Environment and energy

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The REACH baseline study – A tool to monitor the new EU policy on chemicals

Eurostat, in collaboration with the services responsible for environment and for industry of the European Commission, has developed a baseline study and a set of indicators to monitor the implementation of REACH, the new EU Regulation on the Registration, Evaluation, Authorisation and restriction of Chemicals.

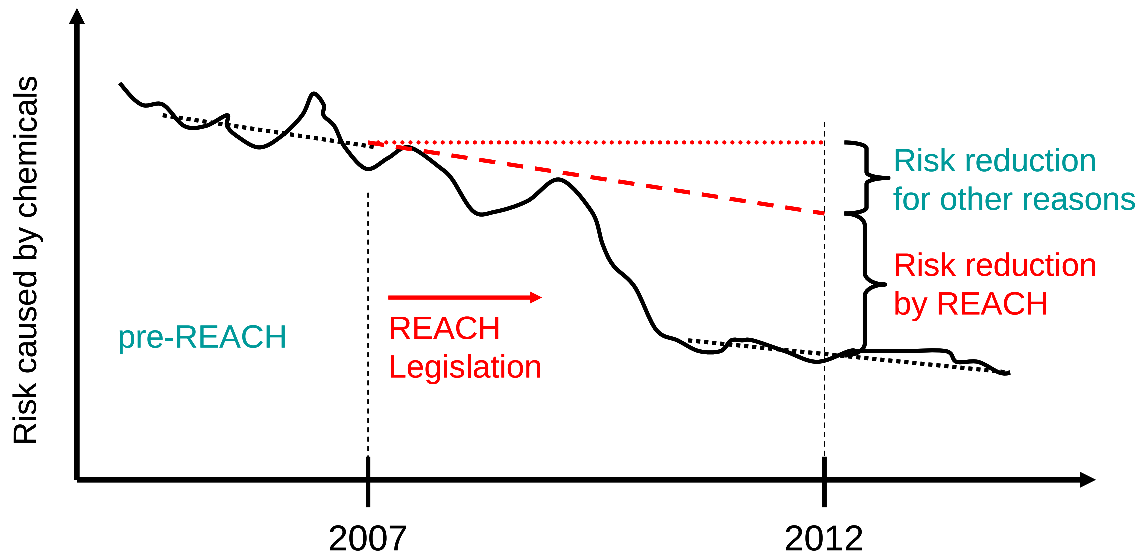
The set of indicators will measure progress towards the major objectives of REACH: to ensure a high level of protection of human health and the environment as well as enhancing innovation of safer chemicals.

The Eurostat study presents a baseline of the (nominal-) risk caused by chemicals and the quality of the underlying data which was available when REACH came into force in June 2007.

The new risk and quality indicators will follow the development over time. In 2012/13 a second risk and quality 'snapshot' will be taken, to see whether REACH by then has already reduced the risk caused by chemicals - and how the quality of the underlying data will have evolved.

This summary publication, based on the comprehensive report available from Eurostat, aims to make the newly developed methodology better known and to trigger the discussion on the results.

Figure 1: Possible future evolution of the risk caused by chemicals



Policy monitoring by indicators: the REACH baseline study

Will there be a decrease in risk? Will our very limited knowledge of the properties of substances and their safe uses increase due to REACH?

This baseline study aims to provide a set of indicators to monitor whether such changes take place — indicating the success of REACH. 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' of the situation before REACH has been taken now, a second will be taken after 5 years of experience acquired with the operation of REACH, additional snapshots will be made later.

Comparing the results should enable the success of the REACH legislation to be monitored and assessed.

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The structure of the baseline indicator system, close to the objectives of REACH

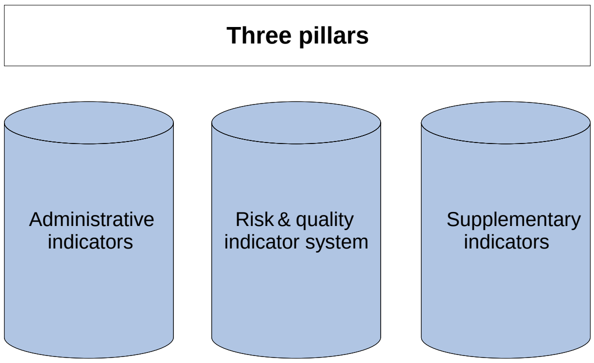
A specific indicator set has been developed that is directly linked to the objectives and key elements of REACH. It is based on three different types of indicators, which build up the three pillars of the system.

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, for example, on the number of substances registered, the number of chemical safety reports documented by the European Chemicals Agency or the number of dossiers being evaluated.

Risk and quality indicators: This set 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 reference substances.

Supplementary indicators: These indicators address specific objectives of REACH not 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 and quality indicator system.

Figure 2: Three different types of indicators used in the baseline indicator system



The objectives of REACH, addressed by the combination of indicator sets

Central elements and 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[1]		
Prevention of fragmentation in the internal market			
Conformity with EU's international obligations under WTO			

[1] The REACH Baseline Study does not address economic and legal aspects.

A system to monitor risks - and the quality of the underlying information

Risk and 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 good is the information 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 system addresses risks to three impact areas (Figure 3):

- the environment, - workers, - 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).

This indicator system directly assesses the nominal risk caused by exposure to chemicals and characterises the quality of the data on which this risk assessment is based. These characterisations can be followed over time.

Figure 3: The impact areas addressed by the risk and quality indicator system

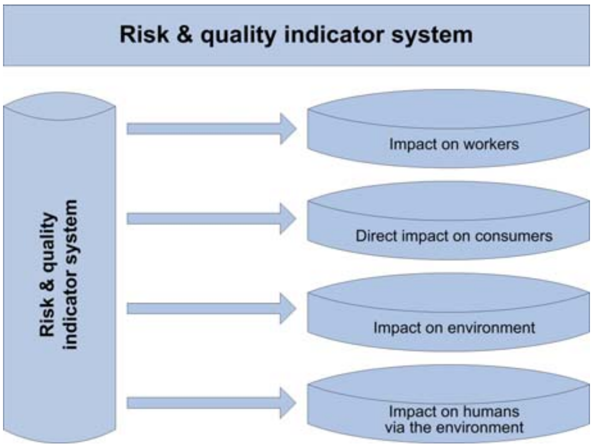
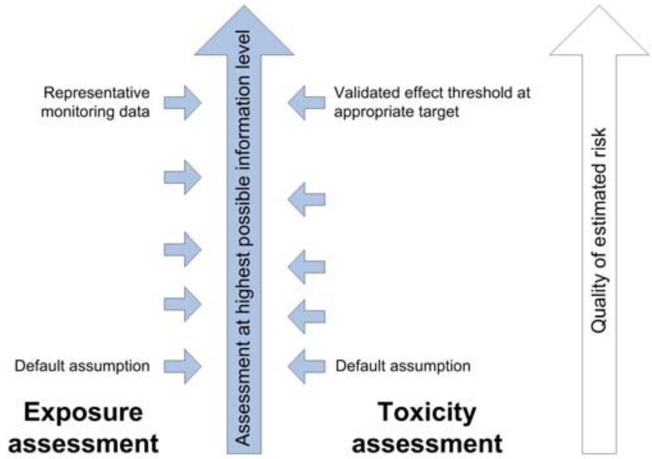


Figure 4: Risk assessment – and the quality of the source data on exposure and toxicity



Since the calculation of the risk and the quality of its assessment 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 tonnes/year as reported to the European 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.

Two figures are calculated for each reference substance: the 'Risk Score' and the 'Quality Score'.

Risk 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 to define a value discriminating risk from no-risk has been made.

In order to determine the risk score, an exposure assessment and a toxicity assessment have to be made. Data on use patterns, volumes and physico-chemical properties are needed to assess the exposure and toxicological data are required for the toxicity assessment.

Quality score

These data sets can be of very different quality: If input data are highly uncertain (default assumptions) the quality of the assessment is regarded as poor. If representative monitoring data and a well defined threshold value are available, the quality of the assessment is regarded as good. A score which ranges from 1 (very good quality of data) to 100 (very poor quality of data) characterises data quality. This quality assessment is a key element of the risk and quality indicator system.

It is assumed that REACH will lead to more complete testing of toxicological properties, to better data provided by alternative testing methods such as modelling, improved reporting, and better information on exposure.

By this means, the quality of the data (i.e. the completeness of the databases 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 expressed by the quality scores.

'Snapshot 2007'

A snapshot has been taken for those proposed indicators for which a baseline needs to be established in 2007. 237 substances have been randomly selected from the 30.000 substances covered by REACH. These belong to four categories: - High Production Volume Chemicals (HPV, more than 1 000 tonnes/year), - Medium Production Volume Chemicals (MPV, 1 000 >> 100 tonnes/year), - Low Production Volume Chemicals (LPV, 100 >> 10 tonnes/year) and 27 identified Substances of Very High Concern (SVHC).

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

In Figure 5, the results are highlighted as an aggregated geometric mean having values of 16 for workers, 34 for consumers, 0.06 for the environment and 30 for humans exposed via the environment, for LPV, MPV and HPV substances combined.

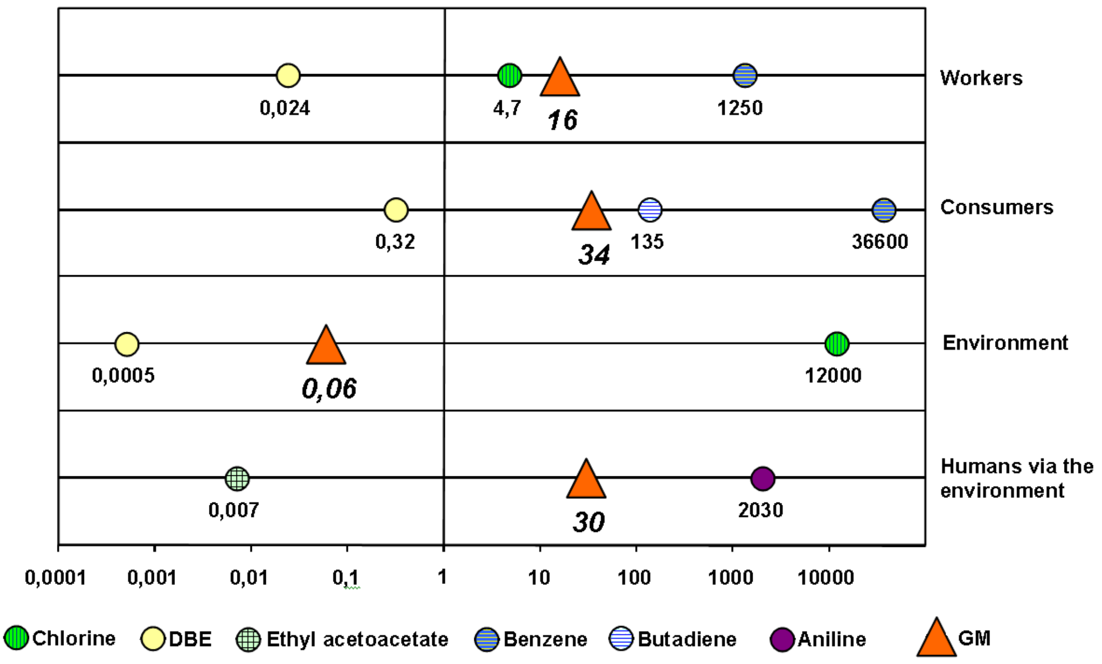
Aggregated baseline risk scores for workers, consumers, the environment and humans via the environment

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 1000 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.

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 scores of well known substances.

Figure 5: Aggregated baseline risk scores (GM: geometric mean, DBE = dibutyl ether)

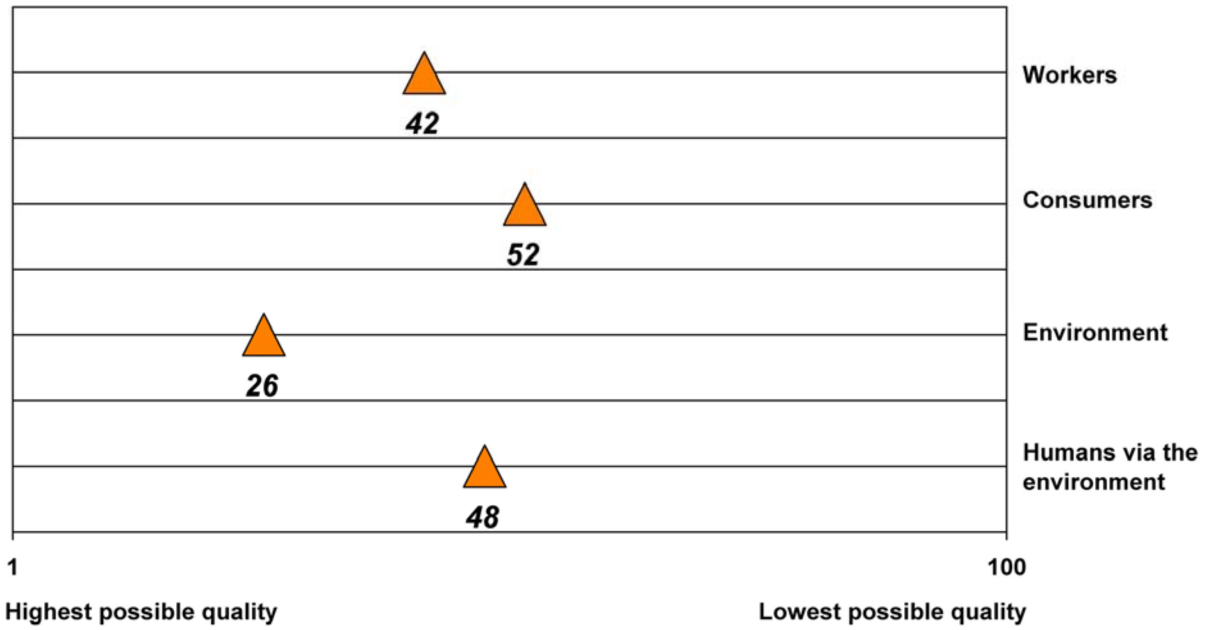


For the impact areas workers, consumers, the environment and humans via the environment, the results for the reference substances chlorine, benzene, butadiene, dibutyl ether (DBE), ethyl acetoacetate and aniline are indicated in Figure 5. The reference substances show risk scores that spread over a wide range. In a future snapshot, the risk scores will be calculated with then available updated data. The risk scores should move to the left to demonstrate the success of the measures undertaken.

Aggregated baseline quality scores for workers, consumers, the environment and humans via the environment

Figure 6 illustrates the quality scores obtained. By definition, the quality scores range from 1 to 100 for every impact area. The geometric mean of the quality score for workers has been calculated as 42, for consumers as 52, for the environment as 26 and for humans exposed via the environment as 48, for LPV, MPV and HPV combined.

Figure 6: Aggregated baseline quality scores



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 scores and quality scores may become a headline indicator for political communication. As these single figures are much too complex for further interpretation and analysis, disaggregated levels are supplemented.

The quality score and the risk score cannot be amalgamated into a single figure. Moreover, any comparisons between different impact areas should be strictly avoided. Such comparisons would be a mis-interpretation because — for example — different reference points for risk calculations are used in different impact areas.

In the following pages some more examples of results are presented. They were extracted from the comprehensive baseline study report available from Eurostat (see further information). The full report presents the results at different levels of aggregation in a way that can be understood by users with different levels of expertise.

The interested public and political decision makers may use the summary format to get a quick overview; scientific and technical experts may use the more detailed 'profile level' and the 'analysis level', where information is shown broken down to substance groups or individual substances.

Two examples for a deeper analysis are given at the following pages, for the impact areas 'workers' and 'humans in the environment'.

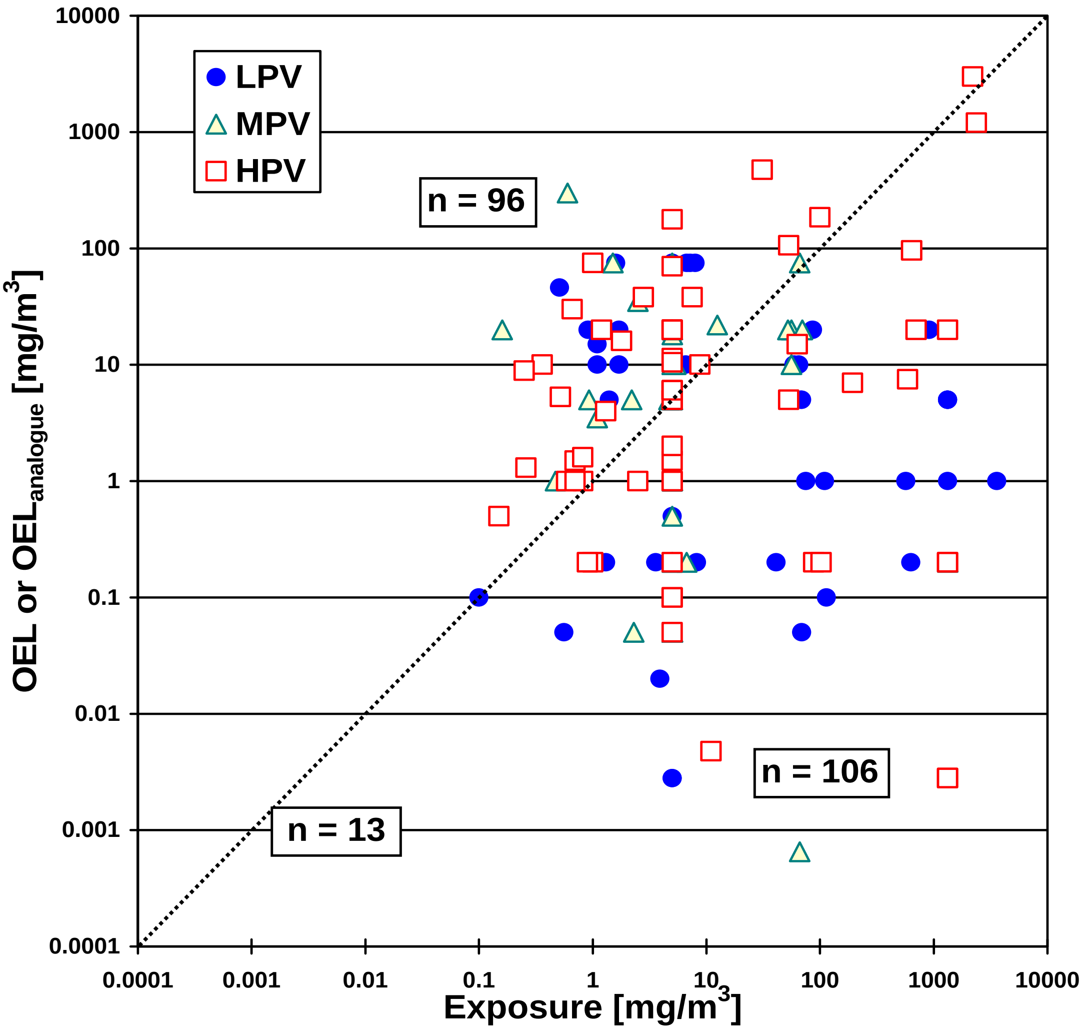
In-depth analysis at disaggregated level: the risk characterisation ratio

The risk characterisation ratio (RCR) follows a deterministic approach: it is the quotient that compares toxicity (the limit value for a concentration at which a negative effect is expected to occur) to the measured or calculated exposure at a workplace or in the environment. A value above 1 is an indication that further investigations and possibly risk reduction measures are required. The RCR presents the results of the risk and quality indicator system at the lowest level of aggregation. Nevertheless, the interpretation of the data needs to be made very cautiously.

Figure 7 shows, for the impact area 'worker', the assumed exposure concentration on the x-axis and the assumed safe concentration (expressed by the Occupational Exposure Limit (OEL) or other available 'OEL $_{analogues}$') 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. All substances with RCR < 1 are at the left of the diagonal line (96 substances) and substances with RCR > 1 are at the right of this dashed line (106 substances).

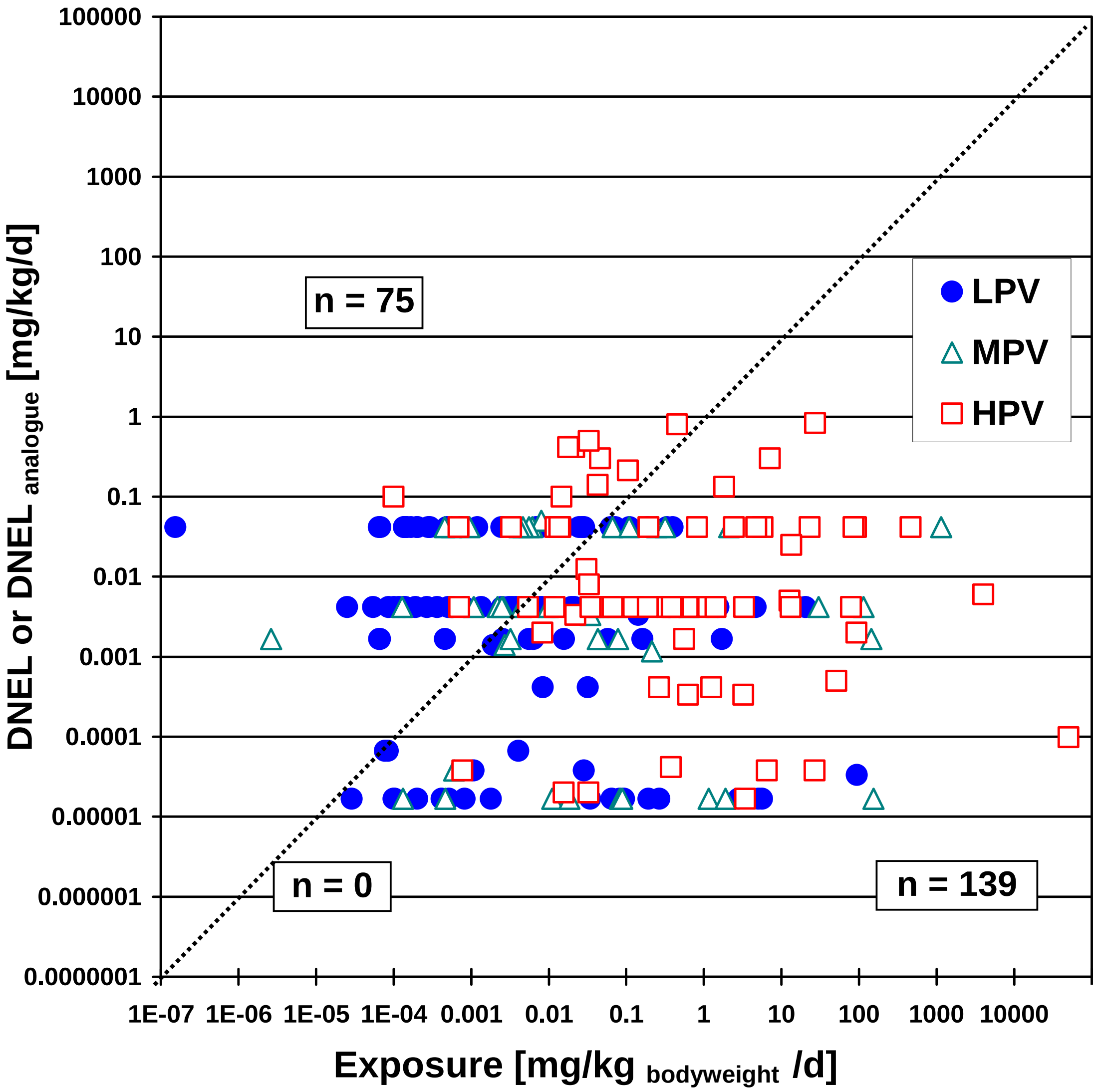
It may be assumed that, as a result of REACH, there will be a clearly visible shift towards RCRs lower than one (move to the upper left-hand triangle in Figure 7) because REACH demands risk management measures ensuring that exposure is below the appropriate limit values.

Figure 7: Baseline analysis of the risk characterisation ratio (workers)



For the area 'consumer' (not shown in this summary) only 39 substances are located on the left-hand side, but 115 on the right-hand side. For humans exposed to chemicals indirectly via the environment (Figure 8, next page) nearly all HPVs exhibit an exposure higher than the corresponding derived no-effect value (DNEL). LPVs and MPVs are located on both sides of the diagonal line. 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.

Figure 8: Baseline analysis of the risk characterisation ratio (humans via the environment)



Conclusions on the risk and quality indicator system

The risk and quality indicator system, the core element of the REACH baseline study, 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 the baseline.

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 made.

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.

The 2007 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 and quality indicator has a lot to tell. It shows detailed substance-specific 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.

Administrative and supplementary indicators

As stated above, the risk and quality indicator system is accompanied by a set of indicators

- to monitor the REACH process:

Administrative indicators
Registration of chemicals
Evaluation of chemicals
Authorisation and restriction of chemicals

- to monitor the progress made in the improvement of the knowledge required for a safer management of chemicals:

Supplementary indicators
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 many of these indicators, i.e. the administrative indicators, the baseline is obviously zero as the data will only become available during the implementation of REACH.

These indicators will be calculated based on information provided by the European Chemicals Agency.

Supplementary indicators can be derived from existing statistics or other data sources that are not always available at European level, but in a number of Member States at national level.

Indicators that are calculated today are e.g. the 'Production of toxic chemicals', 'Cross border transport of chemicals', 'Changes in use pattern' and 'Registration of new chemicals'.

The indicator on the 'Registration of new chemicals' will monitor progress in the substitution of old chemicals by new chemicals:

REACH sets equivalent obligations on existing chemicals and established a 'level playing field' between existing and new chemicals. Over the period of the last 10 years, approximately 300 new chemicals were registered each year. If industry chooses to substitute existing chemicals by newly developed substances, then the registration rate of new chemicals will accelerate.

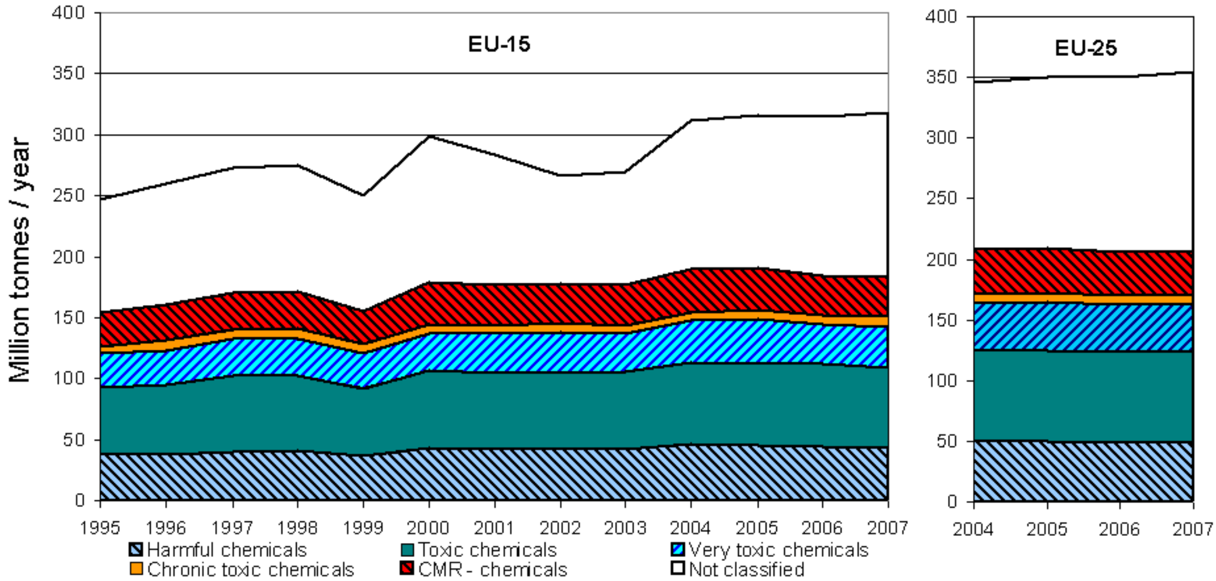
Two more examples of supplementary indicators, derived from production statistics and foreign trade statistics databases maintained by Eurostat are presented in the next pages.

Production of toxic chemicals, by toxicity class

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, 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'.

This indicator is also published as a Sustainable Development Indicator, in Theme 'Public health'.

Figure 9: Production of industrial chemicals: Total volumes and by 5 'toxicity classes'



The indicator presents the trend in aggregated production volumes of toxic chemicals, broken down into five toxicity classes.

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. (This 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 at 36 million tonnes (EU-25).

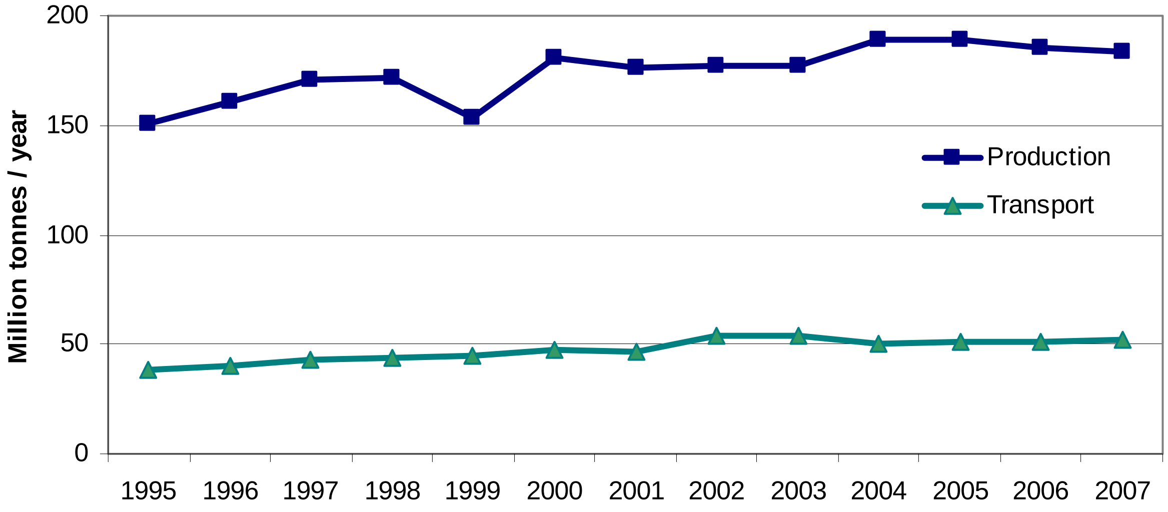
Statistics available from 2004 onwards show that the 10 new Member States produce only around 10% of all toxic chemicals in EU-25. However, an in-depth analysis shows a steady growth of toxic chemicals production in these countries: +18%, with a strong increase for CMR chemicals (+33%). The share of toxic chemicals in the total production increased from 55% to 61% between 2004 and 2007 in these countries.

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 observed.

Cross border transport of chemicals

The indicator monitors the movement of toxic chemicals across borders with the help of 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 indicators described above.

Figure 10: 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 10 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.

Outlook - and further reading

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 set is the innovative risk and quality indicator system. It 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.

Eurostat, supported by a Steering Committee and in close collaboration with the other involved Commission Services and the European Chemicals Agency, will continue the work on chemical indicators: The administrative- and supplemental indicators will be updated and maintained, and further possibilities will be explored to cover areas that are not sufficiently addressed yet, such as the development of alternative testing methods to replace animal testing.

In 2012/13, in the frame of the first effectiveness review of REACH, a second risk and quality 'snapshot' will be taken, to see whether REACH by then has already reduced the (nominal-) risk caused by chemicals - and how the quality of the underlying data will have evolved.

METHODOLOGICAL NOTES

Explanation

REACH is a new European Community Regulation on chemicals and their safe use (EC 1907/2006). It deals with the Registration, Evaluation, Authorisation and Restriction of Chemical substances. The new law entered into force on 1 June 2007.

The aim of REACH is to improve the protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemical substances. At the same time, innovative capability and competitiveness of the EU chemicals industry should be enhanced. The benefits of the REACH system will come gradually, as more and more substances are phased into REACH.

The REACH Regulation gives greater responsibility to industry to manage the risks from chemicals and to provide safety information on the substances. Manufacturers and importers are required to gather information on the properties of their chemical substances, which will allow their safe handling, and to register the information in a central database run by the European Chemicals Agency in Helsinki. The Agency acts as the central point in the REACH system: it will manage the databases necessary to operate the system, co-ordinate the in-depth evaluation of suspicious chemicals and run a public database in which consumers and professionals can find hazard information.

The baseline study developed by Eurostat, in close collaboration with the Environment Directorate of the European Commission, the Directorate for Enterprises and Industry and the Joint Research Centre, is an important instrument to monitor the implementation of REACH and will be a basis for the review of REACH after 5 years of operation.

Details on Data Sources

The data used for the calculation of the baseline scenario and the indicators have been obtained from different data sources or by modelling according to the Commission's Technical Guidance Documents for Risk Assessment of Chemicals.

A main source for production statistics is the PRODCOM database (Eurostat).

Movements of chemicals have been calculated by the use of the foreign trade statistics database COMEXT (Eurostat).

The chemical and toxicological properties and the information on use patterns have been obtained from IUCLID (International Uniform Chemical Information Database, ECHA and Eurostat). All data has been extracted in 2007.

Abbreviations used in this publication

DNEL	Derived No-Effect Level
EU15	EU15 comprised the following 15 countries: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom
EU25	EU25 comprise the following 25 countries: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, United Kingdom
GM	Geometric Mean
HPV	High Production Volume chemicals (< 1000 t/y)
Impact area	Part of the population or the environment for which the nominal risk and quality scores are calculated: Workers, consumers, humans via the environment and the environment as such
LPV	Low Production Volume chemicals (10-100 t/y)
MPV	Medium Production Volume chemicals (100-1000 t/y)
OEL	Occupational Exposure Limit value
PRODCOM	Production statistics database (Eurostat)
RCR	Risk Characterisation Ratio (ratio of observed or modelled exposure versus threshold values for toxicity, such as DNEL and OEL))
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SVHC	Substances of Very High Concern

Further information

Data: Eurostat Website: http://ec.europa.eu/eurostat

Select 'Sustainable development indicators' on the left side of the homepage and then ‘Public health’ from the menu.

The full report 'The REACH baseline study, a tool to monitor the new EU policy on chemicals – REACH (Registration, Evaluation, Authorisation and restrictions of Chemicals)' can be downloaded from the Eurostat website: http://epp.eurostat.ec.europa.eu/portal/page/portal/eurostat/home/

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Eurostat set up with the members of the ‘European statistical system’ a network of support centres, which will exist in nearly all Member States as well as in some EFTA countries.

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