Dutch survey into the consequences of the CLP Regulation for the Dutch business sector

Quickscan into the consequences of European implementation of GHS for the Dutch business sector

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Final report

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Table of contents

Summary

In 2003, the United Nations accepted a resolution in which arrangements were made concerning the classification of substances and mixtures on the basis of their hazardous properties. This system is referred to as the Globally Harmonised System (GHS). At present, consultations are being held in the European Union on its implementation within European legislation in the Regulation for the Classification, Labelling and Packaging of Substances and Mixtures (CLP).

To determine the Dutch position in relation to the implementation of the CLP regulation, the Ministries of Economic Affairs and of Health, Welfare and Sport have had a survey conducted into the consequences of the CLP Regulation for the Dutch business sector in order to obtain a better understanding of:

1. The direct and indirect costs (including administrative burdens) and benefits. A distinction is made in this regard between one-off and recurring costs and benefits.
2. The differences for Dutch companies in relation to the Impact Assessment as carried out by the European Commission.
3. The consequences for national legislation and regulations, which will need to be adjusted or amended as a result of the CLP Regulation.

Principles and working method

The survey into the effects of the CLP Regulation on the Dutch business sector has been carried out in collaboration with experts and businesses. Furthermore, research has been conducted into the target groups' macro-economic data. With regard to this, and in addition to information from the Central Bureau of Statistics (CBS), previous market surveys and analyses that were conducted within the context of the Impact Assessment for REACH[1] have also been used.

The present situation

In the Netherlands, over 52,100 companies are actively involved with hazardous substances. The table below shows how these companies are distributed across the various target groups. In total, these companies produce, process and market approximately 665 different hazardous chemical substances and approximately 345,000 mixtures in which these substances have been used.

Table S1. Overview of target groups and number of companies

No.	Target groups	Number of companies
1	Base chemical industry	260
2	Speciality chemical industry[2]	625
3	Importers	520
4	Traders	2,620
5	Manufacturing industry	1,225
6	End-users	45,055
7	Retailers	1,795
	Total	**52,100**

[1] Registration, Evaluation and Authorisation of Chemicals.
[2] The speciality chemical industry includes speciality chemistry and formulators.

In the current situation, the European Substances and Preparations Directives apply to the classification and labelling of hazardous substances and mixtures. In the Netherlands, this regulation has been implemented in the Chemical Substances Act and the underlying decrees. On the basis of this and other legislation and regulations, the Dutch business sector has obligations in respect of:

1. Classification of substances and mixtures.
2. Labelling of substances and mixtures.
3. Packaging of substances and mixtures.
4. Registration and notification.
5. Maintaining availability of information.

New integral regulation: the CLP Regulation

The CLP Regulation integrates current European regulations to a significant extent and ensures that these link up with the GHS. The supposition in this regard is that the current obligations remain the same and that the current system should be amended by means of reclassification and re-labelling once only. Regarding the implementation of the CLP Regulation, the premise is for a transition period up to 2013 (Scenario 1) or a transition period up to 2015 (Scenario 2).

Quantifying costs and benefits

The Standard Costs Model has been used to calculate the direct and indirect costs (including administrative burdens) and benefits. This model quantifies the total costs of the CLP Regulation for each obligation based on the numbers of substances and mixtures and the number of companies for each target group. Given the fact that the CLP Regulation is a proposal, assumptions and suppositions have been made to obtain an understanding of these obligations. These have been summarised in the table below. Whether these result in an overestimate or underestimate of the actual costs in the calculation is indicated next to each assumption.

Table S2. Overview of overestimation or underestimation of the actual costs for each assumption.

No.	Assumption	Over or underestimate	Explanation
1.	Full compliance.	Overestimate	The survey did not take into account failure to comply with the obligations. Companies that did not comply with their obligations, or only to a limited extent, have lower costs than calculated in this survey.
2.	Required data for the classification of substances are known. Conducting tests is unnecessary.	Neutral	This survey assumes that the data necessary for the classification of substances are already known on the basis of REACH or the Chemical Substances Act. Consequently, additional tests are unnecessary.
3.	The classification for environmental and health hazards according to the CLP Regulation is calculated for mixtures.	Neutral	This survey assumes that manufacturers, although permitted to do so, do not carry out additional tests to establish the classification.
4.	The average replacement period for substances is 10 years.	Neutral	A proportion of the substances, and thus a proportion of the mixtures, will be replaced during the transition period as a result of standard commercial operations.
5.	Large Dutch businesses use specialised ICT systems for classification.	Underestimate	This study assumes that all large manufacturers and producers devote little time to reclassification because they employ specialist ICT applications. In practice, the activities required for classification can be more extensive for a proportion of the companies than assumed by this survey.

No.	Assumption	Over or underestimate	Explanation
6.	Small-scale companies use simple, often semi-manual methods for (re-) classification.	Overestimate	This survey assumes that none of the small-scale manufacturers and producers has any specialist software to use for reclassification. In practice, a limited number of these companies do have ICT solutions at their disposal, making the required activities more limited than is assumed in this survey.
7.	The number of substances and mixtures with a classification does not increase as a result of the CLP Regulation.	Underestimate	The proposal for the CLP Regulation indicates that the number of classified mixtures will increase. This increase has not been quantified in this survey, meaning that the actual costs could come to be higher than calculated in this instance.
8.	The consequences of changes to classification as a result of the CLP Regulation have not been quantified.	Underestimate	A proportion of the substances and mixtures will acquire a different classification as a result of changed cut-off values. This can have consequences for commercial operations (storage, etc.). This survey does not include possible changes to commercial operations as a result of changed classifications. Consequently, the actual costs may come to be higher.
9.	Consumer products are provided with a new label once every 5 years, industrial products once every 10 years.	Neutral	A proportion of the labels will be replaced during the transition period as a result of standard commercial operations.
10.	When making calculations, differences in the dimensions of labels have not been taken into account.	Underestimate	Creating a small label takes more time than a large label. This survey has proceeded exclusively on the basis of large labels with regard to the time required for creating a label. Consequently, the actual costs may be higher than calculated.
11.	The quantity of information on the label remains the same.	Underestimate	The proposal for the CLP Regulation indicates that more space is needed on labels, meaning that fewer languages fit on a label. As a result, the number of labels required may increase. However, it is assumed in this survey that the same quantity of information can be printed, meaning that the number of labels will not increase. Consequently, the actual costs may be higher than calculated.
12.	Only one label is in circulation for every substance and every mixture.	Underestimate	In practice, several sizes of packaging are often available for a substance or mixture. Consequently, several different labels are often in circulation for each substance or mixture. It is assumed in this survey that one label is used for each substance or mixture. Consequently, the actual costs may be higher than calculated.
13.	All of the existing substances have been registered and all of the required notifications have been issued.	Neutral	This survey assumes that all of the substances already on the market have been registered correctly and that no additional notifications are necessary.

The direct costs of the CLP Regulation

Figure S1 illustrates the direct annual costs as a result of the CLP Regulation in terms of the current situation, the transition period and the intended situation. Furthermore, a distinction is made between one-off and recurring costs.

The most important findings in respect of the direct costs are:

1. *The recurring costs for classification and labelling stay the same if the number of substances and mixtures on which the CLP Regulation has been based stay the same.* In other words, the procedures for classifying and labelling hazardous substances do not change. However, the recurring costs probably *will* increase if it should prove – and this has not been taken into account in the current calculations – that, due to the CLP Regulation, more substances and mixtures are to be classified as hazardous and thus will be subject to more stringent rules.

2. *The extent of the one-off costs is determined by the length of the transition period.* In the case of a transition up to 2013, the total one-off costs are estimated at € 276 million, and at € 145 million in the case of a transition up to 2015. This is largely brought about because more labels can be changed in the standard operating process in the event of a longer transition period.
3. *The activities with the highest one-off costs are (1) examination of the new CLP Regulation rules, (2) reclassification and (3) the replacement of labels*. Depending on the chosen transition period, these activities are the top three cost items for the business sector.
4. *The highest one-off costs are for the target groups of the speciality chemical industry and end-users.* Regarding the speciality chemical industry, this is mainly due to the large number of mixtures that are produced. Regarding end-users, this is mainly due to the large number of companies in this target group that are confronted with the CLP Regulation.

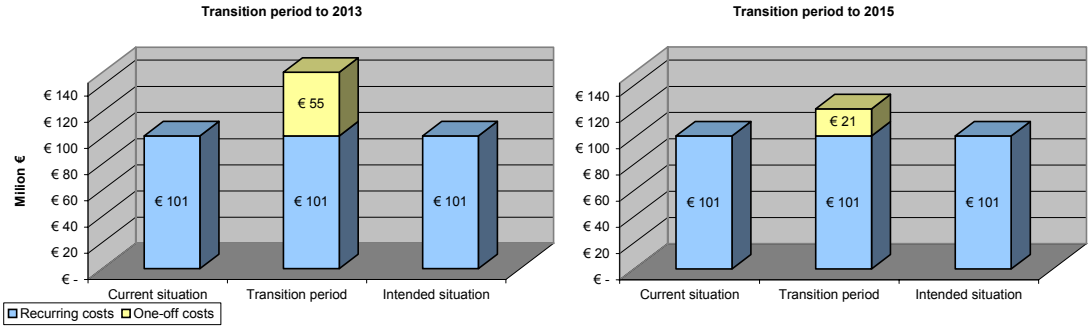


Figure S1. Overview of the progression of the CLP Regulation's annual direct costs for both transition periods.

The indirect costs of the CLP Regulation may rise

With regard to the indirect costs, this largely involves the consequences arising from the classification of substances and mixtures. In specific terms, this may mean that mixtures, which in the current situation have been classified as 'limited risk' or 'not dangerous', will be classified as being dangerous or more dangerous as a result of the CLP Regulation. If current legislation continues to be enforced, this may have the following consequences[3]:

- Different requirements for the establishment due to changes to the quantities of hazardous substances. A shift towards classifications indicating greater danger may mean a report being made to the competent authorities or, in other cases, an amendment of the Environmental Protection Act license.
- Different requirements for storage facilities. The regulations regarding the storage of hazardous substances are related to storage quantities. A more stringent classification means stricter requirements for storage in line with the Dutch Directive on Working with Dangerous Substances[4].
- Different requirements for packaging. A more stringent classification may mean different requirements being set for packaging. One possible example of this is in the soap

[3] The Dutch government intends to amend adjoining legislation in such a way as to limit these indirect consequences as far as possible.
[4] The Dutch name for this directive is: 'Publicatiereeks Gevaarlijke Stoffen' (PGS).

sector. A different classification as a result of the CLP Regulation may mean that agents containing surfactants must be provided with childproof seals.

The consequences of the CLP Regulation affect SME enterprises in particular

The most important costs of the CLP Regulation are caused during the transition period. It is in this period that companies should adjust the classification and labelling of substances and mixtures. Larger companies will be able to implement these changes centrally, keeping costs down in relation to total commercial operations. However, SME enterprises will be more dependent on suppliers during the transition period. Moreover, SME enterprises have less capacity to anticipate the changes resulting from the CLP Regulation. This means that costs may rise considerably in relation to the total costs for commercial operations.

The benefits of the CLP Regulation are largely for companies operating internationally

The primary aim of the CLP Regulation is for global harmonisation of the rules for the classification and labelling of dangerous substances and mixtures. Consequently, the most important benefits of the CLP Regulation focus on international trade and international companies. In specific terms, this means that:

- Dutch companies that trade only within the EU will be faced with more univocal rules as a result of the CLP Regulation.
- Dutch companies that trade outside of the EU will be faced with fewer differing rules. The fact to emerge from this survey is that minor differences still persist between the EU and non-EU countries that are implementing the GHS.
- Companies that trade or work exclusively in the Netherlands will not experience any benefits as a result of the CLP Regulation.

Given the fact that the most sizeable target groups in the Dutch business sector – notably, end-users, traders and retailers – have a largely national focus, the benefits for the Dutch business sector as a whole will remain limited. Therefore, the benefits are not quantified in more detail in this Quickscan.

The CLP Regulation requires the intrinsic amendment of national legislation and regulations

With the implementation of REACH, the Chemical Substances Act will cease to be effective and many decrees will be incorporated under the Environmental Protection Act. As a result of this, it is necessary in the case of the CLP Regulation only to amend regulations that make intrinsic use of the current (Chemical Substances Act) classification system. This relates to:

- the Environmental Protection Act.
- the Risks of Major Accidents Decree.
- the Packaging and Designation of Environmentally Dangerous Substances and Preparations Decree.
- Further rules on packaging and the designation of environmentally dangerous substances and preparations.
- the Safe Packaging of Household Chemicals (Consumer Goods Act) Decree.
- the Registration of Information on Preparations (Consumer Goods Act) Decree.
- the Dutch Directive on Working with Dangerous Substances (PGS).
- General Assessment Methodology for substances and preparations.

As a result of the CLP Regulation, there must be an amendment of the articles in the aforementioned regulations, which employ the classification of hazardous substances and mixtures in order to compile rules for establishments and persons. However, it does not stop at the amendment of these regulations. The licensing authorities and inspectors who work with these regulations should also be properly instructed. Differences of interpretation can result in additional expense and irritation for companies.

The results of the NL and EC Impact Assessment differ on a few points

The Dutch study endorses the view that recurrent effects as a result of the CLP Regulation remain limited. However, the calculated one-off direct costs differ significantly from the EC Impact Assessment. The latter calculates that the costs for the European business sector will amount to € 544 million or € 526 million respectively, depending on whether the transition period runs until 2013 or until 2015. This survey shows that the cost will amount to at least € 145 million for the Dutch business sector alone.

1 Introduction

1.1 Background

In 2003, the United Nations accepted a resolution in which arrangements were made about the classification of substances and mixtures based on their intrinsic hazardous properties. With regard to this, a global system was also established for the labelling (Classification and Labelling: C&L) of these substances and mixtures. This system is referred to as the Globally Harmonised System (GHS). A system based on the GHS for the classification of substances and mixtures according to their hazardousness is already being used in Europe for transport. In relation to the use of substances and preparations, work is being done on hazard classifications and labelling in Europe using the European Directive on Substances and Preparations[5].

At present, consultations are being conducted in the European Union on the implementation of the GHS within European regulations. In the new European Regulation on the Classification, Labelling and Packaging of Substances and Mixtures (CLP), rules in respect of hazard classifications and labelling deriving from the Substances and Preparations Directive are to be incorporated and brought in line with the GHS. To that end, the GHS will also be applicable to the production, use and storage of substances and mixtures in addition to transport. In the current European directives, the classification and labelling for substances and mixtures during production and in the user phase is already largely the same as the regulations relating to working conditions, consumer protection and the environment.

In order to determine the consequences of introducing the CLP Regulation on companies in Europe, the European Commission has had an Impact Assessment carried out. It is not possible to get a hold of the consequences for the Dutch situation, partially because this Impact Assessment lacks the argumentation on which it is based. However, to determine the Dutch position with regard to the implementation of the CLP Regulation, it is necessary for its consequences on the Dutch business sector to be known.

Therefore, the Ministries of Economic Affairs and of Health, Welfare and Sport have had the project carried out entitled “Dutch survey into the consequences of the CLP Regulation for the Dutch business sector”. A Quickscan was conducted in this project to discover the consequences on the administrative burden for the Dutch business sector on the one hand and to gain an understanding of the CLP Regulation’s other consequences (the benefits and the one-off and recurring costs) on the other.

This report presents and explains in detail the results from the Quickscan into the consequences of the CLP Regulation’s implementation for the Dutch business sector.

[5] 67/548/EC and 99/45/EC.

1.2 Project objectives

The objectives of the project entitled "Dutch survey into the consequences of the CLP Regulation for the Dutch business sector" can be described as follows:

- *To obtain an understanding of the consequences of introducing the CLP Regulation for the Dutch business sector, partly with regard to administrative burdens.*
- *To obtain an understanding of the costs set against the benefits for the various links in the chemicals sector supply.*
- *To provide a foundation for determining the position of the Netherlands concerning the findings of the European Commission's Impact Assessment.*
- *To obtain an understanding of the follow-up regulations in the Netherlands based on classification and labelling.*

Box 1. Constituent questions that are answered in this survey.

- What changes does the CLP Regulation result in?
- What are the non-recurring costs for the Dutch business sector for introducing the CLP Regulation in the following transition scenarios:
  - Starting date for substances is the publication date of the regulation until taking effect December 1st 2010. Regarding mixtures, this period runs from December 1st 2010 until June 1st 2015.
  - Starting date for substances is the publication date of the regulation until taking effect December 1st 2010. Regarding mixtures, this period runs from December 1st 2010 until December 1st 2013.
- Which transitional period entails the least cost for the Dutch business sector in addition to the aforementioned transition scenarios?
- Which Dutch environmental, safety and working conditions regulations (both material legislation as well as other obligations, such as the NeR and the directives for the storage of dangerous substances) are based on or refer to classification and labelling regulations? And, in general terms, which of the changes to that legislation as a result of introducing the CLP Regulation would give rise to costs and administrative burdens?
- Are adjustments possible in the EU's proposal for the implementation of the CLP Regulation that would result in fewer costs for the business sector?

2 Principles and working method

In this survey, the costs facing companies within the context of the CLP Regulation will be mapped out as fully as possible by means of a Quickscan. A distinction is made in this regard between administrative burdens, as defined by the Regulatory Influence Governance Group (Regiegroep Regeldruk), and other costs. Section 2.2 explains the definition of the administrative burdens in more detail. The remaining sections in this chapter describe the survey's other general principles. In other words, this not only relates to the principles for calculation of the administrative burdens, but also the other costs and subjects described on a qualitative basis.

2.1 The European Commission's Impact Assessment

The European Commission has had an Impact Assessment carried out in order to map out the consequences of the CLP Regulation for the European business sector. This EC Impact Assessment estimates the extent of three types of economic outcomes:

1. *One-off costs.* These are non-recurring costs as a result of the transition.
2. *Recurring costs.* These are recurring costs as a result of the amended and new regulations deriving from the CLP Regulation.
3. *Benefits.* These are the recurring benefits arising as a result of the CLP Regulation.

The underlying survey has been conducted in order to be able to provide a thorough basis for determining the position of the Netherlands vis-à-vis the findings of this EC Impact Assessment. This survey makes a Quickscan of the consequences of the CLP Regulation for the Dutch business sector on the basis of the principles employed for the EC Impact Assessment. To describe the Dutch situation, additional focus is placed on:

- Subjects that have not been (sufficiently) included in the EC Impact Assessment.
- Subjects regarding which the Dutch situation differs significantly from the EC Impact Assessment's principles.

Remarks regarding the EC Impact Assessment

The EC Impact Assessment makes a clear distinction between subjects that have been included in the study and subjects that have been left unconsidered. This information, combined with the structure of the EC Impact Assessment, provides good starting points for further research. This concerns the following points:

- *National regulations are left aside*. The degree to which national regulations attach obligations to the manufacture, trading and use of chemical substances and mixtures co-determines the consequences of the CLP Regulation for the businesses in a given country. The recurrent effects on companies are greater in countries where, alongside the Directive on Substances and Preparations, few or no obligations apply in respect of chemical substances and mixtures, because they will be faced with a larger number of new obligations. Recurrent effects are fewer in countries where comprehensive additional regulations do apply in respect of this subject, as is the case in the Netherlands. However, the one-off costs for making the transition to another system may be higher.

- *Data lacking adequate foundation.* The provenance of the data used in the EC Impact Assessment is not always known. As a result, it is difficult to verify the accuracy of these figures. Furthermore, this limits the opportunity to employ the data for national analysis.
- *Implementation variances between member states have been left aside.* The draft regulation contains obligations for both companies and member states. The way in which member states fulfil their obligations can differ according to the member state concerned. Consequently, the administrative burdens and compliance costs as a result of the proposed regulation can vary from country to country. At the time of conducting this survey, such possible implementation variances were not yet known. Therefore, this survey does not take them into account.
- *Limited focus given to the effects on SME enterprises.* The EC Impact Assessment makes only a limited distinction between the consequences for large and SME enterprises. The European study indicates that "the overheads for training and IT bear relatively heavily on SME[6] suppliers of chemicals". Moreover, it is noted that SME enterprises are involved principally in the production of mixtures. To limit the costs for SME enterprises, the EC Impact Assessment advises to put in place a transition period for mixtures up until 2015[7]. However, the effects of the CLP Regulation for SME enterprises are not elaborated upon or quantified in more detail.

Deviation from the Dutch situation

The EC Impact Assessment differs significantly from the Dutch situation due to the focus being placed principally on the manufacturers of substances and the producers of mixtures. Consequences for the supply chain, including importers, traders, manufacturing industry and end-users, are not taken into account. These enterprises will also be confronted with the changes resulting from the CLP Regulation. In the EC Impact Assessment a significant proportion of the consequences are left aside due to the large number of enterprises accommodated within these target groups. In addition, the situation experienced by these enterprises is often different from that experienced by manufacturers and producers. A couple of examples of this are:

- *The presence of ICT solutions.* The EC Impact Assessment assumes a situation in which the ICT solutions required are readily available. From the perspective of the manufacturers, this is generally the case. However, the ICT facilities for many other companies are often limited, especially where SME enterprises are concerned. While the large companies often operate using special, tailor-made ICT packages, small enterprises are more likely to use generic programs, such as Excel[8]. The investments required for these enterprises can be significant.
- *Imports to and exports from the EU.* The EU Impact Assessment analysed the import and export of chemical substances and mixtures from the perspective of manufacturers and producers importing to or exporting from the EU. This does not take into account those enterprises ordering substances and mixtures in non-EU countries. Although the suppliers are obliged to provide the correct information, in practice it is now the case

[6] Small and Medium Enterprises, comparable with the Dutch term 'MKB'.
[7] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006, IMPACT ASSESSMENT, 27.6.2007, pages 21 to 23 inclusive.
[8] This was reported by respondents from the smaller-scale enterprises in the survey and demonstrated to the researchers.

that importers have to go to great lengths to acquire this information in full. In some cases, the importers have to compile the information themselves.

Principal issues for the Quickscan

A number of points arose on the basis of the subjects clarified above on which the underlying study focused its attention. These are as follows:

- A number of subjects were not included in the EC Impact Assessment of the CLP Regulation. Nevertheless, these have significant consequences for the Dutch business sector. The subjects to have been included in *this* survey are:
  1. The relevant Dutch regulations affected by the CLP Regulation.
  2. An argumentation for the assumptions and quantitative results.
- The EC Impact Assessment made only a limited distinction between the consequences for large companies and SME enterprises. This survey clarifies and, whenever possible, quantifies the various effects in more detail. To distinguish between the various groups of enterprises, these have been linked to the REACH impact assessment[9] and the breakdown that the Central Bureau of Statistics (CBS) made regarding employee numbers on the basis of the SBI '93 classification of businesses. This type of classification is further explained in Annex VI.
- The EC Impact Assessment principally took the consequences for producers and manufacturers into account. In addition to these consequences, this Quickscan also maps out the consequences for the underlying chain, such as importers and professional end-users.
- Alongside the direct costs – the costs that companies encounter directly because of obligations deriving from the CLP Regulation – indirect costs also need to be examined. These indirect costs are costs that companies have for activities that, while not directly prescribed by the CLP Regulation, arise nevertheless from the effects of the CLP Regulation on the business sector (e.g. as a result of changes to adjoining regulations that have to be amended by the CLP Regulation).

2.2 Definitions and survey methodology

Administrative burdens and compliance costs

To be able to guarantee its public interest, the Dutch government imposes obligations on the business sector for the performance or omission of actions or behaviour (intrinsic obligations) and, additionally, obligations for providing information about such actions and behaviour (information obligations):

- *Information obligations*. To fulfil the information obligations, companies must undertake action, such as the completion of forms or the compilation of supplementary information. The costs incurred by companies in this regard have been defined as administrative burdens[10]. The definition (see text box below) and the methodology for calculating the administrative burdens have been worked out in the manual entitled "Meten is Weten II" produced by the Regulatory Influence Governance Group[11].

[9] 'REACH administrative burden impact assessment', SIRA Consulting, June 2004.
[10] The term 'administrative burdens' is abbreviated to 'AB'.
[11] "Meten is Weten II", Regulatory Influence Governance Group (Regiegroep Regeldruk), 2007.

- *Intrinsic obligations.* To fulfil the intrinsic obligations, companies must undertake certain types of action, such as the display of hazard information on labels and the storage of substances and mixtures in a correctly designed storage facility. The costs incurred by companies in this regard have been defined as the compliance costs. Unlike the administrative burdens, a standard method for calculating the compliance costs is not available. The text box below illustrates the definition of compliance costs employed in this survey. This definition has been coupled with the definition for administrative burdens.

Administrative burdens

Administrative burdens are the costs the business sector has to comply with information obligations stemming from the government's legislation and regulations. This involves the compilation, processing, registration, storage and disposition of information.

These costs relate to the time spent by the companies (expressed in hours and multiplied by an hourly rate) and the (out-of-pocket) expenses incurred (expressed in euros).

Source: Regulatory Influence Governance Group [Regiegroep Regeldruk] (2007), Administrative burdens manual – "Meten is Weten II"

Compliance costs

Compliance costs are the costs the business sector has to comply with intrinsic obligations stemming from the government's legislation and regulations. This involves all actions required to fulfil the content of these regulations.

These costs relate to the time spent by the companies (expressed in hours and multiplied by an hourly rate) and the (out-of-pocket) expenses incurred (expressed in euros).

This survey distinguishes between two types of administrative burden and compliance cost, i.e. non-recurring and recurring costs.

- *Non-recurring costs*. These are the costs that companies must incur once only to be able to comply with the regulations. These non-recurring costs can be broken down into two types:
  - Non-recurring administrative burdens. These are the costs arising from information obligations that have to be carried out only once on the introduction of new rules or an amendment of existing rules.
  - Non-recurring compliance costs. These are the costs that companies must incur only once in order to adapt systems or business operation processes to the new intrinsic obligations. In other words, this relates to non-recurring costs that companies have to incur which do not come directly under the definition for administrative burdens.
- *Recurring costs.* These are the administrative burdens that companies have to incur annually in order to comply with their obligations. These costs can also be broken down into two types:
  - Recurring administrative burdens. These are periodically recurring costs that companies must incur to be able to comply with information obligations in existing rules.
  - Recurring compliance costs. These are the periodically recurring costs that companies must incur to be able to comply with intrinsic obligations in existing regulations.

The CLP Regulation cost model

The costs, consisting of administrative burdens and compliance costs, are calculated in line with the standard cost model (SCM).[12] In an SCM, obligations are specified up to the level of action that companies must undertake in order to fulfil their aforementioned obligations.

The total cost is then determined by multiplying the cost of an action (P) by the number of actions (Q) to which this applies. The costs for an action are calculated as the product of the time spent plus the hourly rate. The following principles have been employed in drawing up and for the use of the CLP cost model:

- *Standard Cost Model (SCM)*. The method for calculating administrative burdens is based on the principles established in the manual entitled "Meten is Weten II" produced by the Regulatory Influence Governance Group (2007). Calculation of the compliance costs adheres to this method.
- *Open structure*. The Standard Cost Model has been created to have an 'open structure'. This means that the SCM includes in manner that is verifiable and allows insight in:
  - The information obligations concerned (the relevant legislative section).
  - The (constituent) actions that companies must undertake to fulfil the obligation.
  - How the calculation of costs for this is to be performed.
- *Average efficient company.* The calculations are based on 'the average efficient company'. These are companies that are representative for their respective target groups and which conduct their business with average efficiency.
- *Compliance.* 100% compliance is assumed when calculating the administrative burden, unless actual compliance is found to differ considerably from this on the basis of the assessment. The model is labelled in such an instance.
- *Only the costs without the benefits*. The SCM gauges only the costs. Possible benefits are left aside. However, these are described separately in this survey, although they do not form part of the calculations using the CLP-SCM.
- *Mixed functions.* A number of information obligations will also be carried out if these have not been laid down in legislation (or international regulations). In the event of these mixed expenses, a label is used to indicate the component of the costs of this mixed function that is as a result of regulation.
- *Previously executed baseline measurements.* Previously executed baseline measurements of administrative burden have been used to determine the administrative burden resulting from the CLP Regulation, i.e.:
  - 'Ministry of Housing, Spatial Planning and the Environment administrative burden baseline measurement', SIRA Consulting, April 2004.
  - 'Ministry of Social Affairs and Employment administrative burden baseline measurement' EIM, February 2004.
  - 'REACH administrative burden impact assessment', SIRA Consulting, November 2005.

[12] This report often uses the abbreviation SCM for the term "Standard Cost Model". The CLP cost model (CLP-SCM) is brought about by specifically implementing the SCM for the CLP Regulation. However, the CLP-SCM calculates the other costs (compliance costs) as well as the administrative burdens.

- *Unamended policy.* The Quickscan assumes a future situation in which Dutch policy has not been amended.
- *Focus on Supply & Use.* This survey is analysing the consequences of the CLP Regulation on the production and supply of chemical substances and mixtures and their use. The indirect effects of regulation on transport and waste have not been included, because these do not come within the scope of the survey.
- *Preventing an overestimate of costs.* When calculating the costs, it has been decided for the purposes of this Quickscan to avoid overestimating the burden as far as possible. This means that costs have been included in the calculations only when it is certain that they will have to be incurred. When, in the absence of reliable, available data, it was necessary to make assumptions, the premise was to take a conservative approach and thus, as far as possible, prevent overestimates. Consequently, the total calculated costs are, as anticipated, lower than the actual costs as a result of the CLP Regulation.

Hourly rates

Two hourly rates are employed in this survey: a high hourly rate for action undertaken by upper management and a low hourly rate for action that can be undertaken by subordinate management and operational personnel (e.g. production staff, retail staff and warehouse staff). The level of these rates is based on data supplied by the respondents and the CBS's pay statistics. Annex V illustrates in more detail how these hourly rates have been determined. The table below provides an overview of the hourly rates for each target group. This relates to the internal, non-commercial, hourly rates, including overheads.

Table 1. Overview of hourly rates for each target group.

Nr.	Target groups	Hourly rate 2007 High	Low
1	Base chemical industry	€ 90	€ 55
2	Speciality chemical industry	€ 90	€ 55
3	Importers	€ 75	€ 35
4	Traders	€ 60	€ 35
5	Manufacturing industry	€ 70	€ 40
6	End-users	€ 60	€ 35
7	Retailers	€ 45	€ 25

Interviews

Twenty interviews were conducted to obtain proper (quantitative and qualitative) insight into the consequences of the CLP Regulation for these companies. The table below illustrates the distribution of interviews among the various target groups. The diversity of activities within the target groups was taken into account when selecting the number of interviews per target group.

Table 2. Overview of interviews for each target group.

No.	Target groups	Number of interviews
1.	Base chemical industry	3
2.	Speciality chemical industry	5
3.	Importers	2
4.	Traders	2
5.	Manufacturing industry	4
6.	End-users	2
7.	Retailers	2

Total	**20**

The companies interviewed were supplied by representatives from the industry and trade associations which were involved in the survey. With regard to this, the representational nature of the companies was considered, as well as the knowledge that the companies already possessed about the CLP Regulation. Interviews were conducted both with companies already aware of the consequences of the CLP Regulation and with companies in which this was not the case. In preparation of the interviews, the respondents received an explanation of the project prior to commencing the interview.

2.3 Risk management

When conducting the survey, a number of risks came to light that could have affected the results of the project. This section mentions these risks and indicates the way in which they were dealt with in the project.

- *Respondents had a limited idea about the CLP Regulation.* Many of the respondents do not have a clear idea of the consequences that the CLP Regulation has for their companies. This varies according to the type of company concerned:
  - The consequences for large companies are sometimes difficult to gauge, because their activities are distributed among several departments or even among several countries.
  - Many SME enterprises do not have a pre-emptive attitude towards taking notice of new regulations. They take notice of new regulations only once they come into effect.

  A great deal of attention was given to providing information, consequently ensuring that all respondents in the survey were sufficiently informed about the CLP Regulation and thus able to supply the correct data. To that end, a comprehensive explanation was compiled that clarified the consequences of the CLP Regulation. This was sent to the respondents in advance so that all of them could familiarise themselves with the anticipated changes. Consequently, the respondents were able to map out the consequences beforehand in the lead-up to the interview. In addition, a great deal of attention was also given to clearing up all areas of confusion both during and after the interviews. This enabled the companies surveyed to answer all of the questions, even if they had not known anything about the CLP Regulation previously.

- *Dealing with uncertainties.* It emerged in the course of the survey that neither the precise consequences of the CLP Regulation nor the number of substances and mixtures to which the regulation relates were yet known in full. In order to arrive at a reliable estimate of the consequences, this was dealt with as follows:
  - A set point of departure was decided upon regarding the proposed regulation. This related to the text of the CLP Regulation dated June 27th 2007. Any subsequent amendments to this were not included in the survey. This to prevented possible confusion among the respondents.
  - Data from the REACH impact assessment and the data obtained from the interviews were used to determine the numbers of substances and mixtures. These numbers were then presented to employees of the Netherlands Organisation for Applied Scientific Research (TNO). Since the number of mixtures has a major effect on the level of cost due to the CLP Regulation, a conservative extrapolation

was made to prevent an overestimate of the number of mixtures and thus the costs involved. Annex III indicates how the number of mixtures was determined.

- *Representational nature of survey data.* This survey takes the form of a Quickscan, whereby the survey information used is amassed on the basis of a limited number of interviews with respondents. A number of measures were taken to ensure that, despite this limitation, a representative view was obtained regarding the consequences of the CLP Regulation:
  - From among the limited number of companies, companies were surveyed in consultation with the industry and trade associations that were representative of the sector that they represented. A focus was also placed on the representational nature of the companies in the interviews.
  - Representatives from SME Netherlands and the Confederation of Netherlands Industry and Employers (VNO/NCW) were closely involved in the survey. They have been presented with all of the results from the survey.
  - The data most affecting the calculations were researched in more detail. All of the assumptions necessary to arrive at the data used have been clarified in the annexes to this report.

3 The Globally Harmonised System

3.1 Current situation

In the Netherlands, the Chemical Substances Act applies to primary substances policy in respect of the environment. This contains provisions that include general rules for the marketing of substances and mixtures. The Chemical Substances Act ends in 2008, and these regulations will be adopted in REACH and in Chapter 9 of the Environmental Protection Act. A brief explanation of these regulations is given below.

Chemical Substances Act

The purpose of this legislation and underlying policy can be summarised as follows: "To ensure the safe use of substances, in all stages of the lifecycle (from chemical product through (consumer) substances and mixtures to waste and recycling), such that the public and the environment are not exposed to any – or only negligible – hazards and risks. Health and safety risks resulting from the professional use of substances should also be minimised in the working environment."[13]

The Chemical Substances Act is largely an enabling act. This means that the execution of this legislation is regulated in part by decrees. These decrees include within them a description of the current system for providing information on substances. The legislation and decrees have been based mainly on European directives and regulations that have been implemented within Dutch regulations by the Chemical Substances Act.

Registration, Evaluation and Authorisation of CHemicals (REACH)

The purpose of REACH is (1) to provide better protection to public health and the environment against exposure to chemicals and (2) to improve the competitive and innovative capacity of the European business sector. According to the European Commission, REACH must result in a system of substance registration in which enterprises are responsible for supplying information about substance properties and risks (to the public and the environment). This involves all substances that are marketed or used as intermediary products. A number of substances have been exempted by the REACH regulations, because separate regulations apply to them. For a comprehensive description of the REACH regulations, please refer to Chapter 2 of the study entitled "The Consequences and Administrative Burden of REACH* for the Dutch Industry" (June 2004) conducted by the Netherlands Organisation for Applied Scientific Research (KPMG/TNO) and SIRA Consulting.

[13] Strategy Statement on Dealing with Substances - Ministry of Housing, Spatial Planning and the Environment, April 2002.

Environmental Protection Act

The Environmental Protection Act came into being on 1 January 1993 deriving from the General Provisions for Environmental Hygiene Act. The Environmental Protection Act is a framework act that includes general rules, such as those in respect of environmental schemes and programmes, environmental quality requirements, establishments, waste materials and procedures. Chapter 9 of the Environmental Protection Act includes regulations in respect of substances and mixtures. With the lapse of the Chemical Substances Act, this chapter will be expanded to include the regulations from the Chemical Substances Act that do not overlap or conflict with REACH. The specific content of the Environmental Protection Act is provided by means of implementation decrees, referred to as Orders in Council.

Other Dutch regulations

There are a great many acts, decrees and regulations that refer to the Chemical Substances Act and which, as a result, are affected by the CLP Regulation. REACH comes into effect in 2008, and all of the sections in the Chemical Substances Act will be adopted in REACH or in the Environmental Protection Act. As a result of this, all existing references to the Chemical Substances Act have to be amended to refer to the correct article or section in REACH or the Environmental Protection Act. A proportion of these technical changes have to be carried out again as a result of the CLP Regulation's implementation. Furthermore, acts, decrees and regulations making intrinsic use of legislation in respect of classification, labelling and packaging have to be amended so that they refer to the correct articles in the CLP Regulation.

The table below provides an overview of the regulations to which significant amendments to the content will have to be made as a result of the CLP Regulation. This overview has been made in collaboration with representatives from the Ministries of Health, Welfare and Sport and of Housing, Spatial Planning and the Environment[14]. Annex VII provides a complete overview of all the regulations that will have to be amended as a result of the CLP Regulation.

Table 3. Acts, decrees and regulations requiring amendment of content due to the CLP Regulation.

Nr.	Name
	Regulation
1	Environmental Protection Act
2	Risks and Major Accidents Decree
3	Packaging and Designation of Environmentally Dangerous Substances and Preparations Decree
4	Further rules on packaging and the designation of environmentally dangerous substances and preparations
5	The Safe Packaging of Household Chemicals (Consumer Goods Act) Decree
6	The Registration of Information on Preparations (Consumer Goods Act) Decree
	Directives
7	Dutch Directive on Working with Dangerous Substances (PGS) *
8	General Assessment Methodology for Substances and Preparations (ABM)

* This directive is now based on the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). Any amendments might be limited as a result of this.

The amendments to the aforementioned legislation and regulations may have a significant effect on the total cost of this regulation for the Dutch business sector. Notably, the regulations and directives referred to in the above table employ the classification of hazardous substances

[14] National and European regulations are interwoven to such an extent that it is not possible to draw distinctions between them in the present case.

to set additional requirements for establishments. If the classification of a substance or mixture changes due to the CLP Regulation, the requirements for establishments may also change. This may result in indirect costs. An example of this has been included in the text box below.

Box 2. Example of indirect costs due to adjoining regulations.

Administrative burden from the Risks and Major Accidents Decree (BRZO) are estimated to amount to € 4.3 million per year divided among 253 companies. (Min. of Housing, Spatial Planning & the Environment's administrative burden baseline measurement, 2002). If fewer or more companies should come under the terms of this regulation due to amendment of the BRZO, the burden will change in proportion to this. Based on the current GHS proposal, the survey's respondents anticipated that more companies would come under the obligations of the BRZO.

In addition to the possible consequences on companies' obligations due to amendment of the regulations, companies will also be faced with the licensing authorities and inspectors who have to interpret these amendments. This survey and other studies on companies' burdens indicate that these interpretations on the part of licensing authorities and inspectors may result in additional costs. This might arise if a licensing authority or inspector has a different interpretation of the obligations from that intended in the legislation and regulations. In addition to costs, this could also result in a great deal of irritation. This irritation would result from:

- Differences of interpretation between licensing authorities and inspectors, as well as among inspectors themselves.
- Insufficient knowledge among licensing authorities and inspectors to enable them to interpret the regulations properly.

Consequently, when amending the regulations, it should also be taken into account that the government will have to incur costs in order to publicise these changes within the various administrative agencies. This also includes the cost of internal notification.

3.2 Target groups

Distinguishing target groups

To calculate the consequences of the CLP Regulation, distinctions have been made between a number of target groups that professionally work with hazardous chemical substances and mixtures. These distinctions have been made, because the consequences of the CLP Regulation can vary according to the target group and, because of this, this can entail varying costs. The table below indicates the distinct target groups in the survey and the number of companies accounted for in these target groups. This corresponds as closely as possible to the categories in the REACH impact assessment[15]. The figures obtained from the CBS have been used only for those target groups for which no figures were included in the REACH study. Annex II indicates how these figures have been compiled and which types of company have been included in each target group.

[15] 'REACH administrative burden impact assessment', SIRA Consulting, June 2004.

Table 4. Overview of target groups and number of companies.

No.	Target groups	Number of companies
1	Base chemical industry	260
2	Speciality chemical industry	625
3	Importers	520
4	Traders	2,620
5	Manufacturing industry	1,225
6	End-users	45,055
7	Retailers	1,795
	Total	**52,100**

Source: REACH impact assessment and CBS

Each company has been included only once in the above table. This means that the total number of companies given corresponds with the number of companies that will be faced with the CLP Regulation in the Netherlands. This classification has been made on the basis of a company's main activity, as done in the SBI '93 classification by the CBS. Annex VI provides an explanation of this classification.

In practice, however, a proportion of the companies can be classified within several target groups. For example, a producer of chemical mixtures can also be a trader. Consequently, the number of companies for each target group will be higher in practice than that shown in the table. However, to use such figures would mean overestimating the total number of companies and the costs for the Dutch business sector.

The target groups indicated above are defined as follows:

- *Base chemical industry:* manufacturers of base chemicals, a significant proportion of which are subjected to further processing in the chemical sector or else sold in large volumes to downstream users. The most significant feature of the base chemical industry is that it involves the large-scale manufacture of substances. The manufacture of petrochemical substances and mixtures fall to the base chemical industry, as well as fertilizers, acids and bases.
- *Speciality chemical industry:* producers of speciality chemicals from base chemicals. A distinction can be made in this regard between companies that make new chemicals by means of chemical reactions and companies that mix substances, referred to as formulators. Formulators manufacture, for example, paints, detergents, cleaning products and medicines.
- *Importers of chemical substances and mixtures:* companies that import substances and mixtures from outside of the Netherlands and which are able to use establishments for storage and transshipment. They do not carry out any processing of the chemical substances, but they are involved in the classification, labelling and packaging of these substances and mixtures.
- *Traders of chemical substances:* This relates to the same type of companies as importers with the difference that these trade only within the Netherlands.
- *Manufacturing industry (downstream users)*: Companies responsible for further processing of substances and mixtures bought from base and specialty chemical industry to produce intermediary products. These substances and mixtures are primarily intended for the wholesale market. These companies do not make any new substances or mixtures but, instead, use these in their production process. The chemical substances and mixtures used, form part of the manufactured end products. Examples of this include companies producing plastic packaging. They use chemicals to produce plastic. Ultimately, the chemicals form part of the intermediary and end products.

- *End-users*: Companies that use substances and mixtures bought from the base chemical industry and the speciality chemical industry in their operations. These companies do not make any new substances or mixtures but, instead, use these in their production process. The chemical substances and mixtures used do not form part of the manufactured end products. Examples of this include companies that treat metal surfaces. They use acids when processing surfaces, but these acids do not form part of the end products.
- *Retailers*: Companies that sell substances and mixtures to consumers. They do not process any substances or mixtures, but they are involved with labelling, packaging and storage of dangerous substances and mixtures.

3.3 Definitions under the CLP Regulation

An overview is given below of the definitions applying to the terms used in this report. When applicable, these have been based on the descriptions found in the wording of the CLP Regulation. Please note that these definitions are not the same as those used by REACH.

Substance
When this report refers to a substance, reference is being made to a substance to which the following properties comply:
- The substance consists of one element or one chemical compound, including accompanying impurities. Its hazardous properties are specific to the substance as long as it is not incorporated in a mixture.
- The substance has a classification under the CLP Regulation as a result of its intrinsic hazardous properties.
- The substance is manufactured with the intention of marketing.

Mixture[16]
When this report refers to a mixture, reference is being made to a combination of substances to which the following properties comply:
- The substances in the mixture do not react with each other and do not create a new substance as a result. However, the various substances can affect each other, meaning that the properties of the substances in a mixture may be different from those of the substances individually.
- The mixture consists to a significant degree of substances with a hazard classification under the CLP Regulation, causing the mixture to be classified likewise as hazardous.
- The mixture is manufactured with the intention of marketing.

ECHA
REACH comes into effect on June 1st 2008. From then onwards, the REACH tests will supply a stream of new information regarding the properties of hazardous chemical substances. After that time, the European Chemicals Agency (ECHA), established in Helsinki (Finland), will manage the registrations, assessments, authorisations and restrictions as regards chemical substances. Following implementation of the CLP Regulation in Europe, ECHA will also start to manage data on hazardous chemical mixtures.

[16] In previously introduced regulations, such as REACH, the Dutch term used was 'preparaten' (preparates). In the proposal for the CLP Regulation, this term has been replaced by 'mengsels' (mixtures).

3.4 Obligations regarding the CLP Regulation according to target group

The CLP Regulation includes obligations for companies. The regulation is in line with the arrangements in the GHS as established by the UN (Titles II and III) and obligations arising from other, non-harmonised, existing European regulations (Title IV onwards). This provides the following obligations for companies. It is indicated under each obligation whether that obligation has been adopted from the GHS or from European regulations[17]:

1. *Classification of substances and mixtures.* The classification system has been adopted entirely from the GHS. This system has then been complemented using classifications not included in the GHS directive from the UN but which are already in use within Europe in the current situation.
2. *Labelling of substances and mixtures.* The prescribed pictograms and warning sentences have been adopted entirely from the GHS. This system has then been complemented using warning sentences not included in the GHS directive but which are already in use within Europe in the current situation.
3. *Packaging of substances and mixtures*. Existing European regulations have been adopted in the CLP Regulation for packaging.
4. *Registration and notification.* The registration and notification system elaborated in REACH will be adopted in the CLP Regulation.
5. *Maintaining availability of information*. The obligation to maintain the availability of information has been adopted from existing European regulations.

Table 5. Information obligations for each target group

No.	Information commitment	Production		Trade			Application	
		Base chemical industry	Specialty chemical industry	Importers	Traders	Retailers	Manufacturing industry	End-users
1	Classification	●	●	○			○	○
2	Labelling	●	●	○	○		○	○
3	Packaging	●	●	○			○	
4	Registration	●		○				
5	Storing information	●	●	●	●	●	●	●

● Always applicable
○ Sometimes applicable

The above table provides an overview of the obligations that apply to each target group. A short description of each information obligation follows below. Afterwards, a description is given of the consequences for the various target groups to which these obligations relate.

Point 1. Classification of substances and mixtures
Once the CLP Regulation comes into effect, every substance and mixture either then being marketed or to be marketed in the future will have to be provided with a CLP classification. This classification will indicate the hazardous properties relating to the substance or mixture in question. A distinction is made in this regard between physical chemical hazards, health hazards and environmental hazards.

If it should emerge on the basis of new data that the classification of an existing substance or existing mixture is not in line with its actual properties, the classification will need to be amended immediately.

[17] In instances where the GHS system does not link up with current European regulations, the CLP Regulation has been complemented by using existing European rules. This has been done in order to arrive at a regulation that links up with the current situation in terms of safety levels.

A classification must be determined for every substance either on the market in Europe or to be marketed in the future. To achieve this, their hazardous properties must first be established. This can be done solely by carrying out tests. This survey assumes that in order to reclassify existing substances, the test data employed to establish the Chemical Substances Act classification can be used to establish a CLP-compliant classification. However, tests will have to be carried out for new substances. Tests will already be carried out under the terms of REACH for substances manufactured or imported in quantities exceeding one tonne. Test obligations under the terms of REACH do not apply to mixtures and substances being marketed in smaller quantities. The CLP Regulation does not impose mandatory testing either. Consequently, costs resulting from the testing of substances have not been included in this survey.

An obligation for classification also applies to mixtures either on the market in Europe or to be marketed in the future. Companies can apply three methods to achieve this: testing, bridging and calculation.

- *Testing.* The CLP Regulation does not provide for any immediate testing obligation. However, in order to determine the classification, the physical parameters do have to be determined. This makes testing necessary, because these properties cannot be calculated. Nevertheless, this survey makes the assumption that, with regard to existing mixtures, the physical parameters will have already been tested in order to determine the Chemical Substances Act classification. As a result of this, they will not need to be tested again.
- *Bridging.* Bridging means that the classification of a mixture is determined on the basis of other mixtures containing the same substances in slightly differing proportions. It is assumed that the classification of these mixtures will then be the same.
- *Calculation.* The classification of a mixture can be determined in part based on the specific properties of the various components that the mixture contains. However, calculation is possible only for environmental and health hazards. The physical hazards can be established only by means of testing. When calculating the hazardous properties of a mixture, the classification is established by mathematical means on the basis of cut-off values laid down in the CLP Regulation. This calculation takes the premise of a worst-case scenario in which the hazardous properties are always at least as severe as those had they been established on the basis of testing. As a result, classification on the basis of calculation can produce a more severe outcome for some of the mixtures than would be the case on the basis of their actual hazardous properties.

Alongside the three methods to determine the classification of a substance or mixture, the CLP Regulation also contains a table that enables the current classification to be translated into a GHS-compliant classification. However, this method, referred to as ‘translation’, can be used only for an existing classification and not to classify new substances and mixtures. Moreover, translation is not possible for all classifications. A further alternative method is the use of ‘Expert Judgment’. This method is explained in more detail in text box 3.

As already discussed above, it is not necessary to determine physical properties by means of testing for existing mixtures. On the basis of the interviews, it became clear that many producers expressed a preference for calculation. Therefore, this survey assumes a situation in which all of the producers use calculation to classify mixtures. This is also the method used most to determine a classification in the current Dutch situation.

Box 3. Classifying mixtures.

Classifying a mixture: Expert Judgment
On the basis of Article 5 of the proposal for the CLP Regulation, it is permitted to apply Expert Judgment to classify a mixture. This process involves taking all of the available data into consideration to reach a classification. However, a clear underlying basis needs to be included in the administration concerning how this final judgment in relation to classification was reached. The inspector verifies the final judgment. This can detract from the legal certainty of companies making classifications on the basis of Expert Judgment. It may be that companies state a preference for calculated classifications, because this method offers them greater legal certainty.

The table below describes the obligations in respect of the classification of substances and mixtures as a result of the CLP Regulation.

Table 6. Classification obligations for each target group.

No.	Target group	Obligation(s)
1	Base chemical industry	▪ All substances and mixtures produced for commercial applications must be classified and provided with product documentation.
2	Speciality chemical industry	▪ All mixtures produced for commercial applications must be classified and provided with product documentation.
3	Importers	▪ All substances and mixtures imported from countries in which the GHS has not (yet) been adopted, and which, therefore, do not have any GHS-compliant classification, must be classified and provided with product documentation.
4	Traders	▪ Product documentation must be passed on to the customer.
5	Manufacturing industry	▪ All mixtures produced for commercial applications must be classified and provided with product documentation. ▪ All mixtures produced for in-house applications, and with which employees come into contact, must be classified and provided with product documentation.
6	End-users	▪ All mixtures produced for in-house applications, and with which employees come into contact, must be classified and provided with product documentation.
7	Retailers	▪ Product documentation for all substances and mixtures must be present and kept up-to-date.

Point 2. Labelling of substances and mixtures
Every item of packaging containing a substance or mixture with a classification must be supplied with a label. This label must display the hazardous properties in the language of the country in which the substance or mixture is being offered. This label consists of two components:

- *Pictograms.* A label must be provided with one or more standard pictograms depending on a substance or mixture's hazardous properties. These pictograms differ from the pictograms used in the current situation under the Chemical Substances Act. Figure 1 below shows a comparison between one of the current pictograms and a GHS version.
- *H and P statements.* A label must be provided with standard hazard statements depending on a substance or mixture's hazardous properties. (These are better known as H statements.) Similarly, it must be provided with safety recommendations. (These are better known as P statements: precautionary statements). These replace the current system of R and S statements, which stand respectively for intrinsic hazards and safety recommendations. On the basis of the H and P statements and the substance or mixture's intended application, users are able to determine the precautionary measures that they should take.

Current	GHS
	

Figure 1. Hazard pictograms to classify flammability.

A substance or mixture's label must be amended with immediate effect when its classification is amended on the basis of new data. The table below describes the obligations for each target group with regard to labelling as a result of the CLP Regulation.

Table 7. Labelling obligation for each target group.

No.	Target group	Obligation
1	Base chemical industry	▪ Each item of packaging containing a substance or mixture with a classification and intended for commercial applications must be provided with a label displaying hazard information.
2	Speciality chemical industry	▪ Each item of packaging containing a mixture with a classification and intended for commercial applications must be provided with a label displaying hazard information.
3	Importers	▪ Each imported item of packaging containing a substance or mixture with a classification, but which has not been provided with a label compliant with the European variant of the GHS, must be provided with a label displaying the hazard information. ▪ When a substance or mixture is repackaged, the new packaging must be provided with a label displaying the hazard information.
4	Traders	▪ When a substance or mixture is repackaged, the new packaging must be provided with a label displaying the hazard information.
5	Manufacturing industry	▪ Each item of packaging containing a mixture with a classification and intended for commercial applications must be provided with a label displaying hazard information. ▪ A label displaying the hazard information for the substance or mixture used must be attached with regard to each application whereby employees may come into contact with substances and mixtures. *
6	End-users	▪ A label displaying the hazard information for the substance or mixture used must be attached with regard to each application whereby employees may come into contact with substances and mixtures. *
7	Retailers	▪ When a substance or mixture is repackaged, the new packaging must be provided with a label displaying the hazard information.

* The labelling obligation arises from Working Conditions Act legislation.

Point 3. Packaging of substances and mixtures

The CLP Regulation attaches provisions to certain hazardous properties. This includes requirements for consumer packaging, such as those in respect of tactile pictograms[18] and childproof seals. Requirements for packaging can apply to all companies that package substances and mixtures. However, these requirements are not new, deriving instead from other European regulations. The table that follows provides an overview of the obligations for each target group.

[18] Tactile pictograms are warnings on packaging produced in relief, enabling recognition by the blind and visually impaired.

Table 8. Obligations in respect of packaging for each target group.

No.	Target group	Obligation
1	Base chemical industry	▪ Each item of packaging containing a substance or mixture with a classification and intended for commercial applications must comply with the packaging requirements as worded in the CLP Regulation.
2	Speciality chemical industry	▪ Each item of packaging containing a mixture with a classification and intended for commercial applications must comply with the packaging requirements as worded in the CLP Regulation.
3	Importers	▪ Each imported substance and each imported mixture with a classification that has not been packaged according to the requirements stipulated in the CLP Regulation must be provided with packaging that complies with the requirements as worded in the CLP Regulation. ▪ When a substance or mixture is repackaged, the new packaging must comply with the requirements as worded in the CLP Regulation.
4	Traders	▪ Substances and mixtures that are repackaged must comply with the applicable requirements.
5	Manufacturing industry	▪ Each item of packaging containing a mixture with a classification and intended for commercial applications must comply with the packaging requirements as worded in the CLP Regulation.
6	End-users	▪ No obligations.
7	Retailers	▪ Substances and mixtures that are repackaged must comply with the applicable requirements.

Point 4. Registration and notification

An obligation of registration applies to all substances manufactured in Europe or imported in quantities exceeding one tonne for the purpose of marketing. A registration dossier for each substance must be supplied to ECHA[19]. Following this, the substances may be marketed in all of the member states of the EU. Since this obligation applies only to substances, it is only the manufacturers and importers of substances that are faced with this obligation. However, the costs of registration have already been calculated in the REACH impact assessment and, therefore, cannot be attributed to the CLP Regulation. A complete overview of the costs of registration has been included in the REACH Impact Assessment[20].

In addition to the obligation of registration, a further obligation of notification also applies in a number of situations on the basis of the CLP Regulation. As with the costs of registration, the costs of notification have already been included in the REACH Impact Assessment. Therefore, both the costs of registration and the costs of notification have been left aside in this survey.

Point 5. Maintaining availability of information

Information relating to the hazardous properties of a substance or mixture should be retained for no less than ten years following the most recent delivery of the substance or mixture in question. This obligation is the same for all target groups.

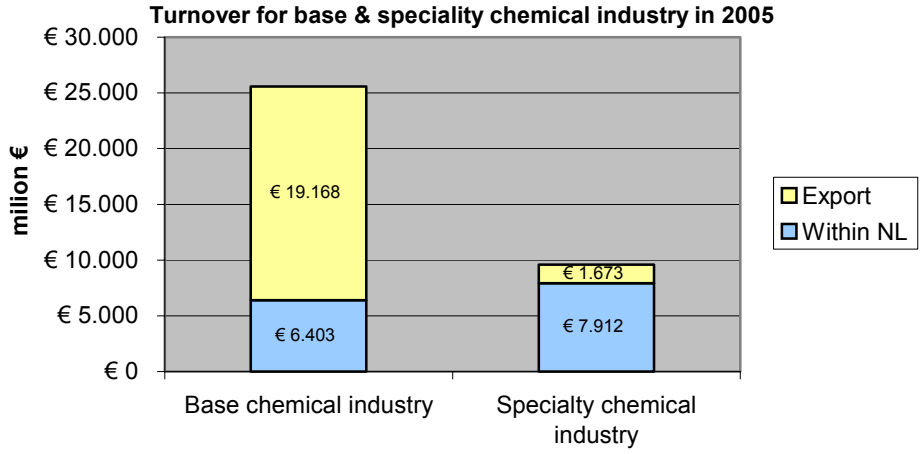
[19] European CHemicals Agency (see Section 3.3).
[20] 'REACH administrative burden impact assessment', SIRA Consulting, June 2004.

4 The Dutch situation

4.1 Economic situation

The effect of the CLP Regulation extends from the manufacturers of chemical substances and mixtures to their end-users. Section 2.2 describes these target groups and the number of companies contained within them. This section describes the economic situation of the various target groups in more detail.

Base and speciality chemical industry
The Dutch chemical industry consists of 260 base chemical industry companies and 625 companies in the speciality chemical industry. Annex I illustrates the types of company that come under both of these target groups. In 2005, the net turnover from these companies amounted to approximately € 35 billion. Based on turnover, the share occupied by Dutch chemical companies in Europe in 2006 was 7.6%. Figure 2 illustrates this and provides a breakdown between both target groups and the turnover related to Dutch domestic sales and exports.



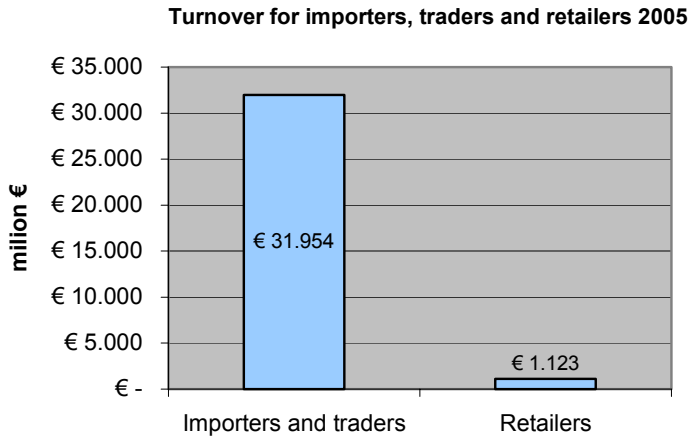
Source CBS, report 'Gevolgen REACH', 2004

Figure 2. Extent of the Dutch chemical sector (turnover in millions of euros, 2005)

Importers and traders of chemical substances and mixtures plus retailers
520 importers and 2,620 traders operate in the Netherlands. In addition, 1,795 companies come under the retailers target group. In 2005, the joint net turnover for the importers and traders target groups amounted to approximately € 32 billion[21]. In the same year, net turnover for the retailers target group amounted to approximately € 1.1 billion. Figure 3 illustrates the

[21] This survey distinguishes between importers and traders. This distinction was not made in the SBI-93 inventory. As a result this, the proportion of this amount applying to each of the target groups cannot be shown on the basis of the CBS data.

extent of turnover. A distinction cannot be made between turnover generated within the Netherlands and turnover from exports on the basis of the CBS data.

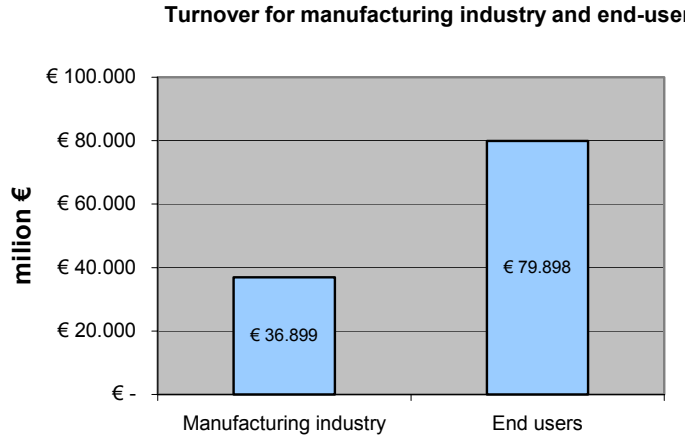


Source CBS

Figure 3. Extent of the Dutch chemical sector (turnover in millions of euros, 2005)

Manufacturing industry and end-users

In the Netherlands, 1,225 companies operate in the manufacturing industry target group, while 44,285 operate in the end-users target group. In 2005, net turnover for the manufacturing industry target group amounted to approximately € 37 billion. In the same year, net turnover for the end-users target group amounted to approximately € 79 billion. Figure 4 illustrates the extent of turnover for both target groups. A distinction cannot be made between turnover generated in the Netherlands and that generated from exports on the basis of the CBS data.



Source CBS

Figure 4. Extent of the Dutch chemical sector (turnover in millions of euros, 2005)

Total overview of the target groups

The supply for chemical substances and mixtures in the Netherlands contains approximately 52,100 companies. Figure 5 below provides a breakdown of the number of companies in the supply according to target group. The producers of chemical substances and mixtures – the base chemical industry and speciality chemical industry – account for less than 2% of the total number of companies to be faced with the CLP Regulation.

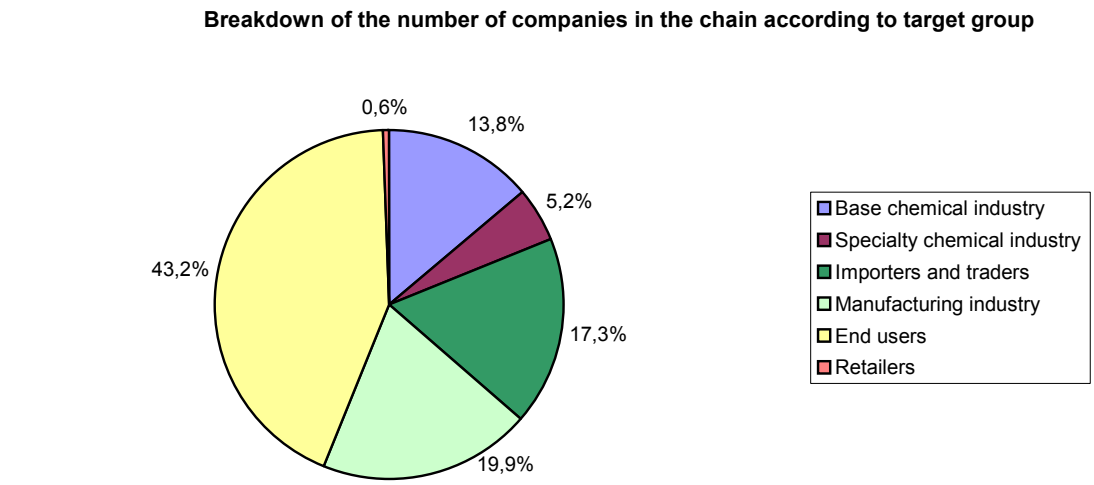


Figure 5. Extent of the Dutch chemical sector (turnover in millions of euros, 2005)

The total net turnover that the companies in the supply generated in 2005 amounted to approximately € 185 billion. Figure 6 below provides a breakdown of this turnover for each target group. This shows in part that the base chemical industry target group, which contains the least number of companies, accounts for almost 14% of the supply's total turnover.

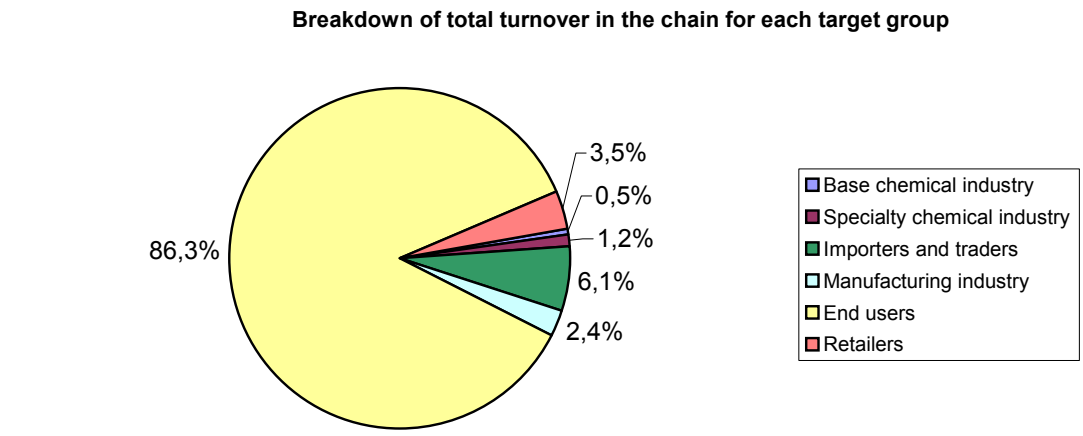


Figure 6. Extent of the Dutch chemical sector (turnover in millions of euros, 2005)

All companies will encounter costs due to the introduction of the CLP Regulation, while only a limited part of the supply will also experience its benefits. Producers exporting hazardous substances and mixtures constitute the group that is to benefit principally from the CLP Regulation. However, the number of companies within this group is small. Otherwise, virtu-

ally none of the other companies in the supply will encounter any financial benefit from the CLP Regulation.

4.2 Number of substances and mixtures

To calculate the costs that companies will be required to incur as a result of the CLP Regulation, it is important to determine the number of substances and mixtures being produced. The REACH impact assessment published data only on the number of unique substances produced in the Netherlands per year in quantities exceeding one tonne. To arrive at an estimate for the number of mixtures produced in the Netherlands, information was used that was obtained from the conducted interviews. The overview below includes the number of substances and mixtures used to calculate the costs. Annex III provides an overview of the way in which the total number of substances and mixtures has been calculated.

Table 9. Overview of existing substances and mixtures in the Netherlands.

No.	Substances in production	Companies number	Existing substances Total	Comparative	Per company
	Base chemical industry				
1	Small-scale companies (upt to 20 employees)	145	110	16.5%	1
2	Large companies (over 20 employees)	115	555	83.5%	5
	Total for base chemical industry	**260**	**665**	100%	

Source: REACH impact assessment

No.	Mixtures in production	Companies Number	Existing mixtures Total	Comparative	Per company
	Base chemical industry				
1	Small-scale companies (up to 20 employees)	145	7,400	2.1%	50
2	Large companies (over 20 employees)	115	37,600	10.9%	330
	Total for base chemical industry	**260**	**45,000**	**13%**	
	Speciality chemical industry				
4	Small-scale companies (up to 20 employees)	400	93,000	27%	230
5	Large companies (over 20 employees)	225	207,000	60%	920
	Total for speciality chemical industry	**625**	**300,000**	**87%**	
	Total	**885**	**345,000**	**100%**	

Source: Interview data, 'REACH impact' report, CBS, TNO

Small manufacturers and producers of chemical substances and mixtures often focus on niche markets. They usually produce small quantities of substances and mixtures specially developed for the buyer ('private labels'). This has been taken into account when calculating the breakdown for the number of mixtures according to company size. However, the exact breakdown can vary according to the sector concerned.

Every year, Dutch companies commence the manufacture and production of new or adjusted substances and mixtures. The classification, harmonisation, labelling and packaging of these new substances and mixtures result in recurring costs for these companies. The following table provides an overview of the estimated number of new substances and mixtures annually put into production and the estimated number of substances and mixtures annually provided with a different classification. This relates solely to substances and mixtures actually being marketed.

Table 10. Overview of the annual number of reclassified and newly introduced substances and mixtures.

No.	Target group	Substances		Mixtures	
		Reclassification	New ïntroduction	Reclassification	New introduction
	Base chemical industry				
1	Small-scale companies (up to 20 employees)	6	2	370	744
2	Large companies (over 20 employees)	28	10	1,880	3,758
	Total for base chemical industry	**33**	**12**	**2,250**	**4,500**
	Speciality chemical industry				
3	Small-scale companies (up to 20 employees)			4,650	9,300
4	Large companies (over 20 employees)			10,350	20,700
	Total for speciality chemical industry			**17,250**	**34,500**
	Total	**33**	**12**	**19,500**	**39,000**

4.3 Non-recurring effects of the CLP Regulation

The introduction of the CLP Regulation has a number of effects on the manufacturers, producers, importers, traders and end-users of chemical substances and mixtures. These effects can be divided into non-recurring and recurring effects. This section explains the non-recurring effects of the CLP Regulation.

Companies working with hazardous chemical substances have a number of actions to perform in order to comply with the new regulations. A distinction is made in this regard between non-recurring administrative burdens and compliance costs.

The one-off effects are described below. The following subjects form the basis for these descriptions:
1. Classification of substances and mixtures.
2. Labelling of substances and mixtures.
3. Packaging of substances and mixtures.
4. Registration and notification.
5. Maintaining availability of information.

Furthermore, companies will have to take action besides this which, although without any direct link to the provisions of the CLP Regulation, will still result in direct costs. This relates to the following action:
6. Familiarisation.
7. Instruction of employees.
8. Adjustments to operations.

Point 1. Classification of substances and mixtures
All existing substances and mixtures will have to be reclassified once the CLP Regulation becomes effective. The product documentation for each substance and mixture will have to be readjusted as a result of this. The following table provides an overview of the one-off actions to be taken by each target group.

Table 11. One-off obligations based on the CLP Regulation for each target group.

No.	Target group	One-off obligation
1	Base chemical industry	▪ New classifications must be determined for all existing substances and mixtures. ▪ Product documentation for all existing substances and mixtures must be adjusted.
2	Speciality chemical industry	▪ New classifications must be determined for all existing mixtures. ▪ Product documentation for all existing mixtures must be adjusted.
3	Importers	▪ New classifications must be drawn up for all existing substances and mixtures from countries in which the GHS has not (yet) been adopted and which, therefore, do not have a GHS-compliant classification. ▪ Product documentation must be readjusted for all existing substances and mixtures imported from countries in which the GHS has not (yet) been adopted.
4	Traders	▪ No obligations.
5	Manufacturing industry	▪ New classifications must be determined for all existing mixtures. ▪ New product documentation must be drawn up for all existing mixtures. ▪ New classifications must be determined for all mixtures produced for in-house applications and with which employees come into contact. ▪ New product documentation must be drawn up for all mixtures produced for in-house applications and with which employees come into contact.
6	End-users	▪ New classifications must be determined for all mixtures produced for in-house applications and with which employees come into contact. ▪ Product documentation must be readjusted for all mixtures produced for in-house applications and with which employees come into contact.
7	Retailers	▪ No obligations.

The following principles have been employed when calculating the one-off costs due to the classification of existing substances and mixtures:

- *The data required for substances and mixtures are available on the basis of REACH or the Chemical Substances Act.* As a result of REACH, a proportion of the chemical substances over one tonne of which are manufactured or imported annually has been tested. The test data used to establish the Chemical Substances Act classifications can be used with regard both to existing substances that have not yet been tested under the terms of REACH and to existing mixtures. Consequently, all of the data required for classification are available for these substances and mixtures.
- *Importers exclusively import hazardous substances already provided with a GHS-compliant classification*. Importers that import non-EU substances are sometimes unable to classify them in line with the CLP regulation on the basis of the supplied data. This situation can arise when imports come from countries where a GHS-compliant classification is not in use. However, it emerges from the interviews that importers virtually never import non-EU substances if the manufacturer does not supply the correct data with them. Therefore, this survey assumes that the data on all of the substances are known.
- *The classification of mixtures is established by means of calculation.* The CLP Regulation does not contain any obligation for testing. While it is permitted to determine the hazardous properties of a mixture by means of testing, it is not mandatory. Therefore, this survey assumes that companies will choose to calculate classifications. This is also the method applied the most in the current situation.
- *Company size affects classification costs.* The amount of time needed to classify a substance or mixture depends on the way in which classification is performed. Large companies have sufficient financial strength to enable them to purchase or design software to extrapolate the classification. These software packages are also responsible for drawing up product documentation in the languages required. However, SME enterprises often lack the financial reserves to purchase such software and make do with ge-

neric programs, such as Excel, which they use to perform calculations and create product documentation themselves. The time spent on this by these small companies is considerably greater. Therefore, this survey makes a distinction between large companies (20 or more employees) and small companies (fewer than 20 employees).

- *A proportion of the substances and mixtures do not require reclassification.* A proportion of the substances and mixtures will be provided with a new classification during the transition period itself regardless of the CLP Regulation. This will happen, for example, because of a change to the classification of one of the raw materials. This survey assumes that companies will change over to the CLP classification at the same time for these reclassifications. Moreover, a proportion of the current product supply will disappear from the market during the transition period with new substances and mixtures appearing as replacements. It applies both to the reclassification and renewal of the range that these are regular activities on which the CLP Regulation will not have a significantly effect. Therefore, these regular activities have been taken into account when calculating the number of substances and mixtures that will have to be reclassified as a result of the CLP Regulation.

One of the principles underlying the CLP Regulation is that the effects of the regulation on burdens must be minimised as much as possible[22]. In line with this aim, the EC Impact Assessment indicates that the number of substances with a classification will not increase significantly[23]. However, if the current proposal is implemented un-amended, this will result in an increase in the number of hazardous mixtures.[24]. The principal reasons for this are:

- Substances and mixtures with a flash point below 55 degrees Celsius are classified as "flammable" in the current situation. Under the CLP Regulation, substances and mixtures with a flash point below 60 degrees will be classified as flammable. This means that all substances and mixtures with a flash point between 55 and 60 degrees will acquire a more stringent classification[25]. This is anticipated to result in only a limited increase.
- The cut-off values included in the CLP Regulation to establish a substance or mixture's classification differ from the cut-off values in the current classification system. This can result in a product being given a more stringent classification than in the current situation, unless it can be demonstrated by means of additional information, such as test data or expert judgment, that the product should be given a lower hazard classification.

The sector has estimated the additional costs regarding the effects of adjusting the cut-off values for mixtures containing surfactants. However, since the necessary degree of adjustment has not been established, this estimate has not been included in the calculations. Neither can it be properly established in relation to the other changes to what extent the number of classified mixtures will increase. Therefore, the consequences of these changes have not been quantified. The most probable consequences of the aforementioned changes are:

- Adjustments to storage areas.
- Reformulation of mixtures to avoid classifications with more stringent requirements.

[22] This aim is expressed in Chapter 3 'Policy Objectives' of the EC Impact Assessment.
[23] Chapter 6 'Analysis of impacts' of the EC Impact Assessment.
[24] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006, 27.6.2007, page 4.
[25] The GHS contains a hazard category for substances and mixtures that are flammable between 60 and 93 degrees Celsius. This hazard category has not been included in the proposal of the CLP Regulation.

- Adjustments to the environmental licenses of companies that, as a result of the CLP Regulation, use more substances or mixtures, or use more substances and mixtures with a more stringent classification.

Point 2. Labelling of substances and mixtures

Once classification of all the hazardous substances and mixtures has been determined, these substances and mixtures should be provided with the correct warnings by means of a label. This has direct consequences for the target groups of the base chemical industry, speciality chemical industry, importers, manufacturing industry and end-users.

- *Base chemical industry.* All substances and mixtures must be provided with a label.
- *Speciality chemical industry.* All mixtures must be provided with a label.
- *Importers.* All substances and mixtures imported from countries in which the CLP Regulation is not yet in force will have to be provided with a label.
- *Manufacturing industry.* Companies using chemical substances and mixtures to produce or treat non-chemical subjects must provide a label for the equipment in which the chemical substance or chemical mixture is present.
- *End-users.* Companies using chemical substances or mixtures to produce or treat non-chemical subjects must provide a label for the equipment in which the substances or mixtures are present.

The following principles have been employed when calculating the one-off costs as a result of the classification of existing substances and mixtures:

- *Re-labelling costs are lower for consumer products.* The respondents indicated in the survey that substances and mixtures aimed at consumers are more often provided with a new label than substances and mixtures for the professional market. The respondents indicated that consumer product labels are amended on average once every five years, while this is done once every 10 years regarding labels for professional substances and mixtures. As a result of this, it is not necessary with regard to the CLP Regulation to provide all substances and mixtures with a new label immediately:
  - In the case of a 3-year transition period, 60% of the substances and mixtures for the consumer market and 30% of the professional substances and mixtures will have already been provided with a new label.
  - In the case of a 5-year transition period, 100% of the substances and mixtures for the consumer market and 50% of the professional substances and mixtures will have already been provided with a new label.
- *One label used for each substance or mixture.* A great many of the substances and mixtures are available in several different types of packaging, resulting in several labels having to be designed for them in many cases. However, producers can decide to use the same label on larger types of packaging as that used for smaller types. Therefore, this survey assumes one label for each product type.
- *The amount of information on the label remains the same.* Although the GHS pictograms are diamond-shaped, they do not take up any more space on the label than the current Chemical Substances Act pictograms. The respondents indicated that the amount of mandatory text on a label could increase. In practice, situations may arise in which less information may be displayed on one label than in the current situation, such as different languages. As a result of this, some of the companies will have to design more labels, which will result in higher costs. However, because the types of substances and mixtures to which this might apply is unclear, a situation has been assumed with regard to calculating

the costs in which the amount of information, e.g. the number of languages for each label, and, consequently, the number of labels, will remain the same.

- *The time spent on designing a small label is the same as the cost for a large label.* Due to the limited space on small types of packaging, designing their labels takes up significantly more time than is the case for large types of packaging. Since this survey has assumed one label for each substance or mixture, and the proportion of substances and mixtures being supplied in small types of packaging is not entirely clear, this survey assumes a situation in which the same time is spent on all labels. This has been based on the time spent for a large label.

Point 3. Packaging of substances and mixtures

Unlike the GHS directive, the European proposal also includes packaging requirements. The classification of a substance or mixture may change as a result of the new, GHS-based criteria. Consequently, stricter requirements may be imposed on the way in which the substance or mixture should be packaged. This change has consequences principally for the speciality chemical industry target group. This group will have to develop new packaging for a proportion of its substances and mixtures (or have such packaging developed on its behalf). In most cases, the other target groups do not (re)package any substances and mixtures[26].

Point 4. Registration and notification

The cost of registration and notification has already been calculated in the REACH Impact Assessment. Consequently, its cost has not been included in this survey.

Point 5. Maintaining availability of information

All information used to establish classifications and all product documentation must be retained. A large amount of new information will be generated, given that all the substances and mixtures are to be reclassified. This information must be retained. This has consequences for the following target groups: the base chemical industry, speciality chemical industry, importers, traders, manufacturing industry and end-users. All of the companies in these target groups will receive new product information from their suppliers based on the CLP classification, which they should archive. Furthermore, it applies to the base chemical industry and speciality chemical industry target groups, as suppliers to the other target groups, that they should archive and forward to their customers all of the new data relating to classifications based on the CLP Regulation for all existing substances and mixtures plus all new product documentation.

Point 6. Familiarisation

It is important for companies to be sufficiently aware of what the changes will entail in order for the changes to the regulations to be implemented correctly. To that end, it is important to be familiarised with these changes. The way in which this is done depends on the options already available in that respect or on the options to be specifically put at companies' disposal with regard to these changes. The amount of time required for familiarisation gives rise to a

[26] Small traders indicated in the survey that they do sometimes repackage substances and mixtures. However, this relates only to a small proportion of the substances and mixtures. Moreover, the number of substances and mixtures involved is also declining, because suppliers are increasingly able to deliver the substances and mixtures using a trader's personalised labels.

non-recurring administrative burden. Annex IV gives a comprehensive description of the basis for calculating the cost of this activity.

Point 7. Instruction of employees

Changes as a result of the CLP Regulation include those to the labels on all substances and mixtures. Furthermore, a proportion of the substances and mixtures will change, which may have consequences for the way in which they should be dealt with. Therefore, everyone who comes into contact with hazardous chemical substances and mixtures in a company should be up-to-date with the changes. This relates to all of the employees in the supply involved with the classification, labelling, transportation, marketing, storage and use of hazardous chemical substances and mixtures.

The amount of time required to instruct each employee can vary from company to company, as well as from department to department within a given company. This Quickscan has, as far as possible, taken into account the differences between business sectors. The time required to instruct employees is responsible for a non-recurring administrative burden. Annex IV gives a comprehensive description of the basis for calculating the cost of this activity.

Point 8. Adjustments to operations

A number of companies will have to implement changes to their operations as a result of the CLP Regulation. The CLP Regulation has direct consequences for the producers and importers of hazardous chemical substances and mixtures. An example of the investments that they will have to make is the purchase or adjustment of ICT systems.

However, the CLP Regulation also has indirect consequences for companies. As classifications will be amended for a number of substance and mixture types, so will instructions for the use of such substances also change. Different requirements may be imposed as a result, such as on the transportation and storage of these substances and mixtures. Although the regulations in respect of storage and transport are not changing, companies will still have to make investments in some cases to be able to continue working with the same substances. The investments that companies will have to make in order to continue working with hazardous chemical substances pertain to non-recurring compliance costs.

4.4 Recurring effects of the CLP Regulation

The CLP Regulation will result in a number of recurring effects in addition to the non-recurring effects as described above. These are as a result of the amended information obligations. The changes resulting from these new obligations are described below for each information obligation. A distinction is made in this regard between the effects on the administrative burden and other effects. This survey has categorised the information obligations into the following groups (these obligations are in line with the obligations in the previous section):

1. Classification of substances and mixtures.
2. Labelling of substances and mixtures.
3. Packaging of substances and mixtures.
4. Registration and notification.
5. Maintaining availability of information.

Point 1. Classification of substances and mixtures

The CLP Regulation requires that the producers of chemical substances and mixtures classify them. Classification is already mandatory in the current situation for chemical substances and mixtures that are to be marketed. These obligations derive from:

- The Environmental Protection Act and decrees and regulations underlying this (all substances and mixtures).
- REACH.
- Regulations for specific substances and mixtures (e.g. cosmetics and household items).

Under the proposed situation, all new chemical substances and mixtures will have to be classified. The data collected on the basis of the REACH tests can be used insofar as it relates to substances for which over one tonne is produced annually. Classifications must be established by another means regarding substances for which less than one tonne is produced annually. In accordance with Article 5 of the CLP Regulation proposal, producers and importers can employ all of the data available on the substance to achieve this, such as that based on the testing of comparable substances and mixtures or data collected on the basis of incidents or complaints. Classifications cannot be established if insufficient data is available for a given substance.

The testing obligations stipulated in REACH apply exclusively to substances. Testing obligations have not been included for mixtures. The CLP Regulation does not include any testing obligations for mixtures either. Consequently, manufacturers, producers and importers should determine the classification of mixtures by some other means. However, determining physical chemical hazard properties can be done only by means of testing, meaning that testing will still have to be carried out despite the lack of a specific obligation for testing. However, other methods can be applied to establish environmental and health hazards, such as bridging or calculation (see Section 3.3 for a description of these classification methods).

Under the current situation, Dutch companies already have to classify all substances and mixtures on the basis of the Chemical Substances Act (on the basis of REACH and the Environmental Protection Act when the CLP Regulation comes into effect) in which the classification process operates in approximately the same way. Consequently, this obligation does not cause any additional cost for the business sector.

During the transition period, companies can decide whether they wish to operate according to the old system or the new one. However, it emerges from the interviews that the classification system that is applied depends on the customer. As a result, companies have to establish two sets of classifications for many substances and mixtures. However, the cost of maintaining a dual product database appears to be limited.

If a company wishes to keep a substance or mixture's classification confidential, a request for confidentiality can be submitted to ECHA. The agency will decide whether a substance or mixture can be exempted from labelling obligations. Opting for confidentiality also exists under the current situation, but this needs to be requested separately for each EU member state. This makes the costs for such a request relatively high at present, above all because it takes a long time for the request process to be completed. Although it will be simpler to request confidentiality in the future situation, information gathered on the basis of the interviews indicates that companies will not be requesting confidentiality any more frequently than is now the case. This means that, just as in the current situation, scarcely any requests for confidenti-

ality will be submitted by Dutch companies. As a result, the effects of this obligation will be negligible.

Point 2. Labelling of substances and mixtures

As in the current situation, each hazardous chemical substance and each hazardous chemical mixture must be provided with a label containing information about its hazardous properties. Labelling obligations also already exist in the current situation, meaning that the new provisions will not result in a structural increase of the administrative burden.

The labelling of a substance or mixture must be amended with immediate effect whenever its classification is adjusted. This will result in a loss to companies if they still have old labels in stock. It will no longer be possible to use these old labels, and new ones will have to replace them. The recurring costs that this will entail are unclear.

These obligations will result in one-off costs for the Dutch business sector. The direct recurring costs will not change much given that companies are already obliged to provide their substances and mixtures with labels. However, the companies do indicate that indirect recurring costs could arise. The reason for this is the layout and the amount of information that has to be displayed on the labels. Since GHS pictograms are diamond-shaped, it is more difficult to position text around them. A greater problem is that more information will have to be displayed on the labels for some of the substances and mixtures[27]. Fewer languages might be displayed due to the CLP Regulation, particularly on small labels that presently contain several languages. This may result in the number of manufacturers and producers' labels increasing. Information is printed straight on to the packaging for some substances and mixtures. In such instances, the number of different types of packaging may increase, which may have consequences for the storage of these products. This issue arises among paint manufacturers, for example. They often use pre-printed paint cans. However, the possible consequences due to an increase in the number of labels or types of packaging have not been quantified in this survey, because the proportion of substances and mixtures to be thus affected is unclear.

Point 3. Packaging of substances and mixtures

The CLP Regulation also sets requirements on the packaging of substances and mixtures in addition to their classification and labelling. The classification of a substance or mixture may change as a result of the CLP Regulation. This has consequences for the way in which the substance or mixture should be packaged. Substances and mixtures faced with stricter regulations may also be faced with stricter requirements for the packaging of those substances and mixtures. Costs will rise as a result. This increase in cost is recurrent in nature. However, predicting the number of new substances and mixtures with a classification as well as the number of substances and mixtures with more stringent classifications is unclear in the current situation. This makes it impossible to quantify these additional costs.

[27] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) no. 1907/2006, 27.6.2007, page 6.

Point 4. Registration and notification

ECHA keeps a register of all substances manufactured or imported in quantities of one tonne or more and which are intended for marketing. A registration dossier needs to be submitted if a manufacturer or importer wishes to put a new substance on the market. Notification needs to be issued in addition to this in a number of cases. The costs as a result of these obligations will be the same in the future situation as they are at present and, consequently, will not result in burdens being increased.

Point 5. Maintaining availability of information

The information that companies collect on the substances and mixtures that they produce should be kept for at least ten years following their most recent delivery. This obligation already applies in the current situation and, therefore, will not result in burdens being increased.

5 The consequences of introducing the CLP Regulation

5.1 One-off costs for each target group

As a result of the CLP Regulation, companies will incur one-off costs as set out in Section 4.3 of this report. This Quickscan outlines the costs for the Dutch business sector. These costs will depend on the transition period that will ultimately apply to the CLP Regulation. In the event of a transition period until 2013, the costs are estimated to amount to approximately € 276 million, spread over the years of the transition period. In the event of a transition period until 2015, the aggregated costs will amount to approximately € 145 million. This, including the differences per target group, is shown in the figure below. It also shows the difference between large and small-scale businesses.

No.	Target group	Size	Total costs per period 2013	Total costs per period 2015	Total costs per period 2013	Total costs per period 2015
1	Base chemical industry	Large	€ 20.300.435	€ 9.140.413	€ 162.403	€ 73.123
		Small	€ 5.164.965	€ 2.514.087	€ 35.620	€ 17.339
		Total	**€ 25.465.400**	**€ 11.654.500**	**€ 94.316**	**€ 43.165**
2	Specialty chemical industry	Large	€ 111.514.782	€ 31.336.709	€ 518.673	€ 145.752
		Small	€ 59.916.443	€ 24.232.257	€ 149.791	€ 60.581
		Total	**€ 171.431.500**	**€ 55.100.900**	**€ 278.750**	**€ 89.595**
3	Importers	Large	€ 3.451.478	€ 3.719.680	€ 11.700	€ 12.609
		Small	€ 880.322	€ 612.120	€ 3.913	€ 2.721
		Total	**€ 4.331.800**	**€ 4.331.800**	**€ 8.330**	**€ 8.330**
4	Traders	Large	n/a	n/a	n/a	n/a
		Small	€ 3.126.100	€ 2.613.600	€ 1.193	€ 998
		Total	**€ 3.126.100**	**€ 2.613.600**	**€ 1.193**	**€ 998**
5	Manufacturing industry	Large	€ 4.178.600	€ 4.646.100	€ 11.143	€ 12.390
		Small	€ 4.510.200	€ 4.042.700	€ 5.306	€ 4.756
		Total	**€ 8.688.800**	**€ 8.688.800**	**€ 7.093**	**€ 7.093**
6	End users	Large	€ 16.582.693	€ 17.727.858	€ 6.465	€ 6.911
		Small	€ 44.597.207	€ 43.452.042	€ 1.020	€ 994
		Total	**€ 61.179.900**	**€ 61.179.900**	**€ 1.322**	**€ 1.322**
7	Retailers	Large	€ 35.794	€ 40.325	€ 2.386	€ 2.688
		Small	€ 1.330.822	€ 1.370.963	€ 748	€ 770
		Total	**€ 1.366.600**	**€ 1.366.600**	**€ 761**	**€ 761**

Totaal	**€ 275.590.100**	**€ 144.936.100**
	Verschil	**€ 130.654.000**

Figure 7. Overview of one-off costs for introducing the CLP Regulation.

Obligations causing the highest costs:

- Classification of the existing substances and mixtures in accordance with the CLP Regulation. The largest proportion of the burden will be borne by the end-users target group. They will have to update information on the hazardous mixtures that they use. The required information will be provided by the suppliers, as a result of which the amount of time spent per mixture will be limited. However, because of the large number of End-users, the total amount of mixtures to be classified is high. As a result, the aggregated costs will be high.

- Re-labelling. The large amount of substances and mixtures, especially in the speciality chemical industry, is responsible for these high costs, because the current labels of all substances and mixtures will have to be replaced. The necessary actions in this respect are producing and consequently printing the labels. Companies that automatically label their packaging will need to make a film. The costs are approximately € 1,000 per label. The speciality chemical industry target group will bear the largest proportion of the burden, because the number of mixtures that has to be re-labelled is highest.
- The introduction costs of the new regulation will be substantial for the Dutch business sector. This mainly concerns the end-users target group, because of the large number of employees in this target group needing to be informed about the CLP Regulation.

In the event of a transition period until 2015, the one-off costs for the introduction of the CLP Regulation will be € 131 million less. These lower costs are mainly accounted for by more substances and mixtures during this longer period of time already being reclassified and re-labelled under normal commercial operations. As a result, this will make it less imperative for the base chemical industry and speciality chemical industry target groups in particular to perform additional actions.

The EC Impact Assessment shows that the coexistence of the current and CLP Regulation systems will lead to additional costs. However, this survey has shown that additional costs will be limited. The respondents did indicate, nevertheless, that it is a nuisance to use two systems side-by-side.

These figures also show that the costs for small companies will be relatively higher than for large companies. Although these companies are often involved with fewer substances and mixtures, they also have fewer or no resources at their disposal to classify and label substances and mixtures, unlike large companies, resulting in these actions taking more time. These additional costs are responsible for a significant part of the CLP Regulation's introduction costs being borne by smaller SME enterprises. The aforementioned costs are often high in relation to the standard costs of commercial operations.

5.2 Recurring costs for each target group

In addition to one-off costs, the Dutch business sector will also encounter recurring costs as a result of the CLP Regulation. However, these recurring costs will be the same as in the current situation, given that the classification and labelling procedures for hazardous substances are not changing. The only things to change are the standards. Recurring costs can occur if substances and mixtures are given a classification with stricter regulations. An example is given in the text box below.

Box 4. Example of the increase in recurring costs as a result of the GHS.

It is possible that specific mixtures or groups of mixtures will be bound to stricter regulations because of the GHS. Mixtures containing surfactants are an example of this. Under current regulations, these mixtures are classified as 'unclassified' or 'irritant'. The business community indicates that these mixtures will (or could) be given the hazard classification 'caustic' if the GHS calculation were to be used. In that case, stricter requirements would be set with respect to packaging. As a result of this, the additional costs for packaging these mixtures could rise by approximately € 12 million per year for Dutch companies. This would lead to a recurring additional financial burden of € 140,000 for each Dutch company in this sector.

5.3 Benefits for each target group

The survey shows several benefits for companies with respect to the introducing the CLP Regulation. The most significant of these is that the CLP Regulation is a uniform global system in which the same pictograms and requirements for hazardous substances are applied. This will benefit companies that operate internationally, enabling them to use the same classifications and labels everywhere thanks to the CLP Regulation.

Companies respond positively towards the principle of a global system. However, it is noted that the way in which the CLP Regulation is to be implemented will vary in different parts of the world. This is because of the fact that the CLP Regulation is made up of 'building blocks'. However, not all countries will be adopting all of the building blocks. The United States, for example, will not be adopting the 'environmentally hazardous substances' building block. Some of the benefits will be cancelled out as a result of this, because different classifications will continue to apply to different regions.

However, the CLP Regulation could indeed lead to a uniform system within Europe. At present, Europe already has a univocal system, namely the Dangerous Substances and Preparations Directive. It appears, however, that in specific cases there are differences of interpretation between the various European member states. In Greece and Scandinavia, for example, mixtures with surfactants, such as detergents, are labelled as irritants. Benefits will arise if these differences of interpretation disappear due to the CLP Regulation.

Benefits from the CLP Regulation have not been found for companies operating only at a national level. This means that the CLP Regulations entails only costs for the traders target group and for the majority within the target groups of manufacturing industry and end-users.

The EC Impact Assessment shows that many SME enterprises are not active in other European countries or elsewhere in the world, because the technical obstacles are too great. The GHS and CLP Regulation should make it easier for SME enterprises to operate internationally[28]. However, it emerges from the interviews that many SME enterprises do not intend to offer their products or services outside of Europe or beyond the borders of the Netherlands.

Apart from uniformity of classification and labelling, the GHS will indirectly lead to a reduction in the amount of animal testing. In the current situation, the cut-off values for classifying a substance can vary between countries or regions. As a result of this, manufacturers wishing to market a substance in more than one country have to undertake more animal testing with regard to health hazards in order to test the different cut-off values. Global implementation of the GHS will make the cut-off values universal. This will reduce the amount of animal testing required to determine hazardous properties.

It has not proved possible to quantify the benefits of the CLP Regulation. The extent to which the GHS will actually be uniformly adopted throughout the world remains too uncertain for this to be done. However, it is clear that the benefits are limited to a small proportion of the Dutch companies affected by the CLP Regulation. The table below briefly outlines the benefits of the GHS according to target group.

[28] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006, IMPACT ASSESSMENT, 27.6.2007, page 15.

Table 12. Possible benefits of the CLP Regulation for each target group according to operational area

No.	Target group	Operational area	Benefits	Description
1	Base Chemical Industry	Worldwide	Yes	Companies that trade their manufactured and produced substances and mixtures outside the EU will benefit, as they will have to determine only one classification. They also have to perform fewer tests to determine the health hazards of new substances.
		Europe	Limited	Companies that only trade substances and mixtures within the Europe will benefit only in part from the CLP Regulation, as the current differences in Europe have already been limited.
		National	None	Companies that trade their substances and mixtures only in the Netherlands will not benefit from the regulation.
2	Speciality Chemical Industry	Worldwide	Yes	Companies that trade their produced mixtures outside of the EU will benefit, as they will have to determine only one classification.
		Europe	Limited	Companies that only trade mixtures within Europe will benefit only in part from the CLP Regulation, as the current differences in Europe have already been limited.
		National	None	Companies that trade their substances and mixtures only in the Netherlands will not benefit from the regulation. These are often SME enterprises.
3	Importers	Worldwide	Yes	Importers that import substances and mixtures from non-EU countries that have introduced the GHS will benefit, as they will need to go to fewer lengths to provide these substances and mixtures (or have them provided) with a classification approved in Europe.
		Europe	Limited	Companies that only trade mixtures within Europe will benefit only in part from the CLP Regulation, as the current differences in Europe have already been limited.
4	Traders	National	None	Traders will not benefit directly from the CLP Regulation, as they do not trade internationally. These are often SME enterprises.
5	Manufacturing Industry	Worldwide	Limited	Companies will benefit only in part from the CLP Regulation, as they do not usually export products to non-EU countries that have a classification after the chemicals have been used.
		Europe	Very limited	Companies hardly benefit from the CLP Regulation, as they do not usually export products within the EU that have a classification after the chemicals have been used.
		National	None	Companies do not benefit from the CLP Regulation, as they do not export.
6	End-users	Worldwide, Europe and National	None	Companies do not benefit from the CLP Regulation, as they do not produce products with classifications.
7	Retailers	National	None	Companies do not benefit from the CLP Regulation, as they only trade nationally.

5.4 Comparison with the EC Impact Assessment

As set out in Section 4.1, the Dutch chemical sector accounts for approximately 7.6 % of the total European chemical sector. Because of this, it is anticipated that 7.6 % of the costs arising for the European business sector due to the CLP Regulation will also relate to Dutch companies. The EC Impact Assessment shows that the one-off costs of the CLP Regulation

will be between € 526 million and € 544 million. This would mean Dutch companies being faced with one-off costs of between € 40 million and € 41 million[29].

The table below shows the figures from the paragraph above. The one-off costs calculated in this Dutch survey are given in addition to this. As the EC Impact Assessment includes only the costs for substances and mixtures, the table shows only the costs to be incurred by manufacturers of substances (base chemical industry) and producers of mixtures (base and speciality chemical industry)[30].

Table 13. Comparison of the EC Impact Assessment with this survey (in millions €).

No.	Description	EC Impact Assessment		This survey
		Total Europe	Total NL (7.6 %)	Total NL
1	One-off costs for manufacturers and producers in a transition up to 2013	544	41	197
2	One-off costs for manufacturers and producers in a transition up to 2015	526	40	67

The table above shows wide variance between the costs for the Dutch business sector depending on whether they are based on the EC Impact Assessment or the Dutch survey. It is notable that the costs for the differing scenarios in the European study differ only slightly, while the Dutch survey shows that a longer implementation period would lead to lower costs. The EC Impact Assessment does not give a complete picture of the way in which the calculated one-off costs have been compiled. As a result, the assumptions that have led to these differences can be indicated only to a limited extent. However, the following comparisons can be made:

- The EC Impact Assessment and the Dutch survey share the same conclusions regarding the recurring costs resulting from the CLP Regulation. Both show that recurring costs due to the CLP Regulation will not increase or only to a limited extent[31].
- For the whole of Europe, the cost of early reclassifications amount to between € 100 million and € 44 million, depending on whether the transition period for mixtures runs until 2013 or 2015. In this Dutch survey, it is estimated that the costs for the Netherlands alone will amount to between € 46 million and € 21 million. Thus the Dutch survey endorses the view that a longer transition period would lead to a reduction of the cost. However, the costs calculated for the Dutch business sector are significantly higher than would be expected on the basis of the European figures.
- The EC Impact Assessment assumes a 2.5% cost reduction as a result of the CLP Regulation. Therefore, a certain loss of income has been assumed in the event of a longer transition period when calculating the one-off costs. The Dutch survey shows that the benefits of the CLP Regulation cannot yet be quantified properly. As a result, loss of income has not been taken into account when calculating the one-off costs for Dutch companies. However, this only relates to a limited proportion of the total cost of EC Impact Assessment, meaning that this point provides only a partial explanation for the differences between the two surveys.

[29] The proportion of target groups relative to each other within the Dutch and European chemical industries may differ. The cost structure may vary as a result of this, whereby the costs for Dutch industry could come to be slightly higher or lower than in the estimate given in this case.

[30] Section 1 of this chapter gives an overview of the total one-off costs (administrative burdens and compliance costs).

[31] If it should emerge as a result of the GHS that a proportion of the substances and mixtures will have to be provided with sturdier packaging, costs as a result of the GHS could indeed increase on a recurrent basis.

5.5 Qualitative description of the consequences of the CLP Regulation

Based on the interviews, qualitative data have been collected on the pros and cons of the CLP Regulation. Further to this, the companies interviewed indicated a positive stance towards the principle of a system such as the CLP Regulation, despite the fact that the benefits of the system as it now stands are extremely limited. The main subjects are briefly explained below.

Harmonisation leads to clarity of terminology
In the current situation, two different classification systems are used in the Netherlands, namely the Chemical Substances Act classification and the ADR classification based on the GHS. As a result, some substances and mixtures have several labels, whereby pictograms that appear to the eye to be comparable do not always have the same meaning. Under the ADR classification, a substance that ignites at a temperature of 58 degrees Celsius is termed as flammable and, therefore, is given a pictogram with a flame. However, the Chemical Substances Act classification for flammable substances only goes up to 55 degrees Celsius, resulting in the substance not being classified as hazardous under the Chemical Substances Act.

The problem of differing classification standards occurs not only in the Netherlands. There are major differences globally too. Differences in classification can result in confusion and, consequently, improper use. By introducing one worldwide standard, these differences will disappear, thus preventing the risk of misinterpretation and, consequently, improper use.

The effects of the CLP Regulation are greater for SME enterprises
SME enterprises have relatively higher costs than large multinationals. The latter have extensive ICT systems at their disposal capable of performing much of the work automatically with regard to classification and labelling. In addition, these large companies have employees who specialise in keeping up-to-date with regulations and who are responsible for compliance with them. However, the costs per company for introducing and complying with the CLP Regulation's obligations do not differ a significantly. Nevertheless, these costs are much higher for SME enterprises in relation to turnover than they are for large companies.

6 Findings and recommendations

6.1 Findings

Obligations and target groups

As a result of the CLP Regulation, Dutch companies will be confronted with changes to the following obligations in relation to hazardous substances and mixtures:

- Classification of substances and mixtures within hazard categories.
- Labelling of substances and mixtures.
- Packaging of substances and mixtures.
- Registration and notification of substances and mixtures.
- Keeping the data on these substances and mixtures.

The consequences of the CLP Regulation apply to all companies involved with hazardous substances and mixtures. An estimated 52,100 companies in the Netherlands will be affected by this regulation. The table below shows these target groups and the number of companies in each target group.

Table 14. Overview of target groups and number of companies

No.	Target groups	Number of companies
1	Base chemical industry	260
2	Speciality chemical industry	625
3	Importers	520
4	Traders	2,620
5	Manufacturing industry	1,225
6	End-users	45,055
7	Retailers	1,795
	Total	**52,100**

The consequences of the CLP Regulation affect SME enterprises in particular

The most significant costs with respect to the CLP Regulation will be incurred during the transition period. This is when companies will have to adjust the classification and labelling of substances and mixtures. Larger companies will be able to implement these changes centrally, thus keeping costs down in relation to the total cost of commercial operations.

However, SME enterprises will be more dependent on suppliers during the transition period. Moreover, SME enterprises have less capacity to anticipate the changes resulting from the CLP Regulation. This means that costs may rise considerably in relation to the total cost of commercial operations. Figure 4 provides an overview by comparing the one-off costs of the CLP Regulation to be incurred by large and small-scale companies for each substance or mixture.

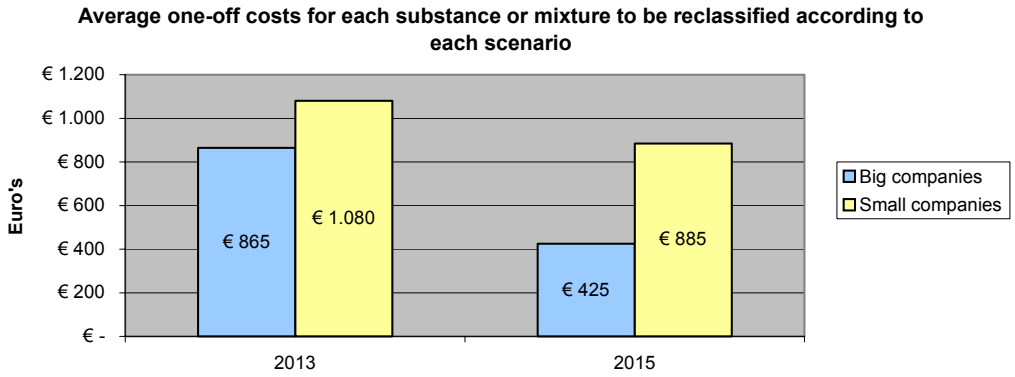


Figure 8. Comparison between large and small companies based on the one-off costs for each substance or mixture.

Direct one-off costs of the CLP Regulation

Direct one-off costs are costs directly arising from obligations as set out in the CLP Regulation. These are the direct costs for companies as a result of introducing the CLP Regulation. This involves:

- Examining new legislation.
- Early reclassification of a proportion of all existing hazardous substances and mixtures.
- Re-labelling all substances and mixtures in accordance with the CLP Regulation.

The highest one-off costs are borne by the target groups speciality chemical industry and End-users.

The highest one-off costs are borne by the target groups Speciality Chemical Industry and End-users:

- *Speciality chemical industry.* The large number of mixtures having to be reclassified early and, as a result of this, re-labelled will lead to high costs. A longer transition period will ensure a reduction in the number of mixtures having to be reclassified early. This will lead to lower one-off costs.
- *End-users.* This target groups high cost are due to the large number of companies that forms this target group. However, the costs per company are limited. The principal cost item is that for familiarisation. Since this cost item is not affected by the length of the transition period, the costs are approximately the same for both transition period scenarios.

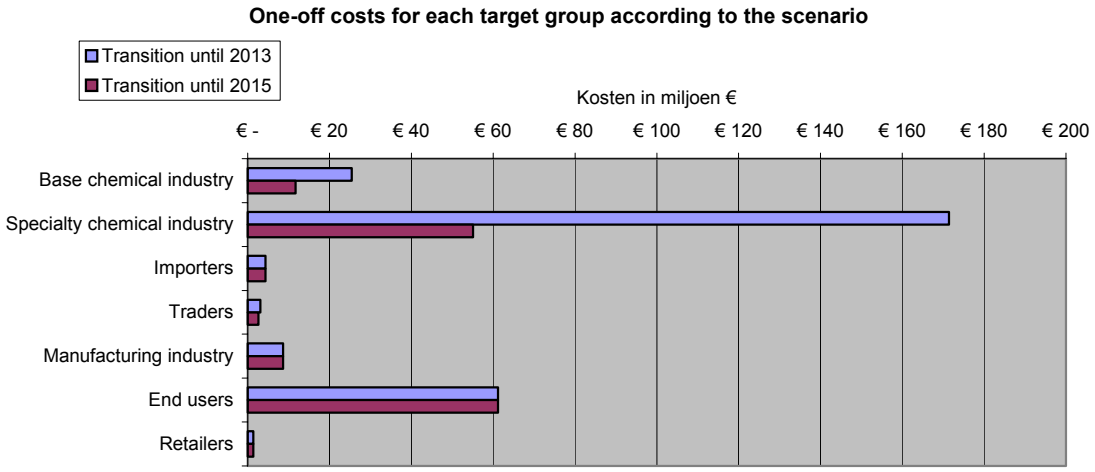


Figure 9. One-off costs of the CLP Regulation for each target group.

The length of the transition period affects the extent of one-off costs

Based on the cost model, the one-off costs for the Netherlands are estimated at between € 145 million and € 276 million respectively for a transition period until 2013 or until 2015. The one-off costs are significantly lower in case of a longer transition period, because a larger number of the substances and mixtures can be reclassified and re-labelled during normal commercial operations.

The share of the one-off administrative burden as a result of the CLP Regulation lies between € 145 million and € 117 million respectively for a transition period until 2013 or until 2015. The CLP Regulation does not cause indirect non-recurrent compliance costs. However, these may occur if storage facilities have to be adjusted as a result of the changeover to the CLP Regulation.

Results of the Dutch and EC Impact Assessments differ on some points

The Dutch survey endorses the view that recurrent effects of the CLP Regulation will remain limited. However, this does assume that existing uncertainties will be clarified and that the CLP Regulation will not result in any indirect effects.

The Dutch Impact Assessment differs significantly from the EC Impact Assessment as far as one-off direct costs are concerned. The EC Impact Assessment calculates that the costs for the European business sector will amount to either € 544 million or € 526 million, depending on whether the transition period runs until 2013 or 2015. However, this survey shows that the costs will amount to at least € 145 million for the Dutch business sector alone. The reason for this difference is that the Dutch Impact Assessment assumes a large number of substances and mixtures. As a result of this, a minor adjustment to the regulations has major consequences. However, a substantiation of the EC Impact Assessment cannot be given on the basis of information available.

Direct recurring costs of the CLP Regulation

Recurring annual costs are direct costs that, in the current and proposed situations, have to be made annually to meet the information obligations set out in the CLP Regulation. These are obligations to:

- Classify new substances and mixtures.
- Label new substances and mixtures.

Based on the cost model, the annual recurring costs will stay the same for the Dutch business sector. It has been assumed that the number of substances and mixtures will stay the same and that existing substances and mixtures will not be given classifications with more stringent regulations[32]. After all, the procedures and amount of time spent on classifying and labelling substances and mixtures will not change as a result of the CLP Regulation. It is only the standards that will be different.

The figure below illustrates the progression of recurring annual direct costs during the different periods. Regarding one-off costs, a distinction has been made between the two different transition periods.

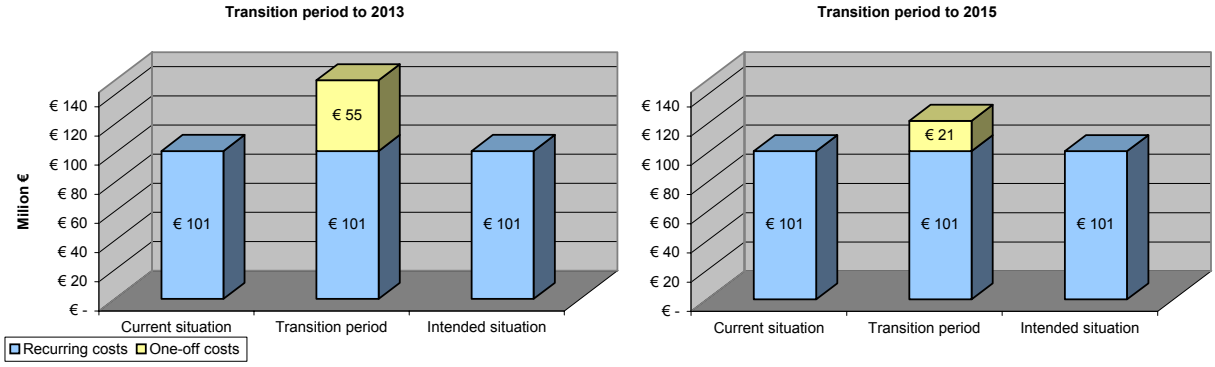


Figure 10. Overview showing the progression of the CLP Regulation's annual direct costs over the two transition periods.

The indirect costs of the CLP Regulation may increase

Indirect costs are those costs not arising as a direct result of obligations under the CLP Regulation, but which do arise as a result of the CLP Regulation's changes. A few of the possible consequences are:

- Different requirements for establishments due to changes to the quantities of hazardous substances. A shift towards classifications indicating greater danger may mean a report being made to the competent authorities or, in other cases, an amendment of the Environmental Protection Act license.
- Different requirements for storage facilities. The storage of hazardous substances is related to storage quantities. A more stringent classification means stricter requirements

[32] The recurring administrative burdens for companies do not change due to the GHS, because the procedures for classification have not been changed. The compliance costs for labelling will also stay the same.

for storage in accordance with the Dutch Directive on Working with Dangerous Substances.

- Different requirements for packaging. A more stringent classification may mean different requirements being set for packaging. A possible example of this is in the soap sector. A different classification as a result of the CLP Regulation could mean that agents containing surfactants must be fitted with childproof seals.

The indirect costs have not been quantified, because a univocal interpretation of the CLP Regulation's indirect consequences cannot yet be given on all fronts. However, it has emerged from the interviews with the companies that indirect costs might rise significantly, especially in the event of structural changes to storage facilities or packaging.

Internationally operating companies will benefit most from the CLP Regulation

The main focus of the CLP Regulation is on the global harmonisation of classification and labelling regulations for hazardous substances and mixtures. Therefore, the most important benefits of the CLP Regulation focus on international trade and international companies. In specific terms, what this means for the Dutch business sector is that:

- As a result of the CLP Regulation, Dutch companies trading exclusively within the EU will be dealing with univocal regulations.
- As a result of the CLP Regulation, Dutch companies trading outside of the EU will be dealing with fewer differing regulations. After all, the survey shows that minor differences will still continue to exist between the EU and non-EU countries that implement the CLP Regulation.
- As a result of the CLP Regulation, companies trading or working exclusively in the Netherlands will not experience any benefits.

Given the fact that the largest target groups in the Dutch business sector – i.e. end-users, traders and retailers – have a largely national focus, the benefits for the Dutch business sector as a whole will remain limited. Therefore, the benefits have not been quantified in more detail in this Quickscan.

The CLP Regulation requires the intrinsic amendment of national legislation and regulations

The Chemical Substances Act will lapse due to the introduction of REACH, and many decrees will already be incorporated under the Environmental Protection Act. Consequently, it is only required to amend those regulations that make intrinsic use of the current classification system. These are:

- the Environmental Protection Act.
- the Risks and Major Accidents Decree.
- the Packaging and Designation of Environmentally Dangerous Substances and Preparations Decree.
- Further rules on packaging and the designation of environmentally dangerous substances and preparations.
- the Safe Packaging of Household Chemicals (Consumer Goods Act) Decree.
- the Registration of Information on Preparations (Consumer Goods Act) Decree.
- Dutch Directive on Working with Dangerous Substances (PGS).
- General Assessment Methodology for Substances and Preparations (ABM).

As a result of the CLP Regulation, those regulations using the classification of hazardous substances and mixtures to set regulations for establishments and persons will have to be amended. Apart from these amendments, it is important that the licensing authorities and inspectors working with these regulations receive proper instruction. Differences of interpretation could lead to additional costs and irritation for companies.

6.2 Recommendations

The survey's respondents have made various recommendations to limit the costs arising from the introduction of the CLP Regulation. This section sets out these recommendations.

Proposals for limiting the implementation costs

Ensuring properly supportive measures for SME enterprises.

This survey shows that the one-off costs for SME enterprises can reach relatively high levels in comparison with large companies. These costs can be limited by:

- *Drawing up European, sector-specific lists containing the hazardous properties of commonly used chemical mixtures.* In some sectors, such as the paint and soap industries, many companies employ the same mixtures for their raw materials. By setting up a database at European level containing information on commonly used mixtures and then making this available to companies, companies will be able to determine classifications for their end products more quickly. This will mainly benefit SME enterprises. Furthermore, by compiling this database at European level, it will be possible to achieve a better degree of harmonisation. Industry and trade associations might be able to play a role in compiling the database.
- *Making a (simple) software package available to determine classifications and draw up product documentation.* In the current situation, a variety of software packages can be supplied to classify mixtures. However, these systems depend on the users input and do not employ one central database. Moreover, these packages prove too expensive for many SME enterprises. The one-off and recurring costs can be reduced by having simple software packages linked up to a central database made available to companies through industry and trade associations. Companies associated with the Royal Dutch Association for the Metal Industry already use such a 'substances manager'.
- *Providing (SME) companies with a helpdesk service.* Large companies often employ one or more policy officials responsible for implementing new regulations. However, small companies have to keep up-to-date with regulations by fitting this in between their regular work. As there is often little or no time for keeping up with legislative developments, these companies are often left with unanswered questions on how to deal with the new rules. By offering a helpdesk service, these companies will need to invest less time in seeking out information, thus limiting the costs of familiarisation and staying informed.

The services of the industry and trade associations can be employed to ensure that these measures are properly geared to the various sectors.

Choosing an implementation period lasting until 2015 for mixtures.

A short transition period for mixtures (until 2013) will lead to higher costs, as all of the mixtures will have to be reclassified in a short space of time and re-labelling cannot be implemented as a part of regular business-related adjustments. Many companies, especially those smaller in scale, indicated that they definitely needed until 2015 for these adjustments. In the event of a shorter transition period, they would need to hire additional staff and, furthermore, would incur additional expenses because labels would have to be changed sooner than usual. A longer period (until 2015) would make it feasible for more companies to carry out the ad-

justments through normal commercial operations. The cost of introducing the CLP Regulation can be kept within limits by opting for a longer implementation period.

Alternatively, it would be possible to incorporate another alteration within the transition periods. Currently, the transition period for substances, produced at the start of the production chain, is shorter than the transition period for mixtures. An additional transition period could be considered regarding substances and mixtures for professional use and one for use by consumers. This separation was also used during the implementation of the RoHS[33] and the logo for small chemical waste (KCA). Companies selling consumer products depend on companies higher up the supply chain. As a result, manufacturers of mixtures who make the transition to the CLP Regulation only at the end of the transition period force the companies they supply to make the transition in a very short period of time. This will increase the costs for these companies.

Minimising the knock-on effect that causes problems for companies at the tail end of the product chain. Encouraging companies not to postpone transition to the CLP Regulation.

Companies at the tail end of the supply may have to deal with suppliers who make the transition to the CLP Regulation only at a late stage. In such cases, companies will incur additional costs, as they will not have the time to have their stock brought in line with the CLP Regulation by means of normal operations. To prevent costs at end of the supply, it is recommended that companies do not postpone the transition to the CLP Regulation unnecessarily. The Dutch government can encourage this by communicating with the companies. The government can involve the industry and trade associations in this regard.

Providing an information campaign aimed at consumers to ensure univocal interpretation within the EU.

Commence an information campaign to provide information to consumers, ensuring that the public at large also understands what the new pictograms mean. It is important to make the meaning of these changes very clear to consumers, particularly in view of the amount of information on labels. Further to this, it is also necessary for consumers to be aware of these changes before they are confronted in the shops with the first substances and mixtures to be furnished with CLP Regulation-compliant labels. The information campaign run by the government with respect to the CLP Regulation must take these points into account.

Setting up a FAQ database.

The government could ensure that the companies having to classify the substances are informed properly, e.g. by setting up a website with a FAQ database. Some matters with respect to the CLP Regulation are still unclear. For example, it is not clear to companies whether they can opt for a classification system during the transition period or whether they will have to operate both the existing and new classifications. The Dutch government's plans to facilitate the introduction of the CLP Regulation should take this into account.

[33] RoHS stands for Restriction of Hazardous Substances. This European directive is aimed at reducing the use of six substances in the electronics industry.

Providing a univocal rule with respect to 'tagging'.

It is not always possible to place labelling on small items of packaging that contain substances and mixtures classified as hazardous substances and simultaneously ensure that the mandatory information on the labelling is readable. Therefore, the CLP Regulation makes it possible to work with 'tags'. Companies gave a positive reaction to this option. However, the requirements attached to it are unclear as yet. Allowing tagging for smaller product units solves the problem of space on small labels. One tag for the whole of Europe or even for the entire world would then suffice. Although the costs of a tag are expected to be higher than for a standard label, the total labelling costs can be significantly reduced. Rules for the use of 'tags' must be drawn up to achieve these cost savings. However, when drafting these rules, it must be ensured that the cost of a 'tag' does not become unnecessarily high.

Proposals for improving the implementation of regulations

Ensuring univocal interpretation within the EU.

At present, companies are encountering problems, because of European rules being interpreted differently within the various member states or being supplemented with national legislation. Denmark, for example, classifies detergents as irritants, while in the Netherlands they are not classified at all. This is in spite of the fact that both countries have to comply with the Substances and Preparations Directive.

The differences between the member states could increase if the national governments of the member states choose to define additional regulations to the CLP Regulation. Therefore, it is important that the harmonisation is as high possible in the event of the various member states introducing derivative regulations. Keeping these differences to a minimum will make it easier to achieve a reduction of costs.

Other national interpretations of the same European Regulation will also result in such differences. As a result, this may partially cancel out the benefits of the CLP Regulation. It is necessary for the European member states to ensure a univocal interpretation of the regulation. This can be done in advance by harmonising and determining all of the points for discussion before the regulation comes into effect. Once it becomes effective, it should be possible to refer established differences of interpretation to one central point in order to reach a univocal interpretation.

Ensuring the meticulous harmonisation of regulations relating to hazardous substances.

During the interviews, it was indicated that companies are currently overwhelmed with new regulations. IPPC, REACH and the CLP Regulation have followed one another in quick succession. Larger companies usually have sufficient manpower to monitor and implement these changes. However, SME enterprises often have to recruit the required expertise from outside the company. Thus, for some SME enterprises, the implementation of new regulations translates into a heavy burden on commercial operations, particularly because they are faced with a great many complex regulations already.

There are different ways for the government to ensure that companies, especially SME enterprises, are given support when dealing with (new) regulations:

- Ensuring clear communication with companies. To that end, drafting clear documentation on the regulations and making this specific to the sectors involved in collaboration with the industry and trade associations. Further to this, indicating not only the regulations' direct consequences but also illustrating their indirect consequences.
- Providing companies with sufficient time to implement the changes necessary at the lowest possible cost. Further to this, ensuring that companies do not have to implement too many changes all in one go.

Recommendations for national use

Ensure that the amendment of adjoining regulations, required due to the introduction of the CLP Regulation, does not result in additional costs to companies.

A number of laws and regulations employing the current classification system will have to be amended as a result of the CLP Regulation. These adjoining regulations will have to be amended in line with the new classification system. When amending these regulations, it needs to be ensured that the costs involved in this for companies do not rise.

Annexes:

Dutch survey into the consequences of the CLP Regulation for the Dutch business sector

I	**Project management and execution**
II	**Overview of company types and numbers per target group**
III	**Number of products**
IV	**Familiarisation**
V	**Hourly rate**
VI	**Explanation of SBI '93 business classifications**
VII	**Overview of regulations to be amended**

I Project management and execution

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II Overview of company types and numbers in each target group

Target group	REACH	SBI'93 (2002)
Base chemical industry	260	270
2411 Industrial gasses industry		5
2412 Dye and pigment industry		20
2413 Other inorganic base chem.		30
24141 Petrochemical industry		15
24142 Other organic base chem.		60
2415 Artificial fertilizer industry		30
2416 Plastic raw materials industry		105
2417 Synthetic rubber industry		5
Speciality chemical ind	625	615
2420 Agricultural chemicals industry		20
2430 Paint, lacquer, varnish, printing ink and mastic industry		140
2441 Pharmaceutical raw materials industry		20
2442 Pharmaceutical product industry		130
2451 Soap, detergent and cleaning agents industry		85
2452 Perfumes and cosmetics industry		75
2461 Gunpowder and explosives industry		5
2462 Glue and adhesives industry		35
2463 Fragrance/flavouring/essential oils		15
2464 Photochemical products industry		10
2465 Data carrier industry		15
2466 Other chemical products industry		55
2470 Synthetic, manmade fibres		10
Importers of chemical products		520
See types of company under 'Traders'. (>10 employers)		520
Traders of chemical products		2,620
5112 Trade advisors: fuels, metals, chemicals		220
51443 Wholesaler detergents, cleaners and cleaning agents		310
51461 Wholesaler pharmaceutical products		490
51477 Wholesaler photography items		105
51511 Wholesaler solid fuels		25
51512 Wholesaler liquid, gaseous fuels		200
51513 Wholesaler mineral oil products (ex fuels)		125
51532 Wholesaler paints and pigments		210
51551 Wholesaler chemical raw materials, chemicals		675
51552 Wholesaler pesticides, fertilizers		220
51553 Wholesaler rubber, other chemical products		40
Downstream users (Manufacturing industry)		1,225
23201 Petroleum refineries		10
23202 Petroleum manuf. (excl. refinery)		30
2511 Rubber tyre industry		0
2512 Tyre renewal companies		5
2513 Rubber manuf. (excl tyres)		75
2521 Plastic sheeting, film, etc.		135
2522 Plastics packaging industry		155
2523 Plastic building products industry		205
2524 Other synthetic manufacturing		500
3340 Optical, picture, film equipment industry		110
End-	44,285	46,270
2851 Surface treatment companies (metal)		770
4543 Finishing floors and walls	4,080	4,030
4544 Painting and glazing	7,280	6,870
50 Trade/car repair/motorbike	20,940	22,835
747 Cleaning buildings, modes of transport	6,230	6,035
7481 Photography (incl. developing)	2,855	2,795
900Environmental services	885	800
921 Activities concerning film and video	1,005	1,070
9301(Chemical) laundries, dyeing rooms, rental	1,040	1,065
Retailers		1,795
52461 Retailer hardware and tools		570
52462 Retailer paint, pigments and wallpaper		540
52481 Retailer photography items		685

III Number of products

This annex provides an overview of the way in which the number of substances and mixtures has been calculated. An additional indication is provided on the significance of these calculations on the end result.

Number of substances

The starting point for determining the number of substances is the REACH Administrative Burden Impact Assessment carried out by SIRA Consulting in 2005. In this assessment the number of substances produced in the Netherlands is calculated. A remark on this is that REACH applies exclusively to substances produced in quantities exceeding one tonne, whereby substances produced in smaller quantities were not included in that study. However, those substances do come under the CLP Regulation's sphere of influence.

It has been calculated on the basis of the conducted interviews that the number of substances determined in the REACH[34] study has to be increased by 10% to calculate the total number of substances produced. A total of approximately 665 different chemical substances are produced in the Netherlands.

Number of mixtures

In contrast to the number of substances, unequivocal figures are not readily available for the number of mixtures produced in the Netherlands. In order to estimate of the number of mixtures produced in the Netherlands, interview respondents were asked how many raw materials their companies bring in and how many mixtures are produced using these raw materials. In addition to this, an assessment was made of the extent to which these companies are representative of the sector and the ways in which these companies differ from other companies in the same sector and other sectors. The following assumptions were made for the purpose of calculation:

- *The size of a company affects the number of mixtures per employee.* The interviews indicate that smaller companies focus mainly on niche markets and, as a result, produce more products per employee than large companies.
- *The number of mixtures per company varies according to the sector.* During the interviews, the differences that existed in the numbers of mixtures produced were assessed for a number of business sectors. Regarding base chemical companies, the focus was particularly on the following sectors.
  - Plastic raw materials industry and synthetic rubber industry (41% of all base chemical companies).
  - Other organic base chemical industries (22% of all base chemical companies).

  Regarding the speciality chemical industry target group, the focus was particularly on:
  - Paint manufacturers (23% of all speciality chemical companies).
  - Soap, detergents and cleaning agents industry (14% of all speciality chemical companies).
  - Glue and adhesives industry (6% of all speciality chemical companies).

[34] REACH Administrative Burden Impact Assessment (*Effectmeting Administratieve Lasten REACH*), SIRA Consulting, June 2005.

The average number of mixtures per target group according to size category was calculated on the basis of data collected during the interviews. To prevent overestimation of the actual number of mixtures, a conservative estimate was used. The average number of mixtures per company was subsequently extrapolated into the total number of mixtures produced by companies in that size category. The table below shows an overview of the total number of mixtures produced in the Netherlands per target group according to size category.

Table B III.1. Number of mixtures produced in the Netherlands

No.	Size category	Number of companies	Number of mixtures*	
			Average per company	Total in the Netherlands
	Base Chemical Industry			
1	Without employees (sole traders)	60	10	600
2	1 to 5 employees	50	20	1,000
3	5 to 10 employees	15	90	1,400
4	10 to 20 employees	20	230	4,500
5	20 to 50 employees	30	200	6,000
6	50 to 100 employees	35	260	9,000
7	> 100 employees	60	380	22,500
	All companies in the Base Chemical Industry target group	**270**	**170**	**45,000**
	Speciality Chemical Industry			
1	Without employees (sole traders)	145	20	3,000
2	1 to 5 employees	145	100	15,000
3	5 to 10 employees	50	600	30,000
4	10 to 20 employees	60	750	45,000
5	20 to 50 employees	80	750	6,000
6	50 to 100 employees	45	1,330	60,000
7	> 100 employees	90	970	87,000
	All companies in the Speciality Chem. Industry target group	**615**	**490**	**300,000**
	Total	**885**	**390**	**345,000**

* The figures in this table are rounded to the nearest ten. As a result, the total number of mixtures may differ slightly.

The estimate was subsequently presented to members of the supervisory committee, in whose opinion the estimate was found to be realistic. Furthermore, the Netherlands Organisation for Applied Scientific Research (TNO) was approached to produce an estimate for the number of mixtures produced per company according to business sector. This estimate was in line with extrapolation given above.

Differences as a result of transition periods

The number of substances and mixtures to be provided with a new classification depends on the number of substances and mixtures to be replaced during normal operations. A longer transition period leads to an increase of substances and mixtures to be provided with a new classification through regular adjustments. The number of substances and mixtures being provided with a new classification prematurely due to the CLP Regulation will decrease as a result of this.

Based on the REACH study, it has been calculated that approximately 1.8% of substances will be replaced per annum. In addition, it has been determined on the basis of the interviews that approximately 5% of substances will be provided with a new classification, and thus also a new label, each year. In specific terms, this means that the number of substances to be reclassified decreases by 6.8%, or by approximately 45 substances, for every year that the transition period continues.

A higher replacement factor applies to mixtures. The data collected during interviews show that new or adjusted mixtures will replace approximately 10% of the mixtures annually. In addition, approximately 5% of the mixtures will be provided with a new classification as a result of adjustments to the classification of raw materials. On an annual basis, approximately 15%, or 51,750, of the mixtures will be provided with a new classification due to both of these effects.

In this survey, two scenarios are used, whereby the transition period for mixtures lasts either until 2013 or until 2015. In the event a transition period up to 2015, approximately 90 fewer substances and 103,500 fewer mixtures will need to be reclassified prematurely than in the event a transition period up to 2013.

The figure below shows the cost reduction that is achieved as a result. The total savings in costs for not having to reclassify and re-label approximately 103,590 chemical substances and mixtures amounts to approximately € 153.6 million. This means that the cost of classifying and labelling a substance or mixture will be approximately € 1,480.

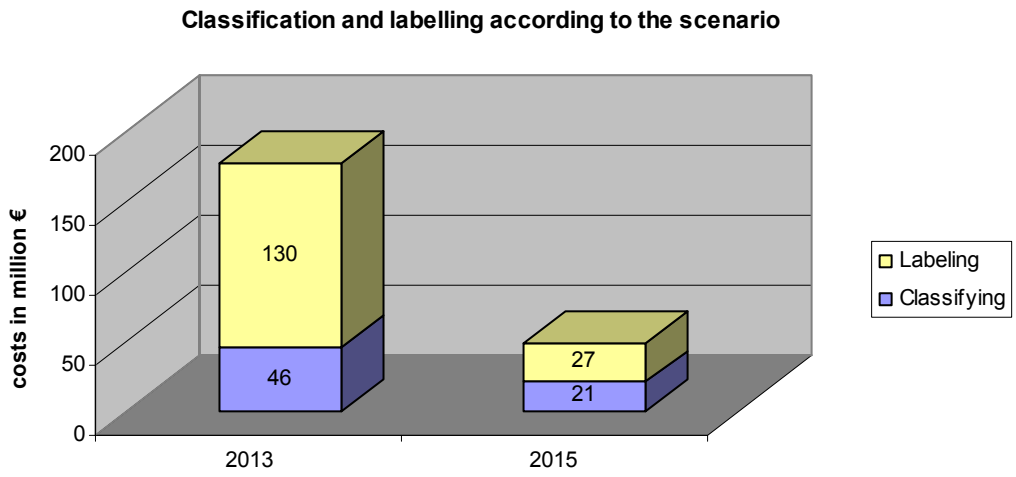

Figure B III.1. Classification and labelling costs according to the transition scenario.

Sensitivity

The main one-off costs of the CLP Regulation are a result of reclassifying chemical substances and mixtures and designing new labels. Therefore, the number of chemical products is a deciding factor in relation to the extent of the total cost.

If the calculated number of 345,000 mixtures should prove to be lower than in reality, this will result in higher one-off costs in practice. The following table illustrates the consequences of a 1% increase in the number of mixtures on the total one-off costs for each transition scenario.

Table B III.2. Cost increase under each scenario resulting from a 1% increase in number of mixtures.

Description	Calculation	Amount
Increase in number of mixtures	345,000 mixtures × 1%	3,450
Increase in number of mixtures replaced or provided with a new classification every year:	3,450 × 15%	520
Cost of reclassifying and re-labelling a mixture		€ 1,480

Transition period until 2013		
Number of mixtures to be reclassified and re-labeled	3,450 - (518 × 3yrs)	1,890
Total additional costs	**1,900 mixtures × €1,480**	**€ 2,797,000**

Transition period until 2015		
Number of mixtures to be reclassified and re-labeled	3,450 - (518 × 5yrs)	850
Total additional costs	**860 mixtures × €1,480**	**€ 1,258,000**

IV Familiarisation

Familiarisation with the CLP Regulation is one of the main cost items for companies. The number of people that need to be made aware of the changes, as well as the total time spent per person, has a major effect on the total one-off costs of the CLP Regulation. This annex explains how the costs of familiarisation have been calculated.

Comprehensive and limited familiarisation

A distinction is made between two types of familiarisation: comprehensive and limited:

- *Comprehensive familiarisation.* A number of persons per company will familiarise themselves fully with the content of the CLP Regulation. On that basis, they will determine the effects that the CLP Regulation is to have on their company and will also take care of informing other employees of the company. The time spent on familiarisation consists of reading documentation, attending meetings and taking courses. The way in which this comprehensive familiarisation is performed depends on a company's size:
  - Large companies will adopt a pre-emptive, sometimes even policy-making, stance. There are wide-ranging consequences for large companies. Therefore, these companies will start familiarising themselves with the CLP Regulation at an early stage. They will take an active part in the implementation of the CLP Regulation through industry and trade associations.
  - Smaller companies adopt a policy-monitoring stance. The consequences for smaller companies can be equally wide-ranging, but such companies lack the manpower to analyse the CLP Regulation in depth. Therefore, they will not take an active part in the implementation of the CLP Regulation; they will only monitor it.
- *Limited familiarisation.* Employees in a company will have to be provided with information once the consequences of the CLP Regulations are known. This involves the new pictograms, the new safety statements and any adjustments to operations. This will entail most companies providing an internal course and given by people who have been fully familiarised with the situation.

Number of people in each company who need to be familiarised

The number of people needing to be familiarised about the changes depends on a company's size. The number of people involved in this has been determined on the basis of the interviews conducted. The following assumptions have been made in relation to this:

- Figures provided by the CBS have been used to categorise companies according to the number of their employees. The CBS employs seven categories for company size:
  - 0 employees (sole traders)
  - 1 to 5 employees.
  - 5 to 10 employees.
  - 10 to 20 employees.
  - 20 to 50 employees.
  - 50 to 100 employees.
  - > 100 employees.

- Comprehensive, 'pre-emptive' familiarisation[35] occurs only in companies with over 20 employees (large companies).
- Comprehensive, 'passive' familiarisation[36] occurs only in companies with fewer than 20 employees (small-scale companies).
- Limited familiarisation appears among all companies. 75% of all employees have to familiarise themselves with adjustments to operations, as well as the new pictograms and safety statements.
- The average number of employees has been calculated for the various CBS size categories. For companies ranging from 0 to 100 employees, the average number of employees per size category has been calculated. For example, a company that comes under the size category of 5 to 10 employees has (5 + 10) ÷ 2 = 7.5 employees on average.
- Companies with over 100 employees are in size category '> 100 employees'. The number of employees for these companies has been assumed at 100. This minimises the risk of overestimating the total number of employees requiring limited familiarisation.

The table below provides an overview of the number of persons per company type according to the type of familiarisation.

Table B V.1. Number of persons to be familiarised per company type.

No.	Company size according to CBS	Number of employees being familiarised		
		Comprehensive (pre-emptive)	Comprehensive (passive)	Limited
1	No employees		1	0
2	1 to 5 employees		1	2
3	5 to 10 employees		1	6
4	10 to 20 employees		1	11
5	20 to 50 employees	1		26
6	50 to 100 employees	2		56
7	> 100 employees	3		75

If the number of persons per company type is multiplied by the total number of companies in each CBS size category, this produces an overview of the total number of employees requiring familiarisation. The following table provides this overview.

Table B IV.2. Total number of persons to be familiarised for each target group.

No.	Target group	No. of companies	No. of persons	
			Total	Average per company
1	Base chemical industry	270	8,140	30
2	Speciality chemical industry	615	13,615	22
3	Importers	520	14,685	28
4	Traders	2,620	8,610	3
5	Manufacturing industry	1,225	22,370	18
6	End users	46,270	248,075	5
7	Retailers	1,795	7,160	4
	Total	**53,300**	**322,700**	**6**

[35] Pre-emptive familiarisation is involved when companies are already involved with new regulations during the development stage. These companies take an active part in the implementation of regulations (whether through industry and trade associations or otherwise).

[36] Passive familiarisation is involved when a company familiarises itself with new regulations only once they have been implemented and the consequences for the business sector have been determined.

Time requirement

The time required for familiarisation depends on the consequences of the CLP Regulation for the company. If the company is confronted with more obligations, the time required for familiarisation will increase. For example, the time spent on familiarisation by a decoration paint manufacturer will be greater than that spent by a paint retailer. The time spent per target group and according to company size was determined on the basis of the conducted interviews. The table below provides an overview of the time spent per company type. .

Table B IV.3. Amount of time required for familiarisation per person in each target group.

No.	Target group	Time required for familiarisation (hours) Comprehensive (pre-emptive)	Comprehensive (passive)	Limited
1	Base chemical industry	160	80	2
2	Speciality chemical industry	160	80	2
3	Importers	80	40	2
4	Traders	Not applicable	16	2
5	Manufacturing industry	16	8	2
6	End users	16	8	1
7	Retailers	16	8	1

Costs

People familiarising themselves comprehensively with the CLP Regulation usually occupy a high position in a company. Consequently, the high hourly rate[37] has been employed for such individuals. People familiarising themselves to a limited degree are usually operational personnel. The low hourly rate has been employed for this type of familiarisation. The total cost for each target group can be calculated by multiplying the number of persons per target group requiring familiarisation by the hourly rate and the time required. The following table provides an overview of the calculation for each target group. The total cost of familiarisation amounts to approximately € 63 million.

[37] See Annex 5 for an extensive description of the hourly rates.

Table B IV.4. Calculation of total cost as a result of familiarisation

No.	Target group	Persons	Hourly rate	Time (hours)	Costs
1	**Base chemical industry**				
	Comprehensive familiarising (pre-emptive)	280	€ 90	160	€ 4.032.000
	Comprehensive familiarising (passive)	145	€ 90	80	€ 1.044.000
	Limited familiarising	7.715	€ 55	2	€ 848.700
	Total				**€ 5.924.700**
2	**Specialty chemical industry**				
	Comprehensive familiarising (pre-emptive)	440	€ 90	160	€ 6.336.000
	Comprehensive familiarising (passive)	400	€ 90	80	€ 2.880.000
	Limited familiarising	12.775	€ 55	2	€ 1.405.300
	Total				**€ 10.621.300**
3	**Importers**				
	Comprehensive familiarising (pre-emptive)	435	€ 75	80	€ 2.610.000
	Comprehensive familiarising (passive)	225	€ 75	40	€ 675.000
	Limited familiarising	14.025	€ 35	2	€ 981.800
	Total				**€ 4.266.800**
4	**Traders**				
	Comprehensive familiarising (passive)	4.984	€ 60	16	€ 4.784.400
	Limited familiarising	2.620	€ 35	2	€ 183.400
	Totaal				**€ 4.967.800**
5	**Manufacturing industry**				
	Comprehensive familiarising (pre-emptive)	665	€ 70	16	€ 744.800
	Comprehensive familiarising (passive)	850	€ 70	8	€ 476.000
	Limited familiarising	20.855	€ 40	2	€ 1.668.400
	Total				**€ 2.889.200**
6	**End users**				
	Comprehensive familiarising (pre-emptive)	3.720	€ 60	16	€ 3.571.200
	Comprehensive familiarising (passive)	43.705	€ 60	8	€ 20.978.400
	Limited familiarising	200.650	€ 35	1	€ 7.022.800
	Total				**€ 31.572.400**
7	**Retailers**				
	Comprehensive familiarising (pre-emptive)	20	€ 45	16	€ 14.400
	Comprehensive familiarising (passive)	1.780	€ 45	8	€ 640.800
	Limited familiarising	5.360	€ 25	1	€ 134.000
	Total				**€ 789.200**
	Total familiarising costs				**€ 61.031.400**

V Hourly rate

The method 'Meten is Weten II', compiled by the Regulatory Influence Governance Group (Regiegroep Regeldruk), indicates the hourly rates of pay used in administrative burden assessments should be based on the hourly rates of pay deriving from CBS wage indexation for the private sector. Further to this, the hourly rates of pay should be adopted from the standard list given in the appendices to the method. However, this list was unavailable at the time of carrying out this survey. Therefore, in this survey data from the CBS and data collected during the interviews have been used. This annex provides an overview of the way in which the hourly rates used in this survey have been calculated.

Agreed wage structures

The starting point for the calculation is the agreed wage structure as established by the CBS for each of the target groups. The table below illustrates the gross hourly rates of pay for each target group, these having been collectively agreed by unions and trade organisations. In addition a basic internal hourly rate has been given for each target group. This basic hourly rate entails the *internal* cost of one hour's work. This amount is comprised of:

- Agreed wage structure (contractual pay).
- Costs borne by the employer[38] (43% of the agreed wage structure).
- Overheads (25% of the agreed wage structure plus the costs borne by the employer).

Table B V.1. Agreed hourly wage structure for each target group according to the CBS.

No.	Target group	Agreed wage '05	Basic hourly rate
1	Base chemical industry	€ 22.53	€ 40.27
2	Speciality chemical industry	€ 22.53	€ 40.27
3	Importers	€ 19.38	€ 34.64
4	Traders	€ 19.38	€ 34.64
5	Manufacturing industry	€ 22.53	€ 40.27
6	End-users	€ 18.39	€ 32.87
7	Retailers	€ 14.33	€ 25.61

Hourly rates calculated for 2005

This survey distinguishes two hourly rates. This relates to a high rate for employees who perform complex work, such as product classification, and a low rate for employees who perform simple(r) work. In both cases, these are internal, non-commercial rates.

The Wage Structure Survey (*Loonstructuuronderzoek or LSO)* periodically undertaken by the CBS has been used in order to calculate the hourly rates. In the Wage Structure Survey the average hourly rate of pay is calculated at each professional level. The Wage Structure Survey distinguishes between five professional levels, from basic (no previous education required) to university-level. The table below provides an overview of the average wage at each professional level.

[38] The costs borne by the employer include among them employed persons insurance schemes (such as unemployment insurance contributions and occupational disability insurance contributions), holiday allowance and/or a bonus, contributions for basic health insurance and pension contributions. Medical expenses are also included among employers' expenses. Source: 'Wat kost personeel?', Chamber of Commerce, February 2007.

Table B V.2. Hourly rates of pay for each professional level in 2002 according to the CBS Wage Structure Survey.

No.	Professional level	Hourly rate of pay Average for all sectors	Index (Lower =100)
1	Basic	€ 11.37	86
2	Lower	€ 13.21	100
3	Intermediate	€ 16.81	127
4	Higher	€ 22.66	172
5	University	€ 27.55	209

The table below provides an overview of the hourly rates for each target group according to professional level for 2005. The given hourly rates are based on the basic hourly rates referred to in Table B V.1. These have been adjusted to the correct professional level by means of the index figures referred to in Table B V.2. The professional level has been determined on the basis of the interviews for each of the target groups.

Table B V.3a. High hourly rate for each target group (2005)

No.	Target group	Professional level	High hourly rate 2005
1	Base chemical industry	University	€ 83.99
2	Speciality chemical industry	University	€ 83.99
3	Importers	University	€ 72.25
4	Traders	Higher	€ 59.42
5	Manufacturing industry	Higher	€ 69.08
6	End-users	Higher	€ 56.39
7	Retailers	Higher	€ 43.94

Table B V.3b. Low hourly rate for each target group (2005)

No.	Target group	Professional level	Low hourly rate 2005
1	Base chemical industry	Intermediate	€ 51.25
2	Speciality chemical industry	Intermediate	€ 51.25
3	Importers	Lower	€ 34.64
4	Traders	Lower	€ 34.64
5	Manufacturing industry	Lower	€ 40.27
6	End-users	Lower	€ 32.87
7	Retailers	Lower	€ 25.61

Hourly rates used in this survey

The table above provides an overview of hourly rates for each target group according to professional level in 2005. These figures have been adjusted to 2007 in this survey by employing the index figures calculated by the CBS. The CBS calculates wage developments for every business sector. The following table provides an overview of the 2005 and 2007 index figures for each of the target groups used in this survey. The CBS uses the year 2000 as the baseline for these figures (Index = 100).

Table B V.4. Hourly rates of pay development for each target group according to CBS (2000 = 100).

No.	Target group	Index 2005	Index 2007
1	Base chemical industry	115.3	120.9
2	Speciality chemical industry	115.3	120.9
3	Importers	111.3	115.6
4	Traders	111.3	115.6
5	Manufacturing industry	115.3	120.9
6	End-users	114.0	117.8
7	Retailers	113.1	117.0

If the aforementioned hourly rates for 2005 are adjusted and rounded off on the basis of the index figures above, this results in the overview given below. This overview shows the hourly rates as used in this survey.

Table B V.5. Hourly rates of pay for each target group in 2007.

No.	Target group	Hourly rate 2007	
		High	Low
1	Base chemical industry	€ 90	€ 55
2	Speciality chemical industry	€ 90	€ 55
3	Importers	€ 75	€ 35
4	Traders	€ 60	€ 35
5	Manufacturing industry	€ 70	€ 40
6	End-users	€ 60	€ 35
7	Retailers	€ 45	€ 25

The interview respondents indicated the hourly rates in the above table were lower than actual hourly rates. However, as no balanced data are available in this regard, this survey has adopted the rates as calculated above. This prevents the costs from being overestimated.

VI Explanation of SBI '93 business classifications[39]

Many reports, analyses and statistics separate commercial activities into categories, such as the chemical industry, the building industry and the insurance business. The CBS has designed the SBI to obtain a uniform classification of the economy, both for its own use as well as for third parties[40]. It is a classification system for all commercially focused activities, i.e. focusing on the production of goods or services. This not only involves activities in the business sector, but also those in non-profit organisations and government. At a micro-level, the Standard Business Classifications are used to classify individual companies according to their (main) financial activities.

There are six levels within the SBI '93, the highest two of which (sections and subsections) are designated through the use of letters; the lower levels are designated through the use of figures (departments, groups, classes and subclasses).

SBI '93 and international classifications
Up to and including the level of classes (four figures), the SBI code is equivalent to the NACE Rev. 1.1 (Nomenclature générale des activités économiques dans la Communauté Européenne) as laid down by Eurostat and which is used in all member states of the EU. Some of the differences from NACE relate to activities that do not arise (separately) in the Netherlands and that have thus not been included in the SBI, such as iron-ore extraction and preschool education. The subclass, indicated by five figures, is a further Dutch differentiation. To make room for separations into subclasses, a four-figure code has been added to the NACE coding. This also accounts for the fact that in some cases the NACE and SBI four-figure codes do not completely match.

At the departmental level (two figures), the SBI '93 and the NACE Rev. 1.1 correspond to the ISIC Rev. 3.1 (International Standard Industrial Classification of All Economic Activities), the classification of economic activities recommended by the United Nations. This was adopted by the Statistical Committee of the UN in March 2002.

SBI code: example
A manufacturer specialising, for example, in the production of turpentine has SBI code DG2414.2. The following figure separates this code into its various levels. The levels deriving from the SBI code that correspond to ISIC and NACE are also illustrated.

[39] SBI stands for Standard Business Classifications (*Standaard Bedrijfsindeling*)
[40] The text of this annex provides a brief summary of the methodology explained in 'The Basis for Standard Business Classifications '93' (*Grondslagen van de SBI '93*) (CBS, 1993), available online from the CBS website.

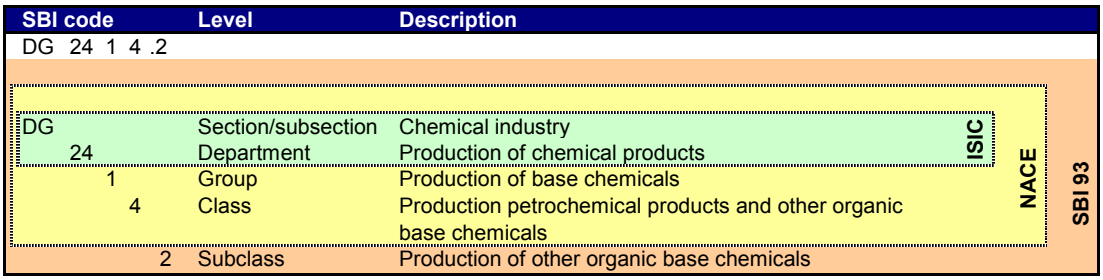

Figure B VI.1. Explanation of the SBI code for a turpentine manufacturing company.

SBI 2008

On the January first 2008, ISIC and NACE have undergone drastic revision. These changes result in SBI 2008. However, statistics connected with the new SBI classifications are not yet available for the time being. Consequently, in this survey the former SBI '93 classifications have been used.

VII Overview of the regulations to be amended

The Chemical Substances Act (*Wet milieugevaarlijke stoffen*) lapses in 2008, partly due to the introduction of the CLP Regulation. As a result of this, some of the Dutch regulations have to be amended. The table below provides an overview of the principal regulations that will require amendment as a result of the CLP Regulation. This overview has been drawn up with policy advisors from the Ministry of Housing, Spatial Planning and the Environment and the Ministry of Health, Welfare and Sports. The regulations that have been marked require the implementation of intrinsic amendments; changes for the other regulations are of a technical nature.

Table B.VII.1. Overview of regulations to be amended

No.	Acts of Parliament
1	Third Tranche General Administrative Law Act (I) (Approximation) Act
2	Medicines Act
3	Chemical Weapons Treaty (Implementation) Act
4	Plant Protection Products and Biocides Act
5	Aircraft (transport of hazardous substances and animals) Act
6	**Environmental Protection Act**

No.	Decrees
7	Activities Decree
8	Working Conditions Decree
9	Asbestos Removal Decree 2005
10	Decree laying down general rules for environmental management of premises
11	Decree on environmental management of electrical and electronic equipment
12	Chemicals Hazard Assessment and Risk Management Decree
13	Decree on the Protection of Antarctica
14	Decree on Bio-fuels for Transport 2007
15	Decree on central review of medical-scientific research involving humans
16	The External Safety Decree
17	Decree on Financial Security Environmental Management
18	Decree on Plant Protection Products and Biocides
19	Decree on Cultivation under Glass
20	Decree on information regarding disasters and major accidents
21	Decree on medical devices
22	Decree on Environmental Quality Requirements
23	Decree concerning Agriculture and Environment Management
24	Decree on Reporting Industrial and Hazardous Waste
25	Decree on breaking up building and demolition waste by means of a mobile unit
26	Fuels Organic Halogen Content Decree
27	**Risks and Major Accidents Decree**
28	**Packaging and designation of environmentally hazardous substances & preparations decree**
29	Decree on Residential Buildings and Lodgings Environmental Management
30	Decree regarding Premises and Permits Environment Management
31	Solvents Decree conversion of EU-VOC Directive

No.	Decrees
32	Asbestos Products Decree
33	Fireworks Decree
34	Consumer Goods Act Decree
35	Consumer Goods Act Decree General Chemical Product Safety
36	Pressure Equipment (Consumer Goods Act) Decree
37	Consumer Goods Act Decree Safe Packaging of Household Chemicals
38	Consumer Goods Act Registration of Information on Preparations

No.	Ministerial regulations
39	**Further Regulations on the Packaging and Labelling of Environmentally Hazardous Substances and Preparations**
40	Regulation on the collection of CFCs and Halogens
41	Regulation on Genetically Modified Organisms
42	Regulation on Coming into Force of Hazardous Substances Directives
43	Regulation on Materials and Chemicals for Tap Water Supply
44	Regulation on Reporting Industrial and Hazardous Waste
45	Regulation on further requirements regarding fireworks 2004
46	Methods for testing toxicity and eco-toxicity

No.	Regulations that only affect the Dutch government itself
47	Directive for supervisory officials and officials with specific implementation duties on the grounds of Social Affairs and Employment legislation
48	Health and Safety Inspectorate special investigative officials Decree 2007
49	DCMR Environmental Protection Agency (Rijnmond) special investigative officials Decree 2007
50	Subsidies, Enforcement and Licensing Board for the province of North Holland special investigative officials Decree 2007
51	Transport, Public Works and Water Management Inspectorate special investigative officials Decree 2006
52	Food and Consumer Product Safety Authority special investigative officials Decree 2007
53	Decree on the creation of REACH agency
54	Inspectorate General for Housing, Spatial Planning and the Environment Mandate and Authorisation of Enforcement Decree
55	Food and Consumer Product Safety Authority organisation Decree
56	Decree on Police Records
57	Mandate Decision Ministry of Agriculture, Nature Management and Fisheries, Department of Food Quality and Animal Health
58	Organisation, mandate and authorisation decree for Working Conditions Board 2005

No.	Directives
59	**General Assessment Methodology for Substances and Preparations**
60	**Dutch Directive on Working with Dangerous Substances**