Ministry of Environment and Food of Denmark
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Effect Assessment of the Chemicals Initiatives 2014 - 2017

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1. Foreword

From May to December 2016, COWI carried out an effect assessment of the Chemicals Initiatives 2014-2017. The purpose of the effect assessment is to determine what qualitative and quantitative impact the Chemicals Initiatives have had and will have in future. The results of this assessment may influence preparations for future actions. The experience from this effect assessment supports the work of the Ministry of Environment and Food in using impact assessments.

The Chemicals Initiatives are divided into three main areas: Non-toxic products, international collaboration and circulating resources; see Figure 1-1. These main areas are further divided into a number of specific initiatives or action areas. For each specific initiative, an effect chain has been drawn up in collaboration with the Danish Environmental Protection Agency's chemicals unit. A total of 14 effect chains have been defined. For the individual effect chains, inputs, activities, outputs and effects of the initiative concerned have been documented. The effect chains have supported the work on the effect assessment in line with the Ministry of Environment and Food's effect assessment concept.

This effect assessment is based on existing analyses and literature produced in the EU and in Denmark, and interviews with businesses and industry organisations.

Any errors and omissions are the responsibility of COWI alone.

Figure 1-1 The three main areas of the Chemicals Initiatives

2. Summary and conclusion

Introduction to the assessment
This report presents an effect assessment of the Chemicals Initiatives 2014-2017. The Chemicals Initiatives consist of three main areas: international collaboration, non-toxic products and circulating resources. From 2014 to 2017, a total grant of DKK 185 million has been made to the Chemicals Initiatives. The main purpose of the analysis is to carry out an effect assessment of the Chemicals Initiatives in order to establish a stronger basis for organising further work in this area.

COWI has produced this effect assessment of the Chemicals Initiatives using the Ministry of Environment and Food's effect assessment concept. The effect assessment has been prepared in close collaboration with the Danish EPA through workshops and discussion meetings. The aim of these was to analyse the effects of the actions taken under the Chemicals Initiatives. By means of three workshops, the individual actions were described in terms of effect chains containing inputs, activities, outputs and short and long-term effects. The Danish EPA also assisted COWI in identifying indicators and relevant data sources. Subsequent assessments and calculations were made by COWI. Based on an extensive data collection exercise using existing reports and interviews with Danish enterprises, COWI arrived at an overall estimate of the effects of the Chemicals Initiatives 2014-2017.

A number of factors limit the possibilities of producing a socio-economic effect assessment of the chemicals area:

- The chemicals area is complex and therefore hard to delineate. Thousands of chemicals are marketed for a whole range of uses in processes, products and industries. These chemicals also have very varied intrinsic properties, which may cause more or less serious toxic effects on people and the environment. In many cases, these effects can only be detected many years later (e.g. cancer cases, where up to 20-30 years may pass before the effects manifest themselves). Toxic effects vary in both type and potency (degree of danger). In terms of human health, these differences can be illustrated by the obvious difference between e.g. irritation and carcinogenic effect. Furthermore, new chemicals and new uses are constantly being developed, and new knowledge of the toxic effects of chemicals is emerging all the time.

- The effect assessment has been carried out as a socio-economic analysis, which attempts to quantify the effects. It is important to note that it has not been possible to quantify all effects of the initiatives, so the calculated socio-economic benefit understates the total gain from these actions.
  - The activities quantified mainly concern the regulation of substances and uses. The effects of activities that support the acquisition and dissemination of knowledge of the use of chemicals were generally impossible to assess in quantitative terms.
  - Primarily the health-related effects can be quantified, while the environmental effects can only be quantified and monetary valued to a limited extent.

Quantitative analysis

The main conclusion of the effect assessment is that the environmental and socio-economic benefits that could be quantified far outweigh the costs associated with the Chemicals Initiatives 2014-2017. The socio-economic analysis suggests a total net benefit of around DKK 1,000 million in net present value over a 50-year period for the effects of the Chemicals Initiatives that can be quantified right now. The results are shown in the table, which includes the socio-economic effects from alternative estimates of costs and benefits.

Table 2-1 Socio-economic effect of the Chemicals Initiatives

Net present value of element	Net present value in DKK millions		
	Low estimate	Median	High estimate
Cost of the Chemicals Initiatives (excl. distortion losses)	-185	-185	-185
With tax distortion losses	-222	-222	-222
Costs to enterprises etc.	-223	-581	-2,605
Environmental and health benefits	680	1,821	12,041
Total	236	1,018	9,214
Total (rounded values)	200	1,000	9,200

Sensitivity and uncertainty analyses were carried out, which show that the results may be considered robust. Apart from calculations using low and high estimates of costs and benefits, sensitivity calculations were performed which show the socio-economic benefit if the time period for the calculations is altered from 50 to either 30 or 70 years. If present values over a shorter period of 30 years is calculated, there is a gain in net present value of approx. DKK 100 million. The calculations are based on the assumption that the environmental and health-related gains are made gradually over 30 years. Sensitivity calculations show that even if still slower realisation of the benefits is assumed, there is a socio-economic gain. As e.g. benefits from the regulation of allergenic substances are seen immediately the regulation takes effect, the assumption of a gradual realisation of the environmental and health-related benefits over a 30-year period is very conservative.

As the effect assessment only includes a quantitative evaluation of a limited part of the initiatives, this net benefit reflects a conservative estimate, and the real value may be expected to be much greater. As the calculations nevertheless show a socio-economic gain, this supports the robustness of the conclusion.

Qualitative analysis

The Chemicals Initiatives are divided into three main areas: Non-toxic products, international collaboration and circulating resources. The main areas have been further divided into a number of specific initiatives or action areas – 14 initiatives in all. The qualitative effect assessment of the 14 initiatives is summarised below.

1. REACH – Candidate list, harmonised classifications, restrictions

The total REACH initiative (actions 1 and 2) amounts to DKK 41 million. This initiative is expected to produce a significant net benefit. The initiative is based partly on knowledge and insights gained from activities under several other action areas, and is absolutely crucial to the overall assessment of the effect of the complete Chemicals Initiatives 2014-2017, as itemised and quantified above. The analysis as a whole indicates that this initiative is overwhelmingly likely to produce a significant net benefit. Denmark is generally very active in the REACH area, and has made and can continue to make a substantial contribution to realising the positive effects of REACH.

2. Registrations and QSAR

This initiative supports the gains to be made as part of the REACH work. The work of assessing REACH registrations is a major factor in ensuring that REACH works, and serves as legislative preparation for REACH.

The Danish QSAR database helps the authorities to prioritise and evaluate EU law (some of it from the Chemicals Agency) and assists in their international work. The database is also internationally accepted as part of the OECD's QSAR toolbox. The QSAR database can also be actively used by enterprises in connection with substitution and product development and to reduce costs and numbers of laboratory animals used to test chemicals. Some published studies conclude that the QSAR tools themselves can produce very large savings, but it has not been possible to assess the quantitative effect of the Danish QSAR database. Given the acceptance of the Danish work, it is estimated that the database could have an even greater positive benefit.

3. Biocides

This initiative totals DKK 23 million. There are no estimates of the health-related and environmental effects of biocide use or of the reduction/restriction of the use of the most harmful active substances brought about by the Biocides Regulation. Nor are there any calculations of the total costs to enterprises of compliance with the Regulation. It is therefore impossible to make an overall quantitative socio-economic assessment of the Danish initiative. If, however, the Danish initiative is assessed from the point of view that the Regulation itself is part of the baseline, the Danish initiative helps to maintain a focus on the most harmful substances, to incorporate specific Danish concerns into our implementation of the Regulation, and to reduce the costs to Danish enterprises of compliance with the Regulation. On this basis, it is fair to say that Danish initiatives in the area of biocides provide an overall socio-economic benefit.

The information campaign is also judged to be helping to reduce the costs to enterprises of meeting the requirements of the Biocides Regulation. The advice and information provided by the Danish EPA make it much easier for enterprises to follow and comply with the rules. It is not possible to quantify the savings they make, but they are thought to be substantial, particularly for SMEs. It would be premature to evaluate the subsidy scheme, as the first subsidies were only allocated in December 2016 as part of the launch of the Chemicals Initiatives.

4. Endocrine disruptors

Several studies evaluate the harmful effects on health produced by endocrine disruptors. These studies have shown that the negative effects on health could amount to around DKK 16 billion per year. There is great uncertainty in this estimate, but with a potential socio-economic benefit of around DKK 16 billion per year and an investment of DKK 7.8 million per year, the initiatives relating to endocrine disruptors only have to reduce the environmental and health-related impact by 0.05% for the initiatives to pay off in purely socio-economic terms. The potentially very large socio-economic benefits point to continued learning with the aim of improving the basis for future regulation of the use of endocrine disruptors. The concrete socio-economic gains in terms of preventing harmful effects on health and the environment from endocrine disruptors are included under other initiatives – mainly the international work on REACH and efforts concerning consumer products. One example of socio-economic benefits based on a specific endocrine disruptor is the proposed restriction on the use of four phthalates, which is part of the international REACH initiative. Here, the annual benefits to health and the environment are estimated at just under DKK 2.7 million, and the costs to enterprises at around DKK 1.4 million per year. This indicates a net gain of DKK 1.3 million per year.

No evaluation has been made of the activities of the Centre for Endocrine Disruptors (CeHoS) in the form of studies, conferences and information meetings and more specific advice to the Danish EPA.

5. International agreements

Danish actions with regard to international agreements and conventions are important in relation to cross-border pollution and are expected to provide a significant socio-economic benefit. International agreements address chemicals that have the potential to spread and cause effects over very large distances. These include the Minamata Convention on mercury, and the Stockholm Convention on POPs (persistent organic pollutants). The total contribution to the global agreements and OECD work is considered to contribute to significant qualitative socio-economic benefits.

The grants for this specific initiative total DKK 4 million. The costs to enterprises of compliance with the global conventions have not been determined. However, there is an estimate for the Minamata Convention of the costs for EU28. Distributed across these countries, the costs to Danish enterprises are in the range from DKK 0.25 million to around 8 million per year. The value of the OECD's efforts to reduce the costs of evaluating and testing substances is estimated at DKK 6 million per year. The savings come mainly from reductions in the costs to enterprises of classifying and testing substances.

The health-related benefits are limited to an estimate of the scale of the gains from the Minamata Convention. Analyses of the harmful effects on health and the environment from exposure to mercury are so significant that, if the Convention reduces these costs by just a few per cent, Denmark will see annual gains in the tens of millions. It should be noted that the adoption of the Minamata Convention is the result of many years of negotiations. The benefits cannot therefore be ascribed to the Chemicals Initiatives 2014-2017 alone.

Even allowing for the uncertainty as to how much the Minamata Convention is reducing the harmful effects of mercury on health and the environment, this global work produces a socio-economic benefit, although it is impossible to quantify here.

Calculations of the possible effects of the Minamata Convention in reducing the use of mercury illustrate the potential for significant health benefits from the international agreements.

6. Chemicals in products

Grants for this initiative total some DKK 14 million in the period 2014-2017.

This initiative generates new knowledge of chemicals in consumer products, which can be used for e.g. information and regulation under other initiatives. It is not possible to estimate a direct effect of this initiative, but knowledge of chemicals in consumer products has a major social impact. The initiative thus contributes to: (i) background knowledge for regulation under other initiatives (to reap the expected net benefits from REACH and product regulation), (ii) background knowledge for information to consumers on possible risks, so they can make more confident/sensible choices whether to use these products or find alternatives, and (iii) consumer confidence in relation to products that have been tested and shown not to pose a risk. The last one is hard to quantify, but may be assigned a positive value in itself.

7. Regulation of consumer products

This initiative has helped to introduce a number of restrictions on the use of harmful substances in specific consumer products. Products used by many consumers, meaning that many people are exposed, may have major negative health costs. So this initiative could reap very large socio-economic benefits, as shown by an estimate of the effect of regulating methylisothiazolinone (MI).

8. Child chemicals package

Approx. DKK 20 million has been allocated to the 'Child chemicals package' under the Chemicals Initiatives. Some of the activities in this initiative are partly covered by the assessment of other initiatives – 6. Chemicals in products and 10. Consumer information. The remaining activities under this initiative take the form of surveillance activities, including information to enterprises concerning the rules. The same considerations apply to this initiative as discussed in relation to 12. Surveillance activities below.

9. National Allergy Research Centre

Contact allergies are a major health problem. Based on details of the number of people affected by contact allergies, the socio-economic costs can be estimated at around DKK 17.8 billion per year. The initiative involves a grant to the National Allergy Research Centre of approx. DKK 20 million in the period 2014-2017. A simple break-even analysis shows that, if the National Allergy Research Centre helps to reduce the number of contact allergy cases by 17 per year over the four-year period, the costs will be repaid. This shows clearly that increased knowledge that can help to reduce these costs can pay off very quickly.

The Centre's knowledge generation has played and continues to play a major role in regulatory and information activities to limit the harmful effects and costs resulting from contact allergies. The results of restricting chromium(VI) in leather goods (approx. DKK 20 million per year) and the ban on MI in some cosmetics (approx. DKK 360 million per year by preventing around 1,000 new allergy cases), confirm that there are very significant benefits from regulating allergenic substances.

An international research review of the Centre concluded that it makes a substantial contribution to building and disseminating important knowledge of contact allergies.

10. Consumer information

Information to consumers is essential. In the period 2014-2017, DKK 4 million was granted to this initiative. It can help to bring about changes in behaviour which could reduce exposure to harmful substances, and also provide greater security when consumers know how to act in order to reduce exposure. The health-related and environmental benefits depend on consumers changing their behaviour. Based on the evaluations made, the conclusion is that altered behaviour as a result of the initiative cannot be documented, even though people display greater knowledge, thus it is impossible to assess the possible health benefits.

11. Information on REACH and CLP

DKK 2.5 million has been allocated for information on REACH and CLP in the period 2014-2017. The benefit of the information work for enterprises is a possible saving from easier access to the relevant information and greater confidence in their ability to comply with the law.

The evaluation of the CLP campaign shows that, of the enterprises that are aware of the campaign, 27% have gained greater knowledge of the CLP rules as a result and 12% have commenced activities prompted by the campaign. This shows that the enterprises have made use of the information provided by the campaign.

There is no direct data to calculate the saving to the enterprises from the information activities. But if it is assumed that the information saves each enterprise 2 consultant hours per year at DKK 1,000/hour and that 1,000 enterprises in Denmark use the information, this will produce a saving of DKK 2 million per year. This calculation shows that, because there are many enterprises that need knowledge of REACH and CLP, just a small reduction in the costs to each enterprise of complying with REACH and CLP will produce a major saving to society. The calculation gives an indication of a possible saving which could perhaps be measured in future specific evaluations of the information initiative.

The economic risk to enterprises of failure to comply with the rules is both that they could be fined and that unregistered substances/products cannot be marketed. In theory this could result in large write-downs for an enterprise that did not register in time.

It is also worth mentioning that interviews with industry organisations raised the question whether these activities are reaching the enterprises that have the greatest need of assistance.

12. Surveillance activities

Surveillance activities are essential to compliance with the law. These activities help to ensure that enterprises comply with the law and hence to realise the expected net gains described under regulatory efforts above. There is no relevant data to help us to assess the effect of the

surveillance activities in themselves.
Surveillance activities also help to create trust that the rules will be adhered to. It is important both for the public who are 'protected' by the rules and also for the enterprises to know that everyone has to obey the rules.

13. Circulating resources – horizontal initiatives
To promote a changeover to a circular economy, it makes sense for harmful chemicals to be substituted as they often make recycling and reuse difficult. Hazardous chemicals in processes and products can constitute a barrier to the circular economy, as these substances can cause exposure and emissions in the environment, often in connection with reuse/recycling. That is why this is a specific action within the Chemicals Initiatives. This specific initiative included input to Council conclusions on the circular economy, input to the new Fertiliser Regulation and a textile partnership.
The initiative can help in the switch to a circular economy, which is considered likely to produce a substantial socio-economic benefit. Various calculations show that the transition to a circular economy could produce a very large socio-economic benefit (with estimates of a 0.8-3.9% increase in GDP, or DKK 15-27 billion per year).
The effect of substitution/reduction of hazardous substances in circulation is hard to assess, particularly given the relatively modest effort under the Chemicals Initiatives 2014-2017. But the potential for social benefits is nevertheless rated as very great.

14. Substitution Centre: It is premature to assess the effect of this initiative as the Substitution Centre has only existed since the autumn of 2014.

Other conclusions from the effect assessment
The analysis distinguishes between three types of output: Knowledge generation, information/communication and regulation. The effects of these outputs differ inherently. The following should therefore be emphasised with regard to the analysis:

- The socio-economic analysis is based mainly on valuations of the regulatory activities carried out under REACH including restrictions and inclusion of substances in candidate and authorisation lists. Quantitative analyses of these regulatory activities have been used to derive indicators of the 'average effect' of different types of regulation. These indicators have been used to generalise the effects of the Chemicals Initiatives.

- Knowledge generation does not directly lead to a reduction in the environmental and health-related costs of harmful chemicals. It is therefore impossible to calculate any direct socio-economic benefit. On the other hand, the knowledge-building activities are needed to drive regulatory activities that lead to reduced effects on health and the environment. That is why the socio-economic analysis has been produced for the whole initiative as one. For initiatives whose primary output is knowledge generation, an assessment has been made of the harmful effects that the activities focus on. For example, the analyses of allergens and endocrine disruptors show that these harmful effects could potentially give rise to very high environmental and health-related costs. The total socio-economic costs of contact allergies are estimated at some DKK 18 billion per year. This shows how relevant it is to launch an initiative to provide a basis for determining the scale of the problems, in order to reduce the socio-economic costs through regulation or other behaviour-changing efforts.

- For initiatives with information and communication outputs, the available data does not support any actual effect assessments. Studies and evaluations show whether e.g. information campaigns have reached their intended target groups and whether these find the information relevant. This is generally the case, but no measurements have been made to show actual changes of behaviour. This would require indicators of actual changes in behaviour to be established in connection with evaluating and measuring the effect of a

given information activity.

- Initiatives aimed at checking compliance with chemicals law (regulation) have not been quantified. Surveillance s are crucial to ensuring that the rules are obeyed, so the environmental and health benefits can be realised. In quantifying the effects of the Chemicals Initiatives, full compliance has been assumed.

- The enterprises interviewed were not generally able to quantify the perceived effects of the Chemicals Initiatives, e.g. in terms of time saved, costs of substitution or impact on market share. However, the industry organisations and the enterprises themselves generally support the assessment of the positive effects of the Chemicals Initiatives. For example, several of them mention that the information and activities are an important aid and that the activities in general have saved them time and provided a sense of security in relation to regulation.

3. Introduction

3.1 Background

The Chemicals Initiatives 2014-17 are based on a political agreement from October 2013 between all of the parties then in the Danish parliament. The agreement expires at the end of 2017. The Ministry of Environment and Food has started work to draw up a new framework in the chemicals area after 2017, to cover both the environment and the food industry. To this end, the two parts of the chemicals area are being combined into a new joint four-year political agreement to run from 2018 to 2021, based also on the activities in the Chemicals Initiatives and Fødevareforlig III (The food settlement III), which runs out at the end of 2018.

By way of input to the new Chemicals Initiatives, there is a need to assess the effects of the present initiatives. The present Chemicals Initiatives account for approx. DKK 185 million shared between three main action areas: International collaboration, non-toxic products and circulating resources. The three main action areas include a long list of specific actions which are closely interrelated and very different in character and scope. The two action areas 'Better control of nanomaterials' and 'List of undesirable substances' in the Chemicals Initiatives 2014-17 were financed via separate grants and have already been evaluated elsewhere. These two action areas are therefore not included in the present effect assessment. The Chemicals Forum was evaluated in 2015 and is not included here either.

3.2 Method

The effect assessment of the Chemicals Initiatives used the Ministry of Environment and Food's effect assessment concept as a basis (see Annex D). According to this concept, first, the overall goal of the initiative is identified, then effect chains for every specific action is established. The Chemicals Initiatives have two overall goals, a better environment and better health. In establishing the effect chains the three action areas were taken into account: International collaboration, non-toxic products and circulating resources. Each area was divided into specific actions, and an effect chain was described for each of these – 14 in all. In an effect chain, inputs, activities, outputs and effects are listed. The effect chains were drawn up in collaboration with the Danish EPA's chemicals unit, through three workshops. This allowed us to share knowledge, collect data and discuss the areas in depth. The effect chains were then validated by relevant experts at COWI, after which interviews with enterprises were conducted. Based on the knowledge gathered, qualitative and, where possible, quantitative analyses of the effects were performed.

The Chemicals Initiatives are a specific grant scheme reserved for a number of specific actions over a four-year period, but the chemicals area also includes other actions. This evaluation focuses on the effects that the Chemicals Initiatives have and are expected to have. In many cases, however, the effort is supported by other activities by the Danish EPA. Although the effects of the Chemicals Initiatives have been isolated as well as possible, there may be areas where the effects are also the result of other activities. No judgement has been imposed on whether this affects the conclusions from the analysis.

The four-year period also means that the key long-term effects in the form of improvements to health and the environment can only be measured 20-30 years after completion of the initiatives. These effects are therefore included in the assessment by quantifying the effects over a 50-year period.

In accordance with the guidelines from the Danish Ministry of Finance, it was decided to restrict the analysis to the Danish effects. However, the Chemicals Initiatives undoubtedly affect health and the environment both in Denmark and abroad, and it may be hard to separate the effects geographically.

These issues have been addressed in the effect assessment, but it has also been clear from the start of the analysis that it is difficult to assess effects caused by the action of chemicals alone. This is partly because the area is not clearly defined, given that chemicals can be found everywhere, in all products and industries. Then there are uncertainties and lack of knowledge of the effects of chemical action. In many areas, therefore, there is uncertainty as to the 'true' connection between exposure to a substance and the resulting effect on health and the environment. There also is a lack knowledge of the interaction from exposure to multiple substances (the 'cocktail effect'). There are also substances, such as persistent, bio-accumulating and toxic substances (PBTs) where the effect will increase as they are accumulated in the eco-systems. For these substances, a risk assessment have been made, i.e. it is not possible to estimate their current epidemiological affect so an assessment has been made as to whether the future effect is such that they should be regulated now. All of these issues limit the degree to which the effect assessment can present sound socio-economic evaluations.

3.3 Structure of the report

The report has seven chapters and four annexes; the first chapters are a summary and conclusions, foreword and introduction. Chapter 4 describes the background and purpose of the Chemicals Initiatives and the associated action areas and their interrelationships. Chapter 5 describes the method used in the effect assessment, including the socio-economic analysis. Chapter 6 discusses the individual effect chains. For each effect chain, the associated indicators and short and long-term effects have been described, finishing with an overall assessment. Chapter 7 describes the results of the effect assessment.

4. The Chemicals Initiatives 2014-17

This chapter outlines the background and purpose of the Chemicals Initiatives. The text of the agreement is appended as Annex A.

4.1 Objective

The overall aim of the agreement on the Chemicals Initiatives 2014-17 from October 2013 is "that children and adults should be able to live without fear of becoming ill from chemicals and that people, animals and plants should be able to thrive in a healthy environment". The Chemicals Initiatives are intended to implement the agreement and so help to take a further step towards a non-toxic world.

The focus is on the hazardous (or problematical) chemicals that needs better control. This will involve knowledge generation, regulation, information, surveillance and development of alternatives to the hazardous and problematical chemicals and should bring about changes in the behaviour of enterprises (including producers and formulators of chemicals[1] and downstream users), citizens and public institutions in their use and handling of chemicals.

4.2 Background

Denmark has a long tradition of broad political support for the Danish Chemicals Initiatives. The agreement on the Chemicals Initiatives 2014-17[2], which forms the overall basis for the chemicals initiatives in Denmark to the end of 2017, is no exception. The agreement was published in March 2014 and is the implementation of a political agreement that was adopted in October 2013 by all of the parties then present in the Danish parliament.

The agreement on the Chemicals Initiatives also enables Denmark to meet its obligations under a number of EU Regulations and international conventions in the chemicals area. Hazardous chemicals can be found in industrial chemicals and products traded across borders, and emissions of hazardous substances and chemicals can also have cross-border effects. Because of the international nature of chemicals and in the interests of harmonisation of the single market (the desire to avoid anti-competitive effects), regulation of the production and use of chemicals in Denmark is mainly driven by the EU. EU law takes account of the relevant global agreements, which Denmark itself also ratifies and supports directly.

Many of the activities in the Chemicals Initiatives therefore help not only to protect Danish citizens and the Danish environment but also to improve health and the environment in other countries. Conversely, Denmark also benefits from other countries' efforts in the chemicals area. The international context poses a number of challenges when it comes to defining and calculating the effects of the Danish Chemicals Initiatives.

[1] Formulators are undertakings that do not produce chemicals but mix them together. They include producers of paints, cosmetics and cleaning agents.

[2] For a quick overview, see: http://kemikalieindsatsen.dk/.

4.3 The Chemicals Initiatives action areas

The Chemicals Initiatives cover a wide range of activities, target groups and direct and indirect effects, so they are hard to delimit clearly. Apart from the direct effects on health and the environment, the Chemicals Initiatives can also help to achieve such disparate political goals as increased reuse (reuse of more products where the materials included in these products are free from hazardous chemicals) and better conditions for enterprises (included greater knowledge of substitution options).

The Chemicals Initiatives consist of three main areas:

1. International collaboration, where Denmark is working in relation to REACH[3] with the candidate list, safety assessments and restrictions, classification, labelling and packaging of hazardous chemicals (CLP[4]) and biocides, and in relation to the impact of the global chemicals agenda.
2. Non-toxic products, where chemicals in consumer products are examined and consumers and enterprises are informed of chemicals and product regulation of toys, cosmetics and electronics.
3. Circulating resources, promoting knowledge of the possibilities of substitution with less hazardous chemicals or completely different solutions, and supporting the development of the circular economy.

Each main area is made up of a number of action areas, the vast majority of which take a multi-year view[5]. In this effect assessment, it has been chosen to divide the three main areas within the Chemicals Initiatives into 14 initiatives, to help to make a better impact assessment:

1. International collaboration
    - Candidate list, harmonised classifications and restrictions (REACH and CLP dossiers)
    - REACH registrations and QSAR (quantitative structure activity relationships)
    - The biocides initiative
    - Endocrine disruptors
    - International agreements/global efforts
2. Non-toxic products
    - Chemicals in consumer products
    - Regulation of consumer products/product regulation
    - Child chemicals package
    - National Allergy Research Centre
    - Consumer information
    - Information on REACH and CLP
    - Surveillance activities
3. Circulating resources
    - Horizontal initiatives
    - Substitution Centre

[3] REACH is the acronym for the key Regulation covering industrial chemicals in the EU. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

[4] The CLP Regulation ensures that employees and consumers in the European Union are clearly informed of the dangers associated with chemicals, by means of classification and labelling of chemicals.

[5] These can be studied in detail at http://kemikalieindsatsen.dk/.

The 14 action areas are described in more detail and discussed in chapter 6.
Then there are the following initiatives: The Chemicals Forum, the Danish EPA's list of undesirable substances (LOUS) and the Nano initiative. These have been evaluated separately and are not included in this effect assessment

5. Method description

5.1 Procedure

The method used in the effect assessment follows the Ministry of Environment and Food's effect assessment concept from March 2016 (see Annex D). The concept contains logical instructions for organising and gaining an overview of a given initiative in order later to be able to document the effects of that initiative and so provide a basis for evidence-based prioritisation and policy-making.

The Chemicals Initiatives 2014-17 were adopted before the Ministry of Environment and Food's effect assessment concept was produced. This means that the Chemicals Initiatives are not organised according to this concept. For this reason, there is no evaluation design for the Chemicals Initiatives which describes beforehand (*ex ante)* the expected effects of the initiative and could be used as a basis for the effect assessment. This effect assessment has therefore been produced with an introductory design phase aimed at establishing an evaluation design as a prerequisite for the actual effect assessment.

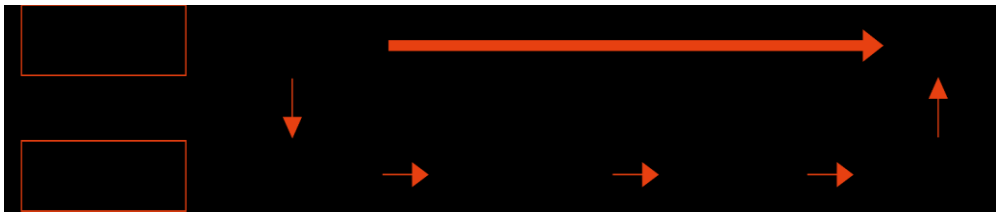
Compared to the concept, the setup of the evaluation design includes the following steps:

1. Goal definition
2. Definition of effect chains for the individual action areas
3. Description of causal relationships
4. Selection of indicators and identification of data sources.

This work was carried out with the active involvement of experts from the Danish EPA and the persons responsible for the individual action areas.

The evaluation design takes an effect chain approach, which is based on the descriptions of the individual actions in the Chemicals Initiatives as illustrated in Figure 5-1.

Figure 5-1 Effect chain approach



The finished evaluation design entails 14 effect chains, one for each of the 14 initiatives described in the previous section. Each effect chain contains a description of the key activities, outputs and effects of a given initiative. Details of the effect chain approach are given in Annex D.

This section presents the main principles and explains how the effect chain approach has been used in this effect assessment.

5.1.1 Initiatives and effect chains

The overall Chemicals Initiatives have been broken down into 14 specific initiatives as described in the previous chapter. Each specific initiative (action area) is presented by way of

an effect chain. The definition of the effect chains focuses on the essential activities, so there are some activities that have not been included. That means that the effects on health and the environment in particular may be assumed to be understated. The effect chains for the individual action areas describe activities, outputs and effects. The effect chain describes the inputs used to perform the activities, i.e. the resources (financial or manpower) allocated to the activities. This is followed by the outputs. Outputs are the concrete results of the activities within the initiative, such as a research report, an information campaign or the production and adoption of proposals for regulation. The last link in the effect chain are the effects, i.e. mainly the effects on health and the environment.

The effect chain template used to describe and analyse the individual initiatives is illustrated in Figure 5-2, which is a more detailed view of Figure 5-1. Annex B contains the effect chains for each initiative.

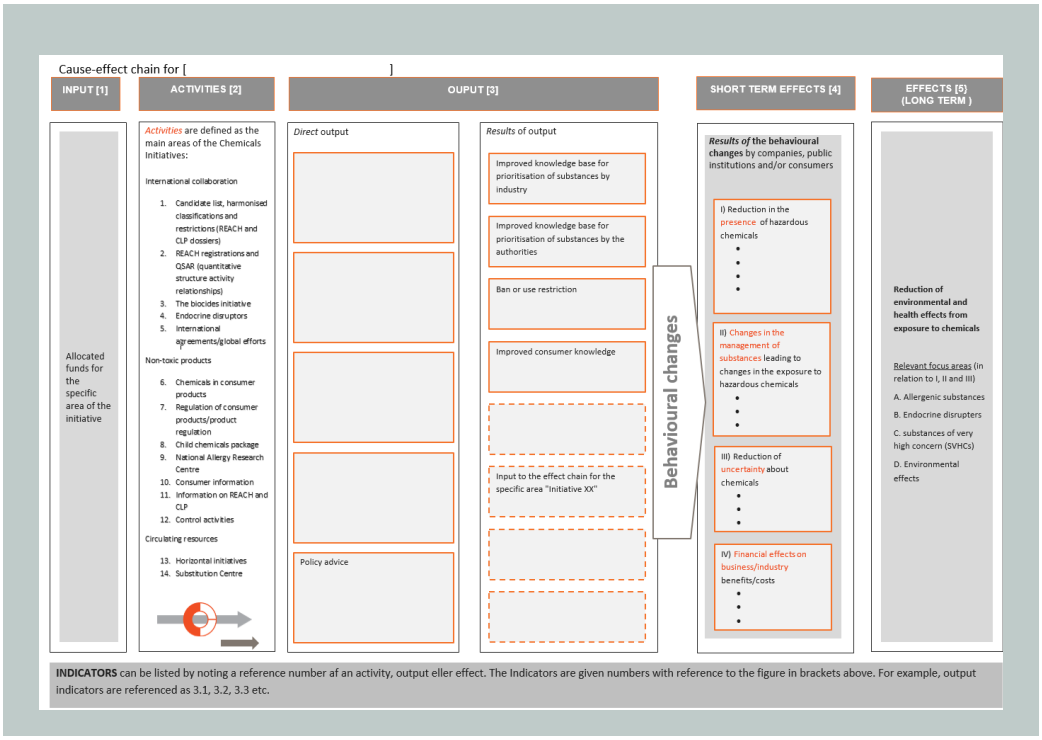


Figure 5-2 Effect chain template

The next section describes the individual elements and assumptions used in the effect chain.

5.1.2 Inputs

The national budget has DKK 185 million set aside for the Chemicals Initiatives. Along with funding from the Chemicals Initiatives, the Danish EPA has used resources from other sources for the activities described in the Chemicals Initiatives, including the Agency's basic grant. These resources have not been included in this effect assessment. It is not possible to make an exact statement of the scope, but it is relatively small, and mainly in the form of manpower. The Danish EPA has allocated and reported the funding around the 14 specific initiatives; see Table 5.1.

Table 5-1 Financial resources allocated to the specific initiatives, in DKK millions

ID	Specific initiative	Budget 2014-2017
	International collaboration	
1	Candidate list, restrictions and CLP	41
2	Registrations and QSAR	
3	Biocides	23
4	Endocrine disruptors	27
5	Global phasing-out of substances	4
	Non-toxic products	
6	Chemicals in products	14
7	Regulation of consumer products*	
8	Child chemicals package	18
9	National Allergy Research Centre	20
10	Consumer information	4
11	Information on REACH and CLP	2
12	European surveillance activities	16
	Circulating resources	
13	Horizontal initiatives*	
14	Substitution Centre	16
Total		185

*There are also some activities which are not specifically financed by the Chemicals Initiatives, but where the evaluation has included the benefits obtained, as the spending on these activities is very small and they are to a large extend based on the work done under the Chemicals Initiatives.
Note that the figures in the table are rounded and that the money includes both funding for external projects and the internal man-years assigned in the Danish EPA.

5.1.3 Activities

The activities are the concrete actions taken to produce the outputs from the initiative (services/deliverables/products) and so achieve the desired long-term effects. The activities are actions which the Danish EPA has some control over. The type of activities will depend on the particular initiative. Activities may include attendance at meetings such as REACH committees or working groups in the EU, production of reports etc. The activities are described in chapter 6 under the different initiatives.

5.1.4 Outputs

Outputs are the concrete results, i.e. decisions, reports, legislative proposals (dossiers) and information campaigns. The many different outputs which are the direct result of all of the individual initiatives can be broken down or grouped into three types of output, according to the outcome of each specific output. There are the following types of output:

- Knowledge generation
- Information and communication
- Regulation (including checking compliance)

For most initiatives or effect chains, outputs can be grouped under one of these three categories. The table below presents an overview showing the type of output that is most prominent for each initiative.

Table 5-2 The 14 initiatives/effect chains and principal output types

ID	Specific initiative	Primary type of output
	International collaboration	
1	Candidate list, restrictions and CLP	Regulation
2	Registrations and QSAR	Regulation (and knowledge generation)
3	Biocides	Regulation, Information and communication
4	Endocrine disruptors	Knowledge generation
5	Global phasing-out of substances	Regulation
	Non-toxic products	
6	Chemicals in products	Knowledge generation
7	Regulation of consumer products	Regulation
8	Child chemicals package	Regulation (checking compliance)
9	National Allergy Research Centre	Knowledge generation
10	Consumer information	Information and communication
11	Information on REACH and CLP	Information and communication
12	Surveillance activities	Regulation (checking compliance)
	Circulating resources	
13	Horizontal initiatives	Knowledge acquisition/Regulation
14	Substitution Centre	Knowledge generation/Information and communication

The next section discusses the relationship between outputs and the effects resulting from the outputs produced.

5.2 Effects

The final link in the effect chain is a description/assessment of the effects, both short and long-term. The main aim of the effect assessment is to identify the effects and attempt to describe them in quantitative terms. The next sub-section discusses the relationship between outputs and effects. It also provides a description of the methodological constraints and requirements for quantifying and evaluating them.

5.2.1 Types of effect and relationship to outputs

5.2.1.1 Types of effect

The effects are the consequences of the outputs resulting from the activities. They are divided into short and long-term effects.

The short-term effects are changes in the behaviour of businesses, consumers and other stakeholders brought about by the outputs during and after the initiative. Ultimately, the short-term effects cover the following types of change:

- Reduction in the incidence of harmful chemicals
- Altered handling of, and hence exposure to and emissions of, harmful chemicals
- Reduced uncertainty as to the risk from chemicals
- Commercial benefits/costs

The first two of the four types of short-term effect can also manifest themselves in long-term effects in the form of reduced impact on health and the environment caused by chemicals. This

last short-term effect is designed to assess the commercial benefits from parts of the initiative. Reduced uncertainty about risk arises from the fact there is often limited knowledge of the effects on health and the environment from the use of chemicals. When an initiative helps to provide and disseminate knowledge, the uncertainty about possible risks is reduced. If the increasing knowledge indicates that there are no significant risks, the public can feel more secure. If the new knowledge identifies concrete risks, consumers and businesses can react immediately to this knowledge, and it can form the basis for implementing specific regulatory measures.

The long-term effects include the reduction in damage to health and the environment from exposure to harmful chemicals.

5.2.1.2 Relationship between outputs and effects

Previously outputs were divided into four types: Knowledge generation, information, regulation and surveillance. In the following section the relationship between knowledge generation, information and regulation is discussed.

Knowledge generation produces no direct effects as it is assumed to come from either information and communication or regulation.

A feature of the chemicals area is that there is a very great need for increased knowledge. There is a large number of chemicals and new ones are appearing all the time, and new types of (eco-)toxicological effects that may be caused by these chemicals are under investigation. In many areas, therefore, there is uncertainty as to the 'true' connection between exposure to a substance and the resulting effect on health and the environment. There is also limited understanding of the interaction from exposure to multiple substances (the 'cocktail effect'). As chemicals are used everywhere in manufacturing, and many chemicals are used because they have specific desired properties which are important to the quality of a given product, it is often far from easy to find a substitute for a substance which is suspected to have negative effects. The fact that there may be very significant effects on health and the environment, combined with the high costs of substitution, justifies a big effort to build up knowledge to reduce these uncertainties, and so provide a basis for effective regulation.

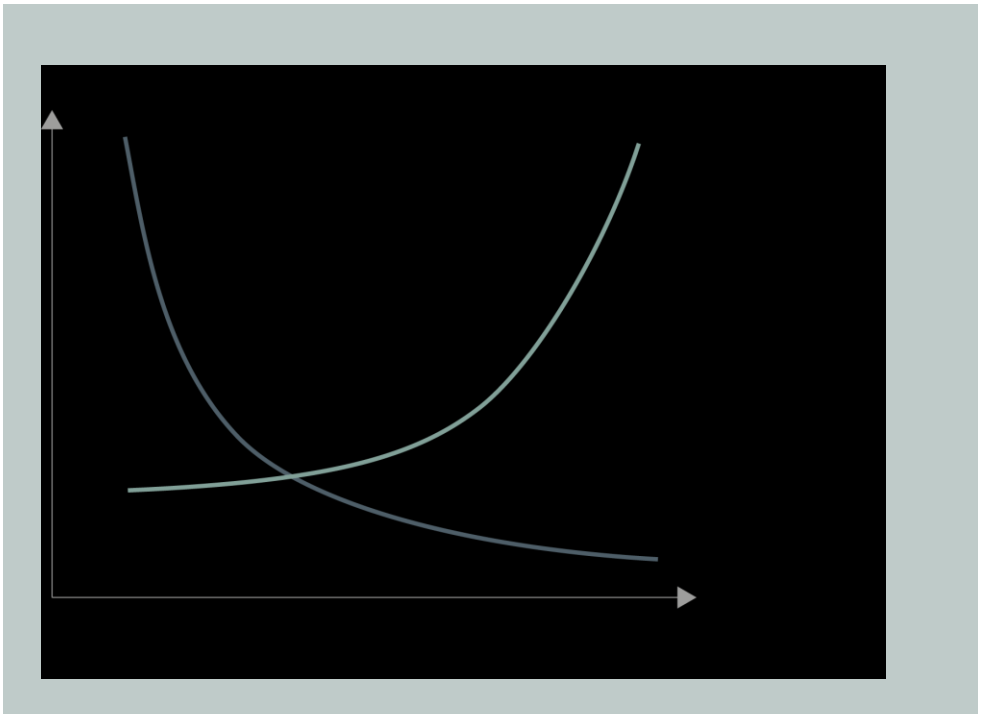
The information and communication activities are intended to support behavioural changes, either where enterprises optimise or reduce their use of hazardous chemicals or where consumers change their purchasing or consumption behaviour and thereby reduce their exposure to hazardous chemicals and so achieve greater protection which goes further than that provided by regulation. This could take the form of information and guidance to businesses on new rules, which will ensure that the rules are complied with and also reduce the costs to these companies of following the rules.

The third type of output are those directed at the production and use of chemicals. The vast bulk of chemicals regulation happens at the international level. REACH and CLP are two of the primary EU instruments for regulating chemicals. There is also EU legislation within product-specific areas such as toys, cosmetics and electronics, and finally there are international agreements. Denmark contributes to the work both within the EU and on the international/global agreements. Regulation is the area which offers the best basis for assessing effects, i.e. evaluating the benefits to health and the environment. This naturally reflects the fact that regulation calls for changes in behaviour and so will have direct effects, while it is often accompanied by some kind of impact analysis.
The relationship between the different types of output can be described at a high level by reference to the costs and benefits as seen by the regulatory authorities:

- Knowledge generation is relatively costly to the authorities and the immediate benefits to health and the environment are limited. ‘Knowledge generation’ here means research and analysis. Knowledge is also generated via the requirements for testing etc. placed on businesses under REACH, CLP etc. It is counted as part of the net gain from the relevant regulatory activities.
- The effect of information and communication depends on whether there is a lack of information and knowledge which restricts the behaviour of the target group. If so, information campaigns can be expected to have an effect, and the more information and communication provided, the greater the effect given the same quality in the initiative. Information and communication assume that there has already been some knowledge generation through research and/or analysis.
- Regulation typically demands fewer resources (if sufficient knowledge has been acquired first), and has by far the greatest direct effects.
- It should be stressed that surveillance is important to ensuring that the benefits from regulation are actually realised, but the benefit cannot be directly measured.

The relationship is illustrated in Figure 3. The figure shows the general relationship between output, price and effect, but there may of course be differences, e.g. concrete regulatory activities that also call for major resources from the authorities.

Figure 5-3 Relationship between output, price and effect



5.2.2 Relationship between initiatives in the effect assessment

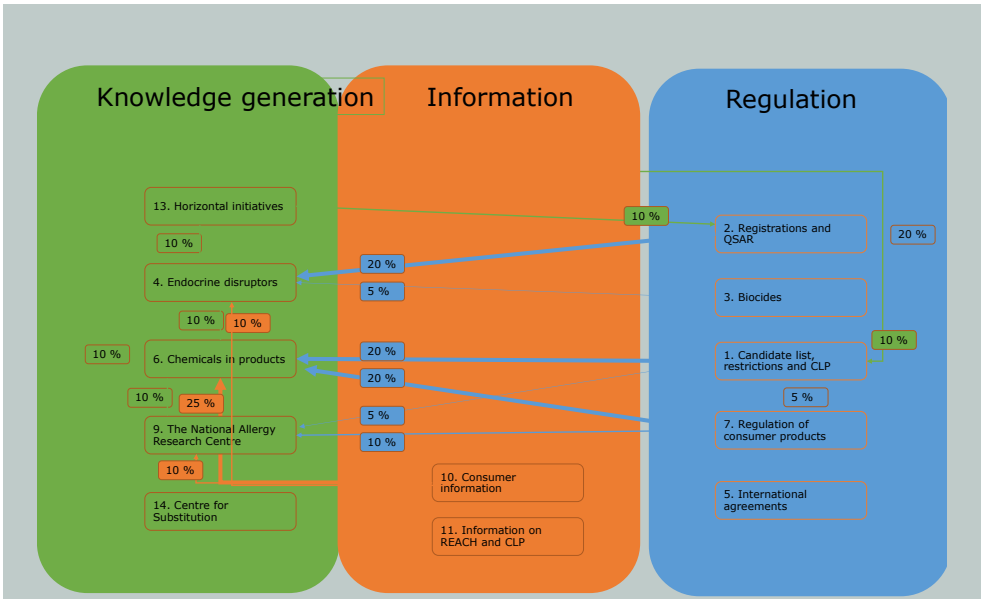
The different action areas in the Chemicals Initiatives are closely linked. For example, the knowledge acquired on allergens and endocrine disruptors as part of the work on REACH and CLP is used to assess and regulate consumer products and biocides and serves as input to activities associated with consumer information. The same is true of the work on endocrine disruptors.

The socio-economic effect assessment therefore views the Chemicals Initiatives as one. In order to illuminate the socio-economic benefit of the individual initiatives, the benefits identified under the specific regulatory activities need to be 'allocated'. New regulation is often

occasioned by knowledge generation, so for example some of the benefit from regulation could be attributed to the initiatives that made this regulation possible.

This is illustrated in the figure below. It shows how the action areas fit together generally. A number of action areas take inputs from other action areas and supply outputs to others further downstream. This connection shows clearly how the effects from the Chemicals Initiatives interact and should perhaps be seen as an 'effect network' rather than separate initiatives.

Figure 5-4 Overview of the relationship between the action areas



The figure mainly shows how the initiatives with knowledge generation as their principal output are important to the initiatives that supply information and communication and those aimed at regulation.

As the pure knowledge generation initiatives do not in themselves produce any changes in behaviour, they will have no significant direct effects in health and the environment. That is why there are no quantitative health and environmental benefits for these initiatives. But as they are crucial for e.g. regulatory activities to be implemented, some of the benefit from a regulatory activity can be attributed to the knowledge-building efforts that form the basis for this regulation.

Table 5-3 shows how the effects are spread across the effect chains. For example, the initiative concerning the candidate list, restrictions and CLP (effect chain 1) can attribute 45% of the benefits to other initiatives (effect chains 2, 6 and 9), as these are judged to be crucial to the regulatory measures resulting from the former initiative (effect chain 1).

Table 5-3 Distribution of effects

Effect chain to which the benefit is reassigned	Effect chain where the benefit is quantified													
	1	2	3	4	5	6	7	8	9	10	11	12	13	14
1							5%						10%	
2	20%												10%	
3														
4		20%	5%			10%				10%			10%	
5														
6	20%						20%	N/a		25%		N/a	10%	
7														
8														
9	5%					10%	10%			10%				
10				10%										
11														
12														
13								N/a				N/a		

It should be emphasised that any such quantified distribution of effects is very rough, and it is reproduced here to give an idea of the interrelationships rather than to present precise estimates.

These relationships mean that many effects of the Chemicals Initiatives cannot be achieved if some initiatives are removed. It is therefore important to look at the relationships within the Chemicals Initiatives when prioritising a future initiative – and not to take the individual initiatives in isolation.

5.2.3 Methodological breakdown of the effect assessment

5.2.3.1 Baseline

The effect assessment focuses on the effects that the Chemicals Initiatives have or will result in, compared to a baseline scenario describing what would have happened if there had been no Chemicals Initiatives. This makes it essential to define the baseline as clearly and precisely as possible. To begin with, the regulation in place and the results of earlier initiatives at the end of 2013 will be treated as the baseline.

5.2.3.2 Timing issues

The effect assessment focuses on the effects arising from the Chemicals Initiatives 2014-17.

The Chemicals Initiatives run to 2017 – the effect assessment was produced in 2016

The Chemicals Initiatives 2014-17 are not yet finished, so all of the activities have not yet been carried out. The Danish EPA has stated what further activities it expects to see within the scope of the initiatives. In some cases, the results are based on an extrapolation of already completed activities, while others reflect what is actively planned for 2017.

Many activities were already under way before 2014, and some will continue after 2017
Many activities cannot be limited to starting and ending in the period 2014-2017. This is true, for example, of regulatory proposals under REACH, CLP and the Biocides Regulation, where the preparatory work may have been done before 2014, or new proposals/dossiers where the work is set to continue after 2017. There may also be consumer projects, for example, which started earlier and were only completed/published in this period, or new projects which will not be completed before the end of 2017. Similarly, global efforts are prolonged in nature.

A pragmatic view of these situations have been taken. In relation to quantifying and evaluating the effects, the regulatory activities under REACH and CLP are especially important. For REACH and CLP regulation, the date of adoption of the activities has been used as a boundary. As the number of regulatory proposals adopted in 2017 is unknown, the figure has been estimated from the average number adopted in the period 2014-2016.

Under each effect chain it will be stated whether the demarcation differs from the general principle described here.

When are the effects realised?
The time frame for *realisation* of the effects is very variable and may sometimes be very long. In many cases, effects on health and the environment will only be realised in 10, 20 or 50 years. Different health-related and environmental effects will occur at different times. Allergies can appear very soon after exposure and, with regulation to limit exposure, some of the positive effects will be seen immediately. On the other hand, the effects of reductions in the use of and exposure to carcinogens will typically manifest themselves after a substantial time lag. For the regulatory activities where the effects have been quantified and evaluated, it is assumed that the effect emerges gradually and reaches its full extent after 30 years. The choice of a 30-year time frame is a conservative assumption which allows us to take these factors into account. Further, the sensitivity calculations performed show the consequences of alternative assumptions as to the time frame.

In order to pick up the full effect of the environmental and health benefits, a present value for the initiative over a 50-year period is calculated. On the assumption that the environmental and health benefits will be realised gradually, a present value calculation for the Chemicals Initiatives will give a higher value the longer the time frame for which this value is calculated. There is no general guideline for the choice of time horizon for socio-economic analyses except that it should be long enough for all costs and benefits to materialise. Calculating the socio-economic present value over a 50-year period allows for the gradual realisation of the effects on health and the environment. The sensitivity calculations also show how long the time frame has to be for the initiative to produce a socio-economic gain.

5.2.3.3 Geographical delineation
The Danish Chemicals Initiatives have implications for health and the environment both in Denmark and abroad, just as initiatives in other countries affect the situation in Denmark. According to the Finance Ministry's guiding principles, it is recommended that socio-economic analyses of Danish policy measures should only include the effects on Danish people and businesses.

Chemicals policy is very much an international matter, and most chemicals regulation is based on EU decisions. Denmark contributes to the international effort, including REACH and CLP, and helps to draw up proposals for regulating the use of specific substances. This raises the question of how the Danish contribution should be measured. There are various models that could be applied:

- The Danish Chemicals Initiatives is credited with the effects on Danish businesses and individuals of all EU regulatory activities, i.e. including proposals submitted by other countries and by the European Chemicals Agency (ECHA)
- The Danish Chemicals Initiatives is credited with the total effects of the concrete proposals produced by Denmark (effects both in Denmark and abroad)
- The Danish Chemicals Initiatives is only credited with the effects on Danish businesses and individuals from the proposals produced by Denmark.

The present assessment uses the first of the three models. The implementation of REACH and CLP is based on EU Member States all contributing, by drawing up proposals for restrictions and classifications or proposals for substances to be added to the 'candidate list'. If no country wants to contribute, there will be no restrictions, and hence no benefits to health or the environment either.

The weakness of this model is that it only indirectly takes account of whether Denmark makes a contribution in proportion to its size, and the effect depends on whether other countries have made more or fewer proposals.

If the second model is used, the assessment depends only on the proposals produced by Denmark. That would mean that, if Denmark did not contribute any direct proposals in a given period, but only took part in working groups etc., it would not be credited with any effect at all, even if it had given comments and input to the negotiations. The third model would have the same drawbacks as the second, and would only take in that part of the effect that concerned Danish businesses and individuals.

In this effect assessment, the first model is used. This model does not consider any difference in effect according to whether Denmark contributes a little or a lot, and it only includes effects on Danish people and businesses, in line with the guiding principles from the Ministry of Finance. It can also be used in cases where proposals are drawn up and negotiations conducted jointly, and an individual country's contribution cannot be determined.

Specifically for the quantitative effects of the initiative described in effect chain 1, where this question is very relevant, an additional qualitative assessment have been made of the total added value from the specific Danish initiative.

5.2.4 Socio-economic method

The basic approach was to produce a qualitative assessment of every initiative. Where there is no data, or no data could be collected to support a quantitative analysis, a qualitative or semi-quantitative assessment has been made. The quantitative assessment is a socio-economic analysis, in which the changes in behaviour and the resulting effects on health and the environment are estimated and quantified.

5.2.4.1 General assumptions

The socio-economic calculation is based on the Ministry of Finance's guiding principles. The results are presented as net present values over a 50-year period, using the Ministry of Finance's 4% discount rate[6].

Part of the work on the specific initiatives was to identify the individual activities. In collaboration with the Danish EPA, the outputs from the individual activities were identified, along with their results in terms of changes in behaviour.

[6] The guidance from the Ministry of Finance uses a discount rate of 4% for the first 35 years and 3% for the last 15 years.

The investments made in connection with the Chemicals Initiatives are mainly funding from the Danish EPA. This would give rise to a tax distortion. This has been allowed for by using a factor of 20%[7].

For the estimates of e.g. health benefits contained in the data sources used, the portion of the benefit that is tax-financed public expenditure should be increased by the distortion factor. However, it is impossible to calculate the proportion of the benefit this should apply to. In principle, this means that the benefit could be understated as a result of this – by up to 20%. In relation to the general uncertainty in the socio-economic calculations, however, this is of little significance.

The estimates of costs and benefits used in the analysis are generally based on market prices. There is then no need to adjust them with the 'net tax factor'. The end-result is that the socio-economic calculations have been carried out with a discount rate of 4%[8].

5.2.4.2 Calculation of the budgetary costs (financial assessment)

The budgetary costs are a reflection of the short-term effects arising from the Chemicals Initiatives. In assessing the budgetary costs, the costs to the public, businesses and the State have been considered. The costs to the public and businesses are based on existing analyses, which are referred to under the particular calculations. The public costs are the financial grants financed by the State and allocated to implementing the initiatives; see Table 5-1

5.2.4.3 Calculation of the impact on health and the environment

The primary benefits from the Chemicals Initiatives will be improvements to health and the environment. These effects have been quantified mainly on the basis of existing studies. When previous restrictions were defined under REACH, socio-economic analyses were carried out which can help to some extent in assessing the expected scale of the costs and benefits from implementing new regulatory measures under REACH. The existing studies, which already were there for chemicals regulated under REACH, are summarised in a recent report from ECHA, for which the background material can be accessed on the ECHA website[9]. It is mainly this material that has been used. Also literature review studies of existing journal articles containing financial estimates of the effects on health of exposure to chemicals[10] has been applied.

Where findings from other countries or overall EU results are used, the effects of international cooperation on chemicals are distributed or recalculated in proportion to population[11] (see also section 5.2.3.3).

The assessment of the environmental and health-related costs is fraught with uncertainty. This uncertainty is due to a lack of knowledge of exposure to a given harmful chemical, and of dose-response relationships, i.e. the level of damage to health and the environment resulting from exposure, and finally there is uncertainty as to the actual cost of these harmful effects on health and the environment. Basing our estimates mainly on the proposed restrictions drawn

[7] See Ministry of Finance guidelines for socio-economic analyses

[8] See Ministry of Finance guidelines for socio-economic analyses

[9] The specific references to reports and data are given in section 6 under the individual initiatives/effect chains.

[10] Literature study carried out for the Nordic Council of Ministers (in progress).

[11] Eurostat data: Population figures for the EU28 of 510 million and for Denmark of 5.7 million, equal to 1.1% of the total EU effect.

up under REACH, it is reasonable to assume that the uncertainty in the overall estimate will be minimised, as the socio-economic analyses under REACH have undergone thorough quality assurance by the ECHA's Committee for Socio-economic Analysis (SEAC). There is still some uncertainty in these estimates, so the calculations include a confidence interval.

It should be noted that most of the estimates are weighted towards the health costs and benefits. That means that the environmental effects are considered to a lesser extent. This is because there is greater uncertainty as to what the environmental effects are, and because things are harder to quantify in this area. This means that the overall effects on health and the environment are very likely understated.

The calculations assume that the rules are obeyed, so the calculated environmental and health benefits can be realised

5.2.4.4 Data sources

The present effect assessment is largely based on existing evaluations, reports, assessments etc. These data sources vary in terms of approach, scope, focus and quality. For example, some data sources address specific substances (such as standalone REACH restriction dossiers), while others take a more general look at a group of substances or type of effect (e.g. estimates of the costs associated with the effects on health of using endocrine disruptors).

As there are typically few recognised data sources to show the effects of the specific initiatives, it has not been possible to define general criteria for deciding what types of data source should be used. Therefore, very different types of data sources have been used to assess the effect of the initiatives. This is not ideal, but it has been necessary given the budgetary constraints. The data sources used have been described in as much detail as possible, and the reader should bear this in mind where the results are to be used in a different context.

A number of interviews were also conducted with businesses and industry organisations. The aim of these interviews was to attempt a possible estimate of the costs to these businesses and possible savings from a number of initiatives. Annex C contains the interview guide. It proved to be difficult to obtain any information of a quantitative nature. This is partly because the companies do not specifically record the time spent on complying with the different regulations and requirements. Rather, the interviews provide essential qualitative information on the effect of the various initiatives.

6. The specific initiatives and their effects

The effect assessment of the initiatives follows the effect assessment template from the Ministry of Environment and Food and the guidelines from the Ministry of Finance for socio-economic analyses. Further details of the methodological approach can be found in chapter 5, including the general definitions and assumptions. Under the individual initiatives below it is stated whether the subject or the data sources made it necessary to deviate from the general methodological approach.

6.1 International collaboration

International collaboration covers the following areas:

- Candidate list, harmonised classifications and restrictions – REACH dossiers
- REACH registrations and QSAR
- The biocides initiative
- Endocrine disruptors
- International agreements/global efforts

6.1.1 Candidate list, harmonised classifications and restrictions – REACH dossiers (Effect chain 1)

6.1.1.1 Purpose of the initiative

A great deal of chemicals regulation is international. It is mainly in the EU (particularly via the REACH and CLP Regulations) that much of the regulation of chemicals is laid down.

The effort can be divided into five main areas in which Denmark submits proposals or participates:

1. Participation in REACH working groups etc.
2. Proposals for harmonised classifications (CLP Annex VI)
3. Proposals for substances to be added to the REACH candidate list
4. Inclusion of substances in the authorisation list under REACH (Annex XIV)
5. Restrictions under REACH (Annex XVII)

The individual activities are described in brief below. Proposed restrictions under REACH are a form of regulation where the data allows indicators for costs and benefits to be calculated. These indicators are also used in assessing the other activities, and reference is made to restrictions in the descriptions of the other activities.

1) Participation in REACH working groups etc.
Denmark's participation in the EU work is a necessary part of EU efforts to assure effective implementation of the REACH and CLP Regulations. The Chemicals unit of the Danish EPA has two nominated members on the ECHA's Committee for Risk Assessment (RAC) and one nominated member on the Committee for Socio-economic Analysis (SEAC). There is also a Danish member on the Member State Committee (MSC). It is essential for the EU Member States to contribute to this work. It is impossible to directly quantify any effect of this work, but the effect of participation is implicitly recognised by the method used in the present

assessment, whereby the effect of the overall implementation of REACH is attributed according to population. See also section 5.2.3.3 on geographical demarcation.

2) Harmonised classifications:
When a harmonised classification of a substance is drawn up, it may affect the use of that substance by individuals and businesses based on the details of effects on health and the environment given in the classification. Some restrictions also enter into force automatically. E.g. when a substance is classified for the most serious effects (CMR – carcinogenic, mutagenic or reprotoxic), as the classification means that such substances are subsequently restricted in mixtures marketed to consumers (REACH, Annex XVII, paragraphs 28-30). Harmonised classifications will therefore often affect other 'downstream' legislation, such as e.g. the Cosmetics, Pesticides and Biocides Regulations. It can therefore be expected either that the use of a substance will be reduced as a result of the classification or that further measures will be taken to protect against emissions or exposure. ECHA is working to develop indicators for the effect of classifications on the type and scale of use. Without such indicators, it is only possible to estimate the effects of harmonised classifications. The estimate will be based on the calculations of the effects of an Annex XVII restriction (the effect of restrictions is quantified below). As described above, there will be some direct effects, but the biggest effects will result from specific measures under 'downstream' legislation, so it is assumed as a prudent estimate that the effect is 10% of the effect of an Annex XVII restriction.
The total number of proposals at the EU level for harmonised classifications was approx. 103 in the period 2014-2016.[12] The number of harmonised classifications to be adopted in 2017 is of course unknown. Therefore, a figure has been estimated based on the average for the period 2014 to 2016. This brings the estimated total number of amended harmonised classifications to 137.

3) Inclusion in the candidate list
Including substances in the REACH candidate list helps to restrict the use of these substances. This may happen in the following ways: Inclusion in the list brings about reduced use of the substance by voluntary action from industry, inclusion leads to subsequent inclusion in the authorisation list (Annex XIV), which reduces use, or the substance is made subject to a restriction. The last two are independent effects, and are described below. It is expected that the mere fact that a substance has been proposed for inclusion in the list will have an effect on use. The experience from previous regulatory efforts is that drawing attention to a substance, which may mean future restrictions on its use, will cause a certain reduction in the use of that substance.

ECHA is working to develop indicators for the effect of including substances in the candidate list. This work is ongoing, and such indicators may be used in future effect assessments.

Until these indicators are available, it is only possible to give an estimate of the effect of including a substance in the candidate list. The estimate will be based on the calculations of the effects of an Annex XVII restriction (the effect of restrictions is quantified below).As a cautious estimate, it is assumed that inclusion in the candidate list produces a benefit equal to 10% of a restriction (REACH Annex XVII).

The total number of dossiers at the EU level for inclusion of substances in the candidate list for the period 2014-2016 is 22[13]. The figure for 2017 is not known, so the number for 2017 has

[12] ECHA Annual update to CLP Annex VI Table 3.1 *Six, Seventh and Ninth Adaptation to Technical Progress* reports

[13] ECHA candidate list data (4 substances were added in January 2017 based on a decision taken in December 2016, so they are included in 2016)

been extrapolated in the same way as for other types of regulation, i.e. as a simple average of the numbers for 2014 to 2016. This brings the estimate for the total number of substances for inclusion in the candidate list to 29 for the period 2014-2017.

4) Inclusion in the authorisation list

If a substance comes onto the authorisation list, the effect is a restriction within the uses where the enterprises do not apply for authorisation, where safe use cannot be documented, or where there are suitable alternatives. In other words, the authorisation scheme puts a stop to the use of the substance by itself or in mixtures below the levels at which the industry receives a time-limited authorisation to continue use. For around 1/3 of the substances on the authorisation list, the industry has not applied for continued use. For the uses that have been authorised, the industry's safety assessments are updated, leading to possible improvements in handling which may reduce exposure.

The scale of the effect in the form of reduced overall use/exposure will depend on how much of the total quantity of the substance was authorised before it came onto the list. There are as yet no statistics to show the effects in the form of reduced quantities resulting from inclusion in the authorisation list. Inclusion in the authorisation list constitutes a direct ban on using the substance, which suggests a significant effect. On the other hand, authorisation may be granted for continued use, even within relatively broad applications. Substances in the authorisation scheme can also occur in items imported from countries outside the EU. As a cautious approximation, the effect is assumed to be 50% of a restriction.

20 substances were added to the authorisation list in the period 2014-2016. This has been extrapolated to approx. 27 substances for the whole period 2014-2017.

5) Restrictions under REACH (Annex XVII)

Restrictions are an important instrument under REACH for restricting the use of specific substances in cases where risks have been identified that are not sufficiently controlled. Proposed restrictions are drawn up by the EU Member States or, at the request of the European Commission, by the European Chemicals Agency (ECHA). When a proposal for a restriction is drawn up, the expected effects have to be calculated (a socio-economic assessment). This socio-economic assessment includes analyses of both costs and benefits. These calculations and evaluations of the expected benefits to health and the environment will form the basis in this project for many of the action areas under the Chemicals Initiatives.

The total number of EU proposals for restrictions adopted by the European Commission in the period 2014-2016 is 8[14]. As for the number of harmonised classifications and inclusions in the candidate list, this figure is extrapolated by calculating an annual average for the first three years and using this as an estimate of the number expected to be adopted in 2017. This gives a total of 11 restrictions in the whole period 2014 to 2017.

Under the analysis of the long-term effects below, the basis for estimating this part of the effect chain is described, which is based on the REACH proposals for restrictions, which include socio-economic calculations.

6.1.1.2 Short-term effects – impact of changes in behaviour – budgetary effects

This section describes the budgetary effects of the initiative. These include both the grants made under the Chemicals Initiatives and the costs the industry is expected to incur to comply with the requirements laid down by the regulatory measures. The costs to the Danish

[14] The ECHA's list of restrictions on use

authorities are a grant of DKK 40.7 million set aside for this initiative and the initiative concerning REACH registrations and QSAR (effect chain 2), as described in the next section.

The estimate of the costs to the enterprises is extrapolated in proportion to the size of the Danish population, whereby the costs calculated for the whole of the EU are divided according to population size. The costs to enterprises are calculated from the cost per proposed restriction. The basis for the calculations is an ECHA report from 2016[15], which contains an analysis of costs and benefits for a number of restrictions.

The table below shows the principal costs that businesses are expected to incur as a result of the proposed restrictions. These costs cover investments and possible increased operating costs from substituting for the restricted substances. A greater or lesser part of any added costs to the enterprises will ultimately be borne by consumers. For some of the restrictions, the costs of implementation by the authorities may be included, but these are typically very limited. This analysis presents costs borne by the enterprises.

14 out of 16 proposals included in the ECHA's 2016 report[16] have been included. There a few other proposals that have not been adopted or are still at the consultation stage. In all, there are costs from 16 proposals. It can be seen that there is great variation in the costs. Looking at the mean per proposal, around EUR 20 million per year is estimated. If the median is used instead, a cost of EUR 8 million per year per proposal is obtained.

Table 6-1 Quantified costs in the EU for proposed restrictions[17]

Restrictions	Annual costs	
	EUR millions	DKK millions
Lead in jewellery	5	37
Chromium(VI) in leather goods	100.8	751
Lead and lead compounds in consumer products	26.9	200
Methanol in sprinkler fluids	40.4	301
Mercury in measuring instruments	10.4	77
Phenylmercury compounds used e.g. in the production of polyurethane coatings	1.3	10
Nonylphenol (NP) and its ethoxylates (NPE) in textile	3.2	24
Decabromodiphenyl ether (DecaBDE) as a flame retardant in plastics and textiles	2.3	17
Perfluorooctanoic acid (PFOA) and its salts, including substances that may degrade to PFOA	36.1	269
Siloxanes D4 and D5 in personal care products	51.3	382
1,4-dichlorobenzene (DCB) in toilet blocks and air fresheners	1.3	10
1-Methyl-2-pyrrolidone (NMP)	5.1	38
Use of asbestos fibres	6	45
Ammonium salts in cellulose as insulating material	0.3	2
BPA	13	97
4 phthalates with endocrine-disrupting effects	16.9	126
TDFA (spray products for consumers)	0	0

Source: ECHA 2016

[15] ECHA, 2016: *Cost and benefit assessments in the REACH restrictions.*

[16] Two proposals were actually updates to existing regulations which were not considered to entail any significant costs or benefits. They have therefore been omitted as irrelevant.

[17] ECHA 2016 *Cost and benefit assessment in the REACH restriction dossiers,* and ECHA 2016, *Annex XV restriction dossier: Four phthalates (DEHP, BBP, DBP, DIBP)* and Danish Environmental Protection Agency 2016, *Proposal for a restriction, substance name(s): (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol and any of its mono-, di- or tri-O-(alkyl) derivatives.*

These values are used as a basis for estimating the cost per proposed restriction. The cost is calculated per proposal. This is judged to be the best indicator given the data available.

Alternatively, one could calculate the cost per tonne or possibly include the degree of toxicity of the product to arrive at a risk-weighted cost. This would require there to be data available on the quantitative effects of restrictions. As this is not currently the case (ECHA is working to develop indicators), it is judged most appropriate to calculate costs per proposal. A calculation per substance might also be a possibility, as some restrictions cover several substances, but restrictions do not always cover a well-defined set of substances. Restrictions can also cover one of more applications – and potentially all uses (= a blanket ban). This is also an argument for looking at the effect of the quantity/use of the regulated substances; however, this information is not available, so the effect per restriction has been used as the best approximation.

The values for the EU have been converted into an estimate for Denmark in proportion to the size of the Danish population[18]. This is the same approach used to translate the benefits to health and the environment. In relation to the costs to the enterprises, this conversion could be less correct, as the costs will depend more on the types of enterprise that exist in different countries. However, this is impossible to assess, given that it would require very detailed data on business structures, as the breakdown will differ from one proposal to another. Where, for example, there are no producers in Denmark, increased costs to producers in other countries will affect Danish importers, as increased costs are passed on in the prices in the longer term. The assumed distribution based on population is therefore judged to be reasonable.

A low, medium and high estimate has been produced for the budgetary costs per proposal. As the costs vary from one proposal to another, the mean is sensitive to whether the highest or the lowest values are chosen. The median is a more robust indicator and has therefore been used as the intermediate estimate. To describe the uncertainty and variation in the estimate, the 25% quartile is used as the low estimate and the 75% quartile as the high estimate. This approach is also used to calculate the benefits to health and the environment; see next section.

The calculated estimates of the costs are shown below as the derived costs to Danish enterprises. The median estimate is thus around DKK0.5 million per year per proposal.

Table 6-2 Key figures for estimates of budgetary costs for enterprises in Denmark of a restriction

Key figures	Cost in DKK millions per year[19]
Low estimate	0.19
Median	**0.50**
High estimate	2.24

Source: COWI calculations

For substances included in the candidate list and the authorisation list and for harmonised classification, the assumed costs are also based on the estimate for restrictions. Section 6.1.1.1 above explains the assumptions, which are also presented in the table below. These are estimates based on what the different types of regulation mean in comparison with restrictions. They are also 'cautious' estimates, which means that they probably understate the effect. For example, when a substance goes onto the authorisation list, all uses are prohibited

[18] See section 5.2.4

[19] Values may be rounded.

unless an authorisation is applied for and received. The restrictions are often only for specific uses, and one could argue that authorisations cover a wider area. Conversely, authorisation may also be given for wider use. Substances in the authorisation scheme can also occur in items imported from countries outside the EU. Overall, therefore, 50% is judged to be a cautious estimate of the effect of inclusion in the authorisation list.

Table 6-3 Indicators for costs to Danish businesses of different types of regulation – estimated cost per proposal based in effect relative to restrictions

Type of proposed regulation	% effect of restrictions	Estimated costs in DKK millions per year		
		Low	Median	High
Harmonised classifications	10%	0.02	0.05	0.22
Inclusion in the candidate list	10%	0.02	0.05	0.22
Inclusion in the authorisation list	50%	0.10	0.25	1.12
Restrictions	100%	0.19	0.50	2.24

Source: COWI calculations

The total costs to enterprises of this specific initiative are calculated from the estimated number of harmonised classifications, the number of substances included in the candidate list, the number in the authorisation list and the number of restrictions. The number of substances or proposals is multiplied by the estimated unit cost to arrive at an estimate of the total cost to the enterprises.

The number of substances or proposals is described in section 6.1.1.1 above, and summarised in the table below.

Table 6-4 Basis for effect calculations – number of proposals adopted in the period 2014-2017

Type of proposed regulation	Proposals adopted 2014-2016	Extrapolation for 2014 to 2017[20]
Harmonised classifications	103	137
Inclusion in the candidate list	22	29[21]
Inclusion in the authorisation list	20	27
Restrictions	8	11

Source: ECHA

The costs will not be incurred immediately a proposal is adopted. It typically takes one to three years for the requirements to enter into force. The calculations below show the costs when the regulatory measures have taken full effect.

[20] The table gives rounded values, e.g. 11 restrictions on use rather than 10.7. The further calculations use the exact figure.

[21] 17 substances were included in the two-year period 2014-15 and only one in 2016. The low figure for 2016 is due to delays in the process. Four substances were added in January 2017 (decided in December 2016) and these are included in 2016. As for the other types, the estimate for the whole period is based on an extrapolation of the expected number for 2017 equal to the average for the first three years.

Table 6-5 Budgetary costs for enterprises in DKK millions per year

Type of proposed regulation	Low estimate	Median	High estimate
Harmonised classifications	2.6	6.9	30.8
Inclusion in the candidate list	0.6	1.5	6.6
Inclusion in the authorisation list	2.6	6.7	29.9
Restrictions	2.0	5.3	23.9
Total	7.8	20.3	91.1

Source: COWI calculations

6.1.1.3 Long-term effects – implications for health and the environment

The calculations of the expected benefits to health and the environment are based on REACH proposals for restrictions (Annex XVII), which include monetary valuations. The valuations made in connection with these proposed restrictions may be considered the best supported analyses and monetary valuations that can be seen in relation to the effects of REACH. They follow the same guidelines (the ECHA's official guidance on socio-economic analyses) and have been thoroughly examined by ECHA's two principal committees, the Committee for Socio-economic Analysis (SEAC) and the Committee for Risk Assessment (RAC), so they also form part of the basis for decision as to whether a given substance should be regulated via a restriction.

ECHA has calculated a value per proposed restriction. In principle values per substance could be derived, but some restrictions cover a group rather than a single substance. Moreover, restrictions cover a varying number of uses. Therefore, a calculation of the value for the benefits to health and the environment from each proposal is the most useful.

This calculation is based on four adopted proposals and three proposals at the consultation stage or under discussion in the two committees (RAC and SEAC). Where it is only possible to include seven proposals, while the cost estimates are based on a larger number of proposals, this is because not all proposals have been fully quantified. In many cases, the proposal only includes a judgment as to whether the possible benefits to health and the environment are greater than the costs.

The table below shows the valuations for the seven proposals.

Table 6-6 Monetary valuations of proposed restrictions[22]

Restrictions	Value in EUR millions per year
Lead in jewellery	16
Chromium(VI) in leather goods	355
Lead and lead compounds in consumer products	27
Methanol in sprinkler fluids	323
4 phthalates with endocrine-disrupting effects	33
TDFAs (polyfluorosiloxane compounds) in spray products	0.3
BPA	4.4

Source: ECHA

[22] ECHA 2016 *Cost and benefit assessment in the REACH restriction dossiers* and ECHA 2016, *Annex XV restriction dossier: Four phthalates (DEHP, BBP, DBP, DIBP)* and Danish Environmental Protection Agency 2016, *Proposal for a restriction substance name(s): (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol and any of its mono-, di- or tri-O-(alkyl) derivatives*

The table shows that there is great variation between the seven proposed restrictions. This variation is due to many factors. Proposals where the effect is a reduction in exposure to contact allergies (chromium(VI) in leather goods) yield big benefits because these are products that affect many people and the costs are relatively well-documented. In other cases where there is less exposure, the benefit is correspondingly less (e.g. TDFAs in spray products).

There is also some uncertainty within each of the seven proposals. However, this uncertainty has been calculated in very different ways, often as a series of sensitivity calculations. This means that there is no actual interval around the estimate given in the table. Based on the seven proposals, a number of indicators can be derived.

Table 6-7 Indicators for possible benefits to health and the environment from a restriction

Indicator	Value in EUR millions per year[23]
Average	108
Lowest value	0.3
Highest value	355
25% quartile	10
Median (50% quartile)	27
75% quartile	178

Source: COWI calculations

The mean benefit is approx. EUR 108 million per proposal, while the median value is around EUR 27 million per dossier. The mean is sensitive to the specific figures in that, if there happen to be more or fewer proposals with very high or very low values in just these seven proposals than there will be in the future, this will have a big effect on the mean. The median is a more robust indicator, which is less sensitive to whether there are more or fewer of the highest or lowest values. The analysis therefore uses the median as the 'best' estimate of the benefits to health and the environment of a proposed restriction. To describe the uncertainty in this median estimate, an interval is used where the 75% quartile is treated as the 'high' estimate while the low estimate is based on the 25% quartile. This gives an interval from EUR 10 to 178 million per year, with EUR 27 million per year as the median estimate.

These values are converted for Denmark in proportion to the Danish population relative to that of the EU28[24]. An exchange rate of DKK 7.45 to the EUR[25] has been used. This gives the following values per proposal.

Table 6-8 Key figures for the value of benefits to health and the environment from a restriction

Key figures	Value in DKK millions per year[26]
Low estimate	0.8
Mid-range (median)	**2.2**
High estimate	14.8

Source: COWI calculations

[23] Values may be rounded.

[24] Eurostat data, see section 5.2.4 The Danish share is thus around 1% of the total effect for the EU28.

[25] The European Central Bank

[26] Values may be rounded.

The values per restriction are indicators that can be used to assess the other types of regulation. The table below shows the assumptions used to calculate the values for classifications and listed substances. The background to these estimates is described above.

The table also shows the median estimate of the value of the benefits to health and the environment from each type of regulation.

Table 6-9 Indicators for benefits to health and the environment from a restriction

Type of proposed regulation	% effect of restrictions	Estimated benefits in DKK millions per year		
		Low	Median	High
Harmonised classifications	10%	0.1	0.2	1.5
Inclusion in the candidate list	10%	0.1	0.2	1.5
Inclusion in the authorisation list	50%	0.4	1.1	7.4
Restrictions	100%	0.8	2.2	14.8

Source: COWI calculations

Based on the number of proposals adopted as shown in Table 6-4 and estimated indicators for the benefits to health and the environment per proposal, Table 6-9, estimates of the total benefits to health and the environment can be seen. The estimated effects are summarised in the table below. These are the benefits related to the harmonised classifications, substances included in the candidate list and the authorisation list, and final restrictions.

Table 6-10 Impact on health and the environment in DKK millions per year

Benefits	Number	Low estimate	Median	High estimate
Harmonised classifications	137	11.5	30.8	203.4
Candidate list	29	2.5	6.6	43.5
Authorisations	27	11.2	29.9	197.5
Restrictions	11	8.9	23.9	158.0
Total		34.0	91.1	602.4

Source: COWI calculations

The table shows that the projected benefits to health and the environment come to around DKK 91 million per year as a median ('best') estimate. The uncertainty in the estimate can be illustrated with an interval from approx. DKK 34 million up to approx. DKK 600 million per year. This estimate is for the benefits when they have taken full effect.

The benefits to health and the environment will be realised gradually. There may be big differences in the speed at which the effects may be expected to appear. Health benefits related to e.g. allergies will take effect relatively quickly, while effects related to a reduced risk of cancer will be seen after a longer period.

6.1.1.4 Socio-economic implications

Base on the calculations of costs and benefits described in the preceding sections, an overall assessment of this specific initiative can be produced.

The socio-economic implications include the budgetary costs to the State and enterprises, and the environmental and health-related costs to the whole of society. The costs to the State are made up of the actual grant to this specific initiative to assist in implementing REACH and CLP. The costs to the enterprises include the estimated costs of complying with the requirements from the regulatory measures that are implemented. These are requirements for changes in behaviour when harmonised classifications of substances are adopted, when substances are included in the candidate list and the authorisation list, and finally when restrictions are adopted.

The Chemicals Initiatives run for 4 years from 2014 to 2017, and the grant covering this specific initiative is approx. DKK 41 million. In calculating the socio-economic implications, the grant has been spread equally over the four years. As the grant is tax-financed, a 'tax distortion factor' of 20% has been used. This produces a total socio-economic cost of around DKK 49 million, equivalent to an annual cost of approx. DKK 12 million in the four years of the Chemicals Initiatives.

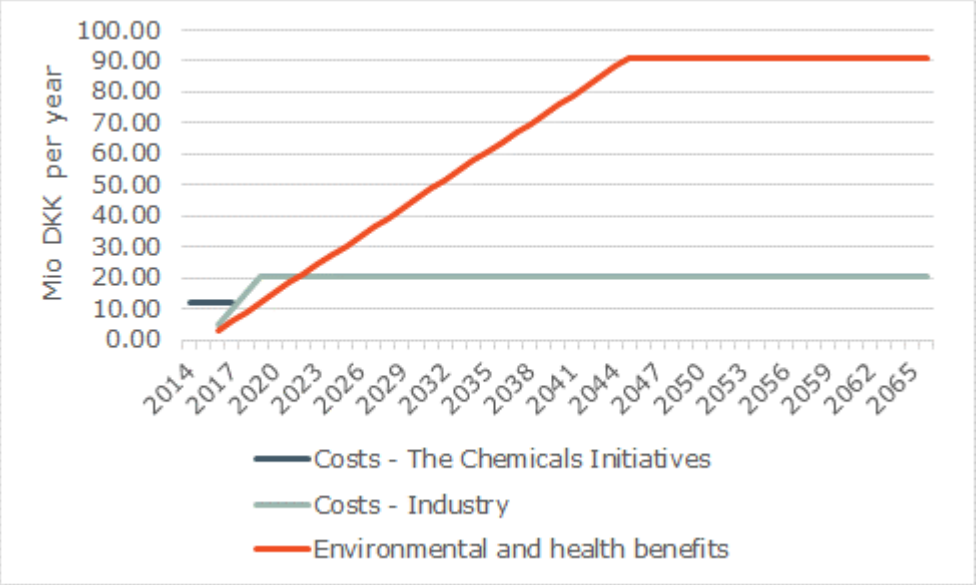
The costs to the enterprises are expected to manifest themselves soon after a regulatory measure enters into force. The socio-economic analysis assumes that these are realised gradually over four years. As described above, these costs are calculated as annual expenditure. Some of the costs to enterprises will be investments in substance substitution. In reality, these come up in the course of the first few years. Increased operating costs, on the other hand, will continue at the same level. The costs are based on restrictions as described above, and here the investment costs are converted into annual costs based on a discount rate of 4%[27].

[27] The European Commission recommends 4% for socio-economic analyses, so this is used in REACH-related analyses.

The benefits to health and the environment are realised gradually. The figure below shows a socio-economic calculation in which the benefits to health and the environment are realised gradually over a 30-year period. The whole calculation has been done for a 50-year period. The figure shows how the annual net benefit grows as the benefits to health and the environment are realised. That means that the total present value increases when it is calculated over a longer time horizon.

The values for the estimated costs to the enterprises and the estimated benefits to health and the environment are based on the mid-range estimates, which are themselves median values.

Figure 6-1 Trend in costs and benefits from regulatory measures



The socio-economic implications are calculated below as present values over a 50-year period. The calculation is based on the change in costs and benefits illustrated in the figure above.

Table 6-11 Socio-economic calculation – present value over 50 years with alternative valuations of costs and benefits.

Effect	Present value in DKK millions		
	Low estimate	Median	Highest estimate
Grants under the Chemicals Initiatives	-41	-41	-41
Grants under the Chemicals Initiatives with 20% tax distortion factor	-49	-49	-49
Costs to enterprises	-220	-580	-2.600
Total costs	-270	-630	-2.650
Benefits to health and the environment	680	1.820	12.040
Total socio-economic net gains	410	1.190	9.390

Note: a negative value is a cost

The analysis points to a clear socio-economic benefit from the Danish contribution to international regulation, mainly under REACH. The calculated net present value is around DKK 1,190 million over a period of 50 years.

The sensitivity calculations performed show that this result is very robust. Considering the low estimate of both costs and benefits, there is still a positive net present value. The way in which the intervals for costs and benefits are calculated means that it is not possible to combine the high estimate for costs with the low estimate for benefits. Regulatory measures such as restrictions are implemented where it can be proven that there are benefits to health and the environment that exceed the costs of the restriction. The high and low estimates mainly reflect the uncertainty as to the net benefits that regulation will bring. The table shows that there are socio-economic net benefits ranging between DKK 410 million and DKK 9,390 million over a 50-year period.

It can be calculated how long it will take before the specific initiative has paid for itself, i.e. how many years will elapse before the present value calculation yields a positive result. That calculation shows that it will take 14 years before the initiative has a positive effect. This is less than the assumption that the benefits to health and the environment will be realised gradually over 30 years. If it is assumed that these benefits will be realised without any delay, the initiative will have a positive present value after just one year, as the annual net benefits are DKK 70 million.

The table below shows the result if it is assumed instead that the benefits to health and the environment are realised over a shorter or a longer time frame. The calculations used the median estimate of the unit value of costs and benefits.

Table 6-12 Socio-economic calculation – present value over 50 years with alternative assumptions for realising the benefits to health and the environment

Effect	Present value in DKK millions			
	10 years	20 years	50 years	100 years
Grants under the Chemicals Initiatives	-41	-41	-41	-41
Grants under the Chemicals Initiatives with 20% tax distortion factor	-49	-49	-49	-49
Costs to enterprises	-580	-580	-580	-580
Total costs	-630	-630	-630	-630
Benefits to health and the environment	2,380	2,060	1,390	700
Total socio-economic net gains	1,750	1,440	760	70

Even if it is assumed that the benefits to health and the environment are only fully realised after 100 years, the calculation still shows a positive net present value.

6.1.1.5 General discussion of assumptions and uncertainties

The following table shows the key assumptions and uncertainties associated with the assessment of the effects of the initiative described in this effect chain, including what has been done to reduce/handle the uncertainty and what could be done in the future.

Parameter/assumption	In the absence of better data, the effects (costs and benefits) of restrictions have been calculated on the basis of estimates of an 'average restriction'.
Uncertainty	Big difference between proposed restrictions, including some with very high costs and benefits and some with low costs and benefits. The differences may be due to several factors, including: - There are differences in what it costs the industry to substitute or change

	the use of different chemicals - There are differences in the potential effects on health and the environment (and the quantities currently used) of different substances - Some proposals cover only a few uses, or just one, while some may cover many uses or constitute a ban - Some proposals cover a well-defined substance, while others cover multiple substances or a group of substances without an immediately well-defined composition
How addressed	- The median value has been used as the mid-range estimate. The median is less sensitive to very high and very low values than an estimate based on the mean - Sensitivity analyses have been performed on high and low estimates too
Outstanding uncertainty	- There is still some uncertainty around the estimate, particularly as there are still not many proposals with quantified benefits
Looking forward	- It will be possible to calculate a better mean estimate when more proposals for restrictions appear over time which quantify the costs and benefits. The figure should therefore be adjusted at regular intervals. - Alternatively, the indicators that ECHA is developing to show how regulation of a substance (or substances) affects the volume and uses of that substance can be viewed. Whether and how this might proceed depends on the indicators that ECHA arrives at.

Parameter/assumption	Precision of estimated effects in proposals for restrictions.
Uncertainty	The choices made in defining the effects of a given proposal often have a big influence on the scale of the estimated costs and benefits. Benefits relating to environmental effects are typically not quantified in proposals, so estimated benefits relate more to the effects on health. It is therefore likely that the overall benefit has been underestimated.
How addressed	Apart from the sensitivity calculations described above, no specific actions have been taken to address this uncertainty, but it is worth mentioning that this is universally accepted in socio-economic analyses. With regard to the proposals that have been considered here, it should be remembered that the content and the estimates used in the individual proposals are considered sufficiently valid to serve as a basis for decision-making on REACH restrictions for the substance being assessed. It should also be noted that the use of median values smooths any fluctuations affecting the individual substances. Particularly when more proposals come in over time; see discussion above.
Outstanding uncertainty	As described under uncertainty: benefits will often be understated as environmental effects and many health-related effects have not been quantified.
Looking forward	It is expected that more proposals will result in (even) better understanding of how to assess and quantify the effects of restrictions, which will reduce the uncertainty.

Parameter/assumption	Use of effects from restrictions to estimate the effect or harmonised classification and labelling, inclusion of particularly problematical substances (SVHCs) on the candidate list and possible inclusion of these SVHCs on the authorisation list (REACH Annex XIV)
Uncertainty	There is great uncertainty associated with extrapolating the effect of restrictions to the effect of harmonised classifications, inclusion in the candidate list and inclusion in the authorisation list. As for restrictions, there may be big differences in whether the individual classification of the individual entry in the candidate list (or authorisation list)

	covers one or several substances, or perhaps a whole group of substances.
How addressed	As described in relation to assessing the effect of these types of regulation, very cautious/conservative assumptions have been used for the effect of these types of regulation compared to that of a restriction; more precisely: - 10% for harmonised classification - 10% for inclusion in candidate list - 50% for inclusion in authorisation list The calculation is 'per proposal', not 'per substance'.
Outstanding uncertainty	The percentages used are believed to understate the effect of these types of regulation. Moreover, the effect has been assessed 'per proposal' (even where a classification or SVHC entry covers multiple substances), which is considered to be cautious/conservative. All in all, it is the impression that there is a very high probability that the calculated effects underestimate the net benefits from these types of regulation.
Looking forward	As mentioned above, ECHA is in the process of developing indicators for the effect of regulation, including that of harmonised classifications, inclusion in the candidate list and inclusion in the authorisation list. These figures may then be used to quantify the differences in the effect of different types of regulation to yield more precise percentages than the 10% and 50% used in the present report.

Parameter/assumption	The geographical demarcation, which assumes that the following can be calculated, for the Danish initiatives: (i) effects on Danish people and businesses (ii) effects of all REACH and CLP regulation, whether or not Danish authorities have contributed to regulating a given substance under REACH.
Uncertainty	It could be debated whether the Danish Chemicals Initiatives are greater or smaller than the average for other EU countries and should therefore be assessed more separately/specifically.
How addressed	The Danish effort as compared to the EU average is discussed in qualitative terms in the next section.
Outstanding uncertainty	Different geographical breakdowns can be used, but it is hard to say which definition will produce the most 'correct' estimate of the effects. Therefore, the most important thing is to state clearly that a given definition has been used. This is explained in detail in chapter 5. As discussed in qualitative terms in the next section, it could be argued that the Danish contribution to REACH has a greater effect than is suggested by the quantitative estimates in the present report.
Looking forward	The Ministry of Environment and Food could discuss/clarify whether a different geographical demarcation should be used to measure the effects of Denmark's contribution to developing and implementing EU law.

Parameter/assumption	It has been assumed that effects on Danish businesses and the Danish population can be extrapolated from the total effect of REACH in the EU on the basis of the population figure, from a desire to assess the effect on the environment and the population in Denmark.

	It would be hard to list all of the conceivable uncertainties associated with this assumption. In summary, there is no basis for determining from an 'average' approach whether the Danish population is exposed much more or less than the average for the EU.
Uncertainty	There is uncertainty as to whether the Danish population is exposed much more or less than the average for the EU, which will affect our assessment of the benefits from the initiatives carried out. There is also uncertainty as to whether the costs to Danish industry can be extrapolated in the same way, as there are fewer Danish chemicals producers.
How addressed	The work (information and guidance) done earlier by Danish authorities could mean that the level of exposure in Denmark is lower on average than in the EU28. On the other hand, the fact that Denmark has a higher per capita GDP could imply a greater consumption of products with potentially harmful effects. So there are opposing tendencies. An uncertainty interval will be calculated for each restriction, and this is expected to cover this issue.
Outstanding uncertainty	It is hard to assess the scale of the outstanding uncertainty. The uncertainty interval used is considered to take account of cases where exposure in Denmark is very different from the average for the EU28.
Looking forward	This is related to the geographical demarcation and the same considerations as described above are relevant here too.

Parameter/assumption	It has been assumed that effects on Danish industry can be extrapolated from the total effect of REACH in the EU on the basis of the population figure.
Uncertainty	It is debatable whether the costs to Danish industry of adapting to EU chemicals regulation are the same as for industry in countries with heavier use of chemicals.
How addressed	As described in connection with assessing short-term effects, this uncertainty is not considered to be great as any increased prices for substituting chemicals will be borne first by Danish importers and then passed on in consumer prices. In socio-economic terms, therefore, costs or savings to industry will affect Danish businesses and consumers.
Outstanding uncertainty	It is hard to assess the scale of the outstanding uncertainty. The uncertainty interval used is considered to take account of cases where the costs to Danish businesses are very different from the average for the EU28.
Looking forward	This is related to the geographical demarcation and the same considerations as described above are relevant here too.

Parameter/assumption	Number of restrictions in the four-year period of the Chemicals Initiatives 2014-2017
Uncertainty	As described in the 'Method' section, there will be some uncertainty associated with the 'number of proposals for regulation' in a given period, as proposals are typically drawn up, discussed, amended and possibly passed into law over a number of years, which could have started before 2014 and might finish after 2017.
How addressed	In the present assessment, the number of proposals adopted have been quantified. There are figures for the number of proposals adopted in 2014, 2015 and in some cases for 2016, whereas the Chemicals Initiatives run until 2017.

	The number of restrictions for the remaining period of the Chemicals Initiatives has been estimated by extrapolating from 2014 and 2015, and sometimes 2016.
Outstanding uncertainty	It is hard to judge the scale of the outstanding uncertainty, but the estimates used are believed to be quite stable. It could be argued, however, that the extrapolations used for the number of proposals adopted in 2017 are at the lower end, as a rising trend has been observed in recent years for the number of harmonised classifications in particular. If so, the net benefit will be understated.
Looking forward	It is difficult to remove this source of uncertainty from this type of time-limited assessment, where activities may start and/or finish outside the time frame of the initiatives. When REACH has been in progress for a while, one could produce a trend analysis to indicate whether the number of proposals adopted seems likely to increase, decrease or remain more or less unchanged over time.

The table above discusses what are considered to be the *most significant* assumptions and uncertainties in the present assessment, and how these have been addressed. Overall, the handling of uncertainties as described here may broadly be considered to underestimate the net benefit of the Chemicals Initiatives. This, combined with the sensitivity analysis, indicates that reasonably robust conclusions can be drawn on the effect of the initiative described in this effect chain.

6.1.1.6 **Overall assessment**

The overall assessment of this effect chain is that it contributes a substantial socio-economic benefit of around DKK 1,190 million (based on a median estimate of costs and benefits over a 50-year period). It has also been assumed that the benefits to health and the environment are only gradually phased in. Calculations of the uncertainty in the estimates show that this conclusion may be considered robust.

The assessment is based on a method which builds on a geographical demarcation, focusing more on the implementation and results of EU chemicals regulation as a whole and less on the Danish initiatives viewed in isolation. There will be cases where Denmark is doing more than the other countries and where the effect is greater than the population figure for Denmark would suggest. The notes above are therefore supplemented with a more qualitative discussion of the effect of the Danish initiatives compared to the EU initiative as such.

One way of viewing the Danish effort is to look at the number of proposals for harmonised classifications, inclusions in the candidate list and restrictions in relation to the total number of proposals across the EU.

For example, Denmark submitted four proposals for restrictions in the period from 2014 to 2016, while the EU adopted a total of nine. These were:

- 4 phthalates with endocrine-disrupting effects (in collaboration with ECHA)
- TDFAs (polyfluorosiloxane compounds) in spray products
- Tattoo dyes (planned for 2017; under discussion with ECHA)
- Chlorinated flame retardants (planned for 2017, possibly in collaboration with ECHA)

With the geographical demarcation used in this effect assessment, Denmark is credited with 1% of the net benefit from REACH (based on population size) although Denmark sometimes contributes much more than 1% of the effort, which is however natural for relatively small countries. Strong Danish Chemicals Initiatives also enjoy great political support in Denmark, as evidenced by the fact that all parties in the Parliament backed the adoption of the Chemicals Initiatives 2014-2017.

So the effect of the Chemicals Initiatives in terms of the relative size of the contribution made by Denmark were calculated, it could be argued that the Chemicals Initiatives 2014-2017 yield greater benefits to health and the environment than the quantitative estimates given in this evaluation.

The Danish Chemicals Initiatives contribute new knowledge, such as the knowledge generated in the Danish National Allergy Research Centre and the Centre for Endocrine Disruptors (CeHos), along with new methods and tools to optimise the assessment of chemicals – particularly the Danish QSAR database. This knowledge and these tools contribute at many levels to the implementation of REACH, assisting with prioritisation and drawing up proposals for regulation (both from Denmark itself and from other EU countries).

Moreover, as will be shown by the evaluations carried out later in this assessment, contact allergies and endocrine-disrupting effects caused by chemicals represent an ever-increasing socio-economic cost. Knowledge of these characteristics could potentially lead to socio-

economic savings if this knowledge is reflected in better handling and regulation of these substances, not least in the REACH implementation

All in all, it is fair to say that the Danish Chemicals Initiatives can contribute very substantially to the benefits obtained if the results can be realised e.g. through REACH.

6.1.2 REACH registrations and QSAR (Effect chain 2)

6.1.2.1 Purpose of the initiative

This specific initiative includes three activities: REACH dossier evaluation, REACH substance evaluation and QSAR work. Dossier evaluation means checking registration details and assessing test proposals. Substance evaluation involves the Danish EPA reviewing a selected number of substances registered under REACH, while the QSAR work consists of an update to the Danish QSAR database.

As part of the obligations placed on Member States under REACH, the Danish EPA contributes to the work of ECHA by running checks on REACH registrations. This leads to more complete and correct registrations. It therefore helps to ensure that REACH is implemented and that the benefits of REACH to health and the environment are realised.

Substance evaluations also help to enhance the quality of REACH implementation and so help to ensure that the benefits to health and the environment are realised. Substance evaluations identify problematical substances, and testing requirements can required by the registrants. For substances that prove to pose a potential environmental and/or health problem, the substance evaluations also typically serve as the first link in the chain leading to regulation of a substance – particularly the types of regulation described under effect chain 1.

ECHA is currently defining indicators to measure whether a substance evaluation has any effect on the use of that substance.
Although a substance evaluation can lead to regulation of a substance if it does prove to constitute a risk, it is not possible to use a percentage of the effect from proposed restrictions to estimate the net benefit of a substance evaluation in the same way as for inclusion in the candidate list or for harmonised classification, as this would mean counting the benefit twice.

Rather, some of the benefits from substance regulation should be ascribed to the work on substance evaluations.

The work of updating the QSAR database is important if this database is to continue to be a useful tool for authorities and enterprises working with chemicals. The QSAR database contributes in a number of areas to the work of reducing the use of the most dangerous and harmful substances. For enterprises required to self-classify substances, access to the database gives them a tool which can provide them with information on substances that have not been properly tested in animal trials. In some cases, it can also help to reduce testing costs, not least because the use of animal trials can be limited. Moreover, when new products are developed or known unwanted substances are substituted at an early stage in the development process, developers can obtain an indication of whether the alternative has harmful properties. This reduces the costs to the enterprises. There are estimates of how much the costs are reduced by the use of QSAR tools. The Danish QSAR database is just one of many QSAR tools.

For authorities – both national and international (including ECHA) – QSAR and similar databases assist in prioritising initiatives and also help to reduce the costs of implementing chemicals regulation. The database makes it easy for the authorities to evaluate/screen a

substance without incurring major testing costs. ECHA has stated that the Danish QSAR database is actively used in the Agency's work in connection with REACH.

6.1.2.2 Short-term effects – impact of changes in behaviour – budgetary effects

The effect of checking registration dossiers is to assure correct implementation of the REACH regulation that has been adopted (to fulfil the goal of REACH). The Danish EPA is thus contributing to the implementation of REACH and so ensuring that the overall goals are met. In the same way, substance evaluation helps to ensure that REACH is implemented and that the effects on health and the environment are realised. The effects of this part of the initiative cannot be quantified directly.

The contribution to developing and maintaining the Danish QSAR database helps to provide the following benefits:

- Reduced costs to enterprises for documenting and registering substances
- Reduced costs to find new and safer alternative substances
- Reduced costs to authorities for checking registrations, prioritising future efforts and other official tasks

The QSAR database helps to reduce the costs of evaluating substances. For enterprises required to register substances, the costs savings can be substantial. Based on K. Stanton, F.H. Kruszewski 2016,[28] this saving is estimated at between USD 190,000 and USD 260,000 per substance for a number of chemicals produced in large quantities ('high-volume substances'), where regulation requires more data than for low-volume substances. The estimated savings assume that the number of specific tests can be reduced, while the use of 380-575 laboratory animals per high-tonnage substance can be avoided.

If the saving per substance is concerted into Danish kroner, it equates to DKK 1.2-1.7 million per high-volume substance.[29] These are typically savings in generating information on substances where the different properties have to be defined and documented.

There is no data on the use by Danish enterprises of the QSAR database. Interviews with Danish enterprises and industry organisations do not suggest any great potential.

Among the industry organisations, which mainly represent the retail sector, there is generally little or no awareness of the Danish QSAR database. In industries that are more representative of producers, there is good knowledge of the database but no indication that it is widely used by their members. The industry organisations say that this is partly because many Danish enterprises are formulators or producers of articles, and so not usually subject to registration requirements as their raw materials are generally purchased within the EU. There is a belief among some of these industry organisations that some larger and/or front-runner enterprises do use QSAR as one of their tools in connection with substitution.

The interviews conducted with enterprises give more or less the same picture. Many smaller 'downstream' user companies are not aware of the QSAR tool. A number of large enterprises that produce chemicals where it might be helpful to use QSAR state that the authorities (including ECHA) do not generally accept QSAR results, so QSAR is little used. Some large

[28] K. Stanton, F.H. Kruszewski *Quantifying the benefits of using read-across and in silico techniques to fulfil hazard data requirements or chemical categories* Regulatory Toxicology and Pharmacology 81 (2016) p. 250-259

[29] The article does not define 'high-volume substances'. REACH defines these as substances produced and/or imported in quantities of over 1,000 tonnes, while the definition in U.S. law specifies 1 million pounds, or approx. 500 tonnes. The savings have been converted at an exchange rate of approx. DKK 6.5 per USD.

enterprises state that the domain of application of existing QSAR tools does not cover the type of substances produced in their businesses. Some large enterprises state that QSAR demands expert knowledge which they do not themselves possess, so they hire consultants with QSAR knowledge, e.g. in connection with substitution projects/deliberations. One enterprise states that the QSAR database is used to evaluate substances in waste water where there are no official limits on emissions, but this company cannot quantify the benefit of this.

On this basis, the direct effects on Danish enterprises are judged to be limited. As the Danish QSAR database is part of the package of tools provided by the OECD (see section 6.1.5, where the OECD work is described), it may help to reduce the costs to businesses at the EU level, and it may have an effect on the prices of chemicals which will also benefit Danish companies.

The principal immediate benefits are the advantages to the authorities of being able to evaluate different substances and target their efforts at the most problematical of them. Without a tool like QSAR, authorities would have only limited ability to evaluate substances and target their actions. This benefit from QSAR cannot be quantified, but it must be considered significant.

Some DKK 41 million has been set aside under the Chemicals Initiatives for this part of the initiative together with work on the candidate list, harmonised classifications and restrictions.

6.1.2.3 Long-term effects – implications for health and the environment

Checks on registration dossiers and substance evaluations are actions that help to ensure that REACH is implemented correctly. Registrations and substance evaluations do not directly give rise to environmental and health benefits, but they are the first necessary stage in the process of limiting the use of harmful substances. As with other initiatives aimed at knowledge generation, this initiative helps to improve the basis for identifying the potentially harmful substances.

Other things being equal, the QSAR tool can help to reduce the use of and exposure to hazardous substances, as it can direct the regulatory focus at chemicals with (potentially) hazardous properties. QSAR also plays a part in substitution. However, the effect cannot be quantified.

6.1.2.4 Socio-economic implications

It is not possible to calculate the socio-economic consequences of this specific initiative. The part of the initiative concerned with quality control of registrations and assistance with substance evaluations is a key part of the implementation of REACH and thereby helps to realise the benefits described under the previous initiative.

The part of the initiative which concerns the Danish QSAR database contributes both to the work of the authorities in prioritising substances and to that of the enterprises in registering the substances that they use, and helps to reduce the impact on health and the environment of exposure to dangerous chemicals.

All in all, the qualitative conclusion is that the development and use of QSAR tools, including the Danish QSAR database, can produce significant socio-economic savings, although these cannot be quantified within this assessment; see also section 6.1.5 on the work of the OECD to reduce the costs of evaluating chemicals.

6.1.2.5 Overall assessment

The activities within this initiative help to realise the benefits to health and the environment from REACH and the other areas of chemicals regulation.

It is also helpful that the QSAR database is accessible to enterprises and authorities. The cost savings that this tool can provide are a further benefit. It is the impression relatively few Danish enterprises use QSAR, but the cost savings obtained by European producers may be expected to lead to lower import prices to Danish importers of substances which have to be registered and for products in which these substances are used in the manufacturing process.

QSAR has a big impact on the authorities. QSAR enables the authorities to evaluate substances and organise their efforts to have the greatest effect. This includes both their assessment of information from enterprises and prioritising future actions.

All in all, the qualitative conclusion is that the development and use of QSAR tools, including the Danish QSAR database, can produce significant socio-economic savings, although these cannot be quantified within this assessment.

6.1.3 Biocides (Effect chain 3)

The purpose of the initiative concerning biocides is to meet Denmark's obligations arising from the implementation of the Biocides Regulation, and also influence the work of the EU to ensure that biocidal products on the market have the least possible impact on health and the environment. The initiative is also intended to help Danish enterprises to comply with the rules without unnecessary costs.

The initiative relating to biocides includes the following main activities:

1. Participation in the EU work on risk assessment of biocidal active substances and developing rules for assessing biocidal products and active substances
2. Information and guidance to enterprises on the biocide rules
3. Grant scheme whereby small and medium-sized enterprises (SMEs) can obtain grants to draw up applications for authorisation of biocides

1) Denmark's participation in the EU's efforts helps to safeguard Danish interests in protecting health and the environment and to maintain progress in the risk assessments and prioritisation and implementation of the Biocides Regulation.

The biocides group in the Danish EPA has nominated members in ECHA's working groups and decision-making bodies for biocide risk assessments (WGs and BPC), in the Commission's coordinating groups (CG and CA) and on the Commission's standing committee.

2) The information to the enterprises includes a website with guidelines and a help desk intended to improve their knowledge of the rules and so raise the degree of compliance with these rules.

3) The intention of the grant scheme is to reduce the costs to the enterprises of placing less hazardous substances on the market. The SMEs receiving this support might not have applied for authorisation if there had been no grant. There is then a requirement for substitution of 'the most harmful active substances', so the grant has helped to provide for substitution while striving to preserve the competitiveness of these enterprises. The deadline for grant applications was 1 November 2016, so it not possible to describe the effect at this time, as the applications have not yet been considered. Thus this part of the initiativewill not be discussed any further.

A total of DKK 23 million has been set aside for the biocides initiative from 2014-2017.

6.1.3.1 Short-term effects – impact of changes in behaviour – budgetary effects

Main activity 1 relating to Denmark's role in implementing the Biocides Regulation
In many ways, this initiative runs in parallel with the Danish initiative relating to REACH and CLP, which is described above under effect chain 1. This main activity is thus driven by the fact that Denmark is required to assist in implementing EU law.

A socio-economic assessment of the initiative should also be undertaken on more or less the same principles as for REACH and CLP, and with the same types of assumption, including the geographical demarcation of EU-related activities and legislation.

The project has looked for data sources to quantify the effect of the Biocides Regulation, including requests to the Chemicals Agency and the European Commission, who do not hold any documentation. Nor has it been possible to identify other data sources that might help with a socio-economic assessment of the area within this project.

It is considered whether anything could be extrapolated from the key figures used to assess the effect of REACH regulation. Authorisation under the Biocides Regulation is generally similar to the principles behind the authorisation scheme under REACH. However, there are a number of differences. For example, the Biocides Regulation requires two authorisation steps (one for the active substance and one for the biocidal product(s)), and the Biocides Regulation also covers products with many different hazard classifications, while the REACH authorisation scheme only addresses particularly hazardous substances (SVHCs[30]). Implementation is a resource-intensive exercise both for the authorities (case-handling) and for the enterprises in the form of testing and documentation requirements and fees to the Chemicals Agency and the Member States. All in all, it is considered unreliable to extrapolate from REACH to the Biocides Regulation.

Based on the potential net benefits identified in other parts of this effect assessment (e.g. for endocrine disruptors), it is however considered likely that restricting the subset of active substances that have especially hazardous properties will give rise to net benefits overall. For less hazardous active substances, it is not possible to assess either quantitatively or qualitatively whether the Regulation will bring a net benefit.

Main activity 2 - Information campaigns
The short-term effects of this initiative are concerned with the savings that enterprises might have made as a result of the information activities.

An evaluation and analysis was carried out in 2015 of the needs of the enterprises for information on the biocide rules and their views of the information provided by the Danish EPA. The evaluation produced by PlanMiljø[31] includes interviews with a large number of players covering their knowledge of the biocide rules and their use of guidance and information to enterprises from the Danish EPA. The evaluation is based on 134 interviews with enterprises, covering producers, importers, distributors and wholesalers.

The principal findings of the evaluation are that the enterprises are generally satisfied with the information from the Danish EPA. The evaluation revealed a need for information particularly among distributors and wholesalers. Producers were generally aware of the rules.

[30] Substances of very high concern

[31] PlanMiljø 2015, *Afrapportering af dataindsamling i forbindelse med informationsprogram om biocider til små og mellemstore virksomheder (Report on data collection for the information programme on biocides for small and medium-sized enterprises)*

The Danish EPA's website is the most used source of information on the biocide rules as compared to newsletters and help desk support. 60% of those questioned use the Danish EPA website as a key source of information. 50% of all respondents are satisfied with the contents of the website and 24% are very satisfied.

Interviews conducted for the present assessment have confirmed that the information is important to the enterprises. The industry organisations express general satisfaction with the information material on biocides legislation and many mention, for example, that the website has improved in the last couple of years. Several people mention that the information material has been a great help to some SMEs, while others say that the information has saved their companies time and given confidence with regard to the rules. However, concerns were also expresses as to whether the information materials/activities are reaching all the relevant enterprises, of whether it is mainly getting through to companies that are already 'ahead of the game'.

The enterprises interviewed for this assessment can be roughly divided into three categories: (i) businesses that are not affected by the biocide rules, (ii) businesses that import or deal in the items concerned, and (iii) businesses that have applied or are applying for product authorisation. Many large and small enterprises that import/deal in the items covered here express satisfaction with the website and the help desk when it comes to clarifying the rules, which has saved time and given confidence and clarity. However, they cannot quantify the saving. There is a wide variation in the replies from enterprises that have applied or are applying for authorisation. Some have not used the materials from the Danish EPA at all, but have used their industry organisation and/or spoken directly with the Chemicals Agency (ECHA). Several enterprises have used both the Danish EPA's material/help desk and the ECHA website, or have gone directly to the ECHA help desk. Some enterprises have based their activities mainly on information material from the Danish EPA and one of them mentions that this has saved consultancy time – but without quantifying this. One company which claims to have drawn great benefit from the information, particularly since the new rules were introduced, estimates that a 'new' enterprise applying for the first time could reduce the time spent by 50%.

Enterprises have generally been pleased with the Danish EPA website, and some mention that it saves time to have the key points of the rules summarised in Danish.

6.1.3.2 Long-term effects – implications for health and the environment

Biocides have a large number of uses, where professional and private users and the environment may be exposed to the active substances that the biocides contain. The Biocides Regulation and the efforts of the Danish EPA are intended to ensure that the biocidal active substances are risk-assessed quickly and that the rules are implemented and adhered to.

Main activity 1 relating to Denmark's role in implementing the Biocides Regulation

As already mentioned under short-term effects, there are no quantified assessments of the effect of the Biocides Regulation, including the effects on health and the environment of exposure to biocides. This is also true of the impact assessment carried out when the Biocides Regulation was drafted. Rather, the benefits are described in qualitative terms, and it is the impression that there are benefits to health and the environment from reducing the use of most harmful active substances or reducing exposure by explaining how biocidal products can be used more safely.

The Danish initiative helps to ensure that the most hazardous active substances are risk-assessed and, in relation to the general implementation of the Regulation, it helps to ensure that these environmental and health benefits are realised.

Apart from correct case-handling, the Danish initiative contributes to prioritisation and the production of guidelines. As with the REACH activities, the Danish initiative focuses strongly on active substances with allergenic and endocrine-disrupting effects, where there is great potential for socio-economic benefit.

The Danish initiative also ensures that Danish interest are safeguarded, e.g. by ensuring that requirements for the use of biocides in fish farming are relevant to Danish conditions.

Main activity 2 - Information campaigns
One aim of the information campaigns is to help enterprises to comply with the rules and so help to realise the possible socio-economic benefits.

6.1.3.3 Socio-economic implications

The impact analysis carried out by the European Commission in connection with the revision of the Biocides Regulation stresses (from a qualitative standpoint) that the increased costs of obtaining approval for active substances and biocidal products need to be balanced against the cost savings from being able to share essential information such as test data and the fact that the product only has to be authorised in one country. It was judged that this would mean unchanged costs overall, or perhaps a net saving to the enterprises[32]. As this impact analysis is only concerned with the amendments to the legislation and not with the wider implications, including possible benefits, it does not support any socio-economic assessment.

As described above, it is possible to expect benefits to health and the environment from reducing the use of the most harmful substances. At the same time, the Regulation imposes a number of costs on enterprises to obtain authorisation both for active substances and for the biocidal product itself. These costs relate both to the authorisation of active substances and the authorisation of biocidal products. This means that costs are also imposed on products based on less harmful active substances. It is therefore impossible to make an overall socio-economic assessment of the Biocides Regulation.

If the Danish initiative is assessed on the basis that the Regulation itself is part of the baseline, the Danish initiative helps to maintain a focus on the most harmful substances, to incorporate specific Danish concerns into the implementation of the Regulation, and to reduce the costs to Danish enterprises of compliance with the Regulation. In this sense, it is fair to say that Danish efforts provide an overall socio-economic benefit. The information campaign is judged to be helping to reduce the costs to enterprises of meeting the requirements of the Biocides Regulation. The advice and information provided by the Danish EPA are very valuable to the enterprises. The information makes it much easier for enterprises to follow and comply with the rules. The savings that they make cannot be quantified, but they are thought to be substantial, particularly for SMEs.

6.1.3.4 Overall assessment

There are no estimates of the health-related and environmental effects of biocide use or of the reduction/restriction of the use of the most harmful active substances brought about by the Biocides Regulation. This makes it impossible to assess the total socio-economic benefits to health and the environment from the Danish initiative. Nor are there any calculations of the total costs to enterprises of compliance with the Regulation. It is therefore impossible to make an overall socio-economic assessment of the Danish initiative.

[32] COM(2009)267 *Regulation of the European Parliament and of the Council concerning the placing on the market and use of biocidal products: Impact Assessment*

In a qualitative sense, however, it is considered likely that there will be a socio-economic net benefit in relation to the particularly hazardous active substances. The Danish initiative helps to focus especially on the most dangerous active substances and hence to pull the implementation in a socio-economically positive direction.

The Danish initiative, which is in any case required in order to implement EU law, also safeguards Danish interests in that guidelines are formulated so as to be relevant to Danish conditions.

The information activities conducted by the Danish EPA in the biocides area are judged to be helping to reduce the costs to enterprises of meeting the requirements of the Biocides Regulation, particularly for SMEs.
It would be premature to evaluate the subsidy scheme, as the subsidies were only allocated in December 2016 as a step in implementing the Chemicals Initiatives.

All in all, it is the impression that the Danish initiative has contributed a great deal to compliance with the rules and also helped towards exclusion, substitution and reduction in the use of the most harmful active substances.

6.1.4 Endocrine disruptors (Effect chain 4)

6.1.4.1 Purpose of the initiative

This effect chain covers the activities targeted at the work on endocrine disruptors. The initiative includes financing the Centre for Endocrine Disruptors (CeHoS) and the secondment of a national expert to the European Commission. The work on endocrine disruptors in the Danish EPA itself is not financed by the Chemicals Initiatives, so is not included in the evaluation.

The purpose of the initiative is to raise the level of knowledge of the effects of endocrine disruptors. This improved level of knowledge will have several direct and indirect effects. It will enable more cost-effective establishment of actual regulation in this area, and it could influence the behaviour of enterprises and consumers towards less exposure to substances that have been found to be especially harmful.

Recognition of the problem of endocrine disruptors is relatively recent, and there is still a great need for documentation and knowledge. Our evaluation of the initiative is therefore based on an assessment of the scale of the problem, and whether the Chemicals Initiatives could (potentially) assist in reducing it. A number of international studies have been produced to estimate the potential harm from endocrine disruptors. The evaluation of this effect chain therefore takes in the following elements:

1. Analysis of the scale of the problem
2. Assessment of knowledge acquisition
3. Better basis for official decisions (internationally and nationally)
4. Indirect effects on enterprises, consumers and the environment

1) Based on international literature, the expected scale of the possible harmful effects – primarily healthcare costs – on Danish society will be described.

2) The activities of CeHoS and the number of e.g. publications, workshops, conferences and information days can be cited. An evaluation of the quality of the information and knowledge provided by CeHoS is not immediately possible. It would require a peer review of the activities

of the Centre and the quality of the knowledge produced, and that is outside the scope of this assessment.

3) The initiative concerning endocrine disruptors is linked to a number of other initiatives, including the efforts to contribute to REACH implementation. The most important aspect is the contribution to drawing up criteria for when a substance is endocrine-disrupting. A proposal was issued by the European Commission in June 2016. This is concerned with criteria for application of the two Regulations: Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market, and the Biocides Regulation (EU) No 528/2012.

4) The acquisition and dissemination of knowledge on possible endocrine-disrupting properties of chemicals could help to influence the behaviour of enterprises and consumers and hence also the effects on health and the environment. Interviews were used to investigate the indirect effects on the behaviour of enterprises. As only a limited number of interviews were conducted, the evaluation only provides indications of possible changes in behaviour.

As part of the Chemicals Initiatives, approx. DKK 27 million per year has been allocated to CeHoS.

6.1.4.2 Short-term effects – impact of changes in behaviour – budgetary effects

The principal short-term effect is the Danish EPA's use of the knowledge generated by CeHoS. This knowledge was crucial to the EPA's ability to draw up proposals for restrictions for four phthalates and to efforts relating to a number of consumer products. The specific initiative concerning endocrine disruptors is thus an example of an initiative primarily aimed at knowledge generation. The section below on the effects on health and the environment describes the problem of endocrine disruptors based on a number of evaluations. It shows that they could potentially do very great harm, which underlines the need for a big effort to build up knowledge.

Information from CeHoS is only directly used by the enterprises in a very small way.

The interviews that were conducted show that the industry organisations questioned, and the great majority of enterprises, are following the debate about endocrine disruptors. Many enterprises have substituted or are working to substitute substances suspected of being endocrine-disrupting – with specific mention of perfluorinated compounds, phthalates and bisphenol A (BPA). However, substitution of endocrine disruptors is not specifically driven by the activities in the Chemicals Initiatives, but rather by the general debate on endocrine disruptors – both in Denmark and internationally. Just one of the enterprises interviewed states that it makes active use of the information generated by CeHoS. Otherwise, the enterprises say that they regard CeHoS as a research institution.

Several of the enterprises interviewed express a certain frustration that no clear criteria have yet been adopted for endocrine disruptors. Among other things, there is a risk of substituting with a substance that could later turn out to be endocrine-disrupting. Many enterprises are therefore awaiting developments. One industry organisation expresses frustration that the Danish EPA does not get more deeply involved in discussions raised by NGOs concerning suspected endocrine disruptors, particularly where there are no better alternatives. A few enterprises are working very proactively to substitute substances suspected of being endocrine-disrupting, and they consider that the resulting good image generally outweighs the substitution costs. Most industry organisations and a number of enterprises are aware of the Centre for Endocrine Disruptors (CeHoS) but do not directly use the results that it generates. Many are however indirectly 'hit', such as when a press release draws attention to a particular substance or results that have been generated are taken further in a legislative context. A few enterprises subscribe to newsletters and/or actively use CeHoS' results in their substitution work.

6.1.4.3 Long-term effects – implications for health and the environment

As mentioned above, this initiative on endocrine disruptors is primarily aimed at raising the level of knowledge. International studies of the possible damage to health from endocrine disruptors show that the annual costs could run into the billions.

A number of studies and evaluations have been produced of the possible impact on health of exposure to endocrine disruptors[33]. The most recent studies are Trasande et al. (2016). This contains an updated estimate of the possible harmful effects when all types of health effect are included.

This study calculated the effects at the EU level, but includes a calculation for each Member State. The results for Denmark are shown below.

Table 6-13 Estimated health-related costs of endocrine disruptors (Trasande et al., 2016)

Estimated health-related costs of exposure to endocrine-disrupting substances		
Total costs per year (DKK millions)	% of GDP	Per capita
16,000	1.29	3000

The study estimated the uncertainty in the calculation with a number of simulations. The table below shows the results of these uncertainty calculations. The table shows that there is a 10% probability that the costs could be less than DKK 3 billion and a 10% probability that they could be greater than DKK 21 billion per year.

- [33] Bellanger, M., Demeneix, B., Grandjean, P., Zoeller, R. T., & Trasande, L. (2015). Neurobehavioral deficits, diseases, and associated costs of exposure to endocrine-disrupting chemicals in the European Union. Journal of Clinical Endocrinology and Metabolism, 100(4), 1256–1266.
- Hauser, R., Skakkebaek, N. E., Hass, U., Toppari, J., Juul, A., Andersson, A. M., … Trasande, L. (2015). Male reproductive disorders, diseases, and costs of exposure to endocrine-disrupting chemicals in the European Union. Journal of Clinical Endocrinology and Metabolism, 100(4), 1267–1277.
- Health and Environment Alliance (HEAL) (2014). Health Costs in the European Union. How Much Is Related To EDCs ?
- Legler, J., Fletcher, T., Govarts, E., Porta, M., Blumberg, B., Heindel, J. J., & Trasande, L. (2015). Obesity, diabetes, and associated costs of exposure to endocrine-disrupting chemicals in the European Union. Journal of Clinical Endocrinology & Metabolism, 100(4), 1278–1288.
- Olsson, I.M. (2014). The cost of inaction – a socioeconomic analysis of costs linked to effects of endocrine disrupting substances on male reproductive health. Nordic Council of Ministers, TemaNord 2014:557
- Trasande, L. (2014). Further limiting bisphenol a in food uses could provide health and economic benefits. Health Affairs, 33(2), 316–323.
- Trasande, L., Zoeller, R. T., Hass, U., Kortenkamp, A., Grandjean, P., Myers, J. P., … Heindel, J. J. (2016). Burden of disease and costs of exposure to endocrine disrupting chemicals in the European Union: an updated analysis. Andrology, 1–8.
- Trasande, L., Zoeller, R. T., Hass, U., Kortenkamp, A., Grandjean, P., Myers, J. P., … Heindel, J. J. (2015). Estimating burden and disease costs of exposure to endocrine-disrupting chemicals in the European Union. Journal of Clinical Endocrinology and Metabolism, 100(4), 1245–1255.
- Hunt, P. A., Sathyanarayana, S., Fowler, P. A., & Trasande, L. (2016). Female reproductive disorders, diseases, and costs of exposure to endocrine disrupting chemicals in the European Union. Journal of Clinical Endocrinology & Metabolism, 101.
- ECHA (2015). Background document to the Opinion on the Annex XV dossier proposing restriction on 4.4'-isopropylidenediphenol (Bisphenol A; BPA)

Table 6-14 Health-related costs of endocrine disruptors – sensitivity calculations

Estimated health-related costs of exposure to endocrine disruptors – DKK millions per year		
10%	Median	90%
3,000	16,000	21,000

Looking at the various studies quantifying the costs related to the negative effects of endocrine disruptors, there is significant uncertainty. However, all of the studies suggest that there are substantial costs. Trasande et al. (2016) is one of the few studies to attempt to include all substances with suspected endocrine-disrupting effects and all of the harmful effects on health of these substances. This study therefore gives an impression of the scale of the problem. It is also important to note that this study, like the others, only evaluated the health-related costs. Any assessment of the scale of the problem therefore needs to include the environmental effects which have not been quantified and evaluated.

A proposal for restrictions for four phthalates, which is being processed by ECHA, contains an estimate of the possible harm from these four phthalates in a number of specific uses. Here, the estimate shows damage of a different order of magnitude, but it also only covers four substances and the value of the proposed restriction. The estimate is approx. EUR 33 million for the whole of the EU. Applied to Denmark in proportion to its population and converted to Danish kroner, the estimated annual costs are around DKK 3 million. The results of the restriction on phthalates cannot be compared with the study of the overall effects because it only covers four substances, whereas the studies discussed above address all endocrine disruptors and all negative effects on health and the environment.

The crucial thing is that there are studies that point to potentially very serious effects on health and the environment. It is therefore essential to acquire more knowledge which can help to determine whether any specific regulatory measures/initiatives should be introduced or whether the benefits do not exceed the costs of increased regulation/action.

6.1.4.4 Socio-economic implications

With a potential socio-economic benefit of DKK 16 billion and an investment of DKK 7.8 million per year, the initiative in the present effect chain only needs to have a small effect on the total potential in order to break even. If this specific initiative leads to a reduction in the harm to health and the environment of just 0.05%, it will have paid off in purely socio-economic terms.

The proposed restriction for four phthalates, which is part of the international REACH initiative (see effect chain 1 above) estimated the annual environmental and healthcare costs at just under DKK 2.7 million per year, and the costs to enterprises at around DKK 1.4 million per year. This indicates a net gain of DKK 1.3 million per year. This proposed restriction has such a big annual net benefit that it can cover most of the costs of the initiative relating to endocrine disruptors.

No specific socio-economic net benefit has been calculated, as the effects on health and the environment are partly covered under other initiatives – mainly the international work on REACH and efforts concerning consumer products. Raising the level of knowledge may also prove to bring further large net savings in the future, as shown by the potentially very great healthcare costs.

6.1.4.5 Overall assessment

A number of studies have been produced to evaluate the harmful effects on health produced by endocrine disruptors. These studies have shown that the negative effects on health could amount to around DKK 16 billion per year. However, there is great uncertainty with any attempt to quantify the possible negative effects on health. The potentially very large effects suggest that there is also a very big socio-economic benefit from to continued learning with the aim of improving the basis for future regulation of the use of endocrine disruptors.

The direct effects of the grant to CeHoS are the production of studies, conferences and information meetings and more specific advice to the Danish EPA. The activities contribute to knowledge acquisition. There has been no actual evaluation of the activities of CeHoS.

Indirect effects of the raised level of knowledge attributable to CeHoS are information to enterprises and citizens on the possible risks from endocrine disruptors and the changes in behaviour prompted by this information.

6.1.5 International agreements (Effect chain 5)

6.1.5.1 Purpose of the initiative

This initiative covers the part of the overall Chemicals Initiatives that concerns the global efforts. Many of the effects on health and the environment of the use of hazardous chemicals are global in nature. This indicates that regulation at the global level has to be a key element of the overall chemicals policy. Denmark contributes to the global effort in various ways.

The initiative includes the following main activities:

- The Stockholm Convention on POPs
- The Minamata Convention on mercury
- SAICM (the Strategic Approach to International Chemicals Management)
- The OECD

The evaluation of this effect chain describes some of the results contributed by global regulation. For the Minamata Convention on restrictions on mercury, socio-economic analyses were produced showing the significant benefits to health of regulating its use. In order to analyse the Danish contribution to the work of the OECD, the possible savings to enterprises and authorities. For the other activities, the effects are described in qualitative terms.

6.1.5.2 Short-term effects – impact of changes in behaviour – budgetary effects

Funding for this work at the global level totalled around DKK 4 million in the period 2014 to 2017.

The international conventions such as Stockholm and Minamata can result in costs to the enterprises when they have to comply with the specific requirements of the conventions. There are only limited analyses of these costs. In the case of Minamata, the European Commission analysed the measures needed to assure compliance with the convention. This analysis indicates that the costs are in the order of EUR 3 to 98 million per year for the whole of the EU. These are costs that relate to a few enterprises, none of which is located in Denmark. Assuming that the increased costs are passed on in product prices, the effect on Danish importers can be estimated at DKK 0.25-8 million per year.

For the Stockholm Convention on POPs (persistent organic pollutants), there are no budgetary analyses.

The OECD's work to coordinate, harmonise and streamline the assessment of chemicals reduces the costs to enterprises and authorities of providing information, testing and classification.

Where foreign enterprises save on costs, these savings may be expected to be passed on in the prices. This means that Danish enterprises benefit from the reduced costs when they import chemicals from the big chemicals producers. The OECD has made an estimate of these savings.

The OECD has calculated and estimated the savings to industry and the authorities from its work with chemicals[34]. The OECD estimates that the benefit is around EUR 168 million per year. The vast bulk of this benefit relates to savings on tests of new chemicals. It may be assumed that Danish enterprises will share in this saving either directly, if they test new chemicals themselves, or indirectly when purchases of chemicals – sometimes in other products – are cheaper because the international producers have made a saving. The Danish share of the saving is not known, but an estimate can be based on the level of GDP in Denmark relative to the whole of the OECD. Using figures from the OECD database, the Danish GDP in 2015 made up about 0.5% of the OECD as a whole, so the saving can be estimated at approx. DKK 6.4 million per year.[35] Baseing the estimate for Denmark on the population size, the result is an annual saving of approx. DKK 5.7 million. In the socio-economic calculation, this figure is rounded to DKK 6 million per year. It should be noted that the Danish QSAR database is part of the set of tools coordinated by the OECD. The possible benefits from QSAR are described under effect chain 2.

The cost saving will also benefit Danish consumers by way of lower product prices. It is not possible to estimate how the saving will be distributed between enterprises and individuals.

6.1.5.3 Long-term effects – implications for health and the environment

The global conventions will yield benefits to health and the environment.

The Stockholm Convention on persistent organic pollutants involves reductions in the production, use and emissions of a number of substances. In this period, for example, the following substances have been included under the Convention:

- Polychlorinated naphthalenes
- Hexachlorbutadiene
- Pentachlorophenol

There are benefits to health and the environment when substances are included within the Convention, with the regulatory actions that follow from this. However there are no quantitative analyses and calculations of the effects of the specific substances added to the Stockholm Convention. However, it may be assumed to have significant long-term benefits to health and the environment.

On the other hand, there are various estimates of the damage to health at existing levels of exposure to mercury, which are relevant to assessing the effects of the Minamata Convention. One study put the costs of mercury exposure in the EU at approx. EUR 9 billion per year[36]. This

[34] OECD 2010, Cutting costs in chemicals management: how the OECD helps governments and industry

[35] Calculated from OECD data on GDP, using an exchange rate of DKK 7.40 per EUR.

[36] Bellanger, M., Pichery, C., Aerts, D., Berglund, M., Castaño, A., Cejchanová, M., Grandjean, P. (2013). Economic benefits of methyl-mercury exposure control in Europe: monetary value of neurotoxicity prevention. Environmental Health 2013

is just the effect on children's intelligence from exposure to high levels of mercury. The study includes results by country, and the value for Denmark is around DKK 750 million per year. Studies are based on mercury concentrations in samples of hair from the different countries. There are various kinds of uncertainty associated with the analysis and the calculations, but the authors of the study believe that their assumptions entail a possible understatement of the actual costs at today's levels of mercury exposure.

However, it has not been possible to find any specific calculations of the benefits to health in the EU or Denmark from the Minamata Convention. An American study calculates the benefit of the Minamata Convention[37] specifically for the USA by calculating the annual economic gain from reduced healthcare costs and higher productivity. This is increasing as the effects of the Convention work their way through, and the benefits rise to USD 6 billion per year towards 2050. It is not directly possible to apply this to Denmark without a detailed analysis of the assumptions behind the calculation compared to the study described above of the damage done at present exposure levels. However, the American calculation shows that a significant economic benefit from implementing the Minamata Convention may be expected. This has to do with the global nature of the problem. High emission levels in other regions affect e.g. the concentration in fish, and the extent to which Danes eat fish caught around the world will affect their exposure. This is an example of how global problems require a global effort. A Danish initiative can therefore have a great impact and value even though the consumption and emissions of mercury are relatively low in Denmark. So if the Minamata Convention only causes exposure and the subsequent effects to be reduced by 10%, this will produce an annual benefit of DKK 70-80 million.

Support for SAICM helps to support the global work and particularly efforts in developing countries to deal with harmful chemicals. As shown by the calculations of the possible effects of the global convention on mercury, it is important to reduce emissions worldwide when dealing with substances with global effects. This could have a major impact on Danes' exposure. Then there are the harmful effects in developing countries which impede their economic development and could also affect welfare in Denmark.

6.1.5.4 Socio-economic implications

The grants to this specific initiative total DKK 4 million.

The costs to enterprises of compliance with the global conventions have not been determined. However, there is an estimate for the Minamata Convention of the costs to the EU28. If these are distributed across the countries, the costs to Danish enterprises are in the range from DKK 0.25-8 million per year. The value of the OECD's efforts to reduce the costs of evaluating and testing substances is estimated at DKK 6 million per year. This comes mainly from reductions in the costs to enterprises.

The health-related benefits are limited to an estimate of the scale of the gains from the Minamata Convention on mercury. Analyses of the harmful effects on health and the environment from exposure to mercury are so significant that, if the Convention reduces these costs by just a few per cent, it will result in an annual gains in the tens of millions. It should be noted that the adoption of the Minamata Convention is the result of many years of negotiations. The benefits cannot therefore be ascribed to the Chemicals Initiatives 2014-2017 alone.

[37] Giang, A., & Selin, N. E. (2016). Benefits of mercury controls for the United States. Proceedings of the National Academy of Sciences, 113(2).

Even allowing for the uncertainty as to how much the Minamata Convention is reducing the harmful effects of mercury on health and the environment, this global effort produces a socio-economic benefit, although it is impossible to quantify here.

6.1.5.5 Overall assessment

The total contribution to the global agreements and OECD work is considered to help towards significant qualitative socio-economic benefits. It mainly takes the form of the improvements to health and the environment resulting from the global agreements. Calculations of the possible effect of e.g. the Minamata Convention in reducing the use of mercury show the potential for significant health benefits. If the Convention reduces these costs by just a few per cent, sociaty will see annual gains in the tens of millions.

The work of the OECD to develop tools will help to reduce the costs of classifying and testing substances. The OECD itself has concluded that its efforts are saving industry substantial costs.

6.2 Non-toxic products

Within the main area of non-toxic products, the following specific initiatives will be evaluated:

- Chemicals in products
- Regulation of consumer products/product regulation
- (Child chemicals package)
- National Allergy Research Centre
- Consumer information
- Information on REACH and CLP
- Surveillance activities

6.2.1 Chemicals in products (Effect chain 6)

6.2.1.1 Purpose of the initiative

The purpose and primary output of the work on chemicals in products is to build up new knowledge to feed into and support the other initiatives by the Danish EPA. The activities involved in this initiative are therefore heavily dependent on the preparation of report contributing to our knowledge of chemicals in consumer products. This new knowledge has two uses:

- to create a better basis for prioritisation by the authorities when it comes to handling risks from harmful chemicals in consumer products
- to provide input to further work towards possible regulation
- to raise the level of knowledge among consumers

The following reports were published in the period 2014-2016:

152: Survey of triclosan in cosmetic products
151: Danish sunbathers' application of sunscreen
150: Chemicals in consumer products imported from countries outside the EU
149: Determination of migration rates for certain phthalates
148: Survey of allergenic substances in products aimed at children – toys and cosmetics
147: Survey and risk assessment of chemicals in rugs for children
146: Chemicals in consumer products that can prevent re-use
145: Survey and risk assessment of toluene and other neurotoxins in the playroom
144: Survey and risk and resource assessment of 3D printers and 3D-printed articles

143: Use in childcare centres of materials from pre-used products
142: Survey and health assessment of UV filters
141: CMRs in toys – inspection and risk assessment
140: Odour from low-energy bulbs
139: Survey and health assessment of phthalates in toys and other products for children
138: Survey and health and environmental assessment of preservatives in cosmetics
136: Per- and polyfluoroalkyl substances (PFAS) in textiles for children
135: Chemicals in car seats and other textile products for children
134: Survey and exposure assessment of methylisothiazolinone in consumer products
133: Use and potential of bio-plastics in Denmark
132: Problematical chemicals in plastic
130: Survey of the use of electronic and cosmetics by children and pregnant women
129: Survey of selected allergens and disperse dyes in clothes
128: Survey and health and environmental assessment of biocidal active substances in clothes
127: Analysis of difficulties obtaining goods not containing DEHP, BBP, DBP and DIBP
126: Survey and health and environmental assessment of flame retardants in textiles
125: Guidance for risk assessment of chemicals in consumer articles and products
123: Survey and health assessment of preservatives in toys

Projects were also launched in 2016 into ecological cosmetics, candles, 3D printers, overall exposure of children to selected chemicals, and car interiors. These reports will be published in the course of 2017.

Because the activities in this effect chain and the results of them mainly act as supporting materials for other effect chains, no direct effects of the present effect chain have been quantified. The value of the activities in the present effect chain will only emerge when the reports start supporting decisions on e.g. a ban on chemicals or become part of communication efforts directed at consumers. The value of the activities in the present effect chain is therefore mainly to support and enable other initiatives. The following actions are based on knowledge generated in this initiative on chemicals in products:

- Effect chain 1: Candidate list, restrictions and CLP
- Effect chain 7: Regulation of consumer products
- Effect chain 10: Consumer information
- Effect chain 13: Horizontal initiatives

6.2.1.2 Short-term effects – impact of changes in behaviour – budgetary effects

Grants for this initiative total some DKK 14 million in the period 2014-2017.

The principal effect of the initiative is increased knowledge of chemicals, which will help the authorities to establish the specific initiative relating to certain substances and uses. The increased knowledge based on studies of how particular substances are used and analyses of possible harm to health and the environment will be used both in the work of the Danish EPA to propose relevant EU regulation and in the national efforts, including information and communication campaigns.

Production of the reports may also lead directly to effects if businesses change their use of certain substances.

6.2.1.3 Long-term effects – implications for health and the environment

The value of the activities in the present effect chain will mainly emerge when the reports start supporting decisions on chemicals regulation or specific information campaigns.

The value of knowledge generation cannot be calculated directly. Section 5 on the socio-economic method addresses this in more detail. It also covers the important fact that reports that do not prompt any regulation, or do not find anything dangerous, also have a positive value in the form of increased security among the public.

6.2.1.4 Socio-economic implications

As described above, the value of knowledge generation cannot be measured directly, as it mainly supports other initiatives.Thus socio-economic analysis of this specific initiative have not been prepared.

6.2.1.5 Overall assessment

The effect of the initiative is to provide a better basis for prioritisation by the authorities when it comes to handling risks from harmful chemicals in consumer products, input to further efforts towards possible regulation, and a higher level of knowledge among consumers and enterprises.

The basic knowledge generation, in the form of studies of consumer products, is essential to realising the effects of other initiatives. A specific socio-economic assessment for this effect chain can not be prepared for this activity. However it should be seen as an integral part of the overall effort.

Reports that do not prompt any regulation, or do not find anything dangerous, can also have a positive value in the form of a higher level of knowledge across the board and increased security among the public. This increased sense of security is not quantified in the present analysis, but there will be a significant positive effect from it.

6.2.2 Regulation of consumer products (Effect chain 7)

6.2.2.1 Purpose of the initiative

The purpose and primary effect of the effect chain ‘Non-toxic products - Product regulation’ is to ensure that bans or restrictions are placed on the use of chemicals in consumer products in product-specific regulatory measures such as the Cosmetics Regulation and the Toy Safety Directive. This happens largely through EU regulation.

The initiative includes the following main activities:

- Participation in international efforts connected to
    - A ban on 3-BC, five parabens and Q-15 in cosmetics. Restriction of two parabens and nine hair dyes in cosmetics.
    - Four phthalates in electronics (the RoHS Directive restricts phthalates in electronics from 2019).
    - Ban on MI in leave-on cosmetics.
- Guidance to industry

This is mainly a matter of participating in international efforts to regulate the use of harmful substances in consumer products.

In evaluating this effect chain, it is considered whether typical regulation of a consumer product could be approximated by calculating the costs and benefits of a restriction. However, this is not directly possible. There is insufficient data to assess whether regulation of consumer products is such as to allow it to be compared with restrictions.

The table below shows an overall calculation of the possible effects of the ban on MI in selected cosmetic products. This specific regulation should be seen more as an example of the regulation of substances that could be allergenic than as an instance of typical consumer product regulation.

6.2.2.2 Short-term effects – impact of changes in behaviour – budgetary effects

The regulatory measures introduced in connection with the ban on MI in selected consumer products and the ban on four phthalates in electronics may impose costs on businesses. There will typically be costs for substitution of the prohibited substances. In the case of MI, there is no analysis of the costs to enterprises.

In the case of the ban on four phthalates in electronics, an impact analysis was produced which points to very limited costs[38]. The estimate is of the order of a few million euros for the whole of the EU. That would equate to a few hundred thousand kroner for Danish businesses.

For the other regulatory measures, no analyses have been produced of the possible substitution costs. In the interviews that were conducted with businesses, they were asked specifically about the costs arising from the ban on MI. Some of the companies interviewed sell cosmetic products in which MI has been substituted. A number of companies that sell other types of product containing MI say that the ban in cosmetics and the general debate have led to a focus on MI in these other legal product types. In some cases, this has led to a loss of image (e.g. from negative comment in social media) and/or efforts to substitute for MI in these products. Respondents say that it can be hard to find alternatives, and that substitution leads to more expensive products. What this means in concrete terms for the bottom line is not quantified. A few of the companies evaluated have completely phased out MI in their products, which has been good for their image. Of the companies interviewed, one reported costs of DKK 150-200,000 for substitution of MI.

All in all, it is not possible to estimate the costs arising from the regulatory measures described under this specific initiative.

6.2.2.3 Long-term effects – implications for health and the environment

No actual quantified estimates have been made of the benefits to health and the environment from the product regulation that has been adopted.

For the ban on phthalates in electronics, for example, the European Commission's impact analysis states that there will be significant effects on health and the environment[39]. There are estimates of the extent to which emissions will be reduced and how many people are currently exposed to the four phthalates in waste processing and recycling of electronic scrap. In the proposed restriction of a number of phthalates which is under discussion in the relevant REACH committees, the benefits to health and the environment are estimated at some EUR 33 million per year. A study of the use of these phthalates shows that around a sixth of them are used in electronics and, based on this assumption, the effects in health and the environment in Denmark may be estimated at approx. DKK 0.5 million per year.

There are no quantified estimates for the substances that are now regulated in cosmetic products.

[38] Umweltbundesamt 2014 *Study for the review of the list of restricted substances under RoHS2*

[39] Umweltbundesamt 2014 *Study for the review of the list of restricted substances under RoHS2*

However, it is possible to make a general calculation for the ban on MI, which has potentially significant benefits to health. Estimates of the benefits to health are based on figures for how many people with allergy symptoms tested positive for MI, what proportion of these are due to cosmetic products, and what effect the ban can be expected to have.

To assess the restriction on MI in 'leave-on' cosmetics, data and information from the National Allergy Research Centre can be used to produce such an estimate. The calculation is based on the following assumptions and conditions. At least 1,000 new cases of allergy to MI are referred to dermatologists each year. This figure is based on fact that around 25,000 people per year are tested for allergies in Denmark and MI allergy is found in approx. 5% of them. It is generally assumed that only 1/3 of those who have the allergy have it diagnosed by a dermatologist[40]. The true number of new cases could therefore be 3,000 per year. It is also assumed that most cases, around 70%, are down to cosmetics[41]. That means that the number of MI allergy cases due to exposure to cosmetics can be put at approx. 2,000 per year. Of these cases, it is further estimated that around half come from leave-on cosmetic products, i.e. the products covered by the regulation. On these assumptions, around 1,000 people each year are thought to develop a contact allergy to MI as a result of the now regulated leave-on cosmetic products. It is assumed that the regulation banning MI in leave-on cosmetic products means that no more new cases will arise. That means that there will be 1,000 fewer cases each year. Apart from the fact that reduced exposure to MI means fewer people developing an allergy, the decreased exposure will mean fewer allergic reactions for those who have already developed the allergy.

The value of a contact allergy case is calculated from an evaluation study which estimated the socio-economic costs of a contact allergy case[42]. This study valued a contact allergy case at approx. DKK 290,000 as a median estimate, with an uncertainty interval of DKK 79,000 to 690,000 per case. These values have been extrapolated to 2015 price levels on the assumption that they follow the general trend in prices[43]. This gives a median estimate of approx. DKK 360,000 per contact allergy case, and an uncertainty interval between DKK 100,000 and 860,000 per case.

If the annual number of MI allergy cases is reduced by around 1,000, the health-related benefit will be approx. DKK 360 million per year. Estimating the uncertainty based on the uncertainty interval for evaluating a contact allergy case described above, a range from DKK 100 to 860 million per year is found. If including the fact that there will also be a benefit for those who already have an MI allergy, these calculations show that the ban on MI will have major benefits to health costs.

It is not possible to generalise from this example to the regulation of consumer products, but it does show that there are potentially very great benefits to regulating allergenic substances. This is discussed in more detail under the initiative concerned with allergens and support for the National Allergy Research Centre; see effect chain 9 below.

6.2.2.4 Socio-economic implications

Participation in international work on requirements for chemicals in consumer products is very important to raising the level of protection. This initiative could lead to regulatory measures such as the ban on MI in some cosmetic products. MI is allergenic and the knowledge of the effects

[40] Thyssen JP, Regulatory Toxicology and Pharmacology, 2009 Jul;54(2):183-7.

[41] Lundov M Contact Dermatitis. 2013 Nov;69(5):271-5.

[42] Serup-Hansen, N., Gudum, A. and Sørensen, M. M. (2004). Valuation of chemical related health impacts cancer and skin cancer. Danish Environmental Protection Agency, Environmental project no 929.

[43] Statistics Denmark Consumer Price Index

of the substance that the National Allergy Research Centre is helping to collect (effect chain 9) is very important. It is not possible to calculate the socio-economic consequences of this specific initiative, but the examples given suggest that there are probably substantial benefits to health and the environment.

6.2.2.5 Overall assessment

This initiative has helped to introduce a number of restrictions on the use of harmful substances in specific consumer products.

Products for which there are many consumers and hence many people exposed may have major negative health costs. That is why this initiative has very large socio-economic benefits, as shown by an estimate of the effect of regulating MI.

The benefit from regulating MI cannot however be used as a general indicator of the effect of product regulation. Assessments need to be made of the effect of other types of product regulation before it is possible to estimate any such general indicator. The available data did not permit further quantification within the scope of this project.

6.2.3 Child chemicals package (Effect chain 8)

6.2.3.1 Purpose of the initiative

In 2014-2016 there was a particular focus on the surveillance initiative relating to products targeted at children and young people. The surveillance initiative was carried out together with an active and differentiated information campaign directed at enterprises to ensure that they knew the rules. The activities here are concerned with providing more information to enterprises before checks are carried out, and a targeted effort to enhance these checks. The products covered are:

- Toys
- Textiles
- Electronics
- Cosmetics

The surveillance s take the form of spot-checks at importers, in shops and via the internet, and are carried out in collaboration with the Central Customs and Tax Administration (SKAT) and the Danish Safety Technology Authority.

Individual consumer projects have also been run under the ‘Child chemicals package’. This is described under ‘Chemicals in products’ in effect chain 6.

Approx. DKK 20 million has been allocated to the ‘Child chemicals package’ under the Chemicals Initiatives.

This effect chain addresses surveillance activities relating to the above product groups. The specific surveillance initiative will help to ensure that the regulation of these product groups is complied with. The surveillance initiative has an indirect effect in that it is important to assuring compliance with laws and regulations and so reaping the benefits listed in the effect chains concerned with REACH, biocides and other regulation.

6.2.3.2 Short-term effects – impact of changes in behaviour – budgetary effects

In the approach taken, checks are seen as necessary to assure and maintain compliance with the rules. The initiative is therefore essential if the benefits of chemicals regulation are actually to be realised.

However, it is very difficult to quantify the specific effects of the initiative, as there is insufficient data on the impact of the surveillance initiative on the trend in compliance.

The types of regulation that are relevant to children and young people cover a very large number of specific rules, so any quantitative analysis will require data on the degree to which any given rule is not being adhered to. There is no such data, nor are there evaluations of all of the regulatory schemes. It is therefore difficult to carry out an analysis to quantify the value of the surveillances in terms of increased compliance. It was not considered possible within this project to carry out any such assessment.

If such an analysis had been performed, it would have had to take account of the risk of understating the value of the surveillance activities. In COWI's view, surveillance activities can help to create trust that the rules will be adhered to. It is important both for the public who are 'protected' by the rules and also for the enterprises to know that they cannot be sure of evading the rules. Without any checks, there could also be doubts as to whether other enterprises – competitors – were in full compliance with the rules. In the long run, a lack of surveillance could undermine confidence and lead to widespread circumvention of the rules, so losing the expected socio-economic benefits.

6.2.3.3 Long-term effects – implications for health and the environment

The surveillance initiative concerned with products aimed at children and young people is especially important because children and young people are more vulnerable to exposure to harmful substances. Small children, for example, will be seriously harmed if their toys contain chemicals that affect the development of their brains. There are great benefits in ensuring that children and young people are not exposed to harmful substances, so this initiative is important to realising the benefits of regulating consumer products for children.

6.2.3.4 Overall assessment

It was not possible within this project to calculate the effect of the 'Child chemicals package', as this was mainly a surveillance initiative. The effect of surveillance initiatives is hard to quantify, but it is important to gaining acceptance and assuring compliance with the law. The surveillance initiative is thus a condition for realising the effect of legislation described in other parts of this evaluation.

6.2.4 National Allergy Research Centre (Effect chain 9)

6.2.4.1 Purpose of the initiative

The initiative in this effect chain covers support to the National Allergy Research Centre. The National Allergy Research Centre helps to prevent allergies to chemicals, including those in consumer products, through research, monitoring and advice. More specifically, this means analysing, or helping to analyse:

- causes of contact allergy
- which products, substances and concentrations trigger allergies
- what levels do not cause illness, so these can possibly be implemented in law

The purpose of this initiative is to raise the level of knowledge of allergies. This improved level of knowledge will have several direct and indirect effects. It will enable more cost-effective establishment of actual regulation in this area, and it could influence the behaviour of enterprises and consumers towards less exposure to substances that have been found to be especially harmful in terms of triggering contact allergies.

The table below illustrates the scale of the problem based on e.g. the regular surveys of the extent of contact allergies carried out by the National Allergy Research Centre. As this initiative is primarily aimed at building knowledge, there are no direct effects that can be quantified. Knowledge generation should here be understood in a broad sense. It encompasses research, studies and analyses which can be more directly used as a basis for decision-making in relation to concrete regulatory proposals. Knowledge built up at the Centre is thus widely used in other activities within the Chemicals Initiatives, including efforts to draw up REACH dossiers and to regulate consumer products.

Regulation of MI in cosmetics, described under the initiative concerned with consumer products, is an example of one of the very big benefits to health and the environment that could result from regulating allergenic substances.

6.2.4.2 Short-term effects – impact of changes in behaviour – budgetary effects

The initiative involves a grant of approx. DKK 20 million in the period 2014-2017.

The short-term effects of the activities carried out by the Knowledge Centre include the authorities' use of the knowledge generated as a basis for various policy measures ranging from communication to regulation.

It is worth mentioning that an international evaluation of the National Allergy Research Centre from 2011[44] concluded that the Centre does work that contributes significantly to increased knowledge of allergies.

The enterprises use the Knowledge Centre to a limited extent. Most industry bodies and around half of the enterprises interviewed are aware of the National Allergy Research Centre. Some follow the Centre's activities closely, and several comment that the Centre provides good material and reliable information. Some industry bodies suggest that the Danish EPA should brand the Centre's activities rather more. Very few enterprises use the Centre's results directly, but many companies in the textile industry do so, e.g. when a case arises in which a textile is 'accused' of triggering an allergy. In this context, the results from the Centre are used as part of a wider information search. Another group of enterprises state that they use the Centre's results in their thinking on substitution.

6.2.4.3 Long-term effects – implications for health and the environment

As mentioned above, this initiative is primarily aimed at raising the level of knowledge. There are therefore no direct effects from the initiative. It is however important as the basis for regulatory measures. The relevance of knowledge generation in the broad sense can best be illustrated by giving an estimate of the scale of the problem of contact allergies.

Population surveys suggest that around 20% of people have contact allergies[45]. Earlier studies from the 1990s point to a level of 15-20%. These earlier studies were concerned with a limited number of substances. There is no doubt that there has been an effect from various types of regulation that have been implemented[46], including e.g. nickel regulation. Based on a recent European study, the total proportion of the Danish population with contact allergies is estimated at 20%[47]. This study shows that 27% of the population of Europe suffer from contact

[44] External evaluation of the Danish national allergy research centre

[45] Knowledge Centre for Allergy - allergy monitoring

[46] See also report on nickel allergy: Environmental project No. 1869 *An investigation of causes of nickel allergy,* 2016

[47] Diepgen T, British Journal of Dermatology 2016 Feb;174(2):319-29

allergies. As Denmark has a smaller incidence of nickel allergy, the proportion of Danes with contact allergies is estimated at 20%.

The level of 20% means that there are very great socio-economic costs associated with allergies. Based on a study of the costs of contact allergies, It is possible to make an estimate of the total health-related costs. The evaluation study[48] estimated the cost at approx. DKK 15,000 per case per year (at 2015 prices)[49].

Based on census figures from Statistics Denmark, the population of Denmark is approx. 5.7 million (2015). If it is assumed, as above, that about 20% of them have contact allergies, then some 1,140,000 people are affected by this. This then means that the annual costs of contact allergies are around DKK 17.8 billion. It is possible to break this figure down into different types of cost. This cost breakdown is shown in Table 6-15.

Table 6-15 Costs of contact allergies

Cost component	Annual cost in DKK millions
Direct healthcare costs	2,400
Lost production	1,200
Lost welfare	14,200
Total	17,800

Source: COWI 2004

The direct costs of approx. DKK 2.4 billion per year cover patients' spending on medication (about one-third), and public health spending (two-thirds).

These calculations show that contact allergies are a very big problem and the socio-economic costs are quite substantial. Focusing only on the direct healthcare costs and lost production from absence through sickness, these costs amount to some DKK 3.6 billion per year. This clearly shows that it is a serious problem, and that increased knowledge that can help to reduce these costs can pay off very quickly.

This can be illustrated with a simple break-even analysis. Given that the annual grant from the budget to this effect chain is around DKK 5 million, then if the National Allergy Research Centre helps to reduce the number of contact allergy cases by 17 per year over the four-year period, the costs will be repaid[50].

If the break-even analysis is related to the budgetary costs alone, around 69 cases per year need to be prevented for the reduction in budgetary costs to the State and to businesses from these few allergy cases to exceed the grant to the initiative.

Looking at the results under effect chain 1 of restricting chromium(VI) in leather goods, and the ban on MI in some cosmetic products under effect chain 7, they show that there are very

[48] Serup-Hansen, N., Gudum, A. and Sørensen, M. M. (2004). Valuation of chemical related health impacts cancer and skin cancer. Danish Environmental Protection Agency, Environmental project no 929 (COWI 2004)

[49] The COWI 2004 study estimated the annual cost per contact allergy case at approx. DKK 12,500 at 2004 prices, and the costs have been marked up to 2015 price levels using the Statistics Denmark consumer price index. Prices rose by around 25% in this period, so the estimate at 2015 prices is approx. DKK 15,600 per case.

[50] This is based on an estimated cost per case over the individual's lifetime of approx. DKK 360,000 (COWI 2004); see calculation of benefits from MI regulation for a more detailed explanation. The calculation includes the grant of DKK 5 million per year, plus 20% for the tax distortion effect, with the result: DKK 5 million * 1.2 / DKK 360,000 per case = 16.7 cases

significant benefits from regulating allergenic substances. The National Allergy Research Centre and its experts have provided vital input to these regulatory efforts, which shows the importance of the knowledge being collected and generated by the Centre.

6.2.4.4 Socio-economic implications

This specific initiative is aimed at knowledge generation in the broad sense. Calculations of the socio-economic consequences of contact allergies are presented above. These calculations point to annual socio-economic costs from contact allergies of around DKK 17.8 billion.

They illustrate the very large scale of the problem. Examples of regulatory measures restricting the use of allergenic substances have shown the great net benefits that often come out of such regulation. The regulation of MI in selected cosmetic products (see effect chain 7) shows a socio-economic benefit of approx. DKK 360 million per year from preventing around 1,000 new allergy cases.

A break-even analysis of the specific initiative, with a grant of approx. DKK 20 million over four years, shows that if the National Allergy Research Centre helps to reduce the number of new allergy cases by around 17 in each of the four years, i.e. by 67 cases in all, the initiative will have paid off.

6.2.4.5 Overall assessment

Contact allergies are a major health problem. Based on details of the number of people affected by contact allergies, the socio-economic costs can be put at around DKK 17.8 billion per year. Studies of the numbers affected by contact allergies (e.g. nickel) indicate that the proportion has fallen. The knowledge that the Centre has built up has played and continues to play a major role in regulatory and information activities which limit the harmful effects and costs resulting from contact allergies. The international research review of the Centre also concluded that it makes a substantial contribution to building and disseminating important knowledge of contact allergies.

6.2.5 Consumer information (Effect chain 10)

6.2.5.1 Purpose of the initiative

This effect chain describes activities aimed directly at consumers. The purpose is to provide consumers with knowledge which could reduce their use of and exposure to products containing harmful substances.

The principal activities were as follows:

- Information campaigns
- Facebook page
- Teaching
- Consumer app

Evaluations of some of these activities were carried out. These evaluations provide the basis for describing this effect chain.

In the period 2014-2017, DKK 4 million was granted to this initiative.

6.2.5.2 Short-term effects – impact of changes in behaviour – budgetary effects

The evaluation of the various information activities generally describes only the number of recipients/users, i.e. the level of awareness of a campaign. It is difficult to assess whether these recipients have changed their behaviour in response to the information received.

However, there is an evaluation of the campaign entitled 'Pregnant? Know your chemicals', which contains an attempt to measure the effect.

Evaluation of the campaign 'PREGNANT? KNOW YOUR CHEMICALS
The campaign entitled 'Pregnant? Know your chemicals' was evaluated[51]. This was done via an online questionnaire based on YouGov's 'Danmarkspanel', which collected responses from around 1,000 Danish women. They were asked about their awareness of the campaign and their view of its relevance, and about their behaviour.

Respondents were well aware of the campaign and found it relevant. As to whether it taught them anything new, the conclusion is less clear. 11% strongly or very strongly agreed that the campaign had taught them something new. 34 agreed 'to some extent', while 40% only partly agreed that the campaign had taught them something new. The evaluation also includes an attempt at effect measurement in which a control group were asked about their behaviour before the start of the campaign. The behaviour is measured by the extent to which respondents followed the seven tips[52] that the campaign was focused around. Surprisingly, the effect measurement shows a fall in the number following the seven pieces of advice. The changes are very small and may fall within the margin of statistical uncertainty of such evaluations. The evaluation cannot therefore document whether there was any effect from the campaign.

Evaluation of the Facebook page[53]
The evaluation of the Facebook page shows that there was a rise in the number of 'likes' from around 6,800 at the beginning of 2014 to 15,000 at the end of 2015. Some posts reached a large number of Facebook users – anything up to around 200,000. There was no measurement of whether those who followed the Facebook page or entered posts changed their behaviour. The evaluation could have asked directly about changed behaviour, or the evaluation of the initiative could have included a 'control group' who did not follow the page, to show the extent of the changes in behaviour.

Evaluation of the 'Tjek Kemien' app[54]
The app was launched in the spring of 2014, and the evaluation was done just under a year later. Over a period of 45 days from October to December 2014, there were around 2,000 users of the app. This was at a time when the app was relatively new. The evaluation also included a questionnaire covering some 270 consumers. This survey shows that 17% of consumers state that the app met their expectations to a great or a very great extent, 41% is under the impression that it did so to some extent, and 26% said that it met their expectations to a small extent.

There was also an evaluation of the perceptions of the enterprises[55]. These perceptions are very mixed. Two-thirds of the enterprises that took part in the evaluation are positive towards the idea behind 'Tjek Kemien'. However, many are dissatisfied with the extra work that the app caused them. This relates to the data that enterprises have to upload, where there were technical problems, and also to questions from consumers that were not actually about the types of product covered by the app. It is not possible to estimate from the evaluation whether the app led to any changes in consumer behaviour.

[51] PlanMiljø 2015, *Effect measurement of the campaign 'Pregnant? Know your chemicals'* Note from October 2015

[52] These were seven pieces of advice for how pregnant women can reduce their exposure to harmful substances.

[53] Marvelous 2014 *Facebook evaluation* and Marvelous 2015 *Facebook evaluation*

[54] PlanMiljø and Kathart Interactive 2015 *Evaluation of the 'Tjek Kemien' app*, Note – March 2015

[55] PlanMiljø and Kathart Interactive 2015 *Evaluation of the 'Tjek Kemien' app*, Note – March 2015

Teaching material
One of the other activities within the initiative was to produce teaching material for young people on fertility and lifestyle, with an accompanying campaign to disseminate this material[56]. There is only an evaluation looking at awareness of the material. It is not possible on this basis to evaluate the effect of the material. This would require an evaluation of perceptions from teachers and pupils who used the material.

6.2.5.3 Long-term effects – implications for health and the environment
The health-related consequences depend on consumers changing their behaviour. As this cannot be assessed, it is not possible to evaluate the possible benefits to health.

6.2.5.4 Overall assessment
Information to consumers is essential. It can help directly to bring about changes in behaviour which could reduce exposure to harmful substances, and also provide greater security when consumers know how to act in order to reduce exposure. As there is no estimate of the probable changes in behaviour, it is not possible to quantify the benefits to health from the initiative.

Based on the evaluations described above, it must be concluded that no major changes in behaviour as a result of the initiative can be documented. This does not mean that the initiative did not or cannot have any effects, only that there are no documented effects at this time.

6.2.6 Information on REACH and CLP (Effect chain 11)

6.2.6.1 Purpose of the initiative
The activities under this effect chain are intended to support compliance with the rules laid down under CLP and REACH. The initiative consists of a number of information activities aimed at enterprises on new rules under CLP for classifying substances and under REACH for registering them, and other REACH regulation of substances and products. The initiative comprised the following main activities:

- CLP campaign
- Help desk for CLP and REACH
- Dialogue meetings

The assessment of the initiative is based on an evaluation of the CLP campaign and questions to selected enterprises on the effect of the information activities.

DKK 2.5 million was allocated from the Chemicals Initiatives in the period 2014-2017.

6.2.6.2 Short-term effects – impact of changes in behaviour – budgetary effects
The CLP campaign comprised a number of activities, including a letter to around 2,400 companies and e.g. a web site, film, ambassadors and PR activities. There was an evaluation of the campaign based on telephone interviews with 250 enterprises[57]. The evaluation shows that, of the enterprises that are aware of the campaign, 27% have gained greater knowledge of the CLP rules as a result and 12% have commenced activities prompted by the campaign.

[56] Publico *PowerPoint presentation of MaybeBaby* – undated.

[57] PlanMiljø 2014, *Evaluation of the information campaign on the CLP Regulation*, Note 2014

This shows that the enterprises have made use of the information provided by the campaign and indicates that the campaign increased the likelihood of them complying with the new rules.

Most of the industry bodies and many of the enterprises interviewed have used the website and the help desk and attended dialogue meetings. There is generally great satisfaction with these activities, and they provide 'important information', 'an indication of what is going on in the regulatory field' and 'up-to-date knowledge', while the meetings create a good network. A number of enterprises say, however, that they obtain information mainly through their industry organisation and/or directly from ECHA, and some have the impression that the Danish help desks cannot answer detailed and/or tricky questions, which is why they often go directly to the ECHA help desk. Some enterprises experience time savings and in some cases a reduced need for consultants, but none of them can give quantitative figures. One industry body says that it is always the same few enterprises that come to the meetings – in other words, the companies that are already advanced. This then raises the question whether these activities are reaching the enterprises that have the greatest need of assistance.

There is no direct data to calculate the saving to the enterprises from the information activities. But if it is assumed that the information saves each enterprise 2 consultant hours per year at DKK 1,000/hour and that 1,000 enterprises in Denmark use the information, this will produce a saving of DKK 2 million per year. This illustrative calculation shows that, because there are many enterprises that need knowledge of REACH and CLP, just a small reduction in the costs to each enterprise of complying with REACH and CLP will produce a major saving to society. The calculation gives an indication of a possible saving which could perhaps be measured in future specific evaluations of the information initiative.

6.2.6.3 Long-term effects – implications for health and the environment

The initiative under this effect chain is assumed to contribute to greater compliance. This then ensures that the benefits to health and the environment are realised.

6.2.6.4 Overall assessment

The effect of the information initiative on enterprises is a possible saving from easier access to the relevant information and greater confidence in their ability to comply with the law. The initiative thereby has an expected indirect effect in the form of greater compliance and hence realisation of the effects of REACH and CLP on health and the environment.

The evaluation of the CLP campaign showed that it achieved the desired effects, which included inducing the enterprises to initiate activities to comply with the rules. The evaluation of the CLP campaign showed that 12% of the enterprises reached by the campaign have commenced activities prompted by it.

The information may also mean that the costs to the enterprises of complying with the rules are reduced. This can be seen if the information provided on the website, via the two help desks or at the dialogue meetings reduces the time spent by the businesses. Interviews with enterprises suggest that this is the case, but it is not possible to quantify the time saved.

The economic risk to enterprises of failure to comply with the rules is both that they could be fined and that unregistered substances/products cannot be marketed. In theory this could result in large write-downs for an enterprise that did not register in time.

It is also worth mentioning that interviews with industry organisations raised the question whether these activities are reaching the enterprises that have the greatest need of assistance.

6.2.7 Surveillance activities (Effect chain 12)

6.2.7.1 Purpose of the initiative

The purpose of the initiative is to provide for consistent handling of chemicals regulation in the EU and to develop risk-based surveillance strategies and strengthen cooperation between regulatory authorities within Denmark.

In relation to the international initiative, the effect chain includes the following activities:

- Taking an active part in supervisory networks for chemicals
- Supporting and developing partnerships across national borders concerned with:
  - Increased focus on checks on consumer products targeted at children and young people
  - Continued checks on companies' REACH registrations
  - Extended checks under the biocides rules
  - End-to-end surveillances focusing on e.g. waste regulation

At the Danish level, this means that funds have been set aside to develop risk-based surveillance strategies in selected areas, to collaborate on surveillance within the EU and to establish cooperation agreements across supervisory authorities in Denmark.

This initiative mainly covers various surveillance activities.

6.2.7.2 Effects of the initiative

Checks and inspections are activities that may be classed as essential to assuring and maintaining compliance. The initiative is therefore vital if the benefits of chemicals regulation are actually to be realised.

However, it is very difficult to quantify the specific effects of the surveillance initiative. There is insufficient data on the trend in compliance resulting from surveillance activities, and any figures for the 'before' and 'after' situation would be misleading. One difficulty is that changes in the scope of surveillances only very slowly affect the level of compliance.

The different types of chemicals regulation cover a large number of rules, so any quantitative analysis will require data on the degree to which any given rule was not being adhered to. There is no such data, nor are there evaluations of all of the regulatory schemes. It was therefore impossible within this project to carry out an analysis to quantify the value of increased compliance.

Even if such an analysis were possible, it would understate the value of the surveillance activities. This is because surveillance activities help to create trust that the rules will be adhered to. It is important both for the public who are 'protected' by the rules and also for the enterprises to know that everyone has to obey the rules. Without any checks, there could be doubts as to whether other enterprises – competitors – were in compliance with the rules. In the long run, a lack of surveillance could undermine confidence and lead to widespread circumvention of the rules.

6.3 Circulating resources

Circulating resources cover the following areas:

- Horizontal initiatives
- Substitution Centre

6.3.1 Horizontal initiatives (Effect chain 13)

6.3.1.1 Purpose of the initiative

The purpose of this initiative is to contribute to the move to a circular economy. A circular economy means that resources are re-used wherever possible – recycled as much as possible. This means less extraction of raw materials, less wastage, less pollution and less waste to be disposed of. It is a major horizontal goal of environmental policy to promote the circular economy and so reduce the impact on resources and the environment from production and consumption.

To promote a changeover to a circular economy, it makes sense for harmful chemicals to be substituted as they often make recycling and reuse difficult. That is why this is a specific action within the Chemicals Initiatives. This specific initiative included the following activities:

- Input to Council conclusions on the circular economy
- Input to the new Fertiliser Regulation
- Textile partnerships

Input to EU work on the circular economy helps to safeguard Danish interests with regard to increased recycling and high levels of consumer protection. The European Commission has produced analyses of the effects of specific measures moving the EU towards a circular economy. These analyses show significant benefits from the changeover to a circular economy.

In many cases, increased recycling of materials and products will require a reduction/phasing-out of hazardous substances, so some of the benefits of moving to a circular economy can be attributed to chemicals regulation. This section describes the scale of the possible benefits from the changeover to a circular economy.

One element of the circular economy is a harmonisation of the maximum permitted levels of a number of substances in fertilisers, with increased recycling of phosphorus (as a fertiliser). The effects of the new Fertiliser Regulation are described below as one of the effects of this initiative. There is an impact analysis produced by the European Commission. However, it does not include any quantitative analysis.

6.3.1.2 Short-term effects – impact of changes in behaviour – budgetary effects

The activities under this effect chain are thought to have limited effects in the short term.

A new Fertiliser Regulation has not yet been adopted, and from the date when it is passed, it will take a few years to have any effect. In principle, harmonised requirements for fertilisers could mean increased recycling of e.g. phosphorus. This offers alternatives to existing commercial fertilisers (based on imports of raw phosphates or artificial fertiliser) and so reduce the price of fertiliser. It will also reduce dependence on imports of phosphates as a raw material. A reduced price for phosphate fertilisers will benefit agriculture. If new fertiliser products can be marketed by Danish companies, this will generate economic activity in Denmark.

The changeover to a circular economy is a long-term process, so there will be no immediate effects from the activities intended to support and promote this transition. The reduction and phasing-out of harmful substances which are a necessary part of the transition will be addressed under various policy areas. REACH will continue to be the main instrument.

The textile partnership, which aims to promote strategic cooperation between relevant enterprises, authorities and other players/stakeholders, is intended to help tackle selected current chemicals-related environmental and health issues within the textiles sector. An evaluation of the partnership[58] after its first year points to results that cannot be directly quantified at the present time. Information material has been produced and a project idea developed. It will be possible to assess these activities in the longer term when there is data on their effects.

6.3.1.3 Long-term effects – implications for health and the environment

For the specific example of requirements for cadmium levels on fertilisers, including artificial fertilisers, Denmark already has a limit for the level of cadmium in artificial fertiliser. A common EU standard will therefore have no direct environmental benefit for Denmark. Depending on what is agreed on, it could entail increased environmental costs in Denmark. If cadmium pollution is reduced in the other EU countries, this will produce benefits to health and the environment in Denmark too, as this type of pollution is a cross-border issue. The possible implications for health and the environment have not been quantified, as there is insufficient data to support such an assessment.

In order to bring about the circular economy, the presence/use of harmful substances has to be reduced, as in the case of cadmium in fertilisers described above. This means that many of the other initiatives are also important to achieving this. It is therefore hard to quantify the effect of this specific initiative.

Apart from the major benefits to health and the environment of reducing the use of harmful substances, the transition itself will bring economic gains.

The European Commission communication containing an impact assessment of the circular economy[59] puts the possible future impact on GDP at 3.9% of total GDP. This effect reflects the value of increased recycling for the whole of the economy. The Commission has not produced any specific calculations for Denmark of the effects of the circular economy.

However, the international Ellen MacArthur Foundation[60] has produced a specific analysis of the benefits to Denmark of switching to a circular economy[61]. The analysis concludes that the benefits to the Danish economy of a changeover to a circular economy could range from 0.8% to 1.4% higher GDP in 2035. This estimate is less than the average for the EU calculated in the Commission's analysis, which is what would be expected in any case, as the Danish economy is more resource-efficient than the EU average. As the scale of the effects identified by the Ellen MacArthur analysis tallies with the Commission's assessment, it supports the view that the analysis gives a reasonably realistic impression of the effects for Denmark.

Based on this, a potential effect can be estimated of horizontal initiatives in Denmark. In 2014, Danish GDP stood at DKK 1,940 billion. 0.8% of this is approx. DKK 15 billion, while 1.4% equates to DKK 27 billion per year. There are thus very significant economic benefits to be had from the transition to a circular economy.

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[58] Danish Environmental Protection Agency 2015 *Partnership for chemicals in textiles: Status report on the process and results* Environmental project no 1812, 2015

[59] EC 2014 *Towards a circular economy: A zero waste programme for Europe* COM(2014)398 final/2

[60] The Ellen MacArthur Foundation is a registered charity whose mission is to support the move to a circular economy.

[61] Ellen MacArthur Foundation 2015, *Potential for Denmark as a circular economy - a case study from: Delivering the circular economy – a toolkit for policy makers*

The Chemicals Initiatives play a part in realising this potential. It is impossible to estimate how much the Chemicals Initiatives could contribute to realising these benefits on the basis of current knowledge.

6.3.1.4 Socio-economic implications

Specific socio-economic consequences of this initiative cannot be determied. As described above, the initiative is important to the possibility of reaping significant economic benefits from switching to a circular economy. Based on the analyses produced by the Ellen MacArthur Foundation, these benefits to Denmark are of the order of DKK 15-27 billion per year. The Chemicals Initiatives can help to realise this potential.

6.3.1.5 Overall assessment

The changeover to a circular economy could bring significant benefits. It is hard to quantify the significance of chemicals regulation for whether these benefits can be obtained. In many cases, it is a condition of increased recycling that the most dangerous substances should either be absent or only present in small concentrations in the materials and products to be re-used. The Chemicals Initiatives could therefore help to realise a very great economic potential from moving to a circular economy.

7. Results and future prospects

This section presents the overall results and findings from the effect assessment of the Chemicals Initiatives. As a whole, the effect assessment shows that the benefits to health and the environment far outweigh the resources spent on the Chemicals Initiatives.

The basis for this effect assessment of the Chemicals Initiatives 2014-2017 is presented below. Then the overall results from the effect assessment are presented broken down into the individual initiatives included in it. This is followed by a discussion of the way forward, including how future Chemicals Initiatives can be defined on the basis of the procedures and tools developed and provided under the auspices of the Ministry of Environment and Food.

7.1 Basis and scope of the effect assessment

7.1.1 Effect assessment concept

The effect assessment followed the Ministry of Environment and Food's effect assessment concept (see Annex D), which can be used in the longer term to evaluate actions in a number of areas within the Ministry. The effect assessment in the present report is the first extensive use of this concept in relation to an initiative within the remit of the Ministry.

The concept has been produced with a view to establishing *a priori* a systematic design for an initiative, which will make it easier to evaluate it and assess its effects later. However, the Chemicals Initiatives were not defined and specified in accordance with this concept, as it did not exist at the time when the Chemicals Initiatives were established and adopted. In practical terms, this meant that the present effect assessment started with a process aimed at formulating effect chains for the main actions within the Chemicals Initiatives and identifying relevant indicators.

7.1.2 Data and complexity in the chemicals area

The chemicals area is complex and therefore hard to delineate. Thousands of chemicals are marketed for a whole range of uses in processes, products and industries. These chemicals may also have very varied intrinsic properties, which may cause more or less serious toxic effects on people and the environment. In many cases, these effects can only be detected many years later (e.g. cancer cases, where up to 20-30 years may pass before the effects manifest themselves). Toxic effects vary both in type and potency (degree of danger). In terms of human health, these differences can be illustrated by the obvious difference between e.g. irritation and carcinogenic effect. Furthermore, new chemicals and/or new uses are constantly being developed, and new knowledge of the toxic effects of chemicals is emerging all the time.

The chemicals area is therefore both dynamic and complex, which poses a number of challenges in connection with an effect assessment. First of all, knowledge of cause-and-effect relationships is constantly changing and not fully understood. This is true of knowledge of: (i) where and in what quantities chemicals are used; (ii) how much people and nature are exposed; and (iii) the relationship between exposure to a chemical and the type/magnitude of the effect of such exposure on people and the environment. This lack of knowledge introduces significant uncertainty into any valuation of the effects in economic analyses. It is also time-consuming to generate relevant data and evaluations. Within the scope of this effect assessment, it was not possible to generate completely new data. The effect assessment is

therefore based overwhelmingly on existing data, studies, reports and impact assessments supplemented with interviews with stakeholders. However, there are only a few quantitative descriptions of the effects on health and the environment of regulating chemicals. The fact that regulation is mainly enacted at the EU level poses a further challenge to any effect assessment limited to Denmark.

7.2 Experience of using the effect assessment concept

The types of activity in the initiatives under the Chemicals Initiatives 2014-2017 can be divided into knowledge generation, information and communication, and regulation. As explained earlier, in our retrospective description of the effect chain for the Chemicals Initiatives it has been helpful to establish individual effect chains for 14 separate areas under the Chemicals Initiatives 2014-2017 in order to carry out an effect assessment. All 14 initiatives are interlinked, which makes it difficult to isolate the individual effects of each action the Chemicals Initiatives.

The effect chains for the 14 initiatives were drawn up in close collaboration between COWI and Danish EPA staff in the respective action areas. The work on the effect chains was based on a common understanding and realisation that it is hard to establish quantitative data for all of the results from the Chemicals Initiatives. Section 7.5 looks at the prospects for future use of the Ministry's concept for effect assessments in the chemicals area.

7.3 Results of effect measurement of the Chemicals Initiatives 2014-2017

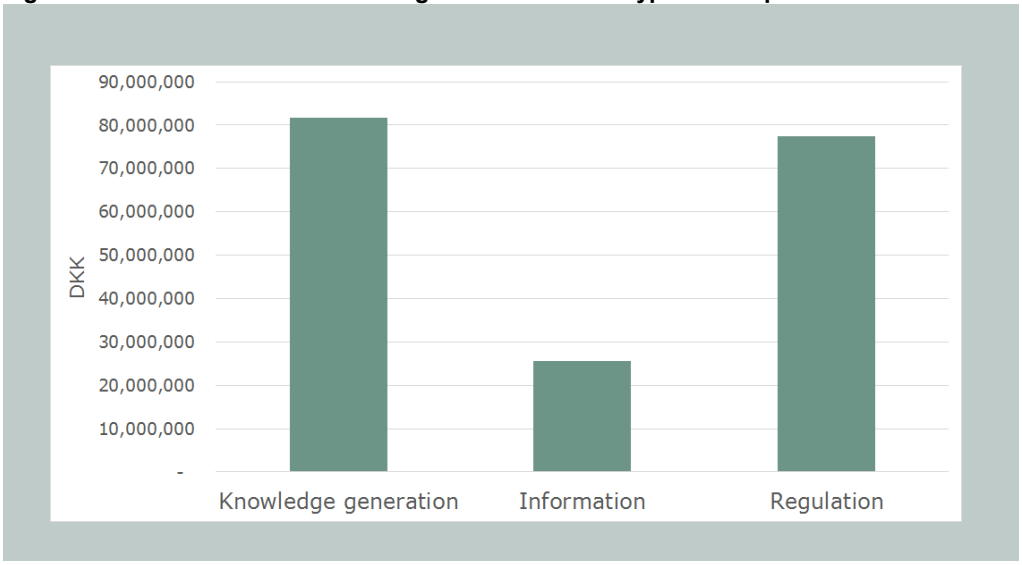
As can be seen from the review and assessment of the 14 separate initiatives in chapter 6, it was not possible to undertake a socio-economic evaluation of every initiative apart from the work on REACH and CLP regulation (effect chain 1). Instead, a socio-economic assessment of the Chemicals Initiatives as a whole was carried out.

This socio-economic analysis includes a budgetary and a 'health and environment' component.

The budgetary assessment includes the costs to the State (of funding the Chemicals Initiatives) and the costs to enterprises of compliance with the regulatory measures adopted. The funding under the Chemicals Initiatives is an input to each specific initiative. The total grant is DKK 185 million. This was split across the 14 separate initiatives. Based on this funding, each initiative generates a number of activities, which have many different outputs; these can then be broken down into knowledge generation, information and communication, and regulation. The allocation is discretionary, as some of the specific initiatives have several types of output. Figure 7-1 shows how the funding is shared between the individual types of output. It can be seen that a large part of the funding is judged to go to either knowledge generation or regulation (which here also includes checking that the regulation is complied with). This is discussed below. The costs to the enterprises are based on the existing socio-economic analyses and reflect the costs that the businesses will incur in adapting to new regulation (or information).

As the benefits to health and the environment are based on the most robust (conservative/cautious) evaluations of the effects of the Chemicals Initiatives, an overall assessment can be made of whether the benefits from the initiatives measure up to the costs. As explained above, not all effects have been quantified, so the estimate of the overall benefits is a minimum figure.

Figure 7-1 Breakdown of funding across the three types of output



The calculation is based on the quantified benefits to health and the environment from actions related to REACH and CLP regulation (effect chain 1). Here, there is some basis for estimating the annual benefits to health and the environment. The quantitative benefits from these two initiatives were then compared with the total funding to the Chemicals Initiatives. This means that there are a lot of effects on the benefits side that have not been included.

The effects that have been quantified and included in the overall analysis cover:

- Evaluation of regulatory measures under REACH and CLP (restrictions, inclusion in the authorisation list and the candidate list and harmonised classifications)

Table 7-1 shows the net present value for the Chemicals Initiatives and for their net benefits. The calculation has been done for a 50-year horizon, as it is assumed that the benefits in the form of reduced damage to health and the environment will only be gradually realised over 30 years[62].

Table 7-1 Socio-economic results of the Chemicals Initiatives

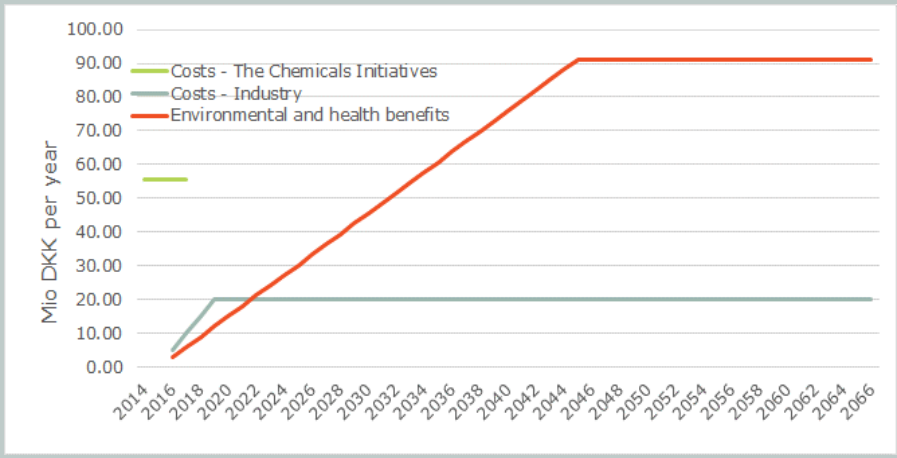
Net present value of element	Net present value in DKK millions		
	Low estimate	Median	High estimate
Cost of the Chemicals Initiatives (excl. distortion losses)	-185	-185	-185
With distortion losses	-222	-222	-222
Costs to enterprises etc.	-223	-581	-2,605
Environmental and health benefits	680	1,821	12,041
Total	236	1,018	9,214
Total (rounded values)	200	1,000	9,200

The calculation shows the sensitivity relating to the use of a low or a high estimate of the net benefit. Even with the low estimate of the net benefit, the present value is positive.

[62] The guidance from the Ministry of Finance uses a discount rate of 4% for the first 35 years and 3% for the last 15 years.

FIGURE 7-2 below shows the estimated progression of costs and benefits over time. It is assumed that the funding is evenly distributed over the period 2014 to 2017. The costs to the enterprises are assumed to be phased in over a few years. The different regulatory measures typically require the enterprises to comply with the regulatory requirements in one to two years. As mentioned above, the benefits to health and the environment are assumed to be realised over a 30-year period. This is an estimate based on the fact that the effects on health and the environment only appear after prolonged exposure, or there may be a gap between the exposure and the effect.

FIGURE 7-2. Socio-economic effects of the Chemicals Initiatives over 50 years



Sensitivity calculations were produced which show that even if this period (until the benefit of the effects is 100% realised) is increased, there will still be a positive net present value (using the median estimate for the effects), up to a break-even at 85 years. This shows that the analysis results are robust with regard to the assumption as to how quickly the benefits to health and the environment will be realised.

The calculations were performed for a 50-year period to ensure that the benefits to health and the environment are picked up. There are no firm guidelines for the length of the period over which the present values should be calculated. When the benefits to health and the environment are only gradually realised, this suggests that the time horizon should be long. The table below shows sensitivity calculations for time horizons of 30 and 70 years.

Table 7-2 Socio-economic results of the Chemicals Initiatives – sensitivity calculation for the choice of time horizon

Net present value of element	Net present value in DKK millions		
	30 years	50 years	70 years
Cost of the Chemicals Initiatives (excl. distortion losses)	-185	-185	-185
With distortion losses	-222	-222	-222
Costs to enterprises etc.	-329	-581	-787
Environmental and health benefits	690	1,821	2,744
Total	139	1,018	1.735
Total (rounded values)	100	1,000	1,700

The calculations, including uncertainty interval and sensitivity analysis, show that the Chemicals Initiatives produce a socio-economic benefit, and that this is a robust result. Even using the low estimate for the effects on health and the environment, there is a socio-economic benefit.

There are also a number of effects that could not be quantified. That means that the calculation of the socio-economic benefit very probably understates the overall result. Some of the benefits not picked up in the socio-economic calculation include:

- The purely environmental effects have not generally been fully evaluated and are therefore understated
- The global conventions on e.g. persistent organic pollutants (POPs) and mercury are thought to have significant net benefits.
- Support to the National Allergy Research Centre and CeHoS could potentially yield great benefits given the extent of these problems.

A good example of the great benefits to be achieved from regulating allergenic substances is the regulation of MI in some cosmetic products. A rough calculation has been made of the health benefits of this regulation. The calculation shows that the new regulation could prevent up to 1,000 new allergy cases each year, with a socio-economic saving of some DKK 360 million per year. The regulation of this substance is based partly on the knowledge built up by the National Allergy Research Centre, and so shows the value of this initiative. The total socio-economic costs arising from contact allergies are put at anything up to DKK 17.8 billion. That means that the specific initiative and funding to the National Allergy Research Centre totalling DKK 20 million over the four-year period will have paid off if the Centre helps to reduce the costs associated with contact allergies of just 0.1% in a single year.

In the figures above, the funding is split according to the type of output from the individual initiatives, and the breakdown shows that most has gone to regulation and knowledge generation. The proportion going to regulation tallies with the idea that the effects are mainly realised when regulatory measures are adopted. In order for this to happen, knowledge-generating activities, e.g. analyses of the use of substances and exposure levels, and scientific studies of the effects of exposure, are vital. This is why it is difficult and not necessarily relevant to attempt a socio-economic assessment of the individual specific initiatives (effect chains) separately. Our analysis of the individual initiatives identified where they support other initiatives and also showed that they are directed at problems with potentially very large socio-economic costs.

The text box below contains a summary of our qualitative and semi-qualitative thoughts on the social effects of the individual initiatives. The text box also contains an evaluation of the potential for the effects of each type of initiative under any future Chemicals Initiatives.

Effect assessment of the individual initiatives

1. REACH – Candidate list, harmonised classifications, restrictions This initiative is expected to produce a significant net benefit. The initiative is based partly on knowledge and insights gained from activities under several other action areas, and is very important to the overall assessment of the effect of the complete Chemicals Initiatives, as itemised and quantified above. The assessment of this initiative is therefore supplemented with a detailed analysis of assumptions and uncertainties, and a sensitivity analysis (see section 6.1.1.5). The analysis as a whole then indicates that this initiative is overwhelmingly likely to produce a significant net benefit. The benefit is achieved partly by focusing the initiative on areas that are generally considered to carry very large socio-economic costs, such as allergenic and endocrine-disrupting chemicals. The Danish Chemicals Initiatives focus partly on knowledge generation in these areas, and Denmark is generally very active in the REACH area and has made and can continue to make a substantial contribution to realising the positive effects of REACH.

2. Registrations and QSAR: This initiative supports the gains to be made as part of the REACH work, and the Danish QSAR database is potentially very useful. The work of assessing REACH registrations is a major factor in ensuring that REACH works, and serves as legislative preparation for REACH. These activities are therefore important if the benefits estimated under the previous initiative are to be reaped. The Danish QSAR database helps the authorities to prioritise and evaluate EU law (some of it from the Chemicals Agency) and assists in their international work. The database is also internationally accepted as part of the OECD's QSAR toolbox. The QSAR database can also be actively used by enterprises in connection with substitution and product development and to reduce costs and numbers of laboratory animals used to test chemicals. There are published studies which have concluded that the QSAR tools themselves can produce very large savings, but it has not been possible to assess the quantitative effect of the Danish QSAR database. Given the acceptance of the Danish work, the database could have an even greater positive benefit.

3. Biocides: There are no estimates of the health-related and environmental effects of biocide use or of the reduction/restriction of the use of the most harmful active substances brought about by the Biocides Regulation. This makes it impossible to assess the total socio-economic benefits to health and the environment from the Danish initiative. Nor are there any calculations of the total costs to enterprises of compliance with the Regulation. It is therefore impossible to make an overall socio-economic assessment of the Danish initiative. In a qualitative sense, however, it is considered likely that there will be a socio-economic net benefit in relation to the particularly hazardous active substances. The Danish initiative helps to focus especially on the most dangerous active substances and hence to pull the implementation in a socio-economically positive direction. The Danish initiative, which is in any case required in order to implement EU law, also safeguards Danish interests in that guidelines are formulated so as to be relevant to Danish conditions. The information activities conducted by the Danish EPA in the biocides area are judged to be helping to reduce the costs to enterprises of meeting the requirements of the Biocides Regulation, particularly for SMEs. All in all, it is the impression that the Danish initiative has contributed a great deal to compliance with the rules and also helped towards exclusion, substitution and reduction in the use of the most harmful active substances.

4. Endocrine-disrupting effects and 9. National Allergy Research Centre: These initiatives focus very much on knowledge generation, which has the potential to turn into very significant economic benefits. A number of studies have suggested that both allergies and endocrine-disrupting effects

caused by chemicals give rise to very high socio-economic costs, possibly several billion kroner each year. This shows that knowledge of the consumption, use and effects of these types of substance can help to achieve great socio-economic benefits through regulation and other changes in behaviour. It should be noted that, as part of this initiative, Denmark has played a major part in drawing up criteria for endocrine disruptors at the EU level.

5. International agreements: Danish efforts with regard to international agreements and conventions are important in relation to cross-border pollution and are expected to provide a significant socio-economic benefit. Many international agreements address chemicals that have the potential to spread and cause effects over very large distances; these include the Minamata Convention on mercury, and the Stockholm Convention on POPs (persistent organic pollutants). It has been concluded on a semi-quantitative basis that limiting exposure to mercury will in itself produce a socio-economic benefit in excess of the costs of the Danish initiative.

6. Chemicals in products: This initiative generates new knowledge of chemicals in consumer products, which can be used for e.g. information and regulation under other initiatives. It is not possible to estimate a direct effect of this initiative, but knowledge of chemicals in consumer products has a major social impact. The initiative thus contributes to: (i) background knowledge for regulation under other initiatives (to reap the expected net benefits from REACH and product regulation), (ii) background knowledge for information to consumers on possible risks, so they can make more confident/sensible choices whether to use these products or find alternatives, and (iii) consumer confidence in relation to products that have been tested and shown not to pose a risk. This last is hard to quantify, but may be assigned a positive value in itself.

7. Regulation of consumer products: This initiative is judged to yield potentially very big socio-economic benefits. There is at best sporadic information to measure the effect of this initiative. However, it was possible to make a rough estimate of the potential socio-economic benefits associated with the regulation of the preservative MI in some types of cosmetic product. This example shows very great potential benefits from regulating allergenic substances in widespread use.

8. Child chemicals package: Some of the activities in this initiative are partly covered by the assessment of other initiatives – 6. Chemicals in products and 10. Consumer information. The remaining activities under this initiative take the form of surveillance activities. The same considerations apply to this initiative as discussed in relation to 12. Surveillance activities below.

10. Consumer information and 11. Information on REACH and CLP: Information is well received, but the effect is often uncertain. A number of evaluations of the Danish EPA's consumer information campaigns and a CLP campaign show that these campaigns often reach their target groups, but for the consumer information campaigns in particular, the completed evaluations did not examine in sufficient depth whether they led to changes in behaviour. It is therefore hard to assess the real effects. The Danish EPA could consider for selected information campaigns whether this element should be included in future campaigns. The website, help desk and dialogue meetings on REACH and CLP are highly valued and give the enterprises confidence that they understand and can therefore comply with the legislation, and the easily accessible information can save time. However, it was not possible to quantify the extent of this saving. In telephone interviews, some people expressed doubts as to whether the initiative reached the whole of the target group – "it is often the same few enterprises that come to the meetings". The Danish EPA could consider whether this could be looked into and if necessary improved in the future.

12. Surveillance activities: Surveillance activities are essential to compliance with the law. These activities help to ensure that enterprises comply with the law and hence to realise the expected net gains described under regulatory efforts above. There is no relevant data to help us to assess the effect of the surveillance activities in themselves.

13. Horizontal initiatives (circulating resources): This part of the initiatives can help in the switch to a circular economy, which is considered likely to produce a big social benefit. Various calculations have been produced which show that the transition to a circular economy could produce a very large socio-economic benefit (with estimates of a 0.8-3.9% increase in GDP). Hazardous chemicals in processes and products can constitute a barrier to the circular economy, as these substances can cause exposure and emissions in the environment, often in connection with reuse/recycling. Substitution/reduction of harmful chemicals in circulation can thus make a substantial contribution to the move to a circular economy, but is it hard to assess the effect of the Chemicals Initiatives on this, particularly given the relatively modest effort under the Chemicals Initiatives 2014-2017. But, as mentioned above, the potential for social benefits is nevertheless rated as very great.

14. Substitution Centre: It is premature to assess the effect of this initiative as the Substitution Centre has only existed since the autumn of 2014.

Finally, it is worth mentioning that our quantitative and qualitative assessment of the individual initiatives did produce a number of useful insights. These include:

- The effects work together in an 'effect network', as many of the action areas receive input from others, which are themselves outputs from further action areas. This is one of the reasons why it has not been possible to evaluate the individual initiatives separately.
- It is hard to break down the overall effects of an initiative which is primarily aimed at the EU into effects on Denmark and on the EU/other countries.
- In many areas, both the level of knowledge and the available data are insufficient for a 'perfect' socio-economic analysis. So there is often uncertainty as to the 'true' connection between exposure to a substance and the resulting effect on health and the environment. There is also a lack of understanding of the interaction from exposure to multiple substances (the 'cocktail effect') Where there is relevant data, it is often not collected specifically for Denmark, and conditions have to be defined for how data can be used in an analysis for Denmark.
- A socio-economic analysis is always fraught with uncertainty. The factors set out above mean that it is especially difficult to produce a socio-economic analysis of the Chemicals Initiatives and resulting regulation. The analysis of the effects that can be quantified indicates a socio-economic benefits from the Chemicals Initiatives, and the uncertainty and sensitivity calculations show that this result is relatively robust.

The evaluation showed that there is no data on voluntary changes in behaviour. Interviews with companies indicate that there is some voluntary substitution away from harmful substances, but there are no figures or data to show the extent of this.

Finally, it should be noted that Denmark is obliged by its membership of the EU to allocate resources so the relevant competent authorities can implement the EU legislation that has been adopted. The present effect assessment has revealed a still very great potential in further funding aimed at generating knowledge and reducing the risk associated with particularly hazardous substances.

7.4 Key figures

As a base for evaluating effects, indicators have been developed based on the effects of restrictions under REACH Annex XVII. It is a requirement in the EU to produce a socio-economic analysis when introducing any restrictions. It has not been possible to produce a full evaluation of the effects of all restrictions, but for many of them there is data to allow us to develop indicators. There are figures for the costs incurred by enterprises and others to comply with the restriction, and figures for the benefits to health and the environment of the restriction.

Table 7-3 Key figures for benefits and costs to enterprises from a restriction

Key figures	Environmental and health benefits	Costs	Net benefit
	Values in DKK millions per year[63]		
Low estimate	0.8	0.2	0.6
Median	**2.2**	**0.5**	**1.7**
High estimate	14.8	2.2	12.6

In using these indicators, it important to bear in mind that the benefits to health and the environment often manifest themselves after a certain time lag, while the costs of complying with a regulatory requirement arise when the requirement takes effect.

The indicators calculated from the effects of the restrictions can be used to estimate effects of other types of regulation under REACH and CLP. This effect assessment makes assumptions as to the likely effect of other types of regulation relative to a restriction; see Table 7-4.

These indicators are based on a relatively limited number of evaluations which quantified the effects – particularly the benefits. Therefore, it has been recommend that these figures should be regularly updated – as and when socio-economic assessments are produced which quantify the benefits from REACH restrictions.

Table 7-4 Use of indicators with different types of regulation – percentage effect relative to restrictions

Type of proposed regulation	Percentage effect relative to a restriction
Harmonised classifications	10%
Inclusion in the candidate list	10%
Inclusion in the authorisation list	50%
Restrictions	100%

Source: COWI calculations.

The table should be read as follows: when analysing the effect of a harmonised classification of a substance under CLP, it has been assumed that the effects make up on average 10% of the effects of a restriction, i.e. the figure for the net benefit will be 10% of DKK 1.7 million – DKK 0.17 million – per year.

7.5 Future prospects

The effect assessment of the Chemicals Initiatives has provided a number of concrete estimates and evaluations of the effects of the initiatives set out above. The actual process of producing the effect assessment also paid dividends for those involved at the Danish EPA, which is particularly important for future work on effect assessments in the Ministry of

[63] Values may be rounded.

Environment and Food. In the following some of the principal insights and findings will be highlighted that could be incorporated into future effect assessments of initiatives.

The Ministry of Environment and Food's effect assessment concept provides methodological rigour. As mentioned earlier, the present effect assessment of the Chemicals Initiatives is the first actual application of the Ministry's concept for effect assessment of a major initiative. The Chemicals Initiatives were a well-chosen 'pilot project', precisely because they are a very complex exercise with many varied and interconnected activities. This was a challenge to the robustness of the concept in many areas. The general conclusion is that the concept, with its consistent focus on effect chains for the initiatives, helps to provide a systematic overview of the relationships between the main activities behind the initiatives and the benefits provided in the short and long term. The concept therefore passed the test in being applied to a complex area.

For the effect assessment of the Chemicals Initiatives, is was however necessary to adapt and expand on the concept and the effect chain model, which can be expected to be needed across all initiatives under the auspices of the Ministry of Environment and Food. For example, the present effect assessment operationalised short-term effects as changes in behaviour both among enterprises that produce and handle dangerous chemicals and among consumers. This supported efforts to establish a clearer logic for the initiatives (and hence the effect chains) in the Chemicals Initiatives.

The concept is primarily designed for use in establishing an initiative

The Ministry of Environment and Food's concept was developed with a view to supporting a systematic approach to initiatives, enabling better ongoing monitoring subsequent evaluation of the activities. Although it does help to provide an overview, as mentioned above, it is mainly designed to describe an initiative *ex ante,* and not when it has been going on for a while.

The reason why the concept is primarily concerned with establishing an initiative is that at this point the relationships between initiatives and between activities within an initiative can be considered. Also, it is relevant to identify good indicators for outputs and effects of these activities, which there are either known data for or where data collection can start from the start of the initiative for use in ongoing monitoring when the evaluation is complete.

The fact that these considerations of natural causes were not included in the definition of the Chemicals Initiatives 2014-2017 was a major issue for the effect assessment. Indicators and data had to be identified retrospectively, which was often impossible. However, this work did generate a good deal of insight into the available data and so provided a solid foundation for organising the next Chemicals Initiatives on the basis of the Ministry of Environment and Food's concept and for identifying suitable indicators at the outset. It should also be acknowledged that, for such a complex area as the Chemicals Initiatives, there will be an ongoing process of identifying relevant indicators that can also be measured with a reasonable level of effort. Therefore, it may be expected that the way in which effect chains are established and evaluated will be regularly adjusted/updated in light of the experience gained.

Similarly, the relationships between the actions under the Chemicals Initiatives have been made explicit, including which of them are closely related and which mainly provide input (e.g. knowledge) to other effect chains.

Involvement of relevant staff in the initiative is crucial

Describing the initiatives that are to be the subject of an effect assessment requires an in-depth insight into the activities and the available data on the initiative in question. Experience from this effect assessment shows that a robust description of the initiative, developing effect chains and identifying indicators and supporting data require involvement from the experts and staff who

are dealing with the initiative on a daily basis. In the present effect assessment, this involvement was secured through three all-day workshops, which also included a basic introduction to the Ministry of Environment and Food's concept followed by comments on the documented effect chains. This proved to be the minimum required to produce a thorough description of the initiatives. In short, experience shows that it is a very time-consuming exercise for the staff involved too.

It is crucial for the quality of the effect chains produced that buy-in should be obtained from the relevant staff for the production of the effect chains. In the present effect assessment there was great commitment from the staff, but their involvement was limited in two areas.

Firstly, it was only possible to set aside two calendar weeks to develop the effect chains (because of summer holidays), which was too little for the staff to work in a thorough and focused way when they naturally had other ongoing tasks to see to.

Secondly, the primary purpose of this work was to support an external consultant (COWI) in the production of an effect assessment. When the Ministry of Environment and Food's concept is next used in connection with new Chemicals Initiatives, the purpose will be even more to establish a good management tool for the employees themselves and to provide an overview of the relationships between activities, outputs and effects, so the definition of activities will focus even more on producing an effect. This offers greater immediate value to the individual employee, so the work on the effect assessment concept will be more of a natural part of establishing the initiatives.

The contribution from the individual initiatives has been made clear

For several reasons, it was not possible to assess the effects of all the activities under the Chemicals Initiatives individually. Work on the effect assessment revealed some of the 'effect network', or complex of effect chains, contained in the Chemicals Initiatives. It became clear, for example, how some initiatives mainly provide input to other effect chains, which is not a problem in itself but is important to be aware of in the work on the Chemicals Initiatives. At the same time, these efforts do not provide direct input to the other initiatives but fulfil more of a supporting function, as with the surveillance activities for example.

The effect assessment also helped to clarify the needs in some of the monitoring of documentation of outputs from a number of the initiatives. One example of this were the behaviour campaigns, which were previously evaluated mainly in terms of spreading awareness and knowledge. This should be maintained, but the effect assessment revealed a need to gather more knowledge of the extent to which the campaigns also help to change *behaviour* within their target groups. This need for knowledge becomes clear when the initiatives are described by way of effect chains.

7.5.1 International effort to improve the base data

This effect assessment showed that existing socio-economic assessments of EU regulatory measures vary in scope and degree of detail. In particular, such assessments often fail to quantify the benefits of a reduced impact on health and the environment.

This is partly because it is hard to quantify benefits with the present level of knowledge and lack of consensus on how benefits to health and the environment should be determined and quantified. To improve this, Denmark can choose to support activities that improve the data and methods for quantifying benefits to health and the environment, including continued support for ongoing activities under the auspices of the Nordic Council of Ministers and the European Commission.

Another reason for the varying degree off detail in the socio-economic assessments that have been produced is undoubtedly that it is relatively costly to produce a detailed socio-economic analysis. It is possible to *estimate* benefits, as can be seen from a number of REACH proposed restrictions, which have provided a basis for evaluations of the REACH initiative in this project (effect chain 1).

As mentioned in this connection, by no means all socio-economic assessments of REACH proposed restrictions quantify the benefits. For biocides and various types of EU product regulation, the existing assessments are also very thin when it comes to quantifying benefits. Denmark could consider asking for benefits to health and the environment to be quantified more than they are now in assessments of EU policies.

A. Agreement text

Agreement on new chemicals initiative 2014-2017

The following agreement has been made between the Danish Social Democrats, the Danish Socialist People's Party, the Danish Social Liberals, Denmark's Liberal Party, the Danish Conservative People's Party, the Danish Red-Green Alliance, the Danish People's Party and the Danish Liberal Alliance on the new chemicals initiatives for the period 2014-2017. A total of DKK 184.8 million has been allocated for the period 2014-2017.

The aim of this agreement on future chemicals initiatives for 2014-2017 is to ensure solid initiatives in the chemicals area. This agreement is based on broad political agreement about the action plans for 2006-2009 and 2010-2013. The future initiatives are also an integral part of the green conversion initiatives, which focus on ensuring a high level of protection of the environment and health, as well as on growth, innovation and resources.

Chemicals and products are manufactured and traded across national borders and therefore international regulation is particularly important. For many years, Denmark has been among the frontrunners in common European chemicals initiatives. This position must be maintained and enhanced in the years to come. Active participation in important international fora as well as strengthened collaboration with other countries in the field of chemicals will give Denmark maximum impact, and Denmark can thus help ensure that all countries strive towards adopting uniform and ambitious regulation.

Consumers must be confident that they can safely use all the products available on the market. This means that there must be better surveillance, requirements for imported products, clear and reliable information, as well as more knowledge about allergies, endocrine disruptors and other harmful aspects of chemicals in consumer products.

The following main areas are prioritised in the chemicals initiative for 2014-2017:

International collaboration (DKK 92 million)

Generally, Denmark will participate actively in setting the international chemicals agenda in order to create the knowledge and ensure the regulation necessary to prevent substances of concern from harming people and the environment, whilst also ensuring that products can be recycled. Initiatives must be based on close dialogue and collaboration between the authorities, enterprises and other stakeholders.

Danish enterprises should have confidence in the registrations of European chemical manufacturers under REACH. Today, the quality of the majority of registrations made by manufacturers is unsatisfactory and they do not contain all the data on chemicals that is necessary. This is a problem for Danish enterprises using chemicals. If Danish enterprises do not have adequate knowledge about the hazards specific chemicals entail, they cannot ensure that these chemicals are used responsibly. Danish enterprises, and ultimately consumers, may thus become affected. Therefore, ensuring that chemical manufacturers meet their obligations under REACH is a priority. Another important area of focus under REACH is the Candidate List which, with Danish contributions, will continuously be developed so that it can be applied by enterprises to phase out substances of very high concern when they are developing new products. In this respect, in collaboration with like-minded countries, Denmark will specifically work on ensuring that the European Commission Road Map on adding all relevant substances of very high concern to the Candidate List by 2020 is implemented. Initial focus will be on regulating substances of very high concern to which people and the environment are likely to be exposed. Generally, it is important that all Danish work on EU legislation focuses on strategic collaboration with other EU Member States and ensuring that chemicals do not prevent recycling of materials and products.

Work on the new EU regulation on biocidal products, among other things, will stress the importance of setting new focus on sustainable use of biocidal products (household poisons like mosquito repellent, disinfectants, wood preservatives, etc.) as well as collaboration with enterprises and retailers. The EU Biocidal Products Regulation strengthens authorisation of household poisons, and stipulates that more decisions are to be made at EU level. According to the rules, treated articles from countries outside the EU may only be placed on the market if the relevant biocides are authorised by the EU. Denmark must be able to influence the EU work on authorisations and prepare Danish enterprises for the new, stricter rules. This requires considerable efforts and close dialogue with enterprises.

Every year, the EU adopts new or changed rules in the chemicals area. Therefore, it is important to ensure compliance with new as well as old rules. Failure to carry out sufficient inspection and enforcement will create unfair competition where law-abiding enterprises are in an unfavourable position and where the environment and health are put at risk. Inspection and enforcement of regulations in the chemicals area comprises many activities, such as information and preparation of guidelines for inspection and enforcement in Denmark and in the EU. The initiatives in the chemicals area must also be seen in the context of other areas, such as imports and exports of waste, as only combined inspection and enforcement will help secure focus on chemicals of concern and recycling. The chemicals initiatives focus on providing information on legislation for enterprises as well as extended collaboration with other authorities and EU countries on carrying out inspection and enforcement. The Chemical Inspection Service will therefore continue its active participation in international inspection networks and promote international collaboration on the exchange of information on illegal chemicals, products and articles so that illegal chemicals or products do not reach the consumer.

Globally, there must be continued active Danish work in relation to the chemicals conventions to prevent globally manufactured articles from being harmful to health and the environment or from undermining the competitiveness of Danish and European industry. Focus must be on collaboration between authorities, industry and NGOs prior to international meetings. Strengthened dialogue with stakeholders in Denmark will improve possibilities to ensure that Danish and EU key issues are high on the global agenda. Stakeholders may contribute by activating their network in other countries and thus gather support. In particular, Denmark will be a frontrunner in global discussions about endocrine disruptors and articles with substances of concern in global markets.

The initiatives on acquiring new knowledge about endocrine disruptors will remain a high priority so that Denmark can contribute documentation to negotiations in the EU and globally. A new Danish national expert in the EU as well as continuation of the Centre for Endocrine Disruptors will enhance this process.

Non-toxic products (DKK 77 million)

In order to protect consumers, new knowledge must be collected about chemicals of concern in products to prevent them from endangering health and the environment. The Danish EPA has a recognised consumer programme in this area, where specific consumer products are inspected to check whether they pose a risk due to their contents or emissions of chemical substances. The Danish consumer programme and the National Allergy Research Centre will continue collecting new knowledge about chemicals of concern in products, particularly in relation to products for children and young people. In addition, there will be continued focus on the use of unnecessary chemicals and fragrances, meaning that, in the long term, the overall aim is to reduce the overall exposure of people to unnecessary chemicals and thus to contribute to reducing the impact on people who are allergic to chemicals and fragrances. In this context it will be ensured that the knowledge collected by the Danish Research Centre for Multiple Chemical Sensitivities will not be lost and will be made available for patients. Among other things, together with the Ministry of the Environment, the Ministry of Health intends to carry on their advisory function for people who are sensitive to fragrances and chemicals.

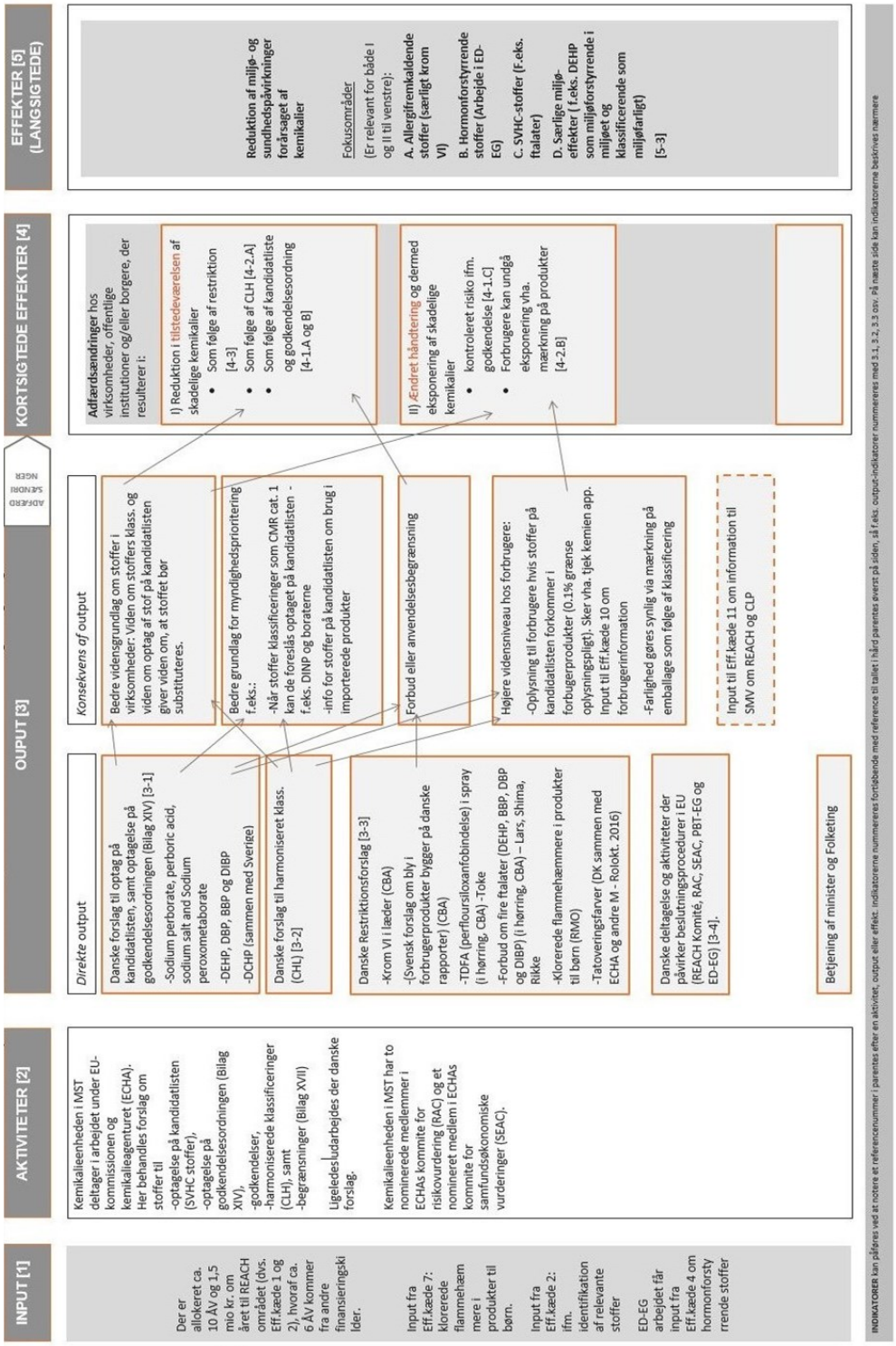
Information campaigns are still an important tool in disseminating knowledge about chemicals in products. There are a number of other possibilities for informing and motivating people, and these are to be strengthened and developed in the future.
The establishment of a new Chemicals Forum consisting of authorities, industry, consumer organisations and other relevant stakeholders is to ensure knowledge-sharing and dialogue in the products area. The Chemicals Forum will recommend commencement of new initiatives, such as analysis, assessment and guidelines based on the challenges facing industry, and it will find new solutions in the product area. In addition, together with the Danish EPA, the Chemicals Forum will also disseminate information on new legislation for enterprises and consumers. The Chemicals Forum can also contribute to voluntary phasing out of certain chemicals, as a lack of dialogue and knowledge-sharing may prevent substitution of chemicals of concern. The Danish EPA will facilitate regular meetings in the Chemicals Forum.
Inspection and enforcement of legislative compliance of consumer products for children and young people will be a special initiative, together with extended collaboration and partnership between authorities on carrying out such inspection and enforcement. Particularly, collaboration with the Central Customs and Tax Administration (SKAT) and the Danish Safety Technology Authority will ensure more effective enforcement.

Circulating resources (DKK 15.5 million)
The chemicals area is an important building block in the field of increasing recycling of resources. Materials should largely be free from the chemicals preventing recycling. This requires knowledge about the impacts of chemicals on the environment and human health. The initiatives for the chemicals area must therefore form the basis for specific initiatives on e.g. substitution. In order to ensure circular exploitation of resources in the future, the existing research-based knowledge about the properties of chemicals in products and processes must be used actively in close collaboration between universities, authorities and enterprises. Therefore, a new collaboration is to be established on substitution of chemicals. The new collaboration will be based on existing facilities at Danish universities, where experience from existing work on substitution of chemicals at specific large enterprises will be exploited. Specifically, new and structured frameworks for dialogue and knowledge-sharing between researchers, authorities and enterprises will help create more sustainable use of chemicals in products and processes in Denmark. Focus is particularly on providing small and medium-sized enterprises with new tools and innovative possibilities to substitute chemicals of concern in products and materials, and thus contribute to improving the competitiveness of Danish enterprises.
An important part of the work on substitution will be to ensure that small and medium-sized enterprises, in particular, can receive consulting services on how to move forward in phasing out chemicals of concern. For example, enterprises can make digital contact through crowd sourcing, where the new facility is to help find specific knowledge and experience in the university environment.
DKK 15.5 million will be allocated for the period 2014-2017 for the establishment of the new facility, which will then be operated independently.

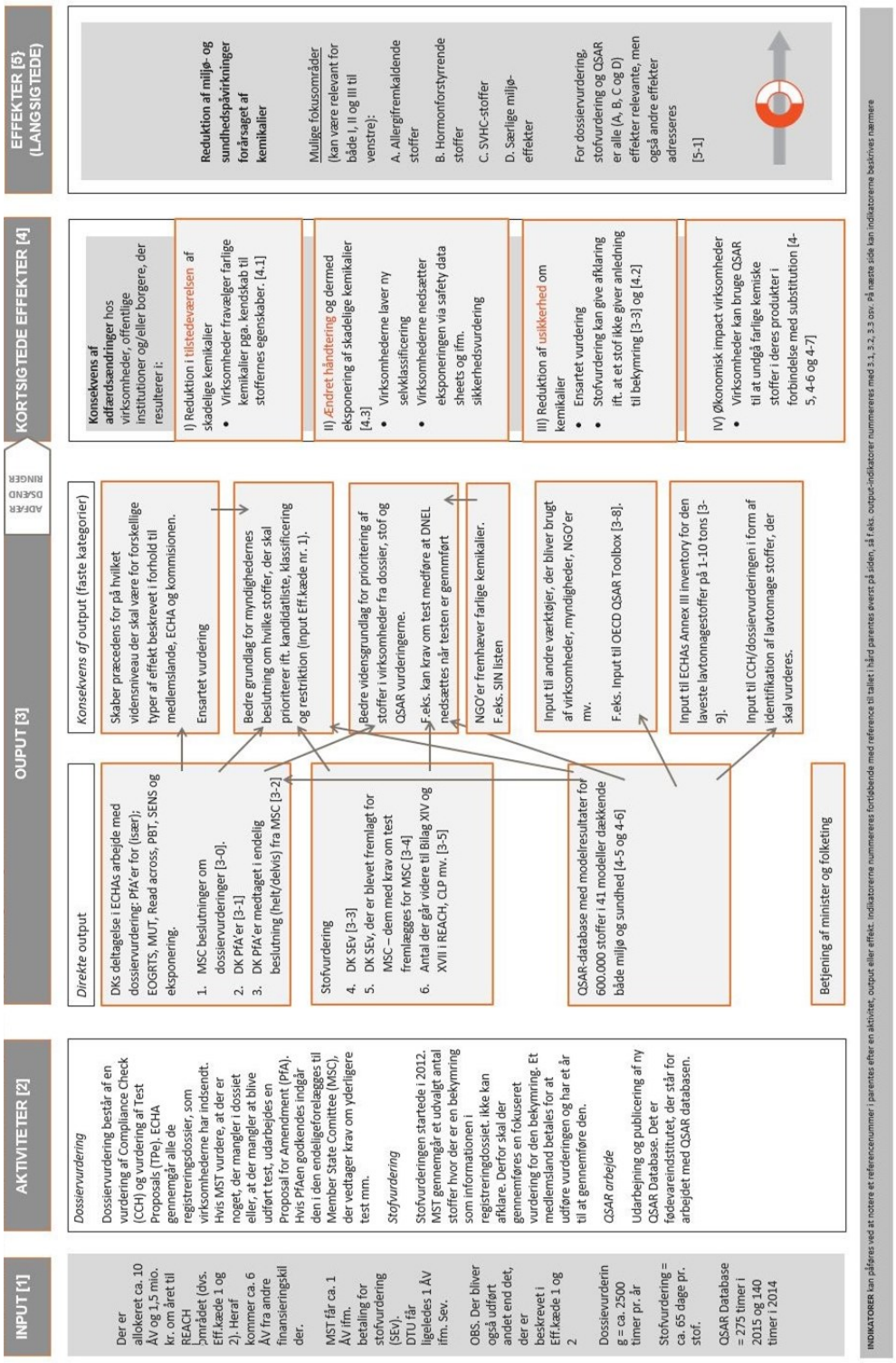
Presentation of new chemicals initiatives
On the basis of the above allocation, the parties agree that the Danish Minister is to present the chemicals initiatives by the end of November 2013. The chemicals initiatives will specify the various elements of the agreement on chemicals initiatives for 2014-2017. The chemicals initiatives will be reviewed and decided together with the current parties to the agreement, with a view to presenting a description of the specific implementation of the chemicals initiatives by mid-December 2013.
The parties have agreed to meet once every year in the period 2014-2017 to review the progress of the agreement.

B. Effect chains drawn up by the Danish EPA

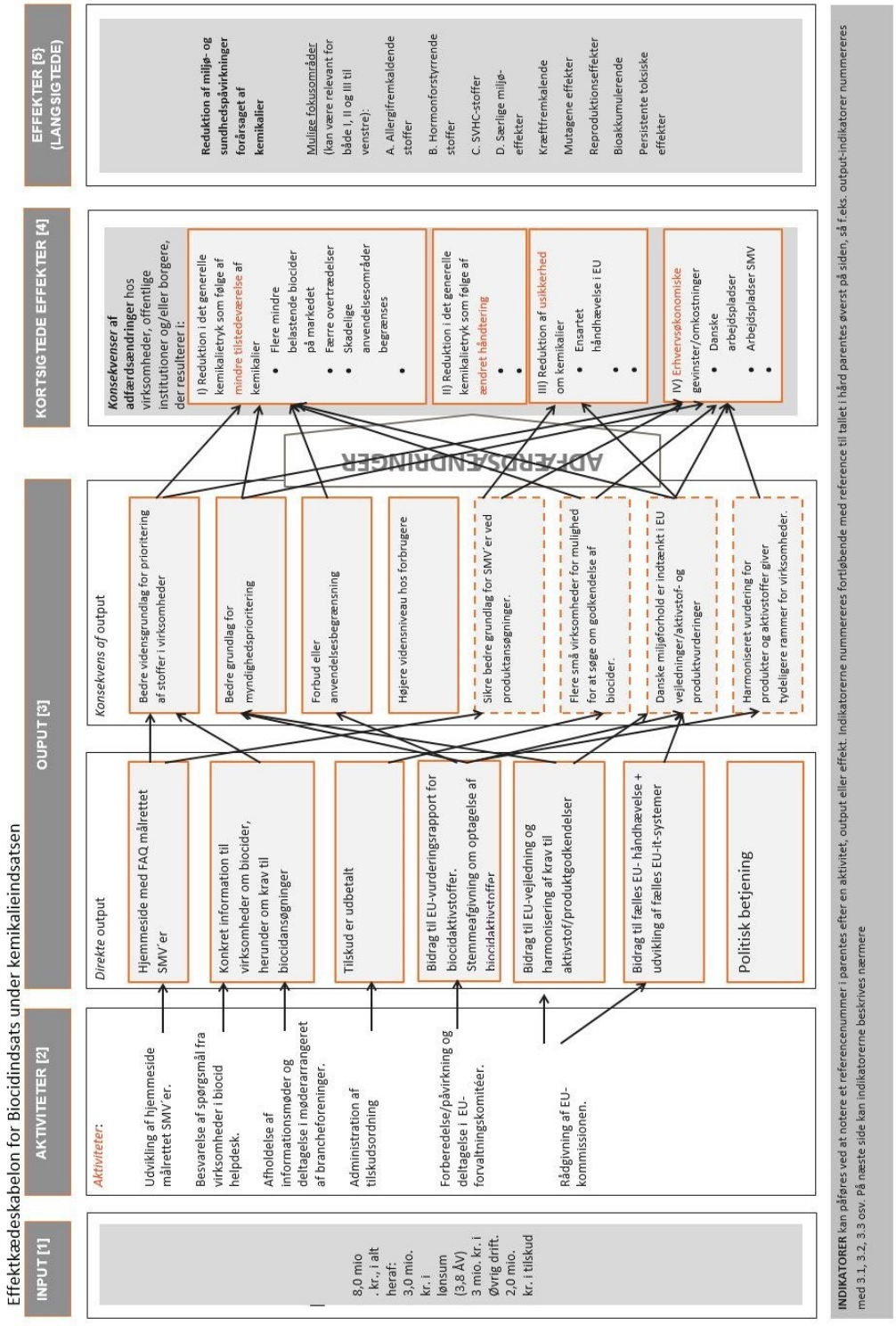
Bilag 1.1 Effect chain for: International collaboration – Candidate list, restrictions and CLP



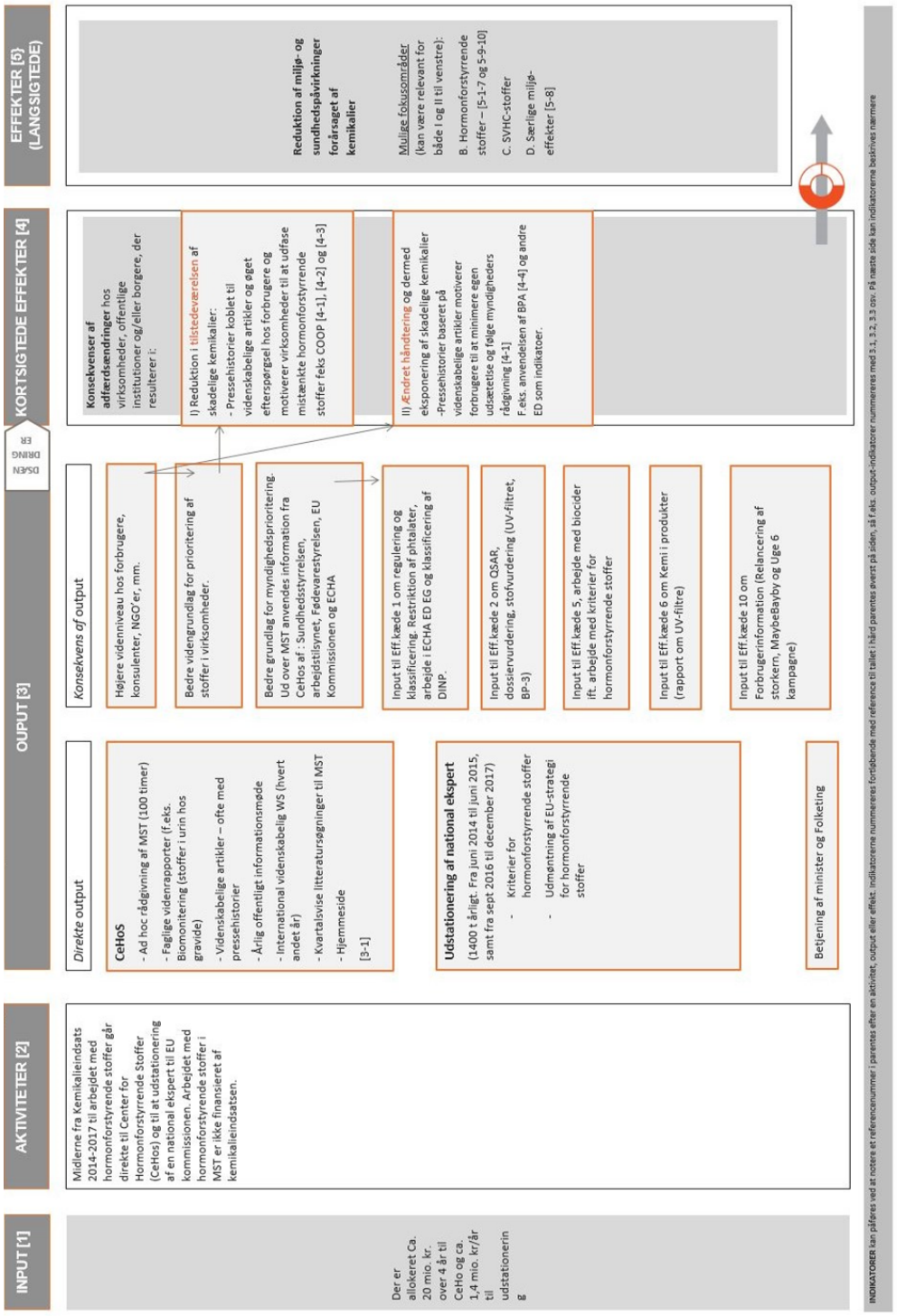
Bilag 1.2 Effect chain for: International collaboration – Registrations and QSAR



Bilag 1.3 Effect chain for: International collaboration – Biocides

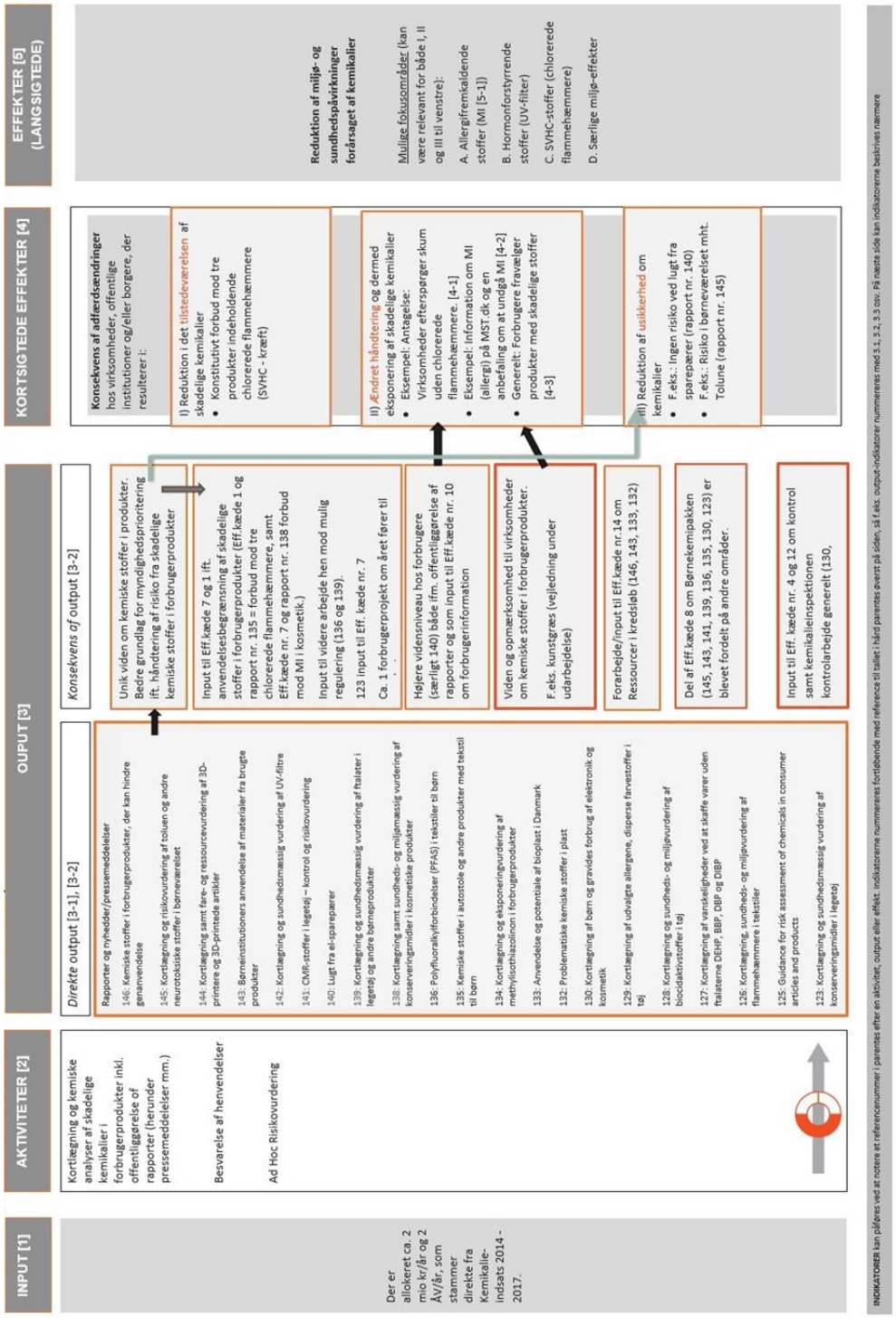


Bilag 1.4 Effect chain for: International collaboration – Endocrine disruptors

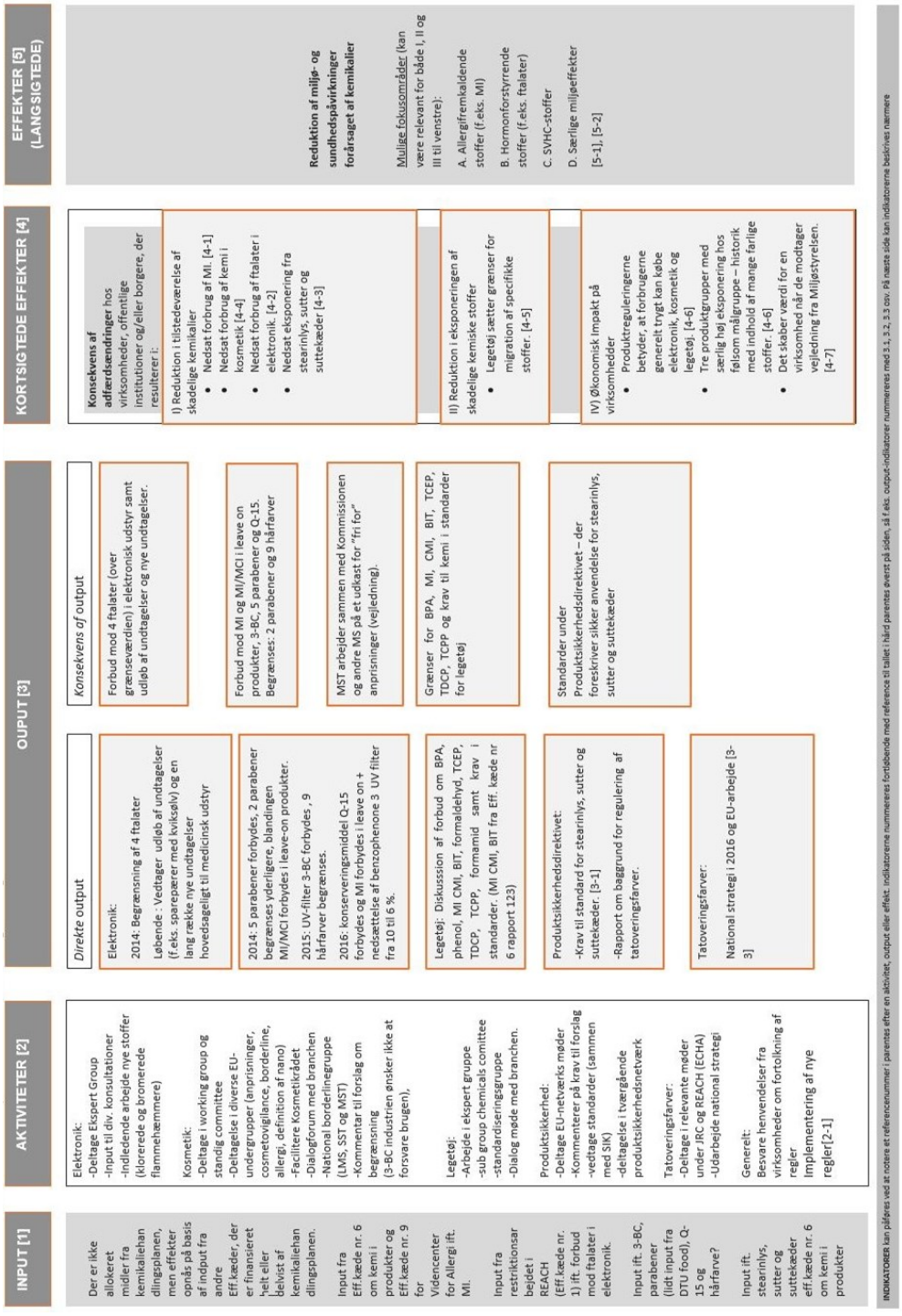


Bilag 1.5 Effect chain for: International collaboration – Global efforts – Conventions in general (Stockholm, Minamata and Rotterdam)

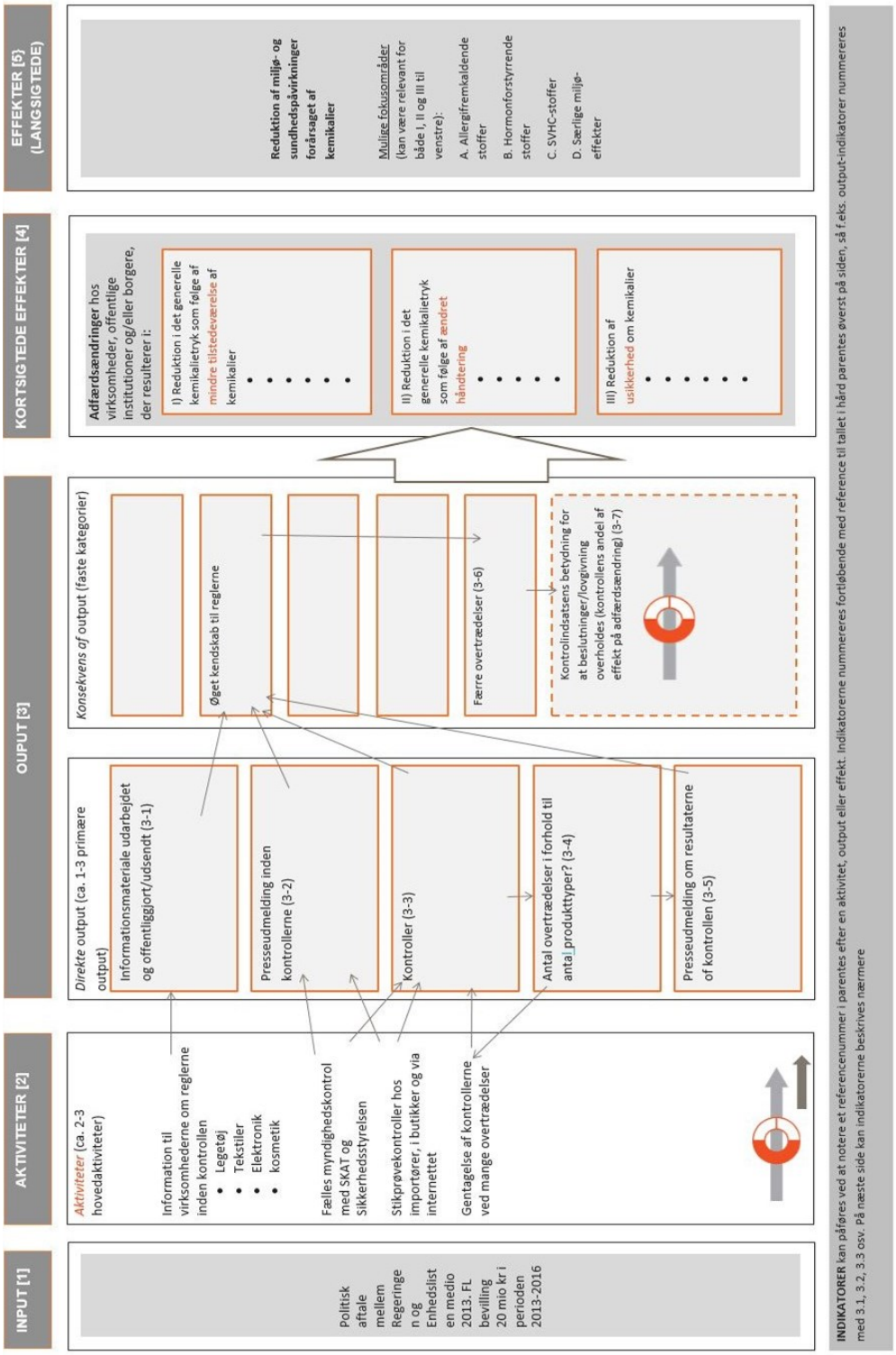
Bilag 1.6 Effect chain for: Non-toxic products – Chemicals in products



Bilag 1.7 Effect chain for: Non-toxic products – Regulation of consumer products



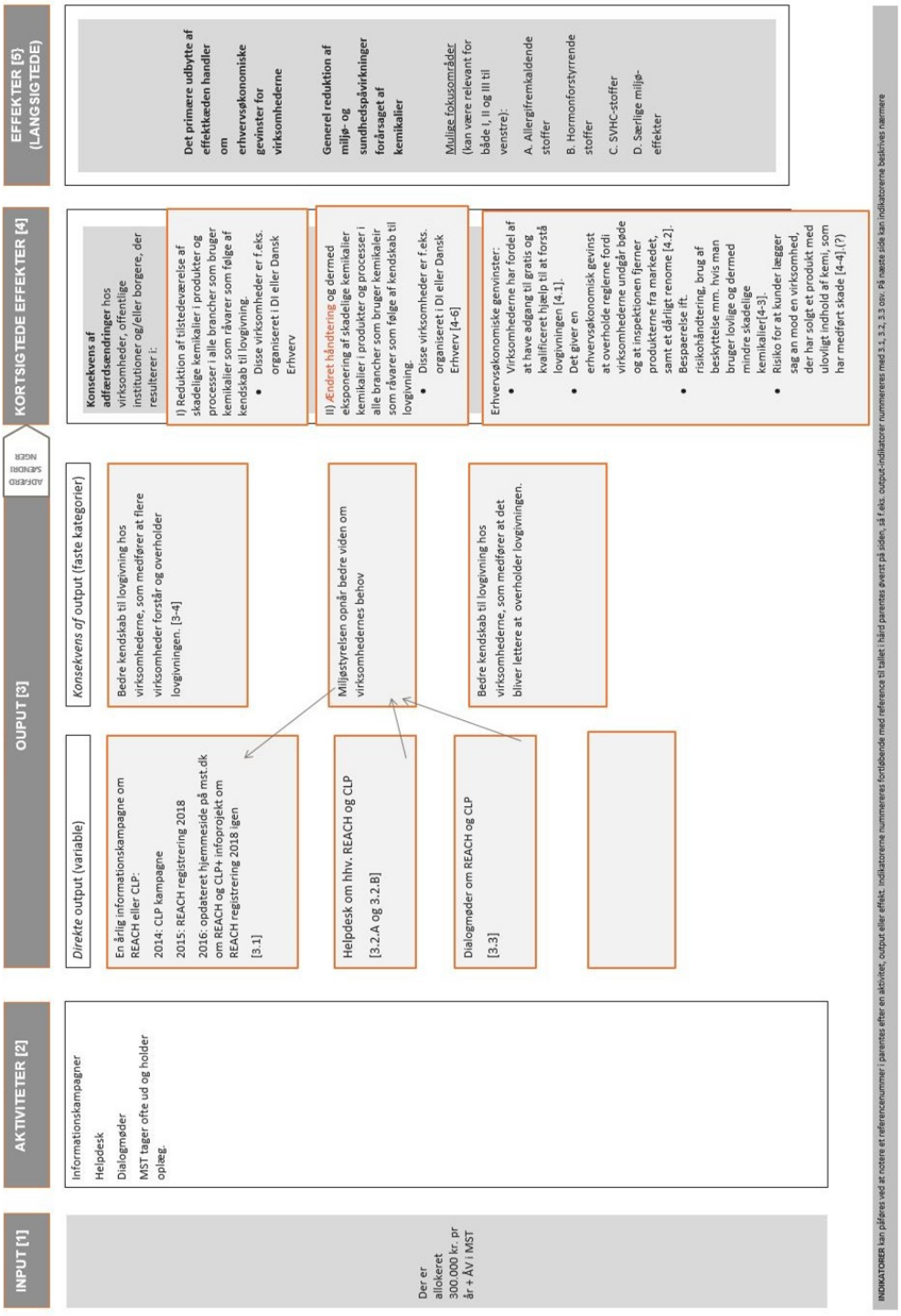
Bilag 1.8 Effect chain for: Non-toxic products – Child chemicals package



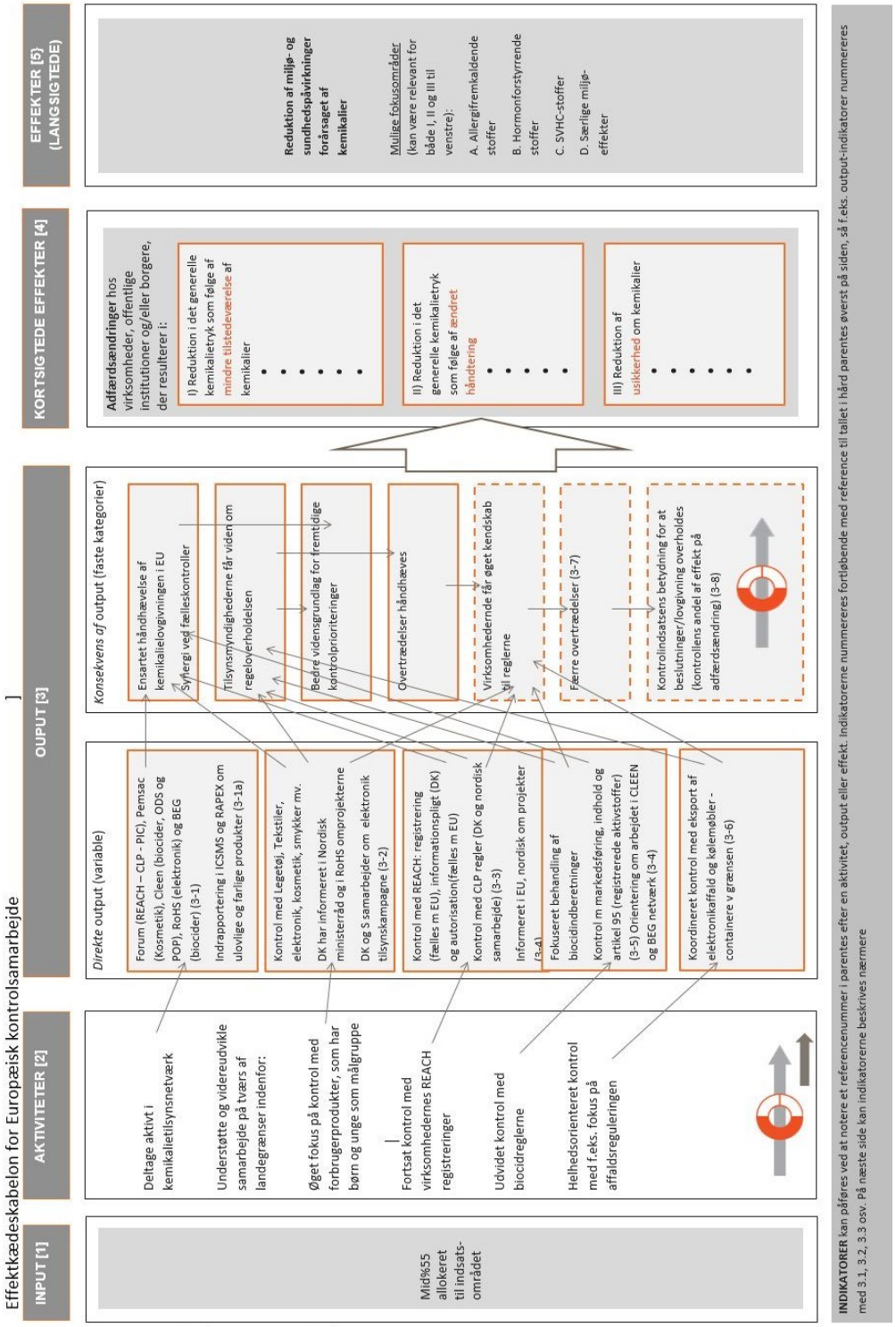
Bilag 1.9 Effect chain for: Non-toxic products – National Allergy Research Centre

Bilag 1.10 Effect chain for: Non-toxic products – Consumer information

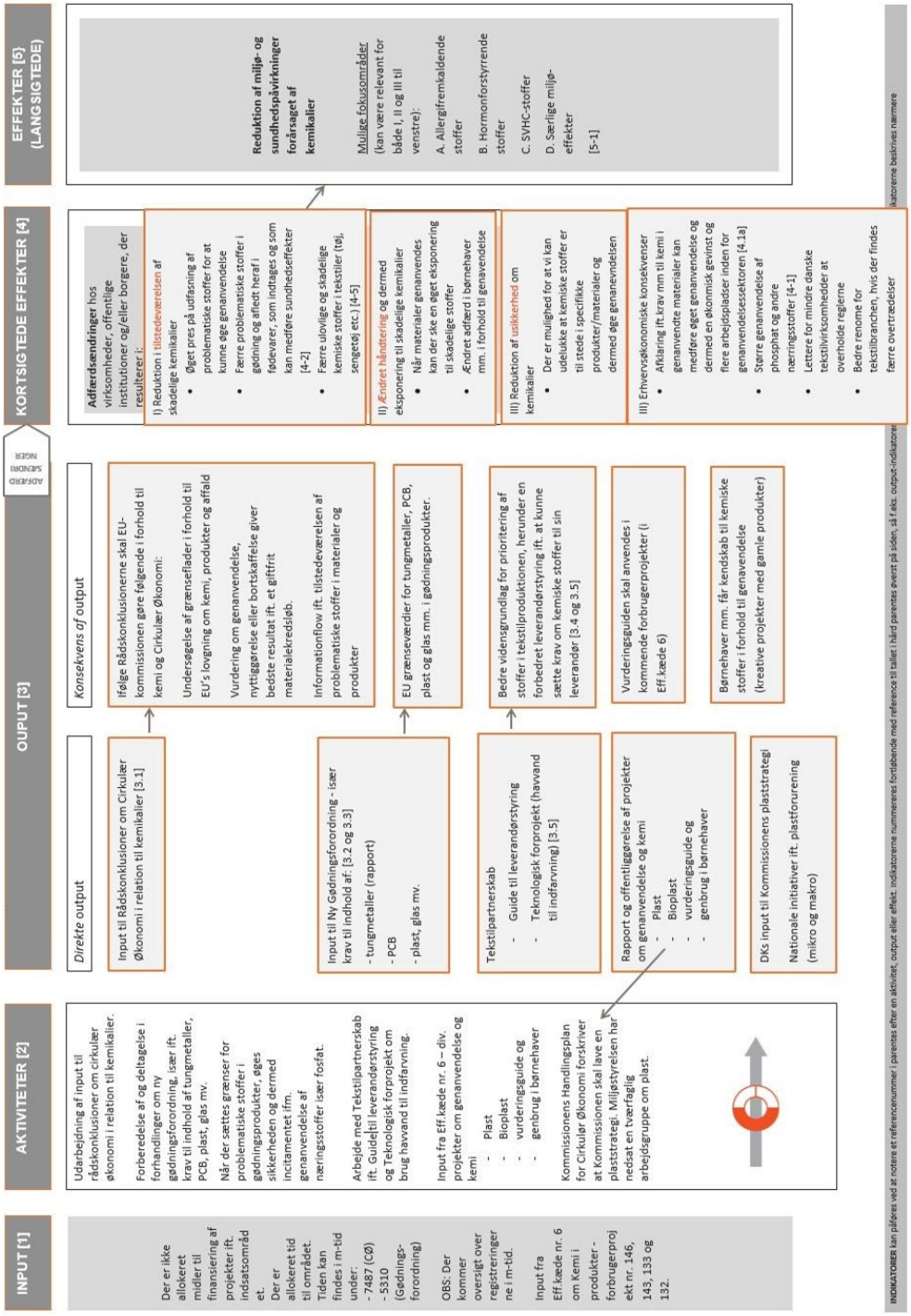
Bilag 1.11 Effect chain for: Non-toxic products – Information on REACH and CLP



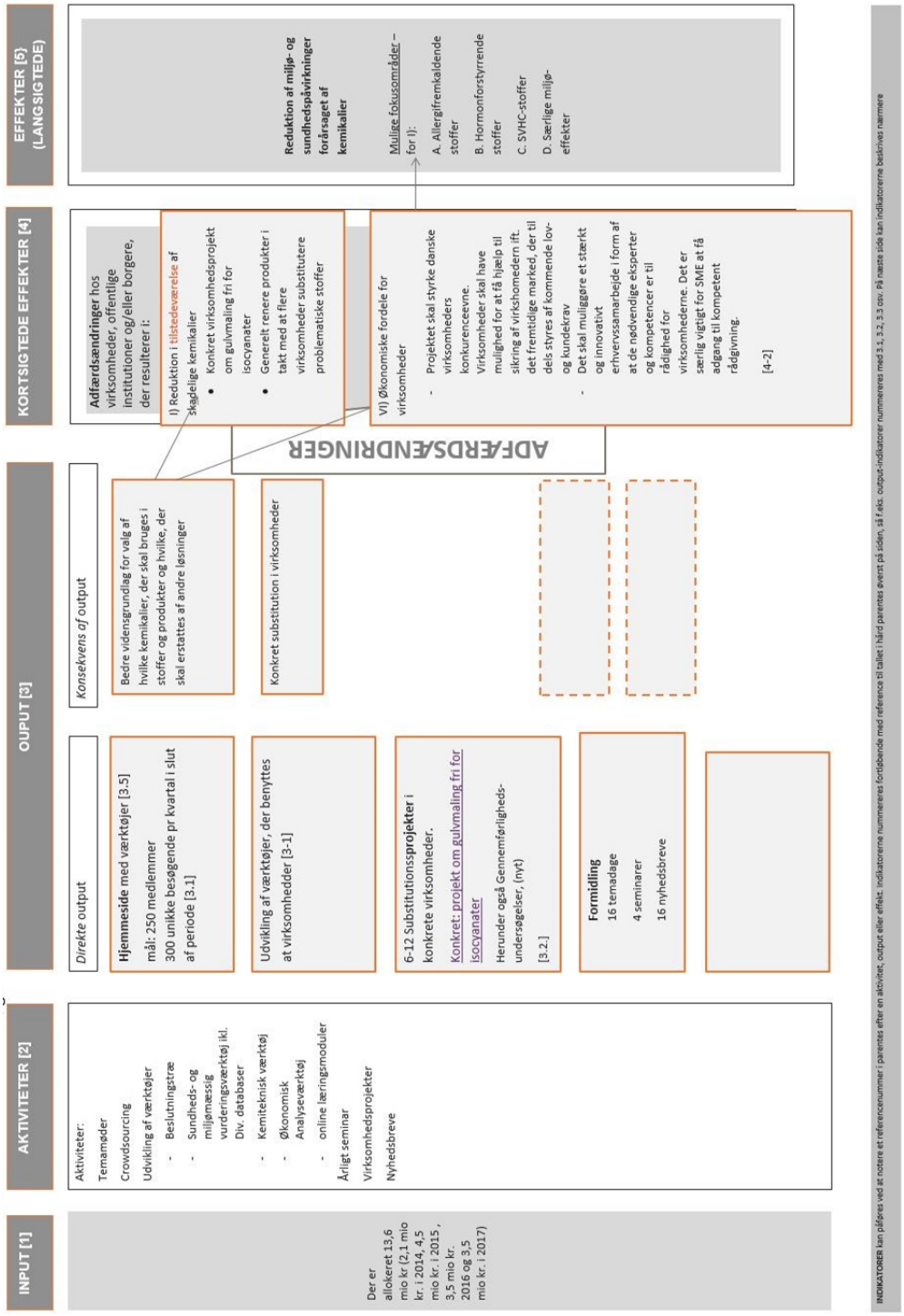
Bilag 1.12 Effect chain for: Non-toxic products – Surveillance activities



Bilag 1.13 Effect chain for: Circulating resources – Horizontal initiatives



Bilag 1.14 Effect chain for: Circulating resources - Substitution Centre



C. Interview guide

A number of enterprises and industries were interviewed, as listed below:

Industries	Contact person
Danish Association of the Pharmaceutical Industry (Lif)	Jakob Bjerg Larsen
Danish Coatings and Adhesives Association (DFL)	Anette Harbo Dahl
Danish Plastics Federation	Thomas Drustrup
Confederation of Danish Industry	Nikolai Stubkjær Nilsen
Confederation of Danish Enterprise	Jakob Lamm Zeuthen
Dansk Fashion and Textile	Pia Odgaard
Danish Association for Suppliers of Electrical Domestic Appliances (FEHA)	Henrik Egede

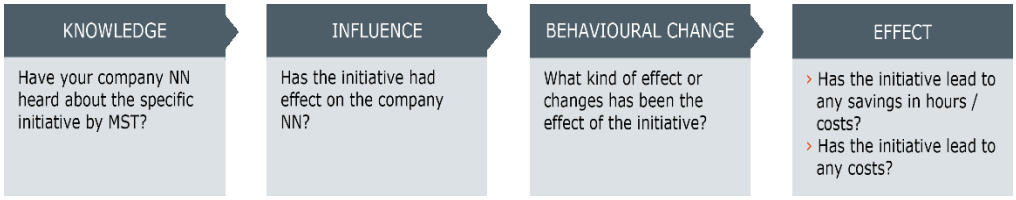
Enterprises	Contact person
Sun Chemicals	Ivan Grønning
Novozymes	Franziska Kramer Birkved
Trinol	Morten Storm Rasmussen
CSS Healthcare	Susanne Kjær Pedersen

The interview guide produced is as follows:

7.5.2 Introduction:

The purpose of the interviews is to gather quantitative data on the behavioural changes at the enterprise level which the activities under the Chemicals Initiatives 2014-2017 may have brought about and, where possible, will bring about. The interviews also include a number of qualitative questions, particularly where it is difficult to provide quantitative data.
A number of industry organisations and enterprises were chosen to answer some of the questions included in this interview guide.
Interviewees and enterprises take part anonymously.

The people conducting the different interviews bear in mind that the aim of the interviews is to identify key figures for the calculations. The focus is on quantifying the effects – in figures, krone amounts or percentages.
The interviewer will also have an idea of the effect chain/calculation concerned in the specific interview, so the discussion can be as concrete as possible. The figure below provides a picture of the interview method.



The session starts with:

My name is ... I'm calling from COWI on behalf of the Danish Environmental Protection Agency. We are carrying out an effect assessment of the Chemicals Initiatives 2014-2017. In this interview we would like to look into the effect of some very concrete activities carried out by the Agency as part of the initiatives. The aim of each question is to find out whether a given activity has a bearing on your business and, if so, what effect that activity has had on your company. The information that you disclose to us will be treated as confidential.

7.5.3 Question

7.5.4 1. Interviewee and organisation

1 NAME & TITLE

…
…

2 ORGANISATION/ENTERPRISE

…

3 CONTACT INFORMATION FOR POSSIBLE FOLLOW-UP

7.5.5 2. Registrations and QSAR

4 WHAT IMPACT HAS THE DANISH QSAR DATABASE HAD ON YOUR WORK?
Do you know about the Danish QSAR database?

If so:

Do you use the QSAR database?

What have you used the QSAR database for?

Have you made financial savings by using the QSAR database instead of running your own tests?

What is your estimate of the financial saving?

Do you have any other experience of the QSAR database where you have seen a financial impact, e.g. for biocides.

7.5.6 Biocides

5 SME project and EU work: WHAT IMPACT HAVE THE DANSH EPA'S GUIDELINES AND INFORMATION ON BIOCIDES HAD ON YOUR BUSINESS?
Is your company classed as a small to medium-sized enterprise (SME)?

Has your company applied for approval for a biocidal active substance or biocide product (we expect Danish businesses to apply for products)? To the interviewer: State whether active substance or product

If so: What did this application cost?

The Danish EPA has drawn up guidelines and information material concerning biocides. Have you used any of this material?

If so:

Which material? (website, guide to applying, other?)

What impact did this information material have on the process of producing your application for approval of a biocide (e.g. time or cost savings)?

Have you used the help desk or gone to information meetings (arranged by the Danish EPA or the industry organisations)?

If so:

What impact did the information have on your business?

If you had not received the information:

Would you then have been sufficiently informed of the requirements for approval of products under the Biocides Regulation? (at the extreme, would this have meant a loss of earnings/closure of the business?)

7.5.7 4. Endocrine disruptors

6 WHAT IMPACT HAS NEW SCIENTIFIC KNOWLEDGE OF ENDOCRINE DISRUPTORS HAD ON YOUR COMPANY?

Are you aware of the debate on endocrine disruptors?

Do you use or have you ever used substances suspected of being endocrine-disrupting?

If so, what substances and for what uses?

Have you changed or considered changing your use of these substances?

Have changed:

Have considered changing:

If you have changed your use of endocrine disruptors, what changes have you made?

Reduced quantities (kg or % change)

What effect did these changes have on your company's

turnover, revenue, image etc.

If you have changed or considered changing your use of endocrine disruptors, have these changes/considerations been influenced by or benefitted from the knowledge provided by the Centre for Endocrine Disruptors? This could include annual information meetings, scientific articles and technical reports.

If so, what influence has this knowledge and information had, and what has been the effect?

7.5.8 7+9. Regulation of consumer products + National Allergy Research Centre

7 WHAT IMPACT HAVE BANS/RESTRICTIONS OF CONSUMER PRODUCTS HAD ON YOUR BUSINESS? (Example of the ban on MI in some cosmetic products)
Has your company used products containing MI?

If so:

What changes have you made as a consequence of the recent ban on MI in selected cosmetic products?

Has your turnover been affected by the fact that there is now a ban on MI?

Has the ban on MI caused any costs to your company?

Questions to companies that work with substances that could be allergenic:

Are you aware of the National Allergy Research Centre?

If so:

Have you used the knowledge provided by the National Allergy Research Centre?

If so, what have you used this knowledge for?

What has been the benefit of using this knowledge?

7.5.9 11. Information to SMEs on REACH and CLP

8 WHAT IMPACT HAS INFORMATION FROM THE DANISH EPA ON REACH AND CLP HAD ON YOUR BUSINESS?
Is your company classed as a small to medium-sized enterprise (SME)?

Have you benefitted from the information from the Danish EPA on REACH and CLP; website, help desk, discussion meetings or other means?

If so:

What has been the benefit from the information?

If not:

Are you fully informed of the requirements to register products under REACH and CLP and the consequences of failing to do so?

(At the extreme, this could mean a loss if a product can no longer be marketed (value of stocks of the products concerned))?

7.5.10 13. Horizontal initiatives

9 THE EU IS CURRENTLY DISCUSSING PROPOSALS FOR HARMONISED LIMITS FOR HEAVY METALS, PCBS, PLASTICS AND GLASS IN THE FERTILISER REGULATION.

9.1 Are you aware of these proposals for harmonised limits?

9.2 If so:

9.3 Have you considered the impact that these possible limits could have on your business?

9.4 Will the Fertiliser Regulation affect your business in any way?

9.5 If so: What impact are you expecting?

---

10 HAS THE INCREASED FOCUS ON REUSE HAD ANY IMPACT ON YOUR BUSINESS?

In recent years there has been an increased focus on recycling, and a greater insistence that the materials to be reused should not be chemically harmful. What impact has it had on your business?

How great do you judge the financial impact to be?

---

11 GENERAL QUESTIONS TO ALL:

What measures could future Chemicals Initiatives support to promote substitution?

What other measures could help your business?

D. Effect Assessment Concept

The Effect Assessment Concept in the Ministry of Environment and Food

1. Why a concept for effect assessments?

It is often difficult to document the effects of actions taken by the Ministry of Environment and Food on business, nature and the environment as well as on growth and employment. This can make it hard to justify the choice of practical initiatives over others and ensure that the most effective actions are prioritised. At the same time, the Ministry, like other authorities, is faced with constantly growing demands and expectations from all quarters to be able to document the effects of its actions – often as a basis for prioritising resources across sectors.

The solution lies in strengthening research (incl. support from authorities) in the area, and also very much in enhancing and systematising the Ministry's own work on effects in policy development. It is therefore proposed to establish a concept to guide the Ministry's work with effect assessments. The aim is to:

1. support the work on effects in policy development (improved policy-making)
2. provide more documentation of the effects of the Ministry's actions as a basis for the correct choice of initiatives and tools (more evidence)
3. create a basis for a more effective environmental and agricultural policy overall (effective policy-making)

The concept is in three parts.

Firstly, effect assessments should be more tightly integrated into policy design by establishing targets, effect chains and indicators for the initiative that we later want to evaluate. Establishing an *effect chain* for an initiative basically means producing an explanation on how and why planned activities are expected to lead to the desired goal of the initiative. Formulating *targets and indicators* enables ongoing monitoring of the initiative, so it can be seen whether the activity and the preliminary results are on the right track in relation to the long-term goals. This also ensures that there is good documentation to support a final *effect assessment of the initiative* at a later date.

The goals established for the initiative are effect targets and are what the effect assessment is based on. The effect targets may be either short or long-term. Examples of effect targets may be effects on nature or the environment, economic effects (exports and employment) and socio-economic effects (growth). A crucial question in the effect assessment is whether the effects can be regarded as a (direct) result of the initiative, which could not have been realised without it. It is therefore essential when establishing an effect chain and associated targets to take an explicit view of the 'baseline', i.e. what would have happened without the action.

Secondly, actual effect assessments should be carried out for major initiatives and initiatives that are part of a political agreement and/or include funding, which is going to run out.

Thirdly, an implementation plan has to be produced. This is meant to define the concept in practical terms and ensure that it is supported throughout the Ministry and across the

individual initiatives. The concept also needs to be incorporated into the Ministry's work processes, to provide for methodological rigour etc. The work on effect assessments must also be established and prioritised at the local level, the necessary skills must be developed, and experience/learning must be gathered across the major projects.

Some ministries have focused on effect assessments in recent years, but with great differences in the depth and breadth of adoption. The former Ministry of the Environment strategically focused on promoting the work on effect assessments, which resulted in the development of an evaluation concept for the Ministry which was approved by the management board in June 2015. However, the concept was never implemented. In 2013, NAER (now the Danish Veterinary and Food Administration) within the Ministry of Food, Agriculture and Fisheries produced guidelines and a tool for economic impact assessments. The aim was to give staff at the Ministry a tool to improve their analysis of costs and benefits to business and/or the Ministry from various policy measures in order to achieve the maximum effect on the target group (effectiveness) for the lowest possible administrative costs to the Ministry (efficiency). This work was well under way, but was not implemented and systematically used throughout the Ministry. Other ministries have worked more systematically with effect assessments; for example, the Ministry of Business and Growth has established an evaluation model which is used for effect assessment of its economic support schemes.

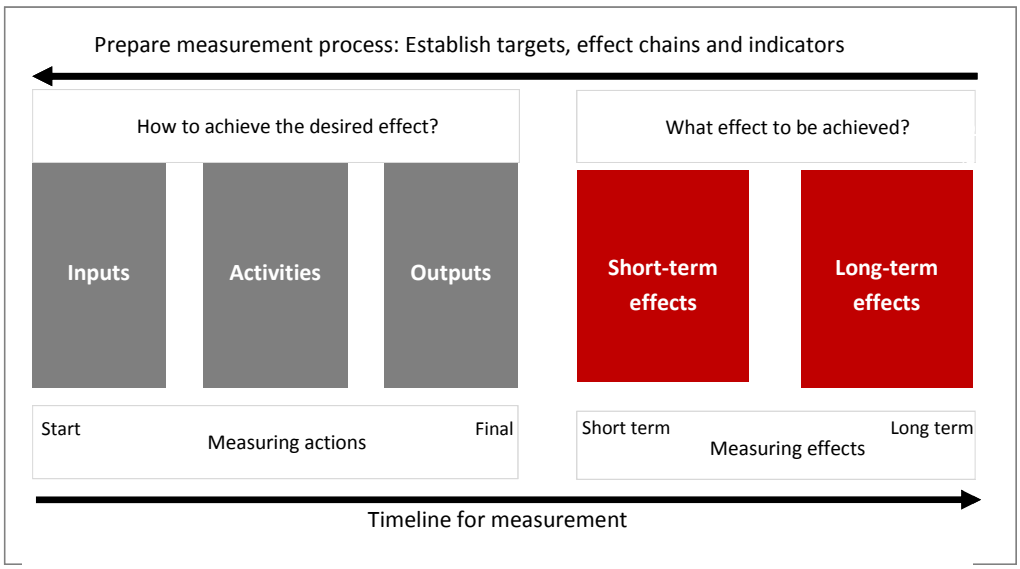
This section describes how the Ministry of Environment and Food can promote the work with effect assessments. The recommendations are based on experience from other ministries and draw inspiration from evaluation theory.

2. How are effect assessments carried out?

A prerequisite for carrying out an effect assessment of an initiative is to create a basis for conducting such effect assessments. This means that evaluation should be considered the moment one starts planning an activity. This can help to analyse and explain to staff and managers how the initiatives are expected to work, how they will produce effects and how the initiatives and their effects will be measured over time. It will also help to create a consistent foundation for subsequent effect assessments of the initiatives that are launched.

Figure 1 depicts the overall framework for measuring the effect of an initiative, including the types of indicators (grey and red boxes) that may be included in the effect assessment of an activity.

Figure 1. Measurement of initiatives



Inputs: The resources that must be in place for the activities within the initiative to be carried out. These may include time, money, human resources, skills, technology, buildings etc.

Activities: The concrete actions taken to produce the outputs from the initiative (services/deliverables/products) and so achieve the desired long-term effects. Activities are actions which one has some direct control over. The type of activities will depend on the particular initiative. Activities could be e.g. 'market consultancy measures' or 'hold event'.

Outputs: Outputs are the results, which are the direct product of the activities within the initiative and which are produced all the time or no later than the end of the initiative. Outputs will usually be concrete and directly measurable. The way on which the initiative affects the world around or specific addressees. An output is the service/deliverable/product created by the activities in the initiative. Outputs can be measured in terms of what is produced and generally also how much.

Effects: Effects should be seen as the benefit from the initiative, and the results the initiative is expected to bring after it ends. The effects may emerge in the shorter or longer term. Short-term effects could be 'increased knowledge of the rules' or 'improved competitiveness', while the long-term effects could be 1) effects on nature or the environment, 2) economic effects (growth, exports and employment in selected industries), and 3) socio-economic effects such as increased growth.

The performance of an evaluation is based on three conditions, which must be met:

A. Formulation of targets for the desired effect of the initiative.
B. Definition of an effect chain for how the effect is to be achieved.
C. Development of precise indicators and criteria for what constitutes successful target attainment in the individual steps in the effect chain.

A. Formulation of targets for the desired effect of the initiative.
Setting precise targets for the desired effect of an initiative is absolutely crucial to being able to measure the effects later. Quantifiable targets expressing what the desired achievement with the initiative should therefore be set from the outset.

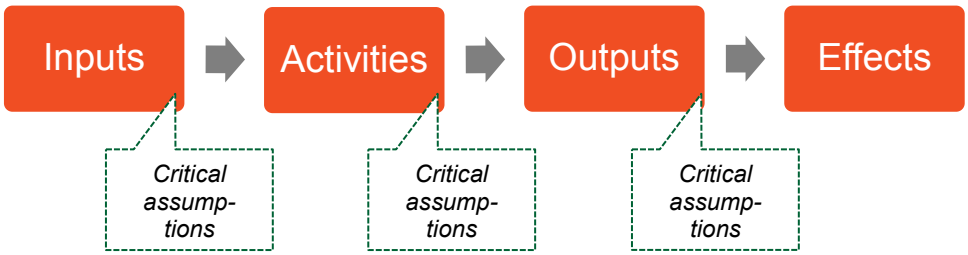
B. Define an effect chain for how the effect is to be achieved.
The effect targets should be used to establish an effect chain for each initiative. The effect chain is set up to define the causal relationship that has to be established to get from the activities performed to the desired effect on users and society. Establishing an effect chain basically means producing an explanation of how and why the individual planned activities are expected to lead to the desired effect.

Some general steps can be identified that can be used to develop effect chains for any kind of initiative:

1. **Identify components of the effect chain**. This is about describing the initiative by specifying its *inputs, activities, outputs and effects*.

2. **Describe relationships within the effect chain**. The next step is to describe the relationships between these components, including mutual relationships between outputs. This is done in the effect chain using arrows.
3. **Describe critical assumptions behind the effect chain**. When all of the causal relationships have been described, the next step is to assess the critical assumptions behind the likelihood of this relationship occurring in practice.

Figure 2. Effect chain



C. Establish indicators and criteria for successful target attainment

When the effect chain has been defined, indicators should be established for the individual links in the effect chain, to enable us to measure and track whether the targets are being attained. Each indicator should have success criteria for what constitutes target attainment. Indicators and success criteria should be established in the effect chain for *inputs*, *activities*, *outputs and effects*. The number of indicators should be limited to concentrate on those that document whether the critical assumptions behind the causal relationships in the effect chains hold up.

Indicators for the *inputs*, *activities* and *outputs* for the initiative can be measured while it is in progress, while the effects can only be measured when the initiative has been completed. Particularly in connection with new initiatives where the final effect is only realised in the longer term, the timeline is used to plan and align expectations of the ongoing requirements for effect documentation. For new schemes, effect indicators should be established with a shorter time horizon, in order to document whether the activity and the preliminary results are on the right track in relation to the long-term goals.

The initiative should be measured by *regular monitoring* (every year) or through *external evaluations* (every few years). The two types of measurement complement each other and provide access to regular effect documentation and data, which make it possible to adjust initiatives on an informed basis when they are not meeting the specified targets.

3. When should the concept be used?

The level of ambition in subsequent evaluations and measurements should depend on the *social consequences* and *political profile* of the initiative, and its *economic importance* (funding, internal resource consumption etc.). These will in turn depend on the nature of the initiatives and tools used. One should also consider whether they are new or existing initiatives.

When new initiatives are developed and launched, causal relationships, critical assumptions and tools should be thoroughly appraised. The establishment of an effect chain is a good tool for thinking through policy development. Establishing an effect chain offers an explanation of how and why the individual planned activities are expected to lead to the desired effect. Targets and indicators should also be set up if the initiative has major social implications, a high political profile or economic importance; see Box 1 below. Economic importance means that at least DKK 10 million per year have been allocated on average over several years. Identifying indicators for the different parts of the effect chain enables regular monitoring and, where necessary, adjustment of the initiative. This is also a condition of being able to undertake an actual evaluation of the initiative at a later stage.

Effect assessments should be carried out for major initiatives, measured in terms of economic volume, and/or initiatives that are part of a political agreement. Wherever possible, financing should be obtained for this when the funding for the initiative is allocated.

Box 1. Criteria for when targets and indicators should be established and when an evaluation may be appropriate

Societal implications	The initiative may have far-reaching socio-economic effects, e.g. on growth, employment and the environment. *Examples:* *Water management plans, EU regulation, the Planning Act*
Political profile	The initiative is part of a policy agreement or an agreement which is about to expire or be renegotiated. *Examples:* *Agriculture and food package* *Chemicals Initiatives, Resource strategy*
Economic importance	The initiative is a major temporary budgetary item or involves heavy use of resources within the Ministry. Economic importance means that at least DKK 10 million per year have been allocated on average over several years.

4. How is the concept implemented within the Ministry?

An essential requirement for the concept to make a difference in the Ministry is that an implementation plan should be produced. This should define the concept in practical terms and ensure that it is supported throughout the Ministry and across the individual initiatives. The concept also needs to be incorporated into the Ministry's work processes, to provide for methodological rigour. Buy-in also requires training and priority to be given to work on effect assessments at the local level. There will also be a need for better knowledge of the data that is available and can be used for effect assessments of the Ministry's activities, and the effect data collected needs to be consolidated.

As part of the implementation plan, a pilot study is run in each agency. The aim is to show how effect assessments can be carried out in specific areas and to gather experience from these to assist in further development of the effect assessment work.

A working group is established with representatives from the the various parts of the Ministry, which will then monitor the pilot studies and produce proposals for the implementation plan. The ministry provide secretarial support and chair the group working group. The project is approved and managed by the future steering group for Economic Analysis, which covers the whole Ministry. The working group presents proposals for the implementation plan to the management board, and the Minister is then briefed on them.

In drawing up the implementation plan, the working group has to take a view on the following:

- How can the Ministry's general work on effect assessments be reconciled with its other obligations in this area (e.g. LDP)?
- How can the concept be combined with existing processes and standards? (e.g. performance contracts)
- What data do the Ministry or other bodies have available that can be used to evaluate the Ministry's initiatives?
- Is there a need for other types of data collection?
- How can it be ensured that experience and knowledge of effects, data and evaluations are gathered and made available to the whole of the Ministry?
- What is the best way to support this?
- What process needs to be initiated in order to implement the strategy? (milestones, resources, time)

Appendix 1 (to Annex D). How is the concept applied in practice?

This guide is meant to help the agencies to use the concept in practice on concrete initiatives. The guide is based on the way in which other ministries work on evaluations in practice. It also incorporates the experience gained in the former Ministry of the Environment.

The use of the concept can basically be broken down into the following steps:

Step 1: Problem description and target group

Step 2: Set up effect chain

Step 3: Describe causal relationships and critical assumptions

Step 4: Establish indicator and success criteria

Step 1: Problem description and target group
When an effect chain is established, the first step is to describe the problem to be solved through an activity. In practice, the effect chain should act as a basis for defining the purpose of the initiative and the long-term effects it is ultimately meant to achieve.

A short description of the initiative should therefore be produced, including the parts that are to be evaluated. It is important to focus on the central part of the initiative and consider whether the goals and associated effects can be divided into sub-goals. The description may be broken down into components containing different activities (which should then have their own targets/effect chains). Table 1 below may be used for this.

The description should include target groups/stakeholders. It is important to define the target group, to ensure that the activities that are initiated are relevant.

Table 1. Description of the initiative

Name	
Description (multiple components)	
Purpose/effect	
Target group(s)	
Focus of evaluation	
Resources	

Step 2: Set up effect chain
When the problem has been clarified and the target group defined, the next step is to establish the effect chain. There is no single template for producing a good effect chain. Good effect chains do however cover a few simple aspects. They must be:

- *Meaningful* – They should describe the whole initiative in detail and in a way that the stakeholders consider to be correct.
- *Credible* – The activities described in the effect chain should have a certain probability of producing the desired results.
- *Achievable* - The effect chain should be realistic and take account of constraints on the capacity and resources of the implementing party.
- *Measurable* – The effect chain should be specific enough to make it possible to measure and hence follow up the implementation and achievement of results and effects over time.

Start from the end – define the effects of the initiative

The first piece of advice when it comes to identifying the components of the effect chain is to 'start at the end' (see Figure 1 below). This means: Start by defining the effects that the initiative is meant to contribute to (in the shorter and the longer term) – in order to arrive at the series of changes, impacts, activity types and finally inputs etc. needed for the ultimate long-term effects to be achieved. There will often be a natural link to the actual scoping of the initiative, including its purpose and the description of its desired effects, which also makes this a natural place to start. This approach helps to ensure that the activities that are initiated are theright ones to achieve the effect targets.

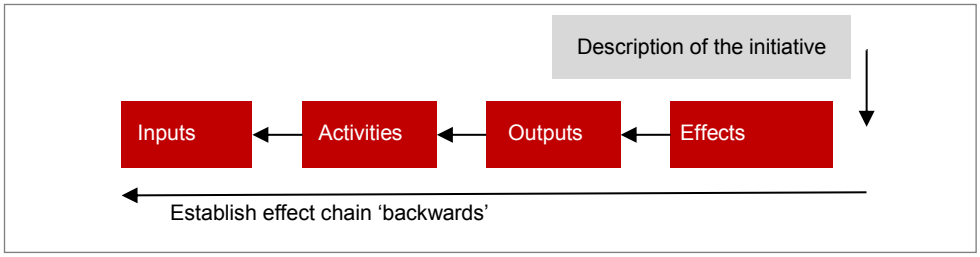


Figure 1. Sequence for establishing the elements in an effect chain

In the description of effects, many initiatives benefit from distinguishing between *short-term* and *long-term* effects, where the latter often only manifest themselves two years or more after the end of the initiative. An example of effects can be seen below.

↳ *Example:* Grant scheme

An initiative might be concerned with using grant schemes to support technological and market development within a specific area (such as water technology) with a view to exports and growth.

This action area can usefully distinguish between a 'new market for water technology' as a short-term effect and 'more new jobs within water technology' as a long-term effect. Between these two effect goals there is an expected relationship and a critical assumption of successful export measures.

On the one hand, it will often help to formulate the effects (especially short-term) so they can be isolated to the initiative in question. 'Improved environment' will then typically be a long-term effect of most of the initiatives, but this effect is not sufficiently meaningful and concrete to serve as the immediate effect of the initiative in the effect chain.

↳ *Example:* Recycling of household waste

The action area 'Recycling of household waste' should focus on dialogue with the municipalities in seeking to achieve the goals of the initiative relating to the recycling

of household waste.

This initiative has a well-defined *long-term* goal of '50% recycling of household waste by 2022'. Many other action areas will be characterised by more generic long-term objectives, which are hard to set quantitative targets for. For most other action areas, these level of specification of the desired effect will have to be formulated under the *short-term* effects.

On the other hand, the effect chains for the action area should ultimately be viewed in a wider context taking in the remit of the whole Ministry. *After* the effect chains have been drawn up, it will therefore make sense to use them as a tool to look for overlapping effects across initiatives and potential for identifying points of contact between initiatives and so make parts of the Ministry's work more cost-effective. Generally, however, this is *not* recommended when the individual effect chains are defined, as this can often lead to confusion.

The recommendation is to defer any consolidation of effect goals until the individual effect chains have been established, as the potential synergies between the initiatives will only be properly visible at this point.

↳ *Example:* Coincidence between long-term effects across initiatives

When effect chains are defined for different initiatives, it often becomes clear how some action areas contribute in different ways to some of the same long-term effects. For example, an initiative such as 'Private afforestation' under the Danish Nature Agency, including a grant scheme for private landowners who can set aside agricultural land for forestry, and the action area 'Biodiversity', aimed at increasing biodiversity by maintaining trees over a whole generation, both contribute to a common effect goal of increased biodiversity.

Identify outputs from the initiative
The next step is to identify the outputs from the initiative (which may be referred to as 'results'). The key questions to ask here are: *"What results must the initiative deliver to show that it can achieve its potential effect?"*

In may be a good idea in this context to define the time frame for the chosen action (part of the description of the initiative). The results delivered by the initiative in the course of the period – and no later than its end-date – can generally be regarded as the *outputs from the initiative.* Results that are realised later than this can usually be treated as *effects* (short-term or long-term). There is often a connection between what could sensibly be entered as an output from an effect chain and the effect goals defined in various performance contracts for the action areas.

As a rule of thumb, you could therefore say that good target outputs can be used in connection with performance contracts, including deadlines and possibly milestones, while effect goals will often be harder to use as management tools. Once a good effect chain has been developed, realisation of the outputs will increase the likelihood of producing an effect.

Inputs and activities
It can sometimes be hard to distinguish between inputs and activities. Here, the simple rule of thumb is to ask yourself whether or not the input/activity can be expressed as 'something you do' (i.e. an activity). Organisational factors, funding/resources etc. are almost always *inputs*.

Step 3: Describe causal relationships and critical assumptions

Causal relationships

When the components of the effect chain have been identified, the next important step is to describe the relationships between the different parts of the effect chain. In practice, this means placing 'causal arrows' along the effect chain. Once again, it an advantage to 'start at the end', i.e. first describe the relationships between outputs and effects, then between activities and outputs, and finally between inputs and activities. This can be particularly helpful in clarifying which activities are related to the initiative but have no direct bearing on the effects of the effect chain.

It is important to remember that some outputs may be required for their outputs – and some may be required for other activities. This may be described with 'backward-pointing' arrows in the effect chain. If there are cyclical relationships between activities and outputs, this should be made clear by the use of arrows. There should generally be no activities or outputs in the effect chain without an arrow pointing onwards.

Critical assumptions

When the components of the effect chain and their mutual relationships have been described, the next step is to consider and formulate the critical assumptions behind the effect chain. A critical assumption is a way of expressing the underlying theory for *how* the initiative works. The basis for the critical assumptions might for example be based on knowledge and experience from processes carried out before, or similar arrangements, theories, convictions etc.

A critical assumption can usually be described with the aid if 'if... then... because...' sentences: For example, *if* this activity is carried out, *then* this effect will be achieved, *because* the target group will be affected in such-and-such a way.

One should generally consider the critical assumptions behind all the relationships described in the effect chain (i.e. all arrows). A major purpose of this work is to avoid 'automatic' and unconsidered relationships in the effect chain.

If the effect chain contains an expectation that activity X will lead to output Y, one should consider what factors need to be in place to make this possible/likely in practice. The more critical assumptions are included in the effect chain, the better one will be equipped for a later effect evaluation of the initiative, which can generate important knowledge and relevant learning. "Why did X not lead to Y as expected? Were our assumptions wrong, or are there other (internal or external) factors that played a part?"

It is essential to be self-critical and play 'devil's advocate' in relation to the critical assumptions and expected relationships. It may be a good idea to bring a 'fresh pair of eyes' to the effect chain to take a critical look at the relationships described. It is therefore worth thinking of making it a fixed element in the production of effect chains to have a person who has not been involved in defining the effect chain or worked in the area take an objective look at the critical assumptions.

Step 4: Establish indicator and success criteria

The last step is for all of the initiatives to have defined goals (preferably SMART; see Appendix 2). For the most part, it will not be possible to directly measure the end-effect that you wish to achieve with the initiative. Targets should therefore be set for activities, outputs and effects, to enable you to track whether you are achieving the various (sub-)goals in the effect chain. For many of the initiatives within the Ministry of Environment and Food, the effect will only manifest itself in the long term. This underlines the need to establish targets and indicators in the different parts of the effect chain, so you can assess whether the long-term goal is likely to be achieved.

The indicators should basically be capable of documenting whether the ongoing initiative is progressing well and whether it ultimately achieves the effect goals that have been set. It is generally advisable to quality-assure the indicators using the so-called RACER principle to determine whether they are appropriate. Indicators do not need to 'measure against the goal' – it is often enough for them to indicate the direction for the effect indicators. Indicators should be credible, and do not need to be evidence-based. The number of indicators should therefore be kept at a realistic level (to minimise costs). An important issue is the data for the indicators; it should be clear where the data comes from and who is responsible for collecting it. For activity and output indicators, data is often gathered via reporting on the initiative. Data will then be easily accessible from monitoring reports. It is generally advisable to use existing indicators for the effects, where data is already being collected for other purposes (see example below). Another important thing is to check that the indicators are accepted by the stakeholders.

In order to measure the progress of an initiative, a baseline needs to be established at the start – the point against which everything is measured. A baseline can be defined for every indicator. For activities and outputs, the baseline is set to '0', as these indicators only measure activities and outputs within the initiative. The baseline for the indicators of short-term and long-term effects is important to have defined, as it is here that the 'effect' will be seen. Here the starting point is described (typically the present situation) that you wish to change. Many indicators are affected by other factors, and it can be hard to isolate the effect. In these cases, it is very important to be clear about how things other than the initiative affect the indicator.

In planning documentation based on a define effect chain, the simple table below may be used.

Table 2. Producing documentation for an effect chain

(Sub-)goal: What is aimed to be achieved?	Indicator: What should be measured?	Success criteria: What is hoped to be achieved?	Measurement method: How should it be measured?
A description of the 'boxes' in the effect chain that are to be documented and tracked.	A description of the unit of measure-ment in which (sub-)goal is assessed.	This is the success criterion for the indicator. When is something a success/failure?	A description of the method of measurement and the data to be collected.

When planning data collection, it is needed to specify how and when the measurement is intended. Some data can and should be collected each year, while other figures can be collected every month. It should also be clear where data comes from and who is responsible for collecting it. For activity and output indicators, data is often gathered via reporting on the initiative. Data will then be easily accessible from monitoring reports. It is generally advisable to use existing indicators for the effects, where data is already being collected for other purposes. Otherwise, it may be so costly to collect data in the indicators that this never happens.

Table 3 below gives an example of how the goals can be formulated. The goals must be specific and include a value and a time frame. However, there are effect goals, e.g. in the medium to long term, that do not yet meet these criteria, as indicated in the table. For each goal, indicators are defined, along with success criteria for what constitutes goal attainment. Indicators for the inputs, activities and outputs of the initiative can be measured while the initiative is under way, whereas the effects can only be measured after it is finished.

There will be big differences in how and what the initiatives can measure. Some initiatives (e.g. coastal defences) are not involved in supervision and follow-up of the authorisations that are granted, so are not close to the effects of the initiative. Others, such as biodiversity, have a detailed knowledge of the effects and long-term impact of the initiatives.

Effect Assessment of the Chemicals Initiatives 2014-2017
The Chemical Initiatives 2014-17 is structured in three main areas: Non-toxic products, international influence and circulating resources. The main area id further structured in 14 sub activities. The study shows that the environmental and health benefits, that could be quantified, out weight the costs. The socioeconomic analysis point towards a net benefit of approximately 1 billion DKK in net present value over a period of 50 years. The sensitivity and uncertainty analysis performed, shows that the result is considered to be robust. As the effect assessment only include quantification of one out of 14 activities, the estimation of the net benefit is considered to be conservative. The real value is expected to be substantially higher. In relation to the qualitative analysis break even analysis has been performed, which shows that the activities only have to make marginal changes in order to pay off. In the analysis three types of activities have been defined, knowledge generation, information and regulation. The effects of the different activities differ. In the analysis primarily regulation has been quantified. Non-the-less the three types of activities should be seen as inter-correlated. In relation to information the report recommends to focus on behavior in order to assess the effects in the future. In relation to benefits from regulation, surveillance is seen as a precondition. The interviewed companies in the survey have not been able to quantify any effects. However, the qualitative observation support a positive net benefit.

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