

Ministry of Economic Affairs

The Consequences and
Administrative Burden of
REACH* for the
Dutch Industry

- Main Report -

Integrated report based on the following two sub-reports:

- The Consequences of REACH for the Dutch Industry (KPMG/TNO)
- Assessment of the Administrative Burden Resulting from REACH (SIRA Consulting).

**Registration, Evaluation, Authorisation and Restriction of Chemicals*

30 August 2004



On behalf of:



Ministry of Economic Affairs

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Summary

REACH stands for the Registration, Evaluation, Authorisation and Restriction of Chemicals. REACH refers to the proposal of the European Commission of 29 October 2003 for new regulations in the field of chemicals.

At the instructions of the Ministry of Economic Affairs, KPMG/TNO (Dutch Organisation for Applied Scientific Research) carried out a study into the consequences of REACH for the Dutch industry. SIRA Consulting carried out an assessment of the Administrative Burden of REACH in comparison to the existing regulations. This key report presents the combined results of both sub-reports. The project was supervised by a supervisory committee, which supports the content of this report.

Direct Costs of REACH: Administrative Burden

The direct costs of REACH are the costs to be made by the industry in order to satisfy the requirements of the legislation. REACH imposes only obligations to supply information, which means that the direct costs of REACH are identical with the Administrative Burden of REACH. The difference in terms of direct costs between the present legislation and the REACH proposal is providing us with insight into expected additional costs and cost reductions.

In both projects, the direct costs for REACH for the industry in The Netherlands are quantified. The table below indicates which additional costs and cost reductions can be expected for which group of industrial users

Industries	Additional costs expected for	Cost reductions expected for
Manufacturers and Importers of substances	- Registration of existing substances and intermediary products. - Actualisation of new and existing substances.	- New substances less than 10 tonnes per year. - Substances in R&D.
Downstream users	- Notification of uses and exposure. - Safety Data Sheets.	
Importers of articles	- Notification of the import of substances in articles.	

One of the goals of REACH is the improvement of the knowledge infrastructure for existing substances. This is a major undertaking and the total of the resulting activities requires a Phase-in period of 11 years. The sum of the direct additional costs during this Phase-in period will amount to about € 46 million per year. These costs are broken down as follows:

- EUR 21 million per year for importers of articles;
- EUR 20 million per year for manufacturers and importers of substances;
- EUR 5 million per year for downstream users.

In addition to the yearly costs during the Phase-in period, the industry has to invest in building up the necessary knowledge about REACH and translating the obligations of the new legislation to their specific situation. Although it is difficult to give a reliable estimate for these costs, their total is expected to be in the order of EUR 250 millions. These costs can be reduced by targeted communication from the government to the industry.

One of the effects of the additional costs for manufacturers and importers is an increase of the cost price. The largest increase – about 6% – is expected for substances with a manufactured or commercial volume between 1 and 10 tonnes per year. This incremental cost increase will be less for substances with higher production or commercial volumes. For substances with a volume exceeding 1.000 tonnes per year, this cost increase will amount to about 0,5%.

The indirect consequences of REACH

There is still a lot of uncertainty about the behavioural effects of the manufacturers and the importers and their consequences for downstream users, which means that only qualitative remarks are possible, and no reliable quantification of the overall effects of REACH on the Dutch industry can be given. The table below presents an overview of the indirect consequences of REACH.

Industries	Cost aspects	Benefit aspects
Manufacturers and Importers of substances	<ul style="list-style-type: none"> - Reduced turnover by banning or limitation of high-risk substances - Reduced turnover for substances with low volumes because of relatively higher price incremental increase. 	<ul style="list-style-type: none"> - Improved transparency about the risks of substances - Reduced costs for the risk management because of the ban on some dangerous substances - Improvement of the competitiveness inside Europe - Reduced risk for liability claims
Formulating industry (1 st line downstream users)	<ul style="list-style-type: none"> - Costs for re-formulating articles - In some cases: reduced competitiveness for exports outside Europe. - Possible delay of innovations due to additional efforts during Phase-in period of REACH. 	<ul style="list-style-type: none"> - Reduced risk for industrial workers - Long term: reduction of work-related illness.
Processing industry (2nd line downstream users)	<ul style="list-style-type: none"> - Costs for the adaptation of articles and processes - In some cases: reduced competitiveness for exports outside Europe 	<ul style="list-style-type: none"> - Reduced risk for industrial workers - Long term: reduction of work-related illness.
Importers of articles	<ul style="list-style-type: none"> - Import barriers for some articles 	
End user		<ul style="list-style-type: none"> - Availability of less harmful articles and products.

Small and medium-sized companies are more sensitive to REACH as a result of a smaller capacity to reformulate products, for instance. This includes segments in the rubber and synthetics processing industry, the ink and paint industry and the special chemicals.

Other effects of REACH

REACH imposes – related to the existing Dutch legislation – no restrictions for substances with volumes less than 1 tonne per year. In addition to that, REACH is less strict for the registration of new substances than the existing Dutch legislation.

Innovation in the chemical industry – one of the goals of REACH – will be stimulated by REACH, because the regime for testing and registration for existing substances will be harmonized with the regime for new substances. This eliminates the present economic disadvantage for introducing new substances as compared with using existing substances.

Another contribution to innovation is the fact that REACH simplifies the registration of R&D-substances. On the other hand, REACH requires additional efforts for testing and registration, which could have some effect on innovation. Another consequence of the disappearance of certain substances is that the “toolbox” for innovation offers fewer choices. In summarising, the net effects on innovation are not certain, but there is evidence that the long-term effects of REACH on innovation are positive.

1 Introduction

REACH stands for the Registration, Evaluation, Authorisation and Restriction of Chemicals. REACH refers to the proposal of the European Commission of 29 October 2003 for new regulations in the field of chemicals. The purpose of the proposal is both to offer better protection to public health and the environment against risks associated with exposure to chemicals, and to improve the European industry's ability to compete and to innovate. The Commission expects REACH to lead to a registration system for existing and new chemicals, with companies being made responsible for providing details of the characteristics and the risks (posed to public health and the environment) of the relevant chemicals.

The Ministry of Economic Affairs launched a study into the consequences of REACH for the Dutch industry. A distinction was made in the study between two separate reviews:

- The Consequences of REACH for the Dutch Industry. This study was carried out by KPMG in cooperation with TNO;
- An Assessment of the Administrative Burden Resulting from REACH: assessment of the Administrative Burden of the chemicals policy in the Netherlands, current regulations compared to the proposed European REACH regulations. This assessment was carried out by SIRA Consulting.

The project was supervised by a broad supervisory committee and a working group, both of which support the content of this report. The members of the Supervisory Committee and the Working Group are listed in Appendix III.

The Consequences of REACH for the Dutch Industry

The first study focused on the consequences of REACH for the Dutch industry. To this end, a start was made with determining the direct additional costs and additional benefits for the Dutch industry. On the basis of the direct effects, an assessment was made of the companies' reactions and their economic impact on the chemical sector and the downstream users (the indirect effects). The review engagement is described in Appendix I, and the results are presented in the first sub-report.

The Administrative Burden of REACH

The assessment of the Administrative Burden focuses specifically on quantifying the information obligations of REACH and comparing these to the existing regulations. Such an assessment also focuses on identifying opportunities to reduce the costs. A specific Dutch method is used as basis for determining the Administrative Burden. This review engagement is described in Appendix II to this report. The applied method and the full results of the assessment are presented in the second sub-report.

Both studies focused on the direct effects as a result of the implementation of REACH. Changes in other regulatory or implementation projects that could influence the effects of REACH were not taken into account. One example are the developments in the field of harmonisation of classification criteria for hazardous chemicals and the labelling systems, the so-called 'Global Harmonization of Classification and Labeling Systems' (GHS).

Accounting for the results

This study is based on forecasts of the situation after REACH has taken effect. At this stage of the project, however, little is known about the way in which the practical implementation of the instructions will take shape. This was taken into account as much as possible. Apart

from that, it came to light during our study that it was not yet known how various sections will actually be implemented. For example, the content of the priority registration form and the filing obligation.

The calculations were made on the basis of the information available at the relevant parties and current understanding of the developments. However, it is not possible to identify all the expected and unexpected developments for all sections and to determine their effects. Based on the study, it is possible to make substantiated quantitative predictions of the direct effects (Administrative Burden and additional costs). These effects can partly be reduced to the different sectors.

As far as the indirect effects on the manufacturers and the importers are concerned, the study only provides a basis for indications about the scale of the effects. An indication can be given of the groups of chemicals that will be most affected; it is not known, however, what volume of these chemicals are produced and imported in which sub-sector of the chemicals industry, other than in general terms. The follow-on of the direct effects on the formulators and the processing industry cannot be quantified because the deliveries between these groups are not known. It can be indicated, though, what type of sectors will experience the effects of REACH to a greater extent.

Only quantitative predictions can be made as far as the consequences for the processing industry and end users, the benefits of REACH and the consequences for innovations are concerned. It is difficult to foresee at the moment what choices companies will make, and discussions about REACH in the chain have not yet started, such that the market developments are uncertain. It is impossible to quantify the effects on specific sectors. Based on indications, it is possible to identify sensitive sectors.

Because the information is not complete, in this report only a partly quantitative picture of the economic effects of REACH on the Dutch industry can be given.

Reading this report

The working method, approach and basic principles of both these reviews are elaborated in the individual reports, in which the backgrounds to and basic principles of the reviews are described in more detail. The results of both sub-reports are presented in this integrated main report. This concerns an outline summary of the economic consequences and Administrative Burden of REACH.

2 Regulations

2.1 The current Dutch chemicals regulations

In the Netherlands, the Chemical Substances Act (*Wet milieugevaarlijke stoffen* or Wms) applies in the field of the primary chemicals policy concerning the environment. By and large, the Wms is a framework Act, which means that the implementation of this Act is partly regulated by decrees. The current information registration system for chemicals is specified in these decrees. The laws and decrees describe a part of the domestic information obligations. The information obligations are actually largely based on European directives and regulations that also form the building blocks for the REACH draft resolution.

With respect to the current situation in the Netherlands, it particularly concerns the following instructions:

1. *The Evaluation and Control of the Risks of Existing Substances Decree.* This Decree is based on Regulation EEC/793/93 concerning the evaluation and control of existing substances. Existing substances comprise all the substances that were on the market in the EU in 1981 and listed in the EINECS. This regulation mainly deals with (1) *the collection and distribution of information about existing substances* on so-called Harmonised Electronic DataSETs (HEDSETs), (2) the updating of this information and (3) the assessment of the risks of the existing substances for the public (including employees and consumers) and the environment;
2. *Notification Decree.* This Decree is based on the Substances Directive 67/548/EEC aimed at new substances. New substances comprise all the substances brought onto the EU market since September 1981. Notification is required of the production or import of 10kg or more of these substances. A technical file must be submitted for a notification – with a distinction being made between a trade notification and a production notification. This file includes information about the characteristics of the substance, the production and its use;
3. *Safety Data Sheet Decree.* This Decree is based on Directive 91/155/EEC, and stipulates with respect to substances classified as hazardous that safety data sheets (SDS) have to be prepared and supplied with the delivery of the substance. The safety data sheet must include information on the manufacturer, composition and characteristics of the substance, risks and measures for its safe use;
4. *Registration Decree.* This Decree has no international instructions as a basis. The Registration Decree basically stipulates that the trade and chemical name, the buyers and – in the case of preparations – the composition must be registered of all the substances produced, imported or traded in the Netherlands.
5. *The Reporting New Knowledge on Environmentally Hazardous Substances Decree.* This Decree is based on Directive 67/548/EEC, and stipulates that new knowledge about substance characteristics or uses must be reported if:
 - the new knowledge will result in a different danger classification;
 - the new knowledge will result in additional warning information;
 - the substance is applied in entirely different situations.

2.2 REACH

REACH compels manufacturers and importers to register existing substances, intermediate products and new substances with a production volume exceeding 1 tonne. Together with the registration, information about both the human and eco-toxicological characteristics should also be supplied, for which a large number of tests have been prescribed. Information about the use and exposure to the substances must be provided in addition.

As under the current regulations, manufacturers and importers must supply safety data sheets to their customer to enable them to take proper safety and control measures. Safety data sheets were included in this study because the introduction of REACH will require additional exposure and other information being included in the sheets. Furthermore, the safety data sheets must also be adapted with respect to the GHS. The same applies to the labelling of substances. Because the latter are not effects of the introduction of REACH, they were not included in the scope of this study.

In addition to restrictions contained in the current regulations, rules for the authorisation of substances are also included for the use of high-priority substances. This means that – depending on the characteristics of a substance – a date is fixed as from which the substance is prohibited, unless that user can demonstrate that controlled use of the substance is justifiable. In that case, temporary permission is granted for the use of the substance.

REACH distinguishes between substances and intermediate products. With intermediate products, REACH makes a distinction between intermediate products manufactured and used on location (*location*) and intermediate products transported under stringent conditions (*transport*). Different information obligations apply to these groups.

Information obligations	Existing substances	Intermediate products	New substances	R&D reports	Articles (Art 6.2)
1. Pre-registration	X	X	X		
2. Registration	X	X	X		
3. Testing	X	X	X		
4. Unidentified uses	X				
5. Safety data sheets	X	X	X		
6. Authorisation	X		X		
7. Reporting				X	X

Figure 1. Information obligations

2.3 Transition from current regulations to REACH

The proposed REACH regulations aim to achieve an unambiguous and coherent substances policy within the EU, with more attention for the effects on the environment and public health. On the one hand, this means that the existing EU directives and regulations will be integrated and, on the other, that in some areas different information obligations about the risks and characteristics of substances are imposed.

For the situation in the Netherlands, it means that the implementation of the REACH Directive will supersede provisions in the existing legislation, decrees and regulations that are inconsistent with the REACH Directive. REACH will be implemented in phases:

1. *Existing regulations:* In the current situation, a distinction is made between ‘existing substances’ and ‘new substances’. After REACH takes effect (passed in 2004), this distinction will no longer be made because the same obligations apply to both categories. The distinction does, however, have consequences for additional costs, because relatively strict demands now already apply to new substances;
2. *Phasing in of REACH:* The substances on the market at the time of REACH becoming effective have to meet the REACH obligations within a period of 11 years. The phasing is regulated depending on the production volumes. To this end, the substances are divided into four categories (1-10 tonnes, 10-100 tonnes, 100-1000 tonnes, and exceeding 1000 tonnes). Substances that are brought onto the market as from 2004 are immediately subject to the obligations set by REACH;
3. *REACH after the phasing in period:* This period starts after the phasing in has been completed, in other words, when all the substances available on the market satisfy the REACH obligations. During this period, information will have to be updated, risk assessments will have to be carried out as applicable and new substances brought onto the market will have to be registered.

3 Target groups and key figures of REACH

3.1 Target groups

REACH applies to the following target groups:

1. *Manufacturers/importers of chemical substances.* Within this group of manufacturers/importers of chemical substances we make a distinction between basic chemicals and fine chemicals. Basic chemicals concentrate on basic substances that are largely processed in the chemicals sector or sold to downstream users in significant volumes. Fine chemicals combine the basic substances, for example, reactions that produce new substances with specific uses;
2. *First-line downstream users (formulators).* These are companies that further process the substances and combine them in preparations and/or articles. We call them formulators and they comprise sectors such as the paint industry, the soap and detergents industry and the rubber and synthetics processing industry;
3. *Second-line downstream users (processing industry).* These are companies that use the preparations or intermediate and other products from the chemical industry for further processing into end products;
4. *Importers of articles.* This concerns companies that import products that are covered by Article 6.2 of REACH. This Article compels traders and importers to report substances that can be released from products. It covers a large and very diverse group of companies, particularly in the SME segment.
5. *End users.* This includes the retail trade, business customers and consumers.

Figure 2 present the overall structure of manufacturers and importers of chemical substances, formulators, processing industry, the importers of articles and end users.

1a) Basic chemicals	1b) Fine chemicals	2) Formulator	3) Processing industry	5) End users
Industrial gases	Dyes and pigment	Paints, coating, mastics and printing inkt	Food products, beverages and tobacco	Basic metal
Other inorganic basic chemicals	Pharmaceutical raw materials	Pharmaceutical products	Textile and leather	Metal products
Petroleum and organic basic chemicals	Agricultural chemicals	Soaps and detergents	Paper industry	Machinery and equipment
Chemical fertilizers	Other fine chemicals including glues and adhesives, perfumes and flavourings, photo-chemicals	Perfumes and cosmetics	Printing industry	Electrical and optical equipment
Plastics in primary form		Rubber and plastics products	Oil industry	Construction
Synthetic rubber			Glass and ceramics	Automotive
Synthetic and artificial fibres			4) Importers of articles	

Figure 2. Overview of the chemical sectors and downstream users in the Netherlands (CBS classification)

The total turnover of the Dutch chemicals sector is more than EUR 30 billion a year. The Dutch chemical sector has a strong focus on exports, as illustrated in Figure 3.

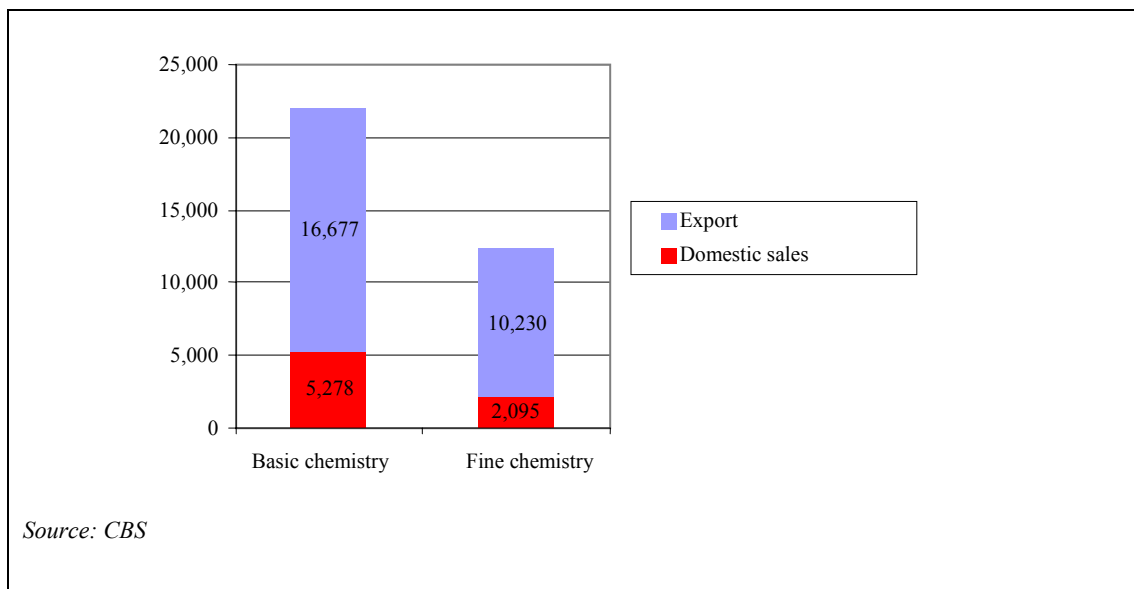


Figure 3. Size of the Dutch chemicals sector (turnover in millions of euros, 2002)

The Dutch share in the total volume of the chemicals sector in Europe is 6%. Compared to Europe, the Netherlands is relatively strong in the sectors belonging to the basic chemicals and less so in the fine chemicals sectors.

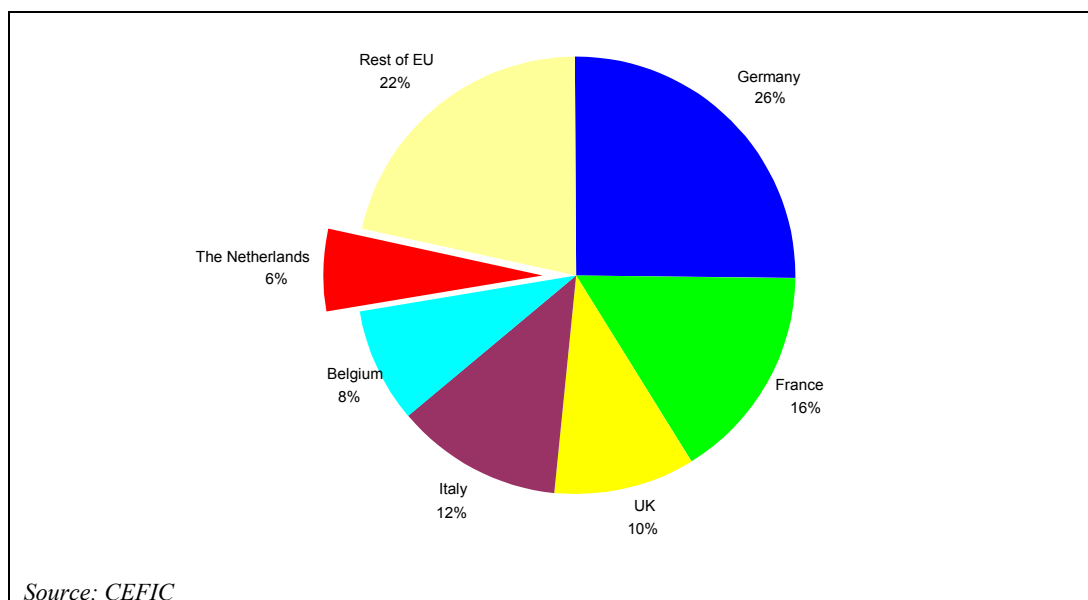


Figure 4. Share of the Dutch chemicals in Europe (as percentage of 2002 turnover)

3.2 Number of substances

The summary below shows the number of substances and intermediate products that are covered by REACH. These numbers are based on the study carried out by RPA at the instructions of the European Commission. The projection of the European situation to the Dutch situation for the existing substances is based on (1) the share and structure of the Dutch chemicals industry and (2) a survey among Dutch manufacturers and importers. It reveals that the Netherlands has a relatively large volume of substances in the 10-100 tonne and 100-1000 tonne volume categories. The numbers for the new substances represent the actual share in new substances that the Netherlands registers. At 8%, that share is relatively high in Europe. The intermediate products assume a 5%-share for the Netherlands, equal to the average share for existing substances.

Number of substances and intermediate products	Tonnage category				Total
	1-10	10 – 100	100-1000	> 1000	
Europe (in numbers)					
Substances					
Before start	20,000	5,300	2,500	2,465	30,265
After start	2,990	540	36	34	3,600
Intermediate products (location bound)					
Before start	1,500	1,000	1,100	2,200	5,800
After start	20	9	1	3	33
Intermediate products (transported)					
Before start	5,000	2,300	1,500	1,700	10,500
After start	68	21	2	2	93
Dutch share (in %)					
Substances					
Before start	3%	8%	14%	4%	5%
After start	8%	8%	8%	8%	8%
Intermediate products (location bound / transported)					
Before start	5%	5%	5%	5%	5%
After start	5%	5%	5%	5%	5%
The Netherlands (in numbers)					
Substances					
Before start	639	419	354	101	1,513
After start	239	43	3	3	288
Intermediate products (location bound)					
Before start	75	49	55	110	289
After start	1	0	0	0	1
Intermediate products (transported)					
Before start	251	113	75	85	524
After start	3	1	0	0	4

Figure 5. Number of substances for the Netherlands

4 The direct effects of REACH

4.1 Introduction

The direct costs of the directive are the costs that companies have to incur in order to meet the obligations of the directive. This can include both substantive obligations, such as implementing measures, and information obligations. The costs associated with information obligations are defined as Administrative Burden. Since REACH only involves information obligations as far as companies are concerned, the direct costs in this instance equal the Administrative Burden.¹

The direct additional or lower costs were determined by comparing the direct costs arising from REACH to the direct costs arising from the current regulations, and were determined for the phasing-in period and the period after the phasing-in. The direct costs are determined for the different substance categories and groups of companies. The assumptions and information used for the calculations can be found in sub-reports.

4.2 Direct costs of the current regulations

The total annual costs arising from the current regulations come to EUR 143 million. The costs associated with meeting the information obligations of the regulations are shown in the table below.

Subject	Annual administrative burden
Notification Decree: VIIC file (10-100 kg), registration and testing	EUR 256,400
Notification Decree: VIIB file (100-1000 kg), registration and testing	EUR 864,100
Notification Decree: VIIA file (1-10 tonnes), registration and testing	EUR 3,278,900
Notification Decree: L1 file (10-1000 tonnes), registration and testing	EUR 1,679,600
Notification Decree: L2 file (>1000 tonnes), registration and testing	EUR 658,900
Notification Decree: PKG file, registration and testing	EUR 150,700
Notification Decree: PKG file (polymers), registration and testing	EUR 1,108,900
Notification Decree: R&D reports	EUR 292,900
Notification Decree: Advance registration	EUR 16,200
Safety Data Sheet Decree	EUR 131,653,400
Reporting New Knowledge Decree	EUR 97,000
Evaluation and Control of Risks of Existing Substances Decree: >10 tonnes	EUR 812,500
Evaluation and Control of Risks of Existing Substances Decree: high-priority substances	EUR 1,847,300
Total	EUR 142,716,400

Figure 6. Average direct annual costs of current substance regulations

¹ The rest of the report will refer to direct additional or lower costs. For the purpose of this study, these terms represent the increase or decrease in the Administrative Burden.

4.3 Direct costs after the implementation of REACH

The total annual direct costs associated with the information obligations following the implementation of are:

1. For the phasing-in period, some EUR 189 million per year (for a period of 11 years);
2. After the phasing-in period, some EUR 141 million per year.

The figure below lists the information obligations contained in REACH, including the corresponding average direct annual costs.

Subject	Phasing-in of REACH	Post-phasing-in of REACH
Pré-registrations	EUR 756,200	EUR 199,800
Registrations	EUR 9,235,900	EUR 3,946,100
Testing	EUR 20,548,100	EUR 3,107,000
R&D reports	EUR 5,800	EUR 5,800
Article 6.2 reports	EUR 20,902,300	EUR 2,071,400
Other information obligations	EUR 136,715,300	EUR 132,077,900
Total	EUR 188,928,000	EUR 141,408,000

Figure 7. Average direct annual costs of REACH

The figure below illustrates the development of the direct costs compared to the current situation. Following the implementation of REACH, it shows that, compared to the current situation:

1. The direct costs increase by EUR 46 million over the 11-year period of the existing substances being phased in;
2. The direct costs decrease by EUR 1.3 million after the phasing-in period. This reduction is due mainly to the testing regime for new substances being simplified.

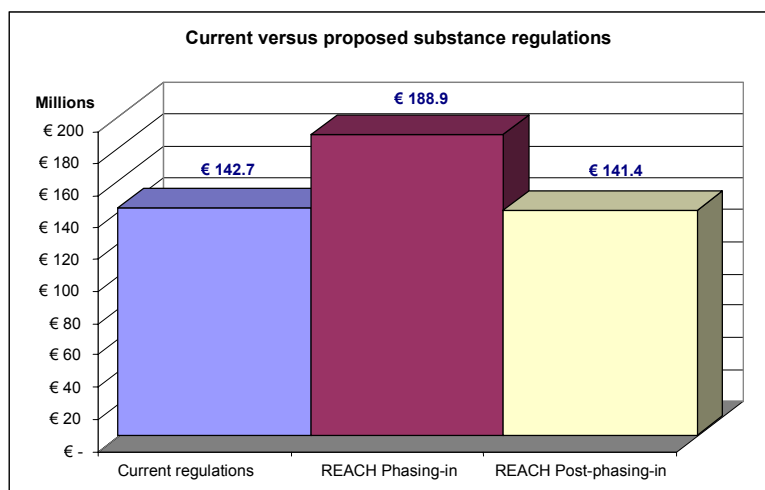


Figure 8. Development of the direct costs compared to the current situation

In addition to the direct costs arising from the information obligations imposed by REACH, companies will also have to familiarise themselves with the new REACH rules. Companies have to ascertain (1) what the consequences of REACH are and (2) what steps to undertake. Based on the cost model for the Administrative Burden, these one-off costs are estimated at EUR 250 million, and are mainly caused by the large number of companies to which REACH applies. The following general principles were observed in determining this Administrative Burden:

- Many companies are just about ignorant of the current substance regulations and will, therefore, have to make a relatively big effort to go through and interpret the regulations;
- One should not only familiarise oneself with the instructions, but also with how these instructions have to be followed in practice.

4.4 The direct additional costs of REACH

The direct additional and lower costs of REACH are important to companies from an economic perspective. They form the basis for decisions about whether or not to register substances and uses. The direct annual costs during the phasing in of REACH amount EUR 46 million. The direct additional costs are spread as follows among the different companies:

- EUR 21 million per year for importers of articles;
- EUR 20 million per year for manufacturers and importers of substances;
- EUR 5 million per year for downstream users.

Figure 9 shows the additional or lower costs per information obligation for the different substances (existing substances, intermediate products and new substances) and volume categories. The figure illustrates the additional or lower direct annual costs during the 11-year phasing-in period compared to the situation without REACH.

	Current regulations	REACH	Additional/lower costs
Existing substances			
Pré-registrations	€ -	€ 556.400	€ 556.400
Registration	€ 2.659.800	€ 4.201.600	€ 1.541.800
Testing	€ -	€ 17.441.100	€ 17.441.100
Not identified uses	€ -	€ 1.852.600	€ 1.852.600
Safety data sheets	€ 131.653.000	€ 135.388.200	€ 3.735.200
Authorisations	€ -	€ 900.000	€ 900.000
Article 6.2 reports	€ -	€ 18.830.900	€ 18.830.900
Total existing substances	€ 134.312.800	€ 179.170.800	€ 44.858.000
New substances			
Pré registrations	€ 16.200	€ 199.800	€ 183.600
Registrations	€ 141.400	€ 188.500	€ 47.100
Testing	€ 7.856.100	€ 3.107.000	€ 4.749.100
Not identified uses	€ -	€ 51.600	€ 51.600
Authorisations	€ -	€ 50.000	€ 50.000
R&D reports	€ 292.900	€ 5.800	€ 287.100
Article 2 reports	€ -	€ 2.071.400	€ 2.071.400
Total new substances	€ 8.306.600	€ 5.674.100	€ 2.632.500
Existing/new substances			
Update registrations	€ 97.000	€ 3.421.500	€ 3.324.500
Update unreg. applications	€ -	€ 284.500	€ 284.500
Report use authorised substance	€ -	€ 22.600	€ 22.600
Other information requirements	€ -	€ 354.500	€ 354.500
Total updates	€ 97.000	€ 4.083.100	€ 3.986.100
TOTAL	€ 142.716.400	€ 188.928.000	€ 46.211.600

Figure 9. Direct additional or lower annual costs per information obligation

The direct additional costs over the entire phasing-in period of 11 years amount to some EUR 508 million. This comes to EUR 278 million for manufacturers/importers of substances and their downstream users, and EUR 230 million for the importers of articles.

If the direct additional costs are discounted at 3%, the total additional costs for the phasing in of REACH amount to EUR 417 million. This comes to EUR 224 million for manufacturers/importers of substances and their downstream users, and EUR 193 million for the importers of articles.

Figure 9 shows that the information obligations associated with the safety data sheets represent 72% of the total costs of REACH. The additional costs for the safety data sheets are limited, because the current regulations also require that safety sheets be supplied to the users. The additional costs come from two new sections being added to the safety data sheet in REACH, as a result of which companies will have to implement system modifications.

Direct additional costs for importers of articles (Article 6.2)

A significant number of importers of articles are faced with the Article 6.2 reporting obligations. It is estimated that total direct additional costs for the importers of articles will come to EUR 21 million per year for the 11-year phasing-in period. The companies facing these costs are mainly from the SME sector. The costs will primarily be incurred by companies that import articles that pose the risk of substances being released, of which clothing is a well-known example. For the vast majority of the importers, this Article will result in minor additional costs.

The direct additional costs for manufacturers and importers of substances and their downstream users

The additional costs for manufacturers and importers of substances and their downstream users follow the registration of substances and their uses. The total direct additional annual costs amount to EUR 25 million (EUR 20 million for manufacturers/importers, and EUR 5 million for downstream users). This EUR 20 million represents less than 0.1% of the annual turnover of the chemical industry.

In absolute terms, the additional costs are relatively the highest for volumes exceeding 100 tonnes, because more obligations apply to the higher tonnages and the Netherlands has a relatively large market share in the 100-1000 tonne category. Figure 11 illustrates the share of the different categories in the total additional costs.

The additional costs in the different categories break down differently:

- for volumes exceeding 10 tonnes, the bulk of the additional costs (60-70%) relates to the testing costs. This already assumes that wide use can be made of alternative testing methods, such as QSARs and waiving, that many companies form syndicates and that animal testing is allowed only once for each substance;
- for the 1-10 tonne volumes, the bulk of the additional costs, some 80%, comprise registration costs. The reason is that the number of tests required have been brought down to a minimum and the registration obligations are only slightly more flexible compared to the volumes exceeding 10 tonnes.

The additional costs for intermediate products are limited because the testing and registration obligations are limited.

Information obligations now apply to new substances from 10 kg upwards. Under REACH, the obligations for substances from 10 kg to 1 tonne are scrapped. REACH will lead to lower costs for these substances. For substances from 1 to 10 tonnes, the testing obligations in particular are less stringent than under the current regulations. REACH will lead to lower costs for this volume category, as well.

4.5 Economic significance of additional costs

For individual companies, it is not so much the total additional costs that count, but the additional costs of REACH in relation to the margin on or the price of a particular substance or article. The total additional costs for downstream users are limited, also in relation to the price of a substance. The additional costs for the importers of articles are also limited because the costs are spread across a very large number of articles. The additional costs are spread unevenly among the manufacturers and importers of existing substances, and the additional costs for certain groups of substances could be high. This section therefore only focuses on the economic significance of the additional costs REACH implies for the manufacturers and importers of substances.

An estimate was made of the average price increases per volume and price category based on information from the above calculations and data about the spread of substances across price categories obtained from a survey among manufacturers and importers² Figure 10 shows the

² The survey enquired about the bandwidth of the prices of substances and not about margins. Information about margins is commercially sensitive and would have resulted in a lower response rate to the survey.

average additional costs and average price per tonne, and the average cost increase for the different volume and price categories. To calculate the additional costs per tonne for the companies, a payback time of five years is applied for all the substances.

Price increase	1-10 tonnes	10-100 tonnes	100-1000 tonnes	>1000 tonnes
Share in total additional costs	8%	21%	46%	24%
Average prices per tonne	10,239	7,585	3,154	1,151
Average additional costs per tonne	641	165	35	6
Average cost price increase	6.3%	2.2%	1.1%	0.5%

Increase per price category:

EUR 0-500	256%	66%	14%	2%
EUR 500-1,000	85%	22%	5%	1%
EUR 1,000-5,000	21%	5%	1%	0%
EUR 5,000-30,000	4%	1%	0%	0%
EUR >30,000	2%	0%	0%	0%

Figure 10. Increase in cost price per tonne of existing substances

The average increase in cost price is the highest in the 1-10 tonne category, amounting to 6.3%, and decreases in the higher categories to 0.5% for chemicals exceeding a volume of 1000 tonnes. Logically, the lower the average prices are, the higher the increase in cost price is too. Substances in the lower tonnages and with lower prices could face relatively high cost price increases and thus face the most of the effects from REACH.

There is no summary available of sectors in which companies have the most of the low tonnage and low price substances. Moreover, it is not known which substances are involved. Therefore, the immediate effects cannot be reduced directly to specific sectors. In general terms, fine chemicals involve more substances in the lower tonnages and are therefore expected to bear a relatively larger part of the additional costs. On the other hand, fine chemicals can also benefit more from REACH because the obligations for substances below 1 tonne are scrapped, and the registration of new substances will not be as stringent as under the current regulations. Fine chemicals comprise both SME companies and large companies.

5 The indirect effects of REACH

The direct additional costs of REACH and, in particular, the additional costs in the low price and low volume categories, as well as the evaluation and authorisation of high-risk substances will lead to changes in the market, because manufacturers and importers of substances will make choices about the registration of substances and uses. These choices will have consequences for the users of substances in their pure form or in products. The choices will have economic consequences and, as such, represent the indirect effects of REACH.

5.1 Consequences for manufacturers and importers of substances

The manufacturers and importers bear the bulk of the additional costs for testing and registering substances and uses, and will therefore decide whether to actually register all the substances and uses. These choices will have economic consequences for the chemical industry in the Netherlands. Here, we present the major costs and benefits.

Enhancing the transparency and the reputation of the chemical sector

REACH harmonises the regulations by replacing the hazardous substances directive, the existing substances regulations, the prohibition directive and the underlying directives and regulations. REACH thus replaces about 60 other pieces of legislation, which creates uniform and transparent procedures for the companies.

REACH offers companies a better instrument for giving account to stakeholders with respect to their substances policy and thus improving the reputation of the chemical sector.

Improving the competitive position within Europe

The current Dutch regulations already contain information obligations not yet included in the current EU rules, but that will be included in REACH. The Dutch industry will have a minor advantage compared to the other companies in complying with REACH.

In addition, the Dutch companies will face lower average cost price increases than European companies because they have fewer substances in the low volume categories, which are exactly the substances with the highest additional costs per tonne.

Restricting high-risk substances and uses

For a number of substances, REACH will lead to decisions about continuing their production or import due to health and environmental risks. Companies do this from a security and liability perspective, and national governments in the context of evaluation and authorisation. It is anticipated that the health and environmental risks will concern only a small percentage of the substances. Stopping with the production or restricting the use of these substances is an intended effect of REACH. Companies probably have a reasonable picture of the categories of substances that pose health and environmental risks.

Market loss due to cutbacks

In addition, some substances will be taken out of production for financial reasons as a result of REACH. The reason is that the direct additional costs are such that the substance in question is no longer profitable. Figure 11 shows the part of the substances found in each volume and price category. On this basis, an estimate was made that 6% of the substances run a high risk of one or more or all suppliers withdrawing because these substances involve a cost increase of more than 20%. It was also estimated that 23% run an increased risk because this part of the substances face a cost increase of 10%.

Share of the substances	1-10 tonnes	10-100 tonnes	100-1000 tonnes	>1000 tonnes
EUR 0-500	3%	1%	3%	3%
EUR 500-1,000	2%	4%	7%	4%
EUR 1,000-5,000	16%	16%	13%	2%
EUR 5,000-30,000	13%	10%	2%	0%
EUR >30,000	2%	0%	0%	0%

Figure 11. Spread of the substances across categories and sensitivity to cutbacks

The turnover represented by these substances is relatively small. The 6% of the substances with a high risk represent 0.1% of the turnover of the chemical industry, and the 23% of the substances with an increased risk represent a little more than 1% of the turnover. Three quarters of these substances only have to be registered in year 11 of the phasing-in of REACH. This does not change the fact, however, that the turnover of companies with a relatively large share of these ‘sensitive’ substances could be vulnerable.

Before companies decide to cut back, they will first have to contact their downstream users to explore the possibilities of a price increase or a contribution to the testing and registration costs. There are sufficient economic incentives for limiting cutbacks. However, it is very difficult to estimate how many substances will eventually disappear from the market.

The small number of ‘sensitive’ substances, the late registration and the interaction with the downstream users result in a limited effect on turnover and employment opportunities of the manufactures and importers of substances, possible exceptions allowed for.

A shift may take place within the chemical industry in the shape of concentration. There will be more cutbacks of substances with a decreasing demand and low margins and at companies that export a lot. The Dutch chemical industry sells 27% to companies outside the EU.

REACH imposes the same obligations on the import of substances and will actually have a greater impact on importers of substances than on Dutch manufacturers. The importers will impose cutbacks sooner than the manufacturers because of their stronger financial focus, the more limited availability of the capacity to register and test, and the fewer obstacles to withdrawing. Therefore there will be no increase in competition on the European market from countries outside the EU.

Market-oriented innovations under pressure in the short term

REACH requires considerable personal effort from the companies’ staff. This effort can be at the expense of staff involved in research for market-oriented innovations, which is a bigger issue for SME companies.

REACH also creates innovations because high-risk substances have to be replaced, as a result of which employment conditions can improve, and products will pose fewer risks for health and the environment.

In the starting phase of REACH, uncertainty on the market increases about companies’ choices and behaviour. Often, uncertainty in companies lead to postponement of investments until there is more clarity about the direction that market developments are taking.

5.2 The consequences for formulators (1st-line downstream users)

The formulators are the first link in the chain faced with the consequences of REACH. Formulators purchase large quantities of substances for making preparations and articles, for example, the paint sector, the soap and detergent sector and the rubber and synthetics processing industry.

More knowledge about substances and uses

REACH leads to an increase in the knowledge about substances, for example, the consequences of exposure, which can improve safety at work. In the short term, it can result in additional costs for companies to implement control measures. In the long term, it will bring about a better working climate for employees and a possible drop in work-related absenteeism.

The improved transparency offers formulators the possibility to improve their reporting on the activities, which, in turn, improves the reputation of the formulators. It does, however, require thorough interpretation of the new information that REACH generates.

Higher costs for formulators

The formulators have to face a cutback in the substances upstream. The chances of a particular product being faced with the disappearance of a substance increase with the more substances required for a product. Ink contains some 20 to 30 substances, soap or detergent contains 10 to 15 substances on average. Paint contains between 10 and 50 substances. Formulators therefore expect that a relatively high number of products will experience the consequences of REACH. Due to the disappearance of individual substances, companies will have to formulate alternatives. Cost indications involving reformulations vary from EUR 0.1 million to EUR 1 million per substance per formulator. The reformulation costs, therefore, quickly exceed the test and registration costs. This implies that there is an economic incentive for formulators to contribute financially to the registration. The formulator does face extra purchasing costs.

Deterioration of the competitive position for exports to outside the EU

The higher costs mean a deterioration of the competitive position for export to customers outside the EU, because they can purchase products outside the EU without any additional costs. It would therefore be difficult for formulators to charge the cost increases on in the prices, which means that the formulator's profitability falls or that a part of the market disappears.

Reformulations also cause a delay in other innovations because companies need the resources for adapting their products and preparations and cannot apply them to market-oriented innovations. This can result in companies falling behind. SME companies are more sensitive to REACH as a result of a more limited capacity to reformulate products. This includes segments in the rubber and synthetics processing industry, the ink and paint industry and specialty chemicals. Reformulation can also improve the quality of the products from a health and environmental point of view because high-risk substances will be replaced.

The threat of cheaper imports of preparations from outside the EU is not an issue here, because the same obligations apply to the imported preparations as to substances. Preparations are not seen as articles. Imported articles have to satisfy fewer obligations within REACH.

5.3 The consequences for the processing industry (2nd-line downstream users)

The processing industry will also experience the consequences of REACH. The processing industry purchases preparations and products and processes these in several steps to end products. The consequences for the processing industry will only partly have something to do with more expensive substances and products. The additional costs are spread over numerous users, and the procurement of substances and products is only part of the overall costs of the processing industry. The consequences will be particularly noticeable at companies where substances disappeared or products gained different characteristics higher up in the chain, such that production processes will have to be adapted. REACH brings with it the following costs and benefits for the processing industry:

Limiting risks

REACH creates benefits for the industry because, through a process of evaluation and authorisation, substances with the highest risks are prohibited or restricted in their use, and more knowledge is created about uses and the consequences of exposure. As a result, the industry can:

- implement proper control measures;
- remove waste more effectively;
- demonstrate that substances are safe to use under certain conditions. This can contribute to the improvement of the companies' reputation.

An overall estimate can be made of the indirect benefits in the field of work-related absenteeism. For the companies, these benefits are expressed in avoiding production losses. Furthermore, less work-related absenteeism also has social benefits because of the lower medical costs and because the drop in absenteeism increases prosperity. The social benefits outstrip the avoided production losses. A Danish study shows that the avoided production loss in the case of cancer is 3% of the total benefits gained from avoided absenteeism. In the case of asthma, it is 20%, and in the case of headaches, it is still 51%. It is very difficult to make an estimate of the production losses, because the causality between illness and working conditions is uncertain.

Competitive position of the processing industry

In contrast to the competitive position of the substance manufacturers, REACH will not change a lot in the competitive position of the Dutch processing industry within Europe. This is because there is a lot of trade between the EU member states, which reduces the differences in additional costs between the various countries.

However, the competitive position with respect to countries outside Europe will change. Additional costs of REACH will be charged on to the processing industry in Europe, which will have a small impact on the cost prices. The products can also obtain different characteristics. Companies will therefore have a minor disadvantage in the export to companies outside Europe.

The competitive position of companies outside the EU also strengthens on the European market. However, Article 6.2 contains provisions that apply to the import of articles, which means that part of the articles will also face additional costs from REACH. It concerns articles containing substances in sufficient volume that can be released. Registration or notification is required for these articles. The question is whether the Article is not sufficient reason for no longer selling the article on the EU market.

Companies with very strict user requirements (in the field of safety and contact with food) experience a stronger impact from REACH, for example, the packaging industry and the automotive sector. The same applies to companies that have to adapt their production processes due to changes in the purchased products. Finally, companies that experience strong competition from countries outside the EU (both for exports and the domestic market) could experience difficulties. This will often be an acceleration of an existing market development, such as the leather industry or iron foundries.

It is not possible to make a substantiated prediction of the impact on turnover and employment in the processing sector because it is unclear what will happen upstream and how the formulators and the processing industry can influence choices upstream.

5.4 The consequences for importers of articles

By virtue of Article 6.2, a significant portion of the additional costs of REACH is faced by the importers of articles. It is expected that the importers of product groups where substances can be released will experience the consequences, for example, textile and synthetic products that have contact with food. At the moment, it is still very unclear how governments will apply this Article and what consequences it will have for the importers of articles.

5.5 The consequences for end users

REACH hardly imposes any immediate obligations on the end users. Companies where there is a lot of exposure to substances, such as painters, parquet fitters and cleaners, could face restrictions on use or additional measures. The consequences will be limited for the other end users, with the exception of the end users of products that could release substances.

6 Economic consequences

One of REACH's objectives is to improve the European industry's capacity to compete and innovate. In this section, we focus on the consequences of REACH for the capacity for innovation and the competitive position. We also focus on the relationship between REACH and competition.

6.1 The consequences for innovation

To improve the capacity for innovation, the R&D reporting obligations have been reduced, and the costs for registering substances below 10 tonnes are lower than under the current regulations. This provides more incentives than in the past for companies to develop new substances.

Some of these additional incentives are expected to materialise in the longer term because, in the short term, part of the capacity for market-oriented innovations will be required for testing and registering substances or reformulating products and preparations. This particularly applies to the SME sector. Furthermore, due to effects of REACH, some substances will also disappear from the market, which means that the 'toolbox' available to companies is getting smaller.

However, REACH also introduces a process in which high-risk substances will be replaced, which will ultimately lead to higher quality products from an environmental and health perspective.

Companies will also gain more knowledge about substances under the application of REACH, with companies identifying more opportunities for new products.

REACH will have an ambiguous impact on the capacity for innovation. The advantages and disadvantages mentioned before apply during the phasing-in period; after the phasing in, REACH offers more opportunities for innovation.

6.2 The consequences for the competitive position

Inside the Netherlands

The aforementioned behavioural effects lead to a tendency among manufacturers and importers to concentrate their efforts. Some manufacturers and importers cannot afford to test and register substances. Other companies will then take over the market from these manufacturers or importers. The result is a reorientation of the market, with the associated financial reconstruction and reorganisations. It also creates opportunities for joining or expanding the market. This reorientation will primarily affect companies that manufacture small volumes of substances with low margins and do not have the financial resources to finance all the testing and registration. Within the larger companies, it could lead to a stronger focus on certain groups of substances.

The market orientation can also change for some of the downstream users. They will face cost increases (including as a result of reformulation costs) and changes in product characteristics. Companies already experiencing difficulties now can disappear from the market, as a result of which the market will become more concentrated. Companies with a strong capacity for innovation, on the contrary, can strengthen their position.

The Netherlands inside Europe

The Dutch chemical companies can strengthen their competitive position in relation to companies in other EU member states because:

- The Netherlands already have strict regulations compared to other countries, thus limiting the additional costs in the Netherlands;
- The Dutch chemical industry has relatively lower additional costs as a result of REACH than European competitors because it has relatively fewer substances in the low volume categories, and these are exactly the categories with relatively high additional costs.

The competitive position in Europe will not change significantly for the formulators and the processing industries, because the companies buy the substances and products in all the European countries and will therefore face a relatively even increase in the costs.

The Netherlands in relation to the rest of the world

With respect to countries outside the EU, there will clearly be changes. The competitive position of the manufacturers of substances on the export market will come under pressure because the European substances will face additional costs, whereas manufacturers outside the EU will not. The companies that already have difficulties competing outside the EU will lose more ground. In that case, REACH will accelerate an existing market development.

The competitive position of Dutch substance manufacturers on the European market will not deteriorate in relation to the import of substances. After all, the same obligations apply to substances from outside the EU as do to substances manufactured within Europe. The same arguments as to the substance manufacturers apply to the European formulators. Indeed, the same obligations apply to the import of substances as do to the production of preparations within the EU.

This is different with respect to formulators and the processing industry that produces articles. Besides a competitive disadvantage on the export market, there is also a competitive disadvantage on the European market. Article 6.2 obligations apply to the import of articles, which can release substances. It is expected that Article 6.2 will impact on specific sectors, such as the textile sector. The position on the European market will improve slightly for the majority of the importers of articles.

As far as the Dutch processing industry is concerned, it is expected that the consequences of REACH will only be noticeable in sub-segments, where the competitive position is already facing pressure and the market share for Dutch companies is already declining, for instance, the leather industry and the iron foundries.

Should, however, the rest of the world adapt a similar policy, companies in the EU will benefit from the so-called first-mover advantages.

6.3 Relationship with competition

In a number of areas, the REACH regulations touch upon the competition policy. In this section, we discuss the most important aspects where this is the case.

Voluntary cartel forming

REACH assumes that cartels will be formed voluntarily for testing and registration. This voluntary nature in forming cartels poses the risk of certain parties being deliberately kept out of the cartel, or of it only being possible to join the cartel under relatively unfavourable conditions. Such a position can, for instance, be taken in respect of importers or entrants to the market. This risk is partly covered by the prohibition of several animal experiments per substance. This forces companies to constantly coordinate testing activities.

Coordinated behaviour

Cartel forming could also result in shared opinions about charging on costs being created, which is in conflict with EU rules on competition. This implies that clear agreements are required about sharing information within a cartel.

Concentration

It is expected that some manufacturers will stop with the manufacture of some substances because of REACH. This can lead to further concentration on the market. This increased concentration poses the risk of an economic position of power being created on some substance markets.

Transparency of the market

REACH will create more transparency concerning chemicals because more information on chemicals will become available. A certain degree of transparency on the market stimulates market forces because clients are better able to make choices. However, 'too much' transparency on the market is also possible. This is the case if parties quickly know what strategic choices their competitors have made.

Strategically, the registration of new uses is important for companies. If this information quickly falls into the hands of the other market parties, it can form an obstacle for innovation.

Closing remarks

- A. There is still a lot of uncertainty about the consequences of REACH, in particular about the indirect effects. This is because manufacturers and importers still do not know what choices they will make with respect to their substances and how the market will reorganize itself. To gain greater insight into the consequences of the implementation of REACH, it is recommended that a monitoring system be introduced, with more detailed insight being created during the phasing-in into the choices of the different parties in the chain and where to identify bottlenecks in good time.
- B. Familiarisation with REACH and the procedures for implementing the regulations will lead to a considerable one-off expense. For the implementation of the regulations, we therefore recommend devoting sufficient attention to communication with the industry;
- C. The additional costs of REACH are spread unevenly. The relatively highest additional costs are centred on substances with low volumes and prices. The additional costs for the lower volume categories are mainly registration costs. We therefore recommend investigating whether efficiency profits can be achieved with the registration of 1 to 10-tonne volumes;
- D. In absolute terms, testing costs are a significant cost item for companies, particularly for substances exceeding 10-tonne volumes. The use of alternative test methods can substantially cut these testing costs. Many of these methods are still in the development stages and still have to be approved by the authorities. Accelerating these developments and approving alternative test methods could have major cost benefits for the industry;
- E. REACH can have unintended effects, such as the disappearance of substances from the market, while it is not necessary from an environmental and/or health perspective. These effects will concern specific sectors. Looking for ways to reduce the testing and registration expenses for these sectors will create added value;
- F. Although the criteria for approval are themselves clearly formulated in the regulations, we recommend interpreting them in detail promptly to enable companies to adapt their policies as soon as possible. It can avoid unnecessary efforts by the industry and thus ensure the widest possible selection of substances on the market;
- G. In a number of areas, REACH touches upon the EU competition policy:
 - REACH assumes that there will be voluntary cartel forming. This could lead to behaviour that restricts competition in practice if parties are excluded deliberately or otherwise, or are only allowed to join a cartel under stringent conditions;
 - REACH initiates a process of chain communication, which is essential for finding the best possible economic solutions with respect to cutting back substances. Vertical coordination is partly covered by the competition policy;

From a competition perspective, horizontal and vertical coordination can lead to undesirable situations. It is therefore recommended that guidelines be issued for companies setting out the approved forms of mutual coordination. Mandatory cartel forming produces only limited cost savings because multiple testing is also not allowed for a large part under the current REACH proposal;

- H. In certain areas, the REACH regulations allow room for interpretation. This could lead to an unintended increase in Administrative Burden. Therefore, it is essential that there are clear instructions on how to deal with the regulations and how the Administrative Burden can be kept down. The current RIPs (REACH Implementation Projects) of the EU offer proper leads in this context;
- I. The substances should be registered with the European Chemicals Agency to meet the REACH obligations, for which a registration form and research data must be submitted. In the context of limiting the Administrative Burden, we suggest strictly observing the recommendation by the European Commission to use electronic data exchange wherever possible. Moreover, it is important to ascertain where and how to use (1) one-time data registrations or (2) pre-completed forms (based on the available data or data delivered once before);
- J. A substantial part of the Administrative Burden is caused by obligations relating to safety data sheets. We recommend – in the context of the new REACH regulations – ascertaining whether it is possible to change the underlying decision. A possible solution is to make SDSs available centrally to enable clients to access this information independently. A similar system is already operational in the Dutch paint sector. The duty to submit SDSs can then perhaps be scrapped;
- K. A very broad interpretation of Article 6.2 is possible within the REACH regulations. In practice, this Article could imply that all the products brought onto the market first be analysed to ascertain whether they contain unregistered substances. If such substances are discovered, it should be established whether they could also be released. Such an obligation is difficult to implement and costly, especially for SME entrepreneurs. We therefore recommend ascertaining whether it is possible to demarcate the scope of this Article;
- L. The purpose of REACH is to make more information about substances available and exchangeable. In the current situation, the information flow is primarily from the manufacturer and the importer to the downstream user and the end user (top-down). However, REACH also includes information exchange from the end user (bottom-up). Facilitating two-way communication in the chain is therefore vital, and could be taken up by the authorities as one of their roles.

Appendices to:

The consequences of REACH for the Dutch industry

Appendices

- I KPMG/TNO Review Engagement**
- II SIRA Consulting Review Engagement**
- III Supervision of the project**

I KPMG/TNO Review Engagement

1. Introduction

The European Commission (EC) strives for a new, integrated substances policy for the entire EU based on a single European regulation. On 29 October 2003, the EC published its proposal for a European Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Its aim is to both offer better protection to the public health and the environment against exposure to chemicals and improve the European industry's capacity to compete and innovate. The REACH Regulation replaces forty existing European regulations and directives. In this way, the EC wants to set up a registration system for existing and new substances. Companies are being made responsible for providing details of the characteristics and the risks (posed to public health and the environment) of the relevant substances.

REACH has potentially huge consequences for the European industry at economic, ecological, as well as social level. It concerns both the manufacturers/importers of substances (chemical industry) and the numerous users of the substances (practically the entire processing industry) and the distributors. The direct involvement of heads of government/state, such as Blair, Schröder, Chirac and Berlusconi, underlines the fact that this issue is recognised at the highest level. It certainly also applies to the Netherlands, given the scale and importance of the chemical industry. Several analyses attempt to provide insight into the consequences of the REACH proposal (including two studies by the European Commission). Nevertheless, there is a need in the Netherlands to ascertain whether these outcomes offer sufficient insight. It is anticipated that decisions about the REACH file will form one of the spearheads of the Dutch presidency of the EU during the second half of 2004. With this in mind, it is essential for the Dutch Government to obtain the most complete picture of the consequences of the proposals for the Dutch industry before the end of May 2004 to facilitate decisions about the REACH proposal. Both the Government and the industry should then have access to the results of an authoritative study, which provides insight into the consequences of the REACH proposal.

2. The issue

The core of the issue is: what opportunities and challenges or, in other words, benefits and costs, does the proposal imply for companies in the Netherlands? The costs include all the direct and indirect costs and the Administrative Burden. The latter concerns a comparison of the costs and benefits of the proposed REACH policy in relation to the prevailing substances policy in the Netherlands.

The aim is for the study to focus on both the manufacturers and the importers of substances and products, as well as the industrial consumers. The emphasis is expected to be on the effects on the small and medium-sized (SME) business sector, particularly with respect to the industrial and other commercial users of the substances.

It is important that the study distinguishes between the different target groups that are affected by the substances policy:

- a. major chemical companies (> 250 employees)
- b. chemical companies in the SME sector (< 250 employees); special attention for companies < 10 employees
- c. the commercial users of substances
- d. the companies that import chemical substances/products
- e. the traders/distributors.

3. Specific questions

Key questions

With reference to the current situation and insofar as applicable, what are, for the companies in each of these sectors:

1. the costs and benefits:
 - of testing the substances?
 - of preparing safety data sheets and reports about substances?
 - of registering the substances?
 - of evaluating the data of the substances?
2. the effects on employment, in both the positive and the negative sense?
3. the consequences for the competitive conditions with respect to other companies that operate elsewhere in the EU or outside the EU (the competitive position of Dutch companies on the markets of third countries outside the EU)?
4. the number of substances, with which companies will work. Pay special attention to companies that focus on so-called 'specialities'.
5. the positive and negative effects on innovation efforts (at larger and SME chemical companies and sectors that process substances)?

Possible additional questions

What could be the consequences of the REACH proposals in terms of the competitive conditions, particularly in the chemical industry?

To what extent is the proposed transparency about the characteristics / risks of the substances at odds with the protection of confidential business information?

II SIRA Consulting Review Engagement

1. Background

The European Commission (EC) strives for a new, integrated substances policy for the entire EU based on a single European Regulation. On 29 October 2003, the EC published its proposal for a European Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Its aim is to both offer better protection to the public health and the environment against exposure to chemicals and improve the European industry's capacity to compete and innovate.

The REACH Regulation replaces more than forty existing European regulations and directives. In this way, the EC wants to set up a registration system for existing and new substances. Companies are being made responsible for providing details of the characteristics and the risks (posed to public health and the environment) of the relevant substances.

REACH has potentially huge consequences for the European industry, at economic, ecological, as well as social level. It concerns both the manufacturers/importers of substances (chemical industry, the distributors and the numerous users and processors (downstream users) of the substances. The REACH file is a priority of the Dutch presidency of the EU during the second half of 2004.

At the instructions of the Ministry of Economic Affairs, a joint KPMG and TNO team is currently carrying out a study of the economic consequences of REACH for the Dutch industry. The study in question does not specifically focus on the Administrative Burden of the REACH proposal at operational level.

For eventual decisions concerning the REACH proposal, it is also important to obtain insight into the Administrative Burden for the industry according to the Standard Costs Model. The Ministry of Economic Affairs has therefore decided to commission a separate investigation into the Administrative Burden of REACH.

As far as REACH is concerned, the State Secretary of Foreign Affairs informed the Lower House of the Dutch Parliament by means of a written notification 'Nieuwe commissievoorstellen en initiatieven van de EU' [*New Commission Proposals and Initiatives from the EU*], no. 13: REACH, Tweede Kamer, 2003-2004 Parliamentary Session, 22112, no. 302, 23 January 2004 that the review would be commissioned by the Ministry of Economic Affairs.

2. The issue

The core of the investigation into the Administrative Burden of the European REACH substances policy is: what Administrative Burden does the proposal impose on companies in the Netherlands and what is the scale of these expenses? The calculation should be based on the current obligations imposed by the prevailing EU regulations, which are incorporated in the Chemical Substances Act (Wms) and of which the administrative costs are determined in the Nulmeting administratieve lastendruk Wms³ [*Wms Administrative Burden baseline measurement*] and the Effectmeting administratieve lasten Wms [*Assessment of the Wms Administrative Burden*]⁴.

³ Cap Gemini Ernst & Young, *Nulmeting administratieve lastendruk. Kernenergiewet, WMS, H10 Wet milieubeheer*. Utrecht, April 2001,

⁴ Cap Gemini Ernst & Young en SIRA consulting, *Effectmeting administratieve lasten*. Nieuwegein, November 2002.

The quoted reports will be made available to the research staff of the consulting firm selected for this engagement. These data should be compared to the REACH proposal, in which certain obligations remain unchanged, certain obligations will be scrapped, and new obligations will be introduced. It concerns a comparison of the Administrative Burden resulting from the REACH regulation with the burden resulting from the prevailing substances policy in the Netherlands to determine the consequences of REACH compared to the WMS. It should not only consider the consequences for the Administrative Burden in the policy area of the Ministry of Housing, Spatial Planning and the Environment (VROM), but also the consequences for the policy areas of other government departments, such as safety data sheets (Ministry of Social Affairs and Employment).

The Administrative Burden should be calculated according to the Standard Costs Model as described in 'Meten is Weten' [*measuring is knowing*] of the inter-departmental Administrative Burden project management (IPAL).

Finally, the review question also includes making recommendations concerning possibilities to reduce the Administrative Burden resulting from the REACH proposal.

III Supervision of the project

Members of the Supervisory Committee

Organisation	Name
Independent	F.J.M. Tummers (Chairman)
Ministry of Economic Affairs	H.C. van Rijswijk (Secretary)
Ministry of Economic Affairs	Chr. P. Buijink
Ministry of Housing, Spatial Planning and the Environment	J. van der Vlist
FME-CWM and on behalf of VNO-NCW	A. Kraaijeveld
MKB Nederland	J. van Walsem
Vereniging Nederlandse Chemische Industrie	Dr. C.A. Linse
Nederlandse Vereniging van Zeepfabrikanten	W.A. Pfeifer
Stichting Natuur en Milieu	A.J.M. van den Biggelaar
Chairman of the Working Committee	F.H. von Meijenfeldt

Members of the Working Group

Organisation	Name
Ministry of Economic Affairs	F.H. von Meijenfeldt (Chairman)
Ministry of Economic Affairs	H.C. van Rijswijk (Secretary)
Ministry of Housing, Spatial Planning and the Environment	J.K.B.H. Kwisthout
VNO-NCW	W.M. Zijlstra
VNO-NCW/Substances Steering Committee	Dr. C.E. Dutilh
MKB Nederland	H.H. de Groot
FME-CWM	A.H.M. Verheggen
Vereniging Nederlandse Chemische Industrie	D.F. Noordervliet
Vereniging Nederlandse Chemische Industrie	H.A.F. van Well
Nederlandse Vereniging van Zeepfabrikanten	J.A.S.J. Razenberg
Verbond van Handelaren in Chemische Producten	F.E. Hes
FOCWA	J. Horák
Stichting Natuur en Milieu	M. Kinket
<i>Special members</i>	
Chairman of the Supervisory Committee	F.J.M. Tummers
Central Planning Bureau	B. Minne
Adviescollege Toetsing Administratieve Lasten	P.F.H. Bont
Inter-departmental Administrative Burden Project Direction (IPAL)	W.A.A. Jansen
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Project team

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