spread of unintentionally produced substances with hazardous properties, and information is available concerning the formation, sources, emissions and spread of the most significant of these substances and their degradation products.
- Contaminated areas have been sufficiently remediated so that they do not represent a threat to human health.
- Knowledge about the environmental and health properties of chemical substances is available and sufficient for the purposes of risk assessment.
- Information is available about substances hazardous to the environment and health that are present in materials, chemical products and articles.
5.1.5 Milestone targets for dangerous substances

The milestone targets in the new environmental objective structure set out the way forward for facilitating attainment of the generational objective and one or more environmental quality objectives. Milestone targets can be established by the Government and the Environmental Objective Committee has a general assignment to draw up proposals for strategies encompassing milestone targets, instruments and measures within the areas that have been prioritised by the Government. The milestone targets are intended to show what Sweden can achieve and explains where initiatives should be carried out in order to bring about the societal changes that are necessary. The milestone targets do not set out the desired state of the environment, as this is done in the environmental quality objectives and associated specifications.

In the report entitled Etappmål i miljömålssystemet81 (Milestone targets in the environmental objective system), the Environmental Objectives Committee presented milestone targets and proposals which also included the first milestone targets within the fields of air pollution, hazardous substances, waste and biodiversity. In April 2012, the Government adopted the specifications and the first milestone targets in the environmental objective system82. Three of these milestone targets concern hazardous substances and belong under the Swedish environmental quality objective A Non-Toxic environment. Additional milestone targets within the field of hazardous substances were proposed by the Environmental Objectives Committee in a report dated June 201283. This report also presented the first proposal for a strategy for the Government's priority area "Sweden's work within the EU and internationally for a Non-Toxic environment". Four new milestone targets concerning hazardous substances were then adopted by the Government in June 201384, with a further target being adopted in October 201385. There are now eight milestone targets relating to hazardous substances.

**Milestone targets for dangerous substances**

The milestone target concerning particularly dangerous substances means that decisions taken within the European Union and internationally on such substances are to include measures which mean that

- By 2015, endocrine disruptors and highly allergenic substances are considered particularly dangerous substances in relevant regulations.
- By 2018, particularly dangerous substances are subject to examination or phase-out decisions under current regulations in all areas of use.
- By 2018, particularly dangerous substances in production processes are only used under strictly regulated circumstances.
- By 2018, the expression ‘particularly dangerous substances’ in relevant regulations also includes substances with serious properties other than those included in the current specific criteria and which give rise to an equivalent level of concern.

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81 SOU 2011:34  
82 dnr M2012/1171/Ma and Ds 2012:23 Svenska miljömål – preciseringar av miljökvalitetsmålen och en första uppsättning etappmål.  
83 SOU 2012:38 Minska riskerna med farliga ämnen! Strategi för Sveriges arbete för en giftfri miljö.  
84 dnr M2013/1740/Ke.  
85 dnr M2013/2682/Ke.
The milestone target concerning knowledge of the health and environmental properties of substances means that decisions taken within the European Union and internationally will require that information on properties of chemicals that are hazardous to the environment and human health is to be available and sufficient for the purposes of risk assessment for all areas of use. Decisions are to include measures which mean that:

- By 2015, relevant regulations require knowledge and information on the presence of nanoparticles and nanomaterials that are sufficient to assess and minimise their impact on health and the environment.
- By 2015, it is possible for relevant regulations to take account of combination effects of exposure to chemicals.
- By 2015, regulations take account of the fact that children are particularly sensitive to the effects of chemicals.
- By 2018, the information requirements for registration under REACH regarding substances that are manufactured or imported in smaller quantities (less than 10 tonnes per manufacturer or importer annually) are enhanced.

The milestone target regarding information about dangerous substances in articles means that:

- Regulations or agreements within the European Union or internationally are to be applied in such a way that information about substances hazardous to health and the environment that are present in articles is available to all parties concerned by 2020.
- The regulations are to be introduced gradually for different product groups, and children’s health is to be given particular focus in the information.
- Information about substances hazardous to health and the environment that are present in materials and articles is to be made available throughout the entire product life cycle through harmonised systems that cover prioritised product groups.

The milestone target concerning the development and application of the EU chemical rules REACH and other relevant EU legislations are to be applied by 2020 at the latest or revised if necessary so that:

- It will to a greater extent become possible to assess and test groups of substances with similar intrinsic properties, chemical structures or areas of use.
- The substitution principle and its application is strengthened in connection with restrictions, consideration of permits and other relevant elements of the regulatory framework.

The milestone target concerning the more effective enforcement of chemicals within the European Union is that decisions are made within the EU by 2018 at the latest that strengthen and streamline enforcement in the Member States and develop supervisory cooperation within the Union regarding rules for chemicals, including dangerous substances in goods and waste.
The milestone target concerning Non-Toxic and resource-efficient ecocycles is that safe use of recycled material from a health and environmental perspective through, as far as possible, avoiding the recirculation of dangerous substances while resource-efficient ecocycles are sought. This is to be achieved through an overall action strategy within the EU, which, by 2018 at the latest, is to result in a number of measures, including:

- The finalisation and coordination of EU regulations on waste, chemicals and goods so that they steer towards non-toxic and resource-efficient ecocycles.
- The establishment of the principle of high and uniform requirements on the content of dangerous substances in newly produced and recycled materials, through a decision where appropriate.

The milestone target to reducing children’s exposure to dangerous chemicals means that decisions are made by 2018 at the latest concerning existing and, if necessary, new regulations and other policy levers which will bring about a significant reduction in the health risks to children as a result of overall exposure to chemicals. The risk reduction is to be assessed in comparison with the situation in 2012.

The milestone target concerning greater environmental consideration in EU pharmaceuticals legislation and internationally is that decisions are made within the EU or internationally by 2020 at the latest that involve existing and any new regulations for medicinal products for human or veterinary use taking greater environmental consideration.
6 Impact assessment

This report presents an account of the Swedish Chemicals Agency's assignment by the Swedish Government in the appropriation directions for 2013. The assignment was to prepare a detailed analysis and a proposal for an action plan for the development and application of REACH. The assignment does not include the preparation of a proposal for a statute and the Government also makes no reference to impact assessments. Despite this, the Swedish Chemicals Agency has decided to carry out an overall qualitative assessment of the possible consequences of the proposed measures.

The report contains proposed measures at a general level, partly as regards the application and streamlining of existing legislation and partly as regards proposals as to how REACH can be developed in the longer term. Most proposals indicate that Sweden should pursue an issue within the EU. This is normally a protracted process and the end result may turn out to be different from what was originally intended when the process was initiated. It is only later in the process, when the proposed measures have become more concrete, that it becomes meaningful to carry out an impact assessment. Within the EU, there is a general requirement for the Commission to carry out impact assessments before reaching a decision.

Some of the proposals in this report mean that an issue must be given further consideration. In such cases, it is a general requirement that an impact assessment must be carried out in the impending study.86

To some extent, the proposed measures in the report coincide with both the Swedish Chemicals Agency's Action plan for a Non-Toxic everyday life - proposed measures, which also contains a general effect and impact assessment and the Government's Chemicals Bill.88 The Government Bill includes a section concerning the impact assessment of the initiatives and measures to achieve the milestone target concerning hazardous substances.

Proposed measures concerning the application and streamlining of REACH

At a general level, the proposed measures concerning the application of REACH are intended to streamline the implementation of the existing legislation. The proposals therefore concern the requirement to comply with existing legislation. This will not involve any amendment to the legislative text or requirements, or to the distribution of responsibility between the public sector (the State) and industry (manufacturers of substances and their customers). The proposed measures concerning application and streamlining in the report are therefore covered by the impact analyses carried out by the European Commission, Member States and industry organisations ahead of the decision to implement REACH. The effects of introducing the REACH Regulation have been subject to an impact assessment in a number of previous reports.

A number of studies concerning the impacts of REACH are available via the Commission's website.89 These concern effects on both companies and health and the environment. A report that was prepared in 2004 during the consideration of the REACH proposal by the Council, on the initiative of the Dutch presidency, also contains a list of 36 impact studies conducted by

87 Handlingsplan för en giftfri vardag – förslag till åtgärder 20120612.
Member States, industry and non-governmental organisations. In the same year, following a Swedish initiative, the Nordic Council of Ministers carried out a study of the costs associated with REACH.

**Proposed measures concerning the development of REACH**

This report largely consists of proposed measures aimed at bringing about changes in provisions and their application at EU level. The proposals represent a gross list of possible initiatives for enhancing REACH and range from changes to working methods and priorities in connection with the application of the regulation to amendments in annexes, guidelines and articles. The degree of concretisation of the proposals varies, but further studies and knowledge acquisition will generally be required in order to formulate priority measures at a more detailed level. These initiatives will need to be carried out both within ECHA and the Commission and at national level. The report contains no proposal for a statute or detailed proposals concerning amendments to guideline documents, etc.

**Contribution of the proposed measures to attainment of Swedish milestone targets**

The aim of this task is to contribute to the attainment of a Non-Toxic Environment and thereby also to attainment of the national milestone targets concerning hazardous substances. In each section of proposed measures in the report, we refer to the milestone target or targets where we believe the measures will result in a marked contribution.

Initiatives for attaining the milestone targets have previously been subject to an impact assessment at a general level in other contexts, i.e. in the Government's Chemicals Bill and in the Environmental Objectives Committee's report to reduce the risks associated with hazardous substances, dating from 2012.

**General assessment of effects on health and the environment**

The primary socio-economic benefits of well-developed chemicals control are associated with reduced damage to human health and the environment. Many studies have been carried out concerning the social costs and potential gains associated with reduced mortality and lower care costs relating to chemicals. Some of these also include economic assessments. Examples of health effects and therefore costs to society associated with the non-sustainable use of chemicals include impaired learning ability and fertility among the population, increased frequency of allergies, fractures and brittle bone disease, as well as other effects on public health which lead to an increase in the need for medical care.

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92 SOU 2012:38 Minska riskerna med farliga ämnen! Strategi för Sveriges arbete för en giftfri miljö.
Examples of the environmental impact of chemical usage include loss of biological diversity and damage to natural resources, such as surface water and groundwater, agricultural land and fish stocks.

In the long term, better chemicals controls will reduce the costs to society for the remediation of polluted areas and other measures for restoration. Insofar as provisions and other measures, e.g. at EU level, also impact on production conditions and the use of hazardous substances in articles in countries outside the EU, it is believed that this will help to further reduce health problems relating to the use of chemicals.

**General assessment of effects for industry**

The Swedish Chemicals Agency believes that the proposals in the report will help to strengthen Swedish industry by clarifying requirements which already exist in the EU's chemicals legislation or areas where further development can be anticipated over the next few years. Clear requirements from society as regards the application and development of the legislation at EU level provide a level playing field for companies throughout the Community. Innovation and development can also be promoted. This gives incentives to develop new products, services and manufacturing processes.

New knowledge within areas in which there are currently no provisions or clear criteria (endocrine disruptors, combination effects and nanomaterials) forms the basis for the objective and scientific handling of regulatory development. The stance and decisions taken by authorities and other players in connection with the prioritisation and implementation of risk management measures will be facilitated.

The Swedish Chemicals Agency has adopted the view that the objective to phase out hazardous substances from the everyday lives of people also encompasses industry. The Swedish Chemicals Agency believes that greater and more effective enforcement of hazardous substances in articles in Sweden and the EU will support industry and lead to fairer conditions in the common market.

In the short term, industry needs to carry out initiatives to comply with the requirements set out in existing provisions, prepare and disseminate information concerning hazardous substances in articles, and voluntarily mitigate identified risks by phasing out hazardous substances from production processes and articles. Industry also needs to work with public authorities to further develop measures to achieve a Non-Toxic everyday life for consumers.

**General assessment of the consequences for public authorities**

In order to achieve the milestone targets, further studies will generally be required by the relevant public authorities in order to analyse and formulate proposals for measures in more detail. The Swedish Chemicals Agency, in particular, will be affected by this, but other public authorities will also be affected. The authorities will need to communicate more with the EU institutions and other Member States in order to discuss and seek support for proposals concerning, for example, new or enhanced EU provisions. Communication concerning these

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101 Interim Evaluation: Impact of the REACH Regulation on the innovativeness of the EU chemicals industry, 14 June, 2012.
issues will also be necessary between public authorities and the research community, individual organisations, industry bodies and companies.

**Initiatives to achieve the milestone targets concerning hazardous substances**

The milestone targets concerning hazardous substances are aimed at bringing about changes at EU or international level, as future provisions and agreements are largely negotiated at such levels. In most cases, it is more cost-effective to devote resources to achieving and maintaining good chemicals controls among manufacturers and importers, i.e. good awareness and correct handling early in the chemical use chain, rather than allocating resources to clean-up measures at a later stage.

Proposed measures in the report which it is believed will specifically contribute to attainment of the milestone targets can primarily be found in the following sections:

Endocrine disruptors (4.1.3)

Information on substances of very high concern in articles (4.2.2).

**Initiatives to attain the milestone target concerning the health and environmental properties of substances**

Knowledge concerning the properties of chemical substances is vital in order for it to be possible to establish measures to reduce the risks associated with such substances. Data from registrations in REACH concerning the properties of substances form the basis for the other REACH processes. The measures are therefore aimed at tightening the requirements concerning the knowledge that companies must have concerning substances in REACH.

Initiatives from the research community in Sweden and the EU are also needed in order to develop more effective test methods which do not involve the use of animal experiments, and in order to develop criteria for areas such as endocrine disruptors, nanomaterials and combination effects.

Proposed measures in the report which it is believed will specifically contribute to attainment of the milestone targets can be found in the following sections:

Nanomaterials (4.1.4)

Information requirements 1-10 tonnes (4.1.5)

Combination effects (4.1.8)

Quality of registrations (4.1.1)

Availability and adaptation of information (4.1.2)

**Initiatives to attain the milestone target concerning the development and application of the EU chemicals provisions**

In a long-term perspective, enhancement of the EU chemicals provisions and the application thereof in accordance with the milestone target is considered to be one of the most effective initiatives for raising the level of protection for human health and the environment as regards chemicals. As the EU provisions relating to chemicals are highly harmonised, they create equal competitive conditions for companies across Member States. Through the development of provisions concerning chemicals in articles and the harmonised application of such provisions, more equal competitive conditions are also created between producers of articles within the EU and producers in third countries whose articles are imported into the EU.

Proposed measures in the report which it is believed will specifically contribute to attainment of the milestone targets can be found in the following sections:

Group assessment (4.1.7)

The work of companies relating to the substitution principle (4.1.9)

Identification of substances of very high concern (4.2.1)
Authorisation (4.3.1)
Restriction (4.4.1)

**Initiatives to develop chemicals enforcement**

Provisions relating to chemicals largely place the responsibility for preparing information concerning environmental and health properties on manufacturers and importers. The same applies to information concerning what is needed to ensure that chemicals are handled safely. Advanced and effective enforcement reduces the risk of hazardous chemicals occurring in prohibited concentrations in chemical products and articles, and ensures that information that is provided is accurate. In addition to preventing damage to human health and the environment, this will also promote an effective market by ensuring that all companies operate under the same competitive conditions. Greater collaboration concerning enforcement is considered to be cost-effective, as it will enable knowledge, recommendations and methods that are developed jointly at EU level to be utilised by the enforcement authorities of all Member States.

Proposed measures in the report which it is believed will specifically contribute to attainment of the milestone targets can be found in section 4.5 Enforcement.

**Initiatives to reduce the exposure of children to chemicals**

The initiatives to achieve the milestone target of reducing the exposure of children to hazardous substances involve a broad raft of measures and include regulatory development aimed at stricter requirements concerning the substitution of hazardous substances and better access to information in the supplier chain. The consequences will thus largely be coincident with those that are described in connection with the milestone targets concerning the development and application of the EU provisions relating to chemicals and Non-Toxic and resource-efficient life-cycles.

From a socio-economic perspective, initiatives aimed at protecting the health of children should be particularly effective in many cases. This is partly because such initiatives can prevent health problems which in many cases can result in socio-economic costs in the form of suffering, higher morbidity with the associated care needs and reduced work capacity for a long period of time following exposure. Measures to protect children also often contribute to the general protection of human health and, in particular, the protection of other sensitive groups, such as population groups at greater risk of developing certain types of disease or ill-health.

Proposed measures in the report which it is believed will specifically contribute to attainment of the milestone target can be found in section 4.1.6 Children.
# 7 List of terms and abbreviations

## 7.1 Term

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Article</td>
<td>An object which during production is given a special shape, surface or design, which determines its function to a greater degree than does its chemical composition.*</td>
</tr>
<tr>
<td>Candidate List</td>
<td>List of SVHC substances which are included in the list in accordance with Article 59 of the REACH Regulation. Substances are candidates for inclusion in Annex XIV to REACH, which means that authorisation will be required in order to use them.</td>
</tr>
<tr>
<td>Chemical products</td>
<td>A chemical product encompasses substances and mixtures.</td>
</tr>
<tr>
<td>Combination effects</td>
<td>Combined effect of exposure of humans or the environment to a mixture of substances, which could be greater than the individual effects of the substances.</td>
</tr>
<tr>
<td>The Commission’s roadmap for substances of very high concern (SVHC Roadmap)</td>
<td>A roadmap for identifying and assessing substances relevant for the so-called Candidate List of substances of very high concern in REACH. The roadmap describes how substances must be evaluated and applies through to 2020.</td>
</tr>
<tr>
<td>Distributor</td>
<td>Any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a preparation, for third parties. *</td>
</tr>
<tr>
<td>Downstream user</td>
<td>Any natural or legal person established within the Community, other than the manufacturer or importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. A distributor or consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) is regarded as a downstream user.*</td>
</tr>
<tr>
<td>Endocrine disruptors</td>
<td>Substances which affect the hormonal systems and can cause damage to organisms, populations or ecosystems.</td>
</tr>
<tr>
<td>Exposure scenario</td>
<td>The set of conditions, including operational</td>
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conditions and risk
management measures, that describe how the
substance is manufactured or used during its life-
cycle and how the manufacturer or importer
tools, or recommends downstream users to
control, exposures of humans and the
environment. These exposure scenarios may cover
one specific process or use or several processes or
uses as appropriate.

Hazardous substances
Substances which are classified as being
hazardous in accordance with the CLP Regulation
and which fulfil the criteria set out in the
provisions for hazardous substances, but which
have not yet been classified. In this report, the
term is generally used to refer to substances
which are harmful to the environment and health,
while substances associated with physical hazards
are normally of lesser interest.

In vitro
Tests that are carried out in tests tubes or on
cultivated cells.

In vivo
Tests that are conducted on live experimental
organisms (e.g. animals, plants, fungi or
microorganisms).

Low-volume substances
Substances manufactured or imported in
quantities of 1-10 tonnes per
manufacturer/importer per year.

Manufacturing
Production or extraction of substances in the
natural state.*

Mixture
A mixture or solution composed of two or more
substances.*

Nanomaterial
Substances in the size range 1-100 nanometres.

Precautionary principle
Fundamental principle within environmental and
chemicals policy which means that, if there is a
threat of serious or irreversible damage to the
environment, the absence of scientific proof may
not be used as an excuse to delay cost-effective
measures in order to prevent environmental
impact. This principle also applies to human
health.

Producer of an article
Any natural or legal person who makes or
assembles an article within the Community.*
Read across
Comparison with another or several other substances in a group (interpolation) where test data for a substance/a group of substances is used to fulfil data requirements for one or more untested substances.

Registrant
The manufacturer or the importer of a substance or the producer or importer of an article submitting a registration for a substance.

Restriction
Any condition for or prohibition of the manufacture, use or placing on the market.

Substance
Chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.*

Substances of very high concern
Substances which have serious and often irreversible properties. In the report, the term normally refers to substances which are carcinogenic, mutagenic or toxic to reproduction (CMR, category 1A or 1B), substances which are persistent, bioaccumulative and toxic (PBT) and substances which are very persistent and very bioaccumulative (vPvB). In connection with the national Swedish environmental quality objective A Non-Toxic environment, the report uses the term in such a way that it encompasses, in addition to the abovementioned criteria, substances which are persistent and bioaccumulative (PB), endocrine disruptors and highly allergenic substances, as well as the metals mercury, cadmium and lead. See also section 2.1 under the heading "Substances of very high concern".

Substitution principle
Fundamental principle within chemicals control which means that hazardous substances must be replaced by less hazardous substances wherever possible. May also involve the use of a different technique or method.

Use
Any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation.*
UVCB substance

Substance of Unknown or Variable composition, Complex reaction products or Biological materials

*Explanation of term taken directly from Article 3 Definitions in REACH.

### 7.2 Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>CARACAL</td>
<td>Competent Authorities for REACH and CLP</td>
</tr>
<tr>
<td>CAS</td>
<td>Chemical Abstract Service</td>
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<tr>
<td>CASG Nano</td>
<td>CARACAL subgroup on nanomaterials</td>
</tr>
<tr>
<td>CHCC</td>
<td>Chemicals of High Concern to Children</td>
</tr>
<tr>
<td>CMR substances</td>
<td>Substances that are carcinogenic, mutagenic or toxic to reproduction</td>
</tr>
<tr>
<td>CoRAP</td>
<td>Community Rolling Action Plan</td>
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<tr>
<td>CSPA</td>
<td>Children’s Safe Product Act</td>
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<tr>
<td>DG</td>
<td>Directorate General</td>
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<tr>
<td>DMEL</td>
<td>Derived Minimal Effect Levels</td>
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<tr>
<td>DNEL</td>
<td>Derived No Effect Level</td>
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<tr>
<td>ECHA</td>
<td>European Chemicals Agency</td>
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<tr>
<td>EEA</td>
<td>European Environment Agency</td>
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<tr>
<td>EFSA</td>
<td>European Food Safety Authority</td>
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<td>EMA</td>
<td>European Medicines Agency</td>
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<tr>
<td>GHS</td>
<td>Globally Harmonized System of Classification</td>
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<tr>
<td>MAF</td>
<td>Mixture Assessment Factor</td>
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<tr>
<td>MSC</td>
<td>ECHA's Member State Committee</td>
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<tr>
<td>EU OSHA</td>
<td>European Agency for Safety and Health at Work</td>
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<tr>
<td>PAH</td>
<td>Polycyclic aromatic hydrocarbons</td>
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<tr>
<td>PBT</td>
<td>Persistent, Bioaccumulative, Toxic</td>
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<tr>
<td>QSAR</td>
<td>Quantitative Structure-Activity Relationship</td>
</tr>
<tr>
<td>RAC</td>
<td>ECHA's Committee for Risk Assessment</td>
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<tr>
<td>RAMO</td>
<td>Risk Management Options</td>
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<tr>
<td>SAICM</td>
<td>Strategic Approach to International Chemicals Management</td>
</tr>
<tr>
<td>SEAC</td>
<td>ECHA's Committee for Socio-Economic Analysis</td>
</tr>
<tr>
<td>SUBSPORT</td>
<td>Substitution Support Portal</td>
</tr>
<tr>
<td>SVHC</td>
<td>Substances of Very High Concern</td>
</tr>
<tr>
<td>US EPA</td>
<td>US Environmental Protection Agency</td>
</tr>
<tr>
<td>vPvB</td>
<td>very Persistent and very Bioaccumulative</td>
</tr>
</tbody>
</table>
8 Legislation


