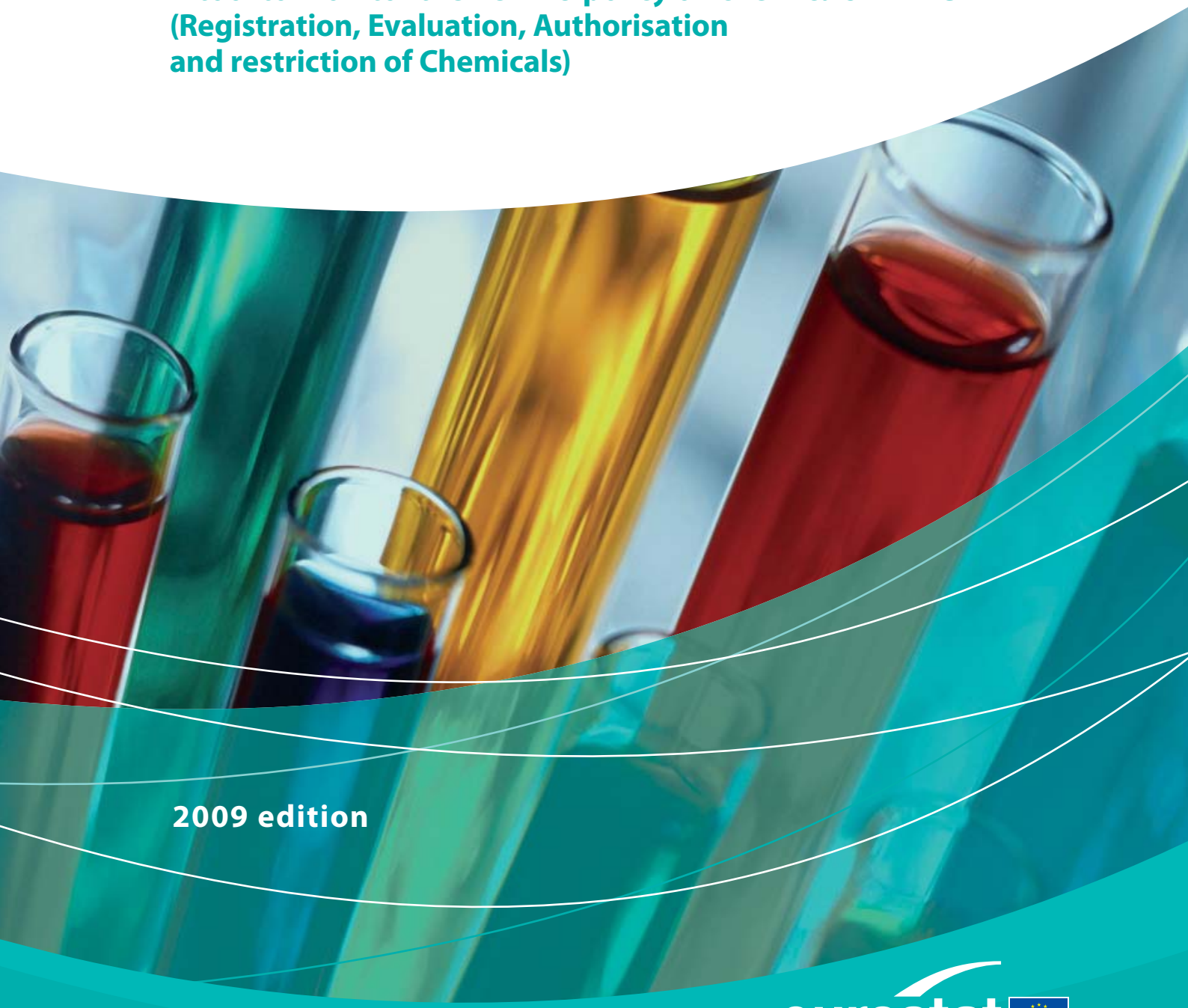
ISSN 1977-0375

eurostat
Methodologies and Working papers

The REACH baseline study

A tool to monitor the new EU policy on chemicals - REACH (Registration, Evaluation, Authorisation and restriction of Chemicals)



2009 edition

eurostat
EUROPEAN COMMISSION

eurostat
Methodologies and
Working papers

The REACH baseline study

A tool to monitor the new EU policy on chemicals - REACH (Registration, Evaluation, Authorisation and restriction of Chemicals)

2009 edition

eurostat
EUROPEAN COMMISSION

How to obtain EU publications

Publications for sale:

- via EU Bookshop (http://bookshop.europa.eu);
- from your bookseller by quoting the title, publisher and/or ISBN number;
- by contacting one of our sales agents directly. You can obtain their contact details on the Internet (http://bookshop.europa.eu) or by sending a fax to +352 2929-42758.

Free publications:

- via EU Bookshop (http://bookshop.europa.eu);
- at the European Commission's representations or delegations. You can obtain their contact details on the Internet (http://ec.europa.eu) or by sending a fax to +352 2929-42758.

Europe Direct is a service to help you find answers to your questions about the European Union

Freephone number (*):

00 800 6 7 8 9 10 11

(*) Certain mobile telephone operators do not allow access to 00 800 numbers or these calls may be billed.

More information on the European Union is available on the Internet (http://europa.eu).

Luxembourg: Office for Official Publications of the European Communities, 2009

ISBN 978-92-79-12197-5
ISSN 1977-0375
Cat. No. KS-RA-09-003-EN-N

Theme: Environment and energy
Collection: Statistical books

EUROSTAT
L-2920 Luxembourg — Tel. (352) 43 01-1 — website http://ec.europa.eu/eurostat

Eurostat is the Statistical Office of the European Communities. Its mission is to provide the European Union with high-quality statistical information. For that purpose, it gathers and analyses figures from the national statistical offices across Europe and provides comparable and harmonised data for the European Union to use in the definition, implementation and analysis of Community policies. Its statistical products and services are also of great value to Europe's business community, professional organisations, academics, librarians, NGOs, the media and citizens.

Eurostat's publications programme consists of several collections:

- **News releases** provide recent information on the Euro-Indicators and on social, economic, regional, agricultural or environmental topics.
- **Statistical books** are larger A4 publications with statistical data and analysis.
- **Pocketbooks** are free of charge publications aiming to give users a set of basic figures on a specific topic.
- **Statistics in focus** provides updated summaries of the main results of surveys, studies and statistical analysis.
- **Data in focus** present the most recent statistics with methodological notes.
- **Methodologies and working papers** are technical publications for statistical experts working in a particular field.

Eurostat publications can be ordered via the EU Bookshop at http://bookshop.europa.eu.

All publications are also downloadable free of charge in PDF format from the Eurostat website http://ec.europa.eu/eurostat. Furthermore, Eurostat's databases are freely available there, as are tables with the most frequently used and demanded short- and long-term indicators.

Eurostat has set up with the members of the 'European statistical system' (ESS) a network of user support centres which exist in nearly all Member States as well as in some EFTA countries. Their mission is to provide help and guidance to Internet users of European statistical data. Contact details for this support network can be found on Eurostat Internet site.

Table of Content

ACKNOWLEDGEMENTS

This publication was prepared under the responsibility of Gilles Decand, Head of Unit – Environmental Statistics and Accounts – European Commission – Eurostat.

Publication editors:

Christian Heidorn, Gerd Steffes – European Commission

Project management team:

Christian Heidorn, European Commission – Eurostat
Finn Pedersen, European Commission – Directorate General Environment
Johan Nouwen, European Chemicals Agency – ECHA
Otto Linher, European Commission – Directorate General Enterprise and Industry
Erik van der Plassche, European Commission – Joint Research Centre

Consultants:

Wolfgang Jenseit Dirk Bunke	Céline Boudet Corinne Mandin François Le Goff	Fritz Kalberlah Jan Oltmanns	Dorte Rasmussen Tina Slothuus Morten Birkved	Dirk Jepsen Heike Lüskow

Steering Committee:

We would like to thank all Members of the Steering Committee for their active contributions to this project.

Further information:

Eurostat website
http://ec.europa.eu/eurostat

Christian Heidorn

Tel (352) 4301 - 35271
Fax (352) 4301 - 30039
E-mail Christian.Heidorn@ec.europa.eu

1 Summary

Monitoring the success of REACH: the background

Since June 2007, REACH — the new EU Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals — has been in force. The major objective of REACH is to ensure a high level of protection for human health and the environment, including the promotion of alternative methods for assessment of hazards of substances as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation in the EU chemical industry (REACH, December 2006, Article1(1))[1].

The existing EU legislative framework for chemical substances has not been able to generate sufficient information regarding the effects of the majority of existing chemicals on human health and the environment. Identification and assessment of risks as well as the subsequent introduction of risk management measures have been too slow, delaying research and innovation in the EU chemicals industry.

REACH introduces a new era of chemicals policy in Europe. It will increase our knowledge of the hazardous properties of chemicals. It is expected to enhance the communication and implementation of conditions of safe use in supply chains and the substitution of dangerous substances by less dangerous ones. Through different types of measures, REACH is expected to cause a decrease in risks to human health and the environment[2] associated with the use of chemicals (see Fig. 1.1).

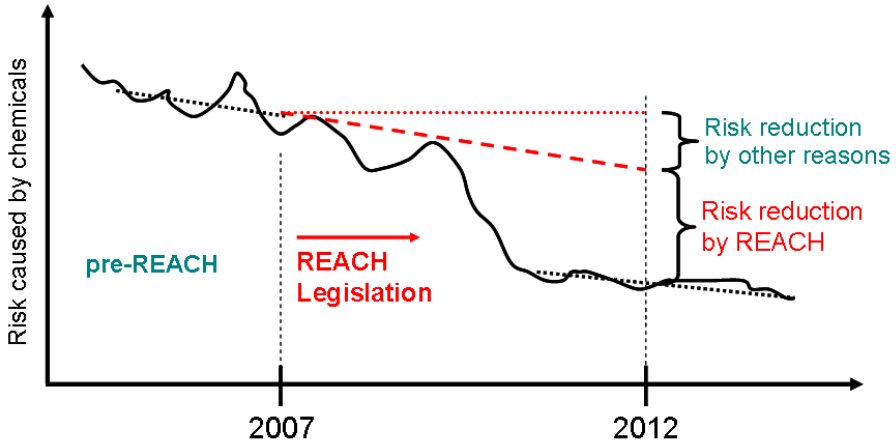


Figure 1.1 Possible future evolution of the risk caused by chemicals. The reduction could be triggered partly by REACH and partly by other systems independent of REACH.

Nevertheless, it is difficult to foresee which reductions in the real risks caused by chemicals will be a result of REACH; different risk evolutions are also feasible. The European Commission has therefore developed instruments to monitor which evolutions really occur and initiated a study of this subject. A team of scientist from five institutes started work on the REACH Baseline Study in January 2006.

Policy monitoring by indicators and the REACH Baseline Study

Will there be a decrease in risks? Will our very limited knowledge about the properties of substances and their safe uses increase due to REACH? The REACH Baseline Study aims to provide an indicator set to monitor whether such changes take place or not — indicating the success of REACH. In doing this, the focus of the Baseline Study is not restricted to indications for the risk itself. The proposed indicator system also enables changes in the quality of the public data on substances and their safe use to be detected. A first "snapshot" has to be taken now for a picture of the situation before REACH ("Pre-REACH-Baseline"). A second and then additional snapshots can be made later when REACH is in force (e.g. 2012). Comparing the pictures should enable the success of the REACH legislation to be monitored and assessed.

---

1 The term "human health" corresponds to workers as well as to the general population. In the latter case, REACH distinguishes between direct exposure of consumers and exposure of people via the environment.

2 Risks in the context of the Baseline Study means: risks to human health and the environment caused by the exposure to chemicals. Other kinds of risks (e.g. economic risks) are not included in the scope of the Baseline Study.

For several reasons, it is not an easy task to develop an appropriate methodology for generating these snapshots in a comparable manner:

1 Direct measurement of the real risks of chemicals to humans and the environment is not feasible.

2 REACH has several objectives and defines a whole set of different tasks for manufacturers, importers, formulators and downstream users, including communication processes in the supply chains. This will most likely trigger a broad variety of effects that cannot be monitored by a single indicator.

3 Risk reduction and further effects will take place as a result of REACH and, at the same time, as a result of other legislation and systems, which means that it is difficult to assign any changes identified directly to an effect of REACH.

The proposed indicator system accounts as far as possible for these difficulties by three means:

1 Instead of gathering scarce data on real risks, the Baseline Study uses available information on hazardous properties, potencies and exposures to characterise the risk[3] of a few randomly selected substances. At the same time the evolution of the quality of these data is evaluated.

2 The Baseline Study uses different types of indicators in order to monitor the different types of expected effects.

3 This indicator system refers directly to changes that are expected to be caused or — at least — strongly stimulated by REACH. These changes are shown in the following table.

Increased knowledge of properties of existing substances
Increased knowledge of uses of substances and related exposures
Improvement of data in extended safety data sheets as the key communication tool
Direct communication of uses which are not supported by the manufacturer/importer
Increased involvement of downstream users in the communication and assessment of safe uses
Cessation of production of substances if no standard set of data is available by the deadline
Cessation of the use of substances of very high concern (if no authorisation is granted by sunset date)
Enhanced reduction in the risks related to chemicals due to a change in the manner of use and/or implementation of more appropriate risk management measures
Enhanced substitution of dangerous chemicals by less dangerous ones

Table 1.1 Changes expected to be triggered by REACH for existing substances (with a production volume of 1 t/y and more) and being addressed by the Baseline Indicator System

The structure of the Baseline Indicator System

In a preparatory workshop (21 to 22 March 2005) the Commission defined the main demands for a system of REACH-related indicators. These findings have been taken into account in the Baseline Study. In addition, experiences with existing indicator systems have been included as far as possible. None of the currently available approaches to assessing risks posed by chemicals have been found to be suitable for monitoring the success of REACH:

- The existing approaches are often restricted to data-rich chemicals, a condition that is not fulfilled for most of the chemicals under REACH;
- The existing approaches do not allow substance-specific decisions on whether to use existing data or realistic default values;
- Sensitive detection of improvements in data quality is not within the scope of the existing approaches;
- The existing approaches have not been designed with reference to the structure and objectives of REACH.

[3] In this study, the term "nominal risk" is used. It indicates that the generic figures calculated here are directly related to the risk (caused by chemicals). At the same time they are at least partly influenced by the methods used and the side conditions which had to be set in order to make the calculations.

Therefore a specific indicator set has been developed that is directly linked to the objectives and key elements of REACH. It is based on three different types of indicators, which build up the three pillars of the system (see Figure 1.2):

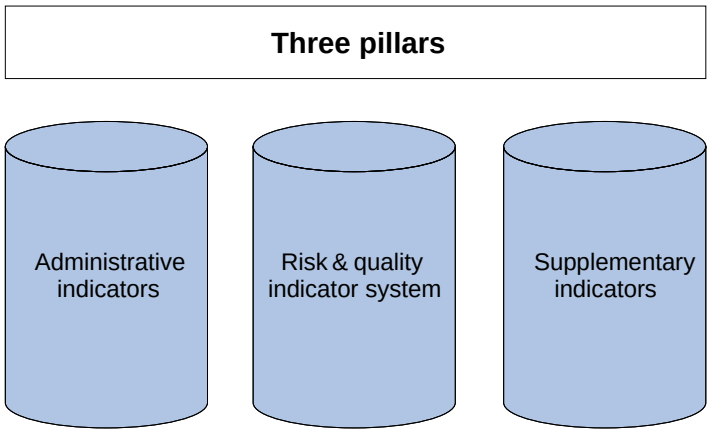


Figure 1.2 The three different types of indicators used in the framework of the Baseline Indicator System

Administrative indicators. These are used to monitor the REACH process. They refer to the registration, evaluation, authorisation and restriction steps defined by REACH. They will provide figures, e.g. on the number of substances registered, the number of chemical safety reports documented in the IUCLID 5 database of the European Chemicals Agency (ECHA) or the number of dossiers being evaluated.

The risk & quality indicator system. This system directly tracks two major goals of REACH: reduction in the nominal risks of chemicals for humans and the environment as well as improvement in the quality of publicly available data. These changes are assessed for a defined set of 237 reference substances.

Supplementary indicators. These indicators address specific objectives of REACH not yet covered by the other two indicator types (e.g. increase in quality of safety data sheets, use of alternative methods for assessment of chemicals instead of animal testing). They can support specific findings from the risk & quality indicator system. Table 1.2 gives an overview of the issues addressed by the supplementary indicators. Most of these are level 1 (policy) indicators. Only the indicator for occupational skin diseases is a level 3 (endpoint or damage) indicator.

Changes in quality of safety data sheets
Availability of hazard data
Availability of use and exposure data
Changes in use patterns in Scandinavia
Changes in classification and labelling
Registration of new chemicals
Production of toxic chemicals
Toxic chemicals in households
Cross-border transport of toxic chemicals
Occupational skin diseases
Use of alternative methods (non-testing and non-animal testing methods) for assessment of properties of chemicals

Table 1.2 Supplementary indicators used in the Baseline Indicator System

The combination of the different types of indicators described above makes it possible within the Baseline Study to address the major objectives of REACH (see Table 1.3).

Central elements & objectives of REACH	Baseline Study Indicator System		
	Administrative indicators	**R&Q indicator system**	**Supplemental indicators**
Registration of chemicals	✓		
Evaluation of chemicals	✓		
Authorisation and restriction of chemicals	✓		
Establishment of a central agency	(indirect)		
Protection of human health and the environment		✓	✓
Improvement of knowledge on properties and safe uses of chemicals		✓	✓
Assessment of existing and new chemicals in a single, coherent system			✓
Increased transparency and consumer awareness			(✓)
Promotion of alternative methods for assessment of hazards of chemicals			✓
Maintenance and enhancement of the competitiveness of the EU chemical industry	Not within the scope of the Baseline Study[4]		
Prevention of fragmentation in the internal market			
Conformity with EU's international obligations under WTO			

Table 1.3 Objectives of REACH and the Baseline Study Indicator System

The risk & quality indicator system

Two questions are of central importance for monitoring the success of REACH:

- How does the (health or environmental) risk change after implementation of REACH?
- How qualified is the information obtained on the hazardous properties of chemicals and on exposure to these substances?

The core of the Baseline Study proposes a system of indicators to answer these questions: the risk & quality indicator system. The structure of this indicator system is given below in Figure 1.3. The system addresses risks to three impact areas: the environment, workers and the general population, whereby impacts on the general population are divided into direct impact on consumers (resulting from the use of chemicals e.g. paints or glues) and impact on humans via the environment (e.g. drinking water).

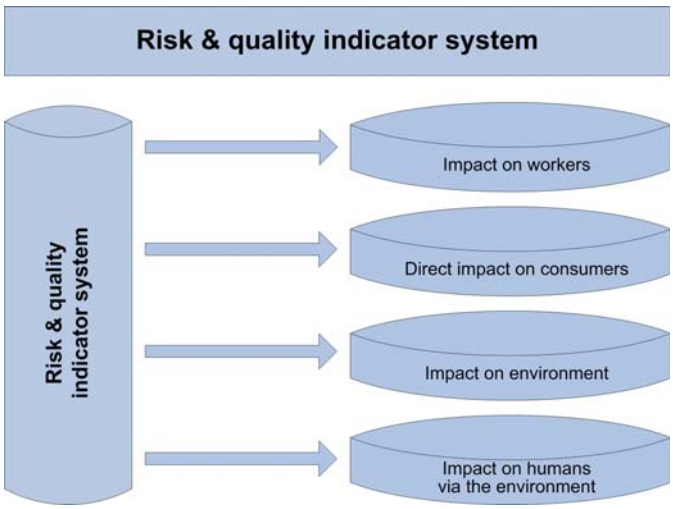


Figure 1.3 Schematic presentations of impact areas addressed by the risk & quality indicator system

[4] The REACH Baseline Study will not address economic and legal aspects. Assessing the last three objectives of Table 1.2 therefore lies outside the scope of this study.

This indicator system directly assesses the nominal risk of exposure to chemicals and characterises the quality of the data on which this risk assessment is based. These characterisations are taken (in the Pre-REACH Baseline and can be followed over time.

Since the calculation of risk and quality is not manageable for all of the (approximately) 30 000 substances within the focus of REACH, a subset of 237 substances has been selected from the known high, medium and low production volume chemicals (approx. 10 000 existing substances in volumes >10 t/y as reported to the Commission). This set is considered large enough to detect with sufficient sensitivity changes taking place in the risks and the quality of the databases for chemicals[5].

Two figures are calculated for each reference substance: the "**Risk Score**" and the "**Quality Score**". The Risk Score is a nominal value that indicates to what extent a risk could be associated with the use of the substance. This score can range from far below 1 to 1 000 and more. High Risk Scores are indications of high risk: however, no attempt has been made to define a value discriminating risk from no-risk.

In order to determine the Risk Score, an exposure assessment and a toxicity assessment have to be made. Both steps use data regarding the hazardous properties, the toxicological potency and the exposures. The quality of both of these data sets is characterised by the "**Quality Score**". If input data are highly uncertain (no detailed knowledge of toxicological properties of a chemical and/or no detailed knowledge of specific exposures to this substance), then the quality of the assessment is regarded as poor. The value of the Quality Score ranges from 1 (very good quality of data) to 10 (very poor quality of data) (see Figure 1.4).

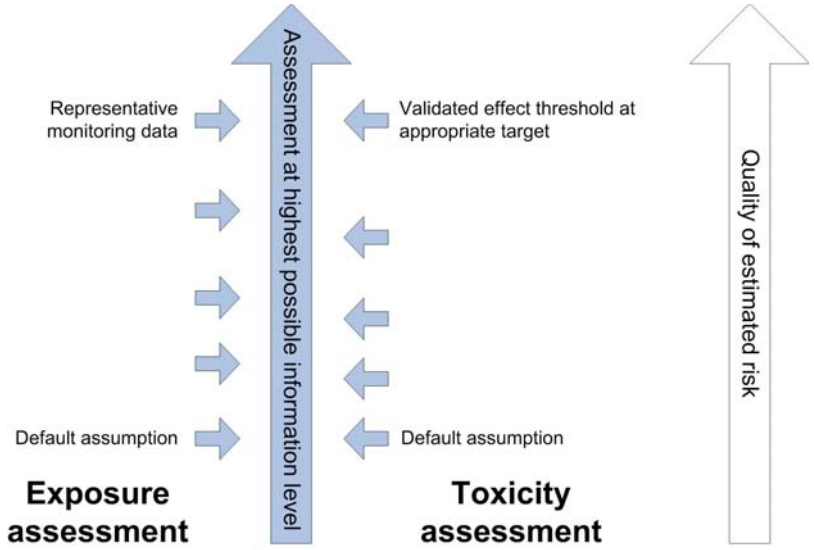


Figure 1.4 Integration of the quality dimension into the risk assessment. The quality of the data used for the exposure assessment and for the toxicity assessment can range from low quality (here default assumptions have to be made) up to very good quality. This influences the quality of the risk estimation.

This quality assessment is a key element of the risk & quality indicator system. It is assumed that REACH leads to more complete testing of toxicological properties, improved reporting, and better information on exposure. By this means, the quality of the database (i.e. the completeness of the database and to a lesser extent the quality of the individual data) is expected to improve and the uncertainty will, consequently, be reduced. This assumption can be assessed by the Quality Scores.

The methodology used in the four impact areas for assessing the Risk Scores is in line with the principles of risk assessments described in the TGD[6]. As soon as additional or new "reference elements" for the assessment of chemicals become available, they can be used in the system (such as PNECs, DNELs or DMELs)[7].

---

[5] The proportion of the number of substances from the different tonnage bands in the reference set has been set in such a way that it is the same as in reality.

[6] As far as possible at the time of development of the methodology for the risk & quality indicator; additional methodological steps proposed in the RIPs have been considered.

[7] PNEC: Predicted No-Effect Concentration; DNEL: Derived No-Effect Level. For non-threshold substances, reference values for a quantitative description of the exposure and for the risk characterisation are currently being developed in RIP 3.2-2 (Expert Group on Human Health Risk Characterisation, derivation of DNELs). As a provisional abbreviation the term "DMEL" is used ("Derived Minimal Effect Level") (References: Concise TGD RIP 3.2-1 (CEFIC 2005), Reference preliminary TGD, Chapter 3, Human health hazard assessment; working paper, version 5 (Kroese and Pronk 2006)).

Snapshot 2007

A snapshot has been taken for those proposed indicators for which a baseline needs to be established in 2007. Those indicators referring to future action have the baseline zero. The most interesting results are discussed.

Approximately 30 000 existing chemicals, which are now regulated under REACH, are used in the European chemical industry. Altogether 387 of these chemicals are documented in the European production statistics (Prodcom, Eurostat), of which 162 are labelled "toxic". The next figure (Figure 1.5) highlights the evolution of the **volume growth** for these chemicals.

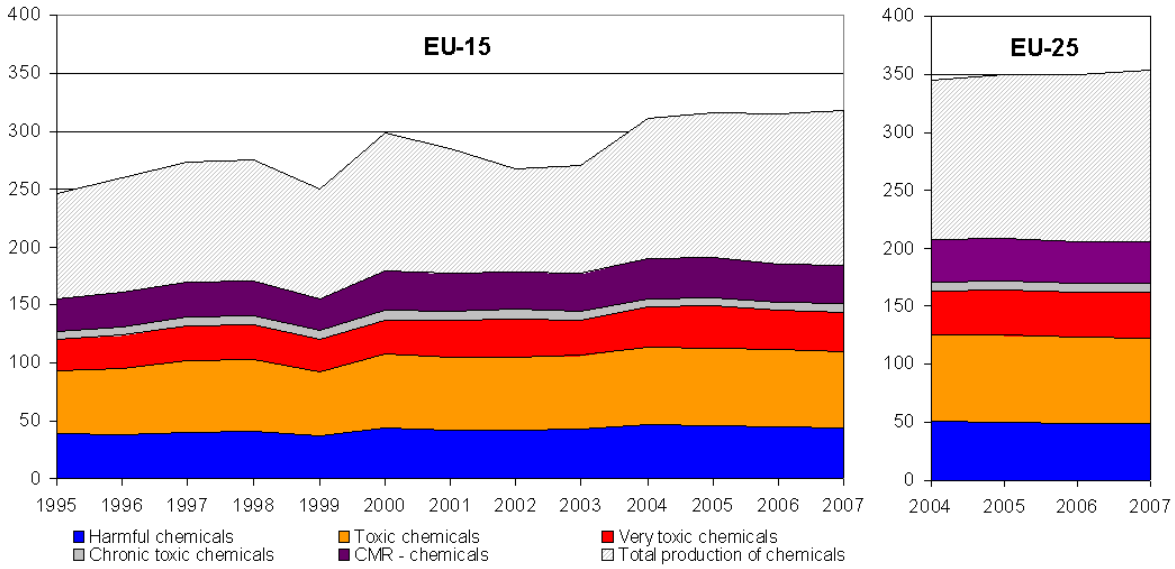


Figure 1.5 Total production volumes of chemicals and production of chemicals broken down into five "toxicity classes", EU-15 and EU-25

The chemical industry is seen as one of the main drivers in economic growth. The growth of Gross Domestic Product (GDP) as a measure of economic growth correlates with the volume growth of chemical production. More importantly, the growth of toxic chemicals or even CMR chemicals (carcinogens, mutagens and reproductive toxicants) is following this trend. The share of toxic chemicals in this period is up to 65% of the total chemicals monitored in Prodcom; the share of CMR chemicals is approx. 11%.

There is a steady flow of these toxic chemicals through the economy. As illustrated in the cross-border transport of toxic chemicals indicator, toxic chemicals are traded and transported all over Europe since chemical production is strongly interwoven. Approximately 30% of toxic chemicals move across borders.

Most of these chemical commodities may be used as "intermediates" and/or used in the chemical industry, which has a long history of safety measures. But some have spread into other economic sectors. As a "satellite", the indicator on changes in use patterns in Scandinavia highlights this issue for CMR chemicals. Approximately 82% of CMR chemicals are used in refining or in the chemical industry. The remainder is in widespread use in the trade and transport sector, the wood and paper industry and in machinery, among other areas. There are big differences for specific chemicals. For example, vinyl chloride is only used in the chemical industry as an intermediate whereas chromium trioxide is only used outside the chemical industry: in the wood and paper industry and machinery.

In total, we have to acknowledge that toxic chemicals are part of our society. Toxic chemicals form a major part of the chemical industry and have spread into other economic sectors as well. There is no indication that the use of toxic chemicals is being reduced or decoupled from growth in the chemical industry.

For existing chemicals, REACH introduces further obligations, which are aimed at reducing the risk of chemicals. The risk & quality indicator system describes the nominal risk and the quality of the risk assessment (mainly related to the completeness of the database) for individual reference substances and allows changes in these values to be monitored over time.

For Pre-REACH Baseline snapshot 237 substances have been randomly selected from the 30.000 substances under REACH). These belong to four categories: HPV — High Production Volume Chemicals (more than 1 000 tonnes/year), MPV — Medium Production Volume Chemicals (1 000 > > 100 tonnes/year), LPV — Low Production Volume Chemicals (100 > > 10 tonnes/year) and SVHC — Substances of Very High Concern.

The results for this first snapshot are shown at different aggregation levels for workers, consumers, the environment and humans via the environment.

In Figure 1.6, the results are highlighted as an aggregated geometric mean of **16** (workers), **34** (consumers), **0.06** (the environment) and **30** (humans via the environment) for LPV, MPV and HPV substances combined.

In order to rank the **Aggregated Baseline Risk Score**, it is helpful to know that a Risk Score of 0.1 would certainly be called "low", whereas a Risk Score of 1 000 would certainly be called "elevated". However, calculated Risk Scores for the substances vary over a much wider range. Additionally, the Risk Scores between workers, consumers, the environment and humans via the environment are not comparable due to differences in the methodology.

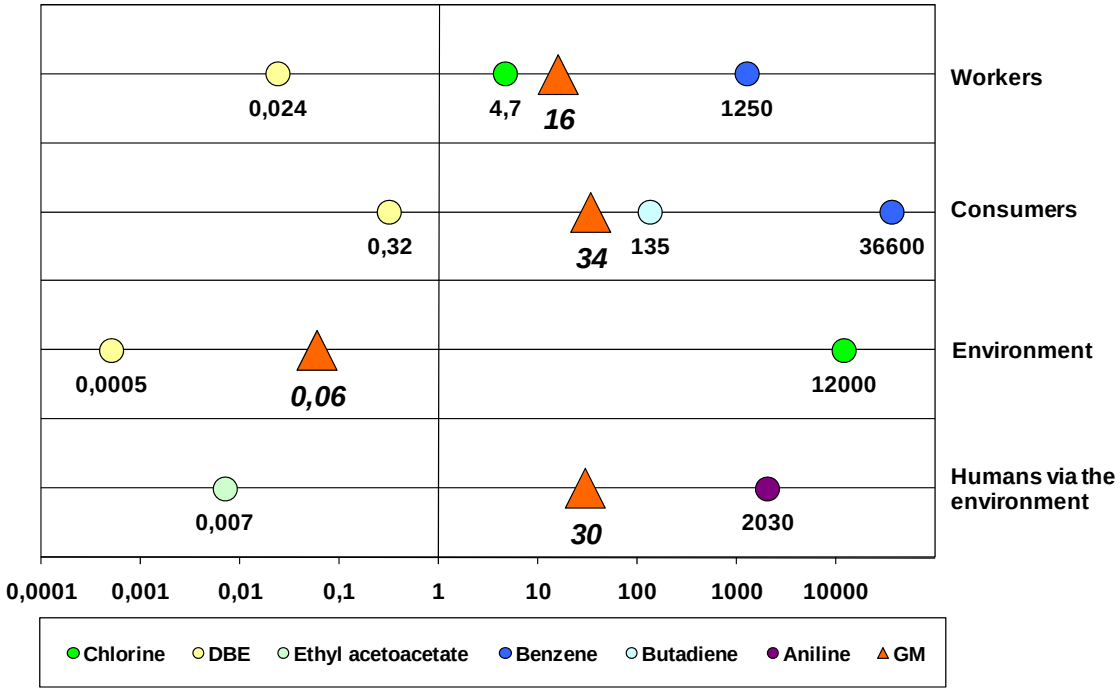


Figure 1.6 Aggregated Baseline Risk Score for workers, consumers, the environment and humans via the environment (GM: geometric mean of Aggregated Baseline Risk Score, DBE = dibutyl ether)

Therefore, no upper or lower bounds were set. Instead, it may be helpful to compare the mean Risk Score for the substances with the Risk Score of well known substances. For the impact areas workers, consumers, the environment and humans via the environment, the results for the reference substances chlorine, benzene, butadiene, dibutyl ether (DBE), ethyl acetoacetate and aniline are indicated.

Dibutyl ether is used as a solvent in low volumes and is characterised by "non-dispersive" use. This leads to a Risk Score for workers of 0.024 for this reference substance, well below the overall geometric mean at baseline.

For chlorine, an EU risk assessment report (RAR) exists with measured exposure data and an occupational exposure limit (OEL). It is assumed that exposure to chlorine is usually well below the OEL. This leads to a Risk Score of 4.7 for this reference substance.

Benzene is a human carcinogen for which a risk of 5.10^{5} was calculated. As indicated in the EU RAR, exposure may currently clearly exceed this concentration at some workplaces. This leads to a Risk Score of 1 250 for this reference substance.

Depending on the toxicity and use patterns, similar figures have been derived for consumers, the environment and humans via the environment. The selected reference substances show Risk Scores that spread over a wide range. As indicated by the reference substances, the results are plausible. In a future snapshot, the Risk Score will be calculated with updated data according to the situation. The Risk Score should move to demonstrate (or not) the measures undertaken.

As the data for the Risk Score calculations have been obtained from different data sources or by modelling, the data is of different quality. REACH addresses data quality in various forms ("data gap"). In the risk & quality indicator approach a Risk Score as well as a Quality Score is estimated for every reference substance.

Figure 1.7 illustrates the **Quality Score** obtained. By definition, the Quality Score ranges from 1 to 100 for every impact area. The geometric mean for workers has been calculated as **42**, for consumers as **52**, for the environment as **26** and for humans via the environment as **48** for LPV, MPV and HPV combined.

At this level, the calculated mean risk and quality scores are mainly intended for comparison to later points in time, i.e. in the year 2012 or later. The change over the years in the Aggregated Baseline Risk Score and Quality Score may be a headline indicator for political communication. As these single figures are much too complex for further interpretation and analysis, disaggregated levels are supplemented. It is proposed that the Quality Score and the Risk Score should not be amalgamated into a single figure. Moreover, any comparisons between different impact areas should be strictly avoided. Such comparisons would be a misinterpretation because — for example — different reference points for risk calculation are used in different impact areas.

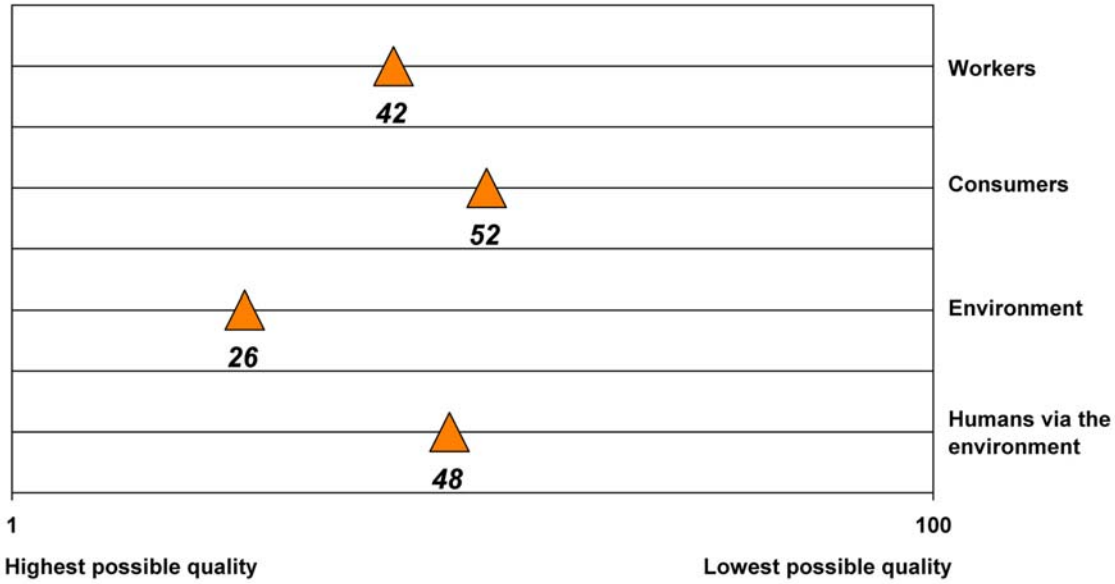


Figure 1.7 Aggregated Baseline Quality Score for workers, consumers, the environment and humans via the environment

In the next graphs the results are split according to these categories using whisker plots.

For the whisker plots, Figure 1.8 demonstrates the intended depth of information while Figure 1.9 and Figure 1.10 show the differentiated results for the 237 substances (including SVHCs) for the impact area workers.

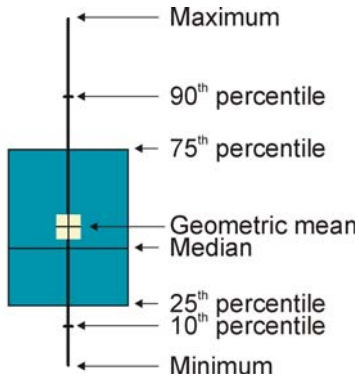


Figure 1.8 Legend to whisker plot

Figure 1.9 demonstrates no obvious systematic differences in assigned Risk Scores for the three production tonnage bands at baseline. This information is helpful in interpreting the appropriateness of the methodology: Even though the quality of information is clearly different for MPVs and LPVs on the one hand and HPVs on the other (see Figure 1.10), this does not mean that the Risk Score would automatically differ. However, for some substances with very high production volumes, it is more likely that the population risk modifier in combination with an elevated risk (e.g. exposure to carcinogens at the workplace) would result in extreme Risk Scores. Therefore, for HPVs, Risk Scores above 10^6 may show up. On the other hand, HPVs are often already assessed and well controlled by risk management measures, even before baseline. Therefore the 25th to 75th percentile range does not differ as much as for LPVs, where often a higher risk has to be assumed (few or no reported risk management measures, more often default assumptions for toxicity and exposure). For some SVHCs, no data were available from the Commission's IUCLID database for information on the number of use categories or even on production volumes. Therefore, so-called high population risk modifiers (see methodology chapter), which are not based on qualified data, were assigned.

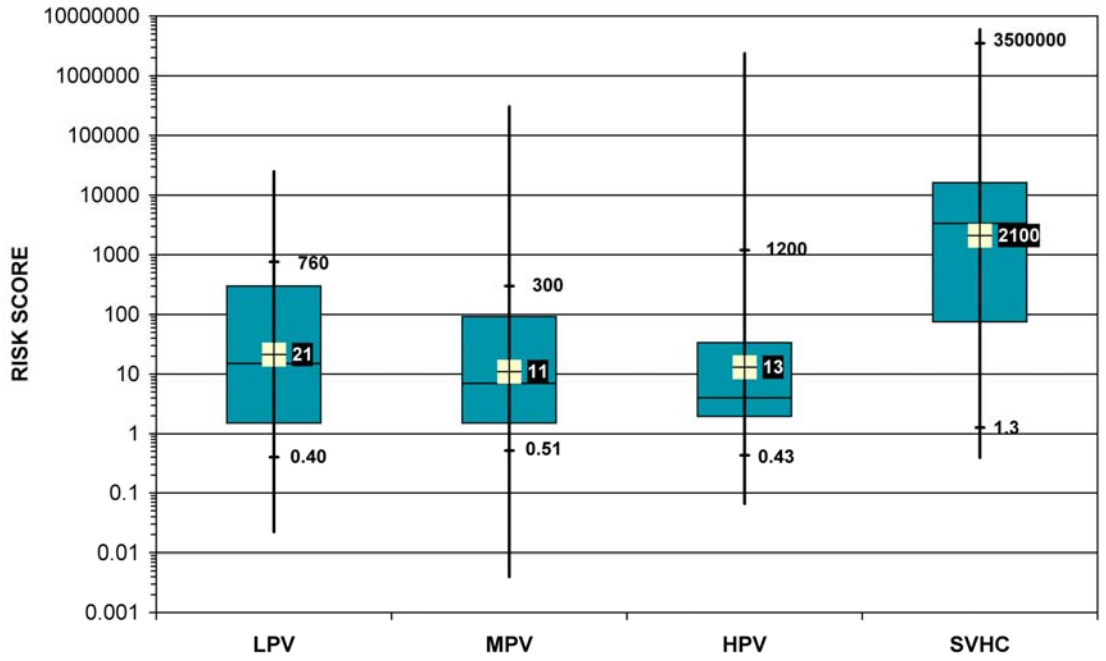


Figure 1.9 Baseline Risk Score Profile (workers). Numerical values given for geometric mean, 10th percentile and 90th percentile

Figure 1.10 clearly shows the better data quality for HPVs (and often SVHCs), compared to MPVs or LPVs at baseline. There is about a factor 2 difference in the geometric mean between HPVs on the one hand and LPVs/MPVs on the other. The very high concern for some substances did not always lead to a thorough assessment at baseline. Therefore, the distribution of SVHCs is much broader compared to the HPV group, which was assessed quite thoroughly in earlier priority programmes. Since REACH will probably provide better quality of information on MPVs in the next decade (and later for LPVs), it is assumed that the Quality Score will most probably decrease significantly (which means that the quality of available information improves), even with the limited set of substances monitored within this indicator system (Please remark an increase of Quality is reflected by an decrease of the indicator due to the calculation method).

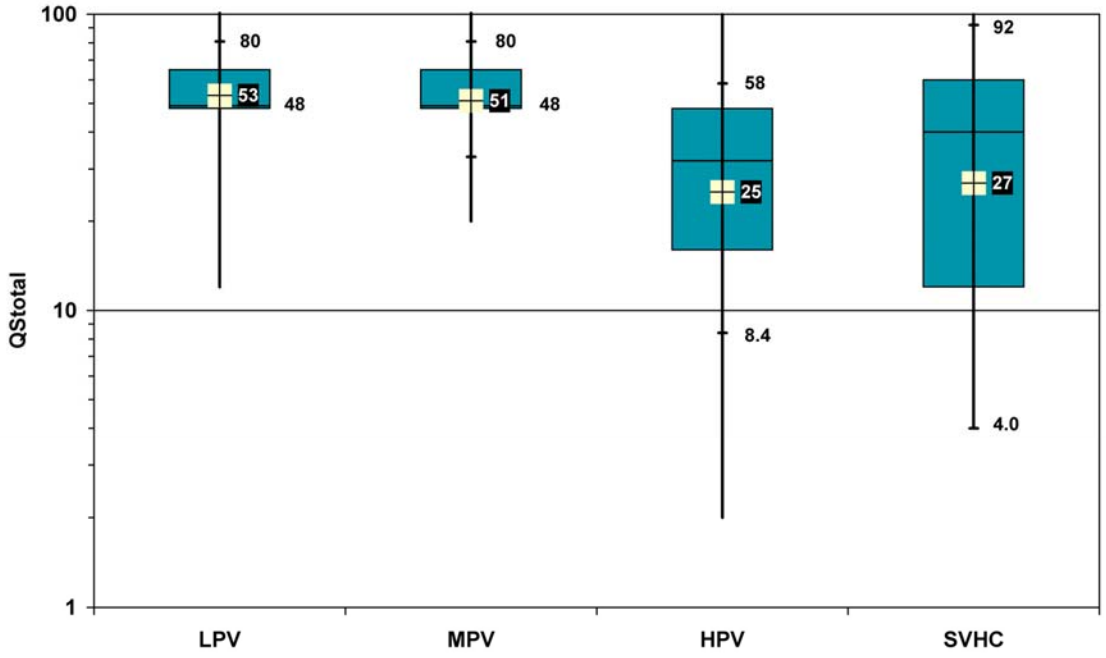


Figure 1.10 Baseline Quality Score Profile (workers). Numerical values given for geometric mean , 90th percentiles and 10th percentiles; note that medians and 25th percentiles have identical values for LPVs and MPVs; in addition, the 10th percentile is also identical to the median for LPVs

The risk and quality profile may also be presented as a cloud, as in Figure 1.11. It shows the risk and quality scores of the selected substances in one graph with a logarithmic scale for the Risk Score to demonstrate the large range of risks for the individual substances. The HPVs are shown as red squares. They are concentrated in the lower left-hand side of the diagram, indicating a lower risk and high quality. For LPVs and MPVs (blue dot and triangle) a similar risk range can be observed but the quality is worse. LPVs and MPVs are located in the upper range, indicating a lower quality. Again, it is demonstrated that the Risk Score for HPVs is often based on higher quality data compared to substances from lower production bands. The situation is different for SVHCs. As shown, it is noteworthy that there are some SVHCs displaying a relatively high Risk Score at a very good quality.

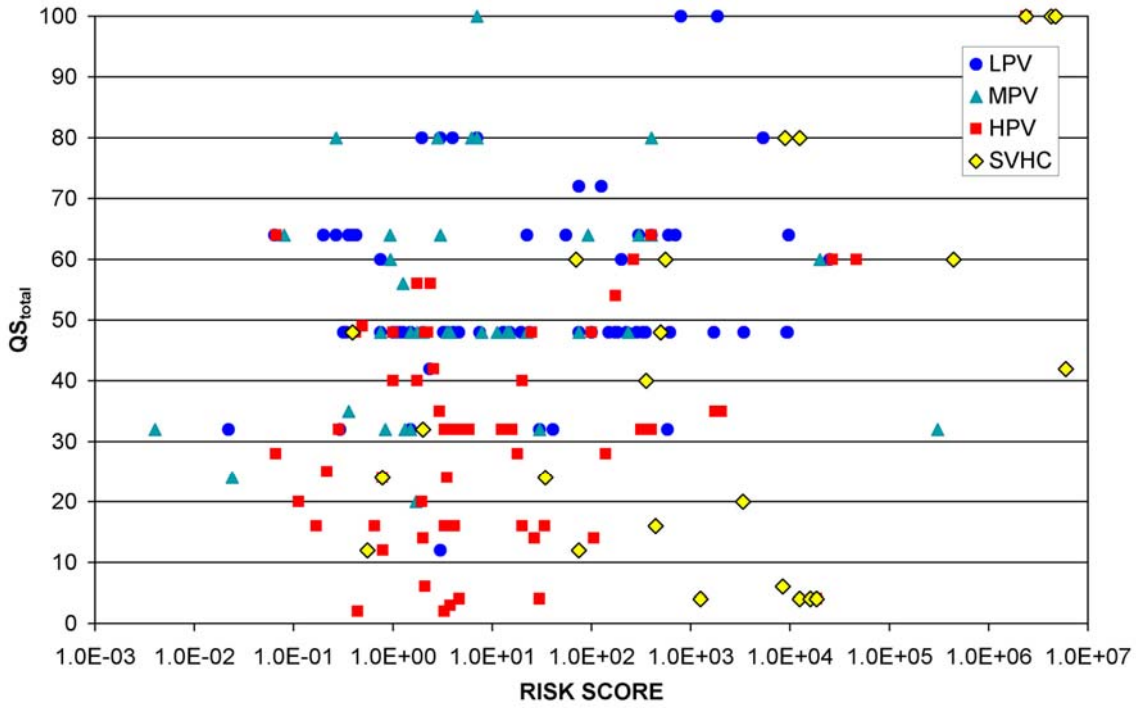


Figure 1.11 Baseline Risk and Quality Scores (workers), log scale for Risk Score

The distribution of Risk Score and Quality Score is quite similar for consumers and humans via the environment. A slightly different figure is given for the environment in Figure 1.12.

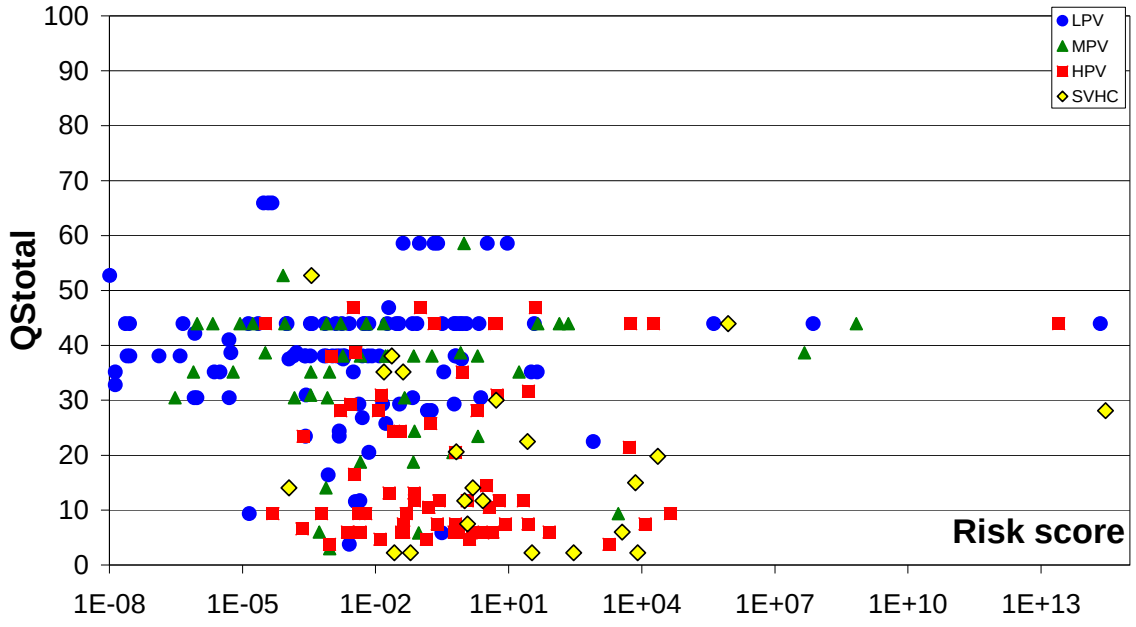


Figure 1.12 Baseline Risk and Quality Scores (environment), log scale for Risk Score

Again, Figure 1.12 demonstrates the large range of Risk Scores for the individual substances. Furthermore, it confirms the observations that, in general, the Quality Scores for the HPVs and the SVHCs are lower than for the MPVs and LPVs. In comparison to workers, consumers and humans via the environment, the spread in Quality Score is significantly reduced.

The Risk Score is based on exposure and toxicity data. Thus, the availability of high-quality input data for toxicity or exposure assessment compared to "second-choice" information is of high importance.

Figure 1.13 provides information on the origin of **toxicity** data for workers. The quality of the toxicity data rises from "default" through "modelling", "NOAEL", "risk phrases" to "OEL".

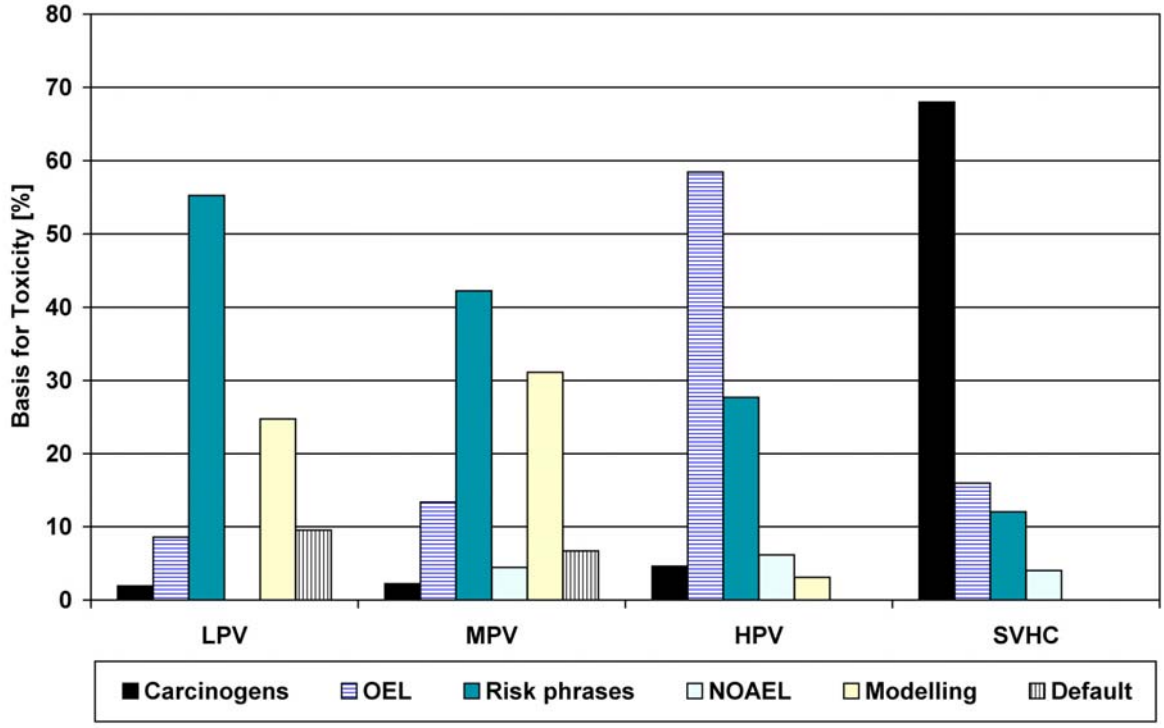


Figure 1.13 Baseline data availability analysis for toxicity data (workers)

The increasing column size from LPVs to HPVs for the use of occupational limit values (OELs) demonstrates that such OELs are mostly available for well-characterised high production volume chemicals (> 58% of substances). On the contrary, for most LPVs risk phrases had to be used to establish $DNEL_{analogues}$ (only few OELs are available; the terms $DNEL_{analogues}$ and $OEL_{analogues}$ are used here interchangeably). This is clearly a second choice. NOAELs are only used if no OELs or risk phrases are available. This was necessary in a few cases for HPVs and MPVs. However, for several LPVs and MPVs, even those NOAELs were not available. Therefore, modelling or defaults had to be used for these substances, which was necessary at all for HPVs only in a very few cases. The SVHCs are somewhat different in that they were chosen — among other criteria — for their classification as carcinogens. There is therefore a high fraction of carcinogens among these substances by definition.

For consumers, the exposure scenario is different than for workers. Here existing toxicological values are first choice. OELs and R-phrases are assessed as second choice.

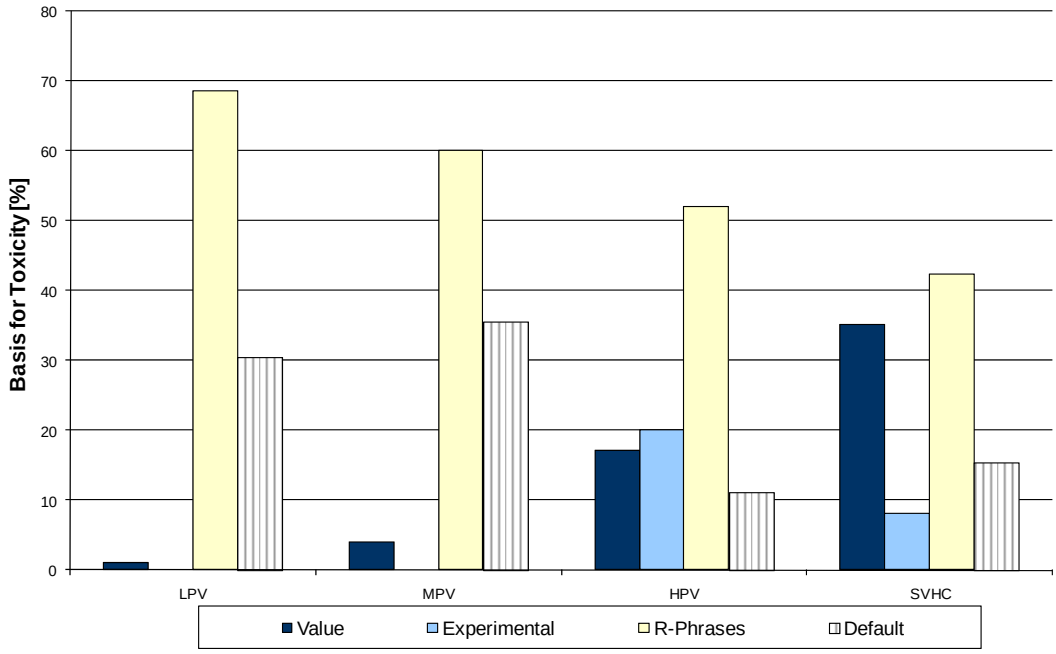


Figure1.14 Baseline data availability analysis for toxicity data (consumers)

In Figure 1.14, the increasing column size from LPVs to HPVs and SVHCs for pre-existing toxicological values demonstrates that such reference values are mostly available for well characterised high production volume chemicals. However, it represents only <20% of HPVs, much less than OELs for workers.

The **exposure** situation is characterised by an even more pronounced difference.

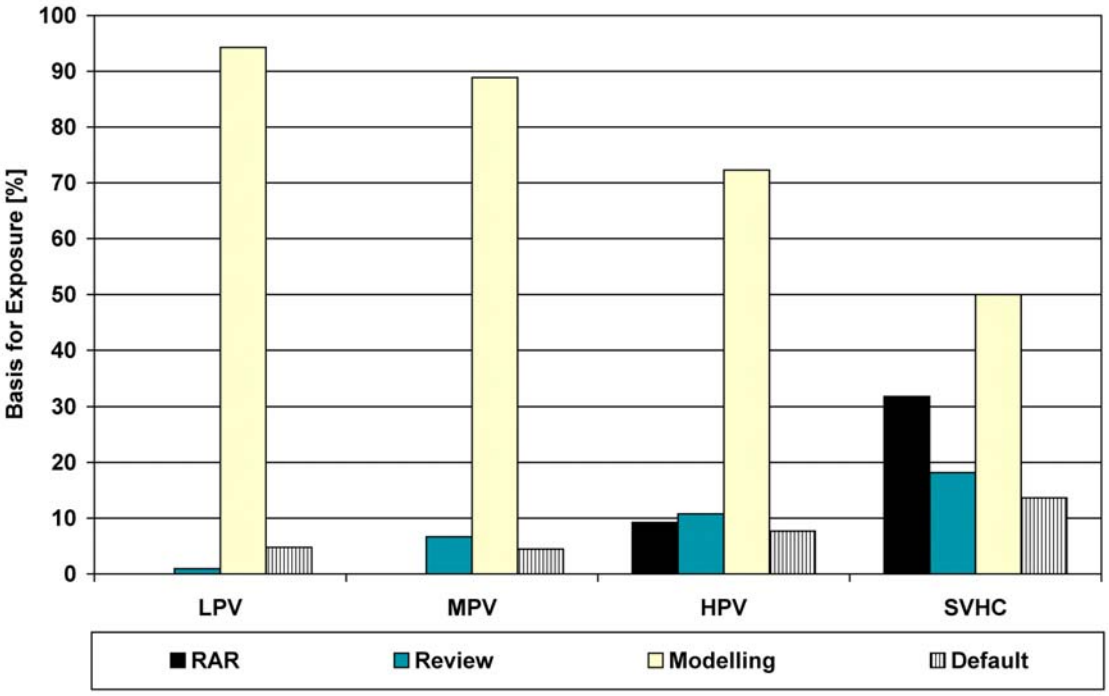


Figure 1.15 Baseline data availability analysis for exposure data (workers)

For workers, most of all the exposure assessments (for LPVs, MPVs and HPVs) had to be done by modelling. However, in 9% of the HPVs, highly qualified exposure assessments from RARs could be used to assess exposure. In addition, in 11% of the HPVs and in 7% of the MPVs, other qualified reviews provided better exposure data. In the case of SVHCs, a higher

percentage of qualified data (in the form of RARs or other reviews) is evident, probably because the high concern associated with these substances had already led to more detailed exposure assessments.

For consumers, the characteristics of the exposure data are quite similar.

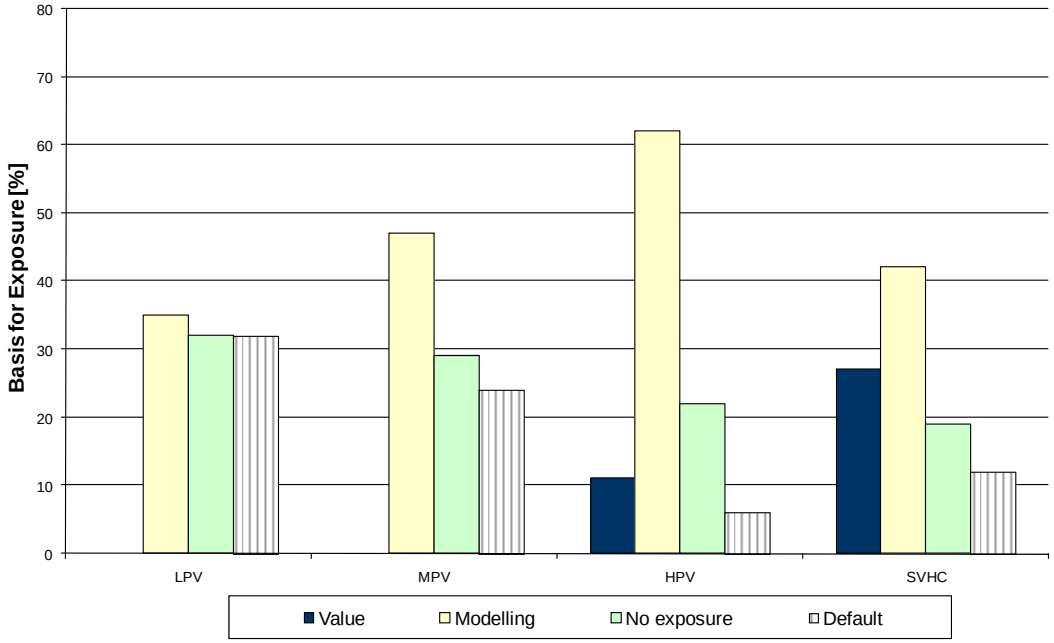


Figure 1.16 Baseline data availability analysis for exposure data (consumers)

Modelling was the main source for exposure assessments for LPVs, MPVs, HPVs and SVHCs. However, in slightly more than 10% of the HPVs and almost 30% of the SVHCs, highly qualified exposure assessments from RARs (see methodology chapter) could be used to assess exposure. It is assumed that future evaluations of exposure assessments from chemical safety reports (CSRs) will become available, serving as high-quality input for the risk calculation.

The quality description above shows the innovative character of the methodology. A clear procedure has been developed which allows estimates for substances even with only few or low quality data. This is achieved by making use of the guidance documents developed under REACH. They provide multiple tools for modelling. For compensation, the quality of the input data for the Risk Score is monitored.

The **risk characterisation ratio (RCR)** is the main part of the Risk Score and gives the ratio of exposure over toxic effect. The RCR is the lowest disaggregated data available. Nevertheless, the interpretation of the data needs to be made very cautiously.

Figure 1.17 shows the assumed exposure concentration on the x-axis and the assumed safe concentration (as expressed by the occupational exposure limit or other $DNEL_{analogues}$) on the y-axis for all 215 substances in the three different tonnage bands. The dashed diagonal line discriminates exposure higher or lower than the OEL.

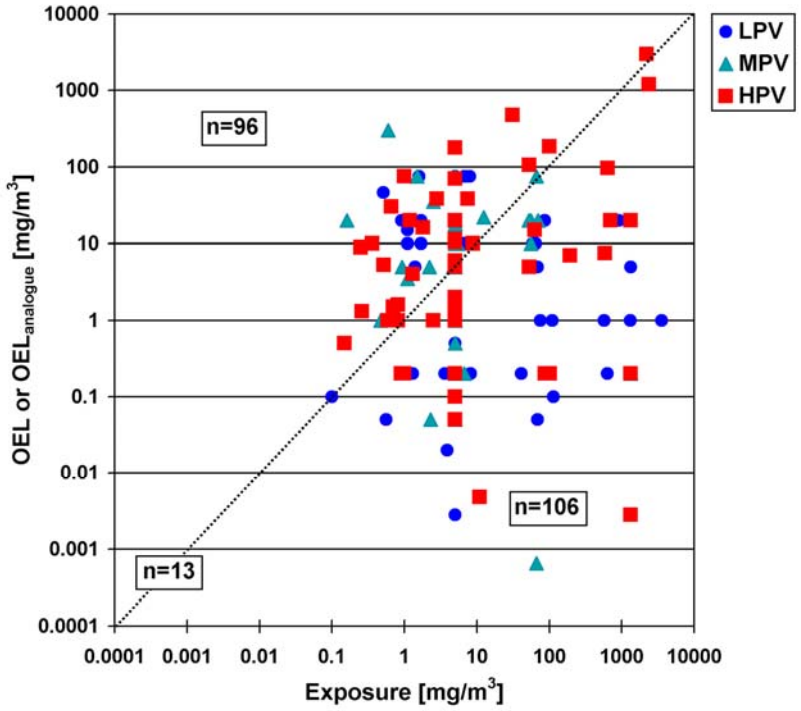


Figure 1.17 Baseline analysis of the risk characterisation ratio (workers)

Figure 1.17 thus shows the risk characterisation ratio (RCR) for all substances with RCR < 1 to the left of the diagonal line (96 substances) and RCR > 1 to the right of this dashed line (106 substances). Overall, 36% of the RCRs are above 10. It may be assumed that, as a result of REACH, there will be a clearly visible shift left towards RCRs lower than one (to the upper left-hand triangle in Figure 1.17) because REACH demands risk management measures ensuring that exposure is below the DNEL.

For consumers, Figure 1.18 shows a different pattern. Only 39 substances are located on the left-hand side but 115 on the right-hand side. The exposure is estimated as zero for a set of 61 substances.

If all substances are considered (including substances for which the exposure score is 0) and if we apply a criterion of 0.01 (RCR < 0.01), 70 substances (30%) can be assumed to be of "low relevance" for consumers based on the set of 237 substances (including SVHCs).

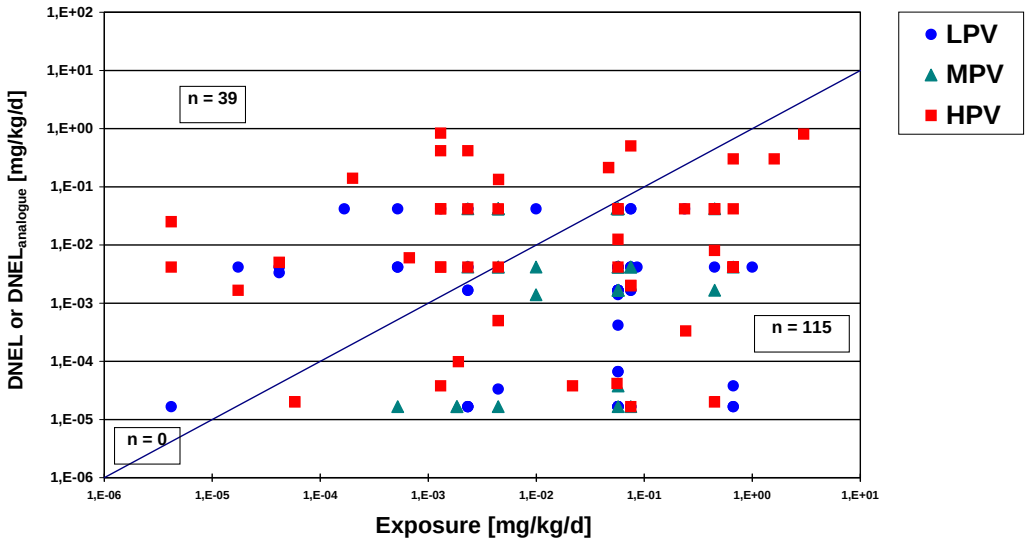


Figure 1.18 Baseline analysis of the risk characterisation ratio (consumers)

For the environment, Figure 1.19 shows the assumed exposure concentration on the x-axis and the effect score on the y-axis. The diagonal line discriminates exposure higher or lower than the effect score value (pseudo-PNEC). Substances characterised as PBT substances and substances classified with R50/53 are emphasized in the figure.

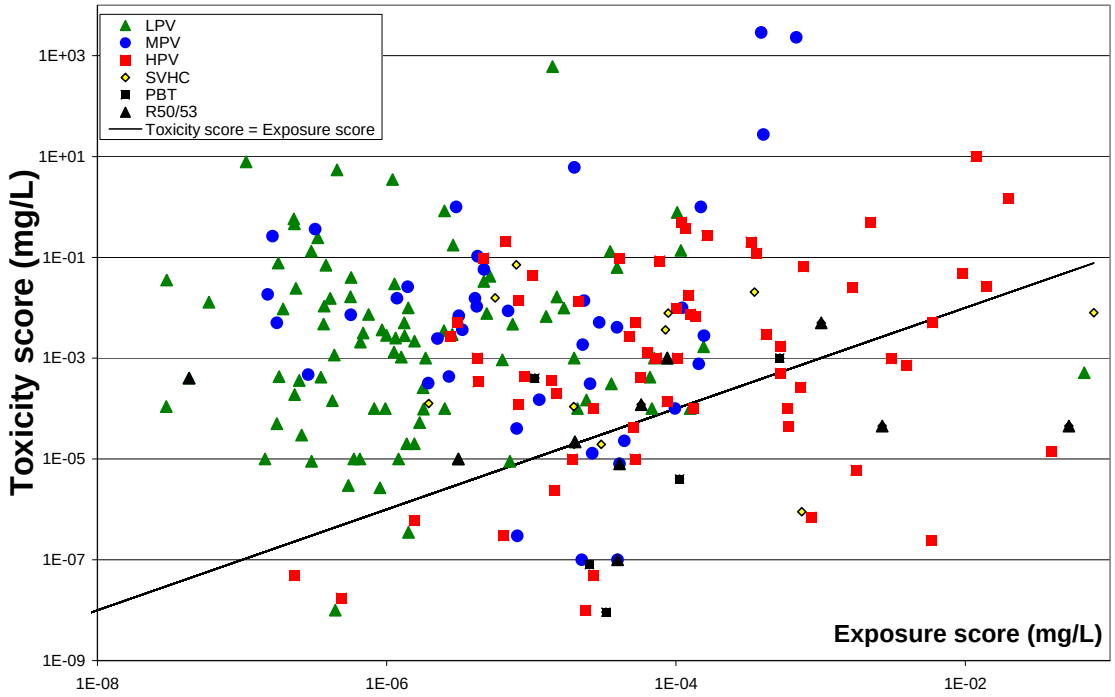


Figure 1.19 Baseline analysis of the risk characterisation ratio (environment). All substances with an RCR<10^{-8} excluded from the plot

Figure 1.19 thus shows the risk characterisation ratio (RCR) for all substances with RCR < 1 to the left of the diagonal line (176 substances) and RCR > 1 to the right of this dashed line (39 substances). Even though the indicator system does not provide results on the absolute and "real" risk for the environment, it may be assumed that, as a consequence of REACH, there will be a clearly visible shift of the substances with an RCR above 1 towards RCRs lower than 1 (to the left in Figure 1.19) because REACH demands the introduction of sufficient risk management measures in order to ensure safe use.

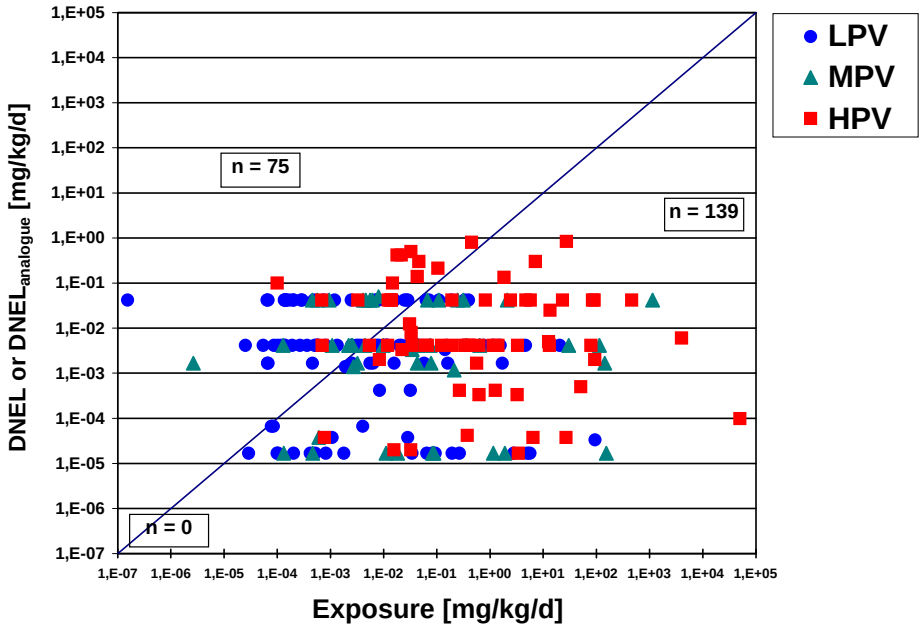


Figure 1.20 Baseline analysis of the risk characterisation ratio (humans via the environment)

For humans via the environment (Figure 1.20), the characteristics are quite clear. Nearly all HPVs exhibit an exposure higher than the corresponding effect value (DNEL). LPVs and MPVs are located on both sides of the diagonal. For 75 substances exposure is estimated to be lower than the DNEL. For 139 substances a sometimes remarkably higher exposure than the DNEL can be observed. The exposure is estimated as zero for one substance.

Conclusion

The Risk and Quality indicator system, the core element of the REACH Baseline Study presented in 2007, has been applied for an additional set of 100 substances in 2008. The system shows reasonable results, differentiation and sensitivity to changes. The calculations permit relative comparisons between substances from the different production bands (HPV, MPV and LPV) and will provide comparisons to future points in time. Both changes in risk and changes in the quality of information can be observed and analysed in comparison to baseline (i.e. the year 2007). This indicator system apparently provides sufficient sensitivity to demonstrate REACH-related changes.

As already described, the indicator system does not provide results on the absolute and "real" risk at baseline or in the future.

However, the calculated figures correlate with a plausible risk profile, established by scientific approximations and widely agreed conventions in handling uncertainty. The depth of assessment is balanced against transparency for non-experts (e.g. only a limited number of sources were used) and the handling of a sufficiently large number of substances to create a meaningful index.

However, because of the relatively simple assessment procedures used and the "nominal" character of the calculated risk, no absolute interpretation of the risk score or the risk characterisation ratio (RCR) should be performed. For example, the interpretation of an RCR >1 as a "dangerous" situation at the workplace or an RCR of <1 as a "safe" situation is clearly an over-interpretation of this parameter. Future changes in risk characterisation ratios and in risk scores will not be trivial. Due to the better quality of information available in the REACH process, some toxicity values may have to be corrected downwards or upwards. Poor modelling results for exposure will be substituted by better calculations or measurements. Again, this may lead to upward or downward corrections of the exposure estimate and thus to some unpredictable changes in the risk characterisation ratio in the future.

However, an overall trend towards RCRs close to 1 or below 1 is predicted according to the principles of REACH. This may include measures for exposure limitations. It will be interesting to observe the speed of this development, the differentiation for substances from the different production bands and the simultaneous changes in information quality.

At the same time, industry may switch to newly developed chemicals. REACH sets equivalent obligations on existing chemicals and established a “level playing field” between existing and new chemicals. The indicator on the 'Registration of new chemicals' will monitor progress. Over the period of the last 10 years, approximately 300 new chemicals were registered each year. If industry chooses to substitute existing chemicals, then the registration rate of new chemicals will accelerate.

As a result of this, the project has set up a consequent and coherent indicator system which will allow the effects of REACH to be monitored. At the core of the indicator system is the innovative risk & quality indicator system. The risk & quality indicator system combines a risk-based approach with a clear procedure to deal with different data sources, modelling, and even data gaps. As a result, every risk score comes with a quality tag providing the reader with transparent results.

The snapshot presents an overview of the major trends in production and uses of toxic chemicals as well as a micro-view into the risks connected to the use of substances. With additional future snapshots an indicator will arise showing the major trends over time.

But even today the risk & quality indicator as a snapshot has a lot to tell. It shows detailed substance-specific data on risk and quality scores. By indicating different tonnage bands, plausible results appear for workers, consumers, the environment and humans via the environment alike, giving the reader a deeper understanding of the existing knowledge of risk.

2 Background

In October 2003, the European Commission adopted a legislative proposal for implementing a new EU chemicals policy. After changes introduced in 2005 and the final reading in the European Parliament, REACH was adopted in December 2006 by both the European Parliament and the Council (Regulation (EC) No 1907/2006). It entered into force in June 2007. The new regulatory system known as REACH (Registration, Evaluation, Authorisation and restriction of CHemicals) is designed to solve some major problems associated with the current legislation:

- Lack of data on intrinsic properties (i.e. hazards) of existing substances;
- Lack of knowledge about how chemicals are used by downstream users;
- Lack of appropriate risk management measures (as a secondary effect of the lack of risk assessments and of the currently insufficient and incorrect classification and labelling of existing substances);
- Insufficient progress by EU Member State authorities in conducting hazard and risk assessments on existing substances as well as slow evolution of proposals for restrictions if unacceptable risks have been identified.

The project team started work on the REACH Baseline Study in January 2006.

The task is the development of a methodology to monitor the success of the REACH legislation and its implementation and prepare a first snapshot for 2007. At a later date (2012/13), another snapshot will be prepared according to the methodology developed. The combined snapshots should allow the success of the REACH legislation to be monitored and evaluated.

The approach taken is to establish a framework of indicators to illustrate the different aspects of REACH. The indicators should make use of available data bases.

The project team introduced the first draft of this framework to the Steering Committee at is first meeting in May 2006 in Luxembourg. At the second meeting in December 2006, a more developed version was presented. The major results were discussed at the third Steering Committee meeting in June 2007 and presented to a wider audience at a 'Launch event' in September 2007. To improve the statistical basis the Steering Committee advised Eurostat to apply the methodology with an additional set of 100 substances: the final results have been presented in December 2008.

Chapter 3 discusses the key objectives of REACH and the derivation of an indicator system. In Chapter 4, the methodology of the risk-based indicator will be introduced. This so-called “risk & quality indicator” is considered to be the most important part of the overall indicator system. Additional administrative and supplementary indicators are presented in Chapter 5. The result of the snapshot 2007 (including the additional set of substances assessed in 2008) is discussed in Chapter 6. The data documentation is summarised in Chapter 7. A short discussion and recommendations are given in Chapter 8. A glossary and literature chapter complete this report.

Appendices I-IV contain a detailed technical description of the risk & quality indicator. A handbook on the risk and quality data base is presented in Appendix V. Appendix VI gives an overview of other risk-based indicator systems. Appendix VII reports the methodology sheets for supplementary indicators.

The project team would like to acknowledge the very fruitful and constructive discussions we have enjoyed with the Steering Committee.

Agnes Palovics	Josef Fodor National Centre for Public Health, Hungary
Alick Morris	DG Employment, Social Affairs and Equal Opportunities
Andreas Ahrens	Ökopol, Germany, now with ECHA
Axel Hahn	Bundesinstitut für Risikobewertung, Germany
Christian Heidorn*	Eurostat, Environment Statistics, chair
Dik van de Meent	RIVM, the Netherlands
Erik van der Plassche*	JRC — European Chemicals Bureau
Finn Pedersen*	DG Environment, currently with ECHA
Gabi Schöning	European Environment Agency, now with ECHA
Gerald Vollmer	European Environment Agency
Gigliola Fontanesi	DG Health and Consumer Protection
Johan Nouwen*	DG Enterprise and Industry, now with ECHA
Kathrine Loe Hansen	Statistics Norway
Leo Heezen	European Chemical Industry Council (CEFIC)
Bernd Kappenberg	European Chemical Industry Council (CEFIC)
Michael Hauschildt	TU Denmark, Lyngby
Peter Pärt	JRC, Institute for environment and Sustainability
Sebastian Gil*	DG Environment
Slawomir Czerczak	NOFER Institute of Occupational Health, Poland
Viveka Palm	Statistics Sweden

* Christian Heidorn, Erik van der Plassche, Finn Petersen, Sebastian Gil and Johan Nouwen are part of the project management team overlooking this project on behalf of the European Commission.

Table 2.1 Steering committee members

3 Policy monitoring of REACH through indicators

The aim of the REACH Baseline Study is to develop a system of REACH-related indicators for chemicals. This indicator set is used to monitor the success of REACH, the new EU Chemicals Regulation. The methodology and the elements of the indicator set are therefore closely linked to the structure of REACH, its objectives and key elements. During the development of the REACH Baseline indicator set, the experiences with existing indicator systems were integrated as far as possible.

Chapter 3.1 provides a short introduction to REACH. This is to explain the methodology used for the development of the REACH Baseline indicator set, which is structured in line with the objectives and the key elements of REACH (see Chapters 3.2 and 3.3). The proposed framework for the indicator set is described in detail in Chapter 3.4 (technical details of indicator elements are given in the corresponding Appendices I-V).

3.1 REACH: structure, objectives and new elements

The purpose of REACH is to ensure a high level of protection for human health and the environment, including the promotion of alternative methods for the assessment of substance hazards as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation (REACH, Dec. 2006, Article1(1))[8]. REACH introduces a new era of chemicals policy in Europe. The former EU legislative framework for chemical substances has not been able to generate sufficient information regarding the effects of the majority of existing chemicals on human health and the environment.

Identification and assessment of risks as well as the subsequent introduction of risk management measures have taken place too slowly, delaying research and innovation in the EU chemicals industry in this regard. The former system developed over time and had several drawbacks (EC 2006):

- Regulation (EC) 793/93 introduced a distinction between so-called "existing" and "new" chemicals. The majority of the chemicals used in the EU are "existing" chemicals (listed in EINECS, with more than 100 000 different substances); "only" 3 800 chemicals were introduced to the market after 1981.
- New chemicals had to be tested before placement on the market. No such provisions were made for "existing" chemicals. For these substances, there is generally a lack of sufficient, publicly available information to assess and use them in a safe way.
- Public authorities were responsible for undertaking risk assessments of substances rather than the manufacturer, importer, or users of the substances. Risk assessments had to be comprehensive instead of targeted and use-specific. As a consequence, since 1993, risk assessment reports have only been completed for the limited number of 141 high-volume chemicals.
- Only manufacturers and importers of chemicals were required to supply information on the properties of chemicals. Downstream users were not involved in this process. As a consequence, information on uses and related exposures of chemicals has been difficult to obtain and is very rare for most substances.
- Notification and testing requirements for new chemicals started from very low production volumes of 10 kg per year — this constitutes a barrier to innovation for the EU chemicals industry. Instead of research on new (and better characterised) substances, this has stimulated the use of less well characterised but existing substances.
- The EU system to restrict the marketing and use of high-risk substances has been very slow.

Taking into account this experience with the existing EU legislation on chemicals, a new system called REACH was developed. REACH has the following central elements:

- Registration of chemicals with a production volume of 1 tonne/year and more;
- Evaluation of registration dossiers and substances;
- Authorisation of chemicals which are of very high concern;
- Restriction of chemicals of very high concern as a safety net;
- Establishment of the European Chemicals Agency to manage the whole system.

[8] The expression "human health" applies to workers as well as to the general population. In the latter case, REACH distinguishes between direct exposure of consumers and exposure of humans via the environment.

The main objectives of the new EU chemicals legislation (as identified in the White Paper (CEC 2001)) are:

- Protection of human health and the environment;
- Improvement of knowledge on properties and safe uses of chemicals;
- Assessment of existing and new chemicals in a single, coherent system;
- Increased transparency and consumer awareness;
- Promotion of non-animal testing;
- Maintenance and enhancement of the competitiveness of the EU chemical industry;
- Prevention of fragmentation of the internal market;
- Conformity with the EU's international obligations under the WTO.

REACH uses existing chemical management concepts — e.g. safety data sheets — as the central instrument for communication between manufacturers and users of substances. At the same time, new concepts have been introduced in order to achieve a real improvement in the management of chemicals. The involvement not only of manufacturers and importers, but also of downstream users of chemicals can be considered to be the key element of REACH for improved exchange of information within the supply chains.

In comparison to the former EU scheme for the assessment of existing substances and the notification of new substances, the following new elements of REACH are of special importance for the REACH Baseline Study:

- REACH defines equal assessment requirements for existing substances and new substances.
- Under REACH, registration is only necessary for substances with production volumes of 1 tonne/year and more (in the past, notification of new substances has been required starting from a production volume of 10 kg/year).
- Registration of substances, including evaluation of the substance properties and the conditions of safe use, is done by the manufacturer/importer of the substances.
- Chemical safety assessments have to be performed as part of the registration for substances with a production volume of 10 tonnes/year and more.
- Exposure assessments (including exposure scenarios) and risk characterisation became obligatory elements of a chemical safety assessment for substances which have to be classified as dangerous according to Directive 67/548/EEC and for substances with PBT/vPvB[9] properties.
- The description of the conditions of safe use should cover the whole life cycle of the substances (including their production, formulation, (industrial/professional/private) use, recovery and disposal).
- The main results of the chemical safety report on a substance have to be integrated into the related material safety data sheet and communicated throughout the supply chains.
- The extended safety data sheets (SDSs) contain reference values for risk characterisation (PNEC and DNEL/DMEL values)[10]; exposure scenarios are communicated as Annexes to the safety data sheets. In addition, the results of the PBT/vPvB assessment are communicated in the SDSs.
- Communication about risk management measures and conditions of safe use will become an essential element of communication in the supply chains.
- Downstream users are involved in the information exchange during registration.
- Downstream users are required to assess the safety of their own conditions of use of substances.
- Evaluation of registration dossiers will be performed by the European Chemicals Agency (examination of all testing proposals and at least 5% of the registration dossiers will undergo a compliance check according to Article 41(5)); substance evaluation will be performed by the Member States (according to Article 45).
- Under REACH, data requirements for substance registration are primarily dependent on production volume (production volume is used as a proxy for likelihood of exposure); in Annex VII–IX of REACH, possibilities for adapting the standard data requirements are described (waiving options). Use of QSARs[11] and read-across options are described in REACH in order to avoid unnecessary costs and to reduce animal testing.

---

9 PBT substances/vPvB substances: substances that are **p**ersistent, **b**ioaccumulative and **t**oxic/substances that are **v**ery **p**ersistent and **v**ery **b**ioaccumulative.

10 PNEC: Predicted No-Effect Concentration; DNEL: Derived No-Effect Level. For non-threshold substances, reference values for a quantitative description of the exposure and for the risk characterisation are currently being developed in RIP 3.2-2 (Expert Group on Human Health Risk Characterisation, derivation of DNELs). As a provisional abbreviation the term "DMEL" is used ("Derived Minimal Effect Level") (References: Concise TGD RIP 3.2-1 (CEFIC 2005), Reference preliminary TGD, Chapter 3, Human health hazard assessment; working paper, version 5 (Kroese and Pronk 2006)).

11 QSAR: Quantitative Structure-Activity Relationships.

- Irrespective of the production volume of the substances, the authorisation step in REACH takes care of substances of very high concern.
- Restrictions allow unacceptable risks of chemicals to human health or the environment to be addressed on a community-wide basis. Decisions on restriction must take into account the related socio-economic impact, including the availability of alternatives. Current restrictions are transferred into REACH.

Going back to the objectives of REACH, the registration, evaluation and authorisation requirements defined by REACH have the potential to increase our knowledge of hazardous properties of chemicals and their uses, which should then lead to a reduction of the risks associated with the use of chemicals. The REACH Baseline Study aims to provide an indicator set to make it possible to monitor whether such a successful outcome takes place or not. In order to ensure that the changes monitored are indeed related to REACH, an indicator set has been developed that is directly linked to the objectives and key elements of REACH.

3.2 REACH, risk reduction and a REACH indicator system

Risks posed by chemicals are determined by the hazardous properties of the chemicals, their toxicological potency, and the exposures taking place during the chemical lifecycle.

REACH — like any other legislation — does not change the hazardous properties or the toxicological potency of pure substances. However, REACH is expected to trigger several changes that are risk-related compared with the previous legislation on existing substances (see Table 3.1 below).

Increase in knowledge of properties of existing substances
Increase in knowledge of uses of substances and related exposures
Increase in knowledge of dangerous substances in articles and communication in the supply chain*
Improvement of data in extended safety data sheets as the key communication tool
Direct communication of uses which are not supported by the manufacturer/importer
Increased involvement of downstream users in the communication and assessment of safe uses*
Cessation of production of substances for which no standard set of data is available by deadline
Cessation of use of substances of very high concern (if no authorisation is granted by sunset date)
Enhanced reduction in the risks related to chemicals due to a change in the manner of use and/or implementation of more appropriate risk management measures
Enhanced substitution of dangerous chemicals by less dangerous ones

* These two changes are actually not monitored by the proposed indicator system of the Baseline Study.

Table 3.1 Changes which are expected to be triggered by REACH for existing substances (with a production volume of 1 tonne/year and more)

REACH aims to enhance society's knowledge of these properties. In addition, communication about risk management and safe use of chemicals is a central element of REACH. Together, this should lead to a change in the way in which chemicals are managed and used.

In addition, REACH encourages the substitution of dangerous chemicals by less dangerous ones where suitable alternatives are available. This will lead to a further reduction of exposure.

The expected result is a reduction in exposure for the environment, workers, and consumers. The use of the most hazardous substances will be severely restricted and a substantial reduction of exposure will take place. For other hazardous substances, risk reduction methods will be implemented to reduce exposure to acceptable levels.

Reduction in exposure means reduction of risk. In order to monitor the success of REACH in this respect, the evolution of risks associated with chemicals can be assessed by data on exposure. As an indication of the potential risk, the ratios between exposures and toxicity-related reference values can be used.

In addition, lack of knowledge (regarding substance properties as well as exposures) itself represents a risk, because appropriate risk management measures for a given substance cannot be determined if these data are missing. As an indication of this kind of risk, the quality of the database available for a specific substance can be used.

Referring to the risk caused by lack of knowledge, any effort made to increase knowledge can be used as an indication of (at least a potential) reduction of risk. Many tasks defined by REACH aim to increase knowledge about properties and uses of substances. Monitoring the process of REACH (e.g. numbers of dossiers received, numbers of chemical safety assessments prepared, etc.) can be used as an indicator for the development of society's knowledge regarding chemicals and their sustainable management. It is assumed that increasing this knowledge will equal reducing the risks associated with chemicals.

3.3 Demands for a system of REACH-related indicators

On the one hand, the REACH Baseline Study intends to provide a "snapshot" prior to the entry into force of the REACH legislation; on the other hand, it should provide a methodology for repeating the same exercise periodically in the future. The comparability of the generated data must be ensured in order to allow a future assessment of the objectives of REACH by comparing the "snapshots".

Different types of chemical indicators exist, as documented in a previous study (Eurostat 2006, Oeko 2006):

- Production volume and consumption volume for a limited set of substances included in Eurostat's Prodcom statistics;
- Concentration of toxic chemicals (e.g. dioxins, organotins, heavy metals) in human tissues or biomarkers (e.g. fish).

Snapshots for a limited time period exist for:

- Knowledge of toxicological properties;
- Chemical accidents (economic impacts);
- Concentration of specific chemicals in the environment.

Some further methodological approaches are published but lack sufficient data bases (Oeko 2006).

Unlike existing indicators, REACH-related indicators refer specifically to the new chemicals legislation and the risks related to chemicals.

In a preparatory workshop (21 and 22 March 2005), the European Commission defined the demands for a system of these types of REACH-related indicators. As with the indicators used in Life Cycle Assessment, three different types of indicators have been identified as necessary elements of a REACH-related indicator system:

- Policy or administrative indicators (level 1 indicators), e.g. number of animal tests, rate of re-classification of substances, public perception of REACH;
- Midpoint indicators (level 2 indicators), e.g. exposure levels in workplaces, exposure modelling, intake modelling;
- Endpoint or damage indicators (level 3 indicators), e.g. cancer rates, allergies, endocrine effects, occupational skin diseases.

Besides the need for differentiation between indicators for environmental health, occupational health and public health, indicators related to communication are considered to be an additional essential element of a REACH-related indicator system.

Three elements for a REACH-related indicator system have been identified as **key issues**:

- It must be risk-based; the direct measurement of incidence and type of damage caused by chemicals is not possible, considering the limitations of the Baseline Study. These limitations are posed, among others, by the European scale, the inability to directly compare data, and the burden of the required action to be taken by national research institutes. Therefore, the best approach for the Baseline Study is a risk-based instead of a damage-based approach.
- It should be set up based on lessons learned from previous efforts. The best way to start building an approach is to learn from previous efforts for developing indicators for hazardous chemicals undertaken by the European Environment Agency, Eurostat, other institutions and research programmes. Taking into account the limited time scale, the Baseline Study should be based on available data and existing methodology (there is no time to generate new data via monitoring or measurements). When using existing concepts, these concepts and methods should be updated in such a way that they focus on the expected benefits of REACH.
- It must evaluate potential risk. A generic assessment is made of the (environmental) risk of chemicals through the extrapolation of available information. This will lead to an estimation of the potential risk in the pre-REACH situation and in the post-REACH situations.

The ideal indicator would display the risk of chemicals related to the years of REACH being in place (see Figure 3.1).

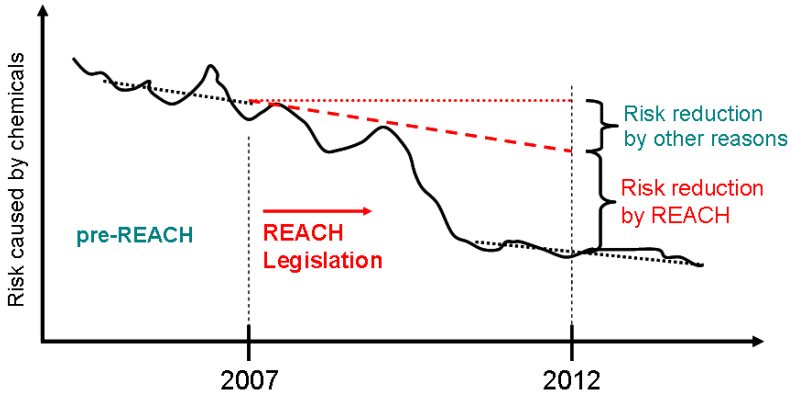


Figure 3.1 The ideal indicator of the evolution of risks triggered by REACH

As shown in Figure 3.1, it may be assumed that risks are decreasing over time. When REACH is enacted, we may also observe a steep fall in risk. This fall would be attributed to the risk reduction by REACH. Unfortunately, this ideal indicator is not available since the real risk cannot be measured. The scheme highlights a second element of risk monitoring with REACH. There is an underlying trend towards risk reduction. It could be assumed that, to a minor extent, risk reduction would take place independently of REACH as an ongoing process in the chemical industry (indicated in the figure by the second red line). Moreover, if REACH had not been developed, the current risk assessment and risk reduction programme would have continued, which would also have led to a continuous reduction of risks due to prioritised substances.

The separation between REACH effects and the effects of other legislation was discussed and identified as a critical issue because it is reasonable to assume that improvements in the environment or human health are due to the combined impact of different sets of legislation. On the other hand, REACH should be considered as a central information system since it entails an all encompassing approach.

At present the future evolution of risks (for human health and the environment) caused by chemicals is unknown. The line given in Figure 3.1 describes only an assumption. The real evolution might be different. The indicator system in the Baseline Study aims to monitor the real evolution. By doing this, the focus of the Baseline Study is not restricted to indications of the risk itself. The proposed indicator system also enables changes in the quality of the public data for substances and their safe uses to be detected.

3.4 The Baseline Study Indicator System

3.4.1 Methodological background to the proposed system

For the development of the Baseline Study Indicator System, the experiences with existing indicator systems have been integrated as far as possible.

In the REACH Baseline Study, existing methods related to indicators on chemicals from various fields have been discussed in order to develop the methodology for the Baseline Study Indicator System. Appendix VI to this report documents the main findings of this discussion.

In summary, many approaches already exist to assess risks posed by chemicals. The existing methodologies on indicators as well as the methods used in life cycle analysis (LCA) for assessing the impact of chemicals on man and the environment all need information that is generally not available at baseline:

- Damage factors and effect factors, as necessary in the DALY approach (**D**isability **A**djusted **L**ife **Y**ears, see Chapter 2.2.1 of VI), usually cannot be calculated with the limited published substance-specific data for most of the 30 000 phase-in substances that are within the scope of REACH.
- Limited environmental testing of chemicals is one of the main drawbacks of the situation at and before baseline. Therefore calculations of the "toxic mode of action", as necessary in the PAF concept (**P**otentially **A**ffected **F**raction of species, see Chapter 2.2.2 of VI), often cannot be performed for many substances within the scope of REACH.
- Risk phrases are important to start the EURAM calculations (the **E**uropean **U**nion **R**isk r**A**nking **M**ethod, see Chapter 2.1.2.1 of VI). However, with this approach account may not be taken of the fact that better data are

available for some substances (such as limit values for the workplace or the consumer) and inferior data are available for many other substances (where insufficient testing has been performed but some toxicity has to be assumed, e.g. from chemical structure). A more flexible methodology would therefore better account for this variable input data profile.

- Several approaches cover only substances with a relatively high amount of data. They do not offer the possibility to take less well characterised substances into account by using default assumptions.
- The methods used so far do not offer the possibility to assess systematically improvements in the quality of the available data (on toxicity or exposure) in a sensitive way.

A main objective of REACH is to provide a more complete set of data for risk characterisation with the possible result of detecting more human health effects or environmental impact and to reduce the risk for both impact areas by appropriate risk-reduction measures. In order to achieve this objective, the new chemicals policy introduces specific elements as described in Chapter 3.1. None of the existing approaches is suitable to monitor the success of REACH:

- The existing approaches are often restricted to data-rich chemicals, a condition which is not fulfilled for most of the chemicals which are under REACH, so that a transparent, non-determined selection process of chemicals under REACH is not possible.
- The existing approaches do not allow substance-specific decisions on whether to use existing data, modelling or realistic default values. For indicators the use of default values must be handled very restrictively.
- A sensitive detection of improvements in data quality is not within the scope of the existing approaches.
- The existing approaches have not been designed with reference to the structure and objectives of REACH.

The only methodology that specifically addresses this (lack of) completeness and quality of the existing data at baseline is the risk & quality indicator system as proposed within this study. In this indicator system, all procedures used to calculate toxicity, exposure or a risk characterisation ratio are closely related to assessment steps also demanded under REACH. Therefore, changes induced by REACH will lead to similar changes in this indicator system. The instruments of life cycle assessment do not directly reflect the consequences of REACH.

The risk & quality indicator system as proposed in this project, together with the administrative and the supplementary indicators, provides a well-balanced approach between a more in-depth analysis with extended expert knowledge and a rough screening tool as usually proposed for priority setting. It allows the available data on toxicity and exposure to be evaluated in a quantitative manner. If a simpler approach had been used, we would have had the opportunity to extend the number of substances to be included in this indicator system. However, we would have lost many characteristics that are assumed to be specifically addressed by REACH and are expected to lead to changes and improvements.

3.4.2 The framework of the Baseline Study Indicator System

The proposed framework of indicators is made up of three pillars as shown in Figure 3.2.

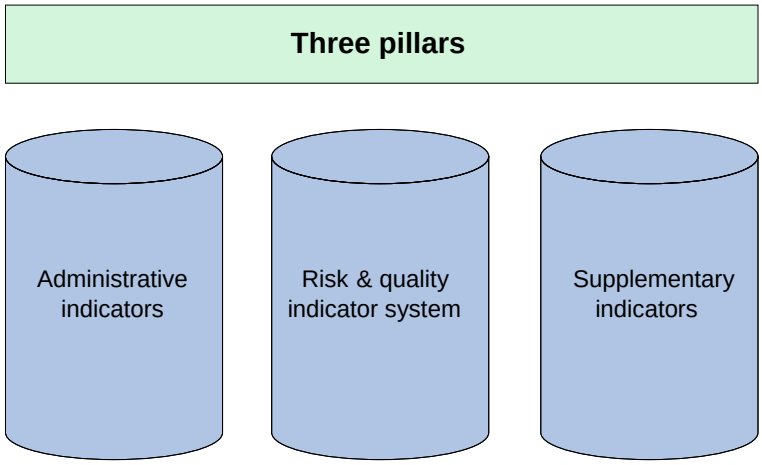


Figure 3.2 Three-pillar framework

A risk & quality indicator system[12] (in short: risk & quality indicator) is proposed as the heart of the framework. This risk-based indicator will track two major goals of REACH on a set of individual substances: the changes in the nominal risk to humans and the environment as well as the corresponding knowledge base. The indicator will depict the changes in the individual substances and, therefore, will allow an in-depth insight into the mechanisms of REACH. The indicator covers the major objectives of REACH but will be limited to approx. 100 substances.

The REACH procedures will be governed by "administrative indicators"[13]. This type of indicator refers to registration, evaluation, authorisation and restriction, which are defined as central elements of REACH (see Table 3.2).

Central elements of REACH	**Baseline Study Indicator System**
	Administrative indicators
Registration of chemicals	✓
Evaluation of chemicals	✓
Authorisation and restriction of chemicals	✓
Establishment of the European Chemicals Agency	(indirect)

Table 3.2 Central elements of REACH and the Baseline Study Indicator System

The administrative indicator will follow the progress of the **registration** process under REACH. This indicator refers to all substances which must be registered according to REACH. It includes also data on substances with a very low production volume (1–10 tonnes/year), which are not included in the R&Q Indicator.

Evaluation, **authorisation** and **restriction** are monitored by a specific group of indicator sets (see Chapter 5.1). In addition, if some of the Baseline reference substances become subject to authorisation or restriction in future, the effects on the potential risks and on the data base for these substances can be detected by the risk & quality indicator system.

One central element of REACH, the **establishment of the European Chemicals Agency**, is not monitored by the Baseline Study; nevertheless, this is one of the essential conditions for the whole implementation of REACH. The indicators for registration, evaluation and authorisation indicate the workability of the REACH system, including the European Chemicals Agency. The administrative indicator sets for registration, evaluation, authorisation and restriction will refer directly to the major tasks of the European Chemicals Agency and the Member State competent authorities.

Indicators in the third pillar are called "supplementary indicators"[14]. They will concentrate on specific issues and will normally make use of a broader data base. Some of these indicators will act as supplements to the risk & quality indicator. They may support specific findings from the in-depth analysis and thus enhance the credibility of the analysis of the risk & quality indicator.

In general, the supplementary indicators cover a special issue under a REACH objective as shown in Table 3.3 below. The table depicts which objectives of REACH are covered by the Baseline Study.

Objectives of REACH	**Baseline Study Indicator System**	
	R&Q ind.sys	Suppl.ind.
Protection of human health and the environment	✓	✓
Improvement of knowledge on properties and safe uses of chemicals	✓	✓
Assessment of existing and new chemicals in a single, coherent system		✓
Increased transparency and consumer awareness		(✓)
Promotion of non-animal testing		✓
Maintenance and enhancement of the competitiveness of the EU chemical industry	Not within the scope of the Baseline Study	
Prevention of fragmentation of the internal market	Not within the scope of the Baseline Study	
Conformity with the EU's international obligations under the WTO	Not within the scope of the Baseline Study	

Abbreviations used in this table: R&Q ind. s.: Risk & quality indicator system; Suppl. ind.: Supplementary indicators.

Table 3.3 Objectives of REACH and the Baseline Study Indicator System

[12] A detailed description is included in Chapter 4.
[13] Administrative indicators will be discussed in Chapter 5.1.
[14] See Chapter 5.2.

For the objectives in Table 3.3, the related supplementary indicators are listed below.

Protection of human health (workers and consumers) and the environment

This objective is addressed by the following supplementary indicators:

1) Changes in the quality of safety data sheets;
2) Toxic chemicals in households;
3) Production of toxic chemicals;
4) Cross-border transport of toxic chemicals;
5) Occupational skin diseases;
6) Changes in use patterns (example: Scandinavia).

Improvement in knowledge of chemical properties and the safe uses thereof

The following indicators are proposed for this objective:

7) Availability of hazard data;
8) Changes in classification and labelling;
9) Availability of use and exposure data;

Assessment of existing and new chemicals in a single, coherent system

Only one indicator is identified as a proxy:

10) Registration of new chemicals.

Use of alternative methods (non-testing and non-animal testing methods) for assessment of properties of chemicals

For the use of alternative methods, one indicator is suggested:

11) Animal testing and the use of QSARs, read-across and waiving options.

The objective "Increased transparency and consumer awareness" is at least partially addressed by indicating the development of the amount of publicly available data on chemicals.

Three objectives are not covered by the Baseline Indicator set:

- Maintenance and enhancement of the competitiveness of the EU chemical industry;
- Prevention of fragmentation of the internal market;
- Conformity with the EU's international obligations under the WTO.

To monitor these objectives, indicators referring to risks of chemicals are not appropriate. The REACH Baseline Study will not address economic and legal aspects. Assessing these objectives is therefore beyond the scope of this study.

Figure 3.3 shows the overall relationship between the three types of indicators used in the Baseline Study and the objectives of REACH, its implementation and the expected changes.

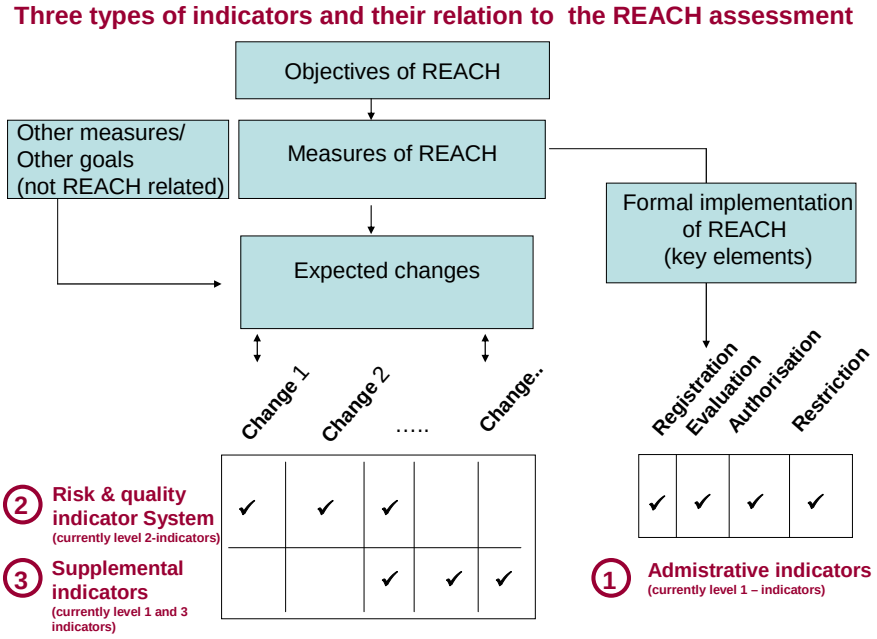


Figure 3.3 Three types of indicators and their relation to the REACH assessment

The administrative indicators (1) monitor the formal implementation steps of REACH. The two other indicators ((2) and (3)) are monitoring changes. These changes may originate from REACH as well as from other measures.

4 Risk & quality indicator system

4.1 Basic concept

The major goals of REACH are

- Reduction of health risks when humans are exposed to chemical substances;
- Reduction of environmental risks when there are emissions into the environment;
- Improvement of our knowledge of hazardous properties, the effect of potency and exposure characteristics in relation to chemical substances (which in turn allows us to assess the achievement of the first two goals more precisely).

The risk & quality indicator system addresses all of these goals. It answers the questions:

- How does the (health or environmental) risk change after implementation of REACH?
- How does the quality of information on the hazardous properties of chemicals and on the exposure to these substances change after implementation of REACH?

The basic idea is to assess the risk of exposure to chemicals "at baseline" (i.e. in the year 2007) and to repeat the assessment in the future (e.g. in 6 and/or 12 years). We can then measure the difference as a quantitative change in risk. We can also characterise the quality of the data on which this risk assessment is based "at baseline" and, again, repeat this exercise at future points in time. If the risk has been reduced and if the quality of the risk assessment has improved, these accomplishments may be a consequence of the implementation of REACH. In fact, a deeper analysis should provide more insight into the anticipated changes and should clarify whether they are causally linked to REACH or to other factors.

As the calculation of risk and quality is not manageable for all of the (approximately) 30 000 substances that are the focus of REACH, a representative subset of high, medium and low production volume chemicals has to be selected for which the assessments will be performed.

It should be possible for these assessments to be carried out by people other than highly skilled specialists or in a time-consuming manner. Unprocessed original data will not be readily available for day-to-day use in these assessments and are of limited practical relevance. Therefore, a balanced procedure was chosen in which risk estimates for these indicators:

- Make use of only a limited number of information sources with a minimum quality required;
- May be calculated with some basic knowledge in risk assessment, but do not require undue specialist expertise;
- Mainly use assessment tools compatible with REACH (see technical guidance documents and results from REACH implementation projects) rather than relying on sophisticated and complex expert judgement;
- Should take relatively little time in order to permit the risk calculation for a sufficient number of substances.

Further principles of this approach are outlined in this chapter (4.1) and are specified for different impact areas in Chapters 4.2 to 4.5. Guiding documents on how to calculate Risk Scores, Quality Scores, and other parameters of the risk & quality indicator system are provided in Appendices I to IV.

4.1.1 Impact areas

REACH is intended to improve health conditions and the knowledge of risks at the workplace and for the general public. Moreover, the environment has to be protected. Consequently, an indicator system should address all of these impact areas (as shown in Figure 4.1).

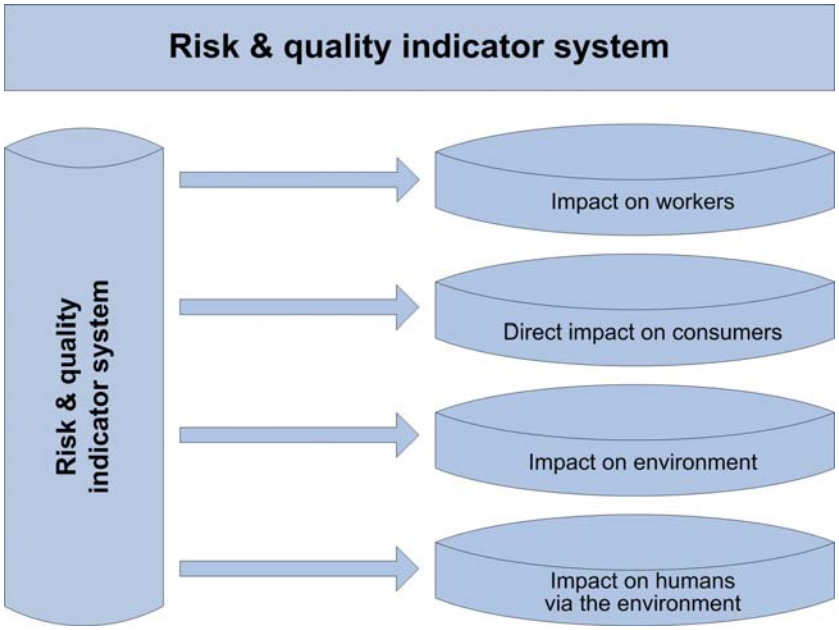


Figure 4.1 Schematic presentation of impact areas addressed by the risk & quality indicator system

There are two main types of impact by chemicals on the general population. One is the direct exposure of consumers resulting from the use of chemicals (e.g. in paints, glues or via air emissions from plastic materials). The other is indirect exposure, when chemicals enter the environment and the population incorporates these chemicals through environmental contact (e.g. drinking water, dust or contaminated food). The original impact area "consumers" is therefore split into two separate fields: "consumers (direct)" and "humans via the environment".

For all impact areas, an identical basic methodology was chosen to derive the risk & quality indicators. Only a few deviations were necessary due to the specific characteristics of the respective impact area or due to differences in the availability of data.

The success of REACH, and thus the risk and quality of information, may differ for different impact areas. Therefore, the proposed procedure not only calculates one single gross figure but allows for a differentiated evaluation for each impact area.

The risk & quality indicator system does not provide for differentiations of the impact on a local, regional or national level. The situation for Europe as a whole (EU-27) is considered.

4.1.2 Exposure assessment

In order to calculate the risk, toxicity has to be compared with exposure. Exposure for workers and humans via the environment may be described by a concentration of a chemical in air (unit: mg/m^3) which is inhaled by humans or a dose, for example taken up by humans drinking contaminated water (unit: mg/kg body weight/day). For workers and humans exposed via the environment, a typical exposure scenario should be selected to calculate the exposure. However, one should not only look for average exposure or for the exposure of most people. If only one reference point of exposure is used for the risk assessment, it is more meaningful to characterise the exposure of those persons who are at the higher end of the exposure range. Thus, we define the exposure reference point as the concentration or dose corresponding to the 90^{th} or 95^{th} percentile of the exposure distribution for a given exposure scenario ("reasonable worst-case" exposure).

The assumption of these upper percentiles for reasonable worst-case exposures is in agreement with the current Technical Guidance Document on Risk Assessment (EC 2003) and with the Preliminary guidelines for REACH (RIP 3.2.2). Exposure is then compared to a toxicological limit value. By its nature, a limit value is met if most exposures (i.e. for example the 95^{th} percentile of the exposures) are below this reference point and a limit value is not met if nearly half of the exposures exceed the reference point. This further supports the choice of the 90^{th} or 95^{th} percentile for exposure assessment.

Measured data are usually favoured over calculated (modelled) data when the measured data are sufficiently qualified and representative. However, for consumers there will be no measured data most of the time. If modelling is necessary, the REACH-related modelling tools to estimate exposure concentrations or doses are usually preferred. Use patterns, which have an impact on the exposure modelling, may be taken from IUCLID data sheets but also from other well-defined sources, depending on the impact areas. If no qualified measurement data are available, the exposure assessment is associated with a higher degree of uncertainty and thus a lower quality is assigned (see Chapter 4.1.5 on Quality Scores).

Environmental exposure is usually modelled since sufficiently qualified measurement data may not be available. Besides substance fate properties, measured concentrations in the environment are a result of several years of emission of the chemical from one or more sources — and not necessarily all sources located within the EU. The emissions and thus the measured concentrations depend mainly on the use and emission pattern. Therefore, in most cases it is not possible to relate one year's emissions to specific concentrations measured in the environment. Furthermore, actual measured concentrations are missing for many substances. Measured concentrations for some selected substances could be used as an indicator for changes in emission/exposure levels. Modelled exposure is mainly determined by tonnage, physico-chemical properties of the chemicals and their use categories because those are input parameters for emission rates and assumed environmental distribution (for further details, see Chapter 4.4.2).

4.1.3 Toxicity assessment

In order to identify a (health or environmental) risk, we have to compare exposure to a toxicological reference point. For human toxicity assessment this reference point is defined as a concentration of a chemical in air or a dose of a chemical that, in general, is assumed not to impair human health. The unit is mg/m^3 (air concentrations) or mg/kg body weight/day (dose, e.g. oral intake).

For the workplace, this reference point is currently provided by health-based "occupational exposure limits" (OELs) that are easily accessible for a number of chemicals. The general population (consumers and humans via the environment) is usually assumed to be more sensitive and a reference point corresponding to lower concentrations or doses compared to the workplace is derived. For example, the "acceptable daily intake" (ADI) of the World Health Organization is such a reference point. Future reference points as proposed by the REACH Implementation Projects (RIPs) have to be integrated. These are called "derived no-effect levels" (DNELs) and will also differ for the two impact areas (DNEL (workers) and DNEL (consumers)).

However, in many cases an OEL or an ADI are not available and a DNEL does not yet exist. Substitute procedures therefore have to be developed for the indicator system to define a chemical-specific reference point at a level of health risk similar to those reference points (see specific procedures for impact areas — Chapters 4.2.3 and 4.3.3 — for details). Substitute procedures lead to OEL analogues, ADI analogues or DNEL analogues, but these analogues are usually characterised by higher uncertainty (less quality) (see Chapter 4.1.5 on Quality Scores).

For the environment, data are available to identify the chronic "no observed effect concentration" (NOEC) in environmental media. The NOEC can be used as a reference point. In contrast to the risk assessment for human toxicity, these NOEC values do not include extrapolation factors. In environmental risk assessment, the PNEC is used in the toxicity assessment. The PNEC, which is the highest concentration in the environment where effects are not expected, is derived by using assessment factors, which are dependent on the quality of the available dataset. In order to normalise the toxicity assessment, the NOEC value has been divided by a constant of 100 — see Chapter 4.4 for details. In human toxicology, the experimental no-effect level (in principle comparable to the environmental NEC) requires comprehensive interpretation and is therefore not to be used in standard procedures. It should only be used as an exception (see Chapters 4.2.3 and 4.3.3 for details).

4.1.4 Risk characterisation ratio and nominal Risk Score

After the toxicity assessment and the exposure assessment have been completed, the results (concentration or dose at the reference points) are compared. A risk characterisation ratio (RCR) is calculated by dividing the exposure estimate by the toxicity estimate. The nominal Risk Score is defined as a weighted risk characterisation ratio and is calculated by multiplying the RCR by a population risk modifier and (optionally) by a severity modifier (see Chapter 4.1.6 for details on these modifiers).

"Risk Characterisation Ratio and Nominal Risk Score"

- **Risk Characterisation Ratio (RCR) = Exposure / Toxicity**

at reference points [mg/m^3 / mg/m^3 or mg/kg x d / mg/kg x d] human risk assessment or [mg/l / mg/l] environmental risk assessment

- **Nominal Risk Score = RCR x Population Risk Modifier (x Severity Modifier*)**

Population Risk Modifier (refers to the expected number of affected persons or the expected size of the affected environmental area)
Severity Modifier* (refers to the type of effects expected)
* optionally

The resulting risk term is called a "nominal" Risk Score because the respective risk may (and almost certainly will) deviate from "real" risk. If, for example, certain toxicological properties of a substance are not known (because of lack of testing), these properties have to be estimated and such an estimate includes uncertainties in the toxicity score. If exposure conditions are not known, the specific exposure parameters have to be estimated. Again, this includes uncertainties. Therefore, the calculated (nominal) Risk Score is influenced by the uncertainty in the toxicological and exposure assessment results. A deviation from "real" risk has to be acknowledged.

4.1.5 Quality Scores

It is assumed that REACH leads to more complete testing of toxicological properties, to improved reporting, and to better information on exposure. The quality of the data is expected to improve and the uncertainty will consequently be reduced. Quality Scores are therefore established within the indicator system to explicitly describe the quality of the exposure and toxicity assessments. With the Quality Scores we are able to compare these determinants of the nominal Risk Score at different points in time.

If input data are highly uncertain (no detailed knowledge of toxicological properties of a chemical and/or no detailed knowledge of specific exposures to this substance), then the quality of the assessment is regarded as poor. Hence, an improvement in the quality of input data may result in a change in the nominal Risk Score, even though the "real" risk remains unchanged. As we do not have access to the ideal (correct) toxicity and exposure data, we do not know the size of the "real" risk. As a consequence, there is no way of preventing Risk Scores always being influenced by uncertainty. The higher the uncertainty, the lower is the quality of an estimate. If the quality of information changes with time, as is assumed for REACH (from baseline to future points in time), the comparison of Risk Scores is always partly influenced by the different quality of calculations at different times.

4.1.5.1 Quality Score (toxicity assessment)

The toxicity assessment should always be performed at the highest level possible with a defined set of information and assessment tools. If no qualified information on toxicity is available, this results in bad quality. Bad quality is reflected in a high numerical value. Good quality corresponds to a low value. All Quality Scores were set to range between 1 (optimal quality) and 10 (inadequate quality). This range allows sufficient differentiation of various categories of input information. If there is a lack of information, default assumptions are normally used. A very high quality toxicity score is only assigned in the case of complete toxicological testing and reporting. Figure 4.2 demonstrates this selection process schematically.

The lowest "Quality of toxicity" score (= highest quality) for the environment is obtained when the ecotoxicity of a substance is measured in a real ecosystem, whereas data from laboratory studies results in a higher quality of toxicity score. The highest quality of toxicity score (= lowest quality) is obtained if only QSAR estimates are available.

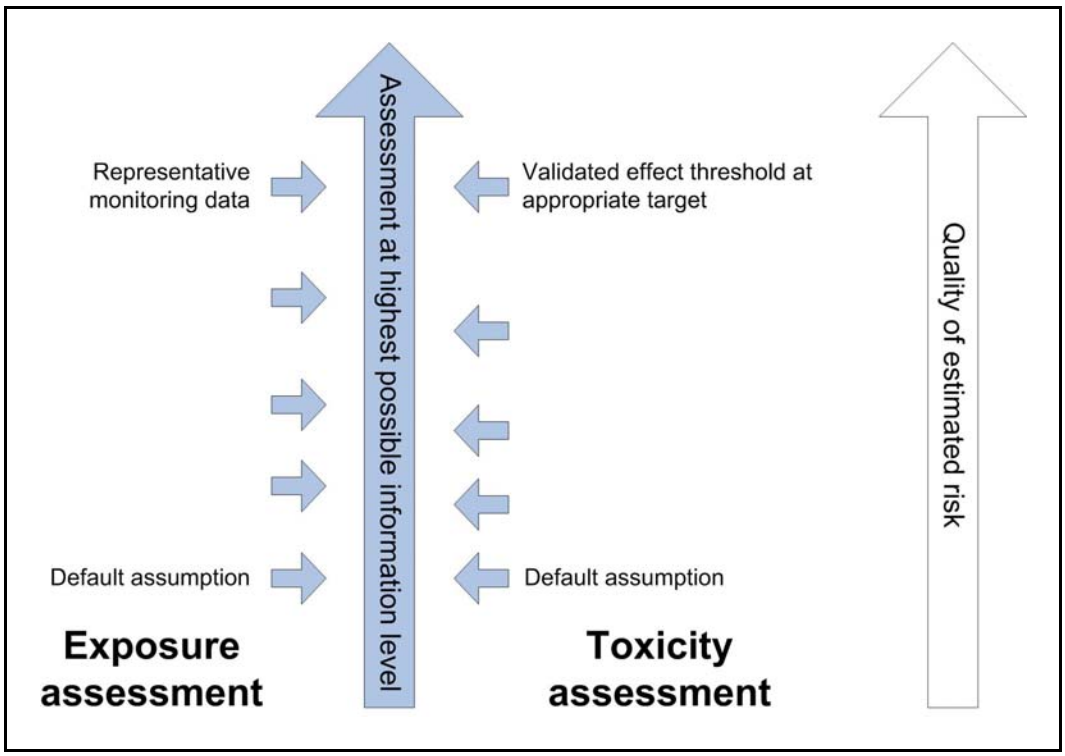


Figure 4.2 Integration of the quality dimension into the risk assessment in the risk & quality indicator system (schematic presentation)

4.1.5.2 Quality Score (exposure assessment)

Exposure assessment should always be performed at the highest level possible with a defined set of information and assessment tools. If no qualified information on exposure is available, this results in bad quality. Bad quality is reflected in a high numerical value. Good quality corresponds to a low value. All Quality Scores were set to range between 1 (optimal quality) and 10 (inadequate quality). This range allows sufficient differentiation of various categories of input information.

The environmental exposure depends mainly on the following three factors: T: tonnage (1), f: emission fraction (2) and S: substance parameters (3). It is primarily the Henry's law constant (H), the octanol-water partition coefficient (log K_{ow}) and the biodegradation rate (BIO) which are important. The Quality Score for environmental exposure is thus a product of the Quality Score for each factor: T, f, S, where S is again assumed to be composed of three factors: H, log K_{ow}, BIO. The Quality Score for exposure varies between 1 and 10.

The quality of the exposure assessment for the humans via the environment impact area depends partially on the quality of the exposure assessment for the environment impact area. To ensure consistency, the Quality Score for environmental exposure is used directly and an aggregated Quality Score is established, again ranging between low quality, with the numerical value of 10, and a high Quality Score of 1, in total. Half the weight is given to the quality of the calculated environmental concentrations and half the weight to the quality of the subsequent assessment of human exposure from environmental media.

4.1.6 Nominal Risk Score modifiers

4.1.6.1 Population risk modifier

Toxicological risk assessment at the workplace and for the consumer often focuses on the risk per person. However, in the risk & quality indicator system, more weight should be attributed to those risks which potentially affect a large section of the population. The population risk is approximated by a number of indicative parameters. For example, the number of production sites and the production volume may influence the population risk for workers, the use pattern of a chemical in household products may point to many exposed consumers, and multiple emission sites may be associated with a widespread environmental risk. On the other hand, if a chemical is only used in closed systems or as a chemical intermediate or if only local emissions are known, this results in a low population risk modifier. The numerical values for this weighting factor range between 1 and 10. This means, for example, that a health risk for chemically-induced allergies is considered to be 10 times more relevant if this chemical is used ubiquitously in Europe compared to a chemical used

only on a laboratory scale with few exposed persons. This is in line with a logarithmic type of risk perception in society as opposed to a linear relationship. Therefore, production volume or the number of exposed persons does not influence the nominal Risk Score in a linear fashion. To simplify, it is assumed that more persons (in absolute numbers) are exposed to the 90th or 95th percentile of the distribution of exposure concentrations if a substance is produced in large amounts, or by many manufacturers, or has many use categories compared to a substance produced in small amounts, by few manufacturers, or with few use categories. This justifies a higher population risk modifier.

4.1.6.2 Severity modifier

If exposure exceeds the toxicological reference point, there may be damage to health as well as to the environment. Usually, no distinction is made as to whether this health effect is, for example, a respiratory tract irritation or teratogenicity. However, these two effects may greatly differ in public perception and acceptance. The inclusion of a weighting factor in the nominal Risk Score was therefore considered to reflect the various severities of different health endpoints. However, when toxicological reference points (like OELs or ADIs) are established, these reference points often already include larger safety factors if a very serious effect is the critical endpoint. Hence, the severity factor is partially included in the calculated risk and an additional severity factor is not required.

In environmental risk assessment, some of the substance properties, e.g. endocrine disrupting properties, may not be covered in a simple exposure/toxicity ratio. Also, the EU Technical Guidance on Risk assessment (EU 2003) suggests including a factor in the derivation of the PNEC value, which is the highest concentration in the environment when effects of the chemical are not expected. However, the TGD has not proposed a methodology for the derivation of this factor.

Because of these methodical problems and the large degree of subjectivity, the severity factor is currently only optionally included in the nominal Risk Score. The critical endpoints are identified and may be used to establish weighting factors for severity in the future.

4.1.7 Interpretation of results

4.1.7.1 Aggregation level

A risk assessment may be performed for the single substance in a single impact area. However, a more complex aggregation is usually wanted for an index. Three aggregation levels are proposed:

- **Summary level:** Aggregated Baseline Risk Score (impact area), Aggregated Baseline Quality Score (impact area);
- **Profile level:** Baseline Risk & Quality Score Profile (impact area);
- **Analysis level:** Baseline Data Availability Analysis (impact area), Baseline Risk Characterisation Ratio Analysis (impact area), and possibly further analysis level indicators.

Summary level

At the summary level the geometric mean of the Risk Scores for all included substances and the geometric mean of the respective Quality Scores for each individual impact are calculated. These mean values represent the highest aggregation level and are mainly to be used for comparison to later points in time, i.e. in the year 2012 or later. The change in the aggregated baseline Risk Score and Quality Score over the years may be a headline indicator for political communication. Since these individual figures are much too complex for further interpretation, the other levels (profile level, analysis level) are supplemented. We propose not amalgamating the Quality Score and the Risk Score into a single figure. Moreover, any comparisons between different impact areas should be strictly avoided. Such comparisons would mean a misinterpretation because, for example, different reference points for risk calculation are used in the different impact areas.

Profile level

The profile level provides some more details for better interpretation compared to the summary level. There is a gradual increase in detail towards the analysis level. We propose that, at the profile level, a distinction between HPVs, MPVs and LPVs should be possible and that more insight into the distribution of the individual Risk Scores and Quality Scores is provided. However, at this level we are still referring to Risk Scores and Quality Scores and not to the various sub-factors.

There are two ways to present the results at profile level:

1. whisker plots, or
2. clouds.

Both of these may be useful for different types of analysis.

These clouds represent a two-dimensional presentation of the Risk Scores for each single substance. With this presentation, clusters in the four fields at different points in time can be identified. Figure 4.3 shows a possible chart for this.

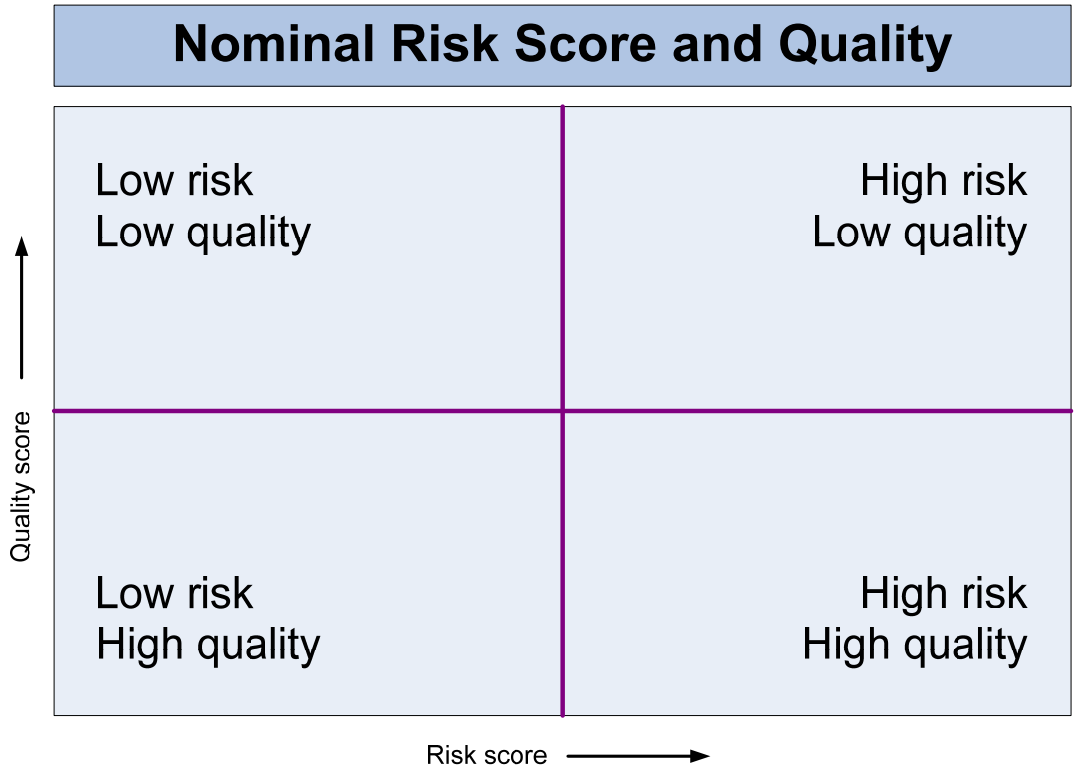


Figure 4.3 Presentation of the aggregated nominal Risk Score and Quality Score for an impact area as a two-dimensional output chart in the risk & quality indicator system

A nominal Risk Score for the workers impact area may not be compared directly to the nominal Risk Score for the general population because the toxicological reference points (e.g. OEL vs. ADI) are different. Similarly, the ecotoxicological Risk Score is based on the NEC and thus leads to other risk levels compared to the toxicological risk assessment for humans. Again, a comparison of risk terms across impact areas is not meaningful.

Analysis level

The type of calculations and the documentation used for the risk & quality indicator system permit many more detailed analyses. For example:

1. The analyst may wish to be informed of the availability of high-quality input data for toxicity or exposure assessment compared to the "second-choice" substitute information which had to be used.
2. It may further be analysed whether the Risk Score or the Quality Score is significantly correlated with the production volume band (and how this possible correlation changes with time).
3. After six years, the change in toxicity assessment outcomes (higher or lower toxicity reference points — percentage change) and exposure assessment results (higher or lower exposure — percentage change) can be analysed. The changes in the Quality Score (toxicity) or Quality Score (exposure) can be analysed in depth.
4. "Outliers" should not be excluded from further analysis because they may prove to be high priority chemicals for risk management action.

Flexibility in the output analysis and the chance to trace back the reasons for the numerical value of the indicator are characteristic for the risk & quality indicator system.

4.1.7.2 Expected changes over time (profile level)

If the expectations of REACH are justified, the difference in the baseline risk & quality indicator compared to the indicator in six years' time should be a shift of the indicator values at profile level to the lower left-hand segment of the plot (see Figure 4.4).

Figure 4.4 Expected shift of the risk & quality indicator for an impact area over time if REACH is successful

One has to be aware that this shift is not necessarily a shift in "real" risk but in "nominal" risk. The risk size may be influenced by a change in the toxicity assessment result, by a real change in the exposure or by better information on exposure. Even though this differentiation is not shown in Figure 4.4, an in-depth analysis of the indicator may partially elucidate the reasons for the shift over time.

If the assessment at baseline was incorrect due to the high levels of uncertainty, the shift of risk and quality may alternatively go from the upper left-hand field towards the lower right-hand field as shown in Figure 4.5. In this case, the risk was underestimated at baseline.

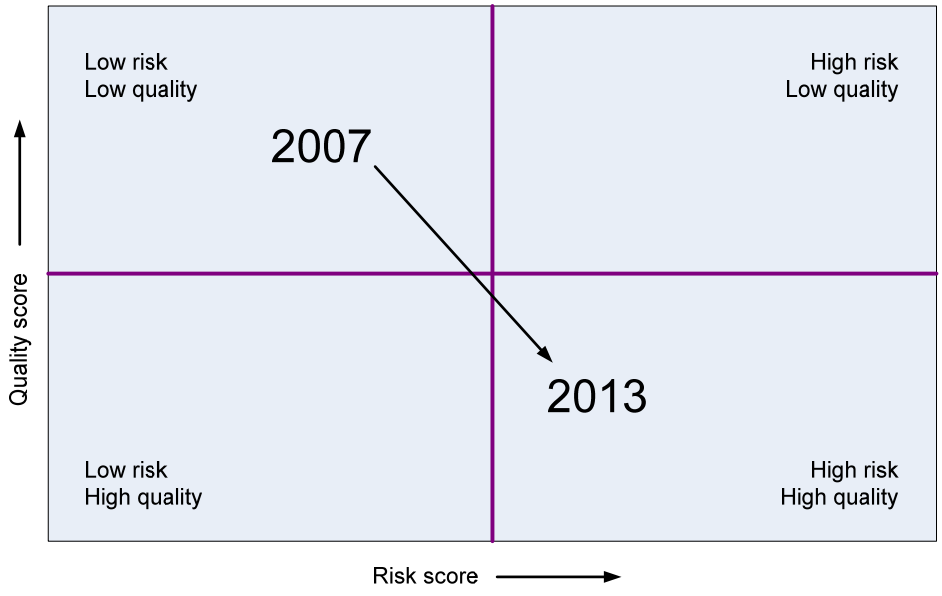


Figure 4.5 Expected shift of the risk & quality indicator (single substance or sum for impact area) over time, if risk was underestimated at baseline due to lack of quality of the input data

The demands on testing and reporting under REACH differ as a function of production volume. The analysis may therefore also be differentiated for the various production volume bands. For example, it is expected that the extent of testing and the quality of reporting for "high production volume" (HPV) substances were already high before REACH (before 2007). Therefore, the Quality Score for these substances should be usually in the lower half of the plot (high quality; see Figure 4.6). If risk management measures were already implemented at baseline, the risk & quality scores should be in the lower left-hand field for HPV substances. If, however, the EU risk assessment report concluded that there was a concern and no risk reduction measures have yet been applied, a shift from the lower right to the lower left-hand field may take place in the future without any relevant improvement in quality.

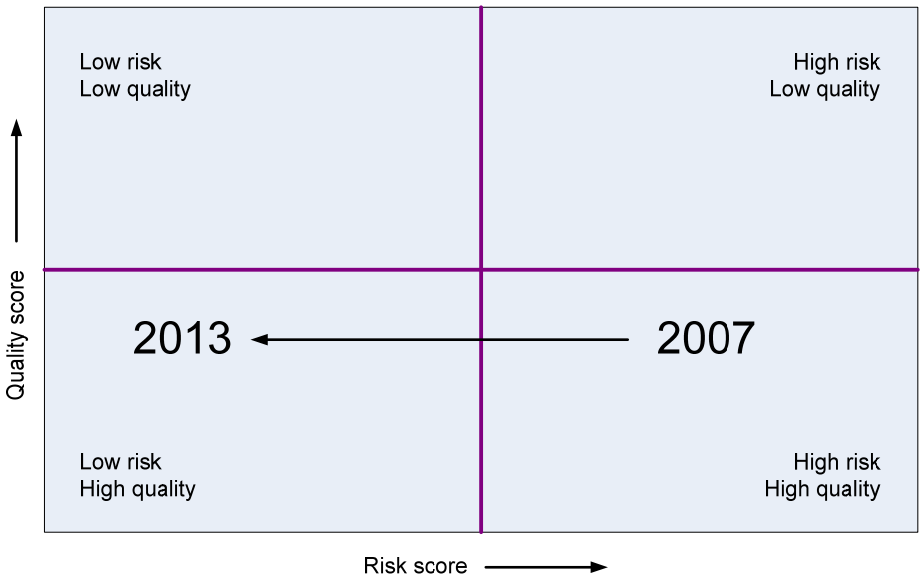


Figure 4.6 Expected shift of the risk & quality indicator for high production volume substances caused by improved risk management measures

A horizontal shift to a lower risk indicates exposure reduction with no change in quality of information, which is in concordance with the goals of REACH. An upward shift to lower quality should only be observed if the quality of information is overestimated at baseline.

4.1.7.3 Accountability (REACH-related changes vs. other causes)

Not all of the improvements from baseline to future points in time may be attributed to REACH. Other risk management measures were started before REACH or were started at the same time. For example, the risk reduction for HPV substances may well be attributed to the Existing Substances Regulation (ESR) programme and not primarily to REACH.

The influence of REACH or other measures on risk and quality may not be easily discriminated. However, when the input data are fed into the database for the indicator, the information should be categorised according to whether it can be influenced by REACH or not. Three categories are proposed:

1. Parameter is probably influenced by REACH to a large degree;
2. Parameter is probably only partly influenced by REACH or the REACH influence is unknown;
3. Parameter is probably only influenced by REACH to a minor degree or not at all.

These assignments may be corrected or confirmed when the re-evaluation takes place at a future point in time. At this future calculation, a total reduction in risk or increase in quality may then be analysed in terms of whether REACH probably has contributed to a large or to a smaller degree to these improvements.

4.1.8 Data sources

The risk & quality indicator system makes use of a limited number of information sources. One priority source for the risk assessment of substances are the current IUCLID 4 data sheets because they reflect the current "official" state of knowledge on a substance in the sense that they are provided on the ECB website. They will later be substituted by the improved IUCLID 5 information level. However, it is known that IUCLID 4 data sheets are often of limited quality and somewhat outdated. This problem is addressed by the following means:

- IUCLID data are supplemented by a limited set of additional published information sources, which are assumed to contain more qualified information, for example toxicity or exposure assessment results from the World Health Organization (WHO) or EU risk assessment reports.
- A very limited set of unpublished high-quality information is added to prevent describing the baseline status at a low quality level although much better unpublished data were apparently available in certain cases.
- Another unpublished source used already in the early stages of this project are the complete IUCLID data sheets for "low production volume" (LPV) substances, from which additional risk phrases or use categories were extracted. These IUCLID data sheets may also be of limited quality (and sometimes are in fact in contradiction with information from the European chemical Substances Information System (ESIS), which is the official data source). However, the inclusion of these unpublished data already represents significant progress in comparison with the very limited LPV data in published IUCLID versions.

4.1.9 Substance selection

The following chapter is divided into the following parts:

1. Total number of reference substances;
2. Groups of substances within the reference set;
3. Analysis of whether the selected substances can be used as reference substances;
4. Documentation of the results of the selection process;
5. Additional reference substances.

4.1.9.1 Number of substances and production volume classes

The total number of phase-in substances, which have to be introduced into the REACH registration system, is estimated to be in the magnitude of more than 30 000 substances (which have a production volume of 1 tonne/year and more)[15]. According to recent figures presented by the Commission, the substances are distributed among the different production volume classes as follows[16]:

Production volume class	Number of substances on the EU market
1-10 tonnes/year	20 000
10–100 tonnes/year	5 300
100-1 000 tonnes/year	2 400
> 1 000 tonnes/year	3 400

Table 4.1 Number of substances in the different production volume classes

Monitoring of all substances within the risk & quality indicator system is not feasible. Therefore it was agreed at the first Steering Committee meeting to define a set of reference substances for the risk & quality indicator system.

For substances with a production volume below 10 tonnes/year, REACH does not establish any obligation to perform a chemical safety report. As a consequence, no remarkable changes in the amount and quality of data regarding exposure are expected for these substances (even if REACH also requires that some relevant information on exposure be provided for these substances in the registration dossier (REACH Annex VI, section 6)[17]. It is therefore reasonable to assume that the Risk Scores and the Quality Scores for these substances will remain stable. Due to this, the reference substances for the risk & quality indicator system are selected from the substances with a production volume of 10 t/y and above. The large number of substances with a production volume below 10 t/y is covered by supplementary indicators, which are described in Chapter 5 of this report.

The methodology shown is very ambitious and it becomes clear that the total number of substances included in the baseline set had to be limited due to the resources needed for the assessment of the Risk Scores and Quality Scores. So ultimately the question arises:

How many substances are needed?

Or, for our case, to put it more precisely:

How many substances are needed to mirror the trend (or changes) for the total amount of substances under REACH?

In standard statistics the question is asked the other way around. You have the results of your experiment and ask whether the number of experiments is sufficient to answer the addressed question. In our case the results of the experiment will show up after the next snapshot in seven years' time. We cannot clearly answer this question but we can approach an estimate via a mental experiment. Imagine that you have a closed box with black and white stones in it. How many stones you would have to draw to get a prediction about the relationship between black and white stones in the box? Two answers are straightforward: if all stones are black drawing one stone is enough. If all but one stone are black you need to draw all stones. For a prediction of how many stones to draw you need a prediction/assumption about the relationship between black and white stones. Under the assumption that a prediction (on how many stones to draw) is fair as long as the Laplace conditions[18] hold, the necessary number of stones can be estimated according to Figure 4.7.

---

[15] Approximately 70 000 substances are listed in EINECS with a production volume below 1 tonne/year without an indication of whether they have a production volume at all. It is unknown how many substances are produced in the EU with a production volume below 1 t/y. Substances with a production volume below 1 t/y do not have to be registered under REACH.

[16] Figures have been taken from the following two sources: Pedersen et al., Assessment of additional testing under REACH (Pedersen 2003), CWG/WS/09/2005, "Impact of REACH on Member States and Agency", Workshop under the Auspices of the Commission Working Group on the Practical Preparations for REACH Planning for the Operation of Key Elements of REACH, Helsinki, 2-3 May.

[17] REACH sets data requirements for these substances as described in Annex VII. But these requirements are much lower than for substances of higher production volumes as defined in Annexes VIII to X.

[18] The minimum number of substances needed is determined by the number of substances that will fulfil the Laplace condition: multiple drawing sessions

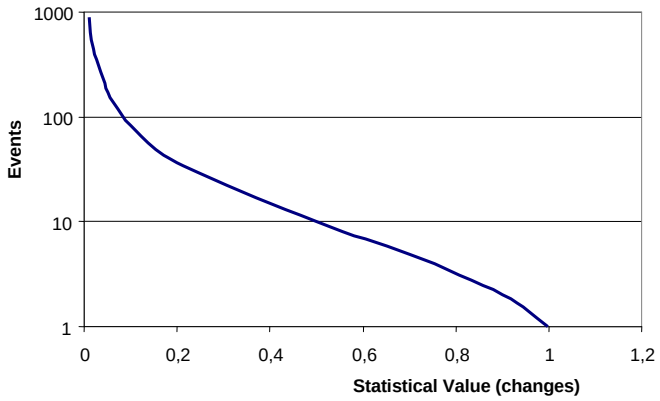


Figure 4.7 Necessary events (drawing of stones) depending on the statistical value (relationship black/white stones)

For our thought experiment we would need to draw 10 stones if half of the stones are black (statistical value=0.5). If only 10% of the stones are black (statistical value=0.1) 100 stones need to be drawn.

Coming back to our original question, a "guestimate" on the number of substances needed depends on the expected value, e.g. the share of substances with significant changes under REACH. Expectations concerning the impact of REACH are hard to quantify. Even in the Commission's extended impact assessment it was stated clearly that it is not possible to predict the benefits of risk management measures taken as a consequence of REACH until information is available for each substance on its intrinsic properties, its exposures and the availability of substitutes.

An explicit quantified expectation concerning the impact of REACH has not been obtained. An approach to quantified expectations may include:

- In an Ökopol review study[19], the impact of REACH is estimated to be a 10% reduction in the overall environmental and health impact of chemicals. Even this proposition could not be translated to our needs; it gives a first indication.
- Taking the RCR results in Chapter 6 of this study, significant measures (RCR > 10) can be expected for at least 36% of the substances for workers (Chapter 6.1.1.3). For the environment impact area the share of substances is 12%. For consumers, only 29% of substances are assessed as of "low relevance" (Chapter 6.1.2.3)

To summarise the findings, the expectations are above 10% and lower than 60%. As a mean we assume 30%. Taking Figure 4.7 from our thought experiment this would translate into a number of substances from 9 (60%), through 25 (30%) to 100 (10%).

So a sample size of more than 100 substances would fulfil even the lowest expectations. As will be shown in Chapter 6, a breakdown to 4 subsets (according to tonnage bands) strongly improves the analysis. At first hand, the number of substances should increase fourfold in this case. So only if our assumption from the RCR analysis (see point 2 above) holds that 30% of substances will undergo changes, then 100 substances are sufficient.

We are aware of the large uncertainties which are typical of impact studies. Now, for a comparable description of the Baseline, we have to accept a large degree of uncertainty regarding the question for how many substances REACH will provide a benefit.

Starting with the statistical reasoning as given in the second Steering Committee meeting, we have seen sufficient plausibility to assume that a set of approximately 100–125 substances (excluding the substances with production volumes below 10 t/y) should be large enough to detect changes in the Risk and quality scores of the substances due to REACH with satisfactory sensitivity. The first calculation of these scores has been done with a set of 137 reference substances. At the same time, we acknowledge that by increasing the number of reference substances assessed by the risk & quality indicators it would be possible to increase the sensitivity of the risk & quality indicator system further. Therefore in the second calculation 100 substances have been added to get a further increase in the sensitivity of the scores.

---

would establish a Gaussian error distribution curve (2 sigma). A fair prediction would yield one result that is within the Gaussian error distribution.

[19] In the study conducted recently by Ökopol (http://ec.europa.eu/environment/chemicals/reach/background/docs/reach_benefit_studies.pdf), several impact studies were reviewed which evaluate possible benefits of the REACH Regulation. Tables 6 and 7 of this overview contain estimations regarding the reduction of impact on human health and on the environment. Some of the studies estimate a reduction in the range of 10%. These figures are not linked to an estimation of the number of substances which might undergo changes due to REACH. Please note that "changes" in the risk & quality indicator might not translate into a risk or effect reduction.

The results from the impact area workers for 215 reference substances support our assumption that we can expect changes due to REACH for an even higher percentage of substances:

- The baseline set of reference substances contains 65 HPVs. For these, the total Quality Score was clearly much better than for the 45 MPVs or the 105 LPVs. Numerically, the geometric mean in total quality was 25 for HPVs and 51 or 53 for the MPVs or LPVs, respectively. These large differences are, for example, caused by existing OELs for all HPVs, whereas hardly any OELs existed for LPVs. Therefore, for LPVs, assessments had to be performed at a lower quality level. Similar significant improvements may be expected under REACH, as DNELs will become available for most MPVs and LPVs by and by.
- For the 215 substances, about half (49%) of the risk characterisation ratios for the impact area of workers are above 1 at baseline (106 substances), and about 36% are above 10 (77 substances). As a consequence of REACH, most of the risk characterisation ratios should decline to a level below 1, if the instruments of REACH work successfully (for example: improved exposure reduction measures). Consequently it may be predicted that either changes in the DNEL or changes in exposure will occur for about half of the substances, with very relevant changes for 36% or more.
- We assume that these changes will partly occur already at the beginning of the registration period. Communication of conditions of safe use can start immediately with enactment of REACH. Changes can therefore also be expected in the case of low production volume chemicals before the second snapshot is taken in 2012.

From these rough estimates, it may be concluded that changes in risk and/or in quality due to REACH will be visible already in a subset of 215 substances and also in the group of 65 HPVs or 105 LPVs, probably also in the group of 45 MPVs.

4.1.9.2 Groups of substances within the reference set

The reference substances belong to three different groups:

- Group 1: chemicals with a production volume of 10-100 tonnes/year (105 substances);
- Group 2: chemicals with a production volume of 100-1 000 tonnes/year (45 substances);
- Group 3: chemicals with a production volume above 1 000 tonnes/year (65 substances).

The chosen sample size for each tonnage band reflects the relative amount of the different tonnage bands in reality (as given in Table 4.1 by the number of substances expected to be in these production volume classes). For each group, the reference substances are selected randomly from a larger list of candidates (e.g. for group 3: the ESIS list of high production volume chemicals (European Chemicals Information System, http://ecb.jrc.it/esis/)). This selection leads to a set of 215 reference substances.

Figure 4.8 below shows the contribution of substances from the different tonnage bands to the set of reference substances.

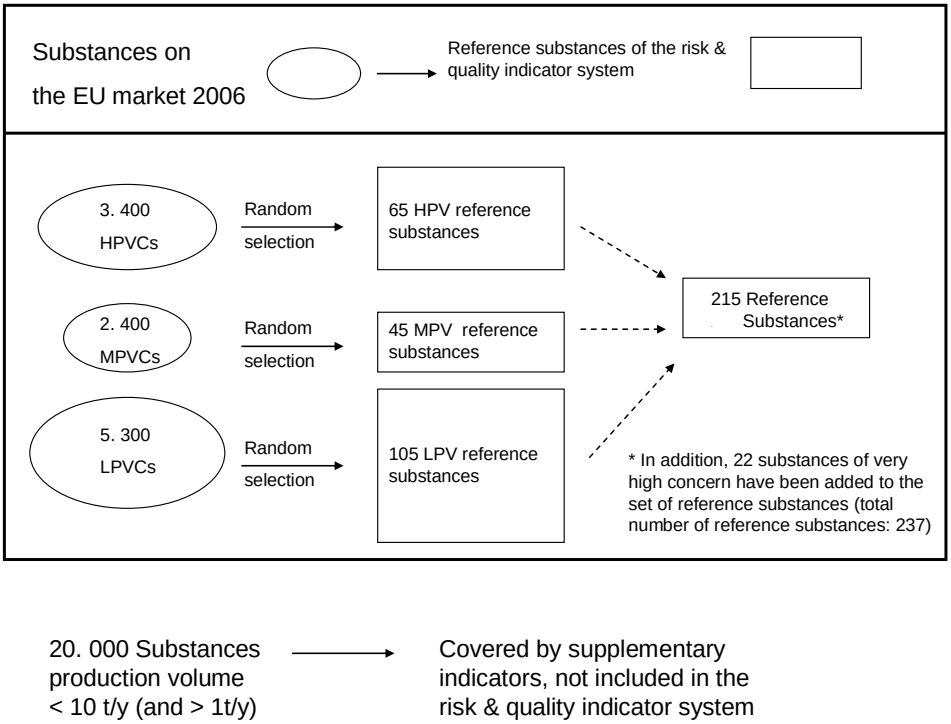


Figure 4.8 Selection of reference substances for the risk & quality indicator system from the three tonnage bands (HPVs: high production volume chemicals (> 1 000 t/y), MPVs: medium production volume chemicals (100–1 000 t/y), LPVs: low production volume chemicals (10–100 t/y.

In addition, the set of reference substances should include at least 25 substances of very high concern as defined in Article 57 of the REACH Regulation, which could be subject to authorisation. Within the substances representing the tonnage bands, there are already three substances of very high concern (e.g. carcinogenic substances). Additionally, 22 substances have been selected randomly from two candidate lists: Annex I of Directive 67/548/EEC and the list of the PBT Working group (JRC Ispra 2007). This increases the set of reference substances by 22 additional substances (total number of reference substances: 215 + 22 = 237).

4.1.9.3 Analysis of whether the selected substances can be used as reference substances

Due to the random selection process, the reference set consists of substances of different classes such as discrete organic chemicals, mixtures of discrete organic chemicals, inorganic compounds (including salts) and substances of unknown or variable composition[20].

After the random selection of substances, a second step for each substance checked whether the following criteria are fulfilled:

- The substance is within the scope of REACH.
- There are indications that the substance is used in the EU.
- Substances of a similar structure have not already been selected for the reference set.

Only if a randomly selected substance met all of the three criteria could the substance be taken as a reference substance. As a consequence, approximately half of the randomly selected substances were not taken as reference substances.

The three criteria are described below in more detail.

[20] For substances of Unknown or Variable Composition, Complex reaction products or Biological material the abbreviation "UVCBs" is used (Allanou et al 1999 / for details: see ECHA June 2007, Guidance for identification and naming of substances under REACH, final report RIP 3.10).

Ad 1: The substance is within the scope of REACH

It was checked that the selected substances are:

- not polymers (according to their chemical structure) (REACH Art. 2(9))[21];
- not only used as an active substances or co-formulants in biocides or plant protection products (comparison with the ECB biocide list and additional lists) (REACH Art. 15(1));
- not only used in medical products for human/veterinary use, in food or feedingstuffs (REACH Art. 2(5));
- not included in Annex IV (comparison by EINECS No and name/group);
- not falling under Annex V,
- not regulated as POPs by the Stockholm Convention (Annexes A, B, C).

It is difficult to decide whether a substance is used only as an active substance or co-formulant in biocides or plant protection products without having an overview of the uses of the substances in the market. Setting of the baseline in the project takes available information on uses from the reference data bases into account. Possibly, in single cases, additional information on uses will become available during the evaluation of the substance. If this information reveals the substances being used as pesticides or biocides only, the reference substance will be taken from the set and replaced by a reserve substance.

In one case, a polymer was selected. It was replaced by the corresponding monomer.

Ad 2: Confirmation that reference substances are currently on the market

The baseline set should contain only substances which were on the European market in 2007. The ESIS lists of HPVs and LPVs are the starting points for the selection of the baseline reference substances. It cannot be assumed that all of the substances listed here are on the European market. Therefore additional information about production is necessary. Indications used were:

- the substance is recorded in retailer online catalogues (if possible, additional information about the status of the substances listed in the catalogue should be requested), and/or
- recent safety data sheets can be found for the substance, and/or
- recent data on exposure have been published for the substance.

If none of these or similar indications are found for a substance, it is assumed that the substance is not on the European market[22]. In this case, the substance is not taken as a reference substance but is replaced by another substance.

An internet screening was performed for each of the randomly selected substances (Google search using the CAS number, check on individual hits obtained) to get an impression of whether the substance is used in Europe or not. Some substances were found to be listed in "sell and buy" portals for chemicals without any additional hint of real use. Other substances are listed in compilations of traders and additional indications are available for their use as listed above: recent safety data sheets and data on exposure. Based on this impression, we considered the occurrence in a "sell and buy" portal alone for the substance selection not to be a sufficient indication for the use of a substance. If additional information was found, the substance was taken as reference substance.

We have to clearly state that uncertainty remains regarding the presence of the selected substances on the market, even after this screening analysis. During the individual assessment of the substances for the risk & quality indicator system, a more detailed analysis of uses has been performed. If additional data during this assessment reveal that the selection decision was wrong for a reference substance, the reference substance will be replaced by another substance. This serves as a safety net for the selection procedure.

Ad 3: Substances with a similar structure have already been selected as reference substances

Petroleum fractions make up a large part of the HPVs listed in ESIS. In order to ensure sufficient diversity of the HPVs selected as reference substances, we decided to limit the total number of such fractions in the set of reference substances and excluded additional ones.

For the substances of very high concern, the majority of the substances were taken from Annex I to Directive 67/548/EEC. This Annex contains a high number of petroleum fractions and a high number of metal compounds. Also, in this case randomly chosen substances have not been taken as reference substances if the set already contains substances of a similar structure.

---

[21] Polymers as such are exempted from the obligation to register; however, monomer assessment for registration has to cover the use of the monomer for polymer production as well as the intended use of the corresponding polymer.

[22] In order to keep the identity of the substances confidential, information gathering by direct contact with potential manufacturers has not been done for this information research.

4.1.9.4 Documentation of the results of the selection process

The substances taken as reference substances have been compiled into a list. This list was divided into four parts: the reference substances for the three tonnage bands and the group of the 25 substances of very high concern.

A second list contains the substances not taken as reference substance. For each substance the reasoning for this decision has been documented.

4.1.9.5 Additional reference substances

If the assessment of the reference substances reveals that, in individual cases, the selected substances are not appropriate for the risk & quality indicator system (e.g. additional research shows that they are neither produced in nor imported into the EU), they will be replaced by reserve substances which are selected according to the principles described above. In addition, these substances will be used as additional reference substances in case the total number of substances included in the risk & quality indicator system can be increased.

4.1.9.6 Handling of changes in the production volumes of substances

The set of reference substances selected for the Baseline Study is appropriately sized to indicate changes in risk due to REACH. In addition, the proportion of low to medium and high production volume chemicals reflects the real proportion at present.

In reality, there is constant change in the set of substances on the market. New substances enter the EU market and at the same time others leave it for different reasons. Even if there are no exact figures for these processes for the different tonnage bands, changes of approximately 4% each year appear to be a reasonable assumption (including the substances with a low production volume of less than 10 tonnes/year). This can lead to considerable changes for the set of reference substances used in the Baseline Study:

- The total number of substances on the market and the proportion of the number of substances in the different tonnage bands might change.
- Reference substances might disappear from the market. This would lead to a reduction in the total number of substances assessed by the risk & quality indicator system (which is set at 237 in the beginning). Referring to the value of 4% mentioned above, 40% of the reference substances selected at the beginning would no longer be on the EU market in 10 years' time[23].

It is important that the results from the application of the Baseline Study methodology are comparable over time. Therefore, the set of reference substances should stay stable regarding size and the proportion of different groups of substances. Changes in the availability of reference substances in reality are reflected in the Baseline Study by two means:

- If production or import of a single reference substance is stopped in reality, in the baseline set the substance will be replaced by another randomly selected substance of the same production volume class. If the use or import of a substance of very high concern is stopped, it will be replaced in the same way by another priority substance.
- The real evolution of the number of substances on the market has to be monitored directly (specified for the five production volume ranges). If significant changes in the proportion (>10%) occur, the composition of the Baseline set will be changed in the same way. The same adaptation will be made if changes in the production volume of the reference substances cause a change in the proportion.

In both cases it will become necessary to select additional reference substances and to calculate for these substances the scores for 2007. In order to be able to do this, central data sources are stored in the version which has been used for the calculation of the risk & quality indicator system in 2007[24].

In the future, the risk & quality indicator system will be used several times. At each point in time, the actual production volume of the reference substances will be determined as well as the proportion of the number of substances in the tonnage bands. If necessary, corrections in the reference set will be made in order to ensure that the reference set reflects the proportion of the tonnage bands at the point in time when the assessment is made.

According to REACH, manufacturers/importers have to inform the European Chemicals Agency about changes in production volume (if it leads to a change in the volume band) as well as about the withdrawal of substances from the market. Therefore, necessary information regarding changes in production volumes must be available.

---

[23] The set of reference substances contains no substances with very low production volumes (below 10 tonnes/year). Therefore it might be that the real "loss" of reference substances is lower than estimated here.

[24] e.g. the ESIS lists of high and low production volume chemicals, the UCLID 4 data files, the compilation of production volumes from UCLID 4 substances, the Annex I of Dir 67/548/EEC (including the 28.ATP) and the SPIN Database Version 2007.

4.1.9.7 Confidentiality

The Steering Committee agreed not to disclose the list of reference substances selected for the R&Q indicator system since making the set of substances public could influence the outcome of the future snapshots. The substance list was only made available to the members of the project management team and one representative of the Steering Committee. The member of the Steering Committee was appointed to review the selection process. The recommendations from the review process have been taken into account during the finalisation of the report.

4.2 Impact area: workers

One aim of REACH is the reduction of health risks for workers handling chemical substances or preparations. Therefore, workers are regarded as an impact area for which the risk & quality indicator system provides information on the nominal risk and the quality of information over time.

This indicator system does not include an evaluation of occupational diseases because the various national statistics are not comparable due to the different legal background and reporting requirements. In addition, no recognised occupational disease will be associated with a substance with currently unknown toxicological properties. Moreover, for many occupational diseases, a significant time lag is to be expected between implementation of REACH and subsequent changes in reported health consequences. However, apart from this risk & quality indicator system, the intention is to establish an indicator specifically on occupational skin diseases because consequences may be more immediate, extra statistics may be available for this endpoint and a relevant influence of REACH is assumed (see Chapter 5.2.4).

The risk & quality indicator system does not discriminate between "general workers" and "chemical workers" as originally proposed in the project specifications. Job descriptions and data availability are not sufficiently specific to justify this separation. Moreover, exposure of downstream users may be more critical and thus more relevant for the analysis of REACH success compared to exposure at production sites of basic chemicals in the chemical industry.

The methodology for the risk & quality indicator system for the impact area workers is consistent with the general approach outlined in Chapter 4.1.

4.2.1 Production and use profiles

For a selected substance (for the selection process, see Chapter 4.1.9), it is important to know the production conditions and the uses because these parameters determine the exposure profile for workers handling the substance (see Chapter 4.2.2, exposure assessment). In addition, the use may also give an indication of whether few or many workers will be exposed to the substance in question (see Chapter 4.2.5.1, population risk modifier).

Production and use information is primarily extracted from IUCLID (section 1.7 in the data sheets), with data for main categories (MC), industrial categories (IC) and use categories (UC). In rare cases, more specific information may be available if qualified assessments have already been performed on a substance (Risk Assessment Reports (RAR) from the EU existing substances programme, Environmental Health Criteria (EHC) from the WHO, Screening Information Data Sets (SIDS) from the OECD and Concise International Chemical Assessment Documents (CICAD), again from the WHO). In addition to these data sources, the SPIN database (Substances in Preparations in Nordic countries) may be evaluated by a systematic search procedure to decide whether there are few or many uses, and only industrial or general (craft, trade, consumer) use. The search for production conditions and use pattern is limited to this narrow list of data sources (see Table 4.2).

Data sources for assessment of production conditions and use patterns
• IUCLID, section 1.7, to identify main categories, industrial categories and use categories • List of qualified existing assessments (RAR, EHC, SIDS and CICAD), to identify major uses, production conditions (e.g. closed system) and additional relevant information for production and use (e.g. "used as an intermediate in closed systems" and "wide dispersive use in the paint industry") • SPIN, to identify major uses according to a systematic procedure

Table 4.2 List of data sources for assessment of production conditions and use patterns

4.2.2 Exposure assessment

For the purpose of this indicator, only inhalation exposure is included in the exposure and toxicity assessment. Inhalation is the most important pathway for uptake of volatile chemicals, aerosols and dust in the case of occupational exposure. In addition, dermal exposure (percutaneous uptake) may be relevant. However, as dermal exposure assessment needs far more expert knowledge and more data on specific exposure determinants, we did not include this pathway in the indicator system.

Generally, we are looking for exposure concentrations for workers:

- who are highly exposed (90^{th} or 95^{th} percentile of the exposure distribution);
- who work in the most relevant industries identified in the production and use profiles (see Chapter 4.2.1 for this selection process);
- preferably based on measured data, if certain minimum quality criteria are met, and if such measured exposure data may be retrieved from a limited defined set of data sources.

4.2.2.1 Exposure assessment based on measured data

For measured data, a limited number of exposure databases (referenced on the "risk observatory" site of the European OSHA) were identified with possibly useful and highly qualified data. However, these databases are privately owned and access permission must be gained prior to a definite conclusion on the relevance of these databases for exposure assessment within the risk & quality indicator system.

Sometimes, several measured data sets are reported so that a decision has to be made as to which exposure data will finally be used. Therefore, a decision matrix has been established providing clear rules on the priorities when only:

- data exist from less relevant uses;
- data exist from well before the baseline (e.g. 10- or 20-year old data);
- data exist from countries outside Europe where technology may be less comparable to EU baseline conditions and where no influence of REACH is expected;
- data on average exposure exist without showing the exposure distribution;
- only local or anecdotal data exist compared to more representative large-scale measurements.

This decision matrix permits the selection of the exposure data to be used for further risk assessment and a certain Quality Score to be assigned to the selected exposure concentration (see Chapter 4.2.4.2). If a minimum score in the decision matrix is not reached, modelled data attain priority.

In addition to data for a few chemicals from the "risk observatory" databases, measured exposure concentrations may be found in a limited set of qualified existing assessments (RAR, EHC, SIDS, CICAD).

4.2.2.2 Exposure assessment based on modelling

If no measured data or only insufficient data are available, modelled data may be used for exposure assessment. Principally, the EUSES software (provided by the European Chemicals Bureau) is to be used for exposure assessment at the workplace. Within EUSES, the EASE module estimates occupational inhalation (and dermal) exposure.

Some information is required as data input:

- Physico-chemical data can be found in the IUCLID data sheet for the respective chemical or in the ChemDAT database (published by Merck KGaA) or must be estimated by EPI suite™ software (published by the US EPA).
- Patterns of use and patterns of control are available from IUCLID data sheets (see Chapter 4.2.1).

Assumptions on process temperature, the number of events per day and the number of contacts per event have to be added to calculate the respective exposure estimates.

In some cases, short-cut simplified exposure assessments are available in accordance with EUSES:

- for closed systems;
- for exposure to dust; and
- for wide dispersive use of liquids and gases.

These tables with calculated approximate exposure concentrations are then used as reference exposure concentration. If such rough, modelled data are applied, a low quality will be assigned to the assessment because estimated exposure is uncertain (see Chapter 4.2.4.2).

If no more specific information is provided by IUCLID or the above mentioned sources, "wide dispersive use" is assumed as the default for exposure assessment.

4.2.3 Toxicity assessment

A reference point is established within the toxicity assessment. This — for the workplace — is the concentration of a chemical in air that in general does not impair the health of workers. Very sensitive individuals may not be covered by this definition. As stated above, only inhalation exposure is included in this assessment. Because highly sophisticated expert judgement is not incorporated into the procedure, use of original experimental toxicological or epidemiological data is the exception. Rather, results of prior assessments, such as occupational exposure limits (OELs) or risk phrases, are proposed as standard tools to determine this reference point. Table 4.3 shows the list of instruments available for OEL derivation in the case of non-carcinogens. Some differences exist for the assessment of carcinogens for which OELs are currently only rarely established.

Hierarchy for establishing OELs and $OEL_{analogues}$ for non-carcinogens
• Use DNELs if available
• Use OELs (a) from SCOEL or (b) the lowest national value
• Use risk phrases and transform into $OEL_{analogue}$
• Derive $OEL_{analogue}$ from experimental data using procedure in accordance with DNEL concept
• Perform QSAR modelling to group into one of three toxicity classes, transform into $OEL_{analogue}$

Table 4.3 Hierarchical procedure to derive OELs or $OEL_{analogues}$ for non-carcinogens depending on data availability and quality

4.2.3.1 Occupational Exposure Limits (OELs)

OELs for a chemical may be selected from the GESTIS International Limit Values for Chemical Agents database according to a priority procedure proposed within the methodology for this risk & quality indicator system. Usually, limit values established by European committees are preferred (i.e. "indicative OELs"[25]). In the future, "derived no-effect levels" (DNELs) with a defined methodology for extrapolation from experimental data to this reference point are the first choice since these DNELs are in accordance with REACH and will exist for far more substances as compared to the few OELs that are currently assigned. However, it may be necessary to consider the differences in the level of precaution included for DNELs compared to OELs in order to avoid a bias in future assessments.

4.2.3.2 OEL derivation based on risk phrases

Risk phrases for many chemicals are available from the ESIS database (identical to data in Annex I of Directive 67/548/EEC on classification and labelling of dangerous substances). In some cases, risk phrases may have been developed by industry and found in IUCLID data sheets or safety data sheets. A transformation procedure has been developed to estimate the order of magnitude of an OEL if only risk phrases are provided. This transformation procedure uses statistical distribution data similar to the "banding" approach in common risk management concepts. The resulting reference values are called $OEL_{analogues}$ (point values derived from the order of magnitude of toxicological potency) since they are only rough estimates without official status. Fewer $OEL_{analogues}$ will be used once DNELs become available in the future. $OEL_{analogues}$ are associated with lower quality than OELs (see Chapter 4.2.4.1).

4.2.3.3 OEL derivation based on experimental data

As indicated, the use of experimental data should only be an exception since this procedure requires relevant toxicological expertise for appropriate use. However, if OELs or risk phrases are not available for a chemical, it may be necessary to search for original toxicological data. Since a high degree of expertise of the assessor — and thus a high level of confidence in the assessment — cannot be generally assumed, a reduced Quality Score is assigned if original experimental data are used. Experimental concentrations without adverse effects or from human voluntary studies may be found in IUCLID data sheets. In addition, a data search in scientific literature (restricted procedure) is permitted. The methodology for this procedure provides detailed rules on how to use these experimental data and which extrapolation factors should be incorporated to derive $OEL_{analogues}$ from such unprocessed data. In some cases, only experimental data from oral studies are available. Generally, these may also be used after a "route-to-route" extrapolation (calculation of an inhalation equivalent).

[25] http://osha.europa.eu/good_practice/risks/dangerous_substances/oel/notes.stm?set_language=en

4.2.3.4 Reference point for carcinogens

For carcinogens of category 1 or 2, experimental data have to be used for risk quantification in many cases because no OELs exist. The reference point should correspond to a low risk level, which is set at 5.10^{-5} (cancer incidence of 5 per 100 000 exposed workers; additional lifetime risk for cancer, if exposed daily to this concentration throughout working life). This risk level is a nominal risk as its calculation depends on many assumptions. The level chosen is similar to the "acceptable risk" as defined for the workplace in the Netherlands and is higher than the risks usually accepted for the general population. It is within the currently discussed range as discussed in the REACH implementation project (RIP 3.2-2). This low risk level includes considerations on the severity of the effect. Therefore, no extra severity modifier is proposed (see Chapter 4.2.5.2). The risk is quantified by linear extrapolation from experimental data in accordance with the Technical Guidance Document on risk assessment (EC 2003). For many substances, a list of compiled experimental carcinogenic potency data is available. For others, calculation from original data may be necessary. However, most category 1 or 2 carcinogens have already been assessed by others. In future, a "derived minimal effect level" (DMEL) has to be integrated into the procedure since this is the REACH-based assessment of carcinogenic potency. However, at baseline this risk figure is not yet available.

4.2.3.5 OEL derivation based on QSARs

If no toxicity data exist at all for the substance in question, quantitative structure-activity relationships (QSARs) have to be used to derive a toxicity estimate where possible. A QSAR tool provided by ECB is toxTree (version 1.0; basis: Cramer rules), which estimates toxic hazard with a decision-tree approach. The results are presented in a semi-quantitative way (three classes of toxicity: "low", "intermediate", and "high") and may be transformed into $OEL_{analogues}$ using the underlying toxicological data, statistical considerations, and by fitting the range of expected effect thresholds to the distribution of OELs for chemicals with known effect thresholds. Additional information may be supplemented from other QSAR approaches (e.g. skin irritation and sensitisation from the Danish EPA QSAR database). However, the quality of such QSAR assessments is low (see Chapter 4.2.4.1). The approach is to be extended and will also provide a proposal on how to derive an $OEL_{analogue}$ if no QSAR is possible. For example, toxTree is not usable for all poorly assessed inorganic compounds.

4.2.4 Quality Scores

4.2.4.1 Quality Score (exposure)

The quality of the exposure estimate depends on the type and amount of data available. The best information would be an IUCLID 5 set of quantitative exposure data (Quality Score: 1), which is, however, not yet available. A relatively high exposure Quality Score is assigned to measured data, differentiated according to the rules of the decision matrix (see Chapter 4.2.2.1). Lower Quality Scores are attributed to modelled data and the lowest (Quality Score: 10) to default exposure assumptions in the case of unknown major uses, production conditions and physico-chemical properties.

4.2.4.2 Quality Score (toxicity)

The quality of the toxicity estimate (reference point) depends on the type and amount of data available. The best information would be a DNEL as given in the chemical safety report (Quality Score: 1), which, however, is not yet available. A relatively high toxicity Quality Score is assigned to OELs derived by committees that were responsible for carefully discussing the complete data background for a substance. Lower Quality Scores are attributed to $OEL_{analogues}$ from risk phrases and the lowest (Quality Score: 10) to default toxicity assumptions in the case of unknown toxicological properties with a rough QSAR analysis for $OEL_{analogue}$ derivation. A similar differentiation is possible for carcinogens with potency estimates by qualified committees (high quality) or linear assessments directly from experimental data (lower quality).

4.2.5 Result modifiers

4.2.5.1 Population risk modifier

The population risk modifier accounts for the number (as an order of magnitude) of workers at risk when handling a specific chemical. Four parameters are used to assign a value to this modifier:

- Production volume from IUCLID data sheets;
- Number of manufacturers/importers from ESIS and IUCLID data sheets;
- Type of main categories (MC) from IUCLID;
- Number of use categories (UC), industrial categories (IC) from IUCLID.

The maximum value for the population risk modifier is 10 (for a chemical of which at least 100 000 tonnes/year are produced/imported by 20 or more companies, with wide dispersive use and more than 6 industrial categories or more than 9 use categories); the lowest value is 1 (for a chemical of which less than 10 tonnes/year are produced by only a few manufacturers, used in a closed system). If use categories (UC) are not available from IUCLID data sheets, the number of uses derived from the SPIN database may be used as a substitute information source (see Chapter 4.2.1).

Note that the exposure data (as assessed in Chapter 4.2.2) do not necessarily relate to the same activities as those which determine the population risk factor. Many workers may be exposed to concentrations of a chemical different from the ones that provide the exposure estimate. However, as a simplification it is assumed that more persons (in absolute numbers) are exposed to the 90^{th} or 95^{th} percentile of the distribution of exposure concentrations if a substance is produced in large amounts or by many manufacturers or has many use categories compared to a substance produced in small amounts, by few manufacturers or with few use categories. This justifies a higher population risk modifier.

4.2.5.2 Severity modifier

A severity modifier serves as a factor to account for the different types of hazards associated with a chemical. For example, teratogenicity is often regarded as a more severe type of effect compared to irritation of the upper respiratory tract. However, when OELs are established or $OEL_{analogues}$ are derived from risk phrases, the difference in severity is usually already accounted for. Therefore, no severity modifier is currently included for workers in the basic version of the risk & quality indicator system. Such a factor may be easily supplemented if considered useful.

4.3 Impact area: consumers (direct)

One aim of REACH is the reduction of health risks for consumers using chemical substances, preparations, or articles. Consumers are therefore regarded as an impact area for which the risk & quality indicator system provides information on the nominal risk and the quality of information over time.

A consumer is defined as a "member of the general public who may be of any age, either sex, and in any state of health, and who may be exposed to a new or existing substance by using consumer products"[26] (EC 2003). One specification of the REACH Baseline Study is that primary consumers only (either adult or child) are considered.

The methodology for the risk & quality indicator system for the consumer impact area is consistent with the general approach outlined in Chapter 4.1. For more details on scenario, parameters or definitions, see Appendix II.

4.3.1 Exposure assessment

The entire rationale is described in the charts at the end of this chapter (Figure 4.9 for physicochemical properties and Figure 4.10 for consumers exposure score) and explained below.

4.3.1.1 Data gathering

In terms of data gathering, the RAR as first choice and the SIDS as second are exclusive sources of data on exposure (direct quantitative exposure score).

If they are not available or do not provide a direct quantitative exposure score for consumers, additional information will be searched for in the following additive sources: Chemrisks[27], IUCLID DB, ESIS, IPCS INCHEM (EHC and CICAD), TOXNET (HSDB, HPDB etc.) and SPIN. Physico-chemical properties as well as qualitative and quantitative input data needed for exposure modelling (tonnage, main categories, and product use) are collected.

If no information is available on physico-chemical properties, Epi-Suite[28] is used.

4.3.1.2 General rationale for the derivation of the exposure score

All routes of exposure are taken into account (oral, dermal, inhalation).

As long as modelling is required (which means no measured data are available AND/OR there is no direct quantitative estimate from RAR or SIDS) AND the product use (PU) is known:

> **1: TRA:** Tier 1 for consumers is used when there are no details available for the consumer's product use category, except for washing and cleaning; the generic exposure scenario data are used by default (Appendix II)

[26] The EU legislation broadly restricts the use of CMRs in consumer products.
[27] Chemrisks is still under development. However, it was asked during the second Steering Committee meeting that this source of data be added to identify consumers' product uses. http://web.jrc.ec.europa.eu/eis-chemrisks/
[28] http://www.epa.gov/opptintr/exposure/pubs/episuite.htm

and are not modified except when children are identified as the primary users. In that case, physiological data from the EU database Expofacts are used[29]. Variability between sources in physiological data for adults (either men or women) does not have a significant impact on the exposure surrogate by comparison with substance-specific data, which are very scarce when consumers' exposure is concerned. As a result, default values from TRA[30] can be used.

Consexpo is used when:

2a: "Washing and cleaning" is identified as the main PU without any details on the specific type of consumer exposure to the chemical under consideration. In that case, the Consexpo Tier 1 scenario is used (see Appendix II for the corresponding default scenario);

2b: Some specifications of the PU are described, sufficient and precise data are totally or partially available, which allow chemical-specific data to be entered and a dedicated exposure scenario to be created. Depending on the reliability of the exposure pattern available, Consexpo modelling can go from a Tier 2 approach (rather realistic exposure scenarios elaborated and all parameters precisely qualified for all exposure pathways) to basic scenarios and default parameters from the TRA library (partly) via basic scenarios with adapted parameters or Tier 2 scenarios with rough parameters. This is reflected in the Quality Score for consumers' exposure.

When several PUs are identified, the one corresponding to the worst exposure case for consumers is chosen (it is not an additive process between PU categories).

When the consumer's PU is not known, default values are used:

- If Wide Dispersive Use (WDU), included into or onto a matrix (MAT), or Non-Dispersive Use (NDU) is identified, the default exposure score is the average of the quantitative surrogates of the TRA generic exposure scenarios ($5.73.10^{-2}$ mg/kg/d).
- If Use as an Intermediate in a Closed System (UICS) is identified, the default exposure score is 0.

When no REACH-related exposure to consumers can be identified in the data sources, then the exposure score for the substance considered is 0.

For synthesis intermediates the exposure score for consumers is 0.

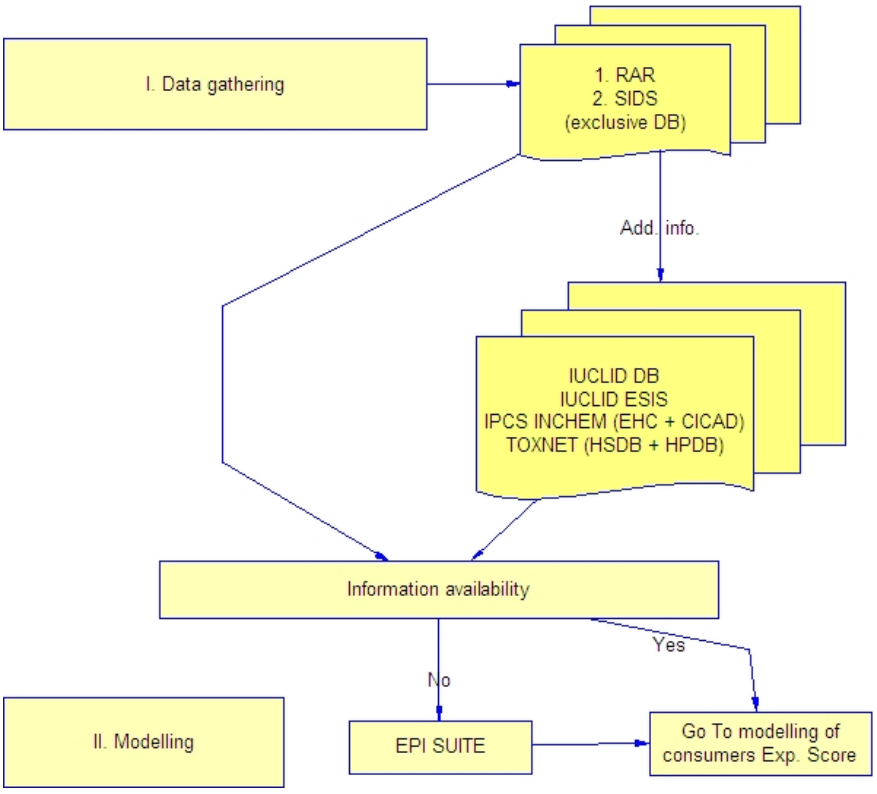


Figure 4.9 Physico-chemical properties

[29] For toddlers, in Expofacts (October 2006), in the categories "child" and "EU-25", the most recent values in averages are: Inhalation rate IR: 32.5 m^3/d; Body weight BW: 9.6 kg.

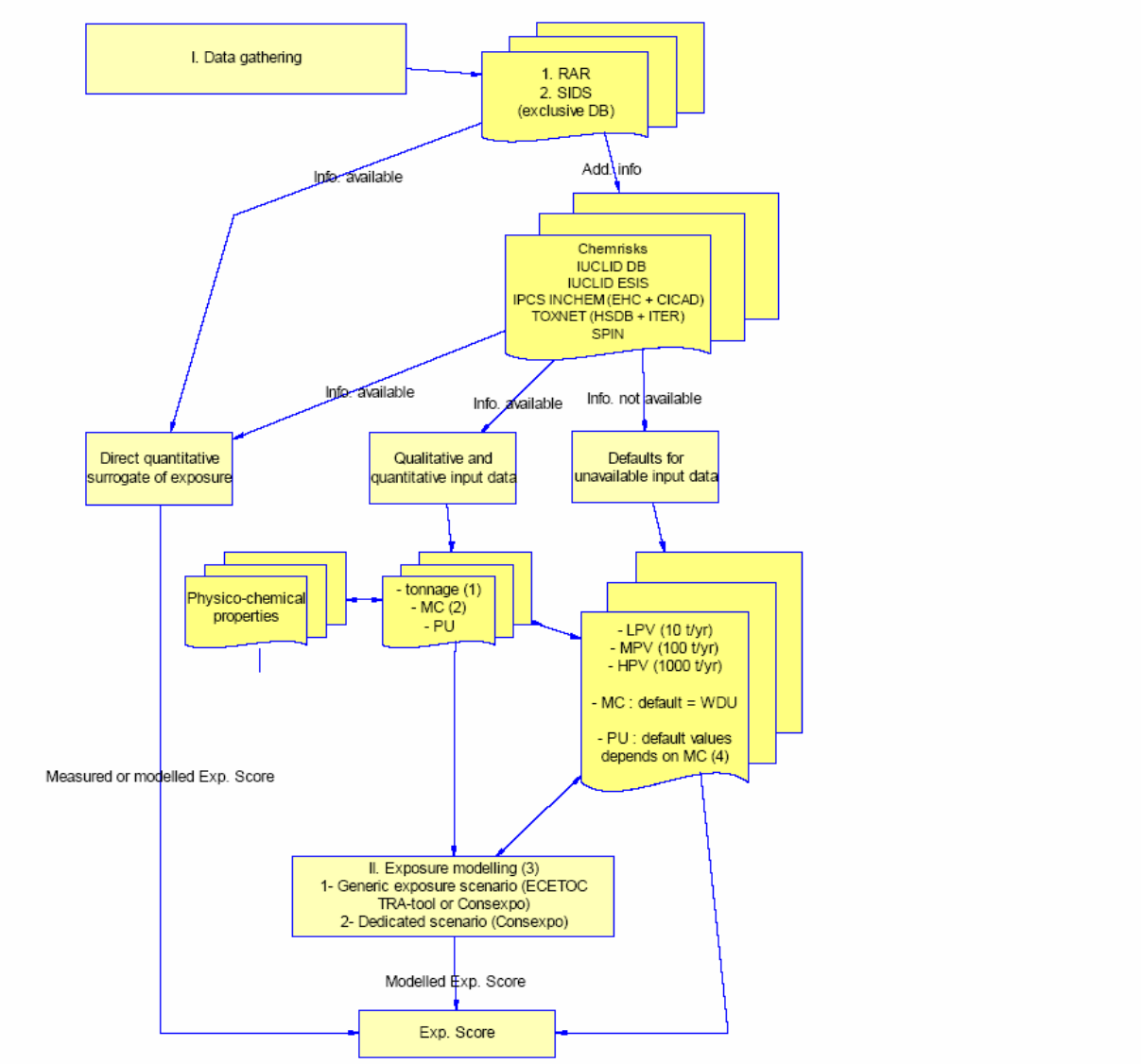
[30] For adults, IR: 24 m^3/d; BW: 60 kg.

4.3.1.3 Remarks

Measured exposure data are very poor where consumers are concerned. However, when they are available, the general approach is followed.

When it is not possible to identify a main category, WDU is considered as default.

When it is not possible to characterise the production volume, defaults are given depending on the tonnage category (HPV, MPV or LPV).



(1) if a range is available, use the higher value
(2) if several MC are identified, use the most conservative (WDU>NDS>UICS)
(3) The exposure surrogate is calculated for each of the PU identified.
The exposure score is the most conservative result (i.e. the most conservative product use for consumers). It is not an additive process in between PU categories.
When no (or few) data are available, the generic exposure is calculated using TRA (except for cleaning and washing uses for which Consexpo is directly used).
(4) For WDU, NDU, MAT : Exp. Score = 5.73.10-2 mg/kg/d (average of generic exposure scenarios).
For UICS, Exp. Score = 0.

Figure 4.10 Consumer exposure score

4.3.2 Toxicity assessment

The entire rationale is described in Figure 4.11. Several concepts have been developed enabling safe human levels to be assigned.

4.3.2.1 Data gathering

The EU RAR as first choice and the SIDS as second are exclusive sources of data on toxicity (direct quantitative toxicity score).

If they are not available or do not provide a direct quantitative toxicity score (which means a so-called "reference dose" or unit risk (UR): pre-existing reference toxicological values), additional information is searched for in the following additive sources: IUCLID DB, ESIS, IPCS INCHEM (EHC and CICAD) and TOXNET (HSDB, IRIS, ITER).

4.3.2.2 General rationale for the derivation of the toxicity score

1. Use pre-existing toxicological values

- For non-carcinogens, as long as they are available in the specified databases, use a TDI, RfC, RfD etc. (reference toxicological values: N(L)OAEL/AF, etc.), which could be compared to the exposure score so as to compute a risk characterisation ratio (RCR).
- For carcinogens, as long as they are available in the specified database, collect the unit risks (UR) and use the concentration at a risk of 10^{-5} as a surrogate for toxicity score to be compared to the exposure score to compute the RCR.

2. Use critical experimental data or risk phrases (R-phrases)

- For non-carcinogens, if no peer-reviewed reference toxicological values are available, derive a value from a critical NOAEL (focusing on repeated dose toxicity, oral) identified in RAR, SIDS or IUCLID, and use this value and default AF (1 200) to derive a toxicity score.
- If no critical NOAEL is available[31], derive a value from R-phrases (following the approach described in TRA with the GLEVs[32]; see Appendix II for definitions) and then apply default assessment factors (AF=1 200) to compute a toxicity score. GLEV refers to hazard potential depending on the R-phrases (respectively low, medium, high). GLEV for oral exposures are considered given this potential (50, 5 and 0.5 mg/kg/d, respectively).
- For carcinogens, if no peer-reviewed data are available, derive a value from critical experimental data (T25) identified in RAR and use this value and default AF (25 000) to derive the toxicity score. The R-phrases approach cannot be applied.

3. Use of defaults

- For non-carcinogens, if no data at all are available, use the OEL identified or derived for workers (with route-to-route extrapolation[33]) and apply AF (1 200) or, if most conservative, use the GLEV (TRA) for oral medium hazard category (5 mg/kg/d) and apply AF (1 200).
- For CMR cat. 1 and 2, if no data at all are available, compute the median of all oral unit risks from the IRIS website (EPA) and use the concentration at a risk of 10^{-5} as a default toxicity score (3.77 10^{-5} mg/kg/d, June 2007).

[31] or if several NOAELs are available
[32] Generic Lowest Effect Values
[33] Basis: BW = 60 kg; inhalation rate = 24 m^3/d (default TRA) — except if children are identified as primary consumers (use data from Expofacts, cf. footnote 29).

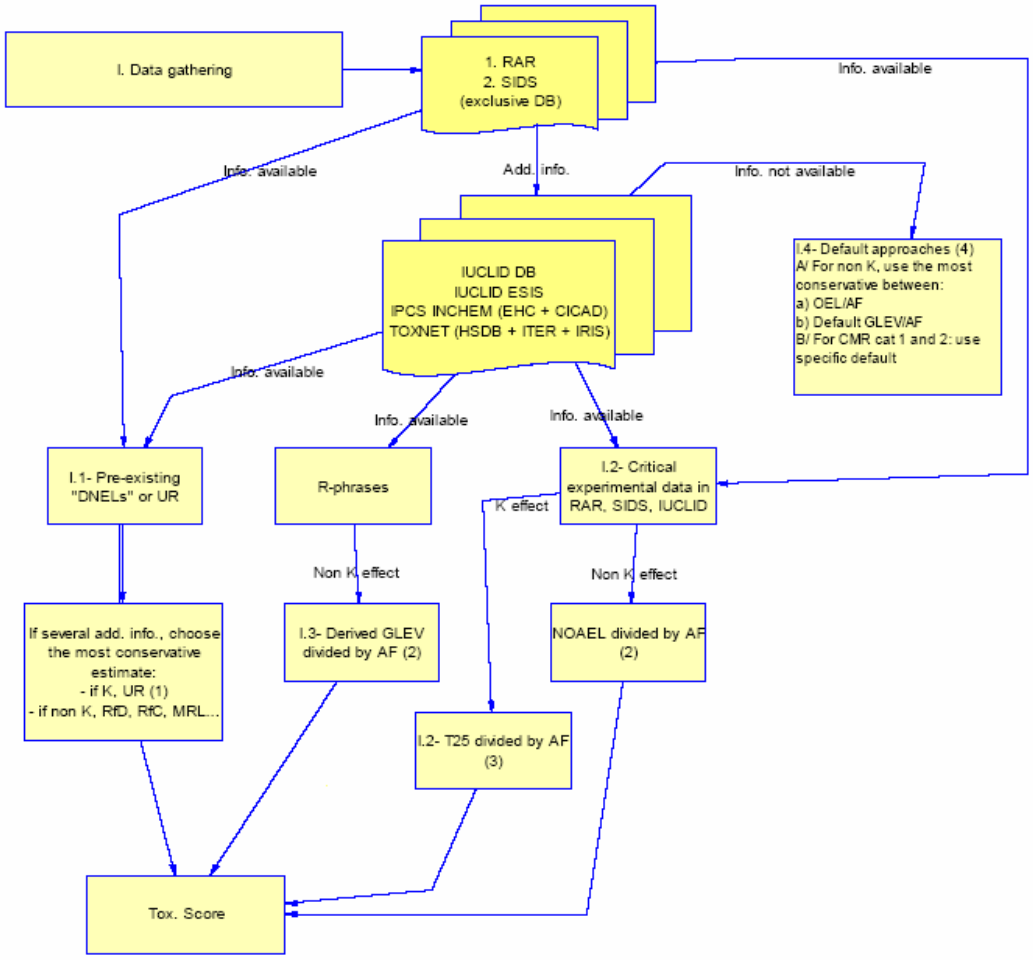


Figure 4.11 Consumers and humans via the environment toxicity score

4.3.3 Quality Scores

4.3.3.1 Quality Score (exposure)

While the quality of the toxicity assessment is similar between the consumers and humans via the environment impact areas, the quality of the exposure assessment is examined differently. Indeed, the quality of the exposure assessment has to be assessed *per se* for consumers, whereas, for humans via the environment, the setting of a Quality Score is closely related to the Quality Score determined for environmental exposure. Based on the general approach and on what was developed for workers, the tables for exposure Quality Score (QS_{exp}) are presented in Appendix II.

4.3.3.2 Quality Score (toxicity)

The quantification of a Quality Score for the consumers and humans via the environment impact areas is done in the same way as both assessments are based on the same data set. Furthermore, thresholds determined for these impact areas are the same. If different toxicity thresholds are taken into account for a classic and complete risk assessment, in order to determine the risk due to several exposure pathways in the context of the development of the risk-based indicators, the worst case is assumed for consumers. Usually, for the risk characterisation of humans via the environment, the worst case from the toxicity assessment is retained. Consequently, in the framework of the development of these indicators, the toxicity assessment for consumers and for humans via the environment will result in the determination of the same thresholds, hence the same Q-scores.

As indicated in the section on Q-score determination toxicity for workers, differences can occur between toxicity assessment for workers and consumers (oral and dermal data may also be considered in addition to the inhalation data). However, if the toxicity threshold can be different between consumers and workers, the assignment of the Q-score is quite similar. The table for toxicity Quality Score (QS_{tox}) is in Appendix II.

The exposure scores for consumers and humans via the environment are expressed in terms of integrated or total exposure, which means that they integrate inhalation, dermal and oral potential routes of exposure. It is expressed in mg/kg/d. As long as oral risk estimates are available, no route-to-route extrapolation is needed. As long as an inhalation risk estimate is available, route-to-route extrapolation is needed except if the potential route of exposure is restricted to inhalation only.

4.3.4 Result modifiers

The population risk modifier (PRM) accounts — apart from the risk for the individual — for a situation where particularly large numbers of consumers or humans via the environment are exposed. Ideally, the specific number of consumers or humans via the environment exposed would be needed for a particular product use. Since this information is not readily available, the HPV/LPV status (as a measure of the overall amount handled), the number of manufacturers/importers (as a measure of the number of facilities) as well as information from RAR, SIDS or IUCLID on the main categories (MCs) and industrial categories/use categories (ICs/UCs) are taken as a surrogate. Information on these parameters is taken from the RAR, the SIDS (exclusive data sources, most recent data for production volume and MCs) and the ESIS system or the IUCLID data sheets (more straightforward for the number of manufacturers/importers and the ICs/UCs).

Concerning the last category

For consumers, only the UCs are taken into account.

For humans via the environment, both the ICs and UCs are taken into account, as for workers.

The matrix in Appendix II is used for the calculation of the PRM. Within each category, take the highest point and add the highest points from all four categories. This will result in a maximum value for the result modifiers of 10.

The IC/UC data are included — although with a smaller influence on the overall PRM, particularly for consumers (where it is very rare to have more than 6 UCs identified).

4.4 Impact area: environment

An aim of REACH is also to ensure the safe handling of chemicals with respect to the environment. The environment is therefore regarded as a central impact area for which the risk & quality indicator system provides information on the nominal risk and eventually on the quality of information.

Ozone depletion and greenhouse effects are impacts that should be considered when making an environmental risk assessment for the air compartment. Data on ozone depletion are available for only very few (approx. 200) substances and with respect to greenhouse effects, contributions from the transport and energy production sectors are suspected to be orders of magnitude higher than the contribution from the chemicals themselves. Therefore, the effects of the chemicals in the air compartment are not considered in the environmental risk indicator.

For most substances, the water compartment will prove to be the compartment apparently at highest risk, but not for all substances. In some cases, the soil or the sediment compartments may apparently be at higher risk. The consequence of only accounting for the water compartment is thus that the contribution to the total risk characterisation score may be underestimated for some substances.

The methodology for the risk & quality indicator system for the environment impact area is consistent with the general approach outlined in Section 4.1.

4.4.1 Exposure assessment

The predicted environmental concentration (PEC) can, in principle, be derived from monitoring studies. However, it is not straightforward to link measured concentrations in the environment with an annual emission into the environment since the PEC might well be a result of many years of emission and non-EU countries may contribute to the measured concentration.

Environmental exposure assessment is therefore based on the principles stated in the EU TGD (EC 2003). For the actual calculations, the Excel sheet (Radboud University Nijmegen & Free University Amsterdam 2007) is used.

Both regional and local PECs in all compartments are calculated by the EU TGD sheet.

For the environmental risk characterisation ratio (RCR) factor, the predicted regional concentration in surface water is used.

The input parameters to the EU TGD sheet are:

Substance physico-chemical and fate properties

- Molecular weight;
- Vapour pressure;
- Water solubility;
- Melting point;
- Octanol-water partition coefficient (log K_{OW});
- Biodegradability;
- Abiotic degradation in water and air.

Substance use

- Tonnage in EU.

Emission pattern

- Fraction of EU production volume in region;
- Release fractions (air, waste water, surface water, industrial soil, agricultural soil);
- Fraction of the main local source;
- Number of emission days per year;
- Local release rates (air and waste water).

The derivation of the various input parameters is described in the following sections.

4.4.1.1 Physico-chemical and fate data

The most important data are the log K_{OW}, vapour pressure, water solubility and biodegradation rate.

The data compilation was planned to require a minimum of effort. A strategy for collecting and selecting the data was also developed. The strategy and recommended data sources are described in Appendix III. Both measured and calculated data using, for example, QSAR-estimated data are included.

4.4.1.2 Substance use pattern data

Tonnage

IUCLID was the primary source for data on tonnage. The tonnage for each registrant of the substance in question for one or more years is given in IUCLID. It is specified as a range, and the middle value for the latest year of registration data is used in the calculations. The annual total tonnage is then found by summing up all tonnages for each registrant. For a few substances, no IUCLID database information was received, and in these few cases, a default tonnage of 10 tonnes/year was used.

Emission pattern

A substance may be released into the environment throughout its whole life cycle. For the estimation of chemical emissions, several sources were reviewed with the aim of locating emission scenarios applicable in the project. These sources are described in Appendix III.

Three parameters outlining the actual operational conditions are important: industrial category (IC), use category (UC), and main category (MC).

Main categories (MCs), ICs and UCs are available in the IUCLID extract. The ICs and UCs are, however, decoupled, which means, for example, that UCs can be allocated to several ICs, therefore making objective and reproducible allocation of tonnage impossible. The principles of the problem are best illustrated by an example:

For substance xx, the following information is provided in the IUCLID extract:

Substance xx (registrant AA): tonnage 100-500 tonnes;

MC: I, III and IV; IC: 0, 1, 3, 5, 14; UC: 33, 37, 48.

Thus, the tonnages are not allocated to specific ICs, which in turn are not allocated to specific UCs.

The OECD emission scenario documents (ESDs) are very useful if you can allocate a tonnage to an industry category (IC) and know how the substance is used in this industry (UC). This is, however, not the case here. The SPIN database can be used and an approach similar to the one applied for the worker area, both to identify the most important industries (IC) and to allocate tonnages to these industrial categories. Similarly, the SPIN database can be used to find the most important use categories and to combine tonnages with these categories.

This was tested for 21 example substances. The result was that, out of these 21 substances, ESDs could only be identified for 2 substances for the life-cycle phases formulation, industrial usage and private usage. Due to this low hit rate and to the uncertainty in identifying the proper tonnage-IC-UC combinations, another approach was used.

This new approach was based on the A and B tables of the EU TGD (EC 2003), which are considered to give conservative estimates of releases. The fractions of the applied tonnage released into the environment are obtained from these tables. The B tables provide the fraction of main source and number of emission days used for local assessments.

The following approach was applied:

Regional tonnages/emission

- The whole tonnage is assumed to be assigned to the continent (the whole of the EU).
- 10% of the whole tonnage is assumed to be assigned to the region.
- For substances for which an EU RAR is available, the emission estimates given in these were used.
- For all relevant combinations of IC codes, MC factors and UC codes specified for the substance in IUCLID, the emission fractions (air, waste water, surface water, soil) from the A tables in the EU TGD were retrieved, and the median emission fractions were used.

Local tonnages/emission

- For all combinations of IC codes, MC factors and UC codes specified for the substance in IUCLID, the number of emission days and fraction of main source were looked up in the B tables of the TGD. The median values of fraction of main source and number of emission days were then applied.

4.4.2 Toxicity assessment

The interpretation of ecotoxicity data and the use of the lowest EC50/NOEC will follow the recommendations of the EU TGD. Only assessment factors explaining the difference between acute and chronic effects will be applied to a derived effect concentration (a factor of 10). The remaining assessment factors, normally applied for the derivation of PNEC (Predicted No-Effect Concentration) and applied to account for the number of taxonomic groups represented in the test set, will be incorporated in the Quality Score (toxicity). If only acute toxicity data were available, in a risk assessment the PNEC is found by dividing the lowest acute E(L)C50 value by 1 000, whereof a factor 10 accounts for the ratio between acute and chronic ecotoxicity data, and the remaining 100 accounts for missing quality of information compared to actual measurements in ecosystems. Therefore, in order to be in line with the TGD and to use a PNEC-like approach in the toxicity assessment, the NOEC is divided by a factor of 100 to derive a pseudo-PNEC. In some situations, it can be demonstrated that the assessment factor should be higher than the default values of the TGD (EU 2003). This is for example the case if knowledge of the mode of action includes endocrine disrupting effects (EU 2003). This is the background for introducing the severity modifier (see Section 4.4.4.2).

We developed and implemented a strategy for selecting ecotoxicity data and listed a number of predefined data sources, including QSAR models. The strategy and data sources are described in Appendix III.

4.4.3 Quality Scores

4.4.3.1 Quality Score (exposure)

The environmental exposure is expressed in the Predicted Environmental Concentration (PEC), which is derived from consumption volume (F), emission fractions (f_{water}, f_{soil}, f_{air}) and a number of fate properties, of which the octanol water partition coefficient (log K_{OW}), Henry's law constant (H) and the biodegradation rate (k_{bio}) are the most important parameters.

$QS_{(Exposure)}$ is assumed to be composed of three contributions: $QS_{(exposure,\ environment)} = QS(F) \times QS(f) \times QS(fate)$

QS(F) varies between 1 and 2.25: it is equal to 1 if precise consumption volumes are available and to 2.25 if the consumption volume is derived from a number of assumptions, e.g. analogy considerations.

QS(f) varies between 1 and 2.25: it is equal to 1 if measured emission rates are available, to 2 if it is derived from the A/B tables in the TGD or the like, and to 2.25 if the emission fraction is set to 1 (conservative assumptions).

QS(fate) is calculated as a product of the Quality Score for the three most important parameters:

$$QS(fate) = QS(\log K_{OW}) \times QS(H) \times QS(k_{bio})$$

- QS (log K_{OW}) varies between 1 and 1.25 (1 if measured data, 1.25 if QSAR estimate).
- QS (H) varies between 1 and 1.25 (1 if measured data, 1.25 if QSAR estimate).
- QS (k_{bio}) varies between 1 and 1.25 (1 if measured data, 1.25 if QSAR estimate).

Overall, the $QS_{(exposure,\ environment)}$ may vary between 1 and ~10 ($2.25 \cdot 2.25 \cdot 1.25 \cdot 1.25 \cdot 1.25 = 9.9 \cong 10$).

4.4.3.2 Quality Score (toxicity)

The quality of the toxicity data used is given a "base" Quality Score. If the data point is of high quality, the value of the base Quality Score is set to 0, and if it is of poor quality, it is set to 1. If the toxicity score is derived from classification data, then the Quality Score (toxicity) is set to 8.

For the derivation of $QS_{(toxicity,\ environment),}$ a factor accounting for the uncertainty of extrapolating from laboratory studies to real ecosystems and taken from the TGD principles of deriving Predicted No-Effect Concentration by means of assessment factors (AF) is then added to $QS_{(toxicity,\ environment,\ base)}$:

$$QS_{(toxicity,\ environment)} = QS_{(toxicity,\ environment,\ base)} + QS_{(toxicity,\ environment,\ AF)}$$

Thus, $QS_{(toxicity,\ environment,\ AF)}$ accounts for the uncertainty of extrapolating single-species test results to effects at ecosystem level, i.e. the number of available data sets. It also accounts for the increasing quality of chronic data compared to acute data, which again has a higher quality than QSAR estimates.

Table 4.4 shows how the $QS_{(effect,\ environment)}$ is derived.

No of acute tests	No of chronic tests	No of QSAR estimates	$QS_{(toxicity,\ environment,\ AF)}$
0	≥3	0	1
1	2	0	4.5
1	2	1	6
2	2	0	2.5
3	2	0	1
3	2	0	1
1	1	0	6
1	1	1	7.5
2	1	0	4
2	1	1	5.5
2	1	2	7
3	1	0	2
3	1	1	3.5
3	1	2	5
3	1	3	6.5
3	0	0	2
3	0	1	3.5
3	0	2	5
3	0	3	6.5
2	0	0	4
2	0	1	5.5
2	0	2	7
1	0	0	6
1	0	1	7.5

Table 4.4 Methodology for deriving $QS_{(toxicity,\ environment}$

4.4.4 Result modifiers

4.4.4.1 Population risk modifier

The population risk modifier for the environment — PRM (environment) — takes into account the fact that the risk is more severe if the chemical is widely dispersed in the environment than if the chemical is limited to a few hot spots.

The following pragmatic approach was used:

$$PRM = \frac{\sum 10 \cdot \text{Tonnage (if "Wide dispersive use")} + 1 \cdot \text{Tonnage (if not "Wide dispersive use")}}{\sum \text{Tonnage}}$$

PRM will vary between 1 and 10. If all tonnage of a substance is assigned a "Wide dispersive use", a PRM factor of 10 will be obtained, and if none of the tonnage is assigned a "Wide dispersive use", PRM will be equal to 1.

4.4.4.2 Severity modifier

The severity modifier — SM(environment) — accounts for effects that cannot easily be reflected in the RCR factor. From the environmental point of view, REACH focuses particularly on two groups of substances: PBTs/vPvBs and endocrine disrupting chemicals. PBT stands for Persistent, Bioaccumulative and Toxic chemicals and vPvB stands for very Persistent and very Bioaccumulative chemicals. As is described, a severity factor is introduced to account for potential endocrine disrupter effects.

As the ecotoxicity of the chemicals enters into the effect and thus the Risk Score, toxicity (T) is accounted for in the proposed Risk Score. Also, the persistency (P) of the chemical is accounted for in the Risk Score, as the environmental exposure score used in the Risk Score is a result of the emission, partitioning and degradation of the chemical, i.e. the exposure score. Thus the Risk Score increases with the persistence of the chemical. The environmental Risk Score does not reflect the potential for bioaccumulation (B). However, the indirect exposure of man via the environment is a measure for the bioaccumulation in the environment. The PBT properties of the chemicals are therefore to some extend reflected in the proposed risk indicator system. However, even though the PBT-properties to some extend already are included in the Risk Indicator set, it was concluded that the PBT/vPvB substances should be more clearly emphasized in the Environmental Risk Indicator.

Five substances in the baseline substance dataset are to be found on the ESIS-list of **PBT/vPvB substances** (including substances listed as "under evaluation" and "deferred"), and **25 substances** in the baseline substance dataset have an **R50/53** classification – indicating potential PBT-properties.

Two possible solutions to more clearly emphasize PBT properties in the Environmental Risk Indicator exist:

1. Application of an extra factor;
2. Flagging of the substances with PBT/vPvB properties.

An application of an extra factor may lead to:

- double counting, as the P and T properties are already accounted for in the proposed Environmental Risk Indicator, and as the B property is to some extend reflected in the indicator for the human exposure via the environment;
- the problem of defining an appropriate factor/multiplier, which increases the meaning of overall results and does not lead to additional uncertainty.

Therefore, it was concluded not to include an extra factor, but to flag the substances with PBT/vPvB properties, and to report the Environmental Risk Indicator calculation results, both where the PBT/vPvB substances are included in the results and where the substances are not included in the results.

In this way, the contribution of PBT/vPvB to the total Environmental Risk Indicator is reflected and a transparent screening of the substances "flagged" as PBT under REACH will be possible during future snapshots.

A severity modifier factor is applied for substances with potential endocrine. The list of substances with either evidence of ED effects (CAT 1) or potential evidence of ED effects (CAT 2) prepared in three EU projects (Petersen et al. 2006, BKH 2000, BKH 2002) is used to determine whether the substance should be assigned a severity modifier factor. If the substance is not on these lists, it is assumed not to have ED effects.

The following values are assigned:

- 5: if the chemical shows endocrine-disrupting effects (CAT 1);
- 2: if the chemical shows endocrine-disrupting effects (CAT 2);
- 1: if the chemical has not been shown to be a CAT 1 or CAT 2 substance.

A severity modifier has currently only been included for the environment in the basic version of the risk & quality indicator system. Only very few of the selected reference substances have so far shown (potential) evidence of ED effects. However, the possibility cannot be ruled out that with improved knowledge of the substance properties, more substances may be shown to have (potential) ED effects.

4.5 Impact area: humans via the environment

For the elaboration of the risk-based indicator for the humans via the environment impact area, along with other specific information, results from two other impact areas will be used:

- The outcome of the exposure assessment from the environment impact area will be used as input into EUSES for the calculation of the total human daily intake.
- The results of the toxicity assessment for consumers will also be used in order to feed the EUSES file with a threshold that will be compared to the exposure dose obtained during the exposure characterisation.

4.5.1 Exposure assessment

Human indirect exposure is assessed by estimating the concentrations and intake of drinking water and food products (root crops, leaf crops, meat, milk and fish). As in standard risk assessments, exposure will be estimated on both the local and regional scale. By default, bioconcentration and biotransfer behaviour is estimated from physico-chemical properties using (Q)SAR approaches. Generally, reliable and relevant measured data are preferable, considering the large uncertainties in the (Q)SARs. However, it is a common practice to perform a rough risk assessment for this compartment based on this type of calculation.

Some parameters, such as chemical properties of the chemical and its concentrations in several media[34], are calculated from EUSES in order to estimate the exposure of humans via the environment. Following the assessment performed for environmental exposure, all these data will be available in a EUSES file.

Six different exposure pathways are taken into account in EUSES for the module dedicated to the exposure of humans via the environment:

- Ingestion of fish;
- Ingestion of plants (roots and leaves);
- Ingestion of milk (cow's milk);
- Ingestion of meat;
- Ingestion of drinking water;
- Inhalation of air.

The calculation of the concentrations in these exposure media is based on a series of equations using several parameters and values: default parameters of EUSES, values calculated previously during the environmental exposure assessment but also specific values for the refinement of the exposure assessment for humans via the environment (see Appendix IV for details on the calculations).

Most of the time exposure data calculated directly from the environmental exposure outputs is used as such for the elaboration of the risk-based indicator. Specific information that could enable the indirect exposure assessment for humans to be refined is often not available. However, in some particular cases, refinement of this default assessment will be possible using the specific data presented in Table 4.5.

Source of exposure	Parameter
Consumption of fish	Concentration in fish (Cfish)
Consumption of plants	Partition coefficient between air and plants (Kplant-air)
	Partition coefficient between air and leaves (Kleaf-air)
	Concentration in leaves of plants (Cleaf)
	Concentration in grass (Cgrass)
	Fraction of total uptake by crops from pore water (Fleafporew)
	Fraction of total uptake by crops from air (Fleafair)
	Fraction of total uptake by grass from pore water (Fgrassporew)
	Fraction of total uptake by grass from air (Fgrassair)
Concentration in milk and meat	Bioaccumulation factor for meat (BAFmeat)
	Bioaccumulation factor for milk (BAFmilk)
	Concentration in meat (wet weight) (Cmeat)
	Concentration in milk (wet weight) (Cmilk)
Concentration in drinking water	Dissolved concentration in surface water (Cwater)
	Groundwater concentration (Cgrw)
	Concentration in drinking water (Cdrw)

Table 4.5 Summary of specific information that can be used to refine the exposure assessment for humans via the environment

Concentrations in the environment can be found in databases but their validity and relevance is difficult to assess and this task could not be performed in this framework. These data will be used only when extracted from EU RAR or SIDS or other similar documents where validity has been assessed.

[34] See list of parameters in IV.

Other parameters, such as partition coefficients or bioaccumulation factors, can be searched for in the data sources indicated in Table 4.6.

Data sources
• Monitoring data and partition coefficients in IUCLID • EU RAR (European Risk Assessment Report) • SIDS (Screening Information Data Set, OECD HPV programme) • EHC (Environmental Health Criteria, IPCS INCHEM) • HSDB (Hazardous Substances Data Base) • HHRAP (Human Health Risk Assessment Protocol) • CalTOX (McKone, 1993)

Table 4.6 List of data sources for the exposure assessment of humans via the environment

4.5.2 Quality Scores

4.5.2.1 Quality Score (exposure)

Although the quality of the toxicity assessment is similar between the consumers and humans via the environment impact areas, the quality of the exposure assessment will be examined differently. The quality of the exposure assessment has to be assessed *per se* for consumers whereas, for humans via the environment, the setting of QS is closely related to the QS determined for environmental exposure.

The QS assignment for the exposure assessment for humans via the environment will be based on the system adopted for examining the quality of data used for environmental exposure. However, this system will be adapted in order to take into account the quality of the specific information that can be used for refining the evaluation of the indirect exposure to humans.

This will result in a QS for exposure for humans via the environment (QS_{exp}) defined by the following equation:

$$QS_{exp} = QS_{exp1} + QS_{exp2}$$

with QS_{exp1} based on the QS_{exp} adopted for the environmental exposure assessment, and QS_{exp2} specifically based on the quality of data available for the assessment of exposure of humans via the environment. The complete methodology for the assignment of QS_{exp} for this impact area is defined in Appendix IV.

QS_{exp1} is based on the QS_{exp} adopted for the environmental exposure assessment and is determined using the following equation:

$$QS_{exp1} = \frac{QS_{exp}(environment)}{2}$$

According to the system for assigning QS_{exp1} to the data set used for assessing the exposure for humans via the environment, an exposure characterisation based only on data from the environmental exposure will be classified as of low quality (QS between 6 and 10).

In EUSES, the transfer of a substance from the environment to humans is, by default, estimated based on Quantitative Structure-Activity Relationships (QSARs). These models rely on correlations established in relation to the K_{ow}, a parameter that is used to give an indication about the partitioning of organic substances between aqueous and lipidic phases of living cells. However, the correlations observed between the K_{ow} and the concentrations of the substance in humans have been obtained for a narrow range of substances (i.e. K_{ow}). For the module of EUSES for the indirect exposure of humans, all models share only a common range of log K_{ow} between 3 and 4.5 (see Table 4.7). In this range, the results obtained from these models have a chance of being accurate (although these models have not been extensively validated using large sets of substances).

In the absence of specific information, the QS_{exp2} could be determined based on the log K_{ow} of the substance. For example, calculations from EUSES will be more accurate for a substance with a log K_{ow} between 3 and 4.5. However, the setting of the QS_{exp2} partly based on the log K_{ow} could also be refined taking into account the main exposure pathway.

QS_{exp2} (see Table 4.8) is used to take into account the quality of any specific information that could be incorporated into the assessment of the indirect exposure to humans (e.g. transfer factors).

Exposure route	Mode of calculation	Validity range
Concentration in fish	The estimation of the concentration in fish is based on the BCF, which can be determined either based on experimental study or based on QSARs.	If QSARs are used: log Kow between 2 and 10 (more valid between 2 and 6)
Concentration in crops (leaf)	Gaseous exchange between leaf and air (Kair-plant)	Depends on the validity of Kair-water (cf. H) and Kplant-water (see below, for this study, the same validity range as for concentrations in root is taken)
Concentration in crops (root)	Calculation based on the partitioning between the plant and water (Kplant-water) Transpiration stream concentration water	Depends on the Kow validity Log Kow –0.5 and 4.5 (pesticides)
Concentration in milk	Based on the bioaccumulation factor for milk	3-6.5 (very high uncertainty)
Concentration in meat	Based on the bioaccumulation factor for meat	1.5-6.5 (very high uncertainty)
Concentration in drinking water	Purification factor based on: biodegradation rate K_{ow} H	(result always considered valid for this study)

Table 4.7 Validity ranges of models used for the humans via the environment exposure assessment

QSexp2	Driving factors for QS assignment
1	Adequate specific information is available to refine the main part of the exposure assessment for humans via the environment (routes of exposure that represent more than 90% of the total daily intake for humans are covered by specific information).
2	Adequate specific information is available to refine the main part of the exposure assessment for humans via the environment (routes of exposure that represent more than 75% of the total daily intake for humans are covered by specific information).
3	Adequate specific information is available to refine the main part of the exposure assessment for humans via the environment (routes of exposure that represent more than 50% of the total daily intake for humans are covered by specific information). OR The main part of the exposure assessment for humans via the environment has been done with models used in their validity range (routes of exposure that represent more than 90% of the total daily intake for humans are covered by model calculations performed in their validity domain).
4	The main part of the exposure assessment for humans via the environment has been done with models used in their validity range (routes of exposure that represent more than 50% of the total daily intake for humans are covered by model calculations performed in their validity domain). OR Isolated specific information is available to refine the main part of the exposure assessment for humans via the environment (routes of exposure that represent more than 50% of the total daily intake for humans are covered by specific information).
5	Default QSexp2

Table 4.8 Assignment of QS_{exp2} for humans via the environment

4.5.2.2 Quality Score (toxicity)

The quantification of a Quality Score for the consumers and humans via the environment impact areas is done in the same way since both assessments are based on the same data set (i.e. toxicity studies). Consequently, thresholds determined for these impact areas are the same. If different toxicity thresholds are taken into account for a classic and complete risk assessment in order to determine the risk due to several exposure pathways, the worst case is taken for consumers in the context of the development of the risk-based indicators. Usually, for the risk characterisation of humans via the environment, the worst case from the toxicity assessment is taken. In the framework of this indicator development, the toxicity assessment for consumers and for humans via the environment will result in the determination of the same thresholds, hence the same QS.

As indicated in the section on QS determination for toxicity towards workers, differences can occur between toxicity assessment for workers and consumers (oral and dermal data may also be considered in addition to the inhalation data). However, if the toxicity threshold can be different between consumers and workers, the assignment of the QS is quite similar.

4.5.3 Collection of data

The collection of data for the calculation of the Risk Score and the corresponding Quality Score for the humans via the environment impact area is performed according to the scheme presented in Figure 4.12.

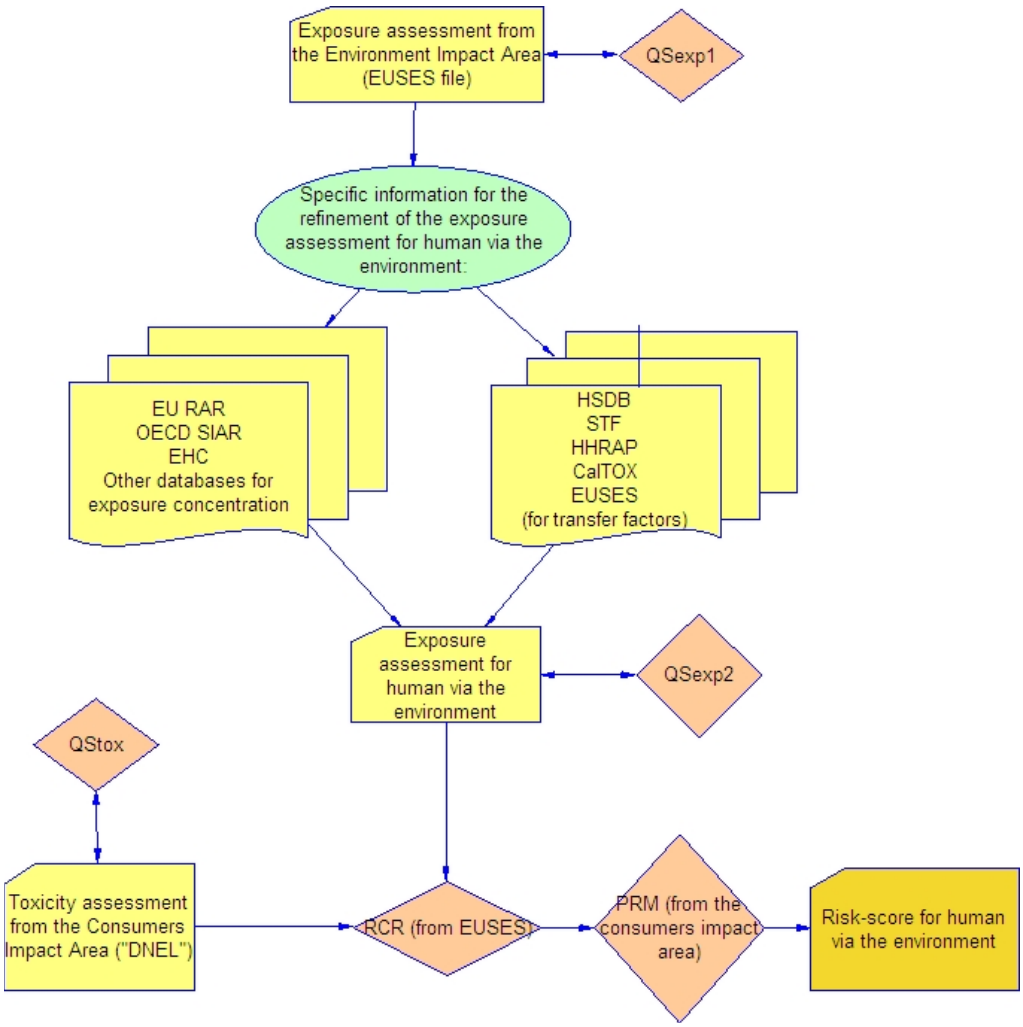


Figure 4.12 Construction of the Risk Score and associated Quality Score for the humans via the environment impact area

During data collection for the construction of indicators for the humans via the environment impact area, the following procedure was executed:

- Collection of log K_{ow} from the environment impact area (for the QS_{exp2} determination);
- Collection of QS_{exp} for the environment and calculation of the QS_{exp1} for humans via the environment;
- Collection of the toxicological reference value from the consumer impact area;
- Collection of the QS_{tox} from the consumer impact area. This value will be used as QS_{tox} for humans via the environment;
- Collection of specific data for refinement the risk characterisation for the humans via the environment. These specific data are for example exposure concentrations in intake media, and measured transfer factor including BCF. For this step, the sources indicated in the flowchart above are reviewed;
- Collection of EUSES files from the environment impact area and run of the EUSES exposure module for humans via the environment;
- Calculation of the Risk Score and collection of the Population Risk Modifier (PRM) — see Chapter 4.3.4 in the consumers' impact area;
- Calculation of QS_{exp2} and then QS_{exp}.

5 Administrative and supplementary indicators

Administrative indicators are related to specific elements of REACH. For these indicators, the data to be compiled at the European Chemicals Agency (ECHA) included in IUCLID 5 are evaluated with regard to the following aspects:

- Progress in registration (see Chapter 5.1.1);
- Progress in evaluation (Chapter 5.1.2);
- Progress in authorisation and restriction (Chapter 5.1.3).

Supplementary indicators set an additional focus on special issues of importance for the monitoring of the success of REACH. They use data recorded in IUCLID 5 and other data sources. For the Baseline Study Indicator System supplementary indicators are recommended referring to the following aspects:

- Safety data sheets are of central importance for communication within the supply chains. Therefore a specific set of indicators is related to quality of safety data sheets, using information recorded in IUCLID 5 and data recorded in safety data sheets (see Chapter 5.2.1);
- Toxic chemicals in households (see Chapter 5.2.2);
- Production of toxic chemicals (see Chapter 5.2.3);
- Cross-border transport of toxic chemicals (which can also be used to monitor the consumption of toxic chemicals) (see Chapter 5.2.4);
- Occupational skin diseases (see Chapter 5.2.5);
- Changes of use patterns in Scandinavia (see Chapter 5.2.6);
- Availability of hazard data (Chapter 5.2.7);
- Changes in classification and labelling (C&L) (Chapter 5.2.8);
- Availability of use and exposure data (Chapter 5.2.9);
- Registration of new chemicals (Chapter 5.2.10);
- Use of QSARs, read-across and waiving options; this indicator set refers also to animal testing (Chapter 5.2.11).

For some of these indicators, no data are available for 2007 because they refer to new elements introduced by REACH (e.g. number of exposure scenarios in chemical safety reports). The baseline 2007 is therefore set to zero for these indicators. In the future, data for these indicators will become available from ECHA. For other indicators described in this chapter, a baseline can be set using existing data from other sources.

Chapter 5.3 informs about related activities to further indicators, which are outside the REACH Baseline study, e.g. monitoring the objective of increasing transparency and consumer awareness, monitoring the substitution of substances of very high concern and others.

5.1 Administrative indicators

5.1.1 Indicators on progress in registration

This indicator set refers to all substances which have to be registered according to REACH. It includes also data on substances with a very low production volume (1–10 tonnes/year) which are not included in the risk & quality indicator system.

The indicator set generates figures on:

- Number of registrations/in addition: numbers specified for the different production volume classes;
- Percentage of substances registered[35].

Data source: European Chemicals Agency (ECHA), IT tools REACH-IT and IUCLID 5.

[35] The percentages refer to the number of substances in the EU/the number of substances expected to be registered under REACH/the number of substances in the four production volume classes.

5.1.2 Progress in evaluation

Evaluation refers to dossier evaluation, substance evaluation and evaluation of intermediates. Within dossier evaluation, the European Chemicals Agency examines any testing proposal set out in a registration or a downstream user report for provision of the information specified in Annexes IX and X[36]. For at least 5% of the registration dossiers, the Agency has to perform a compliance check as described in Article 41 of REACH.

In cooperation with the Member States, the Agency develops criteria for prioritising substances with a view to further evaluation (Art. 44 REACH). The Agency compiles a draft Community rolling action plan specifying substances to be evaluated each year.

Progress in evaluation is monitored by a specific set of share-of indicators, which gives figures on:

- Number of testing proposals examined;
- Total number of registration dossiers evaluated;
- Percentages of registration dossiers evaluated[37];
- Number of substances evaluated.

Data source: European Chemicals Agency (ECHA), IT tools REACH-IT and IUCLID 5[38].

5.1.3 Progress in authorisation and restriction

At the starting point, authorisation and restriction are independent of production volume classes. These procedures can therefore include substances with a production volume of 1-10 tonnes/year (not included in the risk & quality indicator system) and even substances with a production volume below 1 tonne/year (which do not have to be registered according to REACH). (In the process of selecting substances for inclusion in Annex XIV, priority is given to substances with PBT or vPvB properties; or substances with wide dispersive use; or substances with high volumes (Art. 58(3) REACH.)

Authorisation and restriction are multi-step approaches described in Title VII and Title VIII of REACH. They are connected with a number of structural elements that can be used for monitoring by share-of indicators. This indicator set gives figures on:

- Number of chemicals included in the candidate list (Art. 58);
- Total number/percentages/specified for the four tonnage bands;
- Number of Annex XV dossiers related to candidate substances (Art. 58(2), Annex XV);
- Number of substances included in Annex XIV;
- Number of decisions taken related to granting of authorisation,
  Art. 59(2): adequate control/Art. 59(4): risk evaluation, socio-economic analysis, and substitution;
- Number of Annex XV dossiers for restriction proposals (and number of substances documented in the list of Art. 69(5));
- Number of decisions on restrictions taken by the Commission according to Art. 73.

Data source: European Chemicals Agency (ECHA), IT tools REACH-IT and IUCLID 5[39].

---

[36] Priority is to be given to substances of very high concern and substances classified as dangerous according to Directive 67/548/EEC above 100 tonnes per year with uses resulting in widespread and diffuse exposure (Art. 40(1) REACH).

[37] Percentages are related to the number of registration dossiers received/number of substances with a production volume > 100 tonnes/year expected to be registered/number of substances expected to be registered/number of substances in the EU.

[38] Monitoring of the evolution of the quality of registration dossiers and Annex XV dossiers for a restriction proposal does not form part of the Baseline Study.

[39] Monitoring of the evolution of the quality of the authorisation dossiers does not form part of the Baseline Study.

5.2 Supplementary indicators

5.2.1 Changes in quality of safety data sheets

Safety data sheets are the central instrument used to communicate safe uses in the supply chains. According to REACH, extended safety data sheets for substances and for preparations will contain additional information on substance properties (e.g. DNEL values, DMEL values, PNEC values) and appropriate risk management measures. In the case of substances that require exposure scenarios as part of their registration, these exposure scenarios are communicated as Annexes to the safety data sheets. Formulators have to prepare safety data sheets for preparations, including information which they received from the substance manufacturers/importers as well as information regarding the use of the preparations.

Several studies have been performed regarding the quality of safety data sheets at present[40]. We recommend continuing this work and monitoring how additional information is included in the new safety data sheets (e.g. for specific branches).

Within the Baseline Study, it is not intended to perform a complete quality assessment of SDSs at baseline and at future points in time, as this would mean a multidimensional detailed evaluation, which would generate a voluminous workload and cannot be meaningfully aggregated to indicator-type of information.

For the reference substances selected, recent safety data sheets are stored wherever they are available by internet search without contacting the manufacturers of the substances.

Two approaches are recommended to monitor changes in safety data sheets in future.

First, the information recorded in IUCLID 5 should be used to indicate changes related to central elements of the safety data sheets: reference values and exposure scenarios.

- Indicator regarding DNELs, DMELs and PNECs[41]. This monitors in how many cases these reference values for the risk characterisation are included in the chemical safety report. If there is more than one registration for a substance, a screening of the heterogeneity of these reference values can be performed (agreement or disagreement of the reference values in the safety data sheets). This assessment requires an extract of the corresponding cells from the IUCLID 5 data files.
- "Share-of" indicator regarding exposure scenarios. This monitors in how many cases exposure scenarios have been developed (which in the next step are communicated by the extended safety data sheets).

These figures belong to substance safety data sheets, not to safety data sheets for preparations. Nevertheless, SDSs of single substances are the starting point for the SDSs of preparations. The high quality of these SDSs is therefore of great importance for the entire communication in the supply chain.

Second, the following questions can be addressed by assessing limited sets of safety data sheets:

Do SDSs on pure substances regularly report exposure scenarios (at baseline and at a future point in time (gross percentage), and is there a difference in reporting exposure scenarios depending on the production volume band of this chemical (HPV, MPV, SPVC, <10t/y; percentages)? At baseline no such reports on exposure scenarios are expected, but information on risk management measures are part of existing safety data sheets.

Focus: Success in implementing REACH provisions, link to production volume, enhancement of communication of conditions of safe use in the supply chains.

Do SDSs on pure substances regularly report DNELs, DMELs and PNECs, respectively (at baseline and at a future point in time (gross percentage), and is there a difference in reporting exposure scenarios depending on the production volume band of this chemical (HPV, MPV, SPVC, <10 t/y; percentages)? At baseline, no such reports on DNELs, DMELs and PNECs are expected.

Focus: Success in implementing REACH provisions, link to production volume.

For a substance with many uses (as a neat substance or within preparations): Are the substance-specific toxicological properties (DNEL, DMEL, PNEC, classification and labelling, i.e. risk phrases) homogeneously and correctly transferred downstream?

Focus: Downstream communication process under REACH.

---

[40] e.g. http://www.umweltbundesamt.at/fileadmin/site/umweltthemen/chemikalien/ECLIPS_Final_Report.pdf

[41] **PNEC**: Predicted No-Effect Concentration; **DNEL**: Derived No-Effect Level. For non-threshold substances, reference values for a quantitative description of the exposure and for the risk characterisation are currently being developed in RIP 3.2-2 (Expert Group on Human Health Risk Characterisation, derivation of DNELs). As a provisional abbreviation the term "**DMEL**" is used ("Derived Minimal Effect Level") (References: Concise TGD RIP 3.2-1 (CEFIC 2005), Reference preliminary TGD, Chapter 3, Human health hazard assessment; working paper, version 5 (Kroese and Pronk 2006)).

For a substance with many manufacturers: Are the substance-specific toxicological properties (DNEL, DMEL, PNEC, classification and labelling) homogeneously assessed and correctly transferred into the SDS? Are there differences in assessment results? For identical uses: are the exposure scenarios described similar or heterogeneous?

Focus: Downstream communication process under REACH, heterogeneity or homogeneity of implementation of REACH demands.

For establishing those indicators different sets of safety data sheets have to be collected at baseline.

Questions 1 and 2

For questions 1 and 2 (combined) it is proposed to obtain the SDS for all substances that are part of the risk & quality indicator system (see Chapter 4.1). This selection criterion permits potential cross evaluations at future points in time, and it already ensures that all production volumes are adequately covered. This set of SDSs should be supplemented by 30 SDSs from substances with a production volume of less than 10 tonnes/year. It is not necessary to collect more than 1 SDS per substance (the aspect of heterogeneous implementation is not part of question 1 and 2, but of questions 3 and 4, which are based on a different set of SDSs). As a consequence, a set of about 150 SDSs will be collected at baseline. No further data are evaluated on this set of data at baseline. When performing the follow-up evaluation in seven years' time, the identical distributors of the SDS will be contacted for an updated version of the SDS. Providers from different countries should be included. Then a pair-wise comparison will be performed to monitor implementation (some expected non-responders, because of enterprise bankruptcies or mergers, at the second contact will be accepted and accounted for).

Question 3

A set of 20 substances with 10 or more different uses will be selected at baseline (based on the uses as stated, e.g. in the SPIN database). These substances are selected from each production volume band above 10 tonnes/year (4 HPV, 8 MPV, 8 SPLC). An SDS is obtained for at least 10 uses/substance. Providers from different countries should be included. As a consequence, a set of about 200 SDSs will be collected at baseline. No further data are evaluated on this set of data at baseline. When performing the follow-up evaluation in seven years' time, the identical distributors of the SDS will be contacted for an updated version of the SDS. The total set of SDSs will then be used to get an indication of whether the substance-specific information is adapted properly and transferred along the supply chain. The baseline set of SDSs is used for comparisons, to see whether substance characteristics were already known at baseline and whether the level of correct transfer of information improved or decreased under conditions of REACH. The set of SDSs for question 3 may eventually supplement the data from question 1 and 2 to extend the respective database.

Question 4

A set of 20 substances with more than 5 different manufacturers will be selected at baseline (based on the manufacturers as stated e.g. in IUCLID or in a supply catalogue). These substances are selected from each production volume band above 10 tonnes/year (4 HPV, 8 MPV, 8 SPLC). From each manufacturer, at least 1 SDS is obtained. Such an SDS referring to an identical use of the substance is preferred. Providers from different countries should be included. As a consequence, a set of about 100 SDSs (20 substances x 5 manufacturers) will be collected at baseline. No further data are evaluated on this set of data at baseline. When performing the follow-up evaluation in seven years' time, the identical distributors of the SDS will be contacted for an updated version of the SDS. The total set of SDSs will then be used to get an indication of whether the substance-specific information is identically transferred into the SDS by the different manufacturers. Moreover, for identical uses, a comparison of the exposure scenario, as described in the SDS, is performed and homogeneity and adequacy are evaluated by a scoring system (yet to be established). The baseline set of SDSs is used for comparisons, to see whether substance characteristics were already known at baseline and whether the level of correct transfer of information improved or decreased under conditions of REACH. The set of SDSs for question 4 may eventually supplement the data from question 1 and 2 to extend the respective database.

These evaluations for the SDS indicators will need limited effort at baseline (no indicator at this point in time) but will need some analysis in future. The conservation of current knowledge is the main task at baseline. Before a final decision on the selection of these indicators is made, a statistical control will be performed to check whether the numbers of SDSs as proposed above are sufficiently large for a meaningful evaluation.

5.2.2 Toxic chemicals in households

The German BfR (Bundesinstitut für Risikobewertung) owns a consumer product data base. This data base contains information, documentation and assessment of poisonings. It includes information about primary substances, cleaning products, disinfectants, paint and related materials, building materials and glues. Products with dangerous ingredients are notified.

The indicator will depict toxic chemicals in selected household chemicals. As access to the data base is restricted the indicator will be compiled by the BfR.

Data source: Centre for Documentation and Assessment of Poisonings (BfR).

5.2.3 Production of toxic chemicals

The production of toxic chemicals indicator sums up the production volumes of toxic chemicals. Prodcom, a statistical database operated by Eurostat, serves as a database. Member States deliver the data to Eurostat pursuant to a Regulation. The Prodcom database contains the total production of the industry in question in monetary values within the limitation of statistical coverage (small industry, etc.). For certain important products, individual positions are created in physical units and these products are "highlighted" in the statistics. Only if the Prodcom positions are detailed enough, e.g. the position covers a single process or a defined product, will the information on the positions enable us to identify a "substance" to which attributes concerning physical, chemical or toxic properties could be added. The database could serve as a source for a set of chemicals for these detailed positions only. Fortunately, the statistics focus on major chemicals, which have a high production value and volume. Therefore, as long as the indicator derived from this database is based on volume, the result is estimated to be fair. The positions in Prodcom, which cannot be attributed to toxic chemicals, may also contain toxic chemicals. Therefore, these positions should not be named "non-toxic".

All Prodcom positions (24.11.XX to 24.15.XX)	**387**
of which … total toxic according to R-phrases	166
of which …	
Class A	17
Class B	24
Class C	26
Class D	44
Class E	55

Table 5.1 Position of toxic chemicals in Prodcom[42]

Classification of the chemicals follows the R-phrases, a system based on physical and toxic properties of substances according to EU legislation. The 393 Prodcom positions in positions 24.11.XX to 24.15.XX have been investigated and 166 positions with toxic properties have been found (for a detailed list see Eurostat 2006). These 166 positions make up the indicator. Further on, the properties may be classified according to special toxic properties as:

- Class A: chronic toxic with severe impacts as carcinogenic, mutagenic and reprotoxic properties (called CMR substances). These substances are highlighted in the EU White Paper and measures are focused on these substances;
- Class B: chronic toxic e.g. sensitising, etc.;
- Class C: acute toxic as very toxic (poisoning);
- Class D: acute toxic as toxic (poisoning);
- Class E: acute toxic as harmful.

On average, Class D has an acute toxicity that is ten times higher than Class E and Class C has a toxicity that is ten times higher than Class D.

The identified positions have been extracted from the Prodcom database. Nevertheless, there are some restrictions to the Prodcom database:

- Not all data from Member States, delivered to Eurostat, are public.
- Data from Luxembourg, Malta and Cyprus are not reported.
- Chemicals in other Prodcom categories (chemicals, pesticides, etc.) are not covered because they could not be identified according to the above mentioned scheme.
- The Prodcom database is available from 1995 onwards. Some older data may be available at Member State level.
- The database is not available to the public, thus only aggregated data can be published.

The data was updated as Eurostat has implemented its own tool to estimate missing volume data. Data reported before in other reports depend on their own estimates. Therefore data might deviate slightly.

This indicator has been published as a Sustainable Development Indicator (SDI) (Eurostat 2006).

[42] Prodcom positions are "work in progress". The statistic is always subject to changes: positions are combined or divided.

5.2.4 Cross-border transport of toxic chemicals

Transport is not included under the REACH legislation. Nevertheless, this indicator helps to understand the production chain of commodities in the chemical industry. Up to 20 years ago a chemical complex was designed to start with raw materials and end with finished products for other economic sectors. The output of one plant served as the input for others. In this sense an intermediate was a chemical which was the output of a plant and was immediately used in one or more other plants. Today the chemical industry is much more specialised. Plant size is getting bigger and transport is cheap. So more and more chemicals are transported from one plant to another and more people are potentially involved.

This indicator is linked to the production of toxic chemicals indicator and will illustrate the geographical spread of toxic chemicals.

The foreign trade statistics serve as a database and mirror the Prodcom database. Within the trade statistics, the items 27.07.x, 28.x and 29.x have been selected. From these approx. 790 items, 189 items have been identified as toxic chemicals. The 189 chemicals could be classified according to the scheme given in the Chapter "Production of Toxic Chemicals". The 189 items can be directly correlated to the 187 items in the Prodcom database.

The amount of chemicals is calculated as the sum of imports (intra-EU and extra-EU) for every Member State. The EU is the sum of all Member States.

Trade statistics are available from 1990 onwards for 10 Member States and from 1995 for the EU-15. From 2004 onwards the data for the EU-25 is included. For practical reasons, the trade statistics have been exploited for the period 1995 to 2003. So the data corresponds to the EU-15.

HN positions	Number of positions
Totals Class A to E	189
Class A	19
Class B	23
Class C	35
Class D	53
Class E	59
Non-classified	approx. 600

Table 5.2 Number of identified positions of chemicals in the trade statistics

The data from trade statistics shows the cross-border movement of chemicals. This reflects only a part of the actual transport of chemicals. Shipments could be by pipeline, ship, rail or road transport.

Source: Foreign Trade Statistics (Eurostat).

The data used for the calculation of the cross-border transport can also be combined with data on production of toxic chemicals to indicate the apparent consumption of toxic chemicals. This will be part of the project "Maintenance of the chemical indicators set" (EUROSTAT, from 2009 – 2012).

5.2.5 Occupational skin diseases

The high occurrence of occupational skin diseases is one of the major problems in the current occupational safety and health situation in Europe. It is estimated that occupational contact dermatitis accounts for up to 30% of all occupational diseases in many countries[43]. The expectations regarding improvements by REACH are high: for the EU-25 an incidence figure of 40 000 cases per year of occupational skin diseases is assumed to be potentially preventable by the measures of REACH[44]. Therefore it is highly desirable to monitor the factual progress of occupational skin diseases after REACH implementation by some indicator.

Generally, three approaches can be taken:

- Establish a damage indicator, based on national or European statistics on occupational skin diseases;
- Establish a risk indicator, similar to the one proposed in this project for inhalation exposure of workers, but with special focus on dermal exposure and subsequent risk of skin damage;
- Establish some indicator measuring the implementation of REACH with subsequent increased classification and labelling with respect to skin exposure and document changes in exposure prevention measures demanded by registrants regarding skin exposure.

[43] http://www.abw-verlag.com/sample.pdf
[44] http://hesa.etui-rehs.org/uk/newsevents/files/reach-sheffield-complet.pdf

It has been acknowledged that it is currently not feasible to create a simple damage indicator from European statistics. The reporting systems on occupational diseases differ to such an extent that no meaningful figure can be generated (a) for overall incidences, and (b) for REACH-related changes. The estimated number of 40 000 avoidable cases per year, as given above, is strictly related to well-known listed chemicals associated with occupational dermatitis and the assumption that a defined percentage of these cases could be avoided under REACH. However, there are currently no means of validating this assumed damage figure and the achieved changes by international statistics and extending it to further substances.

Instead, the possibility has been discussed of using national statistics and observing the evolution of occupational skin diseases over time after REACH implementation. There may be a relevant decrease in cases notified and/or cases of compensation granted as a consequence of REACH. However, it is assumed that it will not be possible to link this process causally and quantitatively to REACH because:

- Currently many additional REACH-independent occupational safety and health programmes have started to focus on skin diseases, with possible influence on the statistics.
- National changes in skin diseases will differ due to different reporting and compensations systems, where it is not known which country provides the best slope to reflect the changes induced by REACH.
- Occupational skin diseases in national statistics are differently aggregated, with some countries combining allergic and irritant contact dermatitis into one figure and others providing those numbers separately. If the influence of REACH affects these endpoints differently, the changes will be different and not comparable.
- REACH is substance-oriented, whereas many occupational disease statistics refer to professions or branches, where changes may not be able to be directly attributed to substances.

The assumption of a fixed percentage of prevented skin disease to be attributable to REACH is not meaningful because this percentage is the crucial figure in focus for validation. Thus, it should not be an input figure into the calculations.

As a result, it is proposed to establish timelines in national statistics for occupational skin diseases, but the accountability of the resulting trend to REACH will still be a matter of debate.

In addition to or instead of a damage indicator, a risk-related indicator can be considered. For this, the dermal local toxicity of a substance has to be quantified and exposure has to be quantified. It will be rather complicated to establish such quantifications in a routine framework as is necessary for an indicator, which should be based on many substances. If a risk phrase is established, the transformation of qualitative information (i.e. a risk phrase on local toxicity) into a quantitative effect concentration (mg/cm^2 skin) is not yet possible. Similarly, the skin damaging or skin sensitising potential could be calculated by QSAR modelling such as DEREK[45]. However, the results of QSAR models on skin damaging properties are better for describing potential instead of potency. They therefore do not provide a threshold to compare with exposure. Similarly, the exposure assessment will be quite complicated with many substances and use-specific data needed. This prevents such exposure data being calculated routinely.

As a consequence, it is assumed that the risk of skin damage can only be calculated for single substances with qualified data on toxicological properties and uses. For these, changes in risk of skin diseases can be attributed to REACH risk management measures. However, this may currently only be performed for a limited number of substances. Thus, this procedure is beyond the scope of simple indicators and more suitable for a special expert study.

Finally, an indicator can be established reporting the share of substances with established risk phrases reflecting the dermal exposure pathway. The assignment of such risk phrases will be due to more complete toxicity assessments as a result of REACH, either via testing or via QSAR estimates. However, this assignment may only be interpreted as an improvement induced by REACH if, at the same time, more risk reduction measures related to skin exposure are induced. Such requests for risk reduction measures can be screened by selective evaluation of chemical safety reports (CSRs) or safety data sheets (SDSs).

Therefore, a specific evaluation of REACH documents such as SDSs and CSRs with regard to how they report risks of dermal exposure and whether they request exposure reduction measures would be a meaningful indicator. However, this indicator would also not directly quantify the REACH-induced risk reduction or the damage reduction for occupational skin disease.

5.2.6 Changes in use patterns in Scandinavia

The SPIN data base publishes yearly the consumption of approx. 20 000 chemicals in the Scandinavian countries Sweden, Denmark, Finland and Norway. The breakdown of the consumption figures is shown in use categories. Two types of categories are published. One category uses the NACE nomenclature (economic business classes); the other employs technical use categories similar to the HEDSET for existing chemicals.

[45] DEREK for Windows; see http://www.lhasalimited.org/index.php?cat=2&sub_cat=64 for QSAR instruments on chemically induced skin damage.

For a reduced set of toxic chemicals, the evolution of consumption can be monitored. The 2004 data are used initially as a satellite system to track the use patterns of toxic chemicals included in the production of toxic chemicals indicator. As use categories, the NACE sectors have been aggregated according to the categories in Table 5.3.

NACE code	NACE description
1,2,5	Agriculture, fishery
10-14	Extraction
15-16, 17-19	Nutrition, textile
20-22	Wood, paper, printing
23-25	Refinery, chemical, rubber
26	Glass, ceramics
27-36	Metal, machinery, others
40-41	Energy, water
45	Construction
50-52	Trade
55	Hotels
60-64	Transportation
65-67	Banking, insurance
70-74	Housing, services
75-93	Public services
95	Public households

Table 5.3 Aggregation of use categories

The aggregation has been performed to reduce the data sets. The most important sector is the refinery and chemical industry sector.

Data source: SPIN[46].

5.2.7 Availability of hazard data

This indicator set refers to all substances that have to be registered according to REACH. It also includes data on substances with a very low production volume (1–10 tonnes/year) that are not included in the risk & quality indicator system.

The indicator set gives endpoint-specific figures on:

- Total number (and %) of substances for which acute/chronic toxicity data/data on PBT properties are available;
- Substances with a production volume between 1 and 10 tonnes/year: number (and percentage) of substances with the complete Annex V data set/number (and percentage) of substances with a reduced data set (PC properties only) (section 7).
- The baseline (situation 2007) uses endpoint-specific availability of data according to Allanou et al, 1999/RPA & Statistics Sweden 2002.

Data source: European Chemicals Agency (ECHA), IT tools REACH-IT and IUCLID 5.

5.2.8 Changes in classification and labelling

Under REACH, it is expected that there will be an increased number of substances classified as dangerous (due to additional data on hazard properties). Table 5.4 shows the results of a comparison between the classification of existing substances and the classification of new, notified substances (BMU 2005).

[46] www.spin2000.net.

	Existing substances				New substances	
	> 10 tonnes/year		**> 1.000**		**> 1tonne/year**	
Total number	10500	100%	2 750	100%	2 750	100%
Classified as dangerous *	2 300	22%	1 000	37%	1 850	67%
Dangerous for the environment		5%		9%		49%
R48, severe health damage at **longer exposure**		0.4%		1.6%		8%

Table 5.4 Comparison of the classification of existing and new substances (BMU 2005)

Approximately 2/3 of all new substances are classified as dangerous. On the other hand, only 22% of existing substances are classified as dangerous.

This can be explained by the poor availability of data on existing substances (BMU 2005). If this is the case, the increase in knowledge of the properties of substances due to REACH will lead to an increase in classification and labelling. However, another assumption is that most new substances are specialty chemicals developed for specific uses requiring certain technical specifications, which one way or the other coincides with a higher intrinsic hazard.

The assumed increase in the number of chemicals classified as dangerous can be monitored by a specific share-of indicator set. This set gives figures on:

- Total number of substances classified as dangerous;
- Percentage of dangerous substances[47]; this analysis can be done for specific risk phrases (R-phrases) and for groups of R-phrases;
- Change in C&L of substances already included in Annex I;
- Change in C&L of substances by manufacturer as given in IUCLID 4.

As a baseline for the pre-REACH situation, the data from Table 5.4 can be used. Under REACH, the results of the classification and labelling are recorded in IUCLID 5. Over the coming years, changes in classification and labelling due to the implementation of the GHS (Globally Harmonised System of Classification and Labelling of Chemicals) have to be taken into account.

Data source: Annex I: ECB/ECHA; Annex I as of June 2007 has been obtained.

Data source: IUCLID 4/IUCLID 5: ECHA; IUCLID 4 has been obtained by Eurostat.

5.2.9 Availability of use and exposure data

For each substance that is registered according to REACH, at least basic information on the use pattern will become available. In addition, for hazardous substances as well as for PBT/vPvB substances with a production volume > 10 tonnes/year, REACH requires an exposure assessment and a risk description within the chemical safety report. This includes descriptions of the conditions of safe use and the communication of these conditions (by exposure scenarios, communicated as Annexes to the material safety data sheets).

Due to these requirements, a large increase in the amount und quality of data on use and exposure is expected. This increase should be monitored by a specific set of share-of indicators. This set gives figures on:

- Total number (and percentages) of substances with information on use pattern;
- Total number (and percentages) of substances with a CSR;

[47] The percentages refer to the number of registered substances/number of registered substances in the four production volume classes/number of substances in the EU/number of substances expected to be registered under REACH.

- Total number (and percentages) of substances with a CSR including exposure assessment and risk characterisation[48].

With 2007 as the baseline, the availability of data on use and exposure for the reference substances of the risk & quality indicator system is used.

Data source: European Chemicals Agency (ECHA), IT tools REACH-IT and IUCLID 5.

IUCLID 5 data will be compared with the data on use and exposure as given in IUCLID 4 (Section 1.7 (main categories, industrial categories and use categories), Section 1.9).

5.2.10 Registration of new chemicals

The application of REACH to existing chemicals will reduce one major barrier to the marketing of new chemicals. It is claimed that the different treatment between new and existing chemicals has led to a delay in marketing of new chemicals by companies because of the costs of registration and testing. Instead, products are manufactured with existing chemicals even though better, non-registered substances are available. In the future, equal treatment will reduce the bias. Especially for low-volume chemicals, new chemicals will replace existing ones.

The indicator will monitor the registration of new chemicals. Today, approx. 3 000 new chemicals are registered. If the claims made above are correct, the rate of registration will accelerate above the pre-REACH level.

Data source: European Chemicals Bureau (ECB), in future: European Chemicals Agency (ECHA).

5.2.11 Animal testing: use of QSARs, read-across and waiving options

For this indicator, two approaches are discussed:

- The first will show the number of animals used;
- The second will calculate the prevention of animal testing.

Number of animals used

The European Union reports statistics on "protection of animals used for experimental and other scientific purposes[49], the statistical data on the number of animals used for experimental and other scientific purposes in the Member States of the EU", according to Article 26 of Directive 86/609/EEC of 24 November 1986.

Five statistical reports exist:

1. Reports published in 1994 and 1999 with a reduced data base;
2. Reports published in 2003 and 2005 reporting for the year 1999 and 2002 with a new harmonised format;
3. Report due in 2007 reporting data from 2005 for (now) 27 Member States.

The new 2007 report includes:

1. Animals tested by Member State;
2. Animals tested by species;
3. Animals tested by purpose.

The report lists 8 main categories of purpose, among which "Toxicological and other safety evaluation" includes animals tested for chemicals. REACH has an effect on the animals tested, and this effect should show up under this item. At the moment, several estimates exist regarding the potential for reducing the number of animals used for testing by adopting alternative methods. It is unclear to what extent these possibilities will be used (Pedersen 2003, v.d. Jagt et al. 2004). Therefore the indicator is an important instrument to see whether one of the main objectives of REACH (promotion of non-animal testing) is achieved.

The data is reported for each species and Member State. From the total of approx. 12 million animals tested, approx. 1 million come under the category "Toxicological and other safety evaluation".

[48] The percentages refer to the number of substances in the EU/number of substances expected to be registered under REACH/number of substances in the four production volume classes.

[49] OJ L 358, 18.12.1986, p. 1.

The number of animals tested indicator could be presented as:

- Absolute number of animals tested in the category "Toxicological and other safety evaluation", broken down by species;
- Share of number of animals tested in the category "Toxicological and other safety evaluation" in relation to the total number of animals tested, broken down by species.

Data source: DG Environment.

Prevention of animal testing, use of QSARs, read-across and waiving options

In preparing the registration dossier, several options exist in REACH for using all adequate existing knowledge in order to avoid unnecessary testing of animals (here and in the context of REACH, "animals" refers only to vertebrates) and also to reduce costs. All these possibilities are presented in the REACH Regulation either in column 2 of tables setting out testing requirements for the different tonnage bands (Annexes VII to X) or in Annex XI presenting the general rules for adaptation of the standard testing regime.

The frequency of use of the different possibilities for waiving presented in column 2 of the tables in Annexes VII to X will not make up an actual indicator for the promoting role of REACH in reducing animal testing because these waivings partly existed in the framework of new and existing chemicals legislation. Nevertheless, it is reasonable to assume that their use will be stimulated in future by REACH.

In the same way, some adaptations to the standard testing regime presented in Annex XI will not be useable as an indicator for the reduction in animal testing triggered by REACH. Of course, information already available, such as a study result available in the literature, could be used to fulfil REACH requirements. However, this case is not an example for reduction of animal testing. Furthermore, this was already possible in the Existing Substances Regulation (Reg. (EEC) No 793/93). This is also the case when testing is not technically possible.

Other useable information introduced by REACH to replace animal testing includes Quantitative Structure-Activity Relationships that can be used for the prediction of physico-chemical properties and hazardous properties. "Read-across", including those performed in a category of chemicals, can also enable properties of a target substance to be predicted from known properties of reference substances.

Waiving of tests will be accepted under several conditions — one of them being proof that no relevant exposure takes place by the substance (exposure-based waiving). In any event, the use of these options has to be described and justified in the registration dossier by the registrant.

These options build up remarkable flexibility in the REACH data requirements. The use of these options requires good knowledge of the underlying methodology as well as profound knowledge of the substance for which the options are to be used. In addition, for the waiving option the uses and the related exposure situations have to be known in detail.

The use of these options (i.e. QSARs, read-across, exposure-based waiving) is specifically enabled by REACH and can lead to a reduction in the number of animal tests required by this Regulation. Reduction of animal testing has been one important objective of the new chemical legislation.

Description of indicators for monitoring the impact of REACH on animal testing

The approach chosen for calculating these indicators refers to the data stored in future in IUCLID 5 regarding the use of QSARs, read-across and exposure-based waiving. In each case, the use of these options has to be documented in the registration dossier (i.e. the technical dossier corresponding to an IUCLID 5 file).

- Data waiving will be recorded in the field "Data waiving" in the administrative part of each study record in IUCLID 5 (see Figure 5.1).

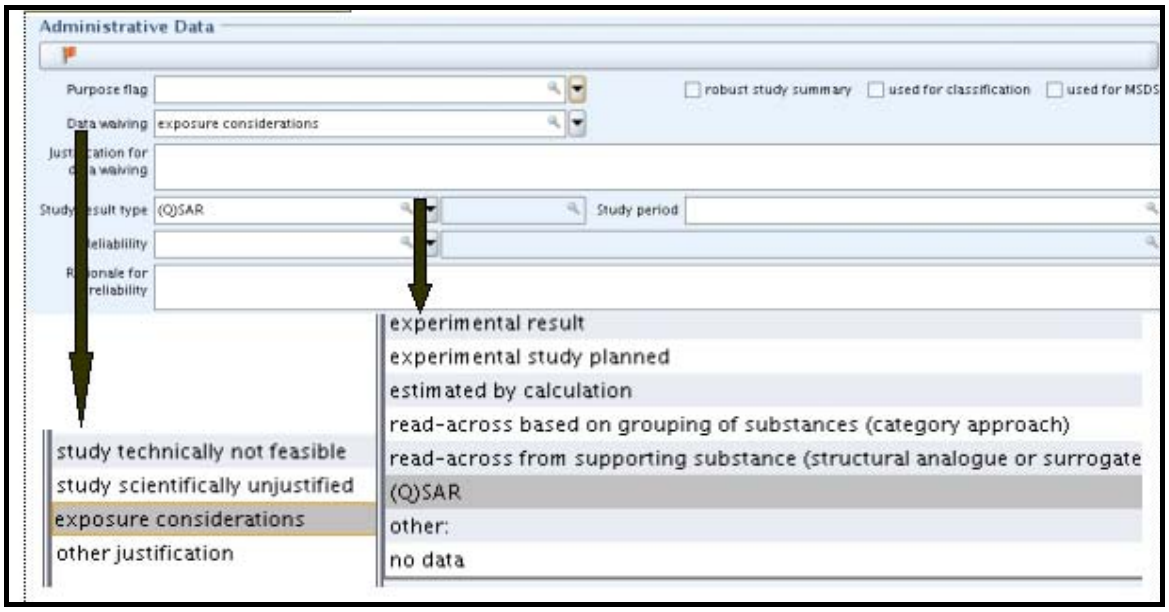


Figure 5.1 Screenshot of the administrative data fields in IUCLID 5 and associated picklists

- In the "Study result type" field, the user will also have to indicate the type of study result proposed in the registration dossier to fulfil REACH requirements: estimated by calculation, read-across based on grouping of substances (category approach), read-across from supporting substance (structural analogue or surrogate), QSAR.

An analysis of the use of QSAR, waiving and read-across should be possible on the basis of documentation of the information recorded in IUCLID 5 for the key studies proposed to fulfil data requirements for tests involving vertebrates (see list of these tests in Table 5.5). To do this, a selected extract of IUCLID 5 data from the corresponding fields should be made.

Test Protocol	Protocols	Animals (+ pups) total
Corrosion Skin	OECD 430 & 431	0
Irritation Eye	-	0
Acute Dermal Irritation/Corrosion	OECD 404	3
Acute Eye Irritation/Corrosion	OECD 405	3
Skin Sensitisation — Maximisation	OECD 406	30
Skin Sensitisation — Buehler	OECD 406	30
Skin Sensitisation — Local Lymph Node Assay LLNA	OECD 429	25
Mutagenicity (bacterial gene mutations)	OECD 471	0
Mutagenicity (mammalian chromosome aberrations)	OECD 473	0
Mutagenicity (mammalian cell gene mutation test)	OECD 476	0
Mutagenicity (in vivo)	OECD 474	50
Acute Oral Toxicity (Toxic Class)	OECD 423	12
Acute Inhalation Toxicity	OECD 403	40
Acute Dermal Toxicity	OECD 402	25
Acute Oral Toxicity (Up-Down Procedure)	OECD 425	15
Acute Inhalation Toxicity (Fixed Concentration Procedure)	OECD 433 (draft)	24
Acute Dermal Toxicity (Fixed Dose Procedure)	OECD 434 (draft)	20
Repeated Dose Toxicity: 28 Day Short Term (Rodents)	OECD 407	40
Repeated Dose Toxicity: 90 Day Subchronic (Rodents)	OECD 408	80
Repeated Toxicity: 365 Day Chronic (Rodents)	OECD 452	160
Repeated Dose 28 Day/Repro & Developmental Toxicity	OECD 422	480
Reproduction/Developmental Toxicity Screening Test	OECD 421	480
Developmental Toxicity (1st Species)	OECD 414	80
Developmental Toxicity (2nd Species)	OECD 414	80
Reproduction 2-Generation study	OECD 416	2080

Test Protocol	Protocols	Animals (+ pups) total
Toxicokinetics (assessment based available data)	-	0
Toxicokinetics (study)	OECD 417	120
Carcinogenicity Studies	OECD 451	400
Chronic Toxicity Studies	OECD 452	120
Combined Chronic Toxicity/Carcinogenicity Studies	OECD 453	400
Acute Neurotoxicity		
Subchronic Neurotoxicity		
Developmental Neurotoxicity		
Acute Toxicity in Fish	OECD 203	42
Prolonged Acute Toxicity Studies	OECD 204	42
Early Life Stage Fish Toxicity Test	OECD 210	600
Fish Short Term Toxicity Test on Embryos	OECD 212	0
Fish Juvenile Growth Test	OECD 215	120
Fish Bioaccumulation	OECD 305	132
Acute Bird Toxicity (dietary)	OECD 205	60
Chronic Bird Toxicity	OECD 206	2832

Table 5.5 List of tests required in REACH and involving animals (ECOPA 2006)

This share-of indicator set should give the following information:

- Number of cases in which QSAR, read-across (including within a category) or exposure-based waiving has been used to fulfil the data requirement and in lieu of animal testing;
- Number of animal tests which have become unnecessary by applying these methods (total number, numbers for vertebrate testing, number for specific test systems);
- Percentage of tests which have been avoided by using these methods.

Calculation of the indicators

Three different main indicators have been defined to monitor the impact of REACH on animal testing:

Number of cases in which QSAR, read-across (including with a category) or exposure-based waiving has been used to fulfil data requirement and in lieu of animal testing

This indicator will be calculated based on the information contained in the registration dossiers (IUCLID 5 files) submitted to the European Chemicals Agency.

- Indicator 1.1: total number of cases;
- Indicator 1.2: total number per substance/registration dossier;
- Indicator 1.3: total number per endpoint;

Number of animal tests which have become unnecessary by applying these methods and total number of animals used

- Indicator 2.1: total number of animals saved by the use of alternative methods or exposure-based waiving;
- Indicator 2.2: total number of animals used;
- Indicator 2.3: total number of animals used per substance/registration dossier.

The indicators 1 result will be used in combination with the number of test animals per endpoint (see list in Table 5.5).

Percentage of tests which have been avoided by using these methods

- Indicator 3.1: total number of tests on vertebrates replaced by alternative methods or exposure-based waiving/total number of tests performed for different endpoints involving the use of animals (see list 1);

- Indicator 3.2: number of (animal) tests performed under REACH at the time of doing the assessment/number of (animal) tests expected under REACH at the time of the snapshot (using ECOPA REACH animal testing calculator)[50].

The figures can be specified for individual tests as well as for individual production volume classes.

Calculation of these indicators at baseline (2007)

Compared to the legislation on new and existing chemicals (Dir. 67/548 and Reg. 793/93), REACH clearly introduces the possibility of using alternative methods such as QSAR and read-across among other accepted derogations from classical testing. Although these tools were already available during the life of these legislations and have undergone extensive development over recent years (and this has been even more visible during the work initiated for the implementation of REACH), their regulatory acceptance was not wide, particularly for the replacement of toxicity testing.

Examples of this use under the new and existing legislation are presented hereafter:

- In a paper circulated to the TC NES (Dr Ros Hanway, March 2006, "The use of toxicological read-across data in the notification of new chemicals", not publicly available), the UK's experience with base-set notifications (level VIIA, ≥1 t/y) of new chemicals including read-across was presented. Between 1998 and 2001, the number of notification dossiers including read-across was around 10% in the UK. Read-across was proposed so as to waive different toxicity testings required at this tonnage level (e.g. acute oral and dermal, skin and eye irritation, sensitisation, 28-day oral).
- A summary of the discussions on the use of QSAR and read-across within the ESR programme was proposed in 2006 (ECB, 5 September 2006, not publicly available). Among the ~130 priority substances already examined under this programme, read-across and QSAR was used to replace (usually one) standard animal testing 16 and 17 times respectively. However, these tools were, in the majority of cases, used in addition to the few standard test results already available, for comparison purposes.
- Read-across has sometimes been used extensively for harmonised classification of substances. The RIP 3.3 report particularly gives the example of metal compounds.

The examples presented above show that alternative methods have been used to some extent under the legislation on new and existing chemicals. Based on the information available, it would be difficult to precisely quantify this use and above all to specifically identify to which tests (involving animals) they have been applied. However, there are some indications that this use has been sporadic.

Consequently, indicators 1 will be set to zero for the baseline (2007). Concerning indicators 2 and 3, the work performed by ECOPA (ECOPA 2006) can be used to estimate *a posteriori* the number of animals that should have been used under this new Regulation if derogation rules had not been in effect. The REACH animal testing calculator (ECOPA 2006) could be used with the number of substances registered for each tonnage band as input (Input 1 of the Excel tool), in order to calculate the theoretical number of animals that should have been used for a given amount of substances. The calculation of the "baseline" for indicators 2 and 3 will have to be performed at each snapshot event.

The second approach includes additionally existing data from the registration of new substances according to the current (pre-REACH) legal demands. In Germany, the Federal Institute for Occupational Safety and Health (BAuA) evaluates the dossiers for new substances registration.

From this data base, a statistic may be derived showing how many animals are used for these substances on average to test basic toxicological properties, including:

- sensitisation (skin);
- irritation (skin, eye);
- repeated dose toxicity.

These data are available mainly for substances with production volumes between 1 and 100 tonnes/year with only few and insufficient data for higher production volumes. The number of animals used may be estimated by assuming that standard animal numbers were tested when a certain test identity is mentioned (e.g. the OECD test number is provided in the substance file). An aggregated number of estimated animals used for these tests can be provided for Germany, serving as baseline (animals/endpoint/substance).

This number is largely influenced by earlier testing with classical animal tests (before REACH and before validation of appropriate new ECVAM-alternative testing methods). It is assumed that the number of animals/endpoint/substance will decline under REACH, if the respective alternatives are available and recommended or requested by REACH. For sensitisation, a larger proportion of substances may be tested with the murine local lymph node assay (LLNA) instead of the earlier Magnusson and Kligman assay, reducing the number of test animals. For corrosivity of the skin, some alternative test methods have been established instead of the earlier Draize tests, e.g. the EpiSkin corrosivity test, the

[50] Depending on the endpoint, data gaps can be filled by animal testing or alternative methods, e.g. read-across or QSAR.

Epiderm corrosivity test, the rat TER corrosivity test. However, for eye irritation, no validated alternative test methods are yet available. Similarly, for repeated dose toxicity, no adequate alternative testing methods are available at baseline. In summary, differentiated evolution of the use of animals/endpoint is expected depending on progress in validating the respective test method and industry's willingness to make use of these new alternative test methods.

Accordingly, the indicator on reduced animal testing is proposed with the following characteristics:

- Includes the following endpoints: sensitisation of the skin, irritation and corrosiveness of the skin and the eye, repeated exposure test (oral) for 28 days;
- Baseline status: quantified using aggregated "new substances" data from Germany for the endpoints stated above (production volume 1-10 t/y; 10-100 t/y);
- Future status: using all registered substances in the 10-100 t/y production volume band (IUCLID 5 data), data on the basic tests as stated above with indication of the test method used (including statements on QSAR etc.);
- The number of test animals used/endpoint/substance (SPVC) at baseline and in future will be used for indicator formulation.

5.3 Links to related activities outside of the REACH Baseline Study

5.3.1 Monitoring the objective of increasing transparency and consumer awareness

The risk & quality indicator system as well as the administrative and supplementary indicators monitor the increase in knowledge of chemical properties and exposures. They are closely linked to the objective of increasing transparency and consumer awareness as mentioned in Chapter 3.4, because, to a large extent, these data are publicly available. This is supported by the activities of the European Chemicals Agency.

ECHA carries out the following tasks:

- Manage and carry out technical, scientific and administrative aspects of REACH;
- Ensure consistency at Community level in relation to these aspects;
- Provide the Member States and the institutions of the Community with the best possible scientific and technical advice on questions relating to chemicals which fall under REACH;
- Manage IT-based guidance documents, tools and data bases;
- Support the national helpdesk and run a helpdesk for registrants;
- Make information on chemicals publicly accessible.

To assist companies in registering substances, the Agency and Member States in evaluating dossiers, and the public in accessing information on chemicals, the European Commission is providing an online support tool: REACH-IT.

REACH-IT serves different purposes:

- It provides an online company homepage to submit registration dossiers on chemicals;
- It also allows the Agency and Member State authorities to review the dossiers;
- The Agency will make non-confidential information accessible on this website.

Regarding the last bullet point, interested parties will have easy access to non-confidential information on chemicals manufactured in or imported into Europe on this website. Once a company has submitted a dossier on a chemical using REACH-IT, the Agency will be able to publish information on the health and safety of the substance to ensure improved transparency of chemical data. Regarding the data requirements which are set by REACH, it is reasonable to assume that the REACH-IT homepage of ECHA will give much more information than is available at Baseline 2007 on the ESIS homepage of the European Chemicals Bureau (ECB) (http://ecb.jrc.it/esis/) (The IT System ESIS provides information on chemicals related to EINECS (European Inventory of Existing Commercial chemical Substances), ELINCS (European List of Notified Chemical Substances), NLP (No-Longer Polymers), HPVs and LPVs (High and Low Production Volume Chemicals) and the related IUCLID 4 data sheets, Information on Classification & Labelling, and the European Risk Assessment Programme.)

5.3.2 Monitoring endocrine disrupting chemicals

The reference set of the REACH Baseline Study contains only two substances which are identified as endocrine disrupting chemicals. Within the REACH Baseline Study an assessment can be made of how many of the reference substances will be characterised as EDCs in the future due to new data about their hazard properties that become available through REACH.

In addition, we recommend addressing the development of the risk associated with these chemicals of very high concern by monitoring the implementation of the Community Strategy for Endocrine Disruptors adopted by the Commission in December 1999 (COM(1999) 706) (http://ec.europa.eu/environment/endocrine/strategy/substances_en.htm).

5.3.3 Monitoring persistent and bioaccumulative chemicals

The reference set of the REACH Baseline Study contains five substances which are persistent, bioaccumulative and toxic (PBT substances). PBT and vPvB substances are also within the focus of the supplementary indicator on authorisation (see Chapter 5.1.3) due to the priority given to these substances according to REACH Art. 58(3).

In addition, it is recommended that the indicator system described in the REACH Baseline Study be supplemented by close monitoring of the evolution of the body burden of humans and the environment by PBTs and vPvBs in the framework of national and EU-wide biomonitoring programmes.

5.3.4 Monitoring the substitution of substances

Substitution of dangerous substances by less dangerous ones is a central instrument to reduce the harmful impact of substances on man and the environment.

The reference set of the REACH Baseline Study contains twenty five substances of very high concern (SVHC). Under REACH these substances of very high concern should be progressively replaced by suitable substances or technologies where these are economically and technically viable. The fate of these substances will be monitored regularly within the risk & quality indicators system of the REACH Baseline Study. Beyond this further efforts should be made to monitor the substitution of substances of very high concern in general (not restricted to the 25 randomly selected substances). It is recommended to do this monitoring in cooperation with different sector groups of the chemical industry which support the substitution of these substances.

Substitution is not restricted to substances of very high concern as defined by REACH. It takes place also for other dangerous substances. Therefore the analysis of substitution processes by further supplemental indicators should also cover substances which do not fulfil the criteria of REACH Art. 57.

6 Snapshot 2007

The baseline for the proposed indicators is described in this chapter. For the administrative indicators as well as for some supplementary indicators the baseline may be zero. Therefore there will be no snapshot for these indicators.

6.1 Risk & Quality Indicator System

The R&Q indicator system is a core part of a larger indicator system, with additional administrative and supplementary indicators proposed (the latter are not discussed below), all developed to mirror major consequences of the new REACH chemicals policy.

As its name suggests, the R&Q indicator system is proposed to show the risk to the subject of protection (i.e. workers, the general public and the environment) and the quality of this information. The risk relates to possible impairments of human or environmental health after long-lasting exposure to a currently assumed exposure level. To calculate this risk, various assumptions for a toxicological reference point and for the level of exposure had to be incorporated, leading to a “nominal” Risk Score for this indicating purpose, which should not be mistaken to be the real size of threat to human or environmental health. To calculate such a “real” risk instead of a “nominal” risk, a much more detailed substance-specific expert analysis would have been necessary, exceeding the scope of an indicator. Moreover, the risk calculations often had to be performed with incomplete data on substance-inherent properties and exposure conditions. It is the characteristic feature of the situation before REACH that many of these data are missing or not reported to the risk assessors. Therefore, the real risk is currently not known (and will only partially be known after implementation of REACH). This is why the R&Q indicator system also includes a quality indicator alongside the risk indicator: whenever a (nominal) risk is calculated, this second figure characterises the quality of this calculation under defined peripheral constraints. The quality is low if many hypothetical assumptions have to be included in the risk quantification for the impact of a substance on the subject of protection, i.e. if no or only few valid substance-specific toxicity or exposure data are available in a set of predefined data sources.

Not all chemical substances which are within the focus of REACH could be included in this R&Q indicator system. Instead, the calculations were restricted to 215 plus 22 randomly selected substances in total. The 215 substances were drawn from the sub-sample of high production volume chemicals (HPVs, >1 000 tonnes per year, n=65), medium

production volume chemicals (MPVs, >100 tonnes per year, n=45) and low production volume chemicals (LPVs, >10 tonnes per year, n=105), with tonnage bands according to IUCLID 4. Substances with no indications of use in the EU or substances definitely excluded from the rules of REACH were replaced by further random selection. In addition, 22 substances were selected for a separate set of substances of very high concern (SVHC), i.e. mainly substances which have to be authorised under REACH. This group may show a distinct evolution due to other REACH rules and may thus serve as a control group. The results on these 22 extra substances of very high concern are not covered below. For all 237 substances, a recalculation of risk and quality is planned in the future (i.e. in 6 years' time and thereafter), in order to monitor the changes under REACH in relation to the year 2007. The identity of those substances is not disclosed to the public in order to avoid selective developments for substances known to be part of the indicator.

6.1.1 Impact area: workers

A risk characterisation ratio (RCR), Risk Score (RS) and Quality Score (QS_{total}, QS_{tox}, QS_{exp}) were calculated for each of the 215 substances and then aggregated at various levels. Below, the results are shown for three levels:

1. **Summary level:** Aggregated Baseline Risk Score (workers), Aggregated Baseline Quality Score (workers);
2. **Profile level:** Baseline Risk & Quality Score Profile (workers);
3. **Analysis level:** Baseline data availability analysis (workers), Baseline Risk Characterisation Ratio analysis (workers), and possibly further analysis level indicators.

6.1.1.1 Summary level

At the summary level for the impact area of workers in the year 2007, the Risk Score is 16 (geometric mean) and the Quality Score is 42 (geometric mean). Figures 6.1 and 6.2 show these scores.

In order to rank the Aggregated Baseline Risk Score (workers), it is helpful to know that a Risk Score of 0.1 would certainly be called "low", whereas a Risk Score of 1 000 would certainly be called "elevated". However, calculated Risk Scores for the 215 substances varied over a much wider range (8 orders of magnitude). Therefore, no upper or lower bounds were set. Instead, it may be helpful to compare the mean Risk Score for the 215 substances with the Risk Score of well known substances and we propose to use chlorine, benzene, and dibutyl ether as reference substances.

For chlorine, an EU RAR exists with measured exposure data. An occupational exposure limit (OEL) was retrieved from a database on occupational exposure limits, which can be used as a $DNEL_{analogue}$. The risk characterisation ratio is calculated as 0.47. This means that exposure to chlorine is usually assumed to be well below the OEL. Due to the extremely high production volume, the large number of manufacturers/importers and the many uses, a population risk modifier (PMR) of 10 (maximum) is assigned. This leads to a Risk Score of 4.7 for this reference substance.

Benzene is a human carcinogen, for which a risk of $5{:}10^5$ was calculated as reference point, corresponding to 28 µg/m^3. Occupational exposure in production and processing (3.5 mg/m^3) may currently clearly exceed this risk level at some workplaces with exposure data directly taken from the respective EU risk assessment report (RAR). Therefore a risk characterisation ratio of 125 was derived. Because of the high production volume, the number of use categories and the possibility of wide dispersive use, the maximum population risk modifier of 10 was assigned. This leads to a Risk Score of 1 250 for this reference substance.

As a representative of low risk at baseline, dibutyl ether is used, which is a technical solvent according to the OECD (one of several uses, not clearly the most relevant). Dibutyl ether is an (eye, skin and respiratory) irritant. The risk phrases were used to derive a $DNEL_{analogue}$ of 20 mg/m^3. Exposure data of 0.165 mg/m^3 were taken from an OECD report, thus leading to a very low risk characterisation ratio of 0.008. Because of the low production volume and "non-dispersive use" as main use category, the population risk modifier is limited to 3. This leads to a Risk Score of 0.024 for this reference substance, well below the overall geometric mean at baseline.

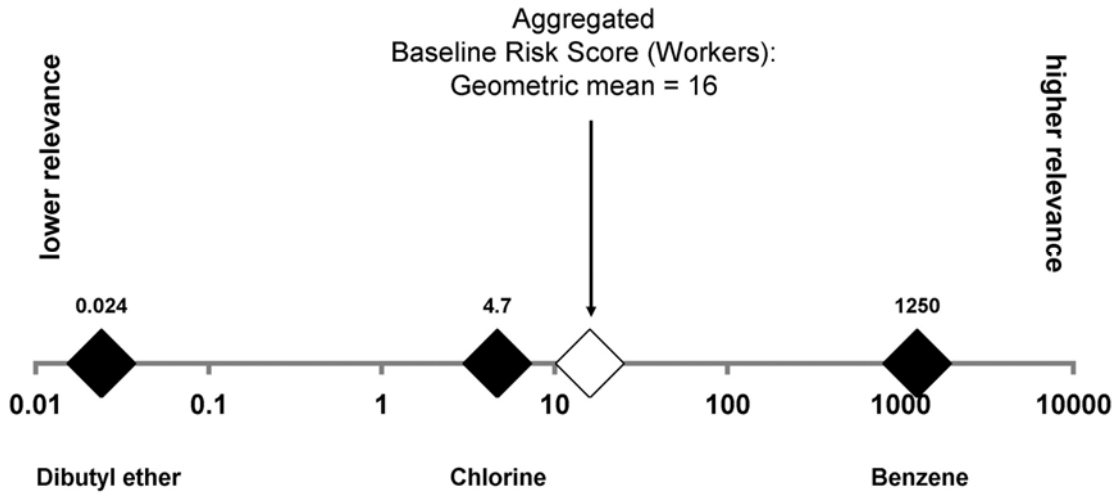


Figure 6.1 Summary level: Aggregated Baseline Risk Score (workers)

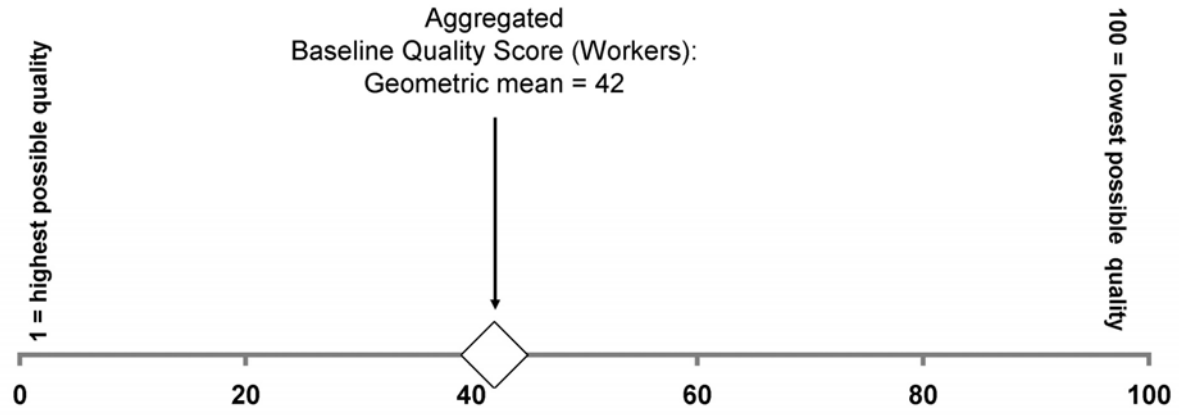


Figure 6.2 Summary level: Aggregated Baseline Quality Score (workers)

It is much easier to rank quality, as there is by definition a theoretical maximum and a theoretical minimum for the Aggregated Baseline Quality Score. Quality Scores between 2 and 100 were assigned to 215 substances in our set, showing all from excellent (QS_{total} = 2, close to the theoretical minimum of 1) to insufficient (QS_{total} = 100) quality. We propose not to use reference substances for quality because of the clear boundaries of the ranking range. Therefore, such substances are not shown in Figure 6.2. However, if again chlorine, benzene and dibutyl ether were used as reference substances, the respective QS_{total} values would be 4, 4, and 24 respectively, demonstrating the very good quality for the well assessed substances (chlorine and benzene), with some remaining uncertainties regarding the completeness of the toxicological database as published in IUCLID 4. For dibutyl ether, measured exposure data (OECD) were not clearly linked to the main use (QS_{exp}=4). Calculation of a toxicity reference point by the risk phrase is only a rough estimate of a DNEL or OEL, which were not established at baseline (QS_{tox}=6). The quality of this assessment (QS_{total}=24) is thus closer to the overall geometric mean of 42 at baseline.

At this summary level, the calculated mean risk and quality scores are mainly intended to be used in comparison to later points in time, i.e. in the year 2012 or later. The change in the Aggregated Baseline Risk Score and Quality Score over the years may be a headline indicator for political communication. Since these single figures are much too complex for further interpretation, the other levels (profile level, analysis level) are supplemented. We propose not to amalgamate the Quality Score and the Risk Score into a single figure. Moreover, any comparisons between different impact areas should be strictly avoided. Such comparisons would mean a misinterpretation because — for example — different reference points for risk calculation are used in the different impact areas.

6.1.1.2 Profile level

The profile level provides some more details for better interpretation compared to the summary level. There is a gradual increase in detail towards the analysis level. We propose that, at the profile level, a distinction between HPVs, MPVs, LPVs and SVHCs should be possible and that more insight into the distribution of the single Risk Scores and Quality Scores is provided. However, at this level we are still referring to Risk Scores and Quality Scores and not to the various sub-factors.

There are two ways to present the results at profile level:

1. whisker plots with statistical parameters of the respective distribution, or
2. clouds showing individual values.

Both of which may be useful for different types of analysis.

For the whisker plot, Figure 6.3 demonstrates the intended depth of information while Figure 6.4 and Figure 6.5 show the differentiated results for the 237 substances (including SVHCs).

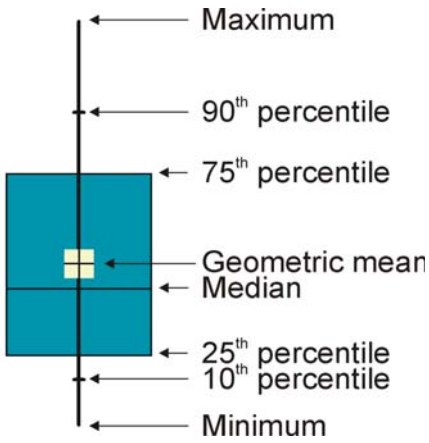


Figure 6.3 Legend to proposed whisker plot at profile level

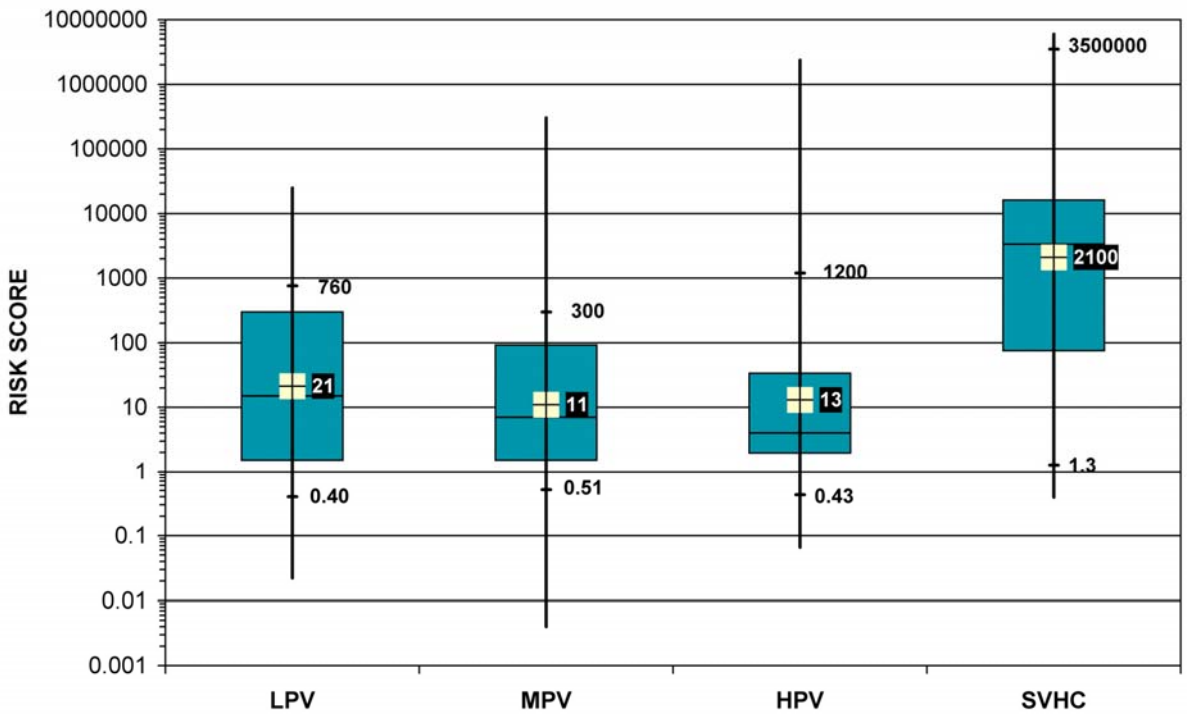


Figure 6.4 Baseline Risk Score Profile (workers). Numerical values given for geometric mean, 10th percentile and 90th percentile

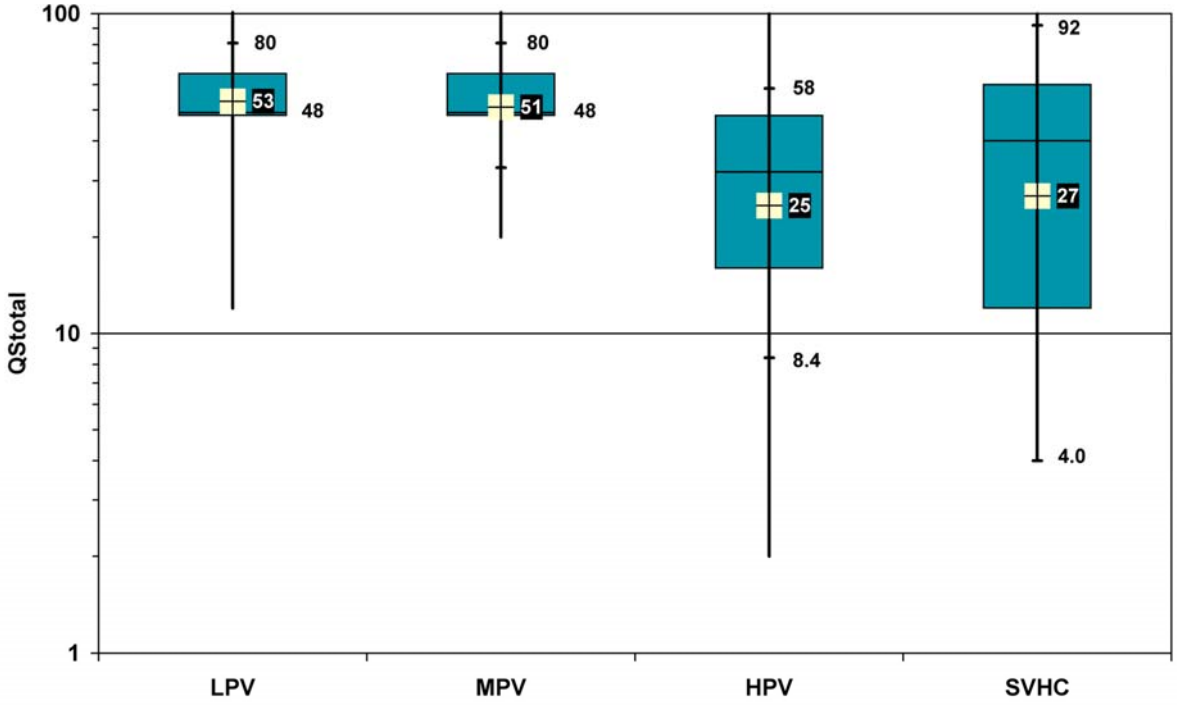


Figure 6.5 Baseline Quality Score Profile (workers). Numerical values given for geometric mean; note that medians and 25th percentiles have identical values for LPVs and MPVs, and the 10th percentile is also identical for LPVs (see the detailed results in the table below)

Figure 6.4 demonstrates no obvious systematic differences in assigned Risk Scores for the three production bands at baseline. This information is helpful in interpreting the appropriateness of the methodology. Even though the quality of information is clearly different for MPVs and LPVs on the one hand and HPVs on the other (see Figure 6.5), this does not mean that the Risk Score would automatically differ. However, for some substances with very high production volumes, it is more likely that the population risk modifier in combination with an elevated risk (e.g. exposure to carcinogens at the workplace) would result in extreme Risk Scores. Therefore, for HPVs, such Risk Scores above 10^6 may show up. On the other hand, HPVs are often already assessed and well controlled by risk management measures, even before baseline. Therefore, the 25th to 75th percentile range does not differ as much as for LPVs, where often a higher risk has to be assumed (few or no reported risk management measures, more often default assumptions for toxicity and exposure). For some SVHCs, no data were available from IUCLID for information on the number of use categories or even on production volumes. Therefore, high population risk modifiers were assigned, which are not based on qualified data.

Figure 6.5 clearly shows the usually better data quality for HPVs (and often SVHCs) than for MPVs or LPVs at baseline. There is a difference by a factor of 2 in the geometric mean between HPVs on the one hand and LPVs/MPVs on the other. The very high concern for some substances did not always lead to a thorough assessment at baseline. Therefore the distribution of the SVHCs is much broader compared to the HPV group, which was assessed quite thoroughly in earlier priority programmes. Since REACH will probably provide better quality of information on MPVs in the next decade (and later for LPVs), it is assumed that the Quality Score will most probably decrease significantly, even with the limited set of substances monitored within this indicator system.

The background result summary data are provided in Table 6.1.

Number of substances	n	105 LPV	45 MPV	65 HPV	25 SVHC[1]
RISK SCORE	Median	15	7.0	4.0	3 300
	GM	21	11	13	2 100
	10th percentile	0.40	0.51	0.43	1.3
	25th percentile	1.5	1.5	2.0	75
	75th percentile	300	92	34	16 000
	90th percentile	760	300	1 200	3.5 106
	MIN	0.022	0.0040	0.066	0.39
	MAX	25 000	300 000	2.4 106	6 106
QStotal	Median	48	48	32	40
	GM	53	51	25	27
	10th percentile	48	32	8.4	4.0
	25th percentile	48	48	16	12
	75th percentile	64	64	48	60
	90th percentile	80	80	58	92
	MIN	12	20	2.0	4.0
	MAX	100	100	100	100

[1] Included in this set are 3 substances already evaluated within the HPV/MPV/LPV categories. Therefore the number of substances given in the single columns exceeds the total number of substances by three.

Table 6.1 Results of Risk Scores and Quality Scores for 237 substances (workers), distribution data (rounded to 2 significant figures)

In addition, the risk and quality profile may also be presented as a cloud (Figure 6.6 and Figure 6.7).

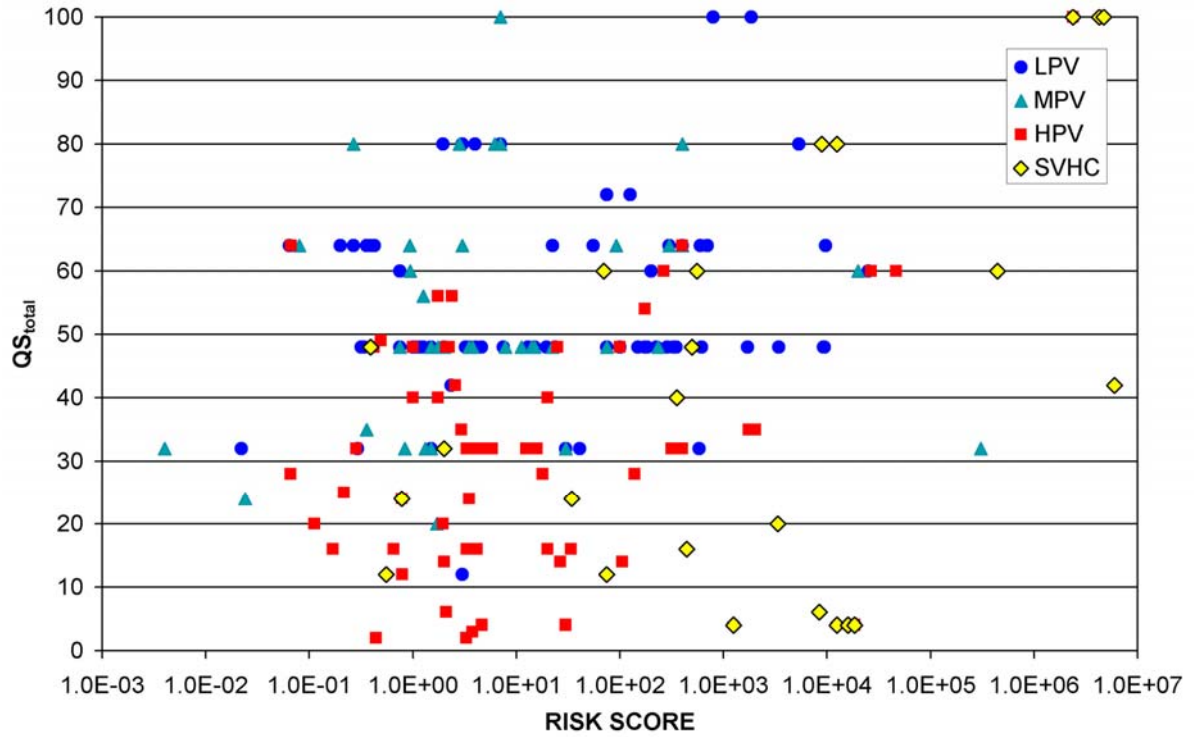


Figure 6.6 Baseline Risk and Quality Scores (workers), log scale for Risk Score

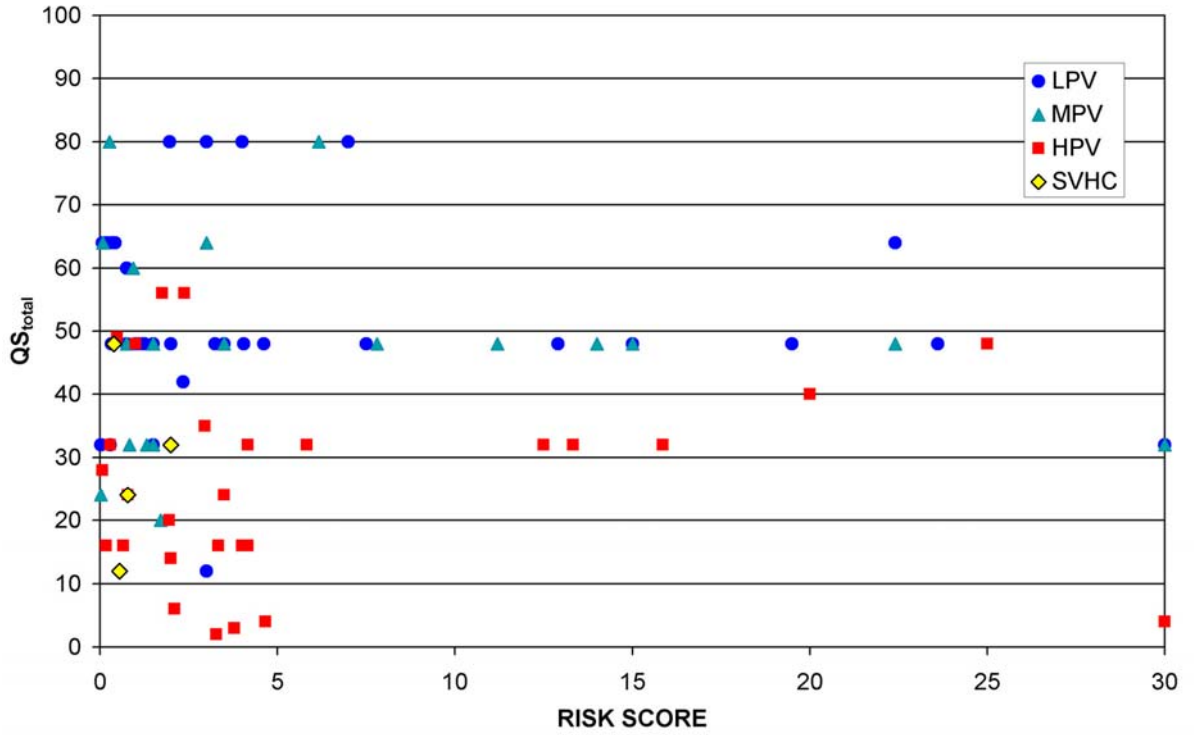


Figure 6.7 Segment of Baseline Risk and Quality Scores (workers), only Risk Scores at or below 30 included

Figure 6.6 shows the risk and quality scores of the selected substances in one graph with a log scale for the Risk Score to demonstrate the large range of risks for the individual substances. Identical parameters are presented in Figure 6.7 with the Risk Score on a linear scale. However, for reasons of readability, in Figure 6.7 all substances with high Risk Scores above 30 were excluded from the plot. Again, it is demonstrated that the risk for HPVs is often based on higher quality data compared to substances from lower production bands. As shown in Figure 6.6, it is noteworthy that there are some SVHCs displaying a relatively high Risk Score at a very good quality.

At this profile level, it would also be possible to exclude subgroups of substances and calculate the respective geometric mean and distribution for the remaining substances only. Such an approach has been performed in order to find out the influence of carcinogens (n=6) on the distribution. The following result was obtained:

	Combined LPV/MPV/HPV	**Combined LPV/MPV/HPV (carcinogens excluded)**
n	215	209
Geometric mean	16	12
Minimum	0.004	0.004
Maximum	$2.4\ 10^6$	$4.7\ 10^4$

Table 6.2 Influence of carcinogens on the geometric mean and distribution of Risk Scores (workers), all substances (without SVHCs)

Table 6.2 shows a remarkable reduction in the geometric mean after exclusion of only six carcinogens, caused by the high Risk Score assigned to them. This high Risk Score in turn largely depends on the "acceptable risk level" of $5\ 10^5$ used for calculation and the usually much higher exposure compared to the resulting $DMEL_{analogue}$. However, when carcinogens are included, a more conservative acceptable risk of $5\ 10^6$ would only slightly increase the geometric mean to 17 with a higher maximum score of $2.4\ 10^7$. In conclusion, carcinogens with less than optimal control have a highly relevant influence on the resulting index. However, it is of minor importance whether an acceptable risk of $5\ 10^5$ or, e.g., $5\ 10^6$ is chosen for the calculations.

6.1.1.3 Analysis level

The type of calculations and the documentation used for the R&Q indicator system permit many more detailed analyses. For example, the analyst may wish to be informed on the availability of high-quality input data for toxicity or exposure assessment compared to the "second-choice" substitute information which had to be used. Figure 6.8 and Figure 6.9 provide such information.

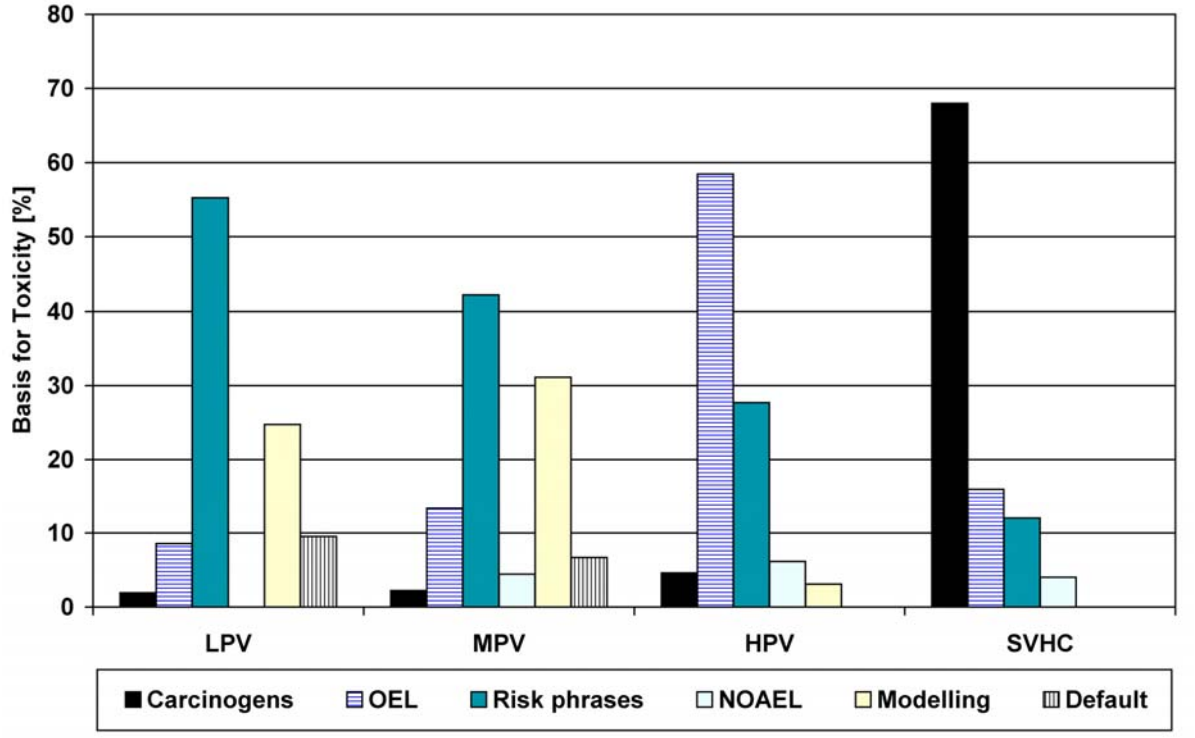


Figure 6.8 Baseline data availability analysis for toxicity data (workers)

The increasing column size from LPVs to HPVs for the use of occupational limit values (OELs) demonstrates that such OELs are mostly available for well-characterised high production volume chemicals (almost 60% of substances). In contrast, for most LPVs, risk phrases had to be used to establish $DNEL_{analogues}$ (few OELs available). This is clearly second choice. In addition, some no adverse effect levels (NOAELs) had to be taken from toxicological reviews, which could not be validated as starting points for $DNEL_{analogue}$ derivation. These NOAELs are only used if no OELs or risk phrases are available. This was necessary in a few cases for HPVs and MPVs. However, for several LPVs and MPVs even those NOAELs were not available. Therefore, modelling or defaults had to be used for these substances, which was only necessary for a very small number of HPVs. The SVHCs are somewhat different in that they were chosen for — among other criteria — their classification as carcinogens. There is therefore a high ratio of carcinogens among these substances by definition.

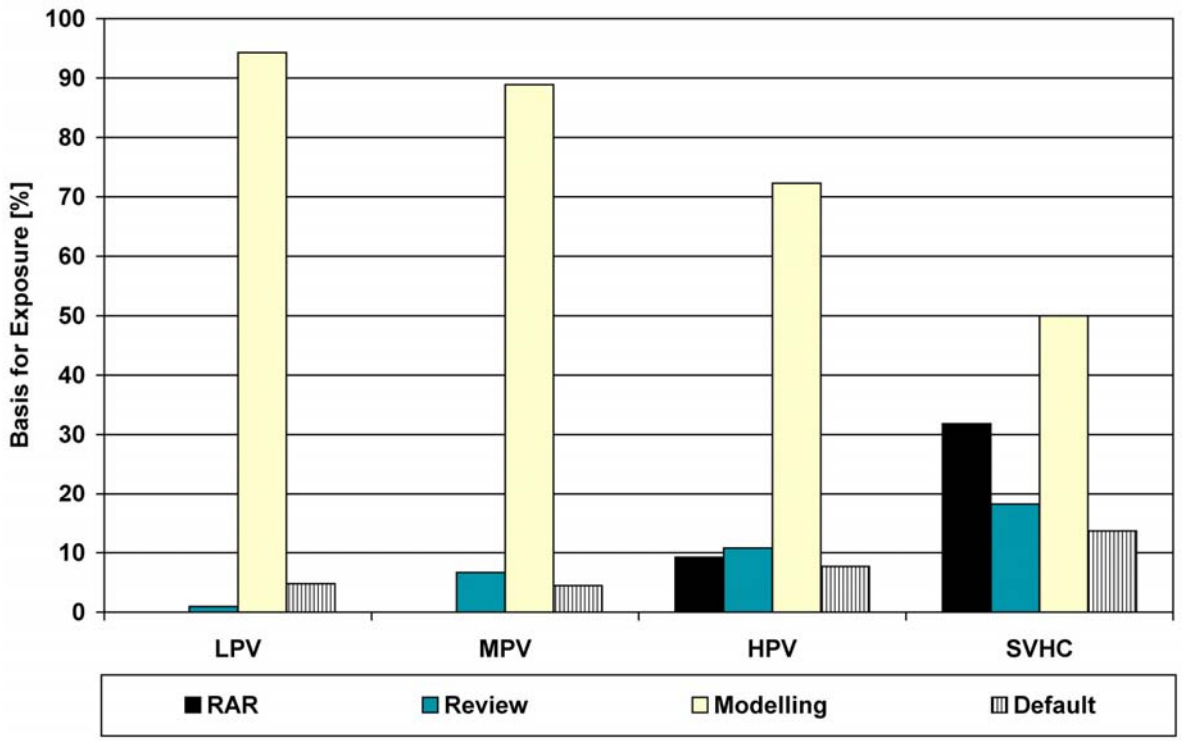


Figure 6.9 Baseline data availability analysis for exposure data (workers)

Figure 6.9 currently provides less differentiation since most of all the exposure assessments (for LPVs, MPVs and HPVs) had to be done by modelling. However, in 9% of the HPVs, highly qualified exposure assessments from RARs could be used to assess exposure. In addition, in 11% of the HPVs and in 7% of the MPVs, other qualified reviews provided better exposure data. In the case of SVHCs, a higher percentage of qualified data (in the form of RARs or other reviews) is evident, probably because the great concern associated with these substances had already led to more detailed exposure assessments. The quality of the toxicity data for SVHCs remained poor (see detailed data in the table below) since some of them were mixtures with no adequate testing. Therefore, the better exposure assessment for SVHCs does not lead to better overall quality compared to HPVs. It is assumed that in future evaluations exposure assessments from chemical safety reports (CSRs) will be available for high-quality input for the risk calculation.

Table 6.3 demonstrates the better quality in toxicity input data and in exposure input data for HPVs compared to substances from the other two production bands. This analysis provides details in addition to Figure 6.9.

		LPV (105 substances)	**MPV (45 substances)**	**HPV (65 substances)**	**SVHC (25 substances)[1]**
QS_{tox}	Median	6.0	6.0	4.0	6.0
	GM	**6.6**	**6.4**	**4.1**	**5.6**
	10^{th} percentile	6.0	4.0	2.0	4.0
	90^{th} percentile	10	8.0	6.6	10
	MIN	4.0	4.0	2.0	2.0
	MAX	10	10	10	10
QS_{exp}	Median	8.0	8.0	8.0	8.0
	GM	**8.0**	**7.9**	**6.1**	**4.8**
	10^{th} percentile	8.0	8.0	3.4	1.0
	90^{th} percentile	8.0	10	8.0	10
	MIN	3.0	4.0	1.0	1.0
	MAX	10	10	10	10

[1] Included in this set are 3 substances already evaluated within the HPV/MPV/LPV categories Therefore the number of substances given in the single columns exceeds the total number of substances by three.

Table 6.3 Quality Score for toxicity and exposure assessments (workers), distribution analysis (rounded to 2 significant figures)

A very interesting analysis is provided in Figure 6.10. This shows the assumed exposure concentration on the x-axis and the assumed safe concentration (as expressed by the occupational exposure limit or other $DNEL_{analogues}$) on the y-axis for all 215 substances. The dashed diagonal line discriminates exposure higher or lower than the OEL.

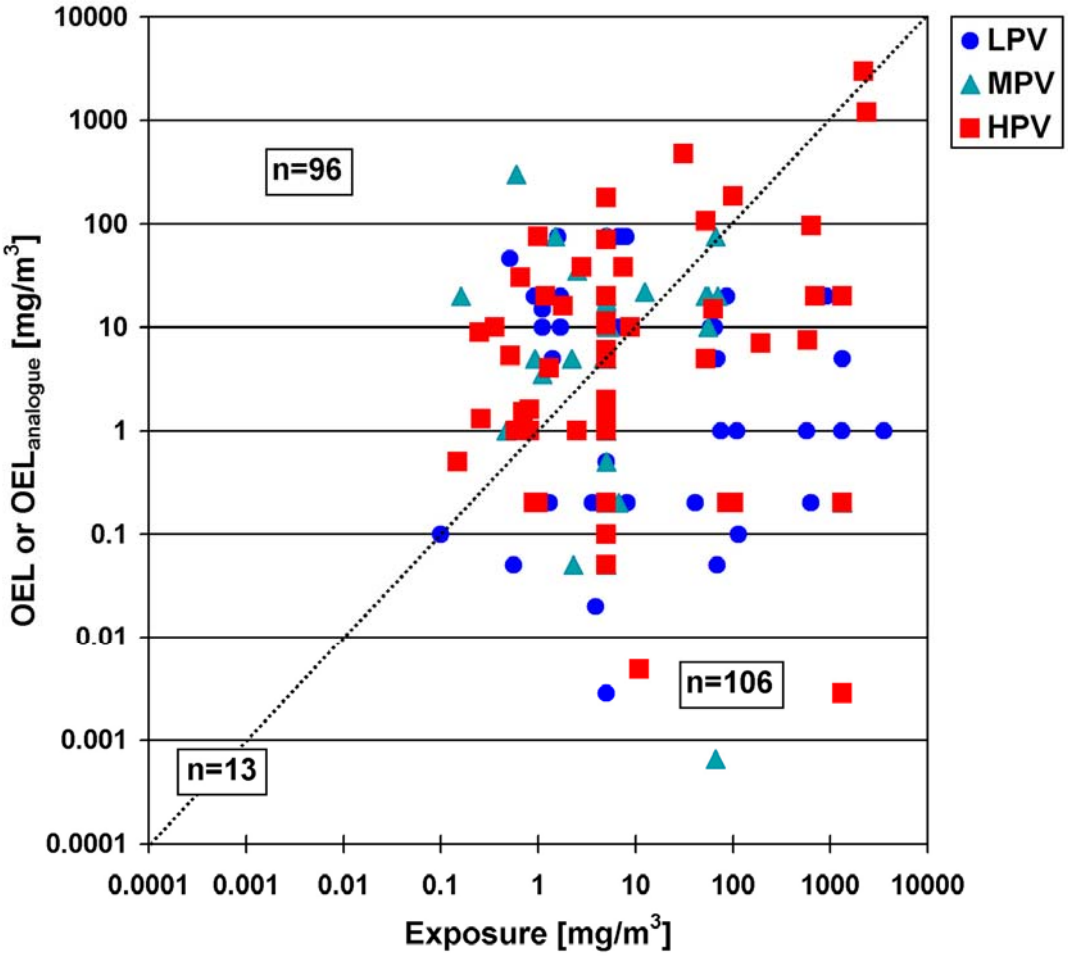


Figure 6.10 Baseline analysis of the risk characterisation ratio (workers)

Figure 6.10 thus shows the risk characterisation ratio (RCR) for all substances with RCR < 1 (n=96) on the left-hand side of the diagonal line and RCR > 1 (n=106) on the right-hand side of this dashed line (for the missing n=13, RCR equals 1). Overall, 36% (77/215) of the RCRs are above 10. It may be assumed that as a result of REACH there will be a clearly visible shift towards RCRs lower than one (to the upper left-hand triangle in Figure 6.10) because REACH demands risk management measures ensuring that exposure is below the DNEL.

Interestingly, the picture is completely different for SVHCs. Instead of the roughly equal number of RCRs above and below 1 seen above, more than 80% of RCRs for SVHCs are above 1. The respective figures (together with the ones for the combined LPV/MPV/HPV group) are shown in Table 6.4. These data also show a much higher percentage of RCR values above 10 in the SVHC group, which supports the identification of these substances as of "very high concern". It is evident that the many carcinogens within this group determine the high risk at baseline. This follows the philosophy of assigning high priority to this group of substances under REACH, with relevant risk reduction measures subsequent to authorisation.

	n	RCR>1	RCR<1	RCR=1	RCR>10
LPV/MPV/HPV	215	106 (49%)	96 (45%)	13 (6%)	77 (36%)
SVHC	25	21 (84%)	4 (16%)	0	20 (80%)

Table 6.4 Distribution of RCRs for workers

Many other types of analyses may be added for a more detailed understanding of the changes in risk and in data quality after implementation of REACH.

6.1.2 Impact area: consumers

The Risk Score (RS) and Quality Scores (QS_{total}, QS_{tox}, QS_{exp}) were calculated for each of the 237 randomly selected substances and then aggregated at various levels. At the profile and analysis levels, the 25 substances of very high concern (SVHCs) are also considered in the results.

Results for consumers are specific since for some substances (61 out of 215 randomly selected substances or 65 out of 237 substances including the 25 SVHCs), the exposure score is estimated to be zero (which means no REACH-related exposure to consumers identified OR the substance is a synthesis intermediate OR it is identified as used in a closed system only).

As a result and for statistical and graphical purposes, these "exposure 0" substances are not included in the exposure score, RCR, and Risk Score levels of analysis. The number of substances considered is indicated at each step in the analysis. These substances are included for the Quality Score level of analysis and for the analysis of the sources of the estimates.

6.1.2.1 Summary level

The summary level excludes the 25 substances of very high concern (SVHCs). It focuses only on the set of 215 randomly selected substances.

At the summary level for the impact area of consumers in the year 2007, the Risk Score is **34** (geometric mean) and the Quality Score is **52** (geometric mean). Figure 6.11 and Figure 6.12 show these scores. Figure 6.11 does not take into account the 61 substances among the 215 randomly selected for which the exposure score is 0.

In order to rank the Aggregated Baseline Risk Score (consumers), it is helpful to know that a Risk Score of 0.1 would certainly be called "low", whereas a Risk Score of 50 would certainly be called "elevated". However, as for workers, calculated Risk Scores for the 215 substances varied over a much wider range. Therefore, no upper or lower bounds were set. Instead, it may be helpful to compare the mean Risk Score for the 215 substances with the Risk Scores of some "well known" substances. For consumers, butadiene, benzene, and dibutyl ether were chosen.

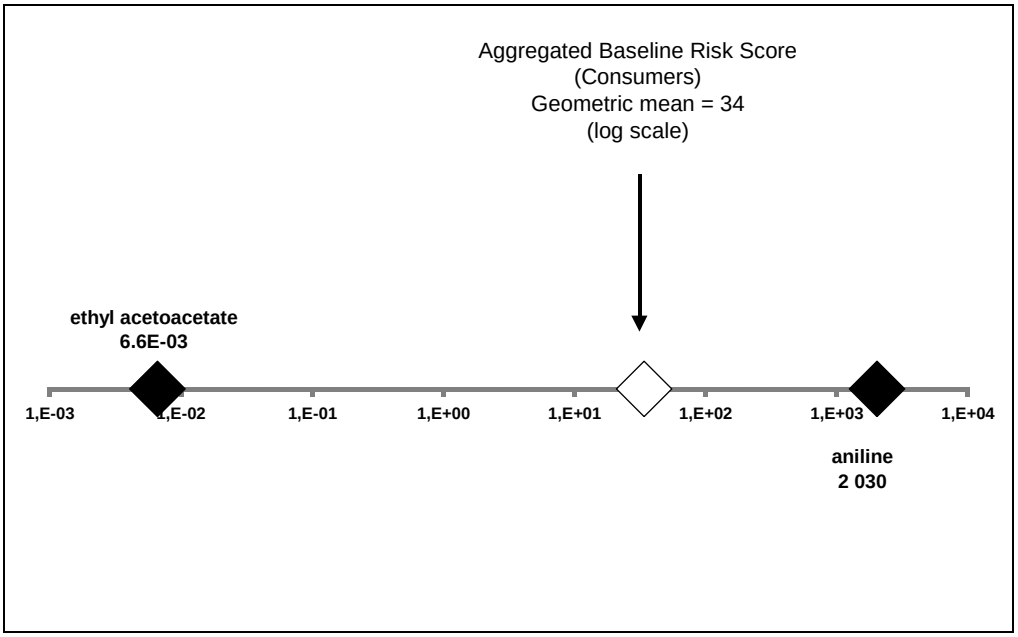


Figure 6.11 Summary level: Aggregated Baseline Risk Score (consumers, 61 substances with Risk Score equal to 0 excluded)

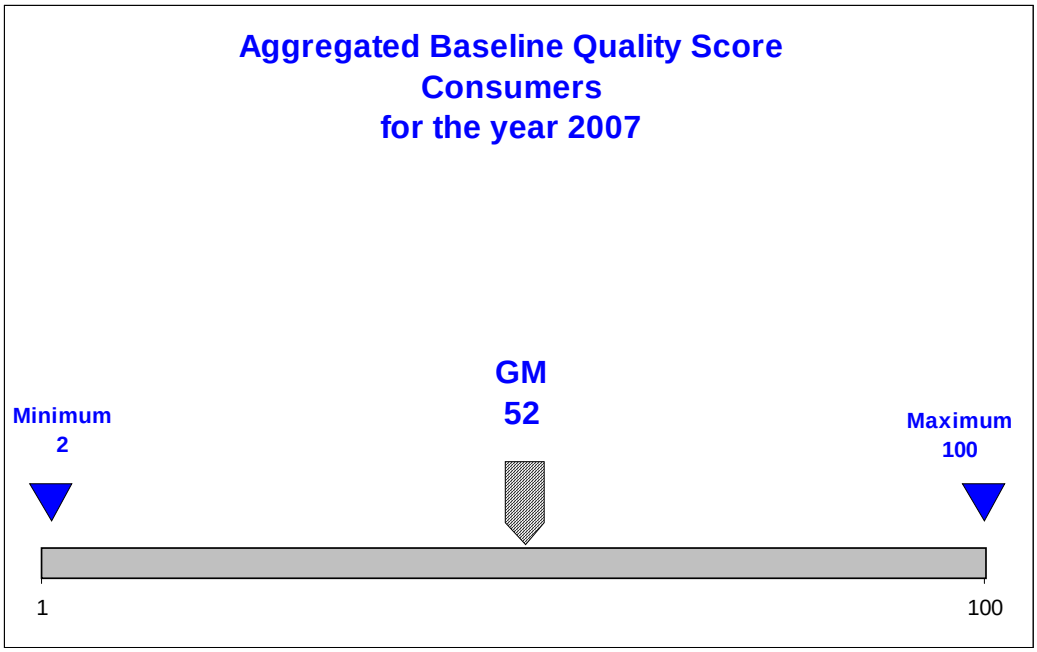


Figure 6.12 Summary level: Aggregated Baseline Quality Score (consumers, all substances)

It is much easier to rank quality, as there is by definition a theoretical maximum and minimum for the Aggregated Baseline Quality Score. Quality Scores between 2 and 100 were assigned to 215 substances in our set, showing all qualities from excellent (QS_{total} = 2, close to 1) to clearly insufficient (QS_{total} = 100). We propose not to use a reference substance for quality because of the clear boundaries of the ranking range. Therefore, such a substance is not marked in Figure 6.12.

At this summary level, the calculated mean risk and quality scores are mainly intended to be used in comparison to later points in time, i.e. in the year 2012 or later. The change in the Aggregated Baseline Risk Score and Quality Score over the years may be a headline indicator for political communication. Since these single figures are much too complex for further interpretation, the other levels (profile level, analysis level) are supplemented. We propose not to amalgamate the Quality Score and the Risk Score into a single figure. Moreover, any comparisons between different impact areas should be strictly avoided. Such comparisons would mean a misinterpretation because, for example, different reference points for risk calculation are used in the different impact areas.

6.1.2.2 Profile level

The profile level provides further details for HPVs, MPVs and LPVs. In addition, results for the 25 SVHCs are also provided. However, at this level we are still referring to Risk Scores and Quality Scores and not to the various sub-factors. The results are shown in whisker plots or clouds. Both of these may be useful for different types of analysis.

Figure 6.13 does not take into account the 65 substances for which the exposure score is 0 among the 237 randomly selected substances. Figure 6.14 takes into account all substances.

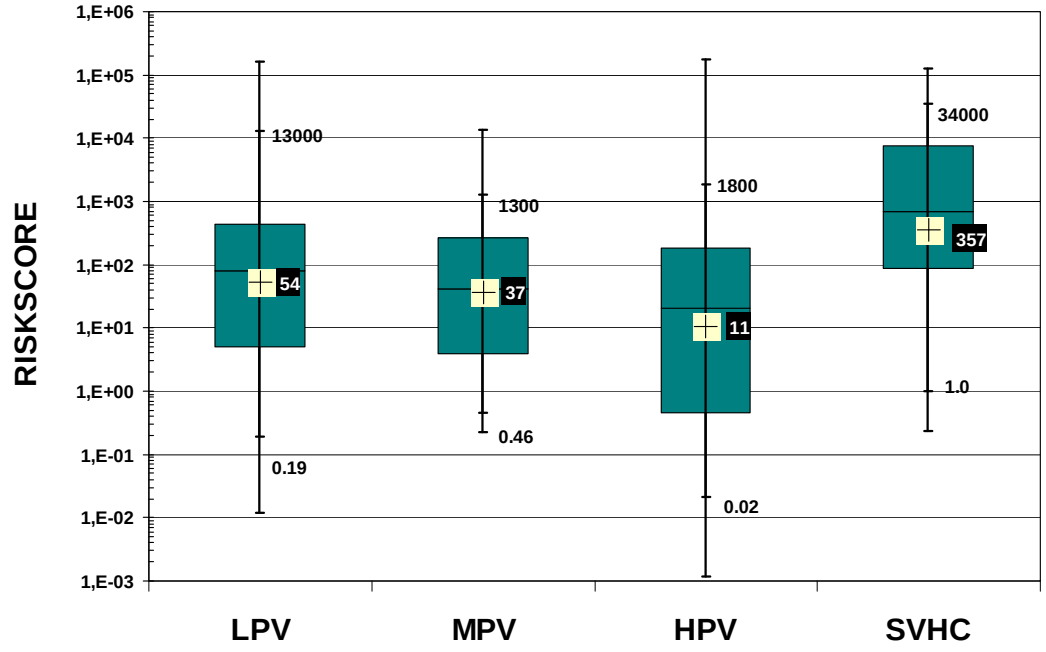


Figure 6.13 Baseline Risk Score Profile (consumers). Numerical values given for geometric mean, 10th percentile and 90th percentile (65 substances for which RS = 0 excluded)

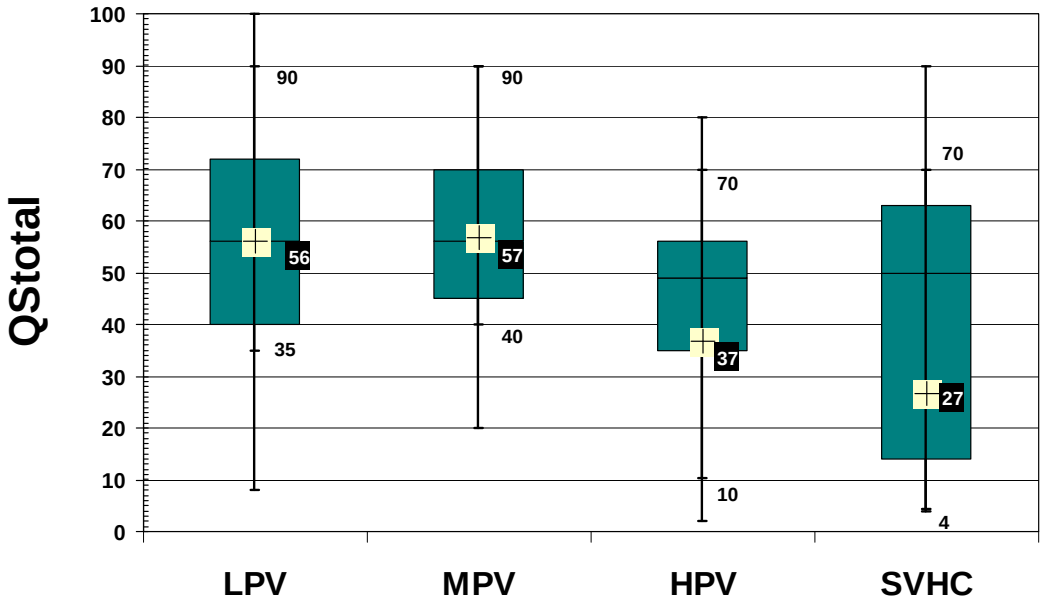


Figure 6.14 Baseline Quality Score Profile (consumers). Numerical values given for geometric mean, 10th percentile and 90th percentile

Figure 6.13 demonstrates no obvious systematic differences in assigned Risk Scores for the three production bands at baseline. This information is helpful in interpreting the appropriateness of the methodology. Even though the quality of information is clearly different for MPVs and LPVs on the one hand and HPVs on the other (see Figure 6.14), this does not mean that the Risk Score would automatically differ. However, for some substances with a very high production volume it is more likely that the population risk modifier in combination with an elevated risk (e.g. exposure to carcinogens) would result in extreme Risk Scores.

Figure 6.14 clearly shows the usually better data quality for HPVs and SVHCs than for MPVs or LPVs at baseline. There is almost a factor 2 difference in the geometric mean for the respective groups. Since REACH will probably provide better

quality of information on MPVs in the next decade (and later for LPVs), it is assumed that the Quality Score will most probably decrease significantly, even with a limited set of substances monitored within this indicator system.

Figure 6.13 also demonstrates a difference between the three production bands at baseline and the SVHCs, for which the Risk Score is much higher. However, Figure 6.14 shows a slight difference between Quality Scores for HPVs and SVHCs.

The background result summary data are also provided in Table 6.5 for the 215 randomly selected substances and in Table 6.6 for the 25 SVHCs.

		LPV, MPV and HPV
RISKSCORE Consumers (n=154)	Median	54
	GM	34
	10th percentile	0,1
	90th percentile	7,E+03
	MIN	1,E-03
	MAX	2,E+05
QStotal Consumers (n=215)	Median	56
	GM	52
	10th percentile	35
	90th percentile	81
	MIN	2
	MAX	100

Table 6.5 Results of Risk Scores and Quality Scores for LPV, MPV and HPV substances (consumers), distribution data (25th and 75th percentiles) not reported

		SVHC
RISKSCORE Consumers (n=20)	Median	687
	GM	110
	10th percentile	1,0
	90th percentile	3,E+04
	MIN	2,E-01
	MAX	1,E+05
QStotal Consumers (n=25)	Median	50
	GM	25
	10th percentile	4
	90th percentile	70
	MIN	4
	MAX	90

Table 6.6 Results of Risk Scores and Quality Scores for substances of very high concern (consumers), distribution data (25th and 75th percentiles) not reported

In addition, the risk and quality profile may also be presented as a cloud. Figure 6.15 shows the risk and quality scores of the selected substances in one graph in log scale to demonstrate the large range of risks for the individual substances.

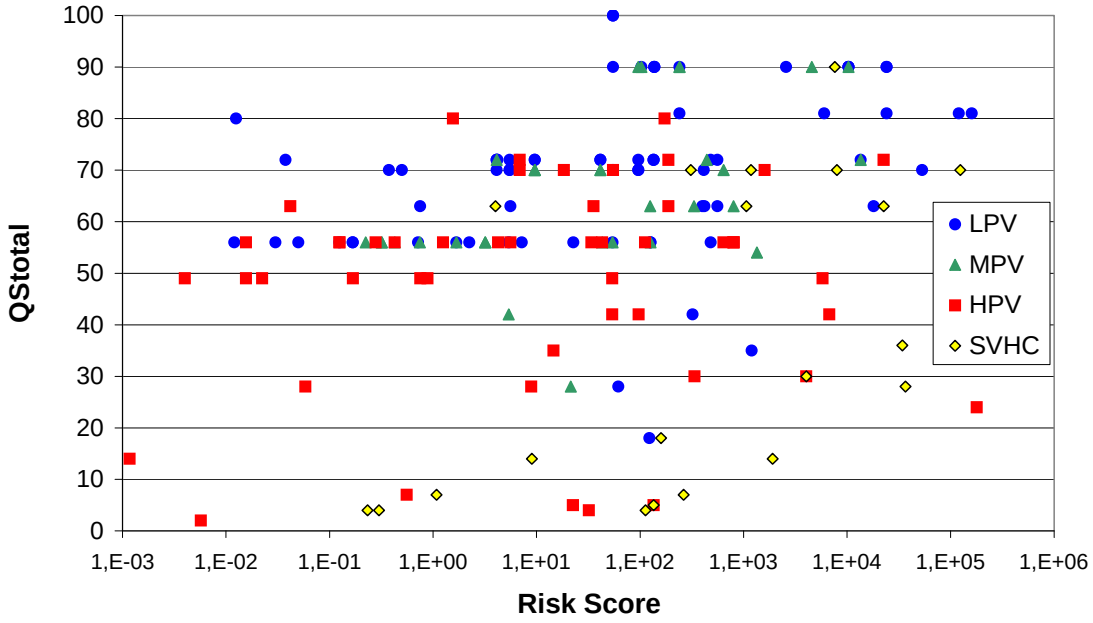


Figure 6.15 Baseline Risk and Quality Scores (consumers), log scale for Risk Score (substances for which RS = 0 excluded)

6.1.2.3 Analysis level

Figure 6.16 and Figure 6.17 provide detailed information about data availability for exposure and toxicity.

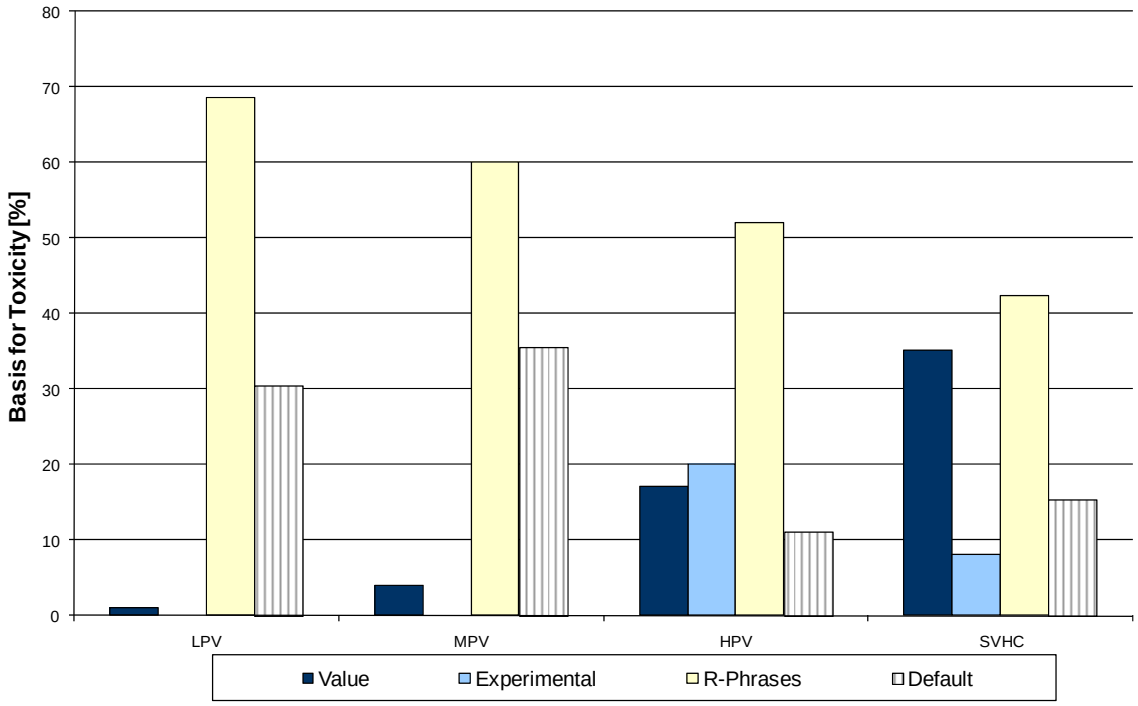


Figure 6.16 Baseline data availability analysis for toxicity data (consumers)

The increasing column size from LPVs to HPVs and SVHCs for the use of pre-existing toxicological values demonstrates that such reference values are mostly available for well characterised high production volume chemicals. However, it represents only <20% of HPVs, much less than OELs for workers.

In contrast, for most MPVs and LPVs, risk phrases or defaults had to be used to establish $DNEL_{analogues}$.

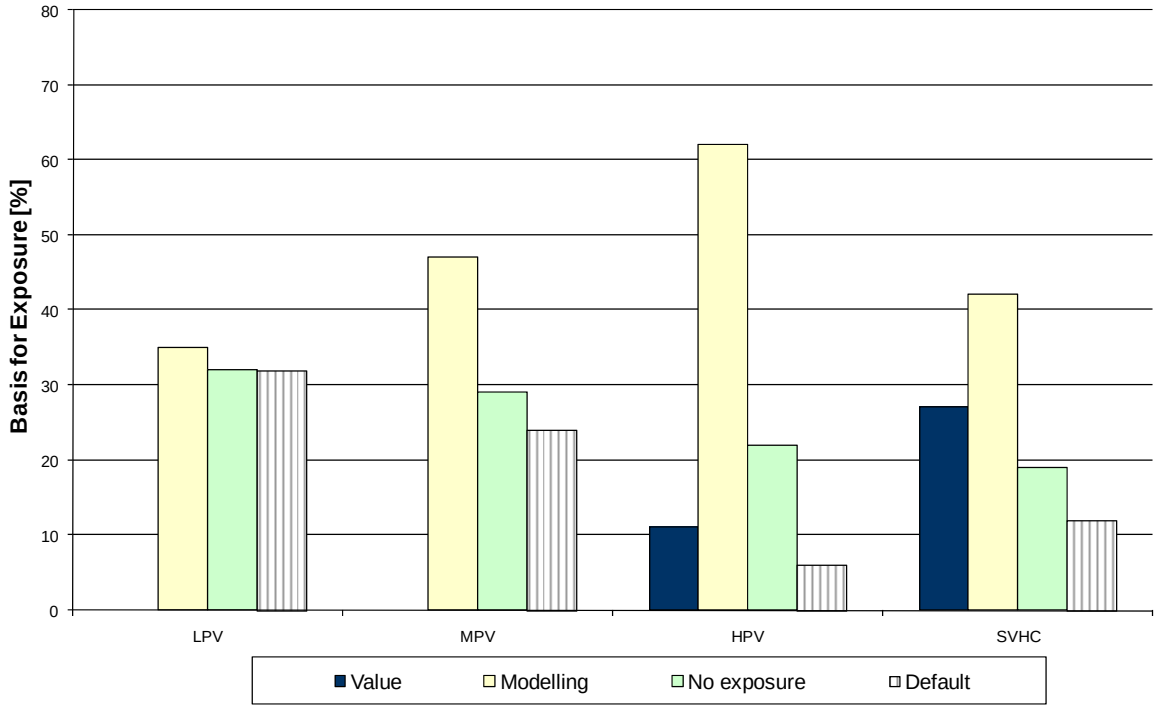


Figure 6.17 Baseline data availability analysis for exposure data (consumers)

Figure 6.17 currently provides less differentiation since most of all the exposure assessments (for LPVs, MPVs, HPVs and SVHCs) had to be done by modelling.

However, in slightly more than 10% of the HPVs and almost 30% of the SVHCs, highly qualified exposure assessments from RARs including in Chemrisks could be used to assess exposure. It is assumed that, in future evaluations, exposure assessments from chemical safety reports (CSRs) will be available to serve as high-quality input for the risk calculation.

Table 6.7 demonstrates the better quality in toxicity input data and in exposure input data for HPVs compared to substances from the other two production bands. This analysis provides details in addition to Figure 6.16 and Figure 6.17.

		LPV (n=105)	MPV (n=45)	HPV (n=65)	SVHC (n=25)
QStox	**Median**	8,0	0,0	7,0	9,0
	GM	6,8	6,8	6,5	6,5
	10th percentile	5,0	5,0	4,4	3,0
	90th percentile	9,0	9,0	9,0	10,0
	MIN	2,0	4,0	2,0	2,0
	MAX	10,0	10,0	10,0	10,0
QSexp	**Median**	7,0	7,0	7,0	7,0
	GM	7,0	7,0	5,4	4,3
	10th percentile	5,0	5,0	1,8	1,0
	90th percentile	10,0	10,0	8,0	9,0
	MIN	1,0	5,0	1,0	1,0
	MAX	10,0	10,0	10,0	9,0

NB: Included in this set are 3 substances already evaluated within the HPV/MPV/LPV categories. Therefore the number of substances given in the single columns exceeds the total number of substances by three.

Table 6.7 Quality Score for toxicity and exposure assessments (consumers), distribution analysis

Figure 6.18 shows the assumed exposure concentration on the x-axis and the assumed safe concentration (as expressed by the $DNEL_{analogues}$) on the y-axis for all 215 substances excluding the substances for which the exposure score is 0. The dashed diagonal line discriminates exposure higher or lower than the $DNEL_{analogue}$.

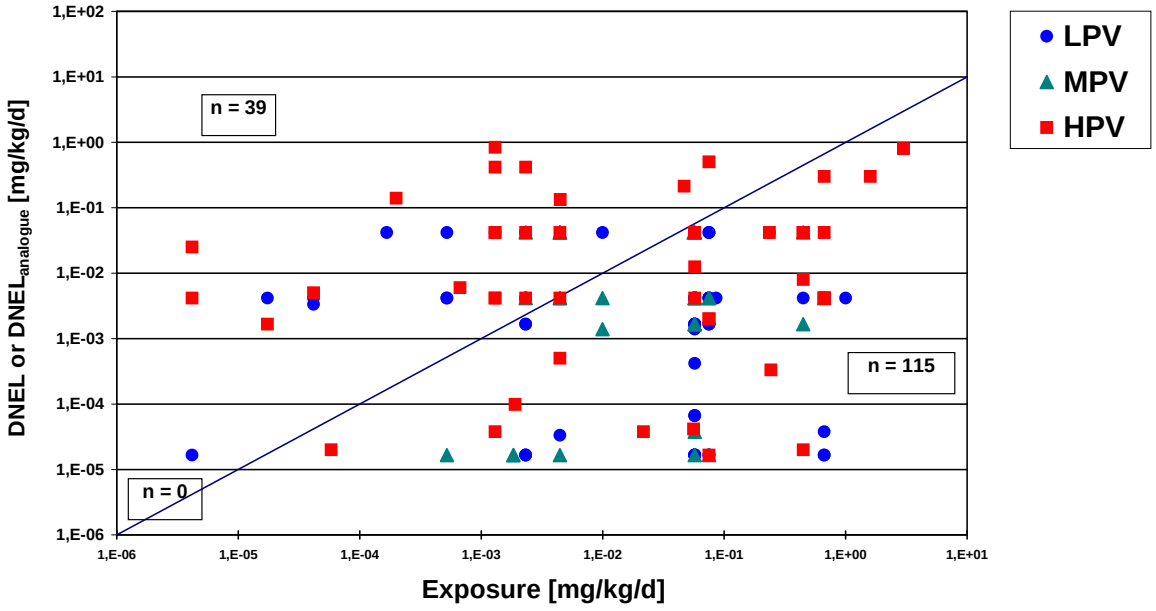


Figure 6.18 Baseline analysis of the risk characterisation ratio (consumers)

Figure 6.18 thus shows the risk characterisation ratio (RCR) for all substances with RCR < 1 (n=39) on the left-hand side of the diagonal line and RCR > 1 (n=115) on the right-hand side of this dashed line. It may be assumed that as a result of REACH there will be a clearly visible shift towards RCRs lower than one (to the upper left-hand triangle in the Figure 6.18) because REACH demands risk management measures ensuring that exposure is below the DNEL. Figure 6.18 does not consider the 61 substances with an exposure score equal to zero.

Based on the set of 215 randomly selected substances, if all substances are considered (including substances for which the exposure score is 0) and if we apply a criterion of 0.01 (RCR < 0.01), 70 substances (33%) can be assumed to be of "low relevance" for consumers.

Based on the set of 237 substances (including SVHCs), if all substances are considered (including substances for which the exposure score is 0) and if we apply a criterion of 0.01 (RCR < 0.01), 76 substances (32%) can be assumed to be of "low relevance" for consumers.

6.1.3 Impact area: environment

6.1.3.1 Summary level

The summary level excludes the substance of very high concern (SVHC). It focuses on the set of 215 randomly selected substances. At the summary level for the impact area of the environment in the year 2007, the Risk Score is **0.04** (geometric mean) and the Quality Score is **26** (geometric mean). Figure 6.19 and Figure 6.20 show these scores.

In order to rank the Aggregated Baseline Risk Score (environment), it is helpful to compare the mean Risk Score for the 215 substances with the Risk Scores of some "well known" substances. For the environment, dibutyl ether (low risk), butadiene (medium risk) and chlorine (high risk) were selected.

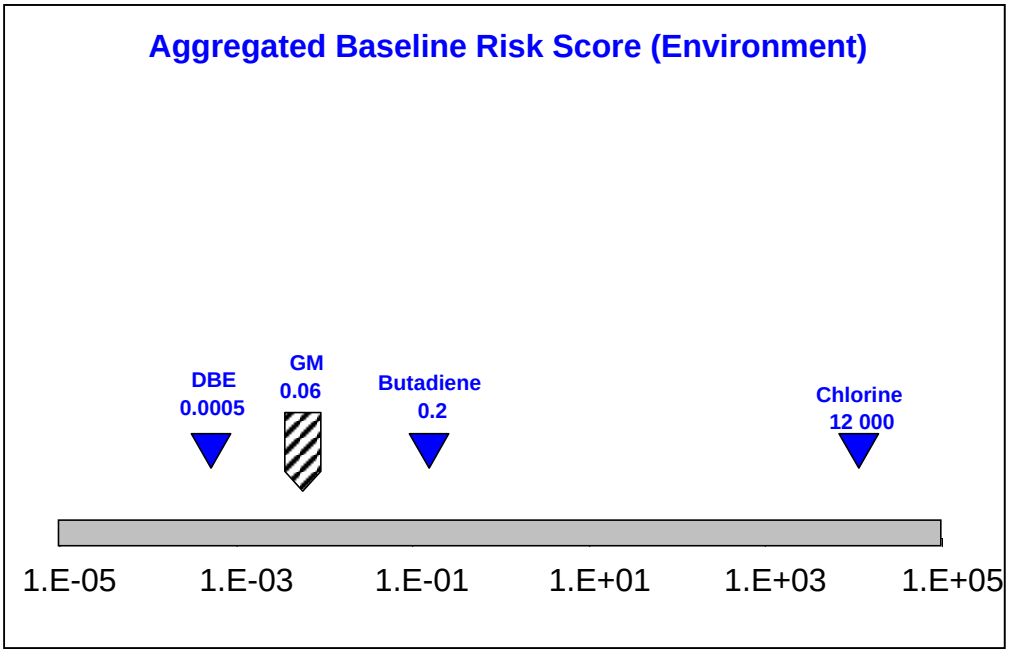


Figure 6.19 Summary level: Aggregated Baseline Risk Score (environment, n=215)

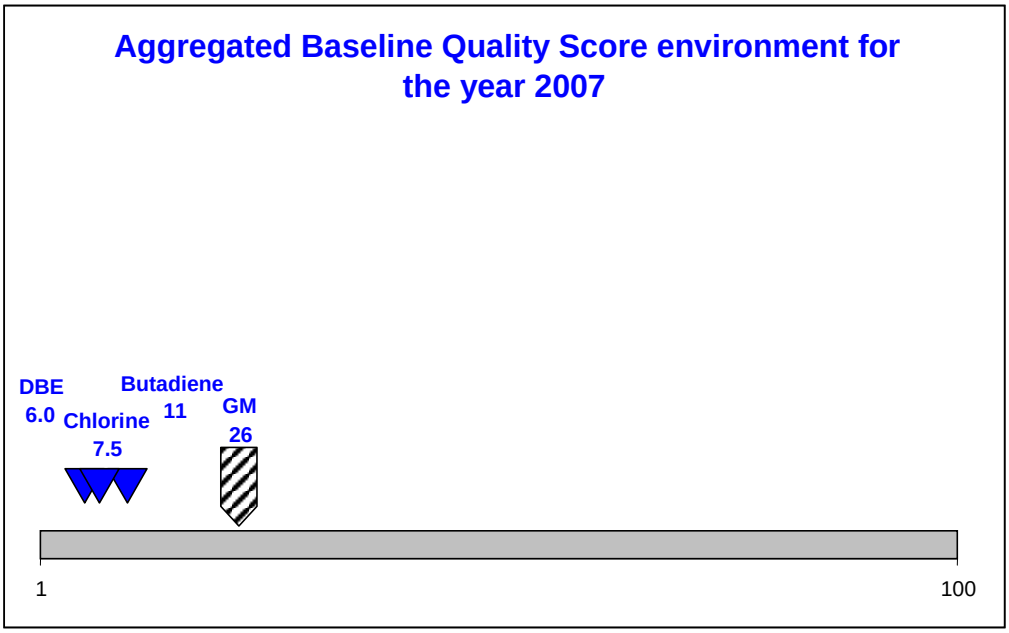


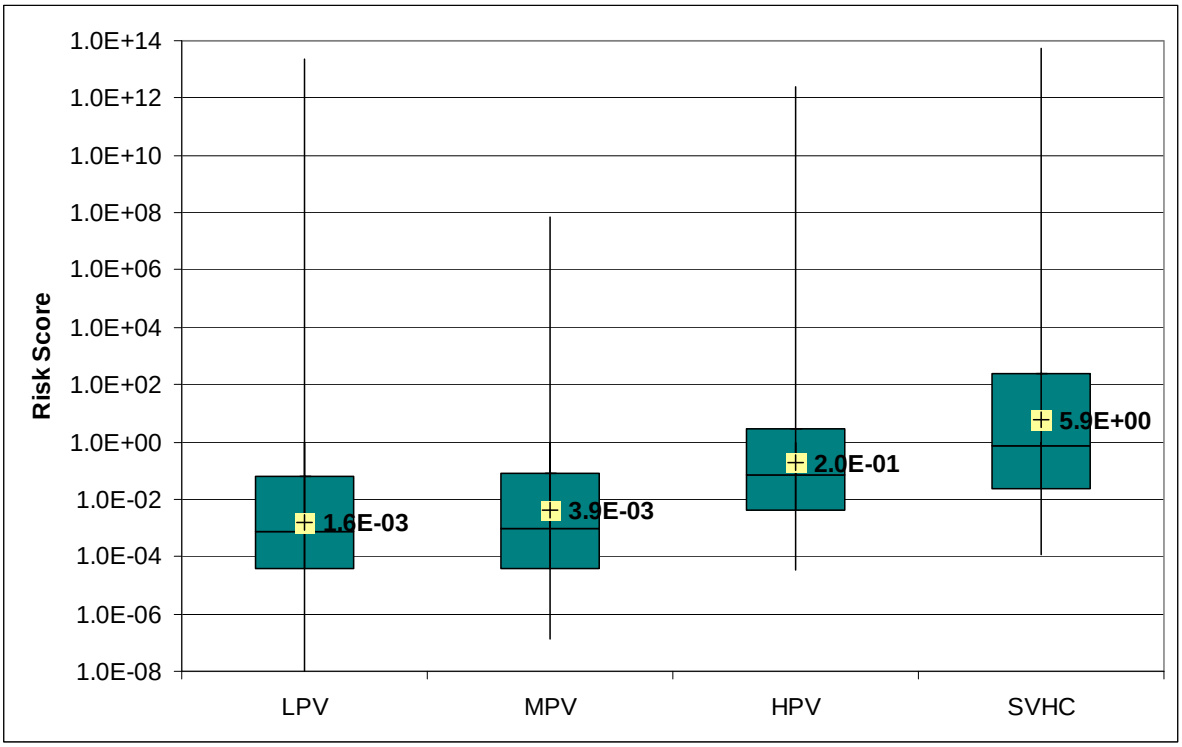
Figure 6.20 Summary level: Aggregated Baseline Quality Score (environment, all substances), n=215

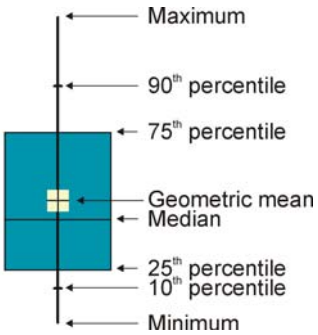
It is much easier to rank quality since there is by definition a theoretical maximum and minimum for the Aggregated Baseline Quality Score. Quality Scores between 3 and 66 were assigned to 215 substances in our set, showing all from good (QS_{total} = 3) to low (QS_{total} = 66) quality.

6.1.3.2 Profile level

As for the other impact areas, whisker plots have been prepared for the environment. Figure 6.21 shows the whisker plot for the Risk Scores and Figure 6.22 shows the whisker plot for the Quality Scores.

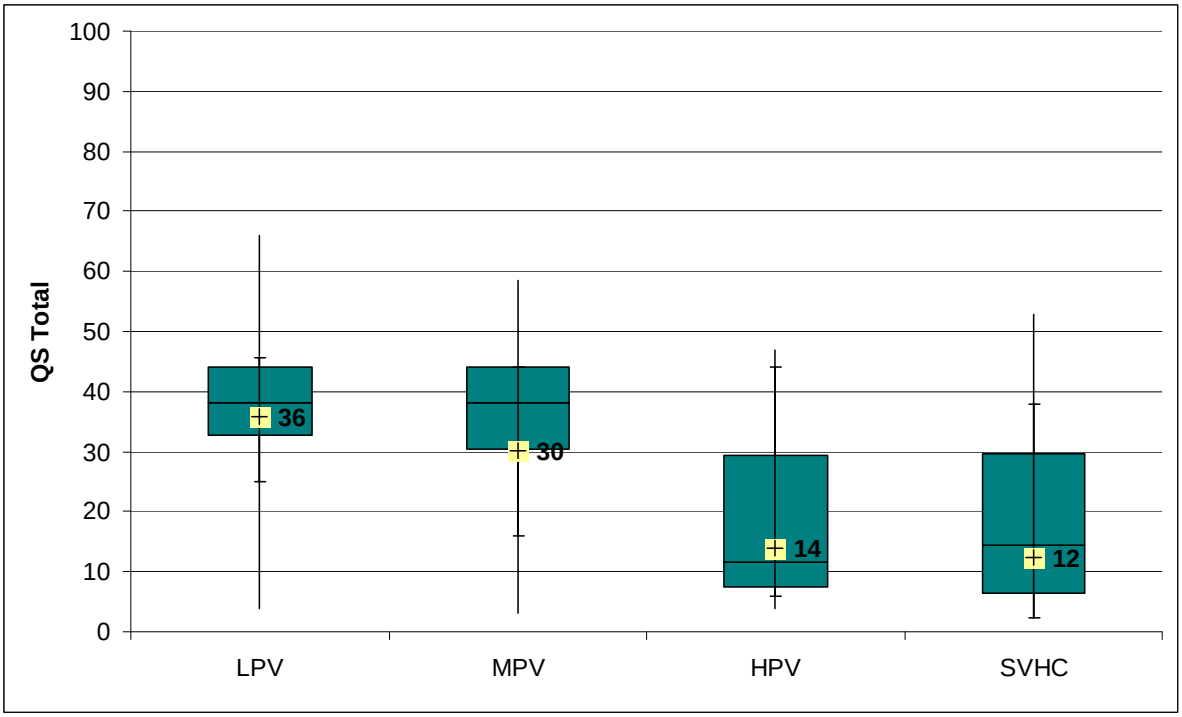
Figure 6.21 demonstrates that there is some interrelationship between the assigned Risk Scores and the three production bands (HPV, MPV, LPV) at baseline. This is to be expected since the exposure scores for the environment are linked to the tonnage of the chemical in question. Furthermore, Figure 6.21 demonstrates that the SVHCs in general have a higher Risk Score than the other substances.

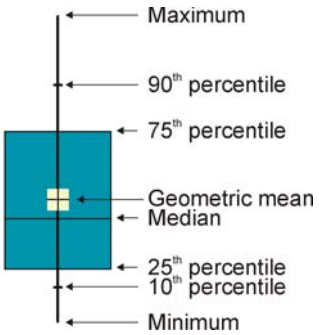




Statistics	LPV	MPV	HPV	SVHC
Min	1.0E-08	1.3E-07	3.3E-05	1.1E-04
Percentile 10	5.0E-07	8.2E-07	6.0E-04	1.2E-02
Percentile 25	3.7E-05	4.0E-05	4.4E-03	2.4E-02
Median	7.5E-04	9.1E-04	7.3E-02	7.7E-01
GM	1.6E-03	3.9E-03	2.0E-01	5.9E+00
Percentile 75	6.1E-02	8.2E-02	2.7E+00	2.5E+02
Percentile 90	6.9E-01	1.8E+01	1.9E+02	3.3E+03
Max	2.2E+13	6.9E+07	2.5E+12	5.6E+13

Figure 6.21 Baseline Risk Score Profile (environment)





Statistics	LPV	MPV	HPV	SVHC
Min	4	3	4	2
Percentile 10	25	16	6	2
Percentile 25	33	30	8	6
Median	38	38	12	15
GM	36	30	14	12
Percentile 75	44	44	29	30
Percentile 90	46	44	44	38
max	66	59	47	53

Figure 6.22 Baseline Quality Score Profile (environment)

Figure 6.22 shows that the data quality for HPVs and SVHCs is usually better than for the MPVs or LPVs at baseline. There is almost a factor 2-3 difference in the geometric mean for the respective groups. REACH is expected to provide better quality of information on MPVs in the next decade (and later for LPVs). Therefore, the Quality Score, especially for MPVs, is expected to decrease significantly within the coming decade — even with a limited set of substances monitored within this indicator system.

In addition, the risk and quality profile may also be presented as a cloud. Figure 6.23 shows the risk and quality scores of the selected substances in one graph. Please note the log scale of the Risk Score. The figure demonstrates the large range of risks for the individual substances. Furthermore, it confirms the observations that in general the Quality Scores for the HPVs and the SVHCs are lower than for the MPVs and LPVs.

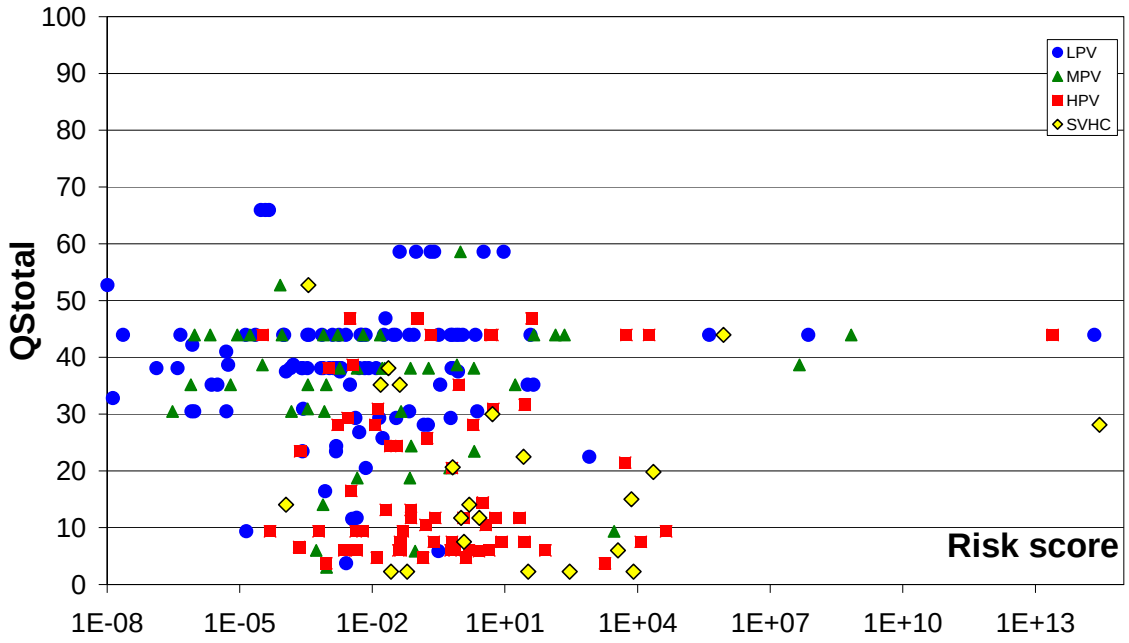


Figure 6.23 Baseline Risk and Quality Scores (environment), log scale for Risk Score, n=232. All substances withn an RCR < 1·10^{-8} discarded

6.1.3.3 Analysis level

The results obtained for the R&Q indicator system permit many more detailed analyses. As an example, Table 6.8 gives a brief overview of the data sources for some of the most essential data: log K_{ow}, biodegradation and ecotoxicity. The number in the table is given in percentage, meaning that for example that for biodegradation data, 10% has been retrieved from IUCLID.

It can be seen that QSAR has been used quite extensively especially for retrieving biodegradation data.

Data source	Log K_{ow}	Biodegradation	Ecotoxicity data
RAR	3	3	1
IUCLID	12	10	15
Other data	16	6	15
QSAR	62	74	60
Default/guestimate	8	7	9

Table 6.8 Data availability for environment

A very interesting analysis is provided in Figure 6.24. This assumed exposure concentration is shown on the x-axis and the effect score on the y-axis. The diagonal line discriminates exposure higher or lower than the effect score value (pseudo-PNEC).

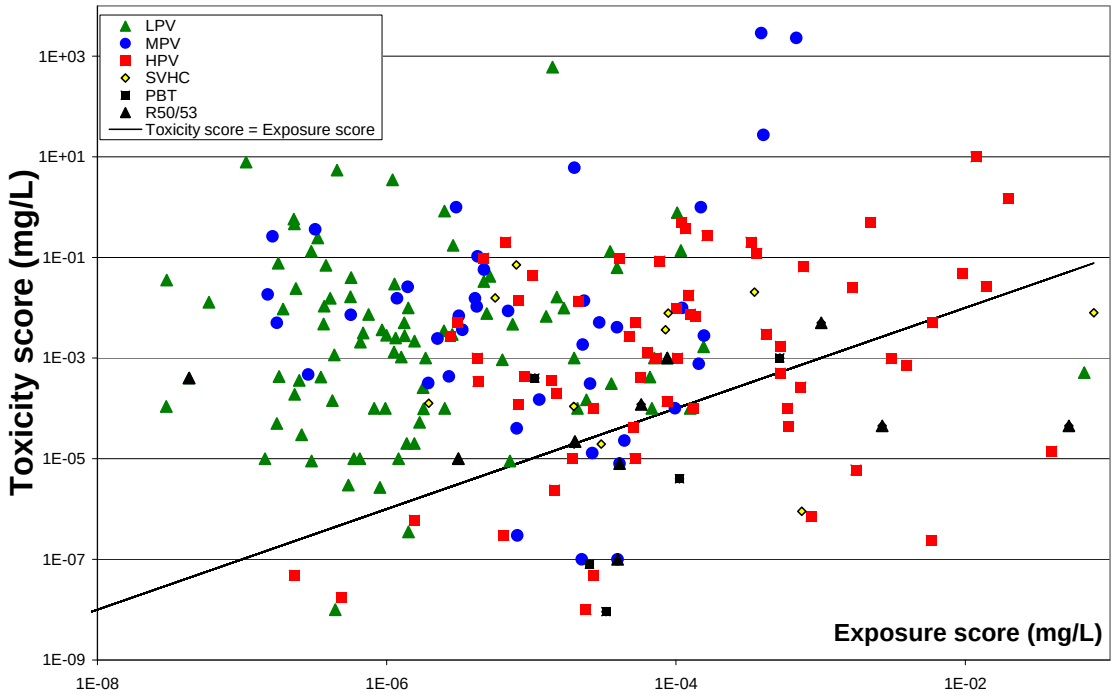


Figure 6.24 Baseline analysis of the risk characterisation ratio (environment). The SVHCs and all substances with an RCR<10^{-8} excluded from the plot

Figure 6.24 thus shows the risk characterisation ratio (RCR) for all substances with RCR < 1 (n=176 (excluding the SVHC, n=184 including the SVHCs) on the left-hand side of the diagonal line and RCR > 1 (n=39 excluding the SVHC, n=53 including the SVHCs) on the right-hand side of this diagonal line. It is interesting to note that the majority of substances with an RCR above 1 are either HPVs or SVHCs. Even though the indicator system does not provide results on the absolute and "real" risk for the environment, it may be assumed that, as a consequence of REACH, there will be a clearly visible shift of the substances with an RCR above 1 towards RCRs lower than 1 (to the left in Figure 6.24) because REACH demands the introduction of sufficient risk management measures in order to ensure safe use.

At this profile level, it would also be possible to exclude subgroups of substances and calculate the respective geometric mean and distribution for the remaining substances only. Such an approach has been performed in order to find out the influence of PBT (n=5) respectively substances classified with R50/53 on the distribution (see Table 6.9).

	Combined	Combined PBTs excluded	Combined PBT and R50/53 excluded
Number of substances	**232**	**227**	**217**
GM	**0.06**	**0.05**	**0.04**
10%	**2.3E-05**	**2.0E-05**	**1.6E-05**
90%	**78.1**	**44.5**	**35.3**

Table 6.9 Influence of PBTs respectively R50/53 substances on the geometric mean and distribution of Risk Scores, All substances with an RCR <10^{-8} excluded

Table 6.9 shows a slightly reduction in the geometric mean after exclusion of 5 PBTs and a higher reduction if also substances with an R50/53 classification. The 10% respectively the 90% fractiles are significantly reduced if the PBTs respectively the PBTs and R50/53 substances are excluded. In conclusion, PBT-substances have some influence on the resulting index.

Table 6.10 shows more details of the distribution of the RCRs (environment). It can be seen that a much higher percentage of the SVHC substances have an RCR above 1 (64%) compared to the LPV/MPV/HPV substances (21%). Around 41% of the SVHC substances have an RCR above 10 and only 12% of the LPV/MPV/HPV substances have an RCR above 10.

Type of substance	Number of substances	RCR≤1	RCR>1	RCR>10
All	232	182 (78%)	50 (22%)	29 (13%)
LPV/MPV/HPV	210	171 (81.4%)	39 (18.6%)	21 (10.0%)
SVHC	22	11 (50%)	11 (50%)	8 (36%)
All - PBT	227	180 (79%)	47 (21%)	26 (11%)
All - PBT and R50/53	217	174 (80%)	43 (20%)	23 (11%)

Table 6.10 Distribution of RCRs (environment)

6.1.4 Impact area: humans via the environment

A risk characterisation ratio (RCR), Risk Score (RS) and Quality Scores(QS_{total}, QS_{tox}, QS_{exp}) were calculated for each of the 115 randomly selected substances and then aggregated at various levels. At profile and analysis levels, the 25 substances of very high concern (SVHCs) are also considered in the results.

As for consumers but to a lesser extent, results for humans via the environment include one substance for which it has been found that there is no exposure to this population.

As a result, for statistical and graphical purposes, this "exposure 0" substance is not included in the exposure score, RCR and Risk Score levels of analysis. The number of substances considered is indicated at each step in the analysis. However, this substance is included for the Quality Score level of analysis and for the analysis of the sources of the estimates.

6.1.4.1 Summary level

The summary level excludes the 25 substances of very high concern (SVHCs). It focuses only on the set of 215 randomly selected substances.

At the summary level for the impact area of humans via the environment in the year 2007, the Risk Score is **30** (geometric mean) and the Quality Score is **48** (geometric mean). Figures 6.25 and 6.26 show these scores. Figure 6.25 does not take into account one of the 115 randomly selected substances for which the exposure score is 0, whereas Figure 6.26 includes all the 215 substances.

In order to rank the Aggregated Baseline Risk Score (humans via the environment), it is helpful to know that a Risk Score of 0.1 would certainly be called "low", whereas a Risk Score of 50 would certainly be called "elevated". However, calculated Risk Scores for the 215 substances varied over a much wider range (14 orders of magnitude). Therefore, no upper or lower bounds were set. Instead, it may be helpful to compare the mean Risk Score for the 215 substances with the Risk Scores of some "well known" substances.

For the humans via the environment impact area, the following substances have been chosen:

- Aniline: for this substance, a risk assessment report (RAR) from the European Commission has been published (Reg. 793/93). The conclusion drawn for humans exposed via the environment is that a risk has been identified. Risk and quality scores have been calculated for this substance using the methodology presented in this report and the data available in the RAR.
- Ethyl acetoacetate: for this substance too, a risk assessment report (RAR) from the European Commission has been published (Reg. 793/93). The conclusion drawn for humans exposed via the environment is that there is no risk. Risk and quality scores have been calculated for this substance using the methodology presented in this report and the data available in the RAR.

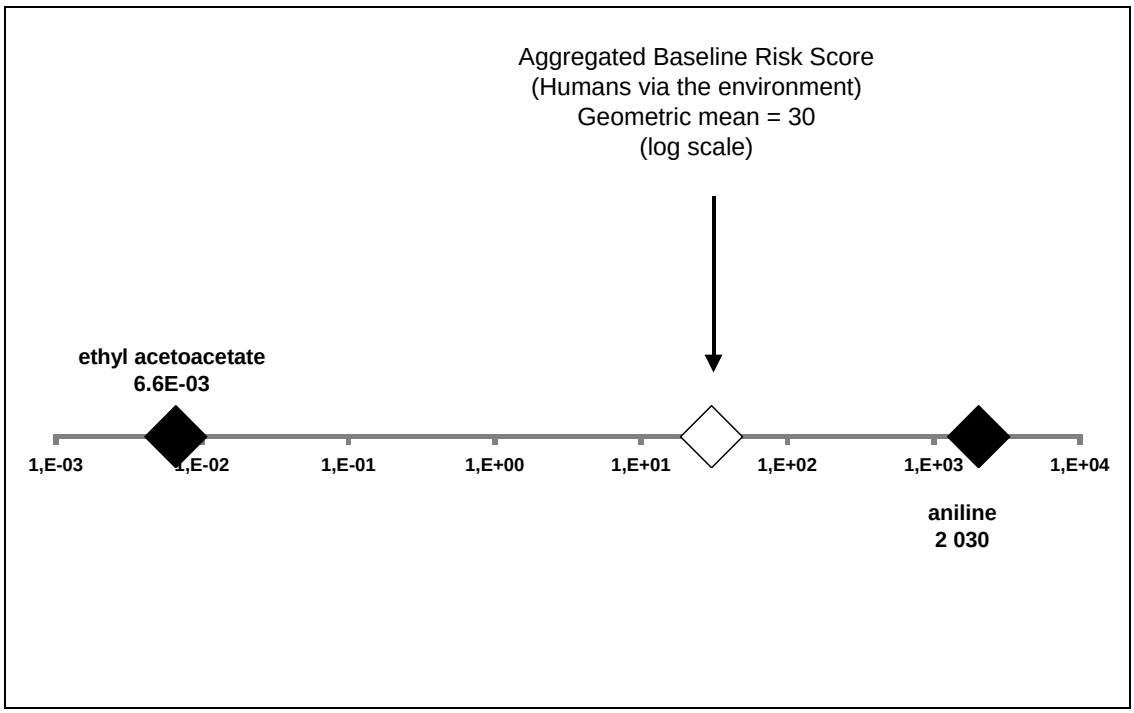


Figure 6.25 Summary level: Aggregated Baseline Risk Score (humans via the environment, 1 substance with Risk Score equal to 0 excluded)

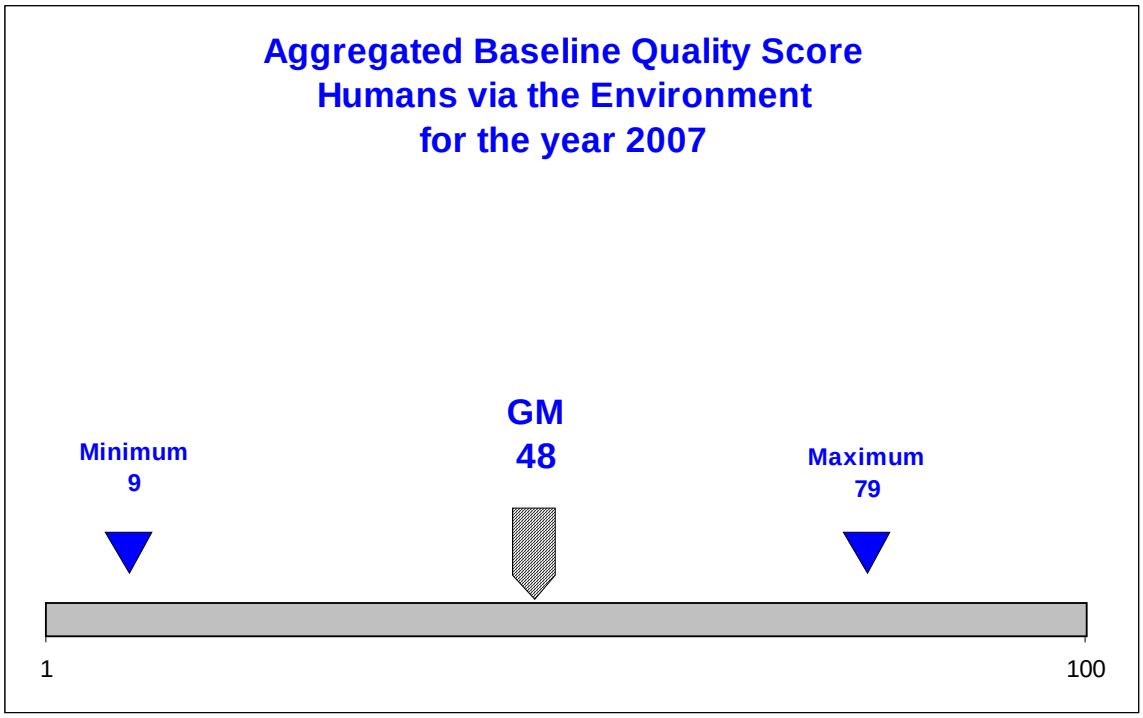


Figure 6.26 Summary level: Aggregated Baseline Quality Score (humans via the environment, all substances)

It is much easier to rank quality, as there is by definition a theoretical maximum and minimum for the Aggregated Baseline Quality Score. Quality Scores between 9 and 79 (Figure 6.26) were assigned to 215 substances in our set, showing all from excellent (QS_{total} = 9, close to 1) to insufficient (QS_{total} = 79, close to 100) quality. We propose not to use a reference substance for quality because of the clear boundaries of the ranking range. Therefore, such a substance is not marked in Figure 6.26.

At this summary level, the calculated mean risk and quality scores are mainly intended to be used in comparison to later points in time, i.e. in the year 2012 or later. The change in the Aggregated Baseline Risk Score and Quality Score over the years may be a headline indicator for political communication. As these single figures are much too complex for further interpretation, the other levels (profile level, analysis level) are supplemented.

We propose not to amalgamate the Quality Score and the Risk Score into a single figure. Moreover, any comparisons between different impact areas should be strictly avoided. Such comparisons would mean a misinterpretation because, for example, different reference points for risk calculation are used in the different impact areas.

6.1.4.2 Profile level

The profile level provides some more details for better interpretation compared to the summary level. At the profile level, a distinction between HPVs, MPVs and LPVs is made. In addition, results for the 25 SVHCs are also provided. However, at this level we are still referring to Risk Scores and Quality Scores and not to the various sub-factors.

Figure 6.27 does not take into account one substance for which the exposure score is 0 among the 215 randomly selected substances plus the 25 SVHCs (n=172). Figure 6.28, showing Quality Scores, takes into account all substances (n=237).

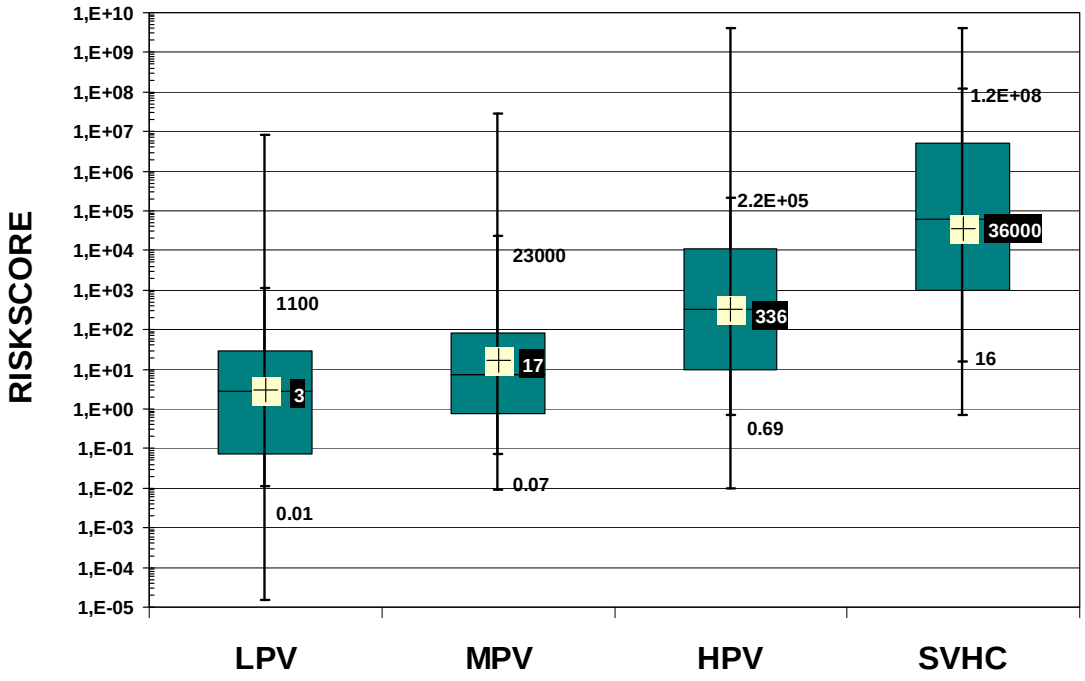


Figure 6.27 Baseline Risk Score Profile (humans via the environment). Numerical values given for geometric mean, 10th percentile and 90th percentile

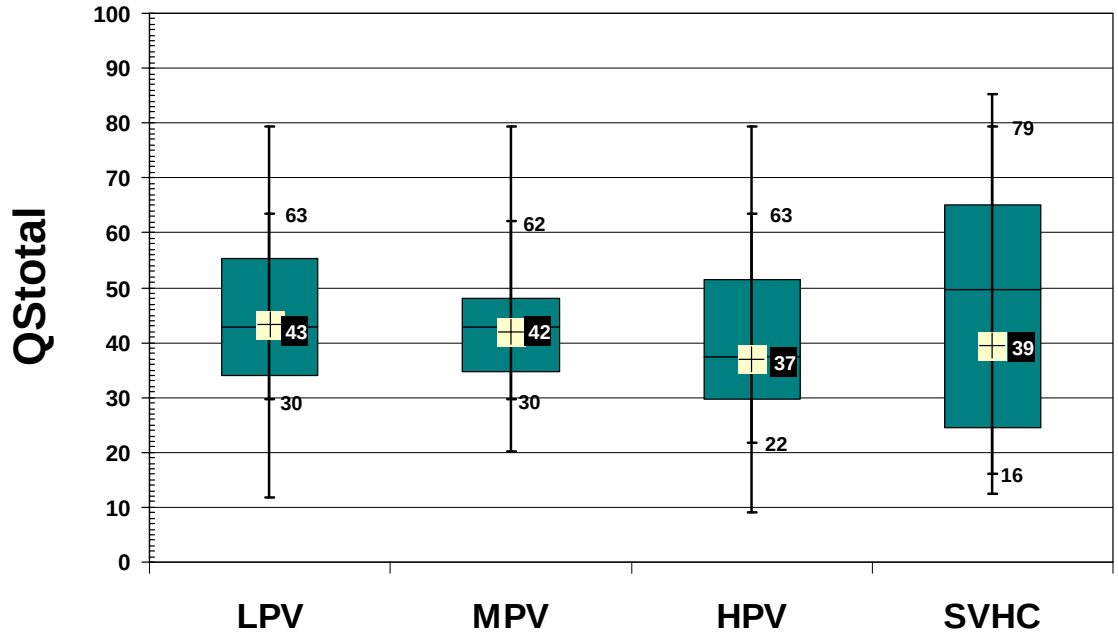


Figure 6.28 Baseline Quality Score Profile (humans via the environment). Numerical values given for geometric mean, 10th percentile, 90th percentile

Figure 6.27 demonstrates an increase in the Risk Scores with the consumption volumes in Europe. This increase is clearly observed from LPVs to HPVs. This can be explained by the way the exposure score is calculated for humans via the environment. The exposure for this impact area is mostly based on the environmental concentrations (in air, water and soil) which are often calculated using exposure scenarios assigning emission fractions to the tonnage of the substance used on a site. Consequently, in the absence of monitoring data for the environment (which is the case for most substances), the higher the tonnage, the higher the exposure score. We can also note an increase in the Risk Scores calculated for SVHCs. This is due to the higher toxicity scores for this group of hazardous chemicals.

Figure 6.28 shows the usually better data quality for HPVs and SVHCs than for MPVs or LPVs at baseline. As REACH will probably provide better quality of information on MPVs in the next decade (and later for LPVs), it is assumed that the Quality Score will most probably decrease significantly, even with a limited set of substances monitored within this indicator system.

The background result summary data are also provided in Table 6.11 for the 215 randomly selected substances and in Table 6.12 for the 25 SVHCs.

		LPV, MPV and HPV
RISKSCORE Human via envir. (n=214)	**Median**	21
	GM	30
	10th percentile	7,E-02
	90th percentile	4,E+04
	MIN	1,E-05
	MAX	4,E+09
QStotal Human via envir. (n=215)	**Median**	48
	GM	48
	10th percentile	34
	90th percentile	71
	MIN	9
	MAX	79

Table 6.11 Results of Risk Scores and Quality Scores for LPV, MPV and HPV substances (humans via the environment), distribution data (25th and 75th percentiles) not reported

		SVHC
RISKSCORE Human via envir. (n=25)	Median	6,E+04
	GM	2,E+03
	10th percentile	2,E+01
	90th percentile	1,E+08
	MIN	7,E-01
	MAX	4,E+09

QStotal Human via envir. (n=25)	Median	51
	GM	38
	10th percentile	16
	90th percentile	79
	MIN	13
	MAX	85

Table 6.12 Results of Risk Scores and Quality Scores for substances of very high concern (humans via the environment), distribution data (25th and 75th percentiles) not reported

In addition, the risk and quality profile may also be presented as a cloud. Figure 6.29 shows the risk and quality scores of the selected substances in one graph in log scale (only for Risk Score) to demonstrate the large range of risks for the individual substances.

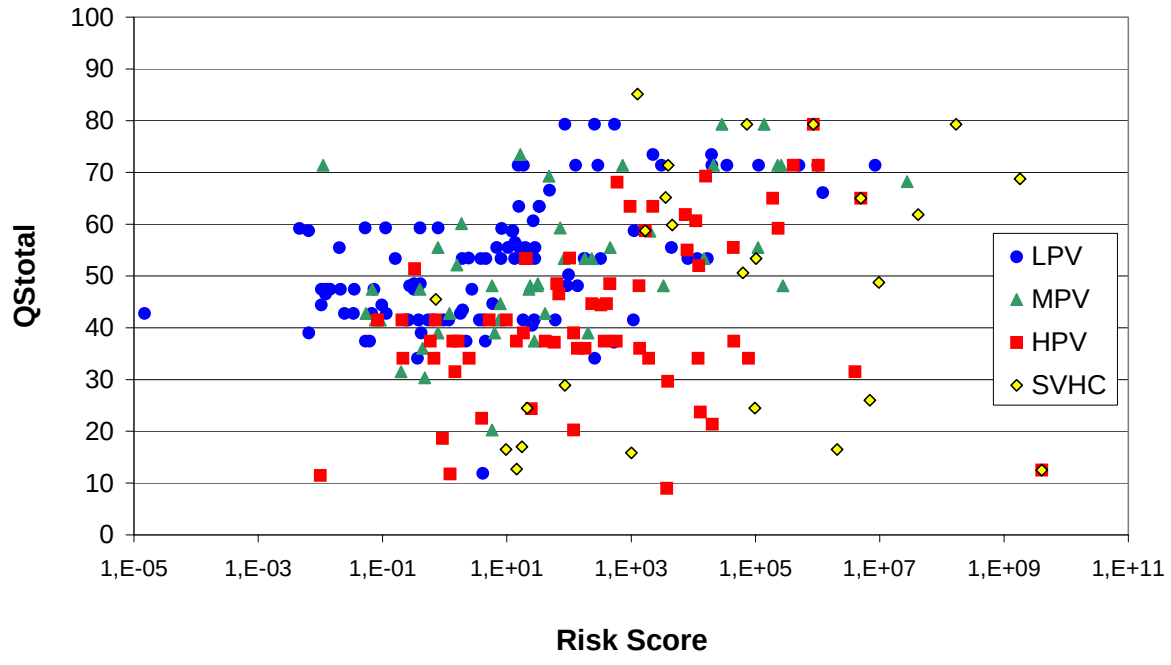


Figure 6.29 Baseline Risk and Quality Scores (humans via the environment), log scale for Risk Score, n=139

6.1.4.3 Analysis level

The type of calculations and the documentation used for the R&Q indicator system permit many more detailed analyses. For example, the analyst may wish to be informed on the availability of high-quality input data for toxicity or exposure assessment compared to the "second-choice" substitute information which had to be used.

For humans via the environment, this analysis should be based on the analysis done in the consumer impact area for toxicity scores on one hand and, on the other hand, in the environment impact area for exposure score determination. However, as indicated in the description of the methodology and in Appendix IV, some specific information can also be used to refine the exposure assessment for humans via the environment. For example, monitoring data and transfer factors have been searched through for the selected substances.

Adequate monitoring data have not been found for any of the selected substances, even when RARs were available. Concerning transfer factors, no data were found in the selected database for the substances included in this baseline study; only measured BCFs for eight substances were found (three HPVs, one MPV and four SVHCs). This picture should change with the application of REACH requirements where bioaccumulation studies will be required for substances produced or imported above 100 tonnes in Europe (Annex IX), i.e. MPVs and HPVs. This information will be particularly important for bioaccumulative substances, enabling a refinement of the Risk Score and triggering a better Quality Score.

Table 6.13 demonstrates the better quality in toxicity input data and in exposure input data for HPVs than for substances from the other two production bands.

		LPV (n=105)	MPV (n=45)	HPV (n=65)	SVHC (n=25)
QStox	**Median**	8,0	0,0	7,0	9,0
	GM	6,8	6,8	6,5	6,4
	10th percentile	5,0	5,0	4,4	2,8
	90th percentile	9,0	9,0	9,0	10,0
	MIN	2,0	4,0	2,0	2,0
	MAX	10,0	10,0	10,0	10,0
QSexp	**Median**	5,9	5,9	5,6	6,5
	GM	6,3	6,2	5,7	6,1
	10th percentile	5,3	5,0	4,5	4,1
	90th percentile	7,9	7,9	7,8	7,9
	MIN	4,7	4,5	2,5	2,5
	MAX	7,9	7,9	8,5	8,5

NB: Included in this set are 3 substances already evaluated within the HPV/MPV/LPV categories. Therefore the number of substances given in the single columns exceeds the total number of substances by three.

Table 6.13 Quality Score for toxicity and exposure assessments (humans via the environment), distribution analysis

Figure 6.30 shows the assumed exposure concentration on the x-axis and the assumed safe concentration (as expressed by the $DNEL_{analogues}$) on the y-axis for 215 substances excluding the substance for which the exposure score is 0. The dashed diagonal line discriminates exposure higher or lower than the $DNEL_{analogue}$.

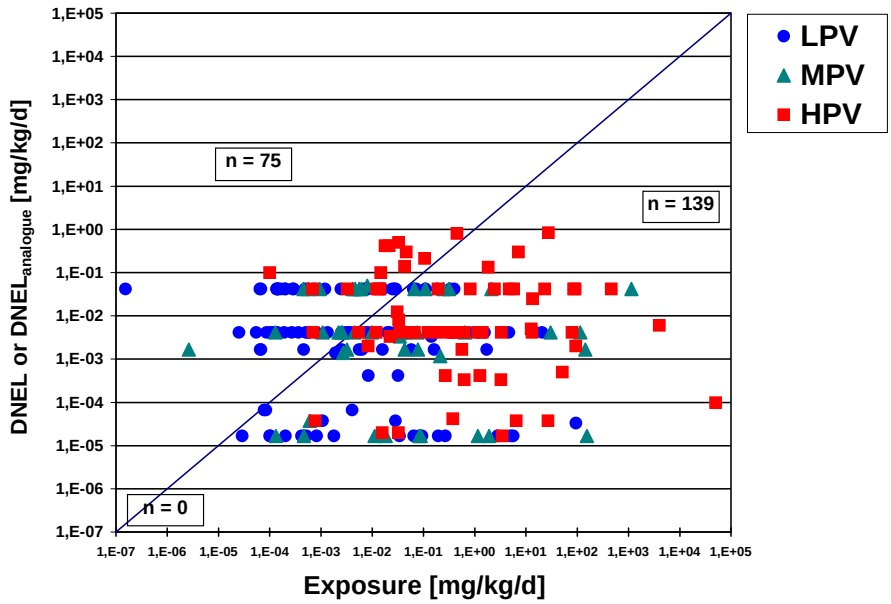


Figure 6.30 Baseline analysis of the risk characterisation ratio (humans via the environment)

Figure 6.30 thus shows the risk characterisation ratio (RCR) for all substances with RCR < 1 (75 substances) on the left-hand side of the diagonal line and RCR > 1 (139 substances) on the right-hand side of this dashed line. It may be assumed that, as a consequence of REACH, there will be a clearly visible shift towards RCRs lower than one (to the upper left-hand triangle in Figure 6.30) because REACH demands risk management measures ensuring that exposure is below the DNEL. Figure 6.30 does not consider one substance with an exposure score equal to zero.

Based on the set of 215 randomly selected substances, if all substances are considered (including the substance for which the exposure score is 0) and if we apply a criterion of 0.1 (RCR < 0.1), 42 substances (18%) can be assumed to be of "low relevance" for humans via the environment (Figure 6.30).

6.1.5 Discussion

The Risk & Quality indicator system in this baseline study as elaborated for workers shows reasonable results, differentiation and sensitivity to changes. The calculations permit relative comparisons between substances from the different production bands (i.e. tonnages above 1 000 tonnes per year, 100 to 1 000 tonnes per year and 10 to 100 tonnes per year) as well as with substances of very high concern and allow for comparisons to future points in time. Both changes in risk and changes in the quality of information can be observed and analysed in comparison to the baseline (i.e. the year 2007). Despite the limited set of substances monitored, this indicator system apparently provides sufficient sensitivity to demonstrate REACH-related changes.

Future changes in risk characterisation ratios and in Risk Scores will not be trivial. Due to the better quality of information available in the process of REACH, some $DNEL_{analogues}$ may have to be corrected downwards or upwards when they become DNELs. Poor modelling results for exposure will be substituted by better calculations or measurements. Again, this may lead to upward or downward corrections of the exposure estimate and thus to some unpredictable changes in the risk characterisation ratio in the future. However, an overall trend towards RCRs close to 1 or below 1 is predicted according to the principles of REACH. It will be interesting to observe the speed of this development, the differentiation for substances from the different production bands and the simultaneous changes in information quality.

As already described, the indicator system does not provide results on the absolute and "real" risk for workers at baseline or in the future. No worker will be exposed throughout his or her working life to the exposure concentration assumed in the scenarios of this indicator and many assumptions in toxicity and exposure assessments include relevant, inherent, and thus unavoidable uncertainties. However, the calculated figures correlate to a plausible risk profile. This risk profile is established by scientific approximations and widely agreed conventions in handling uncertainty. The depth of assessment is balanced against transparency for non-experts (e.g. only a limited number of sources were used) and the handling of a sufficiently large amount of substances to create a meaningful index. However, because of the relatively simple assessment procedures used and the "nominal" character of the calculated risk, no absolute interpretation of the Risk Score or the risk characterisation ratio should be performed. For example, the interpretation of an RCR >1 as a "dangerous" situation at the workplace or an RCR of <1 as a "safe" situation is clearly an over-interpretation of this parameter.

6.2 Supplementary indicators

6.2.1 Production of toxic chemicals

The indicator 'Production of toxic chemicals' depicts a selection of 162 identified toxic chemicals out of a total of 387 chemicals from the European production statistics database (Prodcom[51], Eurostat). The selected chemicals have been chosen from the Prodcom sectors “Manufacture of industrial gases”, “Manufacture of dyes and pigments”, “Manufacture of other inorganic basic chemicals”, “Manufacture of other organic basic chemicals” and “Manufacture of fertilizers and nitrogen compounds”.

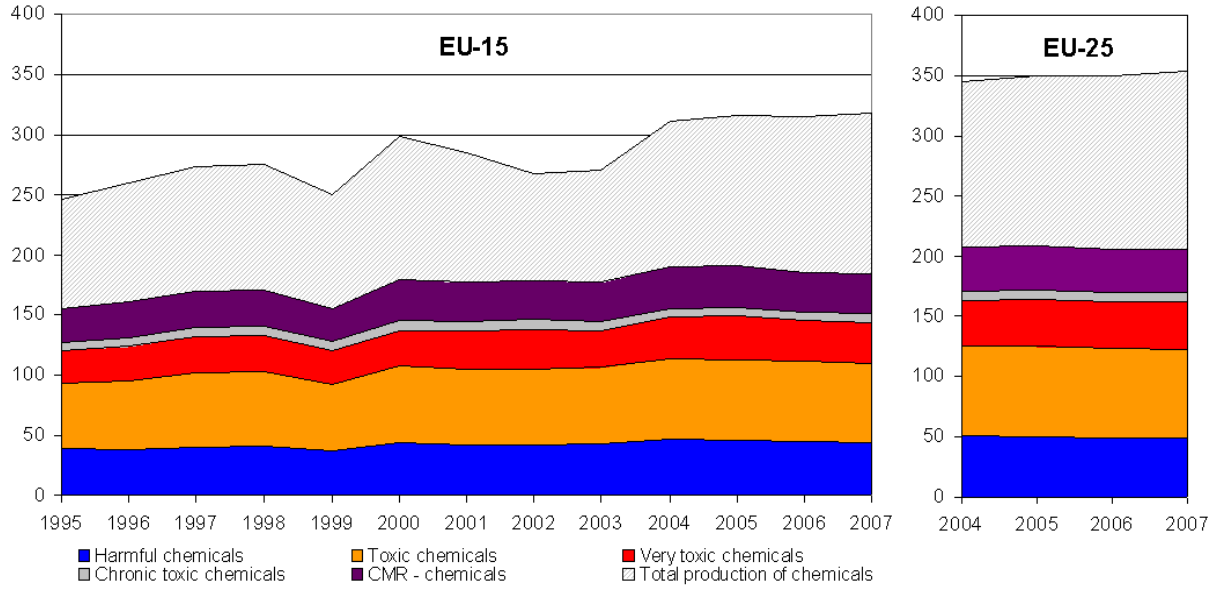


Figure 6.31 Total production volume of chemicals, toxic chemicals and CMR chemicals in EU-15 and EU-25 and NMS-10 (3 years only)

Figure 6.31 shows the indicator presenting the trend in aggregated production volumes of toxic chemicals, broken down into five toxicity classes. Over the 12 years covered, Figure 6.31 highlights the steady volume growth of the chemical industry.

The toxicity classes, beginning with the most dangerous, are: Carcinogenic, Mutagenic and Reprotoxic (CMR-chemicals); Chronic toxic chemicals; Very toxic chemicals; Toxic chemicals and chemicals classified as harmful.

This indicator monitors progress in shifting production from the most toxic chemicals to less toxic classes. (The indicator does not provide information on the risk from the use of chemicals: Production and consumption are not synonymous with exposure, as some chemicals are handled in closed systems, or as intermediates in controlled supply chains.)

Between 1995 and 2007 the total production of chemicals has grown by 28% (EU-15). The production of chemicals classified as toxic increased by 21% between 1995 and 2005 and decreased slightly (-3%) in 2006 / 07. Over the last 12 years statistics highlight the steady growth of total chemicals production volume.

The share of toxic chemicals in the total production is around 58% in EU-15 and EU-25 in 2007. The absolute production volumes of CMR chemicals remained stable at around 33 million tonnes (EU-15) and 36 million tonnes (EU-25).

Statistics available from 2004 onwards show that the 10 new Member States (NMS-10) produce only around 10% of all toxic chemicals in EU-25. However, an in-depth analysis shows a steady growth of toxic chemicals production in these countries: +18%, with a strong increase for CMR chemicals (+33%). The share of toxic chemicals in the total production increased from 55% to 61% between 2004 and 2007.

The coming years will show if the trend to a relative decoupling of toxic chemicals production from the growth of total output and Gross Domestic Product can be confirmed.

[51] The number of chemicals may change with changes in the nomenclature of the statistic from 1995 to 2005.

6.2.2 Cross-border transport of toxic chemicals

The indicator monitors the movement of toxic chemicals across borders with the help of the foreign trade statistics. Trade between Member States (intra-EU trade) and between Member States and non-member countries (extra-EU trade) is covered. The indicator covers the same 162 substances as the indicator on the production of toxic chemicals.

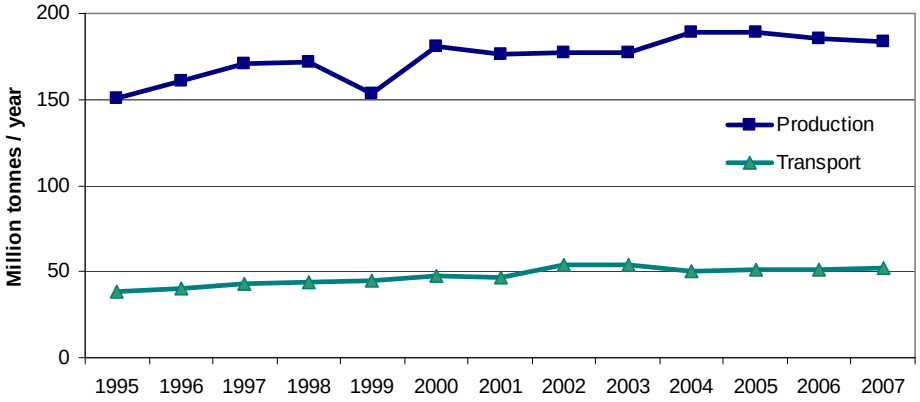


Figure 6.32 Production and cross-border transport of toxic chemicals in EU-15

In the observed selection of toxic chemicals cross-border transport is common. Cross-border transport can take place by road transport, by ship via inland waterways or sea or by pipeline. The statistics give no indication of which type of transport is used.

The data for the production and cross-border transport of toxic chemicals presented in Figure 6.32 covers the period from 1995 to 2007. During the observed period, the production of toxic chemicals increased from approx. 150 million tonnes in 1995 to 183 million tonnes in 2007. At the same time, the cross-border transport of these chemicals increased from 38 million tonnes/year to 52 million tonnes/year.

Comparing production and transport, cross-border transport as a share of production volume increased from 25% to 28%.

The indicator provides additional information on the (geographically) widespread use of toxic chemicals. The European chemical industry has become very specialised and operates in an interwoven network, leading to increased transportation of 'intermediates' and final chemicals products.

6.2.3 Changes in use patterns in Scandinavia

The use patterns for the toxic chemicals monitored in the production of toxic chemicals indicator are explored in the SPIN database via Scandinavian data. As an example, the data highlights the use patterns for those 18 CMR chemicals included in the production indicator. The data have been obtained for Denmark, Sweden and Finland. 6 CMR chemicals are flagged as confidential in SPIN. For the other 12 CMR chemicals, the distribution in economic sectors has been investigated.

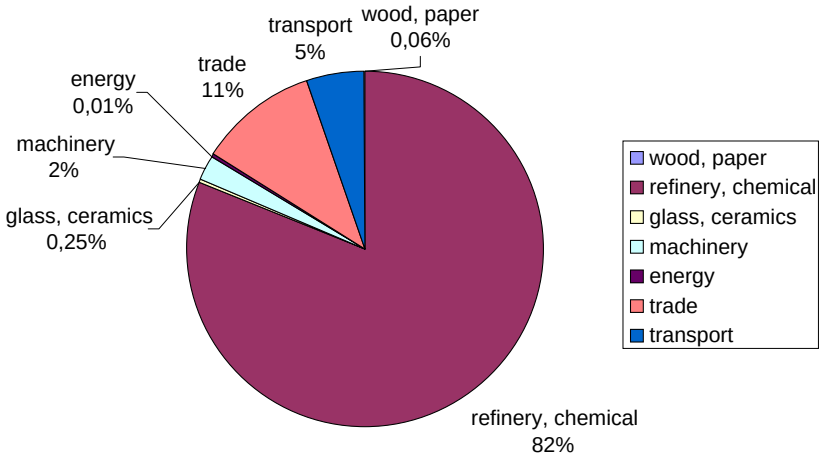


Figure 6.33 Use patterns for 12 CMR chemicals in Scandinavia for the year 2004

Most of the CMR chemicals are used in the refinery/chemical sector for further synthesis. Additional information indicates that the chemicals are used in a wide range of applications. The trade and transport sectors account for 11% and 5%. Both sectors are not specific for chemicals use and may indicate a further distribution of these chemicals. Small amounts of CMR chemicals are delivered to the machinery, glass & ceramic, and wood & paper sector. Other sectors accounting for very small amounts not shown in the figure are agriculture, food preparation, construction and public services.

The distribution among sectors differs significantly for individual chemicals. For example, vinyl chloride is totally absorbed by the refinery/chemicals sector. On the other hand the distribution of chromium trioxide is evenly shared between the wood & paper industry and the machinery industry.

The indicator highlights the use patterns of toxic chemicals in Scandinavian countries. Even for CMR chemicals, the use patterns display a wide variety of economic sectors.

6.2.4 Registration of new chemicals

The ECB maintains a database for new chemicals. This database was retrieved for the year a new chemical was first registered in a Member State. Figure 6.34 illustrates the year-by-year registration performance.

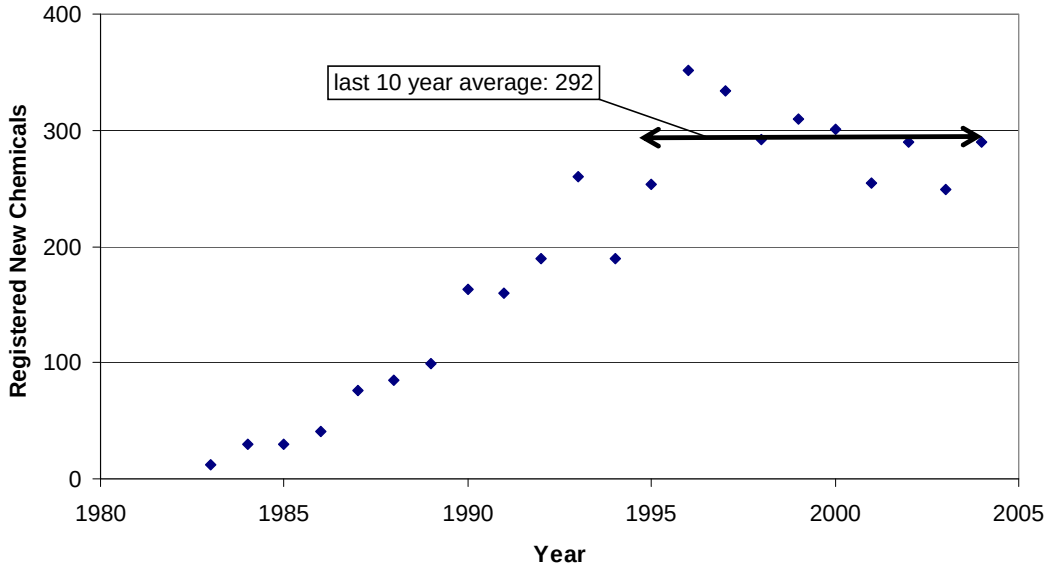


Figure 6.34 First registration of new chemicals

Starting from 1983, the first 12 new chemicals were registered. In the following years the annual registration rate increased to approx. 300 registrations per year. In the year 1996 the registration rate peaked at 351 registrations per year and thereafter stabilised. The 1996 peak in registration is interpreted as a catch-up from the 1980s when registration was significantly lower than in the period after 1990. Based on this interpretation, the evolution after 1995 is seen not as a decrease but rather as stabilisation to a steady-state level.

The last full year available is 2004. For the period of the last 10 years (1995-2004) the average registration rate was 292 registrations per year.

The introduction of REACH, with new obligations for existing chemicals, reduces the relative burden for new chemicals and thus may lead to an innovative era with acceleration in registration of new chemicals. As the deviation for the last 10-year period is below 20%, an increase in registration should be clearly documented by this indicator.

7 Documentation; database(s) for indicators

The REACH Baseline Study will provide a lot of elemental data as a basis for the different indicators. This will be processed to form the snapshot for the baseline year 2006/2007. In six years' time, this process will be repeated by a future contractor to yield the second base. As this operation will be done by Commission departments or by a future contractor, the documentation of the methodology as well as the documentation of the data input and processing is therefore essential.

In the first step, the basic input data will therefore be:

- "Frozen" in the 2007 format on Eurostat premises (confidential version of IUCLID 4) or on CD-ROM if the data is collected from a database;
- Documented electronically in PDF or GIF format if the data originates from web-based databases and stored on CD-ROM;
- Documented electronically in PDF format if the data is included in electronic documents and stored on CD-ROM.

In the second step, the calculation procedure for the indicator needs to be traceable. This will usually be done with an Excel or Access file. Additionally, the results of the project team need to be verified. The calculation and processing of data will undergo an internal[52] review process.

The most ambitious indicator will be the risk & quality indicator system. As has been stressed by the Steering Committee, data documentation and storage is crucial for this indicator. The documentation process for this indicator is therefore illustrated in detail.

The data collection is shown in Figure 7.1 for each of the four indicator impact areas (workers, consumers, the environment and humans via the environment). Each data entry has an attribute (literature etc.).

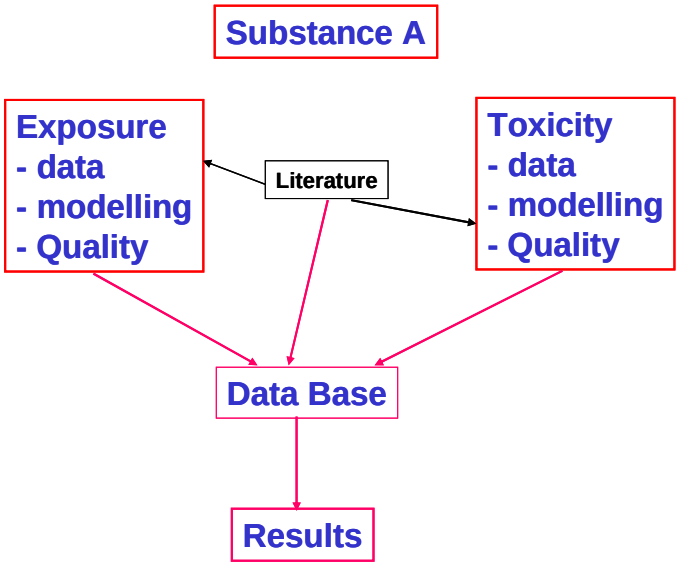


Figure 7.1 Information flow scheme for risk & quality indicator

A complex methodology was developed for each impact area. Thus the database will only use an elemental structure which is reduced to the main issues. For a substance, the literature screening or modelling is performed and the decisions about which exposure or toxicological data should be used are taken outside the data base.

[52] The internal review process will be performed by members of the contract team or, in case of the risk & quality indicator, by an appointed member of the Steering Committee.

Data entering the data base are:

- exposure data;
- toxicity;
- population risk modifier;
- severity modifier;
- accompanying metadata.

The input structure is highlighted in Figure 7.2:

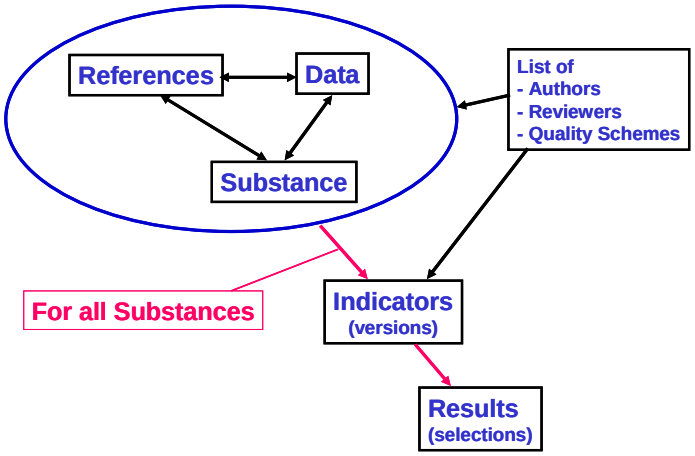


Figure 7.2 Structure of data base

For each substance, the corresponding data, metadata and references are attached with author, reviewer and quality schemes. The substances will then be selected to form the indicator. The database can include different "versions" for one substance according to base year, different data bases, etc. This feature will allow the stability of the indicator to be tested and sensitivity analysis to be performed. The algorithm itself is fixed according to Chapter 4.1 but additional algorithms could easily be added if they are based on the same pool of information. The database will display detailed results.

This documentation database organises the data collection and storage in an Access database and will guarantee an overview of the completeness and integrity of the data sample. It allows a straightforward review process and provides the tool for a verification process or further analysis, e.g. sensitivity analysis. It will help to reproduce the results in further snapshots.

A detailed description of the data base is given in Appendix V.

8 Discussion and further recommendations

After 2 years of project work, an indicator system for chemicals has been established. The proposed system consists of three pillars:

- Three administrative indicators monitor the formal progress of REACH;
- A risk & quality indicator tracks a set of 237 substances for the impact areas workers, consumers, the environment and humans via the environment;
- 11 supplementary indicators provide additional information on REACH-related issues.

The indicator system yields a balanced approach. Most of the REACH objectives are covered. Nevertheless, there is always a trade-off between possible indicators and available data. At the core of the indicator system is the so-called risk & quality indicator. The project team has developed a methodology which allows the risk characterisation of all REACH-relevant substances irrespective of the data quality. This approach includes a procedure from the REACH Implementation Projects (RIPs) which provide guidance and modelling tools. To guarantee reproducibility a detailed procedure for data retrieval was developed and is described in detail in the Appendices.

The snapshot for the risk & quality indicator covers, after the completion of phase II of the project, 237 substances. The procedure to establish it is quite resource-intensive. As discussed in Chapter 6, the 237 substances form an indicator set which exhibits plausible risk and quality scores over a wide range. It is assumed that the substances covered will undergo changes under the REACH legislation which will lead to significant shifts in six years' time. A further development during the project was the breakdown of the substances according to four subsets corresponding to the different tonnage bands. This breakdown allows a very specific analysis, with benefits for the overall interpretation of the results.

In addition, some follow-up action needs to be taken by Eurostat:

- The data for the administrative indicators need to be gathered in future from the European Chemicals Agency (ECHA). Eurostat will need to establish the contacts and ensure the availability of data.
- Many indicators rely on IUCLID data. A copy of IUCLID 4 has been installed at Eurostat. For a future snapshot, Eurostat needs to secure access to the IUCLID 5 database at ECHA.
- The 'Toxic chemicals in households' indicator relies on a BfR database. For reasons of confidentiality and the restrictions in the use of the data, this indicator needs to be compiled by the BfR. Eurostat needs to make an arrangement with the German Federal Ministry for the Environment to secure future access.
- The occupational skin diseases indicator is not feasible at present because of data limitations and data gaps. Eurostat should stay in contact with the administration in charge (DG Employment, Social Affairs and Equal Opportunities) to follow the discussion.
- The 'Changes in use patterns in Scandinavia' indicator relies on the SPIN data base hosted by the Nordic Council of Ministers, Chemicals Group. Eurostat needs to secure the data base from time to time for the future snapshot.
- The data for the change in classification and labelling (I) and for registration of new chemicals has been obtained from the European Chemicals Bureau (ECB). Today it is publicly available. Eurostat has to check for the future holder of the data base.
- The statistics on animal testing are publicly available from DG Environment on a non-regular basis. Eurostat should ensure the availability (and secure storage) of reports for the next study.
- A very detailed indicator for animal testing has been proposed but no baseline 2007 has been established. Eurostat should discuss the different versions of the indicator and whether there is a need for a baseline.
- For endocrine disrupting chemicals and persistent/bioaccumulative chemicals, it is recommended that progress in the existing European activities in this field be monitored.

9 Glossary and abbreviations

ADI	Acceptable Daily Intake — WHO threshold
AF	Assessment Factors
C&L	Classification and Labelling of chemical substances, R-phrases, S-phrases, http://ecb.jrc.it/esis/index.php?PGM=ein
ChemDat	Data base on physico-chemical properties (Merck)
CICAD	Concise International Chemical Assessment Documents — WHO information on exposure
CSR	Chemical Safety Report
DMEL	Derived Minimal Effect Level
DNEL	Derived No-Effect Level
ECB	European Chemicals Bureau — established within the Environment Institute at the JRC in Ispra since 1993
ECHA	European Chemicals Agency — established under REACH as the agency to control registration, evaluation and authorisation, located in Helsinki
EHC	Environmental Health Criteria — WHO information on exposure
EINECS	European Inventory of Existing Commercial Chemical Substances, http://ecb.jrc.it/esis/index.php?PGM=ein
EPI suite	Software to estimate physico-chemical properties (US EPA)
ESIS	European Chemical Substances Information System, ECB database: http://ecb.jrc.it/esis/index.php?PGM=ein
ESIS	European Chemicals Information System, http://ecb.jrc.it/esis/
EUSES	European Union System for the Evaluation of Substances — software supplied by the ECB for exposure estimates
Existing chemicals	Chemicals on the market before 1981, listed in EINECS
GHS	Global Harmonized System of Classification and Labelling, the future substitute of the European C&L (R-phrases, S-phrases)
GLEV	Generic Lowest Effect Value
HHRAP	Human Health Risk Assessment Protocol
HPV	High Production Volume (< 1 000 t/y)
HPVCs	High Production Volume Chemicals (< 1 000 t/y)
HSDB	Hazardous Substance Database
IARC	International Agency for Research on Cancer
IC	Industrial Category — production and use information in IUCLID
ITER	International Toxicity Estimates for Risk
IUCLID	International Uniform Chemical Information Database, database of the European Chemicals Bureau, http://ecb.jrc.it/iuclid/
IUCLID-4	Current version of the International Uniform Chemical Information Database, database of the European Chemicals Bureau, http://ecb.jrc.it/iuclid/
IUCLID-5	Future version of the International Uniform Chemical Information Database, database of the European Chemicals Agency, http://ecb.jrc.it/iuclid5/
K_{ow}	Ratio of the concentration in water to the oily phase (octanol) (Nernst distribution law)
LO(A)EL	Lowest Observed (Adverse) Effect Level
LOAEL	Lowest Observed Adverse Effect Level
LPV	Low Production Volume (10-100 t/y)
LPVCs	Low Production Volume Chemicals (10-100 t/y)
MC	Main Category — Production and Use Information in IUCLID
MPV	Medium Production Volume (100-1 000 t/y)
MPVCs	Medium Production Volume Chemicals (100-1 000 t/y)
NDU	Non-dispersive use
NEC	No-Effect Concentration
New chemicals	Chemicals introduced into the market after 1981
NO(A)EL	No Observed (Adverse) Effect Level
NRS	Nominal Risk Score, see Chapter 4.1.4
OEHHA	Office of Environmental Health Hazard Assessment, State of California (USA), http://www.oehha.ca.gov/
OEL	Occupational Exposure Limit — threshold for workers
Patterns of control	IUCLID category to characterise the emission control of chemicals in industry

PBT substances	Substances that are **p**ersistent, **b**ioaccumulative and **t**oxic
PEC	Predicted Environmental Concentration
PNEC	Predicted No-Effect Concentration
PRM	Population Risk Modifier — see Chapter 4.3.4
Prodcom	Production volume data base of Eurostat
PU	Product Use
QS	Quality Score
QSAR	Quantitative Structure-Activity Relationships
QSexp	Quality Score for exposure
QStox	Quality Score for toxicity
Quality Score	Score to assess the quality of exposure and toxicity, range from 1-10, for risk from 1-100
RAR	Risk Assessment Report
RCR	Risk Characterisation Ratio (ratio exposure/toxicity), see Chapter 4.1.4
RfC	Reference Concentration
RfD	Reference Dose
RIP	REACH Implementation Project expert group
Risk phrases	See R-phrases, C&L
R-phrases	Characterisation of dangerous substances (e.g. toxicity) — see C&L
RWC	Reasonable Worst Case — exposure reference point (90th percentile), see Chapter 4.1.2
SDS	Safety Data Sheet
SIDS	Screening Information Data Sheet — OECD Information on exposure
SPIN	Substances in Preparations in Nordic Countries
SPVCs	Small Production Volume Chemicals (1-10 t/y)
SVHCs	Substances of Very High Concern
T25	Dose descriptor giving a 25% increase in cancer in animals, usually based on the most sensitive tumours
TDI	Tolerable Daily Intake
TGD	Technical Guidance Document
TRA	Targeted Risk Assessment
UC	Use Category — production and use information in IUCLID
UICS	Use as an Intermediate in Closed System
UR	Unit Risk
Use Patterns	IUCLID category (e.g. wide dispersive use) to characterise the use of chemicals in industry
vPvB substances:	Substances that are **v**ery **p**ersistent and **v**ery **b**ioaccumulative
WDU	Wide Dispersive Use

10 References

AGS, Ausschuss für Gefahrstoffe, 2006	TRGS 900 — Arbeitsplatzgrenzwerte online: www.baua.de, accessed: May 2006
Allanou, R., Hansen, B.G. and van der Bilt, Y., 1999	Public Availability of Data on EU High Production Volume Chemicals. European Commission, Joint Research Centre, Ispra 1999
Altschuh, J., Brüggemann, R., Snatl, H., Eichinger, G. and Piringer, O.G, 1999	Henry's law constants for a diverse set of organic chemicals: experimental determination and comparison of estimation methods. *Chemosphere*, vol. 39, No 11, pp. 1871-1887
Anonymous, 2001	Begründungen zu Arbeitsplatzgrenzwerten: Allgemeiner Staubgrenzwert online: www.baua.de, accessed: May 2006
BKH 2000	BKH 2000. Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption — preparation of a candidate list of substances as a basis for priority setting. Report to DG Environment. M0355008/1786Q/10/11/00
BKH 2002	BKH 2002. Endocrine Disrupter: Study on Gathering Information on 435 Substances with insufficient data. Report to DG Environment. B4-3040/2001/325850/MAR/C2
BMU 2005	Wirklich ein "besseres" REACH? Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit (BMU), Bonn, 2005
CEC 2001	Strategy for a future Chemicals Policy: White Paper, COM(2001) 88 final. European Commission, Brussels, 2001
CEC 2006	REACH in brief. European Commission, Enterprise and Industry Directorate General and Environment Directorate General, September 2006
CEFIC 2005	Concise preliminary Technical Guidance Document. Final Report of RIP 3.2 WP 3 – 1 B, 28072005
Cramer, G. M., Ford, R. A., Hall, R. L., 1978	Estimation of toxic hazard — a decision tree approach. *Food and Cosmetics Toxicology*, Vol. 16, 1978, pp. 255-276
DG ENTR 2005	Minutes of the REACH Preparatory Workshop on a Baseline Study. March 2005, European Commission, Enterprise and Industry Directorate-General, Brussels 2005
Dybing, E., Sanner, T., Roelfzema, H., Kroese, D., Tennant, R. W., 1997	T25: a simplified carcinogenic potency index: description of the system and study of correlations between carcinogenic potency and species/site specificity and mutagenicity. *Pharmacology & Toxicology*, Vol. 80, 1997, pp. 272-279
EC 2003	Technical Guidance Document in Support of the Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and the Commission Regulation (EC) 1488/94 on Risk Assessment for Existing Substances and Directive 98/8/EC of the European Parliament and of the Council Concerning the Placing of Biocidal Products on the Market Joint Research Centre, Institute for Health and Consumer Protection, European Chemicals Bureau, Ispra, Italy, 2003
EC 2006	European Commission; REACH in Brief. Brussels, September 2006
ECOPA 2006	REACH animal testing calculator, the CONAM EU 6th Framework Programme project, i.e. the ECOPA Chemical Policy Working Group 6, (originators: Simon Webb, Karsten Müller). Downloadable at http://www.ecopa.eu/download.php?file=Animaluse_REACH_calculator.xls
Eurostat 2006	"Toxic chemicals" in the SDI database: http://epp.eurostat.ec.europa.eu/portal/page?_pageid=1998,47433161,1998_47437052&_dad=portal&_schema=PORTAL#THEME4 Full report Chemical Indicator: http://forum.europa.eu.int/Public/irc/dsis/pip/library?l=/indicators_chemicals
EU TGD 2003	Technical Guidance Document on Risk Assessment in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances, Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market, EU, 2003
Heidorn, C., Jenseit, W., 2003	Towards a chemical risk index. Working Group meeting "Environment Statistics" and" Environmental Accounts", Luxembourg, September 2003
HVBG, Hauptverband der gewerblichen Berufs-genossenschaften, 1999	Existing commercial chemicals — Exposure at the workplace BGAA-Report 1/99e, Sankt Augustin, 1999
JRC Ispra 2007	EU PBT Working Group, Candidate List. JRC, Ispra March 2007
Kroese, D.; Pronk, M. 2006	Reference preliminary Technical Guidance Document (reference p-TGD). Chapter 3, Human health hazard assessment. DNEL-Working Group RIP 3.2-2. JRC, Ispra 2006

Kroes, R., Galli, C., Munro, I., Schilter, B., Tran, L.-A., Walker, R., Würtzen, G., 2000	Threshold of toxicological concern for chemical substances present in the diet: a practical tool for assessing the need for toxicity testing. *Food and Chemical Toxicology*, Vol. 38, 2000, pp. 255-312
Munro, I. C., Ford, R. A., Kennepohl, E., Sprenger, J. G., 1996	Correlation of structural class with no-observed-effect levels: a proposal for establishing a threshold of concern. *Food and Chemical Toxicology*, Vol. 34, 1996, pp. 829-867
McKone T.E.. CalTOX, 1993	A multimedia total exposure model for hazardous waste sites: UCRL-CR-111456. Lawrence Livermore National Laboratory, Livermore, CA, USA, (CalTOX version 4.0 available at: http://eetd.lbl.gov/ied/era/index.html)
Oeko 2006	W. Jenseit et al., Research, Development, Statistical and Analytical Work to Develop Appropriate Environmental Indicators Related to Chemicals, Öko-Institut, Darmstadt 2006
Pedersen 2003	Pedersen, F.; de Bruijn, J.; Munn, S.; van Leeuwen, K. 2003: Assessment of additional testing needs under REACH. Effects of (Q)SARS, risk based testing and voluntary industry initiatives. European Commission, JRC, Ispra 2003
Petersen et al. (2006)	Gitte Petersen, Dorte Rasmussen & Kim Gustavsson (2006). Study on enhancing the Endocrine Disrupter priority list with a focus on low production volume chemicals. ENV.D.4/ETU/2005/0028r
Radboud University Nijmegen & Free University Amsterdam (2007)	EU TGD 2003 Risk Assessment Spreadsheet Model version 1.2 2007/02/01 produced by Radboud University Nijmegen & Free University Amsterdam for the NL center for environmental modelling under contract with Cefic — European Chemical Industry Council
RPA & Statistics Sweden 2002	RPA & Statistics Sweden. Assessment of the impact of new regulations in the chemicals sector. Prepared for the European Commission, DG ENTR., 2002
US-EPA 1991	Soil Transport and Fate database 2.0, ORD / Robert S. Kerr Environmental Research Laboratory, 1991
US-EPA, 1998	Human Health Risk Assessment Protocol for hazardous waste combustion facilities (HHRAP), Peer review draft, Office of Solid Waste, EPA/530/0-98/001A, 1998
US National Library of Medicine	Hazardous Substances Data Bank, HSDB, http://toxnet.nlm.nih.gov
v.d. Jagt et al. 2004	v.d. Jagt, K.; Munn, S.; Torslov, J.; de Bruijn, J. Alternative approaches can reduce the use of test animals under REACH. JRC, Ispra 2004

11 Appendices

Appendices I-IV and further guidance documents (Appendices V-VII) are available on the project website: http://circa.europa.eu/Public/irc/dsis/reachbaselinestudy/home

- Appendices I-IV: Detailed technical description of the risk & quality indicator.
- Appendix V: Handbook on the risk and quality data base.
- Appendix VI: Overview of other risk-based indicator systems.
- Appendix VII: Methodology sheets for supplementary indicators.

European Commission

The REACH baseline study — A tool to monitor the new EU policy on chemicals - REACH (Registration, Evaluation, Authorisation and restriction of Chemicals)

Luxembourg: Office for Official Publications of the European Communities

2009 — 121 pp. — 21 x 29.7 cm

ISBN 978-92-79-12197-5
ISSN 1977-0375

Publications Office
Publications.europa.eu