Reducing the risks of hazardous substances

*A Swedish strategy for a non-toxic environment*

*Translation of SOU 2012:38*

*Interim report by the All-Party Committee on Environmental Objectives*

*Stockholm 2012*
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Stockholm 2012
On 1 July 2010, the Swedish Government decided to appoint a parliamentary committee (ToR 2010:74) with the task of submitting proposals to the Government on how the Swedish environmental quality objectives and the overall goal of Swedish environmental policy, known as the “generational goal”, can be reached. The committee has adopted the name: “The All-Party Committee on Environmental Objectives”.

The Committee’s overarching assignment is to develop strategies with milestone targets, instruments and measures within specific areas prioritised by the Government. The assignment is to be implemented in close cooperation with the business sector, non-governmental organisations (NGOs), municipalities and agencies, and will run until the end of 2020. During this period, the Committee will receive additional terms of reference in accordance with the Government’s priorities. According to the additional terms of reference adopted by the Government on 9 June 2011 (ToR 2011:50), the Committee is to draft a proposal for a strategy on how Sweden should work within the EU and internationally towards a non-toxic environment. The strategy is also to consider the impact of medicinal products on the environment.

A number of special advisers have been coopted to the Committee, including Head of Section Ann-Sofie Eriksson, County Director Anne-Li Fiskesjö, Environmental Policy Adviser Lovisa Hagberg, Chairperson Helena Jonsson, Chairperson Mikael Karlsson, Municipal Commissioner Henrik Ripa, Environment Officer Inger Strömdahl and Head of Environment Klas Lundberg.

A number of other experts have assisted the Committee in its work, including Technical Advisers Stefan Karlsson, Joachim Waern and Kristina Åkesson, Senior Adviser Håkan Alfredsson, and Desk Officers Elisabeth Lidbaum and Ingrid Hasselsten. Several more
people have also assisted the Committee as experts/advisers in special working groups, see Annex 3.

The Committee’s first assignment was presented in an interim report (SOU 2010:101) in December 2010. The Committee’s second assignment was presented in an interim report (SOU 2011:34) in March 2011. The first part of the Committee’s assignment on long-term sustainable land use (ToR 2011:91) was presented in an interim report (SOU 2012:15) in March 2012.

The Committee hereby submits its interim report ‘Reducing the risks of hazardous substances. A Swedish strategy for a non-toxic environment’ (SOU 2012:38) During the drafting of the report, Urban Boije af Gennäs has provided the Committee secretariat with technical assistance in certain issues.

Individual statements of opinion have been submitted by Emma Wallrup, Inger Strömdahl and Mikael Karlsson.

Stockholm, June 2012

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<tr>
<td>Acute toxicity</td>
<td>Immediately poisonous. Refers to harmful effects that can occur after a single exposure or multiple exposures to a substance within 24 hours. (REACH)</td>
</tr>
<tr>
<td>Appropriation directions</td>
<td>Appropriation directions are a government decision setting out the objectives and results that the Government requires of its agencies and their financial prerequisites, including the size of appropriations they may use.</td>
</tr>
<tr>
<td>Article</td>
<td>An object which, during production, is given a specific shape, surface or design which determines its function to a greater degree than does its chemical composition. (REACH)</td>
</tr>
<tr>
<td>Background level</td>
<td>Refers to the concentration at which a substance occurs natural in the external environment and is not the result of human activities. The background level varies depending on factors such as type of rock and soil, climate and vegetation and the formation of the substance as a result of natural processes.</td>
</tr>
<tr>
<td>BBP</td>
<td>Benzyl butyl phthalate. Toxic and toxic for reproduction. Along with DBP and DEHP, it is considered one of most hazardous phthalates. The use of all three is forbidden in toys.</td>
</tr>
</tbody>
</table>
### Benefit-risk assessment
A benefit-risk assessment is performed in connection with the authorisation of a new medicinal product and takes a number of factors into consideration. These factors include: the significance of proven effects, access to alternative treatments, significance of any pre-clinical discoveries, risk of unknown side-effects during long-term treatment, etc.

### Bioaccumulative substances
Substances that accumulate in organic tissue.

### Biocides
Chemical or biological pesticides produced to combat or protect human health or property against harmful animals, plants or microorganisms.

### Biological diversity
Variability among living organisms from all sources, including terrestrial, marine and other aquatic ecosystems, and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems. (The Convention on Biodiversity)

### Brand name drug
The first authorised medicinal product that contains a certain active substance. Protected by patent for ten years. Compare Generic.

### Brominated flame retardant
Organobromide compounds that have an inhibitory effect on the ignition of combustible organic materials. They are very effective in plastics and textile applications, e.g. electronics, clothes and furniture.

### Candidate list
ECHA's list of Substances of Very High Concern (SVHC). Substances on the Candidate list may be subject to the authorisation procedure according to Appendix XIV in REACH. The identification of substances that may be included in the candidate list is a continuous process, which means that new substances are successively added to it.
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<td>Chemical/Chemical product</td>
<td>Chemical substances and mixtures of chemical substances (preparations). Chemical products can be either pesticides or other products.</td>
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<tr>
<td>CLP</td>
<td>Classification, Labelling and Packaging of substances and mixtures; EU regulation containing provisions on the classification, labelling and packaging of substances and mixtures.</td>
</tr>
<tr>
<td>CMR substances</td>
<td>Carcinogenic, Mutagenic, toxic to Reproduction. Substances that are carcinogenic or have an adverse effect on genetic material or reproduction.</td>
</tr>
<tr>
<td>Combination effect (or cocktail effect)</td>
<td>Combined effect of a mixture of chemicals that can be larger than the impact of each substance on its own. Cumulative exposure, i.e. the composite exposure of a substance from different sources or the repeated exposure from the same source is also considered to be a combination effect. In some cases, combinations of substances may even have a lesser effect than each of the substances on its own (antagonistic effect).</td>
</tr>
<tr>
<td>Consumption</td>
<td>The end-use of products and services.</td>
</tr>
<tr>
<td>Cumulative exposure</td>
<td>See Combination effect.</td>
</tr>
<tr>
<td>Data requirement (or in REACH information requirement)</td>
<td>Requirements for substance test data laid down in various legislative acts.</td>
</tr>
<tr>
<td>DBT</td>
<td>DiButyl Phthalate. See BBP.</td>
</tr>
<tr>
<td>DDT (DichloroDiphenyl Trichloroethane)</td>
<td>Persistent organic compound previously used as an insecticide on a large scale. Prohibited since the 1970s.</td>
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<tr>
<td>decaBDE</td>
<td>Decabromodiphenyl ether. Brominated flame retardant. Potential PBT substance. Within the EU, the use of decaBDE in electrical and electronic products is prohibited.</td>
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<tr>
<td>Abbreviation</td>
<td>Description</td>
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<tr>
<td>DEHP</td>
<td>Di(2-EthylHexyl) Phthalate. See BBP.</td>
</tr>
<tr>
<td>DiBP</td>
<td>DiidoButyl Phthlate. Endocrine disruptor. Used e.g. as a fragrance carrier in cosmetics, personal hygiene products and scented candles.</td>
</tr>
<tr>
<td>Diffuse emissions</td>
<td>Total emissions of a chemical substance in an area where the emissions sources are of an undeterminable character, due e.g. to them being numerous, small, mobile, etc.</td>
</tr>
<tr>
<td>Dioxins</td>
<td>Dioxins are environmental pollutants that are formed in small amounts e.g. during the manufacture of chemicals that contain chlorine and during combustion processes, e.g. waste incineration.</td>
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<tr>
<td>ECHA</td>
<td>European Chemicals Agency.</td>
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<td>Eco-labelling</td>
<td>Labelling of products or services that are expected to cause the least possible environmental impact. Systems for eco-labelling are voluntary in Sweden and there are a number of different eco-labels on the Swedish market.</td>
</tr>
<tr>
<td>Ecosystem</td>
<td>A dynamic complex of plant, animal and microorganism communities and their non-living environment interacting as a functional unit. (The Convention on Biodiversity)</td>
</tr>
<tr>
<td>Ecotoxicology</td>
<td>The study of how substances are released into the natural environment and their chemistry, quantities, origin, spread, degradation, secretion and effects in the environment.</td>
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<tr>
<td>EEA</td>
<td>European Economic Area. The EEA countries are Iceland, Liechtenstein and Norway and the EU Member States.</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>Emission</td>
<td>Emission of a substance to air, soil, lakes and the sea.</td>
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<tr>
<td>Endocrine-disruptor</td>
<td>Substances that affect hormonal systems and can cause damage to organisms, populations or ecosystems.</td>
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<tr>
<td>Environmental Code</td>
<td>The Swedish Environmental Code (1998:808) is a piece of framework legislation that contains different instruments to achieve the overarching aim of sustainable development.</td>
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<tr>
<td>Environmental hazard</td>
<td>See Hazard.</td>
</tr>
<tr>
<td>Environmental monitoring</td>
<td>Systematic surveys that indicate the state of the environment and provide knowledge about changes in it. Managed by the Swedish Environmental Protection Agency.</td>
</tr>
<tr>
<td>Environmental objectives system</td>
<td>The environmental objectives system consists of objectives and targets as well as an organization for implementation and monitoring. The aim of the environmental objectives system is to provide structure for environmental work and a mechanism for systematically monitoring environmental policy.</td>
</tr>
<tr>
<td>Environmental quality objectives</td>
<td>The Riksdag has adopted 16 environmental quality objectives that are to be achieved by 2020 (Govt Bill 2009/10:155). The environmental quality objectives stipulate the state of the Swedish environment towards which environmental efforts are to be directed.</td>
</tr>
<tr>
<td>EU15</td>
<td>Used in e.g. statistics to specify that EU statistics refer to the period (1995-2004) when the EU consisted of 15 Member States. From 2007, the corresponding term is EU27.</td>
</tr>
<tr>
<td>European legislation</td>
<td>European legislation refers to treaties, regulations, directives, etc., decided on the EU level.</td>
</tr>
<tr>
<td>Evolution of resistance</td>
<td>Development of resistance in e.g. microorganisms against previously effective agents such as antibiotics, cytotoxins or insecticides.</td>
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<td>Exposure</td>
<td>Refers here to the extent to which humans and the environment come into contact with/are exposed to hazardous substances.</td>
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<tr>
<td>Fass.se</td>
<td>Open database in which environmental data on medicinal products are published. Also used to refer to the voluntary environmental classification system for medicinal products developed by a number of actors in order to provide information on active substances to stakeholders on the Swedish market.</td>
</tr>
<tr>
<td>Generational goal</td>
<td>The Riksdag has adopted a generational goal that provides the direction of the transition in society that needs to take place within one generation in order to achieve the environmental quality objectives (Govt Bill 2009/10:155).</td>
</tr>
<tr>
<td>Generic medicines</td>
<td>Medicines that have the same composition of active substances and the same medical form as a brand name drug.</td>
</tr>
<tr>
<td>GHS</td>
<td>Globally Harmonised System for Classification and Labelling of Chemicals.</td>
</tr>
<tr>
<td>Good Manufacturing Practice (GMP)</td>
<td>GMP is “that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use”. (EMA) The principles and guidelines for GMP are stated by the European Commission in two directives.</td>
</tr>
<tr>
<td>Green chemistry</td>
<td>Refers to the development of new substances with low toxicity and other environment- and health-related good properties and without climate-changing properties, the use of environmentally sound and energy-efficient methods and to increase the use of non-fossil raw materials and renewable energy when manufacturing chemicals.</td>
</tr>
<tr>
<td><strong>Hazard</strong></td>
<td>The hazard is a property or set of properties that make a substance dangerous. (REACH)</td>
</tr>
<tr>
<td><strong>Hazardous substances</strong></td>
<td>Refers here to chemicals and metals with properties that can be a threat to human health and/or the environment. In a legal context, the term 'hazardous substances' (in Swedish <em>farliga ämnen</em>) is used a collective term for a specific group of substances. In addition to particularly hazardous substances (see below), the category includes substances that are very toxic, toxic, harmful to health, caustic, irritating, allergenic and ecotoxic. In this report, the term is used in a non-legal sense.</td>
</tr>
<tr>
<td><strong>Impact assessments</strong></td>
<td>Committee Ordinance (1998:1474) states that cost calculations and other impact assessments are to be presented in committee reports. An impact assessment should be implemented using a broad perspective and include possible impacts both in the short and the long term. The effects of both measures and non-measures should be included.</td>
</tr>
<tr>
<td><strong>Information requirement</strong></td>
<td>Commonly termed a data requirement (see above) called an information requirement in REACH. The difference is that the REACH definition can include information other than just test data.</td>
</tr>
<tr>
<td><strong>Instrument</strong></td>
<td>Instrument used to steer social development, e.g. legislation.</td>
</tr>
<tr>
<td><strong>Interim targets</strong></td>
<td>Milestone targets replace the previous interim targets under the environmental quality objectives. The interim targets for the environmental quality objectives stated that a certain environmental quality was to be achieved or that changes were to have been implemented within a certain time limit.</td>
</tr>
<tr>
<td><strong>Intervention research</strong></td>
<td>Here refers to research undertaken with the objective of finding solutions to environmental problems.</td>
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<td>Definition</td>
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<tr>
<td>In vitro</td>
<td>Term used in biomedical science denoting that an experiment or observation has been done or made in a reaction vessel, test-tube, petri dish, etc., i.e. in an artificial environment and not in a living organism (in vivo).</td>
</tr>
<tr>
<td>Landfill</td>
<td>Waste tip, i.e. defined area for temporary or permanent disposal of waste.</td>
</tr>
<tr>
<td>Life Cycle perspective</td>
<td>Refers in this report to the assessment of environmental impacts associated with all the stages of a product’s life from cradle-to-grave (i.e. from raw material extraction through materials processing, manufacture, distribution, use, repair and maintenance, and disposal or recycling).</td>
</tr>
<tr>
<td>Low-volume substances</td>
<td>Substances that are manufactured or imported in quantities between 1 and 10 tonnes per manufacturer/importer and year. (REACH)</td>
</tr>
<tr>
<td>Medicinal products</td>
<td>What is to be classified as a medicinal product is determined by Section 1 of the Swedish Medicinal Products Act. The classification is primarily based on two factors: the content and purpose of the product. Put simply, the legal wording implies that medicinal products are: a) all substances that are said to be possible to use to treat or prevent diseases in humans and animals and b) all substances that can be used to treat diseases in humans and animals. Also referred to as pharmaceuticals in this report.</td>
</tr>
<tr>
<td>Market surveillance</td>
<td>The competent authority checks that the products or services on the market fulfil the applicable legislative requirements and that they are labelled and tested in accordance with the regulatory framework. See also Supervision.</td>
</tr>
<tr>
<td>Concept</td>
<td>Definition</td>
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<tr>
<td><strong>Milestone target</strong></td>
<td>Milestone targets define steps on the way to achieving the environmental quality objectives and the generational goal (see Govt Bill 2009/10:155). Milestone targets are established by the Government or, if there is special reason to do so, by the Riksdag.</td>
</tr>
<tr>
<td><strong>Nanomaterials</strong></td>
<td>Often defined as materials that are less than 100 nanometres in at least one dimension. A nanometre is a one millionth of a millimetre, or one billionth of a meter. Due to their small size, nanomaterials can acquire entirely different properties and functions.</td>
</tr>
<tr>
<td><strong>Nanotechnology</strong></td>
<td>Technology used to produce nanomaterials.</td>
</tr>
<tr>
<td><strong>Natural cycle</strong></td>
<td>Often used to denote the global turnover of elements or compounds, e.g. water in the natural environment.</td>
</tr>
<tr>
<td><strong>PAH</strong></td>
<td>Polycyclic Aromatic Hydrocarbons.</td>
</tr>
<tr>
<td><strong>Particularly hazardous substances</strong></td>
<td>The environmental and health properties included in the concept of ‘Particularly hazardous substances’ differ somewhat depending on the context in which they are used. REACH uses the term SVHC (see below) which differs slightly from the definition of Particularly hazardous substances used in Sweden’s environmental objectives (previous Interim Target 3).</td>
</tr>
<tr>
<td><strong>PBT substances</strong></td>
<td>Chemicals with PBT properties are Persistent, Bioaccumulative and Toxic.</td>
</tr>
<tr>
<td><strong>PCB</strong></td>
<td>PolyChlorinated Biphenyl. Industrial chemical that had many different areas of use before being prohibited in the 1970s. Some PCB variants are similar to dioxins (See Dioxins).</td>
</tr>
<tr>
<td><strong>Persistent substance</strong></td>
<td>A substance that is not readily degradable.</td>
</tr>
<tr>
<td><strong>PFAS</strong></td>
<td>PerFluoroAlklyl Sulphonate. A group of persistent chemical substances.</td>
</tr>
<tr>
<td>Concepts and abbreviations</td>
<td>SOU 2012:38</td>
</tr>
<tr>
<td>-----------------------------------</td>
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</tr>
<tr>
<td>Pharmaceuticals</td>
<td>Medicinal products.</td>
</tr>
<tr>
<td>Phthalates</td>
<td>A group of chemicals, the uses of which include softeners in plastic. See also BBP, DBP and DEHP.</td>
</tr>
<tr>
<td>Polluter Pays Principle, PPP</td>
<td>The Polluter Pays Principle is the principle according to which the polluter should bear the cost of measures to reduce pollution according to the extent of either the damage done to society or the exceeding of an acceptable level (standard) of pollution. (OECD)</td>
</tr>
<tr>
<td>POPs</td>
<td>Persistent Organic Pollutants.</td>
</tr>
<tr>
<td>Precautionary Principle</td>
<td>Mentioned in several environmental conventions and other regulatory frameworks. Many definitions of the precautionary principle exist. The Swedish Environmental Code, for example, states that precautionary measures shall be taken as soon as there is reason to believe that an activity or action may cause harm or detriment to human health or the environment. The definitions usually also include an obligation to take measures even if some cause and effect relationships have not been fully established scientifically.</td>
</tr>
<tr>
<td>Preparation</td>
<td>Mixture or solution composed of two or more substances. (REACH)</td>
</tr>
<tr>
<td>Product control</td>
<td>Here refers to control of chemical substances in products/articles. See also: Market surveillance.</td>
</tr>
<tr>
<td>Product directives</td>
<td>These directives regulate the requirements that various products or articles must fulfil before being released onto the market with regard to consumer protection, environment, health and safety. The foundation-stone of the EU's system for product safety.</td>
</tr>
<tr>
<td>REACH</td>
<td>European chemicals legislation. REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals.</td>
</tr>
<tr>
<td>Concept/Abbreviation</td>
<td>Definition</td>
</tr>
<tr>
<td>----------------------</td>
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<tr>
<td>Recycling society</td>
<td>A society in which reuse, recycling and resource efficiency are in focus.</td>
</tr>
<tr>
<td>Regulatory</td>
<td>Example: “regulatory requirements” are requirements laid down in accordance with different types of regulatory framework.</td>
</tr>
<tr>
<td>Resource efficiency</td>
<td>Sound management of natural resources and efficient energy use.</td>
</tr>
<tr>
<td>Restriction</td>
<td>Any condition for or prohibition of the manufacture, use or placing on the market of a substance. (REACH)</td>
</tr>
<tr>
<td>Risk</td>
<td>Combination of a hazard and the likelihood of it occurring; combination hazard – exposure.</td>
</tr>
<tr>
<td>Risk assessment</td>
<td>Four-step process by which one can determine the relationship between the predicted exposure to the harmful effects of a substance: hazard identification, dose-response assessment, exposure assessment and risk characterisation. Targeted risk assessment is a less extensive and more specifically targeted evaluation than a full-scale risk assessment.</td>
</tr>
<tr>
<td>SAICM</td>
<td>Strategic Approach to International Chemicals Management; The global chemicals strategy.</td>
</tr>
<tr>
<td>Screening</td>
<td>Refers here to inventories performed to determine whether a substance or group of substances occurs in the environment, within the framework of the Swedish Environmental Protection Agency’s environmental monitoring programme.</td>
</tr>
<tr>
<td>Specifications</td>
<td>For each environmental quality objective, there are specifications that flesh out its practical implications. They guide interpretation of the objectives and serve as criteria for assessing progress towards them. These specifications have been recently revised by the Government.</td>
</tr>
<tr>
<td>Concepts and abbreviations</td>
<td>SOU 2012:38</td>
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<tr>
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</tr>
<tr>
<td><strong>Stockholm Convention</strong></td>
<td>Also known as the POPs Convention, signed in 2001 to protect human health and the environment from persistent organic pollutants.</td>
</tr>
<tr>
<td><strong>Substance</strong></td>
<td>Chemical element and its compounds in natural or manufactured form, including additives that are necessary to retain a product’s stability as well as any pollutants resulting from the manufacturing process, but excluding any solvents that can be separated off without affecting the substance’s stability or changing its composition. (REACH)</td>
</tr>
<tr>
<td><strong>Substitution Principle</strong></td>
<td>Chapter 2, Section 6 of the Environmental Code makes reference to the ‘Product Choice Principle’, aka the Substitution Principle. The principle implies an obligation not to use or sell harmful chemical products (chemical substances or preparations) if there are less harmful alternatives available for the purpose. In European legislation (including REACH) the term ‘substitution’ is often used with a broader meaning which also includes the substitution of a technology or method. We use the concept in its broader meaning.</td>
</tr>
<tr>
<td><strong>Supervision</strong></td>
<td>Supervision is used here to describe independent analysis activity performed to check whether a facility that is subject to supervision fulfils requirements laid down in legislation or other binding regulations (including EU legislation) and where necessary may lead to a decision to implement measures aimed at achieving redress from the facility operator. (Skr. 2009/10:79).</td>
</tr>
<tr>
<td><strong>Sustainable chemistry</strong></td>
<td>See Green chemistry.</td>
</tr>
<tr>
<td><strong>SVHC</strong></td>
<td>Substances of Very High Concern. Term used in REACH for particularly hazardous substances.</td>
</tr>
<tr>
<td><strong>Synergy effect</strong></td>
<td>See Combination effect.</td>
</tr>
<tr>
<td>Concept</td>
<td>Definition</td>
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<td>--------------------------------</td>
<td>---------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Third country</td>
<td>Countries which are not members of the EU.</td>
</tr>
<tr>
<td>Toxic</td>
<td>Undesirable/harmful.</td>
</tr>
<tr>
<td>Toxic for reproduction</td>
<td>Describes a substance that inhibits an organism's ability to reproduce.</td>
</tr>
<tr>
<td>Toxicology</td>
<td>The undesirable/harmful (toxic) effects of chemical substances in biological systems.</td>
</tr>
<tr>
<td>UNEP</td>
<td>United Nations Environment Programme.</td>
</tr>
</tbody>
</table>
The conditions for meeting the environmental quality objective of A Non-Toxic Environment will not be in place by 2020 despite measures having been taken. With the present work, it will take much longer before the objective can be met.

The aim of this strategy is to improve the prospects of meeting the objective. To enable this, society needs to prioritise and concentrate its measures. Enough effort must be devoted to the most important measures to realise the objective. The precautionary principle and the substitution principle are the foundation from which society’s resources are to be used as effectively and cost-efficiently as possible.

In this report, we present what is required to meet the objective of a non-toxic environment, as well as the parts of the generational goal on minimal environmental impact on human health and natural cycles free from hazardous substances. We analyse and prioritise possible measures. We propose milestone targets for the most important measures and select those we deem most effective and cost-efficient. It is important that the measures are proportional to the size of the problems.

Our proposed strategy – concerted effort on priority measures

Society’s joint responsibility to meet the objectives

The Riksdag and the Government are responsible for legislation and for controlling government agencies. However, efforts are necessary from all parts of society – government agencies, research, municipalities, the business world and civil society – to reach the objective of a non-toxic environment and the parts of the generational goal on minimal environmental impact on human health and
natural cycles free from hazardous substances. This is an important basis of the strategy:

- Assessment of society’s joint responsibility for meeting the objectives.

**Previously proposed milestone targets are an integral part of the strategy**

In SOU 2011:34, the All Party Committee on Environmental Objectives proposed three milestone targets to reduce the risks associated with hazardous substances. The Government approved these milestone targets on 26 April 2012. They are an integral part of the strategy.

- Milestone target on particularly hazardous substances.
- Milestone target on knowledge of the health and environmental properties of substances.
- Milestone target on information about hazardous substances in articles.

**The next step in chemicals policy**

There is a clear need to take the next step in the work on chemicals to meet the conditions for a non-toxic environment. Hazardous substances are a cross-border problem, for which the regulatory framework is widely harmonised within the EU. Therefore, to a great extent, the next step in the chemicals policy needs to be taken jointly within the EU. Sweden should take active leadership of these issues within the Union and drive the joint European efforts forward. Improving chemicals safety and stimulating a faster rate of innovation requires significant changes to REACH and other relevant legislation after 2020.

Supervision is an important component of chemicals regulation if it is to have practical impact and thus an effect on health and the environment. Well-functioning supervision reduces the risk of uneven competition between companies and can contribute to the more effective development of regulations if the experiences are taken into account in the legislative process. The regulations in the chemicals area are complex and common practice for the appli-
tion of REACH is still largely lacking. To secure the success of the EU chemicals policy and competitive neutrality, we believe that increased cooperation is needed between EU Member States with regard to supervision in the chemicals area.

Based on the need to prepare for the next step in the chemicals policy to reduce the risks associated with hazardous substances, we propose two milestone targets:

- Milestone target on an innovation-driving REACH II.
- Milestone target on more effective chemicals supervision within the EU.

Here we also raise two particularly important issues through assessments:

- Assessment of more effective chemicals supervision in Sweden.
- Assessment of a strategy for intervention research and innovation, including green chemistry.

**Looking beyond traditional chemicals policy**

Active pharmaceutical substances are a group of substances which should be treated as potentially hazardous chemicals when they reach aquatic environments. Pharmaceuticals often contain several active substances which may potentially have an environmental impact. Pharmaceuticals are regulated in the pharmaceutical legislation and are largely exempt from the general chemicals regulations. Therefore, we see a need for changes that can contribute to reducing the impact of pharmaceuticals in the environment.

An recycling society that is sustainable in the long term presupposes that hazardous substances are phased out from material cycles. It is important that recycling of materials does not lead to the contamination of newly produced goods and products with otherwise prohibited substances. To achieve non-toxic and resource-efficient material cycles, better coordination of the legislation on waste and chemicals is required within the EU.

In the work to reduce the risks involved with hazardous substances, children and young people are particularly important. Children and young people are more vulnerable than adults to the effects of hazardous substances. The current regulations do not take adequate consideration of the particular sensitivity of children.
We propose three milestone targets which primarily lie outside the traditional chemicals policy and are of importance for being able to meet the environmental quality objective of *A Non-Toxic Environment* and the relevant parts of the generational goal:

- Milestone target on increased consideration in EU pharmaceuticals legislation.
- Milestone target on equal requirements within the EU on hazardous substances in recycled and newly produced materials.
- Milestone target on reducing children’s exposure to hazardous substances.

We also raise two particularly important issues through assessments:

- Assessment of prioritised product groups in the ongoing work to reduce the risks associated with hazardous substances.
- Assessment of the reduction of the risks associated with hazardous substances in contact with drinking water.

**Overall impact assessment**

We present an overall impact assessment of our strategy and, in connection with the different proposals, make more specific impact analyses.

The objective of the proposed Swedish strategy for a non-toxic environment is two-fold: to remove the shortcomings, mainly in EU legislation, that impede the realisation of the environmental quality objective of *A Non-Toxic Environment* and to ensure that the implementation of the current legislation is carried out.

One condition to enable the realisation of the EU-related milestone targets, is that Sweden cooperates with other countries that prioritise an active chemicals policy and that also seek to improve the EU regulatory framework. The All-Party Committee on Environmental Objectives assesses that there are Member States that may have an interest in cooperation to strengthen and amend the European chemicals legislation.

The strategy aims to bring about changes in the handling of hazardous substances and products. Changes can, at least in the short-term, involve costs for industry. The indicated magnitude of the additional costs to industry as a result of the strategy shows that these are small. The strategy will not significantly affect the
competitiveness of the European chemicals industry. For Swedish industry, it is important that conditions of competition do not differ between Member States as a result of the national application of EU legislation.

A fundamental principle in Swedish and European environmental legislation is that the polluter pays the costs of the preventive measures required to protect the environment – the Polluter Pays Principle (PPP). The milestone targets proposed in the strategy do not involve any change to the principle that it is the responsibility of companies to take the measures necessary to reduce the risks to health and the environment from hazardous substances.

An important part of the strategy is to include incentives in the chemicals regulations for innovation and self-regulation by the companies concerned through the strengthening of the substitution principle. The strategy means that the European legislation sets boundaries within which the companies can act.

A chemicals policy at EU level that restricts the manufacture and import of hazardous substances is therefore a prerequisite for the cost-efficient restriction of the flow of hazardous substances to natural cycles and the environment. The EU can also act for global measures to limit the manufacture and trade of hazardous substances and environmentally hazardous goods and products.

The costs of reducing the flow of hazardous substances to natural cycles and the environment are borne by industry. The costs incurred by the state are attributable to the work to prepare and conduct negotiations within the EU system to meet the milestone targets.

The proposed milestone targets presuppose Swedish efforts to develop a stricter EU chemicals policy. In some cases, it is also a matter of bringing about a change in the direction of the chemicals policy. Any implementation would place considerable demands on the Government Offices and the government agencies involved in EU efforts to create the conditions for far-reaching decisions within the Union.
Part A.
A Swedish strategy for a non-toxic environment
1 Reducing the risks of hazardous substances

1.1 We will not reach the objective of a non-toxic environment with the present work

The conditions for meeting the environmental quality objective of A Non-Toxic Environment will not be in place by 2020 despite measures having been taken. With the present work, it will take much longer before the objective can be met (Govt Bill 2009/10:155, Report 2009/10:MJU25, Riksdag Communication 2009/10:142).

The aim of this strategy is to improve the prospects of meeting the objective. To enable this, society needs to prioritise and concentrate its measures. Enough effort must be devoted to the most important measures in order to realise the objective. The Precautionary Principle and the Substitution Principle are the foundation from which society’s resources are to be used as effectively and cost-efficiently as possible.

In this report, we present what is required to meet the objective of A Non-Toxic Environment, as well as the parts of the generational goal relating to minimal environmental impact on human health and natural cycles free from hazardous substances. We analyse and prioritise possible measures. We propose milestone targets for the most important measures and select those that we consider to be the most effective and cost-efficient. It is important that the measures are proportionate to the size of the problems. This creates a foundation for the priorities and concentrated efforts that are required to achieve a non-toxic environment.
1.2 Measures in focus

Chemicals constitute an important part in many of the products we use. Chemical substances are contained in practically everything that surrounds us: in construction materials, furniture, clothes, food, hygiene products and electronics. When articles are manufactured, chemicals are added to enable and facilitate production and to give the article its required properties, e.g. to soften a plastic or make a textile water-resistant.

Some chemicals have hazardous properties that can cause problems for human health and the environment. Here we use the term hazardous substances.¹

The problem of hazardous substances is transboundary. Diffuse emissions of substances occur from articles we use in daily life. Many substances remain in the environment for a long time and our use of chemicals is constantly on the rise.

There is a great need for new knowledge about hazardous substances and their effects on human health and the environment. At the same time, it is important not to stop at merely describing the problems or to let the knowledge requirement inhibit us from taking preventive measures. Instead, we need greater focus on how to rectify the problems and hence reduce the risks of hazardous substances. We must find new ways forward to solve the problems with the knowledge we have.

The Precautionary Principle, i.e. taking measures even if we don’t have all the knowledge about the dangers of a substance, is fundamental to our work on hazardous substances. Based on this, we bring the need for measures into focus.

¹ Hazardous substances (“farliga ämnen”) means here chemical substances and metals with properties that can be a threat to human health and/or the environment. In a legal context, the term ‘hazardous substances’ is used a collective term for a specific group of substances. Here the term is used in a non-legal context (SOU 2011:34).
1.3 Children and young people are particularly important

In the work to reduce the risks of hazardous substances, children and young people are particularly important. They are more vulnerable than adults to the effects of hazardous substances, since, among other things, their development is dependent on complex hormonal systems. When we take special care of our children and young people, we also protect adults from hazardous substances in the everyday environment.

1.4 Society’s joint responsibility to meet the objectives

One starting-point for the work of the All-Party Committee on Environmental Objectives is society’s joint responsibility for improving our chances of meeting the generational goal and the environmental quality objectives. Efforts are necessary from all parts of society - central government, municipalities, the business sector and civil society - to create the conditions needed to reach the objective of A Non-Toxic Environment and the parts of the generational goal that relate to minimal impact on human health and the environment.

1.5 A challenging environmental quality objective

The objective A Non-Toxic Environment is one of the most challenging environmental quality objectives. The wording of the objective is as follows:

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.

On 26 April 2012, the Government adopted new specifications for the environmental quality objective ‘A Non-toxic Environment’. According to these specifications the practical meaning of the objective is:

- The combined exposure to chemical substances via all sources of exposure will not be harmful to human health or to biological diversity,
- The use of particularly hazardous substances will as far as possible have ceased,
- The spread of unintentionally formed substances with hazardous properties will be minimal and data on the formation, sources, emissions and spread of the most important of these substances and their breakdown products will be available,
- Contaminated sites will have been remediated as far as possible so that they do not constitute a threat to human health or the environment,
- Knowledge about the environmental and health properties of chemical substances will be available and adequate for risk assessment purposes, and
- Information about ecotoxicological and toxicological substances in materials, chemical products and articles will be available.

Despite the major efforts made, it will be very difficult to create the conditions necessary to reach the objective in its entirety within one generation of its adoption (Govt Bill 2009/10:155, Report 2009/10:MJU25, Riksdag Communication 2009/10:142). Our knowledge about how hazardous substances affect human health and the environment is incomplete. The effects when different substances interact, known as combination effects, remain virtually unknown. Hazardous substances are transported over long distances via water and air and via products and articles. Persistent and bioaccumulative substances from old emissions such as dioxins, mercury and brominated flame retardants will remain, at increased concentrations, in soil and watercourses for a long time to come. The fact that the objective is very challenging provides us with particular reason to join forces and concentrate our efforts on the most important measures to ensure that the objective can be met.

The specifications can be found at http://www.regeringen.se/sb/d/5542 [Retrieved 7 May 2012].
1.6 Choosing the most effective measures

We have identified a few principles that help us to choose the most effective measures that can be performed to reach the objective of A Non-Toxic Environment and the parts of the generational goal that relate to minimal impact on human health and natural cycles free from hazardous substances.

1.6.1 Preventing emissions at source

Hazardous substances create significant problems for human health and for the environment. Many substances remain in soil and watercourses for a long time after the emissions have taken place. Hazardous substances can also be found stored in e.g. infrastructure, buildings and articles, from which they can spread to the natural environment in connection with use, recovery or waste disposal. Measures are therefore needed to prevent emissions of hazardous substances and hence reduce the risks of damage to the environment and human health.

In Sweden, the problems caused by chemicals are different today to what they were in the 1960s and 1970s. Nowadays, the major emissions no longer come primarily from industry but from the use of articles and products. Most of the articles we use today contain chemical substances. The instruments we have at our disposal, e.g. supervision and authorisation procedures under the Swedish Environmental Code, are first and foremost aimed at dealing with emissions from industrial plants and other permanent facilities.

The current situation requires regulation of the substances contained in consumer products. Other methods, such as greater knowledge and available information on the health and environmental effects of chemical substances, are also required. Information together with regulation of hazardous substances also provide manufacturers with the incentive to apply the Substitution Principle and replace hazardous chemicals with other substances, materials or production processes that are better from an environmental and health perspective.
1.6.2 **Interplay between national, European and global measures**

Measures within the EU and internationally are crucial if we are to come closer to achieving the Non-Toxic Environment objective. Hazardous substances are brought into Sweden via the import of articles and products and as water- and airborne pollutants. Many key decisions on chemicals and their use are also taken within the EU and within the framework of international conventions and treaties. Sweden’s actions are based on these conditions and the opportunities there are to act on several different levels. Sweden’s right of determination with respect to achieving the objective is an aspect that we highlight in the strategy and use as one of the grounds for identifying the most effective measures.

The All-Party Committee on Environmental Objectives has previously ascertained that when the EU has no regulatory framework for hazardous substances or their use and there are serious risks to health and the environment, it is important for Sweden to take the lead and implement national regulation and other measures. Assessment of in which cases Sweden should take the lead ought to be based on a strategic analysis of the degree of risk to health and the environment and of the benefit of national actions as leverage to bring about measures at the EU level. Joint initiatives with others increase the likelihood of a positive impact.

There are two main ways that an EU Member State can take the initiative and show the way forward. Firstly, a Member State can actively pursue the need for common EU regulations or other initiatives within the EU and with respect to its Member States. And secondly, it can introduce national regulation and implement other national initiatives. This is permitted when, for example, the EU has no regulatory framework for hazardous substances or their use and there are serious health and environmental risks. There is also some limited scope in the European Treaty, under the “Environmental Guarantee” in Article 114, to maintain existing national provisions, or to even introduce new ones, that go further than the harmonised requirements. National measures may be considered when the active pursuit of issues within the EU has been shown to be far too slow. Common EU measures are how-

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4 SOU 2011:34, p. 104.
5 Treaty on the Functioning of the European Union (EUF Treaty).
ever to be preferred since they have an impact in all 27 Member States with a combined population of over 500 million inhabitants. Several times, however, common EU measures have been shown to come about as a result of national initiatives, as was the case recently concerning the prohibition of bisphenol A in babies’ feeding bottles. One important aim of a national initiative is to pursue an issue to bring about common regulations in all EU Member States.

International efforts, i.e. initiatives outside the EU, have so far been of relatively limited practical significance in the work to achieve the Swedish environmental objective of A Non-Toxic Environment. Sweden and the EU are usually considerably more proactive than many other countries and regions in the world. It has previously proven difficult to create binding global agreements despite extensive negotiations. Sweden should, however, continue to pursue issues relating to reducing the risks of hazardous substances even on the global level. This can help increase awareness of the risks and contribute to reducing them in, for example, many developing countries. It can also improve the conditions for more effective global agreements in the long term.

1.7 Our proposed strategy – concerted effort on priority measures

1.7.1 Society’s joint responsibility to meet the objectives

Efforts are necessary from all parts of society - agencies, municipalities, the business sector and civil society - in order to reach the objective of A Non-Toxic Environment. This is an important foundation of the strategy:

- Assessment of society’s joint responsibility to meet the objectives.

1.7.2 Previously proposed milestone targets are an integrated part of the strategy

In its previous interim report (SOU 2011:34), the All Party Committee on Environmental Objectives proposed three milestone targets to reduce the risks associated with hazardous sub-
stances. The Government approved these milestone targets on 26 April 2012. They are an integral part of the strategy.

- Milestone target on particularly hazardous substances.
- Milestone target on knowledge of the health and environmental properties of chemical substances.
- Milestone target on information about hazardous substances in articles.

1.7.3 The next step in chemicals policy

Based on the need to prepare for the next step in the chemicals policy to reduce the risks associated with hazardous substances, we propose two milestone targets. Linked to the milestone targets, we propose measures, and give proposals for the first step in their implementation.

- Milestone target on an innovation-driving REACH II.
- Milestone target on more effective chemicals supervision within the EU.

Here we also raise two particularly important assessment issues:

- Assessment of more effective chemicals supervision in Sweden.
- Assessment of a strategy for intervention research and innovation, including green chemistry.

1.7.4 Looking beyond traditional chemicals policy

We propose three milestone targets which primarily lie outside traditional chemicals policy and are of importance for being able to meet the environmental quality objective of *A Non-Toxic Environment* and the relevant parts of the generational goal. Linked to the milestone targets, we propose measures, and give proposals for the first step in their implementation.

- Milestone target on increased environmental consideration in EU pharmaceuticals legislation.
- Milestone target on equal requirements within the EU on hazardous substances in recycled and newly produced materials.
- Milestone target on reducing children’s exposure to hazardous substances.
We also raise two particularly important assessment issues:

- Assessment of prioritised product groups in the current work to reduce the risks associated with hazardous substances
- Assessment of reducing the risks involved with hazardous substances in contact with drinking water

1.7.5 Overall impact assessment

We submit an overall impact assessment of our strategy. Linked to the various proposals, we also present specific impact assessments.
2 A strategy with milestone targets and measures

2.1 About the assignment and its implementation

We have been given the task of developing a strategy for a non-toxic environment (ToR 2011:50). This strategy is to be presented by 15 June 2012 at the latest.

As part of its assignment, the All-Party Committee on Environmental Objectives shall:

- Propose a strategy with milestone targets, instruments and measures to reach the generational goal on human health and on natural cycles free from hazardous substances, and the environmental quality objective of *A Non-Toxic Environment*,
- Propose priorities and areas in which Sweden can launch new initiatives at the EU level and in the international arena, and which existing processes should be prioritised,
- Propose what kind of background documentation should be produced and how it can be produced, with a suitable timetable, in those cases where the Committee identifies a need for new milestone targets for which the background documentation is inadequate,
- Propose what further scientific research in the area of chemicals that needs to be performed in Sweden, in the EU and internationally as well as how such research can be set up, and
- Propose how Sweden’s international development cooperation and transfer of technology can contribute to development.

The strategy should contain a detailed description of the challenges that need to be addressed internationally and within the EU.
The working method of the All-Party Committee on Environmental Objectives aims to:

- Create scope for broad social dialogue.
- Create scope for in-depth inquiries in order to be able to formulate concrete proposals and to present adequate impact assessments.

Through its experts and special advisers, the Committee represents many different social sectors and policy areas, which enables a broad dialogue to be pursued. In connection with the work done to compile this interim report, we have invited experts from universities and agencies to deepen the discussion on particular perspectives.

The All-Party Committee on Environmental Objectives has organised three groups of special experts and advisers to help the Committee achieve this assignment. These experts and advisers are presented in Annex 3.

During the course of our work, we have also consulted with the ongoing Pharmaceuticals and Pharmacies Inquiry (S 2011:07).

In addition, the Committee’s secretariat has continuously collected information and comments from agencies, organisations and researchers. In connection with the work to produce this interim report, our meetings with the Swedish Chemicals Agency, National Board of Trade, National Food Administration, Swedish Medical Products Agency, Swedish Environmental Protection Agency and officials from the Government Offices of Sweden should be mentioned in particular.

### 2.2 The key components of the strategy

#### 2.2.1 Milestone targets to describe the necessary transition in society

A central element in the development of the strategy is to identify the transition in society that is required to reach the environmental quality objective of A Non-Toxic Environment and the relevant parts of the generational goal. This is the type of transition that is to be expressed as milestone targets. In other words, milestone targets are to be used to promote the strategic changes that need to be implemented in order to meet the environmental objectives. The

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7 The Government coopts experts to the Committee. It is hence the Committee that decides how to use the experts.
milestone targets shall indicate a clear political direction and contain fundamental considerations in support of the operative work of agencies and the rest of society.

The milestone targets shall constitute a basis for governance and prioritisation. There should therefore not be too many of them. Too many milestone targets will be less effective as a foundation for governance and prioritisation and will be more difficult to communicate to others. Milestone targets should also utilise any synergies between different environmental quality objectives and not be formulated based on one objective at a time.

Many changes, that may well be very important but are more akin to continuous improvements rather than social transition, should not be formulated as milestone targets. All desirable changes to legislation and agency work need not, and should not, therefore be expressed as milestone targets.

The fact that a change is not covered by a milestone target obviously does not mean that the Government and the Government Offices or responsible agency will not act to implement changes within their own remits. It is part of the agencies’ task to work operatively to ensure the environmental objectives are reached within their respective remits. If there is uncertainty surrounding the agencies’ mandate, the issue can be raised in the dialogue between the relevant agency and the Government or via appropriation directions and special assignments.

Transitions that presuppose decisions within the EU can be milestone targets in the strategy. Sweden cannot on its own implement all the measures needed to reach the environmental quality objective of A Non-Toxic Environment. Hazardous substances are brought into Sweden via the import of products and articles that can contain them. An ambitious and appropriate environmental policy within the EU is therefore of crucial importance for Sweden’s chances of reaching the environmental quality objectives.

A starting-point for the All-Party Committee on Environmental Objectives is that Sweden shall have the right of determination to adopt and implement the measures and instruments needed to achieve the milestone targets. They are to be ambitious but also possible to reach. As one of 27 Member States, Sweden has limited right of determination with respect to a social transition that presupposes decisions at the EU level. It may nevertheless be appropriate to express such transition in society as a milestone target, as it would give a clear indication of the strategic focus of Sweden’s actions within the EU.
2.3 The impact of the strategy must be assessed

Impact assessments shall be included in the background documentation produced as a basis for decision by the Riksdag, Government and central agencies. Regulations governing impact assessments can be found in the Committees Ordinance (1998:1474) for committees and other public inquiries that produce background documentation for the Government. As regards the work done by central agencies to draft and issue regulations, there are requirements laid down in the Ordinance on the Impact Assessment of Regulations (2007:1244).

The aim of impact assessments is that they are to form the basis of decisions on strategies, legislation or other proposals put forward by committees or agencies. The content of impact assessments should be adapted to the nature of the proposals being put forward by the committees or agencies. Committee proposals can be extremely varied. At one end of the spectrum, there are proposals for strategies and fundamental policy alignment. The task of the All-Party Committee on Environmental Objectives to develop a strategy for Sweden’s work in the EU and internationally is included in this group. And at the other end, work is done to draft regulations at the agency level.

Following an initiative from the European Council at its meeting in Gothenburg in the spring of 2001, the European Commission introduced a impact assessment (IA) requirement in 2005\(^8\) for the background documentation to policy proposals developed within the Commission.

Impact assessments shall in principle be performed on all legislative proposals that have manifest economic, social and environmental consequences. They are also to be performed for other initiatives which define future policies. This latter group includes Commission white papers, action plans, expenditure programmes and negotiating guidelines for international agreements. The Commission has published guidelines for how these impact assessments are to be designed\(^9\). These guidelines have the same fundamental starting-points as those laid down in the Swedish Committee Ordinance but are more detailed.

The Commission’s guidelines provide concrete guidance on e.g. how the impact assessments should be adapted to the nature of the

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\(^8\) A description of the European Commission’s impact assessment (IA) system can be found at [http://ec.europa.eu/governance/impact/index_en.htm](http://ec.europa.eu/governance/impact/index_en.htm)

proposals. The guidelines define six levels of initiatives and proposals. The highest level relates to strategy documents that set out proposals or commitments for future legislative action. Other categories in “descending” order are cross-cutting legislative measures, “narrow” legislative action (in one particular field or sector), expenditure programmes and comitology decisions. For each category, the guidelines specify the issues that the IA is to focus on as well as what ought to be avoided.

As regards strategic proposals drafted by the Commission, the IA must be kept on an overarching level. An IA on strategic proposals is to focus on descriptions of the general problems within the policy area and the factors that cause them. The objectives that the strategy is designed to reach are to be clearly defined. The assessment shall also specify the measures needed to reach the formulated objectives. The most significant potential impacts are to be described, clearly linked to the specified objectives.

Quantitative and monetary impact assessments should not be performed at this stage. They are to be done later in the process, i.e. once proposals have been set out for the concrete wording of the legislation and expenditure programme that result from the strategy.

The Commission guidelines have been developed for an administrative and committee tradition that is different to the Swedish tradition. Much of what is to be included in an IA according to the Commission guidelines is integrated into the proposal background and reasoning text of a Swedish committee report and is therefore not normally presented in a separate section. There is no reason for the strategy proposal from the All-Party Committee on Environmental Objectives to depart from the traditional way Swedish committees present their considerations and reasoning. This is primarily true of the problem formulation, including the discussion on the causes of the problem.

The issues that are normally included in explicit impact assessments performed as part of Swedish committees and inquiries concern socioeconomic cost and income assessments. Income distribution issues are also discussed, i.e. who pays for and who might receive monetary benefit from a proposal. In accordance with the Swedish Committee Ordinance, impact assessments are also to cover a number of aspects, including the significance of the proposals for employment and service in different parts of the country, for the working conditions of small businesses and for gender equality.
The requirements in the Committee Ordinance for cost and income calculations seem to be mostly directed at committees that are tasked to put forward concrete proposals for legislative action or expenditure programmes. An impact assessment for a strategy should adopt a different perspective. The issues that such an impact assessment is to address are different to those that are addressed in connection with a legislative proposal. Neither is it possible to quantify e.g. the costs of a strategy with the same precision as for a legislative proposal or expenditure programme.

The proposals for milestone targets put forward by the All-Party Committee on Environmental Objectives are to be followed by proposals for the measures needed to reach them. This task should be interpreted to mean that the Committee is to submit proposals for measures on the fundamental level. The introduction of new instruments, such as norms and new hazardous chemical authorisation procedures, presuppose in-depth legal and economic analyses. These analyses will be the first steps in the implementation of the strategy. The same is true of measures in the form of, for example, new forms of supervision or new focus on knowledge-building for agencies, the business sector and the general public. In these in-depth analyses of the proposals’ design, quantitative socioeconomic impact assessments are an important part of the basis for decision-making. Our impact assessments will, as a result of this, correspond to the Commission’s IA, in a structure that is adapted to Swedish committee tradition.

Three evaluation criteria are central to the All-Party Committee’s impact assessments of the proposed strategy.

The first criterion concerns the effectiveness of the proposals. A milestone target shall be an important step in the achievement of the generational goal and the environmental quality objective of A Non-Toxic Environment. The proposed measures and instruments are to contribute to and preferably be sufficient for the achievement of the milestone target.

The second evaluation criterion concerns the issue of the compatibility of the proposals with Swedish and European legislation otherwise and with overarching policy goals - including non-environment policy goals such as full employment, competitiveness, growth and regional development. Sweden’s right of determination as regards implementation is an issue that is central in the context. The assessments will, out of necessity, be on an overarching level. A more in-depth analysis should be presented in
connection with the assessment of the more detailed design of the instruments and measures.

The third criterion concerns the cost-efficiency of the proposals. The objective of A Non-Toxic Environment is a central component of Sweden’s environmental policy and is difficult to reach. It is hence important to ensure that the measures implemented are effective. Some quantitative analyses of the strategy would be associated with considerable uncertainty. These should instead be included further down the line when the measures are to be designed in detail.

In addition to this, we also assess the distributional impacts of the proposals, as well as the effects on the government budget and public administration.
3 Society's joint responsibility to meet the objectives

3.1 Society’s joint responsibilities to meet the objectives

The All-Party Committee’s assessment is that:

Efforts are needed from all parts of society - agencies, municipalities, the business sector and civil society - in order to reach the objective of A Non-Toxic Environment.

- Manufacturers and suppliers can take an active lead and phase out hazardous substances in products and production processes without waiting for agency regulations or binding legislation to be introduced.

- Consumers - municipalities, central agencies, businesses and private citizens - can influence development by placing demands on manufacturers and suppliers to phase out hazardous substances in the products or articles they put on the market. Municipalities and central agencies should utilise the opportunities that already exist within the framework of the public procurement system.

- Central agencies should, as part of their assigned tasks, actively promote development on the national level, within the EU and internationally to reduce the risks of hazardous substances.

3.1.1 Reasoning

The milestone targets included in the strategy for a non-toxic environment increase our chances of reaching the environmental quality objective and the relevant parts of the generational goal. The
milestone targets point out a clear political focus for the efforts of the Government and the central agencies to develop legislation and activities nationally and within the EU as regards the regulation and control of the import, manufacture and handling of chemicals and hazardous substances. We consider that the milestone targets provide the legal and organisational conditions for the national efforts to reach the environmental quality objective.

The Riksdag and the Government are responsible for legislation and agency instructions. However, efforts are necessary from all parts of society – central agencies, research, municipalities, the business sector and civil society – to reach the objective of A Non-Toxic Environment and the parts of the generational goal relating to minimal environmental impact on human health and material cycles free from hazardous substances. The legislation sets boundaries for those who manufacture, import, distribute or use hazardous substances or products that contain such substances. It is the decisions and actions of these stakeholders that ultimately will make a significant contribution to the achievement of the environmental quality objective.

The central agencies have been tasked to implement measures that contribute to the attainment of the environmental quality objectives within the boundaries of current legislation. Their task also includes taking the initiative for changes in regulatory frameworks and for instruments in order to target and rationalise society’s resources and submit background documentation as a basis for political measures when conditions change as a result of e.g. new knowledge or consumption patterns. As a result of their experience of benchmarking, supervision and environmental monitoring, the relevant central agencies in this area, the Medical Products Agency, the National Food Administration, the Environmental Protection Agency and the Swedish Chemicals Agency, are well placed to be able to actively contribute to developments on the national level, within the EU and internationally in order to reduce the risks of hazardous substances.

The municipalities can not only control compliance with the regulations but also identify problem areas and provide a basis for allocating priorities in the chemicals policy. An example is public spaces where the municipalities are responsible for protecting children and young people. Preschools and schools are premises where a non-toxic environment should be an undisputed objective and a priority area for the municipalities’ environmental monitoring activities.
Target-oriented municipal environmental monitoring also underpins Swedish efforts to reach the milestone target of tougher European chemicals legislation.

Public procurement is one of society’s most powerful ways of phasing out hazardous substances from many consumer products. *Municipalities and county councils* can influence the development towards a non-toxic environment in their procurement of e.g. equipment and materials for hospitals, schools and preschools. The public sector is collectively a major customer on the market as it procures products used in activities that often affect children and young people. Target-oriented procurement therefore creates incentives for municipal suppliers to be able to supply products and articles that do not give rise to health and environmental risks.

Public procurement regulations are to a large extent harmonised within the EU. In many ways, the legal situation is unclear, which means that organisations looking to proactively utilise procurement in order to phase out hazardous substances in their activities need to possess good legal skills. This is one reason why the Government has appointed the Procurement Committee (ToR 2010:86). The aim of the Committee is to investigate whether the current procurement regulations enable procuring agencies to sufficiently utilise competition on the market while at the same time use their purchasing power to improve the environment, show social and ethical consideration and promote business opportunities among small and medium-sized enterprises. The Procurement Committee will submit its final report in November 2012. The current Government’s action plan for green public procurement already establishes that environmental demands should be stipulated in public procurements. The Swedish EMAS Council supports the agencies in this respect by drafting procurement criteria that contain both environmental and social demands. An important task for the municipalities and county councils that want to contribute to a non-toxic environment is to create a strong procurement organisation that is highly skilled in, for example, legal issues. There are municipalities and county councils that have the necessary resources for this and that can pave the way for municipalities with fewer resources. Municipalities also need to work together on this issue. Target-oriented and systematic environmental monitoring and public procurement can have a major impact on the efforts to create a non-toxic environment. A municipality has the opportunity, for example, to establish the objective that preschools and
Schools must offer a non-toxic environment to both pupils and staff. Systematic environmental monitoring can identify the chemicals that occur in these premises. Using environmental monitoring as a driver provides the prerequisites for the proactive municipal procurement of articles and materials in order to protect children and young people from exposure to hazardous substances in schools and other public environments.

**Businesses and business sector organisations** can play and do play an important role as regards the phase-out of hazardous substances.

Many Swedish textile importers place demands on the content of their articles that are tougher than is required by the legislation. The trade organisation the Swedish Textile and Clothing Industries’ Association (TEKO) has produced a green product declaration as an aid to purchasers. TEKO is also working to harmonise different lists of requirements. The textile importers have produced a guide to chemicals containing a number of guidelines. Many businesses also have their own lists of hazardous substances that should be replaced.

The construction industry has developed a system that focuses on chemicals in building materials (BASTA). The aim of BASTA is to contribute to the phase-out of hazardous substances from the construction sector. The BASTA system is supported by Sweden’s biggest building and construction technology companies. It is run as a non-profit limited company owned jointly by IVL, Swedish Environmental Research Institute and the Swedish Construction Federation. The practical work is performed by staff at IVL.

The textile and construction sectors have here exemplified the work that can be done by businesses to phase out toxicological and ecotoxicological substances in their products. These sectors are consumer-oriented and feel the pressure exerted by consumers. This gives them an incentive to detoxify their supply chains and to sell products that do not put customer health and the environment at risk. It is also of central importance that the chemicals industry, which supplies “semi-finished” products to the consumer product industry, has the incentive to replace hazardous chemicals with substances that do not pose a risk to human health and the environment.

An integral element in our proposal for a strategy for a non-toxic environment is the establishment of European legislation that is innovation-driving for the chemicals industry as regards the substitution of hazardous substances. The legislation will have an even greater effect as a result of intensive pressure for change being
put on the chemicals industry from the consumer product trade and procuring central agencies, municipalities and country councils.

Voluntary organisations that bring together committed citizens and consumers fulfil an important function as knowledge disseminators and opinion shapers in the broad sense. Environmental organisations and consumer groups put pressure not only on the consumer product trade to sell products that are not hazardous to health or the environment but also on agencies to perform tougher chemicals surveillance.

One example is Chemsec\textsuperscript{10}, which is run by four Swedish environmental organisations. Chemsec’s ambition is to build a bridge between the political system, the business sector and the scientific community when it comes to phasing out hazardous substances. The organisation’s work is primarily focused on European chemicals legislation but it also offers support to Swedish businesses looking to phase out hazardous substances from their products. Chemsec’s primary instrument is the SIN list\textsuperscript{11} of particularly hazardous substances that has been established and is used to drive forward their phase-out.

This review shows that societal actors within the framework of current legislation influence the development towards a non-toxic environment by stipulating requirements for the phase-out of hazardous substances from articles and products. But the significance of active stakeholders is greater than this. Proactive efforts when it comes to environmental monitoring, procurement and purchasing policy that are a step ahead of European chemicals legislation provide strong support to the development of European chemicals policy in accordance with our proposal for a non-toxic environment strategy.

All the stakeholders in society are dependent on and affect each other when it comes to working towards a non-toxic environment. Non-governmental organisations (NGOs) put demands on authorities and businesses but can also support them in their opinion-shaping and knowledge dissemination. The effect of the whole, i.e. all the efforts put together, can be greater than that of each of the parts. Cooperation projects between the actors involved can help utilise

\textsuperscript{10}International Chemical Secretariat. The member organisations of Chemsec are the Swedish Society for Nature Conservation, WWF Sweden, Nature and Youth Sweden and Friends of the Earth Sweden.

\textsuperscript{11}Substitute It Now-list.
this power and the interest shown by society in a non-toxic environment.

An example of a cooperation project on the local level is the Stockholm Chemicals Forum, the aim of which is for the city administration and trading companies in the region to help each other to reduce the impact of toxicological and ecotoxicological substances on Stockholm’s natural environment and its inhabitants. On the national level, a campaign to encourage patients to return waste medicinal products to pharmacies has been running during the spring of 2012. The campaign is being supported by LIF (Swedish Association of the Pharmaceutical Industry), the Medical Products Agency, the Swedish Association of Local Authorities and Regions, the Swedish Water & Wastewater Association, the Swedish Association of Convenience Goods Traders, the Swedish Pharmacy Association, the Association for Generic Pharmaceuticals in Sweden (FGL), the Pharmaceutical Distributors’ Association and Avfall Sverige (Swedish Waste Management).

In its product strategy\(^\text{12}\), the Swedish Chemicals Agency has proposed that everyday commodities, such as clothes, shoes, toys and other articles intended for children, should be a priority for the agencies over the next few years. In this area, there are many challenges for the agencies and other stakeholders in society where cooperation on the national, regional and local level can be appropriate. An example of one possible cooperation project is the abovementioned non-toxic environment theme in preschools, which involves municipalities, product suppliers, parent and staff organisations and supervisory authorities. Another area of cooperation that may develop is the exchange of information and transfer of knowledge on municipal procurement issues.

4 Previous milestone targets on hazardous substances are included in the strategy

4.1 Previous milestone targets

In its interim report (SOU 2011:34), the All Party Committee on Environmental Objectives proposed three milestone targets to reduce the risks associated with hazardous substances. The Government approved these milestone objectives on 26 April 2012. They are an integral part of the strategy.

- Milestone target on particularly hazardous substances.
- Milestone target on knowledge of the health and environmental properties of substances.
- Milestone target on information about hazardous substances in articles.

The adopted milestone targets comprise several very important issues. Among these, we wish to highlight the issues of cumulative exposure and combination effects, endocrine disruptors, powerful allergens, data requirements for low-volume substances, the environmental impact of cosmetic and hygiene products, nanomaterials, the need for better protection for the health of children and other vulnerable groups, and the fact that our consumption places high demands for information about hazardous substances in articles. The previous milestone targets, followed by a description of the above aspects, are presented below.

13 The adopted milestone targets can be found at http://www.regeringen.se/sb/d/2055/a/191671 [Retrieved 7 May 2012].
4.1.1 Milestone target on particularly hazardous substances

In accordance with the milestone target on particularly hazardous substances, decisions taken within the European Union and internationally on such substances shall contain measures that involve:

- Endocrine disruptors and powerful allergens being considered as particularly hazardous substances in all relevant regulatory frameworks by 2015 at the latest,
- Particularly hazardous substances being subject to authorisation or a decision on phase-out under the applicable regulatory framework within all areas of use by 2018,
- Particularly hazardous substances in production processes only being used under strictly regulated circumstances no later than 2018, and
- The term “particularly hazardous substances” (or in REACH Substances of Very High Concern) in relevant regulatory frameworks including substances with serious properties other than those covered by current specific criteria and that convey a similar degree of doubt by 2018 at the latest.

The milestone target aims to create the conditions needed to reduce the use of and, in the long term, phase out particularly hazardous substances\(^{14}\). The work on particularly hazardous substances has been allocated priority as they can cause major harm to human health and the environment.

\(^{14}\) The environmental and health properties included in the concept of particularly hazardous substances differ somewhat depending on the context in which they are used. REACH uses the term Substances of Very High Concern (SVHC) which differs slightly from the definition of particularly hazardous substances (in Swedish 'särskilt farliga ämnen') used in Sweden’s environmental objectives (previous Interim Target 3). Endocrine disruptors and powerful allergens can, for example, be covered by a special criterion in REACH. This criterion covers substances that do not fulfil the other criteria in REACH but that have effects that cause the same amount of concern as substances that do fulfil one or more of the other criteria.
4.1.2 Milestone target on knowledge of the health and environmental properties of substances

The milestone target on knowledge of the health and environmental properties of substances involves decisions taken within the European Union or internationally stipulating that information about health and environmental properties of chemical substances shall be accessible and adequate to enable a risk assessment of all areas of use. The decisions shall contain measures that involve:

- Relevant regulatory frameworks stipulating a requirement for knowledge and information on the occurrence of relevant nanoparticles and nanomaterials that is sufficient to be able to assess and minimise their health and environmental effects by 2015 at the latest,
- Prerequisites being in place so that relevant regulatory frameworks can take into consideration the combination effects of chemicals exposure no later than 2015,
- Regulatory frameworks taking into account that children are particularly vulnerable to the impact of chemicals no later than 2015, and
- The information requirements in connection with registration in REACH for substances that are manufactured or imported in lower volumes (less than 10 tonnes per manufacturer or importer and year) being strengthened by 2018.

Knowledge of the health and environmental properties of chemical substances is an important prerequisite in order to be able to take preventive measures to minimise the risks of hazardous substances. Milestone targets that create better conditions to increase knowledge about hazardous substances are therefore needed.
4.1.3 Milestone target on information about hazardous substances in articles

The milestone target on information about hazardous substances in articles involves:

- Regulatory frameworks or agreements within the European Union or internationally being applied so that information about ecotoxicological and toxicological substances in articles is available to all stakeholders no later than 2020,
- The legislation being introduced stepwise for different product groups and the information paying particular attention to child health, and
- Information about hazardous substances contained in materials and articles being made available during the article’s entire life cycle by means of harmonised systems that cover priority product groups.

Access to information about hazardous substances in articles is an important prerequisite in order to reduce the risks associated with the handling of such articles during manufacture, use and end-of-life disposal. The milestone target aims to improve the information about hazardous substances in articles and materials.

The All-Party Committee on Environmental Objectives also submitted a number of proposals for assessments of hazardous substances and milestone targets and assessments of waste that is linked to the Non-Toxic Environment objective and the parts of the generational goal relating to human health and natural cycles free from hazardous substances. These milestone targets have also been adopted by the Government. The adopted milestone targets and proposals for assessments are presented in Annex 5.
4.2 Priority areas covered by previous milestone targets

4.2.1 Endocrine disruptors

A number of different hormonal systems interact in a complex fashion in order to control development and bodily functions. Discoveries are increasingly being made that point to what are known as endocrine disruptors being harmful to human reproduction and affecting both the foetus and a child's subsequent development. These types of disruptions have been observed in animals, both in vitro and in vivo. Studies from the United States and Denmark report that children are reaching puberty significantly earlier. Studies in Denmark have shown impaired sperm quality in younger men, which can threaten human reproduction in the long term. The extent to which these effects on humans can be linked to chemicals exposure is still unclear, however.

The starting-point must be that measures in accordance with the Precautionary Principle are to be taken even when there is scientific uncertainty about the risks. This can apply to knowledge-building that provides a better basis for decisions on suitable measures in the long term. At the same time, it is important to act in order to prevent and reduce the risks of possible serious damage even if the basis for decision-making is incomplete. The All-Party Committee on Environmental Objectives has therefore proposed that endocrine disruptors be considered as particularly hazardous substances in relevant regulatory frameworks no later than 2015. The Government has adopted the proposed milestone target (Milestone target on particularly hazardous substances).

4.2.2 Powerful allergens

Many people suffer from allergies and other hypersensitivity reactions. Potential allergens are used in a vast array of consumer products. Metals, aroma compounds and preservatives are just some of our most common allergens. Contact allergy is an allergic reaction that occurs as a result of direct contact with an allergen. It can be caused by more than 3 700 substances. Nickel is the commonest cause of contact allergy. Other substances that can lead to skin problems include
preservatives and perfumes. Contact allergy often starts in childhood and adolescence and continues throughout life.

Allergens are often contained in everyday commodities such as skin creams, make-up, textiles, washing and cleaning detergents and toys. Powerful allergens should be considered as substances of very high concern in European legislation. This is also the import of the previous milestone target on particularly hazardous substances.

4.2.3 **Environmental impact of cosmetic and hygiene products**

There are several examples of environmental problems associated with cosmetic and hygiene products. There are reports, for example, indicating that the UV filters used in sun protection products are toxic to aquatic organisms. These substances are also found dispersed in the natural environment\(^\text{15}\).

Since cosmetic and hygiene products are used directly on the skin, hair and in the mouth, the exposure and hence the health risks are substantial. This is why health aspects are central in the legislation. The most common examples of health problems that may be caused or triggered by cosmetic and hygiene products are contact allergy and skin irritations. Powerful allergens are covered by the milestone target on particularly hazardous substances, which the Government has adopted following a proposal from the All-Party Committee on Environmental Objectives (Milestone target on particularly hazardous substances). It is our assessment that the wording “all relevant regulatory frameworks” also includes European cosmetics legislation. See also Section 12.4 Environmental impact of cosmetic and hygiene products.

4.2.4 **Better protection for the health of children and other vulnerable groups**

Child health protection is important to highlight in the work to reduce the risks of hazardous substances. Measures to protect children often lead to adult health being better protected against the risks associated with chemicals. Furthermore, the ambition

\(^{15}\) Results from the Swedish National Screening Programme 2009 IVL report B1971, Subreport 3: UV-filters.
should also be to protect other population groups that for one reason or another can be particularly sensitive. This may refer to people suffering from a specific disease or who are on specific medication.

There are several reasons why children and young people are more vulnerable than adults to the impact of chemicals. Their bodies, including their brains and nervous systems, reproductive and immune systems and various internal organs, are still developing. Disturbances to this development can have major consequences. Children are more vulnerable than adults since their biological and physical activity, as well as their social behaviour, are different from that of an adult individual. Children eat, drink and breathe more than adults in relation to their body weight. Smaller children are exposed when they chew and suck things. They are also close to the floor and therefore more exposed to dust-bound chemicals. All this means that children, in relation to their body weight, risk assimilating higher concentrations of many chemicals than adults do. During childhood and adolescence, exposure to chemicals occurs mostly in the home but also in preschool and in school where children spend a great deal of their time.

Over the last 50 years, the ways in which children and young people have been exposed to chemicals has radically changed. Exposure to certain particularly hazardous chemicals, such as lead, is nowadays much lower than previously. At the same time, however, they are now exposed to many more chemicals, since they have a lot more toys, clothes, cosmetics and other articles that contain many different chemicals.

The current regulations do not take adequate consideration of the particular vulnerability of children. Regulatory frameworks considering children as particularly sensitive to the impact of chemical substances are part of the milestone target on knowledge of the health and environmental properties of substances. We also propose a new milestone target on reducing children’s exposure to hazardous substances (see Section 12.2 Milestone target on reducing children’s exposure to hazardous substances).

4.2.5 Nanomaterials

Nanotechnology has developed rapidly in recent years and an increasing number of chemical products and articles containing nanoparticles can now be found on the market. These particles and materials have properties that differ from substances produced by conventional methods. These different properties are often the very reason for using nanotechnologically produced materials, but they often involve new health and environmental risks at the same time. There is currently a general lack of testing methods to obtain data on possible health and environmental risks associated with these substances and materials. The All-Party Committee on Environmental Objectives has therefore proposed that knowledge requirements in relevant chemicals and consumer product legislation must be sufficient to be able to assess and stipulate requirements for a minimisation of the health and environmental effects of nanoparticles and nanomaterials, no later than 2015. The Government has adopted the milestone target following a proposal from the All-Party Committee on Environmental Objectives (Milestone target on knowledge of the health and environmental effects of substances).

4.2.6 Cumulative exposure and combination effects

Humans and the environment are exposed to the same substance via several different exposure routes, from several different sources and on repeated occasions. The cumulative exposure is crucial for any possible toxic effects. At the same time, there is continuous exposure to combinations and mixtures of chemical substances. Current research indicates that simultaneous exposure to several substances in doses/at levels that are not expected to have harmful effects individually still cause damage as a result of some form of combination effect. Despite the growing knowledge about combination effects, risk assessments of chemical substances are as a rule carried out on individual substances, i.e. one substance at a time, in accordance with the current legislation. The milestone target on knowledge of the health and environmental properties of substances also stipulates that relevant regulatory frameworks shall consider the combination effects of exposure to chemicals.

In order to be able to manage the large volume of chemicals from different sources which humans and the environment are exposed
to, considerable efforts will be required to improve knowledge and develop principles for legal solutions. Such a proposal can be found in Section 6.1 Milestone target on an innovation-driving REACH II. Furthermore, a broad review of risk assessment methodology and of both environment- and health-oriented legislation is required (see Section 8.2 Research and knowledge development on environmental and health effects).

4.2.7 Data requirements on low-volume substances need to be improved

Under the current provisions in REACH\textsuperscript{17} and CLP\textsuperscript{18}, it is the manufacturer or importer who is obliged to ensure that the relevant knowledge about the substances for sale is available. The requirements for information vary depending on the quantity of the substance being manufactured or imported. The information requirements concern aspects such as the substance’s different properties, use and management. The knowledge requirements regarding substances that are manufactured in smaller quantities (less than 10 tonnes per manufacturer/importer and year) are insufficient bearing in mind that many substances can be harmful even in small volumes. The milestone target on knowledge of the health and environmental properties of substances includes a call for more stringent information requirements in REACH regarding “low-volume substances”.

In order to enable this part of the milestone target to be reached, Sweden should also work on the issue of tougher data requirements for substances under 10 tonnes and submit proposals for how such requirements could in principle be formulated\textsuperscript{19}. This work needs to begin in good time before 2018. It could possibly be done in connection with the planned 2012 review of REACH. Sweden should


\textsuperscript{19} The issues regarding knowledge requirements for low-volume substances are analysed more closely within the framework of the government assignment regarding a legal analysis of European chemicals legislation and proposals for changes in priority areas presented in the Swedish Chemicals Agency report Improved EU rules for a non-toxic environment (2012) Report no. 1/12.
pursue discussions with other Member States, the Commission, the European Chemicals Agency (ECHA) and relevant industries on how the requirements can be formulated.

An important issue in connection with data on low-volume substances will be the development of methods, etc., to search for hazardous properties and identify the most hazardous ones among the large volume of substances. See Section 8.2 Research and knowledge development on environmental and health effects for a more detailed discussion on the need for alternative testing methods.

4.2.8  **Our consumption places high demands for information about hazardous substances in articles**

Our substantially increased consumption, the ever-faster turnover of articles in society in combination with their complexity (components, materials and chemical content) and the ever-greater import of articles from countries with poor chemicals surveillance increase the risk of exposure to hazardous substances. The aim should be to ensure that information about substances that have been classified as hazardous to human health and the environment and that are contained in articles, components and materials is eventually made available during the entire life cycle of the article, including the waste stage. This is also the import of the milestone target on information about hazardous substances in articles which the Government has adopted following a proposal from the All-Party Committee on Environmental Objectives.
Part B.
The next step in chemicals policy
5 Time for the next step

The conditions for meeting the environmental quality objective of *A Non-Toxic Environment* will not be in place by 2020 despite measures having been taken. We now need to take the next step in chemicals policy to create the conditions needed to reach the objective. This will require the priorities to be set and efforts to be concentrated around the most important factors.

The problem of hazardous substances is transboundary. The regulatory frameworks are to a great extent harmonised within the EU. Therefore, the next step in the chemicals policy needs primarily to be taken jointly within the EU. Sweden should take active leadership of these issues within the Union and drive the joint European efforts forward.

The need for societal change has been identified and based on this, two milestone targets are proposed:

- An innovation-driving REACH II.
- More effective chemicals supervision within the EU.

We also make two assessments:

- More effective chemicals supervision in Sweden.
- Intervention research and innovation, including green chemistry.
6 New chemicals regulation in the EU

6.1 Milestone target for an innovation-driving REACH II

The All-Party Committee on Environmental Objectives proposes as a milestone target:
Sweden’s efforts contribute to a revision of REACH and other relevant European regulatory frameworks, which means that:

- Chemicals regulation makes it possible to assess, treat and test groups of substances based on certain intrinsic properties, chemical structure and/or areas of use.
- The Substitution Principle shall constitute a primary basis for the authorisation of particularly hazardous substances.

No later than 2020 shall the changes be adopted within the EU and their implementation begun.

Proposal for measures:

- Development of regulations and practices in REACH for risk reduction and risk limitation based on the overall assessment of the risks associated with substances and groups of substances. The risks can stem from the intrinsic properties, chemical structure or areas of use of the substances. The existing scope in current legislation and the kind of rule changes required need to be examined more closely.
- Development of regulations and practices in REACH under which an application for authorisation of a particularly hazardous substance must always be assessed in accordance with the
Substitution Principle, i.e. in relation to the possibility of phasing out or substituting the use of the substance.

- Development of regulations and practice in a similar way in other relevant European chemicals legislation.

**Proposal for the first step of implementation:**
The Government should prepare Sweden’s negotiating position prior to the forthcoming revisions of REACH and other relevant regulatory frameworks in order to achieve the milestone target.

The Government should also task the Swedish Chemicals Agency to cooperate with the other stakeholders to set out an in-depth analysis and work plan for how Sweden should pursue the issue within the EU and in relation to other Member States. This task should also include looking into the possibility of introducing national regulations as leverage in order to develop the Substitution Principle on the EU level. The assignment should be presented no later than 2013.

### 6.1.1 The prospects of meeting the milestone target

The milestone target involves a fundamental change to REACH, which presupposes ambitious preparatory work. Sweden should also seek to ally itself with other EU Member States and other important stakeholders to bring about a radical revision of REACH.

There is a set timetable for the evaluation and revision of REACH, with sessions taking place every five years. In 2019, the Commission is to put forward proposals for changes and a major expansion of REACH. One basis for these is the general report on the application of REACH which is to be submitted in 2017. In light of this, it is our assessment that 2020 is a suitable goal for the achievement of the milestone target.

A discussion is ongoing in the European Commission in which a certain consensus have been reached regarding clarification of the fact that substitution is the ultimate objective when it comes to authorisation. Sweden should therefore support the Commission and work to improve the regulations on this point. According to the Swedish Chemicals Agency, the issue may be discussed by the
Commission in the 2012 review. This implies that a first step towards the Substitution Principle constituting a primary basis for authorisation can be taken as part of the major REACH revision that is scheduled for 2014.

To ensure that comprehensive changes to chemicals policy are in place in 2020, work to develop proposals for new regulatory principles needs to start now.

6.1.2 Reasoning

Products are developing at a much faster rate than the legislation at the same time as the import of goods from countries with very poor or non-existent chemicals surveillance is increasing rapidly. Chemicals policy therefore needs to develop in order to deal with the challenges we face.

Fundamental to the achievement of the environmental quality objective of A Non-Toxic Environment is the implementation of preventive measures that prevent humans and the environment from exposure to hazardous substances. The development of chemicals surveillance, and hence the conditions needed to reach the objective, has been in a phase of important change, including new and tougher regulations, for several years. Despite a positive development as a result of new instruments and measures in different areas, the current efforts are inadequate to put the necessary conditions in place by 2020.

REACH is an important but insufficient tool to generate knowledge on hazardous substances and to deal with the risks associated with them. Despite the increasing knowledge about the combination effects of exposure to hazardous substances, REACH does not take a holistic approach to the total use of chemicals by society and the environmental and health risks it poses. This is why there is still a need for supplementary efforts to reduce the risks in the chemicals area. Above all, the pace at which particularly hazardous substances are being phased out is too slow.

There are hence several areas where REACH needs to be improved. We have dealt with some of these in our previously proposed milestone targets that have been adopted by the Government. This applies, for example, to the need for better information require-

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ments for low-volume substances and the scope for dealing with endocrine disruptors, combination effects and nanomaterials (see Chapter 4). These milestone targets aim to improve REACH by 2020.

At the same time, it is our assessment that there is a clear need to take the next step in the work on chemicals to reach the conditions needed for a non-toxic environment. To strengthen chemicals safety and quicken the pace of innovation, significant changes need to be made to REACH and to other relevant legislation after 2020.

It must be possible to assess the risks of hazardous substances in groups

Making risk assessments for a large number of substances and developing a basis for authorisation or limitation measures in accordance with REACH involve a great deal of work. As yet, only a handful of substances have been prioritised for authorisation. A more general approach to regulation is therefore needed in order to increase the protection of human health and the environment more quickly. Stronger incentives for industry to replace hazardous substances are also needed.

Under the current legislation, substances are risk-assessed and classified individually, i.e. one substance at a time. The aim of the milestone target is to introduce regulations and practice for risk reduction based on the combined assessment of the risks associated with groups of substances. Substances can be grouped for this purpose based on common properties in their chemical structures, knowledge of common mechanisms of action (e.g. perfluorinated compounds or certain phthalates) or based on areas of use. Certain types of uses where a specific function is the aim, e.g. softeners in plastics or flame retardants in a certain product group, can give rise to the similar spread of and exposure to the substances used. Certain functions can also be associated with special properties, e.g. low degradability. These properties could also constitute a basis for the grouping of substances.

Polychlorinated biphenyls (PCBs), dioxins, polycyclic aromatic hydrocarbons (PAH) are groups of substances that have been known to be hazardous to health or the environment for a long time. The substances in these groups have a similar impact. This knowledge has led to the development of special methods for risk assessment.
which take into account the combined exposure from the substances in the group.

Risk assessments otherwise seldom take the combined impact on the environment from many different sources caused by a substance or by the effects caused by the interaction of several substances in the environment. The problems caused by chemicals are often due to the combined exposure, however. Persistent organic substances can be found in many different variants, the risks of which should be evaluated together. They sometimes have properties that are problematic for human health and the environment and new variants are always being developed. Combined assessments are also important for substances that have similar harmful effects. These include endocrine disruptors that can affect child development and our reproduction21.

In addition, light is gradually being shed on new groups of problem substances. Examples of such groups include extremely persistent perfluorinated and polyfluorinated substances used in e.g. textiles, shoes, detergents, car-care products and ski waxes. Employing the Precautionary Principle, it is therefore important to be able to take measures even if not all the risks of a specific substance are known.

It is well known that substances with unacceptable properties in an area of use are often replaced by substances with the same function, often with a similar chemical structure and similar properties - which in many cases also means the same hazardous properties. An important step for chemicals surveillance would therefore be the possibility to perform risk assessments on groups of substances (groupwise risk assessment). The risk assessment should be based on the combined exposure to the substances in the group, and risk-reducing measures relating to the overall risk scenario.

Focus should first and foremost be put on groups of substances to which children are at particular risk of exposure since many toys and everyday articles can contain small amounts of certain substances which children risk assimilating in different ways. These include brominated flame retardants, perfluorinated compounds, phthalates and heavy metals.

One group of substances that should be prioritised both for environmental and a health reasons is extremely persistent and bioaccumulative substances. Substances that resist degradation to a high degree and are bioaccumulative always constitute a risk for human

21 See footnote 20.
health and the environment because if and when negative effects manifest themselves, it takes a very long time before restrictions and other measures show results. Extremely persistent and bio-accumulative substances are currently not included in the REACH definition of substances of very high concern. It is our assessment, however, that they can be included under the heading “Substances that cause a similar degree of concern”.

The wording of the objective stipulating that a decision shall have been adopted by 2020 enabling the management of groups of substances provides scope for different solutions in connection with risk assessment and limitation. The existing scope in current legislation and the kind of rule changes required need to be examined more closely.

A strengthened Substitution Principle

There is a general goal in REACH stating that substances of high concern that are subject to authorisation shall be gradually replaced by alternative substances or technologies, when it is economically and technically feasible. These regulations are similar to the general rules of concern in the Swedish Environmental Code with a few important differences, namely that they only cover particularly hazardous substances and only certain areas of use. Neither are the regulations on authorisation in REACH totally consistent as regards the application of the Substitution Principle.

The Substitution Principle in REACH is weaker and more unclear than in other European legislation, where requirements for the “best possible technology” have driven forward development and innovation for stronger environmental protection. In the same way, REACH needs to be strengthened so that it promotes innovation to a greater degree and provides strong incentives for industry to phase out and substitute particularly hazardous substances more quickly. The Substitution Principle should be a primary basis for the authorisation of particularly hazardous substances.
6.1.3 Measures

We propose the following measures to contribute to achievement of the milestone target:

- Development of regulations and practices in REACH for risk reduction and risk limitation based on the overall assessment of the risks associated with substances and groups of substances. The risks can stem from the intrinsic properties, chemical structure or areas of use of the substances. The existing scope in current legislation and what type of rule changes are required need to be examined more closely.

- Development of regulations and practices in REACH under which an authorisation application for a particularly hazardous substance must always be assessed in accordance with the Substitution Principle, i.e. in relation to the possibility of phasing out or substituting the use of the substance.

- Development of regulations and practice in a similar way in other relevant European chemicals legislation.

Development of regulations and practice in order to be able to assess the risks of groups of substances

REACH is a piece of legislation that is focused primarily on the assessment of individual substances. REACH has no system for dealing with broad evaluations of chemical groups. REACH should be reviewed as soon as possible and improved so that it is better adapted to evaluating groups of chemicals since there is a clear need for such legislation. Within the EU, the need to deal with groups of chemicals has so far been solved via strategic political decisions in each individual case. Some examples are heavy metals like cadmium and mercury. REACH would be a natural piece of legislation to evaluate groups, which would also transfer the responsibility for developing background documentation from the Commission to industry. This should include changes both in the requirements for registration and in the regulations on substance evaluation. Since this implies a fundamental development of REACH, it will be the right time to discuss the issue in 2017–2019, when large parts of REACH are scheduled for review.

22 See footnote 20.
There are no formal obstacles to regulating substances in groups as regards risk management in REACH (authorisation and restrictions). This has also been done in some cases (e.g. for variants of asbestos and phthalates in children’s articles). Denmark has recently (2011) proposed general restrictions for a group of four phthalates in certain product groups that are used in the indoor environment or where there is direct skin contact. Denmark proposes that these substances are to be treated the same as a group, based on an overall risk assessment of the combined exposure to phthalates since they can have endocrine-disturbing effects.

Risk assessment and substance evaluation in REACH are strongly focused on the assessment of individual substances, however. There are admittedly suggestions in the regulations on substance evaluation that belonging to a group may be a basis for prioritisation (Articles 44.1 and 47.1), but there are several more problems associated with using substance evaluations to assess the risks of groups of substances.23

One problem is that the evaluation is limited to registered substances24. Substances that occur in volumes less than 1 tonne per year and manufacturer/importer can therefore not be included, and existing substances that are handled in volumes below 100 tonnes can only be included after 2018. The industry has no obligation to supply background data on substances that are not subject to registration, which makes risk assessment more difficult. Furthermore, substances that are to be evaluated are handled individually. The Member State Committee at ECHA determines which substances are to be prioritised following proposals from the competent authorities in the Member States. The authorities in each Member State therefore have considerable influence over which substances are to be prioritised, which means it is more difficult to have a uniform strategy across the EU. Furthermore, there is no “product register” on the EU level, which means that it is difficult

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23 See footnote 20.
24 Substances manufactured or imported in volumes of at least 1 000 tonnes per manufacturer/importer and year, CMR substances manufactured or imported in volumes of at least 1 tonne per manufacturer/importer and year, substances that fulfil the criteria for being classed as very toxic for aquatic organisms and that can cause harmful long-term effects in the aquatic environment in accordance with Directive 67/548/EEC and that are manufactured or imported in volumes of at least 100 tonnes per manufacturer/importer and year subject to current registration requirements. From 31 May 2013, the requirements also apply to substances manufactured or imported in volumes of at least 100 tonnes per manufacturer/importer and year. From 31 May 2018 the requirements also apply to substances manufactured or imported in volumes of at least 1 tonne per manufacturer/importer and year.
to know which products containing a certain substance are on the market\textsuperscript{25}.

There are other regulations within the EU that require risk assessments, including those governing medicinal products, pesticides, food contact materials and cosmetics. These regulatory frameworks can in certain cases be targeted at groups of substances, e.g. allergens in cosmetics and hygiene products.

**Development of regulations and practices that strengthen the Substitution Principle within REACH**

Under REACH, substances of concern are to be replaced by less hazardous substances or technologies, where suitable economically and technically viable alternatives are available. The regulations on authorisation in REACH are however not totally consistent as regards the application of the Substitution Principle\textsuperscript{26}.

A change in the authorisation procedure should also be pursued in order to develop the Substitution Principle and create incentives for the phase-out of hazardous substances. It is currently not made clear in all the parts that the person applying for authorisation is obliged to analyse the existing alternatives and assess the scope for substitution.

In addition to improving REACH, the regulations and practices in adjacent European legislation are in need of review. In connection with the review and revision of relevant European legislation (e.g. regulations governing biocides, medicinal products or relevant product directives), a systematic review of the principles of substitution in the current and adjacent legislation should also be performed, in order to create the conditions needed for concordant chemicals regulation in the EU.

As a first step towards implementation of the milestone target, we propose that the Government tasks the Swedish Chemicals Agency to examine the scope for improving and rationalising REACH, focusing primarily on the possibility of treating and authorising groups of substances based on e.g. chemical composition, intrinsic properties and/or areas of use. The scope for making the Substitution Principle

\textsuperscript{25} See footnote 20.

\textsuperscript{26} Article 60.2, for example, states that diffuse and dispersive uses of the substance are to be taken into account when granting authorisation, i.e. impact via other routes than the current area of application are also to be considered. The same should apply when granting authorisation in accordance with Article 60.4, which is not the case today.
a primary basis for authorisation should also be examined. In parallel, a strategy for contacts with the European Commission and other Member States should also be developed. This strategy should also develop different proposals for testing the practical possibilities of groupwise assessment in the current legislation, similar to the Danish restriction proposal on phthalates.

6.1.4 Impact assessment

Effectiveness

The contribution made by the milestone target to the environmental quality objective

If the proposed milestone target is reached, it will mark an important development in European chemicals regulation. A change in accordance with the milestone target so that risk assessment and authorisation can be targeted at groups of substances based on certain intrinsic properties, chemical composition and/or area of use will accelerate the phase-out hazardous substances. The focus of the milestone target on more substitution will also increase the incentives for innovation and self-regulation as regards the manufacture and use of hazardous substances.

The connection to other environmental objectives

The occurrence of hazardous substances affects our chances of reaching several other environmental quality objectives, above all the water-related objectives of Flourishing Lakes and Streams, Good-Quality Groundwater and A Balanced Marine Environment, Flourishing Coastal Areas and Archipelagos, but also A Good Built Environment, Limited Climate Impact and A Rich Diversity of Plant and Animal Life. The occurrence of hazardous substances also affects public health.
Alternative courses of action

There are two different courses of action that should not be seen as alternatives but rather as supplements to the change in focus proposed in the milestone target.

One way is to continue to authorise substances more or less one by one. A precondition for reaching the environmental quality objective within a reasonable time limit using this working method is for EU institutions, Sweden and other Member States to allocate significantly greater resources to the area than is currently the case. It is our assessment that this method is not really feasible. Authorising individual substances will nevertheless continue to be an important part of chemicals surveillance and should be seen as a supplement to groupwise authorisation.

The other course of action is to focus regulation on areas or product groups where hazardous substances occur. This working method has also been traditionally used within the EU, including as part of product directives for specific product groups. Examples of such directives include the Toy Safety Directive\textsuperscript{\ref{ref:27}}, the Directive on Electrical and Electronic Products\textsuperscript{\ref{ref:28}} and the Directive on Batteries and Accumulators\textsuperscript{\ref{ref:29}}. Our assessment is that product-specific directives are needed to supplement the overarching REACH regulation.

The European REACH regulation represents a new focus of chemicals policy as it puts responsibility onto manufacturers and importers for guaranteeing safe use of the substances and for ensuring that the health and environmental properties of manufactured and imported hazardous substances are well documented. The new approach to chemicals policy that is behind the implementation of REACH provides much better prerequisites for reaching the environmental quality objective of \textit{A Non-Toxic Environment}.

The main focus of the efforts to rationalise chemicals policy should therefore be on improving REACH.

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\textsuperscript{29} DIRECTIVE 2006/66/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC.
Compatibility

Right of determination

The milestone target presupposes a major change in the fundamental European chemicals legislation, REACH. The scope for influence lies in driving forward development in the desired direction, i.a. in connection with the planned reviews of REACH. This requires contacts and cooperation with EU institutions and key Member States.

The current REACH is to be fully implemented by 2018. The intention is to review major parts of REACH in 2017-2019.

The part of the milestone target relating to a strengthening of the Substitution Principle can be included in the continuous review of REACH. It is the assessment of the Swedish Chemicals Agency that this issue, linked to particularly hazardous substances, may be considered in the 2012 review.30

The competitiveness of the business sector

The milestone target implies above all a faster phase-out of hazardous substances without tightening the requirements or expanding the scope and application for REACH.

Chapter 14 presents calculations of the costs to Europe’s chemicals industry of implementing REACH. These calculations were done prior to the decision on REACH at the beginning of the 2000s and presuppose the achievement of the REACH objectives within an eleven-year period. The annual costs of REACH were estimated at that time to be around one percent of the chemicals industry’s value added. The calculations were done at the beginning of the 2000s and were based on the industry in the EU at that time (EU-15) and on certain assumptions. They should therefore be seen as indicators of the current costs associated with REACH.

One of the aims of the milestone target is to achieve a faster phase-out of certain substances by subjecting them to the authorisation procedure groupwise instead of individually. REACH came into force in 2007. According to the milestone target, groupwise authorisation shall begin to apply around 2020, i.e. 13 years after the introduction of REACH. The faster phase-out goal in the milestone target is to be considered in this perspective, which

30 See footnote 20.
means that the target will probably not increase costs for the industry compared to the calculations made prior to the decision to introduce REACH. Implementation of the target’s measures can in general not be assumed to lead to any noticeable deterioration in the profitability and competitiveness of the chemicals industry.

It should also be possible to strengthen competitiveness through regulation since it benefits businesses that are pioneers in the chemicals area. The fact that hazardous substances are phased out and replaced by less hazardous ones should also benefit industries that use chemicals.

**Cost-efficiency**

Our assessment is that the two components of the milestone target; the scope for the groupwise authorisation of substances and the Substitution Principle, create the conditions needed for greater cost-efficiency in the efforts to reach the environmental quality objective.

There are two types of efficiency gains. The first is connected to more rational management of risk assessments and authorisation of hazardous substances. A risk assessment that covers groups of substances with common properties should rationalise information collection and the documentation of tests and analyses. It saves both time and resources. The measures would therefore lead to cost savings for both the businesses involved and the authorities on the national and European level.

The other type of efficiency gain is more dynamic and is connected to the fact that the measures proposed are innovation-driving. The main aim of groupwise authorisation of hazardous substances is to accelerate the phase-out of hazardous substances. A fast phase-out provides scope for, and even necessitates, a development of new products and new production methods. Businesses that are able to utilise this situation can strengthen their competitiveness.

Stronger and more effective European supervision will reinforce the effects of an improved and innovation-driving REACH, see proposals for milestone targets in Chapter 7.
**Distributional impacts**

It is our assessment that the milestone target will not lead to any distributional impacts. The measures associated with the milestone target are to be seen as efforts to achieve an efficient implementation of the objectives that underpin REACH. In addition to producers and importers, users in industry, trade and services, as well as consumers, may be faced with higher costs for articles that contain chemicals. On the other hand, the trade sector, consumers and purchasers in the public sector alike will have access to products and articles that contain fewer hazardous substances. The price increases of chemicals resulting from a full implementation of REACH are deemed to be very limited (see Chapter 14 An impact assessment of the strategy for a non-toxic environment).

**Effects on government finances**

In a first step, the proposal means that the relevant agencies, primarily the Swedish Chemicals Agency, will need to set aside resources in order to carry out an in-depth analysis and draw up a work plan for how Sweden is to pursue the issue in the EU and in relation to other Member States. The Swedish Chemicals Agency also needs to lobby EU institutions and other Member States to gain support for the Swedish position on a development of REACH along the lines stipulated in the milestone target.

It is the assessment of the All-Party Committee on Environmental Objectives that these working tasks can be performed within the current resource framework.
7 Effective supervision

7.1 Milestone target on more effective chemicals supervision within the EU

The All-Party Committee on Environmental Objectives proposes as a milestone target:
Sweden’s efforts shall help to bring about a decision by the EU on improved cooperation regarding the supervision of hazardous substances, both concerning EU regulations and international conventions, no later than 2016.

Proposal for measures:

- Revision of EU Recommendation (2001/331/EC) providing for minimum criteria for environmental inspections in the Member States.

- More systematic support for exchanges of experience and methodological development for effective supervision.

- Development of goals and indicators for supervision on the EU level.

- Introduction of a voluntary review system for the supervisory authorities in the Member States.

In addition to these measures, knowledge within the EU about how supervision and implementation are performed in the Union should be developed. In connection with the review and revision of relevant European environmental legislation, supervision and compliance in the current and adjacent legislation

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Effective supervision should also be systematically reviewed and strengthened in order to create the conditions needed for harmonised supervision in the EU.

**The first step in the implementation:**
The Government should task the Swedish Chemicals Agency to cooperate with the other stakeholders and develop an in-depth analysis and work plan for how Sweden should pursue the issue within the EU and in relation to other Member States. The Agency should present the results no later than December 2013.

### 7.1.1 The prospects of meeting the milestone target

If the milestone target is to be reached, the European Commission needs to prioritise measures that aim to achieve more formalised cooperation on supervision in the chemicals area. A review is currently ongoing within the EU of how environmental supervision and the implementation of environmental law can be improved. In this work, the Commission is prioritising measures aimed at strengthening compliance with European environmental legislation. The provision of knowledge on supervision and cooperation among the Member States is also being prioritised. These measures primarily concern the supervision of hazardous operations. Other supervision, e.g. market surveillance, is not included. It is our assessment that a revision of the Recommendation so that it also includes market surveillance of hazardous substances is a rather long process. It may therefore be difficult to reach this part of the milestone target by 2016.

The other measures do not require any policy changes and should be achievable by 2016. It should therefore be possible over the next four to five years to come to a decision within the EU that is in harmony with the milestone target.

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32 COM(2012) 95 final. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Improving the delivery of benefits from the EU environment measures: building confidence through better knowledge and responsiveness.
7.1.2 Reasoning

Supervision\(^{33}\) is an important component of chemicals regulation if it is to have practical impact and thus an effect on health and the environment. Well-functioning supervision reduces the risk of uneven competition between companies and can contribute to the more effective development of regulations if the lessons learned from supervision activities are taken into account in the legislative process.

Chemicals legislation has basically been harmonised within the EU, while it is the responsibility of each Member State to check that its businesses fulfil the requirements in e.g. REACH. It is important that the supervisory authorities in the Member States cooperate with the European Chemicals Agency, ECHA, to ensure efficient application and development of REACH. There is currently cooperation among Member State supervisory authorities in the form of various intra-EU inspection projects\(^{34}\). One such project was implemented in 2011 which concerned i.a. the control of data sheets and information to employees on the substances they handle.

The regulations in the chemicals area are complex and common practice for the application of REACH is still largely lacking. To secure the success of the EU chemicals policy and competitive neutrality, we believe that increased cooperation is needed between EU Member States with regard to supervision in the chemicals area. This relates to the supervision of both chemical products and of hazardous substances in articles. The supervision of articles imported from countries outside the EU is in particular need of development.

A development of EU supervision requirements can be aimed at promoting systematic and risk-based supervisory measures. The

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\(^{33}\) Supervision is used here to describe independent analysis activity performed to check whether a facility that is subject to supervision fulfils requirements laid down in legislation or other binding regulations and where necessary may lead to a decision to implement measures aimed at achieving redress from the facility operator in accordance with the Government’s definition (Communication 2009/10:79) This report deals primarily with chemicals supervision which means the supervision of chemical products and articles or their import, export and handling pursuant to rules that we have chosen to discuss. Applies primarily to supervision in accordance with REACH and CLP, a few other EU regulations, certain product directives and the Swedish Environmental Code.

\(^{34}\) Forum for the Exchange of Information on Enforcement (compulsory for EU Member States and EEA countries) that discusses the implementation and application of REACH. Cooperation also takes place within CLEEN (Chemicals Legislation European Enforcement Network) in which European enforcement authorities consult on common action projects in order to coordinate and improve compliance with European chemicals legislation. CLEEN is basically a forum for the exchange of information and is a voluntary undertaking for the Member States.
accountability and self-inspection of businesses cannot however be replaced by supervisory measures. There is therefore a need to improve the feedback of experiences from supervision activities, for example, by disseminating best practice examples and providing method support both within the EU and nationally.

The supervision of hazardous substances in articles is particularly demanding as a result of the complex regulatory framework and the large number of facilities subject to supervision. Increased cooperation between supervisory authorities in the Member States would probably also be part of the solution for article supervision. The Forum for Exchange of Information on Enforcement (Forum) is a network comprising the supervisory authorities of the Member States\textsuperscript{35}. The goal is to coordinate and develop chemicals supervision within the EU. The Forum has the status of a committee under ECHA and its work has helped improve supervision activities in Member States and led to greater cooperation among them. The Forum should be able to serve as an example of supervision cooperation, even with regard to other regulatory frameworks. Greater cooperation among supervisory authorities, industrial organisations and NGOs can also contribute to more effective supervision.

The option of imposing some form of minimum requirements for supervision on the Member States should be considered. Requirements for Member State supervision are imposed in other regulatory areas, but are basically non-existent in chemicals and product legislation.

7.1.3 Measures

We propose four main measures that can help achieve the milestone target on improved supervision cooperation within the EU:

- Revision of the EU Recommendation providing for minimum criteria for environmental inspections in the Member States (2001/331/EC)
- More systematic support for exchanges of experience and methodological development for effective supervision.

\textsuperscript{35} REACH, Articles 76f, 77.4 and 86.
• Development of goals and indicators for supervision on the EU level.

• Introduction of a voluntary review system for the supervisory authorities.

In addition to these measures, knowledge within the EU about how supervision and implementation are performed in the Union should be improved. In connection with the review and revision of relevant European environmental legislation, supervision and compliance in the current and adjacent legislation should also be systematically reviewed and strengthened in order to create the conditions needed for harmonised supervision in the EU.

Revision of the EU recommendation on environmental inspections

The EU Recommendation providing for minimum criteria for environmental inspections in the Member States[^36] is from 2001 and has not been revised since then. This means that it does not consider the new Industrial Emissions Directive[^37], the new Waste Framework Directive[^38] or various strategic documents such as the Road Map to a Resource Efficient Europe[^39]. The recommendation covers inspections of hazardous operations. A revision should also include the introduction of minimum criteria for market surveillance in accordance with REACH and other relevant regulatory frameworks. The introduction of minimum criteria for chemicals supervision should constitute an important basis for systematic and risk-based supervision.

[^36]: See footnote 31.
More systematic support for exchanges of experience and methodological development

More systematic support for exchanges of experience and methodological development for effective supervision can be provided, for example, by the European Commission promoting transnational cooperation on supervision. Potential promotion measures include the development and promotion of the use of platforms and networks. The feedback of supervision experience and support for disseminating best practice and method support can be improved both on the EU level and on the national level.

Development of goals and indicators for supervision on the EU level

This work should focus on promoting systematic and risk-based supervision measures.

Introduction of a voluntary review system for the supervisory authorities

A voluntary review system can be based on the same model as the IMPEL Review Initiative. IMPEL is an informal cooperation project among environmental agencies in the Member States. The network has been in place since 1992 and is an important forum for exchanges of experience and the dissemination of best practice.

The aim of these initiatives is to strengthen supervision on the EU level in order to promote better implementation of EU environmental legislation. Many decisions have been taken within the EU in the environmental field but implementation is poor both within the EU and in Sweden. Greater harmonisation in supervision is welcome if it leads to major improvements.

In a first step, the Government should task the Swedish Chemicals Agency to examine how cooperation on supervision within the EU can be improved, based on our proposals. The Agency should also submit proposals for how Sweden can drive forward this issue within the EU.

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40 IMPEL (Implementation and Enforcement of Environmental Law) is an informal association of environmental authorities in the EU Member States, candidate countries and EEA countries. The aim of IMPEL is to pursue work in the EU to ensure effective application of environmental legislation. See http://www.impel.eu
The Agency should present the results no later than June 2013. The work should also include looking at the experience gained from IMPEL.

7.1.4 Impact assessment

Effectiveness

The contribution made by the milestone target to the environmental quality objective

Efficient and effective supervision and surveillance are central if the chemicals policy is to have a practical impact and hence the intended effect on human health and the environment. Cooperation between national supervisory authorities that is deemed to be inadequate, along with differing, and sometimes far too low, levels of ambition in the supervision, lead to shortcomings in the surveillance of articles and products that contain hazardous substances.

The connection to other environmental objectives

The occurrence of hazardous substances affects our chances of reaching several other environmental quality objectives, above all the water-related objectives of Flourishing Lakes and Streams, Good-Quality Groundwater and A Balanced Marine Environment, Flourishing Coastal Areas and Archipelagos, but also A Good Built Environment, Limited Climate Impact and A Rich Diversity of Plant and Animal Life. The occurrence of hazardous substances also affects public health.

Alternative courses of action

The milestone target on more effective chemicals surveillance also involves greater harmonisation of supervision in the Member States. The measures to achieve the target also include initiatives to increase voluntary cooperation among the supervisory authorities in the Member States. An alternative course of action is to rely entirely on voluntary cooperation between the Member States and ECHA without binding requirements from EU legislation. As is clear from the reasoning for the milestone target, it is our assessment that this approach is not sufficient.
Compatibility

Right of determination

Chemicals legislation is basically completely harmonised within the EU. One exception is the enforcement of the legislation under which it is the responsibility of each Member State to ensure that its businesses are fulfilling the requirements in e.g. REACH.

The milestone target relating to cooperation on the Member States’ enforcement of the chemicals legislation also involves greater influence from the EU as regards decisions on the scope and focus of national supervision. This concerns issues such as common standards for analysis methods and minimum inspection levels.

Circumstances in which the EU is given powers of influence over the supervision activities of the Member States and where the fundamental regulations of supervision are harmonised are nothing new within the Union. Requirements on the supervision of the Member States are in place within other regulatory areas.

The competitiveness of Swedish industry

Swedish industrial organisations have called for initiatives to accelerate EU efforts to bring about a common approach and common practice at Member State supervisory authorities in order to create a level playing field for the chemicals industry. The milestone target for more effective chemicals surveillance within the EU is a step forward in the efforts to create fair and even market conditions for businesses in EU Member States.

Cost-efficiency

A well-functioning internal market will help ensure the necessary transition of chemicals management in Europe can take place efficiently and at a low cost to society. Weak national supervision can function as an indirect subsidy of a Member State’s own chemicals industry, which constitutes a deviation from the principles of the internal market. One consequence of the measures in the milestone target is that the differences between supervision in the Member States as regards level of ambition and focus will diminish. This will strengthen the internal market.
The milestone target for more effective chemicals surveillance in the EU will help bring about the necessary transition of chemicals management in Europe in a cost-efficient manner. It should be emphasised, however, that the main aim is to ensure that European chemicals legislation will have the desired impact.

**Distributional impacts**

Well-functioning supervision is a fundamental condition that needs to be in place if the objectives of European chemicals legislation are to be reached. The measures associated with the milestone target are to be seen as efforts to achieve an efficient implementation of the objectives that underpin REACH. The distributional impacts of the integrated strategy for a non-toxic environment are assessed in Chapter 14 to be virtually negligible. The milestone target on more effective chemicals surveillance in the EU applies in general to the entire chemicals policy and therefore has no specific distributional impacts.

**Effects on government finances**

Increased cooperation among supervisory authorities in the EU will require resources to be set aside primarily within the Swedish Chemicals Agency. This is particularly true if Sweden has ambitions to take a leading role in the development.

### 7.2 Clear and strategic governance of chemicals supervision in Sweden

<table>
<thead>
<tr>
<th>The All-Party Committee’s assessment is that:</th>
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<tr>
<td>The comprehensive and in parts complicated regulatory framework for chemicals creates a special need for clear and strategic governance. This is not least true of the supervision of articles that contain hazardous substances. The Government should direct the central agencies in order to further rationalise the supervision of articles and other chemicals supervision on the national, regional and local level.</td>
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7.2.1 Reasoning

The responsibility for chemicals supervision is divided among different central agencies and the municipalities. The Swedish Chemicals Agency is responsible for the operative supervision of manufacturers and importers (primary suppliers) and for providing guidance on supervision to county councils and county administrative boards. The supervision may refer to e.g. labelling, child protection, pesticides, REACH, product safety and prohibited substances in articles. The agencies with adjacent remits for supervision and supervision guidance include the Swedish Environmental Protection Agency, the Swedish Civil Contingencies Agency, the Swedish Work Environment Authority, the National Board of Housing, Building and Planning and the Medical Products Agency.

As regards prohibited substances in articles, the Swedish Chemicals Agency partly shares the responsibility for supervision with the municipalities when it comes to the retail trade. There are an estimated 30 000 businesses that need to be supervised, but since there are no compulsory product registers, as there are for chemicals, it is difficult for the supervisory authorities to determine who and what is to be subject to supervision.

In its final report, the REACH Inquiry pointed out that it is unreasonable to expect several central agencies, 21 county administrative boards and 290 municipalities, who each set their own priorities based on different starting-points, to be able to coordinate themselves without some form of coordination of at least the central agencies[41]. The All-Party Committee on Environmental Objectives shares this view. Strategic governance of supervision is also important so that the resource pool for supervision can be used as effectively as possible.

A new environmental supervision ordinance (2011:13) came into force on 1 March 2011[42]. The objective of this new ordinance is to clarify the regulatory framework for supervision. The new ordinance does not mean, however, that the need for strategic governance has been reduced. This is particularly true with regard to article supervision. Supervision of substances in articles requires methods that are adapted to the diversity of articles and activities that exist on the market. Supervision of articles and products is fundamental to

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[42] Replaces the previous ordinance (1998:902) on supervision in accordance with the Environmental Code (supervision ordinance).
prevent hazardous substances in articles that are manufactured in other countries from entering our natural cycles (see SOU 2008:73 for a detailed description of this problem).

The Swedish Chemicals Agency’s ongoing assignment to develop an action plan for a toxic-free everyday environment includes increasing article supervision in order to increase knowledge about hazardous substances in articles among both suppliers and users. In December 2011, the Swedish Chemicals Agency presented the results of its assignment to develop a strategy for the supervision of environmental and health risks associated with chemicals in articles. The strategy has two main parts: one that concerns those groups of articles and industries that should be allocated priority in article supervision and one that concerns cooperation with the municipalities. The proposals in the report are expected to lead to improved competition within the priority industries and a reduction in the occurrence of hazardous substances in articles. Cooperation with the municipalities is expected to lead to an increase in their supervisory skills and to more geographically widespread article supervision.43

The Swedish Chemicals Agency has also previously proposed different ways of improving the effectiveness of article supervision, e.g. by setting strategic priorities, cooperation among agencies and by coordinating it with instruments, e.g. feeding the experience gained from supervision to improve rule-making.44 The Agency is currently working on various supervision projects on, for example, product and article type, statutory requirement or regional inspection rounds, often in cooperation with municipalities and county administrative boards. In 2012, the Swedish Chemicals Agency has run a cooperation project with the Swedish Environmental Protection Agency, municipalities and county administrative boards, focusing on REACH. The aim of this project is to increase the knowledge about REACH among the supervisory authorities and to contribute to increasing knowledge about the regulation at inspected businesses.45

45 Swedish Environmental Protection Agency and Swedish Chemicals Agency REACH-supervision 2012 (Promemoria) 2 December 2011.
8 Intervention research and innovation, including green chemistry

8.1 Strategy for intervention research and innovation, including green chemistry

The All-Party Committee’s assessment is that:
There is a need for more intervention research on hazardous substances, including green chemistry⁴⁶. Research and innovation are critical in order for industry to be able to increase the pace of phase-out and substitution of hazardous substances. This should be reflected in forthcoming research bills and innovations strategies.

Proposal for measures:
In forthcoming research and innovation policy bills, the Government should highlight the opportunities that intervention research provides as regards hazardous substances, when it comes to both environmental and innovation benefits.

The Government should also task relevant R&D financiers to develop a strategy including a programme for intervention research and innovation in the chemical area, including green chemistry. This assignment should be reported to the Government no later than December 2013.

⁴⁶ Green chemistry refers to the development of new substances with low toxicity and other properties that are good from an environmental and health point of view and do not affect the climate. It also refers to the use of environmentally sound and energy-efficient methods and increasing the use of non-fossil raw materials and renewable energy when manufacturing chemicals.
8.1.1 Reasoning

Research, development and innovation are of crucial significance if we are to be able to reach the environmental objectives. This is particularly true of the environmental objective of *A Non-Toxic Environment*, the aim of which is to protect human health and the environment from hazardous substances. Research and innovation in this area also create innovation policy opportunities.

The chemicals area has important potential for innovations

There is a considerable need to replace hazardous substances and production processes with new substances and processes that are less hazardous to health and the environment. The driving-forces behind the substitution of hazardous substances include European chemicals legislation and businesses that work consciously and proactively to avoid hazardous substances in their articles and products.

Research, development and innovations are key, if we are to be able to substitute hazardous substances. New substances and production processes in the area have even been shown to lead to other positive effects, including major energy savings for businesses as a result of new production processes.

Through goal-driven cooperation between research and business, Sweden can become one of the leading innovation nations in the area known sometimes as “green chemistry”. Sweden should utilise and develop this potential, which not only contributes to a better environment but can also create the conditions needed for the development of modern innovative Swedish industry.

Research strengthens Sweden’s negotiations in the EU and internationally

In light of the fact that chemicals policy is more or less harmonised within the EU and that a great deal of cooperation already occurs internationally, Sweden needs to work actively both within the EU and internationally to drive forward developments in these areas. Research-based evidence is very important if Swedish viewpoints are to have an impact in negotiations.
Intervention research leads to cost-efficient policies

Intervention research is important to allow society to be able to choose the most effective and cost-efficient measures and instruments possible in our efforts to reach the objective of A Non-Toxic Environment. More of society’s research resources should be used to rectify the problems and not just to describe the environmental problems we face as regards hazardous substances.

Under REACH legislation, it is the responsibility of businesses to generate data on individual substances and their potentially hazardous properties.

Following proposals from the All-Party Committee on Environmental Objectives, the Government has adopted a milestone target on knowledge of the health and environmental properties of substances, a target that is also part of the strategy for a non-toxic environment (See Chapter 4).

Development of screening methods

In order to deal with the particularly explicit lack of data on the environmental and health effects of low-volume substances, research and the development of screening methods are required to be able to identify the substances that pose a potential risk. In this context, it is probably important to develop computer-based methods and what are known as in-vitro methods (e.g. cell cultivation trials) and other alternative test methods.

Opportunities for research and innovation policy

It is the All-Party Committee’s opinion that the focus of intervention research and innovation in the chemicals field should be reflected in the Government’s forthcoming research bills for the next four years and the forthcoming national innovation strategy. Both are to be presented during the autumn of 2012. On 15 March 2012, the Committee submitted a report to the Government prior to the forthcoming research bill containing overarching assessments on the need for research in the chemicals field.

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47 Communication from the All-Party Committee on Environmental Objectives prior to the 2012 research policy bill, 15 March 2012.
8.1.2 Measures

We propose two measures aimed at promoting more intervention research and innovation, including green chemistry:

- In forthcoming research and innovation policy bills, the Government should highlight the opportunities that intervention research provides as regards hazardous substances, when it comes to both environmental and innovation benefits.

- The Government should also task relevant R&D financiers to develop a strategy including a programme for intervention research and innovation in the chemicals field, including green chemistry. The assignment should be reported no later than December 2013.

Intervention research on hazardous substances should be highlighted in forthcoming research and innovation policy bills

As a consequence of the development of REACH and other EU regulations in the chemicals field, many of the particularly hazardous substances used today will gradually be phased out. When the next step is taken in the development of Reach, as we propose above, the phase-out of particularly hazardous substances will be further strengthened.

Research and innovation is therefore required that can promote the development of “green chemistry”. As a result of such an initiative, academic research can be coupled together with the development and innovation work done in the business sector. It provides opportunities for the compiling and dissemination of knowledge on green chemicals, at the same time as the development of such substances can be accelerated.

An efficient use of energy and physical resources, along with an increased share of bio-based raw materials at the expense of petroleum-based ones, can generally contribute to reducing the spread of hazardous substances. There is also a major need for the use of chemical substances in the development of new technology in these areas. The driving forces of industry to pursue development with regard to resource efficiency and low climate impact are deemed to be strong. But there are not the corresponding driving forces to develop chemicals and/or production processes with sound environmental and...
health properties from a toxicological point of view. It is therefore important to stimulate such a development. This can simultaneously lead to synergies in energy and resource efficiency and reduced climate impact.

The concept of green chemistry includes the aim of avoiding hazardous and climate-damaging properties when developing new chemical substances, striving for low toxicity in substances that are used in various production processes, the use of green and energy-efficient methods and increasing the use of non-fossil raw materials and renewable energy when producing chemicals. The concept of green chemistry was formulated in the early 1990s. Today, the overlapping concepts of “green chemistry” and “sustainable chemistry” are used internationally, partly with the same meaning as the above objectives but also often in a wider sense. Sustainable chemistry often includes economic and social aspects in addition to environmental ones.

A strategy for intervention research and innovation in the chemicals field

The Government should also task relevant R&D financiers to develop a strategy including a programme for intervention research and innovation in the chemicals field, including green chemistry. This assignment should be performed in cooperation with the business sector and research and look at the conditions and focus for a strategy to promote intervention research and development of green chemistry. This assignment should be reported to the Government no later than December 2013.

The strategy should i.a. contain initiatives to promote the development of green chemistry, i.e. research and innovation to develop sustainable chemicals and sustainable chemical use. To promote the substitution of hazardous substances, initiatives for innovation should include the development, manufacture and use of substances and manufacturing processes that can lead to reduced environmental and health risks.

The focus of the measures means more research on the effectiveness and the socioeconomic effect of different types of instruments and measures in the chemicals field. Research is needed into which methods are effective at reducing the risks of exposure to hazardous substances. A good knowledge base is a prerequisite for being able
to allocate the right priorities in the development of both chemicals policy and regulations.

The research should be performed in close cooperation with agencies and industry. Cross-cutting approaches are above all needed where the research problems are formulated jointly based on different science, technology, medicine and social science disciplines. Measures and instruments cannot be seen from a strictly scientific perspective and social and economic aspects must also be considered. Increased international cooperation is also required.

Measures close to the source are central if problems are to be solved as effectively as possible and to prevent humans and the environment from being exposed to hazardous substances. To find the most effective measures, a life cycle perspective is needed that takes into consideration the risk of exposure in all stages, from production, via use, to recovery and disposal.

The strategy should utilise the opportunity to strengthen Swedish research and industrial development in order to give Sweden a competitive edge and prominent place in the development of tomorrow’s chemical alternatives on international markets.

8.2 Research and knowledge development on environmental and health effects

8.2.1 Central areas for future chemicals surveillance

Chemicals surveillance is fundamental in order to prevent damage to human health and the environment. This requires knowledge of the properties and spread of chemical substances. Continued research and other knowledge development in the chemicals field is vital and should be prioritised.

One of the lessons learned from the work on this strategy is that the lack of general knowledge about the environmental and health effects of chemicals as well as the lack of data on the properties of individual chemicals often hinder the development of chemicals surveillance and the formulation of objectives, strategies and measures. Similar conclusions have been reached in the action plan for a toxic-free everyday environment developed by the Swedish Chemicals Agency at the request of the Government. There is an

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adopted milestone target for greater knowledge about the environmental and health properties of substances (see Section 4.1.2). This target focuses primarily on the knowledge generated as a result of different types of data requirements, such as those stipulated in REACH.

Under REACH legislation, it is the responsibility of businesses to generate data on individual substances and their potentially toxicological and ecotoxicological properties, i.e. impact research. Our assessment is therefore that society's resources should be used to a greater extent than they are today to improve our knowledge about the measures required to solve the problems associated with the manufacture and use of hazardous substances, i.e. intervention research (see above). We would, however, also like to highlight a few research areas concerning health and environmental effects that are central to future chemicals surveillance and that should be considered within the framework of current research funding.

Sources of exposure and dispersion routes

Research is needed into the sources and flows of chemicals and articles in society. In order to take action, it is necessary to know what chemicals are in use and in what volumes and in what ways they are used. Using this knowledge, we can then see where the most serious exposure to humans and the environment occurs. Large volumes of a substance can, for example, be used in an area without contributing to any major exposure, while the same substance may be used in much smaller quantities elsewhere but be a major exposure risk. This might be a substance used in large volumes in industries that do not generate any emissions, while the same substance is used in small quantities in common articles and therefore gives rise to appreciable leakage into the environment.

Significant exposure to many chemicals takes place in the indoor environment via clothes, furniture, dust and electrical appliances, for example. The methods for analysing exposure need therefore to be improved so that we can implement the necessary risk limitation measures in the most effective way. More light must also be shed on the occurrence of other chemicals in the environment and in the human body through research. It is particularly important to identify chemicals whose occurrence in human and the environment is on the increase.
Composite and synergy effects

Humans and the environment are exposed to the same substance via several different exposure routes, from several different sources and on repeated occasions, which can give rise to what are known as combination effects. The cumulative exposure is crucial for any possible toxic effects. It is especially important to study the combined exposure and combination effects on children and other particularly vulnerable groups in society. Research should focus more on groups of substances, e.g. groups that have similar biological effects. Certain groups of substances, including those with endocrine-disrupting properties, are especially important as they can affect children’s development and our reproductive capacity.

Combination effects have recently been receiving an increasing amount of attention but our knowledge about them and their significance for our health is very fragmentary. For some groups of substances, there are methods that can be employed to make aggregate risk assessments of the effects of complex mixtures on human health. Dioxins and PAHs are two examples of substance groups for which such risk assessment methods have been developed. New methods must be developed in other areas, however.

As new knowledge on the combination effects of different substances is generated, new regulatory approaches may also be needed. We have proposed a milestone target that aims to provide scope for groupwise risk assessment within the framework of the REACH legislation (see Chapter 6).

Development of methods for the risk assessment of hazardous substances

A central factor as regards reducing the risks of hazardous substances is improved risk assessment methods. It must be possible to perform risk assessments more quickly, cheaply and based on more relevant data.

Methods need to be developed to improve the reliability, accuracy and effectiveness of health risk assessments. Methods that consider the combined exposure and identify the most important exposure routes need to be developed. The analysis methods used to develop the risk assessments should primarily not involve experiments on animals, however. Several of the regulatory frameworks on chemicals
specify that experiments on animals are to be avoided as far as possible. Such requirements are also stipulated in the European Directive on the protection of animals used for scientific purposes. Animal protection is beyond the scope of this inquiry, but we would nevertheless like to stress the importance of developing alternative testing methods for the risk assessment of hazardous substances.

New animal-free testing methods have major advantages. By identifying the chains of events and mechanisms behind toxic reactions, a combination of modern methods such as cell-based tests, chemical analysis methods, computer-based methods and genomics can be developed and used to evaluate the risks of chemical substances. Since mainly human cells and tissue systems are used, the major problem of the results of animal experiments not being automatically transferable to humans is avoided.

Using automated testing systems, it will also be possible to test substances in significantly larger dose intervals and combinations of chemicals, which is extremely significant. Supplementary information can be obtained by using different calculation models to predict the combined effect of a mixture of chemicals.

As regards individual substances, it is particularly important to have knowledge that enables the identification and limitation of substances that can cause long-term harmful effects, such as those that are toxic for reproduction, persistent and bioaccumulative. Regarding endocrine disruptors, there is still a lack of testing methods to identify certain types of hormonal impact.

Nanotechnology has developed rapidly in recent years and an increasing number of chemical products and articles containing nanoparticles can now be found on the market. These particles and materials have properties that differ from substances produced by conventional methods. These different properties are often the very reason for using nanotechnologically produced materials, but they often involve new health and environmental risks. There is currently a general lack of testing methods to obtain data on possible health and environmental risks associated with these substances and materials.

8.2.2 Other needs for knowledge development and skills provision

Central agencies have the task of working within their respective remits to ensure the environmental objectives are reached. During our work on the strategy for a non-toxic environment, many proposals for knowledge development have been highlighted. One issue that has been given prominence is the need to establish a centre of excellence for greater substitution, knowledge-building, information and communication in the product chain, in order to increase our knowledge about hazardous substances in articles and promote greater substitution.

Another similar proposal is a national centre or network in the field of environmental and health assessment. The main purpose of such a centre is to contribute to the development of method and skills provision in the area of national environmental and health assessment with regard to i.a. endocrine disruptors and combination effects.

Another area highlighted is the need for knowledge about environmental effects and treatment technologies at wastewater treatment plants in order to reduce the risks of hazardous substances by implementing treatment measures. This has been given particular prominence in connection with the issue of the environmental impact of medicinal products (see Chapter 11).

The All-Party Committee on Environmental Objectives welcomes initiatives from competent authorities in these areas.
9 Global cooperation

9.1 Difficult to create binding agreements on the global level

Everything points to the continuing need for global regulations and agreements in an evermore globalised world, with ever-greater international flows of articles and chemical products. There are several examples of important agreements in the chemicals field. These cover a limited number of substances but have been instrumental in pushing chemicals issues higher up the global agenda.

International initiatives, i.e. initiatives outside the EU, have so far been of limited practical significance in the efforts to reach the environmental quality objective of A Non-Toxic Environment. Chemicals policy in Sweden and the EU is generally more ambitious than in many other countries and regions of the world. It has proven difficult to create binding global agreements despite extensive negotiations. Sweden should, however, continue to drive forward issues relating to reducing the risks of hazardous substances even on the global level. This will no doubt help to increase awareness of the risks and can, in the long term, pave the way to more effective global agreements. This is important, not least because many of the problems are transboundary.

9.2 Future initiatives in global chemicals management

It is inefficient to negotiate new conventions on one substance at a time. In order to be able to restrict e.g. problem substances that are transported over long distances via trade and not least via the environment, Sweden should encourage the EU to develop a strategy for the establishment of an international instrument that would enable
reasonably rapid policy responses to chemicals-related global issues. This requires a more general approach. International expert groups probably need to be established in order to develop criteria for identifying chemicals that constitute problems on a global level and to investigate the need for including other important components in chemicals surveillance. The UN global summit on sustainable development in Rio in June 2012 (Rio +20) may provide an initial opportunity to discuss the issue. Prior to the Rio summit, the EU has expressed the need to establish processes to be able to deal rapidly with substances that constitute a risk on the global level.

The current state of knowledge regarding chemicals is inadequate and there is therefore a need for an international research group that can develop, evaluate and gain support for knowledge about the spread of environmental toxins and the consequences for humans and the environment. It is our opinion that the Government should take the initiative to form a chemicals panel in line with the ones that are already in place for climate change and biological diversity.

Sweden has introduced the “8 Years - 8 Actions” initiative that identifies the eight most important areas for strengthening the implementation of commitments that have already been made, i.e. within the framework of SAICM (see below). This initiative was presented in connection with the international conference on sustainable lifestyles and innovative solutions, Stockholm +40, in April 2012. The overarching purpose is to strengthen the conditions needed to achieve the global objective of sustainable chemicals management by 2020, established at the 2002 World Summit on Sustainable Development in Johannesburg. The initiative shall create a platform for dialogue among international stakeholders from different parts of society. The dialogue is also a way of highlighting the chemicals issue in the run-up to the Rio +20 summit.

Another important issue for global chemicals surveillance is to develop and implement existing conventions and agreements. This is a question, for example, of continuing to drive forward the development of a global programme for information systems on chemicals in articles within the global chemicals strategy, SAICM. It is also a

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51 Strategic Approach to International Chemicals Management (SAICM) is a global agreement on chemicals management adopted in 2006 under the auspices of the United Nations. The strategy contains objectives and measures to ensure that by 2020 chemicals are produced and used in such a way that limits their harmful effects on human health and the
question of encouraging the EU to nominate more POPs\textsuperscript{52} to the Stockholm Convention\textsuperscript{53}. Sweden should also continue to work to ensure that the EU implements its mercury strategy and prohibits the use of mercury in tooth fillings, batteries and measuring instruments. Such measures should also have an effect on the phase-out of mercury on the global level.

For global conventions and agreements to have the desired effect, it is important for them to be implemented. In this context, it is vital that support is available in the form of capacity-building and technical cooperation to developing countries and countries undergoing rapid economic development. The development of global instruments needs therefore to be followed by development cooperation that can help the countries to introduce and comply with the instruments. Sweden should therefore work to ensure that countries prioritise chemicals surveillance in their development plans.

Long-term funding for SAICM and for global chemicals and waste conventions is an important issue for Sweden and the EU. Global acceptance for the advantages of clarifying the role and responsibility of businesses is an important component of global chemicals management. Since 2009, the UNEP\textsuperscript{54} has led a consultative process on funding and achieved good results. It is important that the continued discussions on e.g. the funding of the mercury convention and SAICM make use of the results of this process.

environment as far as possible. It does not contain any binding rules for the signatory countries.

\textsuperscript{52} Persistent Organic Pollutants (POPs).

\textsuperscript{53} The Stockholm Convention on Persistent Organic Pollutants was signed in Stockholm in 2001 and prohibits the production, use and handling of certain substances. It presently covers 21 substances. A total of 170 countries have signed the convention.

\textsuperscript{54} United Nations Environment Programme.
Part C.
Looking beyond traditional chemicals policy
The All-Party Committee on Environmental Objectives has identified three subject areas that lie mainly outside the realms of traditional chemicals policy and that are important if the environmental quality objective of *A Non-Toxic Environment* is to be met. These are: the environmental impact of medicinal products, hazardous substances in food and hazardous substances in products and articles. In-depth analyses in special expert groups have been carried out in these areas.

Three milestone targets are proposed based on these analyses:

- Increased consideration in EU pharmaceuticals legislation.
- Equal requirements in European legislation on contents of hazardous substances in recycled and newly produced materials.
- Reduce children’s exposure to hazardous substances.

We also make two assessments:

- Priority product groups in the current work to reduce the risks of hazardous substances.
- Reduce the risks of hazardous substances in contact with drinking water.

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55 A list of those who have participated as experts and advisers to the Committee can be found in Annex 3.
More environmental consideration in our use of medicinal products

11.1 Milestone target on increased environment consideration in European pharmaceuticals legislation

The All-Party Committee on Environmental Objectives proposes as a milestone target: Sweden’s efforts shall contribute to decisions being taken that lead to environmental aspects being considered in existing and, where necessary, new regulatory frameworks concerning pharmaceuticals, no later than 2020.

Proposal for measures:


- Introduction of environmental requirements into the European Standards on Good Manufacturing Practice (GMP), Commission directive 91/412/EEC (veterinary medicinal products) and Commission directive 2003/94/EC (medicinal products for human use). The change also requires amendments to be made to the medicinal products directives (2001/83/EC and 2001/82/EC)

- Introduction of more stringent testing requirements for medicinal products and better environmental risk assessments

56 Both medicinal products for human and veterinary use.
More environmental consideration in our use of medicinal products

SOU 2012:38

in accordance with EMA guidelines
(EMEA/CHMP/SWP/4447/00 corr 1).

- Creation of a database at EMA to collect environmental data on active pharmaceutical substances and make these data available.

Proposal for the first step of implementation:
The Government should task the Medical Products Agency to cooperate with the other stakeholders and develop an in-depth analysis and work plan for how Sweden should pursue the issue within the EU and in relation to other Member States. This assignment should be reported to the Government no later than December 2013.

11.1.1 The prospects of meeting the milestone target

A prerequisite for achieving the milestone target is that the European Medicines Agency prioritises the issue of the environmental impact of medicinal products. The Commission also needs to submit proposals aimed at revising the foundations of pharmaceuticals legislation. It will probably take several years to develop a basis, formulate legislative proposals and pursue the issue within the EU. By way of comparison, it is worth mentioning that the process of developing the European REACH legislation took ten years.

It is the opinion of the All-Party Committee on Environmental Objectives that a realistic time perspective should be employed when establishing a target year. On the other hand, this target should not be set too long in the future as this might stall the process. Since the objective involves a change to the basic purpose of pharmaceuticals legislation that requires both an advocacy process and the implementation of legal amendments within the EU, it is our assessment that a target year before 2020 would be unrealistic.

The Medical Products Agency has submitted proposals to the Government on how the advocacy process can be designed as regards the component of the objective that involves the introduction of environmental requirements into European GMP
legislation. A first step towards highlighting the issue within the EU has already been taken in connection with an informal ministerial meeting in June 2011.

### 11.1.2 Reasoning

Pharmaceutical waste is spread into the environment in Sweden primarily as a consequence of our medicinal product use. Pharmaceutical residue that is secreted and gets into our wastewater treatment plants is probably a greater problem than emissions from pharmaceutical production. Environmental problems connected to the production of medicinal products are, on the other hand, seen as a problem in low-income countries.

Pharmaceutical substances that are secreted from the body are assumed to be the biggest source of pharmaceutical residue in wastewater. To a certain extent, it may also be a question of left-over medicines being flushed down the toilet. Over 150 different pharmaceutical substances have been reported in surface water and in treated municipal wastewater in Sweden and other western countries. Measured levels vary from under 1 μg/litre up to a few μg/litre, depending on the substance and the efficiency of the treatment plant. Another possible dispersion route is via sludge to the soil.

Active pharmaceutical substances are a group of substances which should be treated as potentially hazardous chemicals when they reach aquatic environments. Pharmaceuticals often contain several active substances which may potentially have an environmental impact. Pharmaceutical waste in the environment is also a public health issue.

Current levels of pharmaceutical waste in aquatic environments are so low that there is no risk of acute toxicity. There is however a lack of knowledge as to the long-term effects on both human health and biological diversity. As regards the development of antibiotics resistance, we can already see a very worrying trend in some manufacturing countries.

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57 Medical Products Agency (2011) Analysis of how the work to revise the GMP legislation should be designed to have the greatest possible chance of success.
59 An active substance in a medicinal product can be described as the component in the product that give it its therapeutic function. Medical Products Agency (2009).
So as not to risk harming the development of children and young people or disturbing human reproduction capacity, the Precautionary Principle must prevail. Children and young people can be more vulnerable to the effects of pharmaceutical waste, since, among other things, their development is dependent on complex hormonal systems. The use of substances that have hazardous or particularly hazardous properties should be restricted unless the benefit outweighs the risks of use. Medicinal products are mostly exempt from general chemicals regulation, however. Therefore, we see a need for a milestone target that can contribute to reducing the impact of medicinal products in the environment.

The objective of pharmaceuticals legislation is that all medicinal products shall be safe for the patient and have the intended therapeutic effect. Pharmaceuticals legislation is therefore primarily designed from the individual’s perspective. Emissions of pharmaceutical substances can, however, have a negative impact on human health. One example is the risk of bacteria that are resistant to antibiotics developing in the environment as a result of the emission of antibiotics in connection with the production of medicinal products. The development of resistant bacteria is one of the most serious public health problems of our time.

An important issue as regards the risk assessment of pharmaceuticals is that humans and the environment are continually exposed to chemical preparations. It is the combined effect of a chemical preparation that constitutes the environmental and health risk, not each individual substance. Pharmaceuticals do not differ from other types of substances in this respect.

In recent years, a number of initiatives have been taken on the national level as regards the issue of pharmaceuticals and the environment. The Swedish pharmaceutical industry has made voluntary undertakings on several levels and is working with different methods. This may be a question of using environmental management systems, voluntary inspections of sub-contractors, development of green technology, industry-wide associations, etc.

Other national initiatives are being taken in areas such as procurement and environmental classification. The health service purchases around 10 percent of the medicinal products used in Sweden and there is scope for stipulating environmental requirements in conjunction with their procurement. The county councils and their medicinal product committees are working actively to provide information and training regarding current knowledge of pharma-
ceuticals and the environment. Regarding environmental classification, there is a voluntary system on the national level (Fass.se) based on the environmental risk assessments that businesses must submit in connection with authorisation applications. In 2011, the Swedish Association of the Pharmaceutical Industry (LIF) also took the initiative for round-table discussions on green pharmaceuticals.

In Sweden, the pricing of medicinal products is regulated by the Act (2002:160) on pharmaceutical benefits, etc. The purchasing and sales price of a medicinal product that is included in the pharmaceutical benefit system, and hence subsidised by society, are established by the Dental and Pharmaceutical Benefits Agency, TLV. TLV takes decisions on subsidies based on the Act on pharmaceutical benefits, etc., and on the overarching aim of Swedish healthcare to ensure good health and care on equal terms for the entire population.\(^{60}\)

The issue of the scope for taking environmental aspects into consideration in connection with decisions on medicinal product subsidies is currently being investigated by the Pharmaceuticals and Pharmacies Inquiry (S 2011:07) which is due to report to the Government in September 2012 (ToR 2011:82). The Inquiry is also to review the pricing of brand name drugs without generic competition and certain other issues.

Initiatives on the national level are deemed to have a limited effect since the pharmaceutical sector, with the exception of retail trade, has mostly been harmonised within the EU. It is our assessment therefore that more far-reaching initiatives must be carried out on the EU level. A long-term strategy on legislation and other instruments within the EU and internationally is needed in order to achieve further changes.

Greater knowledge about the long-term effects and relevant risk assessment methodology is a fundamental prerequisite if it is to be possible to take environmental aspects into consideration in connection with the authorisation of medicinal products. Without relevant data and well-supported environment risk assessments, it will be difficult to consider the environment in e.g. the benefit-risk

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\(^{60}\) The objective is stated in Section 2 of the Health and Medical Services Act (1982:763).

\(^{61}\) The Member States are basically free to introduce different types of price regulation models for medicinal products. There is a special legal instrument in the area, COUNCIL DIRECTIVE 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems. This directive does not however regulate the content of national benefit systems, only the pricing procedures used by the Member States.
assessments of a medicinal product. A database should also be established at the EMA in which environmental data on active pharmaceutical substances are collected and made available to the general public. Environmental data on pharmaceutical substances are also needed in order to be able to stipulate requirements in connection with their manufacture. Knowledge development and the scope for considering the environment in pharmaceuticals legislation are closely connected to each other and should be grouped together in a common milestone target.

We therefore propose a milestone target aimed at creating the conditions and incentive needed for the pharmaceutical industry to develop medicinal products that are as green as possible. This milestone target also aims to reduce the risks of environmental impact in connection with the manufacture of pharmaceuticals. Changes to EU pharmaceuticals legislation that provide scope for increased consideration will also provide better prerequisites for other measures. These include, for example, the scope for introducing a well-developed system for the environmental classification of pharmaceuticals and for stipulating more appropriate environmental requirements in connection with the procurement of medicinal products.

Due to the community process, changing EU legislation can take many years. We are therefore of the opinion that it is important that the national initiatives continue and are also further developed, awaiting relevant policy amendments on the EU level.

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62 A benefit-risk assessment is performed in connection with the authorisation of a new medicinal product and takes a number of factors into consideration. These factors include: the significance of proven effects, access to alternative treatments, significance of any pre-clinical discoveries, risk of unknown side-effects during long-term treatment, etc. The possible environmental risks of the medicinal product for human use are not considered.
11.1.3 Measures

We propose four measures to achieve the milestone target of increased environmental consideration in EU pharmaceuticals legislation:

- Introduction of scope to consider environmental aspects in the benefit-risk assessment carried out in connection with the authorisation of medicinal products for human use (Directive of the European Parliament and the Council 2001/83/EC\(^{63}\)).

- Introduction of environmental requirements into the European Standards on Good Manufacturing Practice (GMP), Commission directive 91/412/EEC\(^{64}\) (veterinary medicinal products) and Commission directive 2003/94/EC (medicinal products for human use).\(^{65}\) The change also requires amendments to be made to the medicinal products directives (2001/83/EC and 2001/82/EC\(^{66}\)).

- Introduction of more stringent testing requirements for medicinal products and better environmental risk assessments in accordance with EMA guidelines (EMEA/CHMP/SWP/4447/00 corr 1.\(^{67}\)).

- Creation of a database at EMA to collect environmental data on active pharmaceutical substances and make these data available.

Introduction of scope to consider environmental aspects in the benefit-risk assessments carried out in connection with the authorisation of medicinal products.

Increased environmental consideration when authorising medicinal products is primarily a question of amending legislation (European directive on medicinal products for human use) so that the environmental risks associated with use can be considered in the benefit-risk


\(^{67}\) Guideline on Environmental Risk Assessment of Medicinal Products for Human Use (EMEA/CHMP/SWP/4447/00 corr 1.).
assessment for medicinal products for human use in accordance with clear criteria.

For chemicals that are subject to authorisation procedures, both health and environmental aspects are considered during the procedure. If the environmental effects are not dealt with by a special legal instrument, they can be handled by another general legislative action that deals with the risk of chemicals, e.g. REACH. The provisions in REACH do not normally apply to the authorisation of medicinal products. Even though there is a requirement to submit an environmental risk assessment when applying for authorisation, any environmental problems identified in the risk assessment must not influence the authorisation process for medicinal products for human use. When carrying out the benefit-risk assessment of a veterinary medicinal product (2001/82/EC, however, every risk of undesirable environmental effects during use shall be considered during approval.

The scope of the medicinal product directives should be extended to cover the consideration of environmental effects in the benefit-risk assessment of a product carried out in connection with authorisation.

Partially amending the aim definition for a judicial area, so that environmental consideration becomes an explicit purpose, can take a long time. The process has already been started, however, as a result of the requirements for environmental risk assessments that are already in the directives, and that may be used when carrying out the benefit-risk assessment for veterinary medicinal products. Sustainable development is furthermore one of the cornerstones of the EU and a high level of environmental protection is an important aim in the treaty.

In order for environmental risks in connection with the use of a medicinal product to be fully considered when assessing whether a product is to be authorised, an amendment to directive 2001/83/EC is needed. This amendment would consist of medical products agencies having the opportunity to consider environmental risks when assessing the benefits of a medicinal product in relation to the risks involved in its use.

A basic issue in this is the consideration of environmental effects versus the consideration of the patient. The aim of introducing scope for considering environmental risks in the benefit-risk assessment is not to entirely prevent medicinal products that carry serious environ-

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mental risks from reaching the market. What level of environmental impact is acceptable for a medicinal product depends for example on how serious the disease is deemed to be from a medical and socioeconomic point of view and whether alternative and similar treatments leading to less environmental impact are available. The potential effects on public health of exposure to pharmaceutical waste in the environment should also be considered. Instead, introducing scope for considering environmental aspects in the benefit-risk assessment will make it possible to refuse to authorise additional products that contain an environmentally harmful substance when there are already products on the market that satisfy the medical need in question. Access to effective pharmaceutical treatment will not therefore need to be influenced to a great degree by the fact that environmental aspects can be considered in the benefit-risk assessment.

Introducing environmental consideration into the benefit-risk assessment may also lead to medicinal products that have already been approved being subject to the requirements for environmental assessments. One issue that should be dealt with is that the benefit-risk balance may be changed after authorisation if new information comes to light. If a medicinal product is shown to lead to serious medical side-effects that were not known at the time of authorisation, the authorisation can be withdrawn\textsuperscript{69}. Similar scope can be considered for medicinal products that are subsequently shown to lead to serious environmental damage. This issue should be investigated.

\textbf{Introduction of environmental requirements in the European Standards on Good Manufacturing Practice (GMP)}

Without efficient environmental protection, there is a risk of large amounts of pharmaceutical waste being emitted from production plants. A regulatory framework is therefore needed that can prevent such emissions.

Within the EU’s borders, both legal and technical conditions are needed to be able to stipulate requirements on the removal of active substances from the wastewater coming from pharmaceutical

\begin{footnotesize}\textsuperscript{69} Directive 2001/83/EC, Articles 23.4, 116 and 117.\end{footnotesize}
production plants. The costs must not on the other hand be high in relation to the environmental benefit derived from the treatment.\(^70\)

A large percentage of pharmaceuticals are currently manufactured in low-cost countries outside the EU. In order to influence the production conditions in these countries, measures within the EU that can have an effect in third countries are also required.

The Medical Products Agency has made the assessment that there is no scope for stipulating environmental requirements in connection with manufacturing pursuant to currently applicable pharmaceuticals legislation.\(^71\) The scope for environmental consideration based on European pharmaceuticals legislation should also therefore cover requirements for environmental consideration during pharmaceuticals manufacture. It is reasonable to have manufacturing requirements that don’t just cover the quality of the medicinal product itself but also consider the possible environmental consequences of the emissions. Incentives for increased consideration during the production of medicinal products can for example be created by improving the European regulatory framework on Good Manufacturing Practice (GMP).

The Medical Products Agency has developed a proposal for how regulations on environmental surveillance in the pharmaceuticals legislation can be incorporated by stipulating GMP requirements. According to the Medical Products Agency, a system of environmental surveillance within the framework of GMP is the most appropriate way of bringing about a regulation that enables surveillance of emissions into the environment and ensuring the regulation has a substantial impact not just within the EU but also globally.\(^72\)

The Medical Products Agency’s proposal briefly involves the following:

- The introduction of an obligation in the medicinal product directives for pharmaceutical manufacturers to follow the requirements in a special legislative act, a new EU regulation, in

\(^70\) Medical Products Agency (2011) Background documentation to support a revision of European legislation on Good Manufacturing Practice (GMP) to include environmental consideration.

\(^71\) Medical Products Agency (2009) Presentation of a government assignment into the scope for tighter environmental requirements on the manufacture of medicinal products and active substances.

\(^72\) Medical Products Agency (2011) Background documentation to support a revision of European legislation on Good Manufacturing Practice (GMP) to include environmental consideration.
which emission levels for certain substances are stipulated. In
the medicinal products directive, the new obligation should be
added to the requirement for fulfilling GMP during manu-
facture.

- A new EU regulation should be formulated, in which the sub-
  stances that need surveillance are stipulated together with limits for
  permitted emission levels.
- The substances that should be prioritised in the EU regulation as a
  first step are pharmaceutical substances that have a scientifically
  proven negative impact on the external environment and hence
  public health (e.g. antibiotics and endocrine disruptors).
- The regulation should include a procedure for identifying further
  substances, etc.

Our proposal above on expanding the scope of the medicinal product
directives to include environmental effects should also facilitate the
proposal for introducing requirements for environmental consider-
ation into GMP.

**Introduction of more stringent testing requirements for
medicinal products and better environmental risk assessments in
accordance with EMA guidelines**

In order to be able to consider environmental aspects in the benefit-
risk assessment, knowledge about the environmental impact of
medicinal products needs to increase. The tests used for environ-
mental assessment need to be improved, especially when it comes
to the long-term environmental impact of medicinal products and
the effects linked to their biological activity. In order to increase
knowledge about the potential long-term effects of pharmaceutical
substances on human health and the environment, the EU
guidelines on environmental assessments of such substances need
to make a contribution.

The requirements for environmental testing currently placed on
medicinal products under the pharmaceuticals legislation are less
extensive than the fundamental requirements laid down in REACH.
Basic data on the potential environmental effects of pharmaceutical

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73 Guideline on Environmental Risk Assessment of Medicinal Products for Human Use
(EMEA/CHMP/SWP/4447/00 corr 1.).
More environmental consideration in our use of medicinal products

substances are required in order to be able to evaluate risks and measures. Requirements for environmental assessments are formulated in guidelines that need to be revised based on the possibilities of carrying out more reliable environmental risk assessments for medicinal products. Introducing tougher requirements for tests on degradability and bioconcentration would provide a much better basis for environmental risk assessment than is the case today. Such data provide scope for estimating the exposure that can be expected in aquatic organisms. This will give us an initial scientific estimation of the risks. For pharmaceutical substances that are not easily degradable or that bioaccumulate, medical product agencies should be given the option of requesting further information.

Creation of a database at EMA to gather environmental data on active pharmaceutical substances and make these data available

In order to be able to prioritise pharmaceutical substances that should not be released into the environment, more comprehensive information on the properties of input substances is needed. There is currently no coordinated environmental data on active substances, either at the Medical Products Agency or at the EMA. A coordinated database is therefore needed. Such a database, containing easily accessible information on environmental risk assessments etc., would make it easier to update lists of priority substances and to set relevant limit values based on the substances’ ecotoxicological properties.

The value of gathering information on environmental effects is considerable even if it is not possible to consider environmental effects in the benefit-risk assessment during the authorisation process. Pharmaceutical companies should be given the responsibility to gather and report data similar to the way they are required to do so under REACH. This should be of interest to the companies since it also gives them the opportunity to show that a substance is safe and does not imply any major risk to the environment. The database could also be used to limit the environmental risks during the production of medicinal products.

Pharmaceutical data are available in Sweden via Fass.se. The system has been developed by LIF in cooperation with a number of other players to provide information on active substances to stakeholders on the Swedish market. The lessons learned from developing Fass.se should be utilised when building up a common database within the EU. A great deal of data has already been published. The possibility of utilising Swedish experiences has been highlighted by the Medical Products Agency in connection with the EU conference on sustainable development and medicinal products organised by the agency during the Swedish EU Presidency in 2009.

Proposal for a first step in the implementation of the measures

The All-Party Committee on Environmental Objectives proposes that the Government task the Medical Products Agency to develop the basis required to pursue the issue of increased consideration in European pharmaceuticals legislation. The measures that should be investigated within the framework of this assignment include:

- Expanding the scope of the medicinal product directives to include environmental effects and give medical product agencies the option of considering environmental effects in the benefit-risk assessment that is performed before a medicinal product is authorised.

- Better environmental risk assessments of medicinal products with the aim of increasing knowledge about their long-term effects on the environment. The testing requirements laid down in pharmaceuticals legislation should be developed in order to allow an appropriate risk assessment of a medicinal product’s environmental impact.

- The possibility of establishing a database at the European Medicines Agency (EMA), in which environmental data on active pharmaceutical substances are collected and made publicly available.

This assignment should be performed in close cooperation with other relevant agencies, county councils, municipalities, businesses and the research community. The assignment should be reported no later than December 2013.
The Medical Products Agency has previously analysed and submitted proposals for changes to the European GMP Guidelines. The agency has also developed a proposal for how Sweden should work to pursue the issue within the EU.

11.1.4 Impact assessment

Effectiveness

The contribution made by the milestone target to the environmental quality objective

Chemicals in medicinal products are exempt from the general European chemicals provisions laid down in REACH. No assessment of the environmental effects of a new medicinal product for human use is performed during the authorisation process. The environmental risk assessments performed in accordance with EMA guidelines are not sufficient to be able to assess the potential risks posed by pharmaceutical substances to the environment.

One of the aims of the proposed milestone target on increased consideration in EU pharmaceuticals legislation is to introduce environmental aspects into the benefit-risk assessment that is performed in connection with the authorisation of new medicinal products. In this way, the risks of harmful effects on the environment caused by medicinal product use can be reduced.

More stringent requirements for the testing of a new substance’s environmental effects and for environmental risk assessments will increase knowledge about the ecotoxicological effects of substances, how they are transformed and dispersed in the environment, their degradability, etc. The results of these improved environmental risk assessments constitute an important basis for the extended benefit-risk assessment of medicinal products.

Consideration of the environment in the benefit-risk assessment of medicinal products for human use means that the use of pharmaceutical substances that are very problematic from an environmental point of view may decrease in the long term. This will eventually reduce the costs for society, although these are difficult

75 Medical Products Agency (2011) Background documentation to support a revision of European legislation on Good Manufacturing Practice (GMP) to include environmental consideration.

76 Medical Products Agency (2011) Analysis of how the work to revise the GMP legislation should be designed to have the greatest possible chance of success.
to estimate since the link between a particular substance and any environmental effects from it are difficult to establish.

The aim of the milestone target is to change the requirements within the EU. One measure that is proposed as part of the target is to introduce environmental requirements into the European GMP Guidelines. The aim of the measures is to control emissions of substances that are particularly problematic during the manufacture of medicinal products. The intention is for the regulation to have as large an impact as possible, even on the global level.

The connection to other environmental objectives

Medicinal products for human use and pharmaceutical waste are spread into our local environment primarily via wastewater. The milestone target therefore contributes to the achievement of Sweden’s water-related environmental quality objectives - Flourishing Lakes and Streams, Good-Quality Groundwater and A Balanced Marine Environment, Flourishing Coastal Areas and Archipelagos.

Alternative courses of action

Alternative or supplementary actions to the proposed milestone target include national measures such as the environmental classification of medicinal products, environmental requirements on the procurement of medicinal products, environmental consideration when deciding on subsidies and a requirement for the treatment of municipal wastewater to prevent pharmaceutical waste from reaching the environment.

Having binding requirements for environmental classification systems is deemed to be incompatible with European legislation. Initiatives are also required on the EU level in order to improve the prerequisites for the environmental classification of medicinal products and for stipulating relevant environmental requirements in public procurement. The first steps to achieving this are embodied in the milestone target in the form of better environmental risk

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77 Reduced waste is also usually highlighted as regards medicinal products and the environment. There is however a clear producer responsibility under the Ordinance (2009:1031) on producer responsibility for medicinal products. All pharmacies have producer responsibility and hence an obligation to collect and dispose of residual medicinal products.
assessments as well as the scope both for considering environmental aspects in the benefit-risk assessment and for gathering environmental data on medicinal products in a database at the EMA.

The issue of environmental consideration in connection with decisions on whether a medicinal product is to be included in the national benefits system, and hence be subsidised by society, is currently being investigated by the Pharmaceuticals and Pharmacies Inquiry (ToR 2011:82).

Technology is currently available that can reduce concentrations of pharmaceutical substances in outgoing wastewater. These methods have been evaluated by the research community in Sweden and in other countries (Switzerland in particular). Further research and evaluation are needed however as to what the implementation of these technologies would mean in terms of better water quality and increased costs.

Earlier on in this report, we presented our proposals for more intervention research and innovation focusing on i.a. green chemistry. Greater knowledge about e.g. the environmental effects of medicinal products and treatment technologies is accommodated within these proposals.

Compatibility

Right of determination

The milestone target presupposes changes to the European pharmaceuticals legislation. It is the Commission that puts forward the proposals necessary to change the legislation. There is nothing to stop a Member State from taking the first initiative by highlighting the issue. Political support from other Member States is important.

Public interest in the development of new medicinal products, patient safety and healthcare

The effect on the costs of medicinal products is minimal. An introduction of scope for considering the environment in the benefit-risk assessment when authorising new medicinal products may increase the costs of developing them. In accordance with the Polluter Pays Principle, it is the pharmaceutical industry that should foot the bill for this. The direct costs that may be incurred by the pharmaceutical
industry can in the long term be reflected in pricing, which indirectly increases the costs for healthcare (county councils), the general public and central government.

The costs of medicinal products for the general public are affected both by the prices established by TLV on the central level and by patient need and how the council councils and doctors choose to prescribe medicinal products to satisfy this need. These actors jointly define the costs of medicinal products.

The medicinal product market can be divided into two parts:

1. One part with “generic” drugs, and
2. One with brand name drugs

There is strong pressure on generic drug prices due to the fact that when a drug is prescribed, it is replaced by the cheapest generic alternative at the pharmacy. This naturally provides an incentive for manufacturers to set the lowest price.

The conditions for brand name drugs are different. Even if there are several similar brand name drugs within a specific group of medicinal products, the pharmacy cannot exchange one for another. This does not generate the same competition for prices as for generic drugs. The model used, known as value-based pricing, can improve efficiency since the aim is that the price should reflect the cost-efficiency of the drug. Prices are set by taking the future positive effects of drug treatment into consideration. The price of the drug shall therefore reflect the clinical value of the treatment for both patients and the health service. Society’s willingness to pay and the value of the drug thereby determine the pricing of brand name drugs.\(^7\)

The total costs for medicinal products in Sweden in 2011 was just over SEK 30 billion.\(^79\)\(^80\) The costs of developing a medicinal product are thought to be around SEK 5-10 billion. The manufacturing costs for a medicinal product, of which development costs are a part, are assumed to constitute about 20 percent of its market price.\(^81\)

\(^7\)The system for pricing brand name drugs is currently under review (ToR 2011:82).
\(^80\) The cost of the state-financed medicinal product benefit system was approximately SEK 20 billion. Patients’ out-of-pocket expenses for subscription medicines amounted to approximately SEK 6 billion. Around SEK 3 billion worth of over-the-counter products were purchased. The costs of medicinal products in in-patient care can be estimated at around SEK 5 billion.
\(^81\) Medical Products Agency (2009) Presentation of a government assignment looking into the scope for tighter environmental requirements on the manufacture of medicinal products and active substances.
The extra costs of performing the tests and analyses required for an environmental assessment are deemed to be minimal in relation to the total development costs. It is difficult to judge how a relatively minor increase in development costs might influence the final costs of a medicinal product. It seems, however, unlikely that a more extensive environmental assessment would markedly affect pricing.

The impact of manufacturing costs in the final price applies primarily to generic drugs, where market competition creates strong pressure to keep prices down. In light of the price model used for brand name drugs, where TLV decides the purchasing and sales price of those drugs that are subsidised subsequent to an assessment of the benefit of the drug versus society’s willingness to pay, any increased manufacturing costs are deemed to have little or no impact on the final price.

More extensive environmental assessment can affect the development of new medicinal products. A requirement for environmental consideration in the benefit-risk assessment could run the risk of prolonging the authorisation process for a new medicinal product as the environmental assessment requires new tests and analyses. A prolonged authorisation process may undermine the patent period for the product and hence impair the economic conditions for developing it, providing in turn less incentive for the industry to develop new drugs. The environmental tests will make up a marginal percentage of the extensive medical tests that are required prior to a new medicinal product receiving authorisation. The environmental tests could take place in parallel with the medical tests. The risk of the authorisation process being prolonged to such an extent that it has economic consequences for drug development is deemed minimal.

Environmental assessment will not hinder the manufacture and use of new effective medicinal products. The aim of considering environmental risks in the benefit-risk assessment is not to entirely prevent medicinal products that carry serious environmental risks from coming out onto the market. One aim of the proposal is to be able to refuse to authorise new products that contain an environmentally harmful substance when there are already products on the market that fulfil the relevant medical need.
Cost-efficiency

The purpose of the milestone target is to stop the release of toxicological and ecotoxicological substances at source, which generally involves lower costs than preventing hazardous substances from reaching the environment later on during use. The alternative courses of action that can be considered, including wastewater treatment, are deemed to be more costly.

Distributional impacts

The measures included in the milestone target may increase the costs of developing new medicinal products. Higher prices of medicinal products as a result of these cost increases may have a negative effect on certain patient groups and also put pressure on the pharmaceutical benefits system. It is our assessment, however, that the impact of the measures on medicinal product prices is minimal and that the milestone target will therefore not lead to any distributional impacts.

Effects on government finances

The Medical Products Agency may be given an extended responsibility for checking environmental risk assessments in connection with the authorisation of medicinal products. The Agency may need to improve its skills as regards the analysis and evaluation of environmental risk assessments. The assessment of the All-Party Committee on Environmental Objectives is that this extended responsibility and need for skills development may require a certain reallocation of priorities within the Agency’s remit.
Reducing the risks of hazardous substances in materials, articles and products

12.1 Milestone target on equal requirements in European legislation on the content of hazardous substances in recycled and newly produced materials

The All-Party Committee on Environmental Objectives proposes as a milestone target:
Sweden’s initiatives have contributed to a decision being taken within the EU to establish the principle of equal requirements being placed on recycled and newly produced materials, as regards their content of hazardous substances, no later than 2016, in order to create non-toxic material and resource cycles in the long term. Waste shall be managed in accordance with the waste hierarchy established in the European Waste Framework Directive. The recycling of nutrients from waste sludge is not included in the milestone target. This issue should be dealt with separately and the All-Party Committee on Environmental Objectives has previously proposed milestone targets for this in SOU 2011:34.

Proposal for measures:
In-depth inquiry in order to identify effective and cost-efficient measures to reach the milestone target. Decisions on contents of hazardous substances in recycled materials are currently taken under many different regulatory frameworks. An in-depth

Reducing the risks of hazardous substances in materials, articles and products

and integrated analysis of the changes needed to reach the milestone target is therefore required.

**Proposal for a first step towards implementation:**
The Government tasks the Swedish Chemicals Agency and the Swedish Environmental Protection Agency to cooperate with the other stakeholders and develop an in-depth analysis and work plan for how Sweden should pursue the issue within the EU and in relation to other Member States. The assignment should be reported no later than December 2013.

### 12.1.1 The prospects of meeting the milestone target

It should be possible to establish the principle of placing equal requirements on recycled and newly produced materials, as regards their content of hazardous substances, by 2016, if Sweden works actively and together with other Member States within the framework of ongoing processes at the EU level.

Resource efficiency has recently been high on the EU agenda as a result of the Commission’s efforts to develop a strategy for resource-efficiency to within the framework for the EU’s strategy for smart, sustainable and inclusive growth (Europe 2020). In December 2010, EU environment ministers adopted council conclusions on sustainable materials management and sustainable consumption and production. One point in the conclusions was that the recirculation of hazardous substances in material cycles is to be avoided.

The 7th Environmental Action Programme is to be adopted in 2013. Thereafter, the Commission can draft proposals that include better coordination of the legislation for waste, chemicals and products that can be adopted in 2016. In this context, Sweden should highlight the issue of hazardous substances in material cycles.

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12.1.2 Reasoning

The generational goal states that the goal of environmental policy shall be material cycles that are resource-efficient and as far as possible free from dangerous substances. Cycles of articles and materials are not toxic-free. Previously manufactured articles and products, such as construction materials, may contain hazardous substances. A recycling society that is sustainable in the long term presupposes that hazardous substances are phased out from material cycles. It is important that the recycling of materials does not lead to the contamination of newly produced articles and products by otherwise prohibited substances. Current regulatory frameworks do not guarantee the removal of hazardous substances in articles and products that are reused and recycled.

The European legislation that regulates waste and chemicals is comprehensive and is incorporated into a large number of regulations and directives. The waste regulations are minimum rules that are based on the European Waste Framework Directive and appurtenant special directives. An important starting-point in the Waste Framework Directive is what is known as the “waste hierarchy”, which is a priority order for legislation and policies relating to the prevention and disposal of waste.

The five steps of the waste hierarchy:

1. Preventing waste from being generated.
2. Preparing for reuse.
4. Recovery in some other way, e.g. energy recovery.
5. Disposal.

The proposed milestone target does not affect the waste hierarchy. To achieve non-toxic and resource-efficient material cycles, better coordination of the legislation on waste and chemicals is required within the EU. The principle of equal requirements on recycled and newly produced materials as regards their content of hazardous substances should form the basis for the development of legislation, recommendations and other instruments within relevant areas.

The principle of rectifying the problems of hazardous substances as far as possible at source is important in the work to create resource-efficient material cycles. Materials, articles and products that contain hazardous substances make recycling more difficult. Certain problem
substances that are contained in articles, buildings and infrastructure continue to be a problem in the waste stage for many decades, even after use of the substances has been phased out. Substances that impair recycling should not be used. This should also apply to recycled materials. A high level of ambition as regards recycling, including requirements that the materials contain only low concentrations of hazardous substances, increases the incentive for phasing out and replacing hazardous substances.

The recycling of nutrients from waste sludge is not included in this proposal for a milestone target. As a result of the special risks associated with the recovery of nutrients from waste sludge, this issue should be dealt with separately. The All-Party Committee on Environmental Objectives has previously proposed milestone targets for this in SOU 2011:34. The Government has subsequently decided to task the Swedish Environmental Protection Agency to investigate the sustainable recovery of phosphorus. This assignment involves the Agency analysing the phosphorus resources in society that might be recoverable, proposing an investment support mechanism for new technology, drawing up criteria for the spreading of sludge/digestion and compost residue etc. on various types of land (arable land, forest land and other land) in order to recover phosphorus, and proposing a milestone target for phosphorus recovery. The assignment is to be reported to the Government in its entirety no later than 12 August 2013\(^86\).

In December 2010, EU environment ministers adopted council conclusions on sustainable materials management and sustainable consumption and production\(^87\) that underline the importance of the Commission’s Strategy on Resource Efficiency not only focusing on energy but also on sustainable materials management and increased recycling. The environment ministers also called for the use of hazardous substances to be reduced and their recirculation in material cycles to be avoided. These council conclusions are an important first step for future measures aimed at ensuring that resource-efficiency also takes chemical risks into consideration.

The 7th Environmental Action Programme is to be adopted in 2013. In this context, Sweden should highlight the issue of hazardous substances in material cycles, for example as a thematic action strategy (similar to the strategies developed in the previous environmental action programme).

\(^{86}\) Government assignment M2012/317/Ke
\(^{87}\) See footnote 85.
12.1.3 Measures

Measures and instruments for increased recycling are to focus on materials that are the most valuable from a resource-efficiency point of view and at the same time have a low hazardous substance content. We propose that an analysis be developed in order to identify the measures and instruments needed to reach the milestone target. The following issues should be analysed:

- Which instruments and measures are the most effective and suitable in order to regulate hazardous substances in both recycled and newly produced materials (life cycle perspective)?
- Which instruments and measures are the most suitable to use in order to achieve synergies between non-toxicity and resource efficiency?
- How can decisions in different regulatory frameworks be guaranteed to go in the same direction?

The relevant agencies need to develop background documentation, including the analysis of the need for changes in European legislation, which also explains and underpins the proposal. Achieving this will require close cooperation between the Swedish Chemicals Agency, the Swedish Environmental Protection Agency and other agencies. The relevant industries, researchers, etc., should also be involved. A first step is the analysis of the area that is covered in the Swedish Chemical Agency’s report *Improved EU rules for a non-toxic environment* (2012).

There is no general product legislation that regulates chemicals in products/articles/materials. Only a small number of articles are covered by detailed regulations on chemical content. The aim of REACH is to ensure that all substances are used safely, but this can be difficult to achieve in practice for recycled materials.

Even if the product legislation does not make the difference between different materials, there is a risk that recycled materials are more contaminated since there is often a lack of knowledge about the hazardous substance content of articles and waste. Product legislation only covers certain types of articles and products and regulates only some substances, which means that there are significant gaps in the legislation. Chemicals legislation regulates more (but not all) substances. Furthermore, prohibitions and restrictions are often based on the substance’s intended area of use. There will therefore be combinations of substances and areas of use...
that are not covered by either the product or the chemicals legislation. These legislative acts therefore need to be combined with requirements for separation of the most hazardous substances via the waste legislation\textsuperscript{88}.

Since the regulatory frameworks are complex, it is important to perform an integrated analysis of the legislative changes required to achieve the milestone target. The analysis can then form the basis of a EU-wide action plan for non-toxic and resource-efficient natural cycles.

An integrated action plan on the EU level

As a starting-point for the relatively long-term work on both changes in current regulatory frameworks and any possible development of new instruments, an integrated action plan on the EU level is needed. It should be a high priority for Sweden to work to ensure that the Commission drafts a proposal for such an action plan. The action plan should aim to guarantee use of recycled materials that is safe from both a health and environmental point of view through better coordination between waste, chemicals and product legislation. The plan should also cover the common measures of the EU to promote non-toxic and resource-efficient material cycles in a global context. As regards the action plan, Sweden should stress the following aims in particular:

- Particularly hazardous substances (or Substances of Very High Concern, SVHC) are not to be used in new articles.
- Measures and instruments for increased recycling and recycling are to focus on materials that are the most valuable from a resource-efficiency point of view and at the same time have a low hazardous substance content.
- Information about hazardous substances in articles is to be available to actors during the article’s entire life cycle.
- To attain a long-term sustainable recycling rate, equal requirements must be placed on recycled and newly produced materials with regard to hazardous substance content.

Particularly hazardous substances (or SVHC) are not to be used in new articles

As early as in the design stage, it should be possible to describe how new products are to be disposed of in a resource-efficient way when they reach the end of their useful life. This applies to design, choice of materials and the use of hazardous substances in materials or as additives in articles. If it is to be possible to attain non-toxic and resource-efficient material cycles, the use of the most hazardous substances must cease (see Section 4.1.1 Milestone target on particularly hazardous substances). Today we can see examples of how particularly hazardous substances that are used in large volumes prevent the recycling rates of certain materials from increasing. This problem will persist for many years after use of the substance has been discontinued in new products. A concrete example of this is brominated flame retardants in electronics and vehicles.

Focus on materials that are the most valuable from a resource-efficiency point of view and have a low hazardous substance content

It is important to stimulate recycling of those materials that are the most valuable from a resources point of view. There can be major differences between different materials both regarding the environmental benefits of recycling and the potential for increased recycling. When designing instruments and measures for increased recycling, we should look for synergies between the resource-efficiency and non-toxicity objectives by focusing on materials that have a low hazardous substance content. This type of analysis should be performed at an early stage, before the work on the separate collection and recycling of a material begins. Such an analysis could, for example, be performed as part of the work to reach the EU’s target of a 70-percent recycling rate for construction and demolition waste (which has also been adopted as a milestone target, see Annex 5).

Information about hazardous substances in articles is to be available to stakeholders during the article’s entire life cycle

The current information requirements that provide information to the waste management sector on the content of chemicals in articles are mainly labelling requirements for batteries and vehicles. Require-
ments are also in place for electronics. As regards the information requirements in REACH, the waste management sector does not receive information on particularly hazardous substances by right. As the information about the properties of hazardous substances and their occurrence in articles increases, it should also be made available to the waste and recycling sector to the extent needed for the sector to be able to minimise the risks of hazardous substances (see Section 4.1.3 Milestone target on information about hazardous substances in articles).

Equal requirements on recycled and newly produced materials

To achieve a recycling rate of articles and materials that is safe for human health and the environment in the long term, equal requirements are to be placed on recycled and newly produced materials with regard to their hazardous substance content. Product and chemicals legislation should not in most cases differentiate between recycled and newly produced materials as regards e.g. prohibitions and limit values for hazardous substance content.

As the most hazardous substances are phased out and we gain more knowledge about the content of hazardous substances in articles, it is reasonable to require recycled materials to also be free from hazardous substances. This is important in order to strengthen the competitiveness of recycled materials, which benefits recycling in the long term. Recycled materials must not be a substandard alternative. This is also important in order to prevent the diffuse spread of and exposure to substances that are prohibited in new products. With regard to the Precautionary Principle, products and articles that are made of recycled materials shall be safe.
12.1.4 Impact assessment

Effectiveness

The contribution made by the milestone target to the environmental quality objective

The milestone target on equal requirements in European legislation on hazardous substances in recycled and newly produced materials aims to bring about the changes needed to ensure that hazardous substances are phased out of material cycles. The target supplements the milestone targets presented earlier in this report which involve more stringent requirements for restrictions or prohibitions on the manufacture, import and use of hazardous substances (see Section 4.1 and Section 6.1), the aim of which is to prevent hazardous substances from reaching material cycles altogether.

The connection to other environmental quality objectives

This milestone target makes a general contribution to the achievement of parts of the environmental quality objectives of A Good Built Environment that relate to the indoor environment, waste and recycling. The milestone target may also be of significance for the phase-out and reduced environmental impact of substances that are listed in the Annex to the European Water Framework Directive. The milestone target therefore contributes to the achievement of the environmental quality objectives - Flourishing Lakes and Streams, Good-Quality Groundwater and A Balanced Marine Environment, Flourishing Coastal Areas and Archipelagos. The milestone target also plays an important role in reaching the indents in the parts of the generational goal that concern human health, material cycles, management of natural resources and the consumption of articles.

In the short-term, there is a conflict between the target of increased recycling on the one hand and the target of material cycles free from dangerous substances as far as possible on the other. In the environmental objectives system, a conflict occurs between the environmental quality objectives of A Non-Toxic Environment and A Good Built Environment. In the short term, it may appear attractive to simplify the increased recycling target by lowering the requirements regarding the hazardous substance content of recycled
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materials. This would, however, result in increased recycling leading to greater spread of and exposure to hazardous substances.

In a more long-term perspective, there are many synergies between the aim of increased recycling and the aim of reducing the overall risks of chemical use. In both perspectives, it is desirable to phase out particularly hazardous substances and to reduce the use of other hazardous substances.

Compatibility

Right of determination

The milestone target presupposes changes to European waste, chemicals and product legislation. There is however a general acceptance within the EU that recirculation of hazardous substances in material cycles is to be avoided. It is deemed possible to establish the principle of equal requirements on recycled and newly produced materials with regard to hazardous substances by 2016. This presupposes active work by Sweden within the framework of ongoing processes in the EU, i.a. within the 7th Environmental Action Programme.

Other societal objectives

Sound resource management by way of waste recycling is an important objective in both Swedish and European environmental policy.

More stringent environmental requirements regarding materials and products that are reused or recycled may appear to hinder and increase the costs for waste management and the recycling of certain materials and articles.

In a longer perspective, however, regulations in combination with requirements for information and better information systems will facilitate recycling by helping to increase trust and creating a larger market for recycled materials. This can in turn contribute to even higher rates of recycling. At the same time, the regulations contribute to reducing the risk of exposure to hazardous substances during the entire life cycle of materials and articles.

89 See footnote 85.
Cost-efficiency

The long-term aim of strategy work on the EU level is improved, clearer and in some cases more stringent regulations governing recycled materials. In the shorter term, the regulations may involve increased costs for businesses at different points in the product supply chain and for waste disposal and recycling companies.

A cost-driven factor is the need to produce information on the occurrence of hazardous substances in materials and articles and make it available in the supply chain. Costs for substituting hazardous substances in articles may also be incurred. In certain cases, investments may be needed in equipment for the treatment and separation of waste in connection with recycling.

Costs may also arise for the combustion or landfill of waste fractions that are not suitable for recycling. Such costs will above all arise in the initial stages, in connection with the regulations being made more stringent.

It should be possible to keep the costs for updating i.a. information systems and data and the day-to-day costs at a low level. It should also be possible to keep the costs for gathering and handling information low or very low per article or product group in so far as they are the same for all the suppliers on a market. To a large extent, the costs will also be transferred to the purchaser of the article in the supply chain and to the end-consumers.

Both the reduced use of hazardous substances in articles and improved access to information about them can help reduce the business risks for companies and help them avoid significant costs in the form of e.g. damages, negative publicity, lower brand value and the recall of sold articles. Reduced occurrence of hazardous substances and better information can also combat the distrust of recycled materials.

Distributional impacts

The costs that arise as a result of the measures in the milestone target are considered to be relatively low. In accordance with the Polluter Pays Principle, these costs should be charged to manufacturers, users and the recycling industry. This also applies to the costs that can be attributed to the combustion and landfill of environmentally hazar-
The costs are generally considered to be relatively low. The milestone target will therefore not lead to any obvious distributional impacts.

Effects on government finances

To reach the milestone target, it is vital that Sweden, via the Council of Ministers and through direct contact, urges the European Commission to take initiatives in this direction. As a basis for the work, Sweden needs to present well-supported proposals and evidence. This in turn requires the relevant agencies to put resources into their analytical work and increased cooperation. The assessment of the All-Party Committee on Environmental Objectives is that this extended responsibility may require a certain reallocation of priorities at the agencies.

12.2 Milestone target on reducing children’s exposure to hazardous substances

The All-Party Committee on Environmental Objectives proposes as a milestone target:
Sweden’s efforts shall contribute to decisions being taken within existing and where necessary new regulatory frameworks that lead to a significant reduction in the environmental and health risks for children in the use of hazardous substances, no later than 2018.

Proposal for measures:
The Government should task the Swedish Chemicals Agency to cooperate with other relevant agencies and analyse particular environmental and health hazards for children linked to specific product groups, product groups or substances with certain properties, and, based on this analysis, propose an action plan to reduce the risks by the end of 2018. The analysis should cover i.a. hazardous substances in textiles, construction and furnish

90 Many articles and products are covered by the producer responsibility which is regulated in the Swedish Environmental Code. Producer responsibility involves a physical and financial responsibility for i.a. the collection and disposal of articles when they become waste.
products, electrical and electronic products, toys and other products for children, biocides in textiles and the use of antibacterial substances in articles and products for children. The analysis should also cover how the Swedish Chemicals Agency’s ongoing work on phasing out particularly hazardous substances should be prioritised in order to reduce the environmental and health risks for children in particular, with regard to bisphenol A in food packaging, decaBDE, DEHP, DBP, BBP and DiBP. The assignment should be reported no later than December 2013.

The Government should also task the Swedish Chemicals Agency and the National Board of Housing, Building and Planning to cooperate with other relevant stakeholders and perform an analysis of how the environmental and health risks for children can be reduced in children’s public environments, and, based on this, propose a plan of measures for how to reduce the risks by the end of 2018. The assignment should be reported no later than December 2013.

12.2.1 The prospects of meeting the milestone target

A significant reduction in the environmental and health risks for children in conjunction with the use of hazardous substances is crucial if the objective of A Non-Toxic Environment is to be reached. Several of the areas affected by the milestone target are dealt with in the EU within the REACH framework. The current REACH legislation shall be fully implemented by the end of 2018 and it should therefore be possible to implement the measures needed to fulfil the milestone target by then.

12.2.2 Reasoning

In the work to reduce the risks associated with hazardous substances, children and young people are particularly important. They are more vulnerable than adults to the effects of hazardous substances, since, among other things, their development is dependent on complex hormonal systems. When we take special care of our children and young people, we often protect adults from hazardous substances in the everyday environment as well.
There are several reasons why children and young people are more vulnerable than adults to the impact of chemicals. Their bodies, including their brains and nervous systems, reproductive and immune systems and various internal organs, are still developing. Disturbances to this development can have major consequences. Children are more vulnerable than adults since their biological and physical activity, as well as their social behaviour, are different from that of an adult individual. Children eat, drink and breathe more than adults in relation to their body weight\(^{91}\). Smaller children are exposed when they chew and suck things. They are also close to the floor and therefore more exposed to dust-bound chemicals. All this means that children, in relation to their body weight, risk assimilating higher concentrations of many chemicals than adults do. During childhood and adolescence, exposure to chemicals occurs mostly in the home but also in preschool and in school where children spend a great deal of their time.

Over the last 50 years, the ways in which children and young people have been exposed to chemicals has radically changed. Exposure to certain particularly hazardous chemicals, such as lead, is nowadays much lower than previously. At the same time, however, children and young people are now exposed to many more chemicals, since they have a lot more toys, clothes and other articles that contain many different chemicals.

The current regulations do not take adequate consideration of the particular vulnerability of children. Greater consideration in regulatory frameworks for the particular vulnerability of children and young people is part of the previous milestone target for increased knowledge about the health and environmental properties of hazardous substances, adopted by the Government following a proposal from the All-Party Committee on Environmental Objectives. This new proposed milestone target highlights in particular the need to reduce children’s exposure to hazardous substances as a clear basis for priority allocation in society’s efforts to reduce the risks of hazardous substances.

12.2.3 Measures

We propose the following measures to contribute to achievement of the milestone target:

- A plan to reduce the risks of particular environmental and health hazards for children.
- A plan to reduce the risks of hazardous substances in children’s public environments.

A plan to reduce the risks of particular environmental and health hazards for children

The Government should task the Swedish Chemicals Agency to cooperate with other relevant agencies and analyse particular environmental and health hazards for children linked to specific product groups, product groups or substances with certain properties, and, based on this analysis, propose an action plan to reduce the risks by the end of 2018. The analysis should cover i.a. hazardous substances in textiles, construction and furnishing products, electrical and electronic products, toys and other products for children, biocides in textiles and the use of antibacterial substances in articles and products for children. The analysis should also cover how the Swedish Chemicals Agency’s ongoing work on phasing out particularly hazardous substances should be prioritised in order to reduce the environmental and health risks for children in particular, with regard to bisphenol A in food packaging, decaBDE\textsuperscript{92}, DEHP, DBP, BBP\textsuperscript{93} and DiBP. The assignment should be reported no later than December 2013\textsuperscript{94}.

A plan to reduce the risks of hazardous substances in children’s public environments

The Government should also task the Swedish Chemicals Agency and the National Board of Housing, Building and Planning to cooperate with other relevant stakeholders and perform an analysis of how the environmental and health risks for children can be reduced in

\textsuperscript{92} Brominated flame retardants. Potential PBT substance.
\textsuperscript{93} DEHP, DBP and BBP are among the most dangerous phthalates. Toxic for reproduction.
\textsuperscript{94} Substances that are toxic for reproduction.
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children’s public environments, and, based on this, propose a plan of measures for how to reduce the risks by the end of 2018. The assignment should be reported no later than December 2013.

12.2.4 Impact assessment

The proposed measures involve the development of analyses and plans to reduce children’s exposure to hazardous substances. One of the tasks of the committees that are to propose measures is to analyse the consequences of these measures more closely, including calculating the costs involved and assessing the costs and benefits.

12.3 Priority product groups in the current work to reduce the risks of hazardous substances

The All-Party Committee’s assessment is that:
Over the next few years, the measures should focus especially on certain product groups in order to ensure that the resources used by society to reduce the risks of hazardous substances are used as efficiently as possible. In its product strategy, the Swedish Chemicals Agency has proposed that priority should be allocated to everyday articles that many people come into contact with:

- Building products and interior furnishings and fittings,
- Electrical and electronic equipment,
- Clothes as shoes and
- Toys and other articles/products intended for children.

The All-Party Committee on Environmental Objectives agrees with the Swedish Chemicals Agency’s assessment.

12.3.1 Reasoning

The annual import of articles into the EU has more than tripled from 536 million tonnes to 1 798 million tonnes between 1999 and 2008. An increasing share of article imports come from developing and transition countries. Chemicals surveillance in these countries is often poor or sometimes non-existent, which increases the risk of imported articles containing substances that can be harmful to the environment and human health.

As regards measures implemented over the next few years, special focus should be put on certain product groups so that society’s resources can be used as efficiently. In its product strategy, the Swedish Chemicals Agency has proposed the product groups that should be prioritised in the work done by agencies to reduce the risks of hazardous substances. Work should focus primarily on everyday articles that many people come into contact with and that can constitute a risk for direct exposure to hazardous substances, articles that constitute a potential risk of exposure to vulnerable groups and articles that generate large volumes of waste and/or constitute a risk of hazardous substances spreading to the environment and natural cycles. Based on these prioritisation aspects and current knowledge, the Swedish Chemicals Agency proposes that, in the next few years, society’s resources should focus on:

- Building products and interior furnishings and fittings,
- Electrical and electronic equipment,
- Clothes as shoes and
- Toys and other articles/products intended for children.

The All-Party Committee on Environmental Objectives agrees with the Swedish Chemicals Agency’s assessment. In our opinion, the relevant agencies and municipalities should bear in mind the proposals in the Swedish Chemicals Agency’s strategy when selecting areas for supervision and other initiatives. The product groups should be prioritised in connection with the development of regulations and instruments, both as regards the phasing-out of particularly hazardous substances and reduction in the use of hazardous substances in articles, and when it comes to improving knowledge and developing information systems on substances in articles.

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97 See footnote 95.
It should also be possible to use the priority product groups as guidance for voluntary initiatives as part of the self-initiated work of industries on chemicals surveillance. Every industry obviously has a responsibility for the articles it manufactures, handles and sells. The general requirements in the Swedish Environmental Code (1998:808) and the Product Safety Act (2004:451) place a clear responsibility on businesses to obtain information and exercise the necessary caution to protect human health and the environment.

In its product strategy, the Swedish Chemicals Agency ascertains that there is a need for a more general approach to reach the Government’s target of a toxic-free everyday environment. The Agency intends therefore to perform an analysis of how to ensure that particularly hazardous substances (primarily substances that are carcinogenic, mutagenic or toxic for reproduction, known as CMR substances) do not occur in articles intended for consumers. Such a general requirement should first and foremost be incorporated into REACH or the European Product Safety Directive. See earlier in this report for proposals on how to improve REACH.

It is our assessment that no adjustments to society or legal changes are needed to achieve a prioritisation of certain product groups in our chemicals management. The Government Offices of Sweden and other agencies have the tools needed to prioritise their current efforts within their respective remits.

12.4 Environmental impact of cosmetic and hygiene products

12.4.1 Focus on health aspects in legislation

In our terms of reference, cosmetic and hygiene products are identified as an important product group about which there is currently limited knowledge about the potential risks of use.

There are several examples of environmental problems associated with cosmetic and hygiene products. There are reports, for example, indicating that the UV filters used in sun protection products are toxic to aquatic organisms. Another area of specific interest is the use of preservatives and antibacterial substances in cosmetics. Some of these substances are also used as preservatives.

in other types of chemical products and articles. Since these types of substances are intended to be biologically active, they also have potentially harmful properties.\(^9\)

Since cosmetic and hygiene products are used directly on the skin, hair and in the mouth, the exposure and hence the health risks are substantial. This is why health aspects are central in the legislation.\(^10\)

A significant amount of product residue gets into wastewater, e.g. when people wash themselves, or in certain cases directly into surface water, e.g. suntan lotions.\(^11\) In other words, potentially ecotoxicological substances that are contained in products can get into rivers and streams and put pressure on wastewater treatments plants. Since cosmetic and hygiene products are mostly widely used consumer products, it is important to improve surveillance also when it comes to environmental aspects.

12.4.2 **Cosmetic and hygiene products are covered by the overarching proposals from the All-Party Committee on Environmental Objectives**

**Allergens**

The most common examples of health problems that may be caused or triggered by cosmetic and hygiene products are contact allergy and skin irritations.

Data on substances that cause skin allergies are already available to a certain extent via the European classification system and through special initiatives that categorise “contact allergens” in the cosmetics field. In the forthcoming years, these data will probably be further improved, both in terms of quality and accessibility, which increases the scope for prioritising the phase-out and restriction of these substances in cosmetic and hygiene products. Powerful allergens are covered by the milestone target on particularly hazardous substances (see Section 4.1). It is our assessment that the wording “relevant regulatory frameworks” also includes European cosmetics legislation.

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\(^11\) Results from the Swedish National Screening Programme 2009 IVL report B1971, Subreport 3: UV-filters.
Special initiatives may however be justified, for health reasons, to reduce the use of allergens in cosmetic and hygiene products. Such initiatives may include both voluntary undertakings from the business sector and further restrictions on such substances in cosmetics legislation. For example, there may be a need for regular and systematic review of the rules on substances in the European regulation on cosmetic products. Measures focusing on health aspects are primarily outside the scope of the All-Party Committee on Environmental Objectives. We also note that the new European cosmetics legislation, which has yet to come into force, contains regulations on, i.a. allergens and nanomaterials. Planned reviews shall also cover endocrine disruptors.

Environmental risk assessments of low-volume substances

In a report from 2004, the Medical Products Agency states that there is a basic lack of data on the ecotoxicological properties, such as degradability and toxicity for aquatic organisms, of ingredients in cosmetic and hygiene products. This lack of ecotoxicological data is still seen as a problem in 2012. The Medical Products Agency also ascertains that very few surveys have been performed of the occurrence of such substances in the environment.

Within the framework of its task, the Medical Products Agency looked at a small number of potentially ecotoxicological substances using a calculation model for environmental risk assessments. For some of the substances for which data were available, it was found that environmentally harmful properties could not be eliminated. In the report, the Medical Products Agency proposed a number of measures to improve the prerequisites for dealing with the environmental aspects of cosmetic and hygiene products.

These measures include requiring companies to generate environmental data. Via REACH, there are currently such requirements for

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102 The “substance rules” in the cosmetics regulations state which substances may be used under special conditions and restrictions. The committee procedure by which the substance rules are issued, which includes risk assessment in a scientific committee, means that the agencies provide a kind of guarantee for the safety of the substance. When new knowledge emerges from e.g. researchers the substance rules are not reassessed, however, i.e. the approval of a substance is not in certain cases based on the latest knowledge. The protection level for the substance therefore risks being inadequate. Rules may therefore be necessary on the regular reassessment of the substance rules in the regulation’s lists of substances in Annexes III-VI.

103 See footnote 99.
data on ecotoxicological and toxicological properties for substances that are used in cosmetic and hygiene products. It is likely however that the data needed for environmental risk assessment will still be missing for many substances, since they are handled in volumes under 10 tonnes per year. There is an earlier milestone target that i.a. covers tougher requirements in REACH on generating data for what are known as “low-volume substances” (see Section 4.1). Even the other adopted milestone targets and the new proposal for milestone targets in Section 6.1 in this report will contribute to tougher requirements for substances contained in cosmetic and hygiene products.
Reducing the risk of hazardous substances in contact with food

### 13.1 Reducing the risks of hazardous substances in contact with drinking water

**The All-Party Committee’s assessment is that:**
Measures aimed at reducing the risks of hazardous substances that come into contact with food shall be continuously implemented within the framework of current food and chemicals policies. There is also a need to review the risk management of materials that come into contact with drinking water. It is the Committee’s assessment that this can take place within the framework of current legislation.

**Proposal for measure:**
The Government should task the National Board of Housing, Building and Planning, the National Food Administration and the Swedish Chemicals Agency to cooperate with other stakeholders to analyse the risks of materials that come into contact with drinking water and propose the measures needed to ensure that drinking water from the tap is free from substances that pose potential risk to human health. The measures shall be introduced no later than 2016.
13.1.1 Reasoning

Focus on preventive work to reduce the occurrence of hazardous substances in the environment

Many of the foreign substances that occur in food get there as a result of being assimilated from the ambient environment or from animal feed, or are formed in the food as a result of e.g. production processes. Bearing in mind the vast flow of chemicals in society, it is important to prevent potentially harmful substances from spreading to food.

It is equally as important to create the conditions needed to be able to identify both “new” and “old” hazards and risks associated with chemical substances in food. It may be too late, or require far too much action, to eliminate the risks, once high concentrations of hazardous substances have already been found in food.

The focus of the work to achieve a non-toxic environment should be put on preventive work and on measures carried out at source. The adopted milestone target on particularly hazardous substances (see Section 4.1) and the proposals we are submitting in Section 6.1 in this report have an important role in this work. By reaching these targets, the risk of hazardous substances getting into food can be reduced.

The risks associated with hazardous substances in food handling should decrease

Hazardous substances can get into food during raw material processing, distribution and preparation. The existing regulations and supervision in this area are, in our opinion, mostly satisfactory. There is however a need for improvement in two areas in order to reduce the risks of materials that come into contact with food.

Packaging materials contain a large amount of chemical substances that can migrate from the packaging into the food. The extensive European legislation\textsuperscript{104} along with the European food industry’s self-inspection procedures are deemed to function well and the field can be considered relatively safe.

\textsuperscript{104} The overarching legislation is the framework regulation that applies to all materials and products that come into contact with food: REGULATION (EC) No 1935/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.
Regarding materials in contact with food, the Commission provides the Member States with the opportunity to take measures under Article 5 of the Framework Regulation. These measures include carrying out evaluations and issuing ordinances regarding certain specified groups of materials and substances.

The National Food Administration has developed a risk profile for materials in contact with food aimed at identifying packaging materials, domestic appliances or chemical substances that pose a potential health risk to the consumer. Knowledge about the risks of food contamination is incomplete but is gradually increasing. It is vital that the requirements on materials and products in European food legislation can be adapted when new scientifically based risk assessments are performed.

This area is covered by the milestone target on knowledge of the health and environmental properties of substances (Section 4.1). Under this target, Sweden’s efforts shall contribute to decisions being taken within existing or where necessary new European or international regulatory frameworks that require data on the ecotoxicological and toxicological properties of chemical substances to be available and that the data are sufficient to enable risk assessment to be performed for all areas of use. The concept of “all areas of use” also includes materials in contact with food.

Tougher requirements on the purity of packaging can limit the use of recovered materials. Section 12 of this interim report contains an in-depth discussion on the conflict between the objective of increased recovery and the requirement for low concentrations of substances that are contained in recovered material.

Drinking water quality is of central importance for public health. Even though the quality of Swedish drinking water is generally considered to be good, there is a risk of substances with obvious negative health effects being assimilated into drinking water from the water pipes that transport it to the consumer’s taps. Safe water pipes, i.e. pipes that do not emit hazardous substances into the drinking water, are a prerequisite for the successful achievement of the environmental quality objective of A Non-Toxic Environment.

Drinking water constitutes the basis of all food production and preparation and its safety must therefore be guaranteed so that it does not contain substances that might constitute a risk to human health and the environment. Drinking water differs from other

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105 National Food Administration’s report series 5-2011; Risk profile of materials in contact with food.
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SOU 2012:38

Foodstuffs in that it is consumed by both infants and adults, and is consumed every day throughout life. Drinking water that contains hazardous substances cannot be recalled in the same way as other foodstuffs can be. It is hence even more important to regulate and inspect drinking water.

Environmental legislation has appropriate regulations protecting raw water from pollution. New challenges such as climate change and the impact of hazardous substances are a threat, however. There is also a risk that substances with obvious negative health effect can get into drinking water via the water pipes that transport it to the consumer’s tap.

Within the EU, drinking water issues are primarily regulated by the Drinking Water Directive. This directive states i.a. that the Member States shall establish the values that are to apply for a larger number of drinking water parameters. According to the directive, a Member State may lay down more stringent requirements than the values specified. Furthermore, a Member State may establish quality values for additional parameters. The directive does not contain regulations on how Member States are to work to achieve the established values. There is currently a lack of legislation that clearly regulates materials in contact with drinking water, both within the EU and nationally in Sweden.

The European Drinking Water Directive states that Member States shall take measures to ensure that no substances or materials for new installations used in the preparation or distribution of drinking water pose risks to human health. Member States have the right of determination to develop their own legislation to regulate health issues associated with drinking water distribution. Four Member States (France, the Netherlands, the UK and Germany) are working to try to harmonise requirements on materials and products in contact with drinking water. The aim is to agree on a list of acceptable substances, product standards, standards for testing methods, common surveillance systems and what is known as a “positive list” of materials. The National Board of Housing, Building and Planning participates in meetings within the framework of this work.

In a few cases, warnings have been sounded in Sweden regarding high concentrations of lead as a result of drinking water coming into contact with lead alloys in water valves and fittings. Even though high

concentrations are unusual in Sweden, lead can nevertheless be seen as a risk when it comes to drinking water\textsuperscript{107}.

Other substances that should be monitored are those used in the renovation and repair of water pipes. Both public and privately owned pipes are of considerable economic value and the costs of replacing old piping can amount to several thousand Swedish kronor per metre. The homes built as part of the million-homes project in the late 1960s and early 1970s will soon need of major repair. According to the water and wastewater industry, this may lead to the increased use of epoxy pipe lining to repair deteriorating piping. The method is marketed as simple and cost-efficient and increased use is therefore likely.

When relining pipes using this method, the inside is coated with a plastic film which is then allowed to harden. Epoxy plastic is often used as a bi-component material in which bisphenol A, which is classed as an endocrine disruptor, constitutes one of the components. The risks associated with bisphenol A have been highlighted in other contexts. As from 1 March 2011, it is no longer permitted to manufacture babies’ bottles containing bisphenol A and as from 1 June 2012, such bottles can no longer be bought within the EU\textsuperscript{108}. The Government decided in April 2012 to implement further studies and measures linked to bisphenol A. One such measure is to prohibit the use of bisphenol A in the packaging of food intended for children under the age of three. The Swedish Chemicals Agency has furthermore been tasked to look into a prohibition on the use of bisphenol A in thermo-paper which is used in e.g. cash register receipts and tickets. After consultation with the Swedish Consumer Agency, the Chemicals Agency shall also carry out an analysis of the extent to which bisphenol A occurs in and can be emitted from toys and children’s articles\textsuperscript{109}. The Chemicals Agency has also been tasked to cooperate with the National Board of Housing, Building and Planning and the National Food Administration and study the extent to which bisphenol A can be

\textsuperscript{107} EFSA and Joint FAO/WHO’s Committee on Food Additives (JECFA) evaluated the risks of lead in 2010. Both EFSA and JECFA were of the opinion that the previous PTW1 (25 μg/kg bw), established by JECFA, was no longer applicable since there was not considered to be an apparent threshold for critical effects of lead. EFSA (2010) did, however, establish a number of health-based reference points for lead exposure. EFSA ascertained that the exposure for pregnant women (foetuses) and children in Europe is on a level that is close to or over the reference value (0.5 μg/kg bw/day).

\textsuperscript{108} COMMISSION IMPLEMENTING REGULATION (EU) No 321/2011.

\textsuperscript{109} Government assignment M2012/1034/Ke The final report of the assignment is to be presented by 15 September 2012 at the latest.
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emitted in connection with water pipe refurbishment and to propose measures to reduce exposure. A final report on this assignment is to be presented no later than December 2013. The recently initiated assignment (see above) will provide important knowledge on this subject. A large percentage of the Swedish housing stock will have to be refurbished over the coming decades. With efficient systems for ensuring that new or refurbished water pipes do not emit foreign substances - often with unknown effects - it is possible to ensure that everyone has access to drinking water that corresponds to the objective of A Non-Toxic Environment within a relatively short period of time.

The regulations issued by the National Board of Housing, Building and Planning contain provisions on water pipes. In accordance with these, tap water installations are to be made of materials that do not emit unhealthy concentrations of harmful substances into the tap water. There are no guidelines or instructions regarding the risks associated with different materials, however.

It is the assessment of the All-Party Committee on Environmental Objectives that there is a need to review the risk management of materials that come into contact with drinking water in water purification plants, water piping and property installations, up until the point at which the water comes out of the tap. This review should cover all the substances that are suspected of constituting a risk. It is the Committee’s assessment that this can take place within the framework of current legislation.

13.1.2 Measures

The Government should task the National Board of Housing, Building and Planning, the National Food Administration and the Swedish Chemicals Agency to cooperate with other stakeholders to analyse the risks of materials that come into contact with drinking water and propose the measures needed to ensure that drinking

110 Government assignment M2012/1035/Ke
112 National Board of Building, Housing and Planning Building Regulations (BR) 6:11.
water from the tap is free from substances that pose a potential risk to human health. The measures shall be introduced no later than 2016.

A first step has already been initiated by the Government in its assignment to the agencies to analyse which materials are used to refurbish drinking water pipes and the risks of these materials connected to bisphenol A. We see however that there is still a need to perform a broad review of the risks of materials that come into contact with drinking water.

Experiences from countries that already have national regulations in this area should be utilised in the analyses. The basic principles for risk assessment and legality in these countries are the same even if there are national differences in both their design and actual approval procedure. One aim in the Swedish analyses should be to lay the groundwork for Swedish participation in the cooperation project to establish community-wide requirements on manufacturers and the construction industry.

13.1.3 Impact assessment

Effectiveness

There is a need to ensure that water pipes do not consist of or are coated with substances that can be emitted to drinking water and that can be harmful to health. It is the assessment of the All-Party Committee on Environmental Objectives that this need can be satisfied within the framework of current legislation. The sort of measures required to ensure drinking water quality do not therefore need to be expressed as a milestone target.

The Committee would nevertheless like to highlight the issue of drinking water quality by suggesting that the Government task the relevant agencies to propose measures to ensure that drinking water is free from hazardous substances. Drinking water quality is of central importance for public health.

The consequences of forthcoming measures

One of the most important results that can be expected from the forthcoming proposals for measures put forward by the agencies is enhanced safety for one of our most important foodstuffs, drinking water.
Restrictions in the choice of materials and products in connection with new production and refurbishments may lead to greater investment costs for property owners. One consequence of the proposal is that it will make it easier for water producers and property owners to fulfil the stipulated safety requirements. In the long term, this means that society will avoid unnecessary costs in the form of investment or the risks associated with materials that have been shown to have negative environmental and health effects. One task for the committee that is to propose measures is to calculate the costs more precisely and to perform an appropriate cost-benefit analysis.

13.2 Knowledge building and skills provision

Knowledge about the health and environmental properties of chemical substances is an important prerequisite in order to be able to take preventive measures to minimise the risks of hazardous substances in food. Skills, greater knowledge and research resources are required for Sweden and the EU to be able to pursue an ambitious policy in this area. Sweden can contribute knowledge and be a driving-force as regards development and innovation in the common efforts on environmental and health risk assessments within the EU and internationally. Chapter 8 of this report presents a detailed discussion on the knowledge requirements in the chemicals field.
Part D.
Overall impact assessment
14 Impact assessment of the strategy for a non-toxic environment

14.1 Introduction

This chapter presents an overall impact assessment of Sweden’s integrated strategy for a non-toxic environment. The strategy includes eight milestone targets, three of which were proposed in the Committee’s report Milestone Targets in the Swedish Environmental Objective System (SOU 2011:34). These milestone targets have been established by the Government in a decision on 26 April 2012. As regards the five milestone targets proposed in this report, specific impact assessments have been presented in earlier chapters. The same is true of the measures that have been proposed as a result of the assessments we have made with regards to particularly important issues.

The impact analysis begins with a review of the changes to environmental policy regarding hazardous substances that need to be implemented in order to be able to reach the environmental quality objective of A Non-Toxic Environment and the generational goal. There is then a description of how our proposed strategy for a non-toxic environment deals with this need for policy change. The aim is to answer the question whether the strategy is appropriate and whether it eliminates several of the obstacles that stand in the way of reaching the environmental quality objective and the relevant parts of the generational goal. Regarding the issue of effectiveness, alternative ways of reaching the objective are also examined.

The impact analysis also highlights issues relating to the strategy’s compatibility with Sweden’s membership of the EU and other international commitments. Whether the strategy is compatible with other policy goals is also discussed. The conditions needed for cost-efficient
impact assessment of the strategy for a non-toxic environment

As we have indicated in this report, Sweden’s current chemicals policy will not achieve the environmental quality objective of *A Non-Toxic Environment* by 2020 despite measures having been implemented.

### 14.2 The strategy’s effectiveness

#### 14.2.1 The strategy focuses on the need for development in chemicals policy

The aim of the strategy for a non-toxic environment with its eight milestone targets proposed by the All-Party Committee on Environmental Objectives is to improve our chances of reaching the environmental quality objective of *A Non-Toxic Environment* in the long term. The milestone targets focus on four main areas and several of them are important for development in more than one area.

**Far too slow phase-out of hazardous substances**

The far too slow phase-out of particularly hazardous substances is dealt with by four of the milestone targets:

- An innovation-driving REACH II.
- New and better regulations on particularly hazardous substances (SOU 2011:34)
- Increased environmental consideration in EU pharmaceuticals legislation.
- New and better regulations to reduce children’s exposure to hazardous substances.

The milestone target on risk assessments of substances based on certain intrinsic properties, chemical structure and/or area of use and tougher requirements for the substitution of hazardous substances is of key significance here. The milestone target involves a radical development of European chemicals regulation. A change in accordance with the milestone target so that authorisation can be
directed at groups of substances based on e.g. intrinsic properties, is one of the conditions needed if we are to be able to reach the environmental quality objective of *A Non-Toxic Environment* within the foreseeable future. The milestone target involves more effective prohibitive legislation as regards the supply and use of particularly hazardous substances. The focus of the milestone target on greater substitution will also increase the incentives for innovation and self-regulation as regards the manufacture and use of hazardous substances.

The introduction of a REACH II is an extensive project and presupposes cooperation with strategically selected EU Member States. It is our assessment that 2020 is a realistic time target for a major revision of REACH. It presupposes, however, that the work to develop proposals for new principles starts as soon as possible.

The aim of the milestone target on particularly hazardous substances is to set a goal for the timetable for the phase-out of particularly hazardous substances within the framework for what is possible within the current chemicals legislation. The work on particularly hazardous substances has been given priority and is central to the efforts to reach the environmental quality target of *A Non-Toxic Environment*. Implementation of the milestone target is an important step to creating the prerequisites for a non-toxic environment. This work can be done within the framework of current European chemicals legislation. The milestone target should therefore be reachable no later than 2018 and independently of how REACH II develops. A change in accordance with the milestone target will lay a sound foundation for the groupwise phase-out of substances, which is the aim of the milestone target on REACH II.

The milestone target on *environmental consideration in pharmaceuticals legislation* aims to include pharmaceuticals among products that are subject to authorisation before they are marketed, in so far as it shall be possible to consider environmental aspects in the benefit-risk assessment that is performed in connection with the authorisation of a new medicinal product. This product group is important since pharmaceutical waste can harm aquatic organisms. This is not least true of endocrine disruptors that are often contained in medicinal products. Pharmaceutical waste in the environment is also a public health issue. The Precautionary Principle must be the prevailing norm here, especially so as not to risk harming the development of children and young people or human reproduction. Children and young people can be more vulnerable to the effects of pharmaceutical
waste, since, among other things, their development is dependent on complex hormonal systems.

The milestone target on reducing children’s exposure to hazardous substances points to the particular need to reduce children’s exposure to hazardous substances as a clear priority in society’s efforts to reduce the risks of hazardous substances. The current regulations do not show adequate consideration of the particular vulnerability of children.

**Need for information and knowledge development**

Two milestone target concern the current lack of knowledge and information on hazardous substances:

- More stringent requirements for knowledge about the health and environmental properties of substances (SOU 2011:34).
- Better availability of information on hazardous substances in articles (SOU 2011:34).

According to the milestone target on knowledge of the health and environmental properties of substances, chemicals legislation in the EU shall require that data on chemical substances are available and that they are sufficient to enable a risk assessment for all areas of use. A central issue in this milestone target is the added data requirements in REACH in connection with the registration of “low-volume substances”. The target also covers knowledge about combination effects. According to the target, the regulations shall consider the particular vulnerability of children to the impact of chemicals by latest 2015. The information requirements are one of the prerequisites for a rational phase-out of particularly hazardous chemicals from the European market.

The aim of the milestone target on information about hazardous substances in articles is to make it easier for users to make active choices, e.g. in procurement procedures. Available and adequate information about hazardous substances in articles also facilitates their use and waste disposal. The milestone target can be seen as an important step in the work to phase out particularly hazardous substances from the market and also creates the prerequisites for reducing the risks associated with the handling of chemical substances. The implementation of a REACH II can also improve the prerequisites for users to obtain information on the potentially harmful
effects of substances on human health and the environment. By focusing authorisation and registration on groups of substances with the same toxicological and ecotoxicological properties, the volume of information needed should be less than that required for each specific substance.

**Material cycles free from hazardous substances**

The objective of creating material cycles that are as far as possible free from hazardous substances is covered by one of the milestone targets:

- Equal requirements within the EU on hazardous substances in recycled and newly produced materials.

The aim of this milestone target is to eliminate hazardous substances from material cycles and supplements the milestone targets that are aimed at prohibiting the manufacture, import and use of hazardous substances.

A phase-out of hazardous substances means that it will no longer be possible to use them in the manufacture of articles and products. Previously manufactured articles and products, such as construction materials, may however still contain hazardous substances. One of the environmental policy goals of the EU is that materials in articles and products are to be seen as a resource and are to be recycled. It is important that the recycling of materials does not lead to the contamination of newly produced articles and products by otherwise prohibited substances.

**Effective supervision**

One milestone target concerns the issue of effective supervision in chemicals policy:

- More effective chemicals supervision within the EU.

The aim of this milestone target is to enhance the quality of national supervision of chemicals legislation in the Member States. The aim is to create the same conditions on the European internal market and thereby ensure that an ambitious European chemicals policy has a forceful impact. The milestone target identifies a stra-
The eight proposed milestone targets are the lynchpin of a Swedish strategy for a non-toxic environment. They describe the areas in which strategic changes are needed above all to European legislation.

A prerequisite for the achievement of the objective of a non-toxic environment is the ongoing work at the relevant agencies. The All-Party Committee on Environmental Objectives has identified a number of priority areas for this work. In some cases, this will require the relevant agencies to reallocate their priorities and modify their working methods.

### 14.2.2 Alternative courses of action

Two fundamental choices have been made in the proposed strategy. The first is to focus on the prevention of environmental damage by implementing measures at source, i.e. preventive measures to stop hazardous substances from reaching the market and getting into material cycles, thereby reducing the risks of damage to the environment and human health. The other choice is to focus the milestone targets on changes to European legislation.

**Regulation of specific chemicals use is a supplement to measures at source**

Seven of the eight proposed milestone targets focus directly on measures at source. One milestone target – on effective supervision within the EU – shall contribute to better achievement of chemicals policy goals and hence support the other seven targets.

An alternative to a policy that concentrates on measures at source is to focus regulation on areas or product groups in which hazardous substances occur. This course of action has also been traditionally used within the EU, including as part of product-specific directives for particular product groups. Examples of such directives include the Toy Safety Directive[^13], the Directive on

Electrical and Electronic Equipment\(^{114}\) and the Directive on Batteries and Accumulators\(^{115}\).

The European chemicals regulation, REACH, which is a central tool in European chemicals policy that came into force in 2007, involves a new direction for chemicals policy in that it places a responsibility on manufacturers and importers to guarantee the safe use of substances and to ensure that the health and environmental properties of manufactured and imported chemical substances are well documented.

The new approach to chemicals policy that is the reason behind the implementation of REACH provides much better prerequisites for reaching the environmental quality objective of *A Non-Toxic Environment*. Additional initiatives are however necessary to reach the environmental quality objective. The potential for the preventive measures in REACH needs to be better utilised. The regulations in REACH need to be developed to ensure a more effective phase-out of toxicological and ecotoxicological substances.

A Swedish strategy for a non-toxic environment should have preventive initiatives as one of its starting-points. The focus of the strategy should be on measures at source for it to fulfil its purpose. This standpoint is expressed via the proposed milestone targets.

A focus on measures at source does not exclude the likelihood that measures may often need to be directed at specific areas. The All-Party Committee on Environmental Objectives has analysed a few issues that require such initiatives. These include food, where measures are required to reduce the risks associated with drinking water distribution.

**European legislation is an effective instrument to reduce the risks of hazardous substances**

Trade in chemical articles and products both within the EU and between the EU and the rest of the world is extensive. In order to ensure as broad an impact as possible in this area, the milestone targets on a non-toxic environment are directed towards changes in


European legislation. Ensuring that the EU is a strong player on the world market can also help pursue global level agreements where and when appropriate.

A fundamental principle of European chemicals legislation is that it is the manufacturer or importer of hazardous substances or articles and products that contain them who has the main responsibility for ensuring that the information on the properties of such substances is adequate for downstream users and agencies. It is also the manufacturer, importer and user who are expected to replace hazardous substances with (new) substances and/or production processes that are less harmful to human health and the environment.

Swedish national measures can be justified as a supplement to initiatives on the EU level. The All-Party Committee on Environmental Objectives has identified a number of national initiatives that are essential for reducing the risks to public health and to the environment and hence important for reaching the objective of a non-toxic environment. These initiatives can be mostly implemented within the framework of current legislation and as part of the routine work of the relevant agencies.

14.2.3 Socioeconomic benefits of implementing the strategy

The objective of the proposed Swedish strategy for a non-toxic environment is two-fold: to remove the shortcomings, mainly in European legislation, that impede the realisation of the environmental quality objective of *A Non-Toxic Environment* and to ensure that the implementation of the current legislation is completed.

There are no complete studies of the socioeconomic costs of the currently inadequate legislation and the slow pace of implementation. An indication of these costs is given in a report published by the European Commission in the autumn of 2011, which estimated the costs of ill-health caused by the shortcomings in the implementation of the current REACH regulation to be 4-5 billion euros per year. It is stressed however that this is an underestimation of the costs since it only includes cases of ill-health caused by direct exposure to hazardous chemicals. Neither have the environmental

costs of inadequate implementation been included here. The aim of the proposed strategy is also to tighten the legislation, which will generate further socioeconomic benefit.

The socioeconomic income for the EU of an implementation of the strategy can therefore by calculated at more than 5 billion euros per year. The costs of introducing REACH incurred by the European chemicals industry have been estimated at around 1 million euros per year; see Section 14.2.2 for more details. Provided that the strategy can be fully implemented, the socioeconomic benefit can therefore be estimated to be at least 5 billion euros per year.

14.3 Compatibility

This section looks at issues connected to Sweden’s right of determination regarding the decisions that need to be made in order to implement the strategy and the consequences of implementation for the competitiveness of the business sector.

14.3.1 Right of determination

The eight proposed milestone targets presuppose changes to European legislation. Some of them also necessitate an increased level of ambition in European chemicals policy, which means that it is even more of a challenge for an individual Member State to implement them.

One condition to enable the realisation of the EU-related milestone targets, is that Sweden cooperates with other countries that prioritise an active chemicals policy and that also seek to improve the EU regulatory framework. It is the assessment of the All Party Committee on Environmental Objectives that there are Member States that may have an interest in cooperation to strengthen and amend the European chemicals legislation. An important initial step in the Swedish strategy for a non-toxic environment is for the Government Offices and the relevant agencies to identify suitable cooperation partners and together with them to plan a process for achieving the changes to European legislation targeted in the strategy.

One of the milestone targets may involve an encroachment on the Member States’ discretionary powers in relation to decisions on the EU level. Chemicals legislation is almost completely harmonised
within the EU although one exception is supervision. It is the responsibility of the Member States to ensure that their companies are fulfilling the requirements in e.g. REACH. The milestone target on more effective chemicals supervision within the EU therefore involves the EU having greater influence regarding decisions on the scope and focus of national supervision. This concerns issues such as common standards for analysis methods and minimum inspection levels.

Circumstances in which the EU is given powers of influence over the supervision activities of the Member States and where the fundamental regulations on supervision are harmonised are nothing new within the Union. Requirements on the supervision of the Member States are in place within other regulatory areas, both within and outside environmental policy, even though they are currently lacking in chemicals and product legislation.

14.3.2 The competitiveness of the business sector

The strategy involves additional costs for the European chemicals industry...

An important policy goal both within Sweden and the EU is to promote and strengthen the competitiveness of industry. One issue is therefore whether the Swedish strategy for a non-toxic environment can come into conflict with the goals for competitive industry.

The strategy aims to bring about changes in the handling of hazardous substances and products. These changes may, at least in the short-term, involve costs for industry. It is in accordance with the Polluter Pays Principle that those who handle hazardous substances are to pay for the risk of causing environmental damage.

For companies that manufacture, import and market hazardous substances or articles and products that contain such substances, the changes will mean tougher requirements for information on their properties and the composition of products.

The central aim of the policy for a non-toxic environment is to phase out hazardous substances from the market, from natural cycles and from the environment. To achieve this aim, less hazardous substances have to be developed or technologies and manufacturing
methods need to be developed that render hazardous substances unnecessary.

The tougher knowledge and information requirements placed on manufacturers and importers involve costs that, it can be assumed, will be transferred to the users of chemicals, including the manufacturing industry. Costs arising from the prohibition of certain substances will also be incurred by manufacturers that use chemicals in their production processes.

... but these additional costs are minimal

An indication of the magnitude of the costs that industry will incur as a result of the strategy being implemented can be obtained by examining the calculations made in connection with the introduction of REACH.

In the impact analysis performed by the European Commission in 2003, prior to the decision on REACH\(^{117}\), the additional annual costs, calculated as a present value, to the European (EU-15) chemicals industry were estimated at 2.3 billion euros. The costs to other chemical-using industries, e.g. the textile industry, as a result of certain chemicals having to be replaced by less hazardous alternatives or new production methods, must be added to this sum. These costs were broadly estimated to be between 0.3 and 2.9 billion euros as a calculated present value.

The Commission’s impact analysis ascertains that the aggregate additional costs of 2.8-5.2 billion euros as a result of REACH seem very limited in a macroeconomic perspective. A large proportion of the costs are incurred by the European chemicals industry. One question is the extent to which the costs affect the industry’s competitiveness.

In 2004, the Nordic Council of Ministers published a study of the potential costs to the European chemicals industry (EU-15) of an introduction of REACH\(^{118}\). The study assessed the costs for the implementation of REACH in its current form, and of a more extensive REACH regulation in accordance with the Commission’s


original proposal (REACH+). REACH+ includes i.a. additional data requirements for new and existing “low-volume” chemicals (1-10 tonnes per year) and safety reports for all chemicals.

The direct costs for testing and registration were estimated for REACH+ at about 4 billion euros calculated as an aggregate present value, which corresponds to 0.4 billion euros per year or just over 0.06 percent of the chemicals industry’s total sales revenue. This amount is slightly higher than the Commission’s estimate. Indirect costs must also be added to this. These consist of both the cost increases caused by the fact that certain chemicals have to be replaced by others, and the decrease in sales that can be anticipated as a result of higher prices for the industry’s products.

According to the models used in the study, the total costs for the industry, i.e. including the indirect costs, would be 1.5 to 2.3 times greater than the direct costs, which would mean total costs of around one billion euros per year. REACH+ would therefore involve costs for the chemicals industry amounting to just a fraction of a one percent of its total sales.

A more relevant indication of the impact on profitability can be obtained by putting the cost increases in relation to value added in the European chemicals industry. In 2001, value added (EU-15) amounted to 107 billion euros. The industry’s costs of around one billion per year would therefore correspond to about one percent of value added.

The Nordic Council of Ministers’ study ascertains that price changes of a similar magnitude as the costs for REACH are an everyday occurrence in the industry and do not stand in the way of continued profitable operations. Changes in the weekly price of crude oil on the spot market are usually greater than this. The price indices for industrial input goods (produced by one company and used by another) within the EU-15 group show greater changes than these almost every month.

Most of the milestone targets included in the proposed strategy affect the REACH legislation. They are basically in line with REACH+ in the Nordic Council of Ministers’ report, although they go further in certain respects. It should be noted, however, that the milestone target on groupwise authorisation of substances based, for example, on intrinsic properties, does not tighten the requirements or broaden the scope of REACH. The aim of this

119 See footnote 117.
milestone target is to accelerate the authorisation procedure, which brings forward the costs for the industry. The other milestone targets do not affect the industry’s costs to any great extent.

The indicated magnitude of the additional costs to industry as a result of the strategy show that these are small. The strategy will not significantly affect the competitiveness of the European chemicals industry. This does not however exclude the fact that it may be more expensive to export certain products from the EU and hence have a negative effect on competitiveness on markets with less stringent environmental requirements than in the EU. We have not analysed the extent to which this will negatively affect individual companies that focus on this type of product.

**Enhanced competitiveness for the Swedish chemicals industry**

The proposed strategy mostly involves initiatives on the European level, of which the Swedish chemicals industry is a part. For Swedish industry, it is important that conditions of competition do not differ between Member States as a result of the national application of EU legislation. Chemicals legislation within the EU is harmonised. Most supervision is done nationally, however, and its scope and focus are also determined on the Member State level.

Swedish industrial organisations have called for initiatives to accelerate EU efforts to bring about a common approach and common practice at Member State supervisory authorities in order to create a level playing field for the chemicals industry. The milestone target for more effective chemicals surveillance within the EU is a step forward in the efforts to create fair and even market conditions for businesses in EU Member States.

The proposal by the All-Party Committee on Environmental Objectives to task the relevant research and development financiers to develop a strategy for intervention research and innovation in the chemicals field is of significance for the Swedish industry’s competitiveness. Research, development and innovations are key if we are to be able to substitute hazardous substances. New substances and production processes in the area have even been shown to lead to other positive effects, including major energy savings for businesses as a result of new production processes.

Through goal-driven cooperation between research and business, Sweden can become one of the leading innovation nations in the area
known sometimes as “green chemistry”. This creates the conditions necessary for the development of a modern, innovative Swedish industry.

The strategy is also of significance for other environmental quality objectives...

The occurrence of hazardous substances affects our chances of reaching several other environmental quality objectives. This is particularly true of the water-related objectives and in particular *Flourishing Lakes and Streams, Good-Quality Groundwater and A Balanced Marine Environment, Flourishing Coastal Areas and Archipelagos*. Successful implementation of the strategy for a non-toxic environment will achieve important steps on the way to reaching these objectives.

The proposed milestone target on equal requirements within the EU on hazardous substances in recycled and newly produced materials may cause a conflict between the environmental quality objectives of *Limited Climate Impact* and *A Good Built Environment*. By stipulating the same requirements on recycled articles as on newly produced materials, there is a risk that recycling rates will decrease. An important element in the work to limit the effects of climate change is the creation of resource-efficient cycles of materials, articles and products. Reuse and recycling are also of importance to the parts of the Good Built Environment objective that concern waste.

It is our assessment, however, that this conflict between the two objectives is only short-term. In the longer term, there are many synergies between the aim of increased recycling and that of a general reduction in chemicals use. In both perspectives, it is desirable to phase out particularly hazardous substances and to reduce the use of other hazardous substances.
... and has no obvious consequences for other political objectives or other stakeholders

The strategy can affect the competitiveness of small and medium-sized enterprises (SMEs). This issue is discussed later on in this chapter under the heading Distributional impacts. As regards other policy areas, the strategy proposal is not expected to have any obvious consequences.

14.4 Cost efficiency

Given that the milestone targets are reached, it is important that the costs associated with the data and information requirements and the faster phase-out can be kept at a low level, i.e. that the transition to a non-toxic environment takes place in a cost-efficient manner.

The strategy has a few fundamental cornerstones that create the prerequisites for cost-efficiency. One such cornerstone is that the strategy is based on the Polluter Pays Principle, which places the responsibility for implementation of the adopted environmental protection measures on industry. This creates the prerequisites for green and innovative product and process development in the business sector. Another cornerstone of the strategy is that the measures are to be implemented on the EU level. Furthermore, the strategy is based on pollution being tackled at source, i.e. before hazardous substances reach the material cycle. The consequences as regards the administrative costs for businesses and agencies of satisfying the data requirements for authorisation are substantial.

The Polluter Pays Principle - a cost-efficient phase-out of particularly hazardous substances.

A fundamental principle in Swedish and European environmental legislation is that the polluter pays the costs of the preventive measures required to protect the environment – the Polluter Pays Principle (PPP). The milestone targets proposed in the strategy do not involve any change to the principle that it is the responsibility of businesses to take the measures necessary to reduce the risks to health and the environment from hazardous substances.

An important part of the strategy is to include incentives in the chemicals regulations for innovation and self-regulation by the
businesses concerned by strengthening the Substitution Principle. The strategy means that the European legislation sets boundaries within which businesses can act. This applies to knowledge requirements, legality (prohibition) and information regarding hazardous substances. Giving industry the opportunity to make suitable choices within this framework creates the prerequisites for a cost-efficient improvement of the environmental situation. PPP also provides individual businesses with the incentive to do this.

A community-wide chemicals policy aimed at reducing the occurrence of hazardous substances in the environment is cost-efficient.

Sweden would have major difficulties in reaching the objective of A Non-Toxic Environment on its own. Toxins and other substances harmful to the environment and health are brought into the country as air pollution. Hazardous substances enter the Baltic Sea, Kattegat and Skagerrak not just from Sweden but also from our neighbouring countries. Hazardous substances are brought into Sweden via the import of products and articles that can contain them. A chemicals policy at EU level that restricts the manufacture and import of hazardous substances is therefore a prerequisite for the cost-efficient restriction of the supply of hazardous substances to natural cycles and the environment. The EU can also act for global measures to limit the manufacture and trade of hazardous substances and environmentally hazardous goods and products.

Measures at source are the most effective way of preventing pollution.

Once a hazardous substance gets into food, construction materials, consumer products or other articles, it is normally costly and technically difficult to prevent it from coming into contact with humans or reaching the environment. It is therefore cost-efficient to prevent hazardous substances from being added to products and reaching material cycles. This is also one of the starting-points of the strategy.
The administrative costs for businesses and authorities should be taken into consideration.

In an earlier section of the impact assessments, we have dealt with the administrative costs for industry, mainly in connection with tougher data requirements. These will increase the costs for industry as a consequence of more substances being included. It is our assessment, however, that these costs will be relatively minor.

According to the strategy, more substances will also be subject to authorisation. It can be assumed however that the change in the focus of authorisation will lead to a rationalisation for both businesses and agencies, since under our proposal it will be groups of substances that are subject to authorisation rather than each substance individually.

14.5 Distributional impacts

One of the aims of the strategy is to ensure that the health and environmental effects of all chemical substances that are manufactured in or imported into the EU are known, documented and disseminated. Furthermore, substances with particularly hazardous properties will be prohibited. The costs for this transition will be incurred by the chemicals industry and its customers.

As previously described, the costs for the European chemicals industry can be estimated at around one percent of the industry’s value added.

For other stakeholders, including the manufacturing industry, households and the service sector, the costs associated with our proposal will be negligible.

In the chemicals industry, the costs for small and medium-sized enterprises (SMEs) will be greater than is indicated by the estimates of the average costs. The requirements for knowledge, information and substitution can create difficulties for a smaller business that does not have access to its own expert in, for example, chemicals issues.

Bearing in mind the major health and environmental risks associated with the incorrect handling of chemicals, there is, however, no reason to exempt SMEs from the general requirements in the environmental legislation. On the other hand, it is also important for market and competition reasons to ensure that all stakeholders have access to relevant information.
Access to information is a central issue in the previous milestone target on information about hazardous substances in articles and an important precondition for the competitiveness of SMEs on the chemicals market. The United Nations Strategic Approach to International Chemicals Management (SAICM)\textsuperscript{120} should also be noted in this context. One of the objectives of SAICM is for all stakeholders to have access to the information they need no later than 2020. The information shall be user-friendly, relevant and appropriate to the needs of all stakeholders.

14.6 Effects on government finances

The costs of reducing the flow of hazardous substances to material cycles and the environment are borne by industry. The costs incurred by the state are attributable to the work to prepare and conduct negotiations within the EU system to meet the milestone targets.

The proposed milestone targets presuppose Swedish efforts to develop a stricter EU chemicals policy. In some cases, it is also a matter of bringing about a change in direction of chemicals policy. Any implementation would place considerable demands on the Government Offices and the central agencies involved in EU efforts to create the conditions for far-reaching decisions within the Union.

\textsuperscript{120} Strategic Approach to International Chemicals Management (SAICM), see also Section 9.2 Future global initiatives in the field of chemicals.
Individual statement by Committee Member Emma Wallrup

The proposals from the Committee are good. For them to have an impact, it is important that the work done to achieve the environmental quality objectives is adequately funded. Along with good governance in the system, the issue of funding is vital if we are to reach the objectives. It is therefore necessary to review the needs going forward. For example, there is a current need for more resources to be allocated to basic research and supervision in the chemicals field, both on the regional and the local level, for county administrative boards and municipalities.

The proposals to strengthen the Substitution Principle and to assess hazardous substances in groups in order to avoid substitution by other hazardous substances are very positive. It is important that the regulations are not watered down in connection with an innovation-driving REACH. Clear regulations facilitate transition and also contribute to accelerating the innovation of less harmful and greener solutions. Working with other incentives must not result in less forceful governance in the system.

Emma Wallrup (Left Party)
Individual statement by Special Adviser Mikael Karlsson

The members of the All-Party Committee on Environmental Objectives are once again in agreement across party political boundaries and have put forward a strategy for a non-toxic environment that, if implemented, will be an important step towards goal achievement.

The Committee points out serious shortcomings in the chemicals policy and repeats, within the framework of the strategy, its proposals on a number of important milestone targets and measures (Section 4), including one for a mandatory knowledge requirement concerning nanomaterials, combination effects and low-volume substances; stricter regulation of endocrine disruptors and powerful allergens; and much better information to, for example, consumers. These proposals have now been supplemented by milestone targets and proposals for measures on supervision (Section 7.1), green chemistry (Section 8.1), medicinal products (Section 11.1), and the groupwise management of chemical substances based on their intrinsic properties (Section 6) - which are absolutely crucial for a goal-driven and cost-efficient chemicals policy - and strictly innovation-driving substitution in connection with authorisation.

Regarding the latter, it is unfortunate that the Committee did not broaden the proposals and make substitution, where relevant, into a legal requirement on the EU level not only for authorisation, but also for manufacture, use, registration, evaluation, supervision and restrictions of chemicals, and then not only in the REACH regulation, but also in other relevant legislative acts. Such an approach is more innovation-driving for the chemicals industry and chemical-using companies, and the Committee has probably underestimated the possibilities of, in this way, strengthening competitiveness in the business sector at the same time as achieving major benefits for the environment and human health. Another shortcoming is that the Committee has not proposed that extremely persistent and bio-accumulative substances be explicitly defined as particularly hazardous in REACH, and the fact that the proposed targets have been often set to 2020, which is unreasonably late bearing in mind the possibilities and the fact that the objective of A Non-Toxic Environment is to be reached in the same year.

The proposals from the Committee focus to a large degree on measures within the EU and internationally. This is correct and
important. At the same time, the Committee ascertains (Section 1.6.2) that EU measures are often the result of national initiatives and that it is perfectly possible to introduce new national regulations, including those that go further than harmonised European legislation. This is followed by various proposal for measures from the Committee, not least under the milestone target on reducing children’s exposure to hazardous substances (Section 2.2), which constitutes a broader and more ambitious and concrete approach than the focus on particularly hazardous substances that the proposals have otherwise. The measures for children are particularly important as children are more vulnerable and sensitive to chemicals than adults are, and since the proposals target everyday products and a group of extremely hazardous - sometimes directly toxic - substances that many adults and children are exposed to on a daily basis. All such substances need to be phased out as soon as possible from e.g. consumer products.

The Government’s desire to implement the milestone target on protecting children quickly is an important indicator of how well the new environmental objectives system is working and how much confidence it has in the All-Party Committee on Environmental Objectives.
Individual statement by Special Adviser Inger Strömdahl

I view the existence of harmonised and far-reaching chemicals legislation on the EU level in a positive light but at the same time realise the necessity of increased harmonisation on the global level as well in order to ensure safe management of both chemical products and articles.

Businesses in Sweden’s various industries are currently making intensive efforts to introduce and comply with European chemicals legislation, REACH, which will not complete until 2018. REACH is more than just chemicals legislation. By involving all the stakeholders in the value chain, from manufacturers of chemical substances to manufacturers of articles and from primary manufacture right through to the waste stage, REACH will be innovation-driving and via market forces will promote i.a. increased substitution of substances whose handling involves unacceptable risks.

Several reviews and evaluations of the REACH legislation are planned over the coming years. A review of many important aspects is taking place this year (2012) and there is a fixed timetable for evaluations right up to and beyond 2018.

In my opinion, therefore, it is unfortunate that the All-Party Committee on Environmental Objectives has entitled Chapter 6 “New chemicals regulation in the EU”. This may lead the reader to believe that the existing REACH regulation is a) already “complete”, and b) more or less a failure, which is why new chemicals legislation needs to be developed. Neither of these assertions is true, as the implementation of REACH is still ongoing and a timetable for review and subsequent modification of the legislation is already enshrined therein. The proposals in Chapter 6 cannot in my opinion be said to lead to “new chemicals regulation in the EU” but rather to a revision of the existing chemicals legislation.

The concept of “an innovation-driving REACH II”, introduced in Section 6.1 can lead the reader to believe that REACH in its current form would not encourage businesses to innovate, which, in my opinion, isn’t true either. On the contrary, REACH is more innovation-promoting than its wording actually suggests. The business sector will participate in forthcoming reviews of REACH and thereby contribute to changes that may be necessary in order to guarantee good health, a good environment, fair competition
and good growth for Europe. I am of the opinion that these reviews should constitute the basis for any revisions of REACH. Several of the specific issues raised in “Part B - The next step in chemicals policy” are excellent areas for these evaluations.
The Committee terms of reference (Dir. 2010:74) are available in Swedish in the original report.
Committee terms of reference

The Committee supplementary terms of reference (Dir. 2011:50) are available in Swedish in the original report.
List of experts and advisers

A list of experts and advisers who have assisted the Committee in its assignment to propose a Swedish strategy for a non-toxic environment.

<table>
<thead>
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The generational goal and the environmental quality objectives

The generational goal

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.

What the generational goal means in practice

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.
- Material 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.
Sweden’s 16 environmental quality objectives

Reduced Climate Impact

The UN Framework Convention on Climate Change provides for the stabilization of concentrations of greenhouse gases in the atmosphere at levels which ensure that human activities do not have a harmful impact on the climate system.

This goal must be achieved in such a way and at such a pace that biological diversity is preserved, food production is assured and other goals of sustainable development are not jeopardized. Sweden, together with other countries, must assume responsibility for achieving this global objective.

Clean Air

The air must be clean enough not to represent a risk to human health or to animals, plants or cultural assets.

Natural Acidification Only

The acidifying effects of deposition and land use must not exceed the limits that can be tolerated by soil and water. In addition, deposition of acidifying substances must not increase the rate of corrosion of technical materials located in the ground, water main systems, archaeological objects and rock carvings.

A Non-Toxic Environment

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.
A Protective Ozone Layer

The ozone layer must be replenished so as to provide long-term protection against harmful UV radiation.

A Safe Radiation Environment

Human health and biological diversity must be protected against the harmful effects of radiation.

Zero Eutrophication

Nutrient levels in soil and water must not be such that they adversely affect human health, the conditions for biological diversity or the possibility of varied use of land and water.

Flourishing Lakes and Streams

Lakes and watercourses must be ecologically sustainable and their variety of habitats must be preserved. Natural productive capacity, biological diversity, cultural heritage assets and the ecological and water-conserving function of the landscape must be preserved, at the same time as recreational assets are safeguarded.

Good-Quality Groundwater

Groundwater must provide a safe and sustainable supply of drinking water and contribute to viable habitats for flora and fauna in lakes and watercourses.

A Balanced Marine Environment, Flourishing Coastal Areas and Archipelagos

The North Sea and the Baltic will possess a long-term sustainable productive capacity and their biodiversity will be preserved. Coasts and archipelagos must be characterized by a high degree of biological diversity and a wealth of recreational, natural and cultural assets. Industry, recreation and other utilization of the seas, coasts
and archipelagos must be compatible with the promotion of sustainable development. Particularly valuable areas must be protected against encroachment and other disturbance.

**Thriving Wetlands**

The ecological and water-conserving function of wetlands in the landscape must be maintained and valuable wetlands preserved for the future.

**Sustainable Forests**

The value of forests and forest land for biological production must be protected, at the same time as biological diversity and cultural heritage and recreational assets are safeguarded.

**A Varied Agricultural Landscape**

The value of the farmed landscape and agricultural land for biological production and food production must be protected, at the same time as biological diversity and cultural heritage assets are preserved and strengthened.

**A Magnificent Mountain Landscape**

The pristine character of the mountain environment must be largely preserved, in terms of biological diversity, recreational value, and natural and cultural assets. Activities in mountain areas must respect these values and assets, with a view to promoting sustainable development. Particularly valuable areas must be protected from encroachment and other disturbance.
A Good Built Environment

Cities, towns and other built-up areas must provide a good, healthy living environment and contribute to a good regional and global environment. Natural and cultural assets must be protected and developed. Buildings and amenities must be located and designed in accordance with sound environmental principles and in such a way as to promote sustainable management of land, water and other resources.

A Rich Diversity of Plant and Animal Life

Biological diversity must be preserved and used sustainably for the benefit of present and future generations. Species habitats and ecosystems and their functions and processes must be safeguarded. Species must be able to survive in long-term viable populations with sufficient genetic variation. People must have access to a good natural and cultural environment rich in biological diversity, as a basis for health, quality of life and well-being.
Adopted milestone targets

The adopted milestone targets are available in Swedish in the original report.
Previous assessments by the All-Party Committee on Environmental Objectives on hazardous substances and on waste

In its interim report SOU 2011:34, the All-Party Committee on Environmental Objectives submitted a number of assessments of hazardous substances and of waste.

Assessments on hazardous substances

National action concerning hazardous substances

The All-Party Committee on Environmental Objectives has previously made the following assessment:

When the EU lacks a regulatory framework for hazardous substances or their use and there are serious health and environmental risks, it is important that Sweden takes the lead and introduces national regulation.

The assessment of in which cases Sweden should take the lead should be built on a strategic analysis that includes i.a. the degree of risk and benefit of national initiatives as leverage to stimulate measures on the EU level or internationally.

The assessment forms an important starting-point for Sweden’s work on the national level.
Exposure to cadmium

The All-Party Committee on Environmental Objectives has previously made the following assessment:
The Government should task the Swedish Board of Agriculture, Swedish Chemicals Agency, National Food Administration and Swedish Environmental Protection Agency to propose a milestone target for cadmium exposure via food, including proposals for measures and instruments on the national level.

The assessment is that a milestone target on cadmium exposure is needed, but more investigation is required into e.g. tolerable daily intake of cadmium and to obtain proposals for suitable instruments and measures.

Remediation of contaminated sites

The All-Party Committee on Environmental Objectives has previously made the following assessment:
The Government should task the Swedish Environmental Protection Agency to propose a milestone target on the remediation of contaminated sites, including proposals for measures and instruments.

In light of the current situation, it is important that the remediation of priority areas continues at a quicker pace if A Non-Toxic Environment is to be reached. Since the problem of contaminated sites is widespread and since achieving the objective with the current level of efficiency requires substantially increased resources, it is our assessment that further investigation is needed before a milestone target can be formulated.
Assessment on waste

Increased reuse and recovery of paper, metal, plastics, glass, etc. from households

The All-Party Committee on Environmental Objectives has previously made the following assessment:
Continued increased reuse and recovery of paper, metal, plastics, glass, etc. from households is vital to efficient resource use in society. Milestone targets on this require further investigations.

The Government should task the Swedish Environmental Protection Agency to propose a milestone target for increased reuse and recovery of paper, metal, plastics, glass, etc., from households based on the work on the national waste plan and no later than in December 2011.

Sweden is deemed to already be very close to achieving the 2020 objective in the European Waste Framework Directive of 50-percent reuse and recycling of paper, metal, plastic, glass, etc., from households. Our assessment is that Sweden needs to have a more ambitious target that the objective stipulated by the EU. There is currently insufficient background information to be able to formulate a milestone target in the area.