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The REACH baseline study 5 years update

Summary report

2012 edition

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Glossary

CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
DNEL	Derived No-Effect Level
DMEL	Derived Minimal Effect Level. Value used to assess the remaining risk in case of substances without a threshold for toxic effects
ECHA	European Chemical Agency
GM	Geometric mean
HPVC	High Production Volume Chemical
IUCLID 5	International Uniform Chemical Information Database
LPVC	Low Production Volume Chemical
MPVC	Medium Production Volume Chemical
NOAEL	No Observable Adverse Effect Level)
OEL	Occupational Exposure Limit
PEC	Predicted Environmental Concentration
PNEC	Predicted No-Effect Concentration
PRM	Population Risk Modifier
PROC	Process category, element of the Use Descriptor System
QS	Quality Score (1= high quality – 100 = low quality)
QSAR	Quantitative Structure Activity Relationships
QS_{exp}	Quality Score for the quality of the exposure data
QS_{tox}	Quality Score for the quality of the toxicity data
QS_{tota}	Total Quality Score (Quality Score Exposure x Quality Score Toxicity)
RCR	Risk Characterisation Ratio
REACH	Registration, Evaluation, Authorisation and restriction of Chemicals
RMM	Risk Management Measure
SVHC	Substance of very high concern
TGD2003	Technical Guidance Document

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Executive summary

In the REACH baseline study, a set of indicators has been developed to monitor the performance of REACH and its central elements. The **'Risk and Quality' Indicator System** of the study tracks two major goals of REACH:

- **Improvement in the quality of publicly available data for the assessment of chemicals;**
- **Reduction in the risk of chemicals to humans and the environment.**

Inter alia, this study presented a baseline estimation of the risk caused by chemicals and of the quality of underlying substance-specific data, which were available when REACH came into force in June 2007. It refers to a representative set of 237 randomly selected reference substances. The nominal risk and the quality of the data available for these substances have been determined and expressed as 'Risk Scores' and 'Quality Scores'.

The main objective of the 5 years update of the REACH baseline study has been to calculate the Risk Scores and the Quality Scores (and the related figures) for the situation in 2011 – and to compare them with the figures of 2007. The key findings of the 5 years update are described in this report and can be summarised as follows:

Key question 1: Does REACH lead to an improvement in the quality of publicly available data for the assessment of chemicals?

Development of the Quality Scores

1. The 5 years update of the REACH baseline study found a considerable improvement of the quality of the underlying data for the assessment of the 62 substances (46 HPV chemicals and 16 SVHC)([1]). It is expressed in a reduction of the total Quality Score from 2007 to 2011 (with lower Quality Scores indicating higher quality).
2. The improvement in quality is evident in all four impact areas ([2]).
3. For the majority of HPV chemicals and SVHC, the quality of the data underlying the exposure estimate (Quality Score Exposure) and the toxicity estimate (Quality Scores Toxicity) improve.
4. For the first time, some of the reference substances reach the best quality possible (total Quality Score equal to 1) in some impact areas.
5. Due to the registration, DNELs, PNECs and more detailed information on uses and exposures become available for a large number of substances.

Conclusion 1: The results of the 5 years update show a marked increase in the quality of the data available for the assessment of the registered substances included in this evaluation.

Key question 2: Does REACH lead to a reduction of the risks which are posed by chemicals to humans and the environment?

Development of the Risk Scores

1. A marked decrease has been found of the Risk Scores in the aggregated evaluation of 62 substances.
2. The decline in Risk Scores is almost entirely due to decreases in Risk Characterisation Ratios.
3. The analysis shows a pronounced reduction of the fraction of substances with RCRs at or above 1 and/or RCRs above 10 in all four impact areas.
4. For almost all substances, changes in at least one of the key input parameters for the RCR (toxicity estimate, exposure estimate) took place indicating changes in the knowledge about the substances.

Conclusion 2: The results of the 5 years update show a marked decrease in the Risk Characterisation Ratios and the Risk Scores from 2007 to 2011. This indicates a better control of risk, which is largely believed to be due to REACH.

([1]) Three of the HPV chemicals were also evaluated in the SVHC group, leading to a total number of SVHC of 19.

([2]) Impact areas: workers, consumers, the environment, humans exposed via the environment.

Additional key findings

1. In 2011, a remarkable number of reference substances still show RCRs above 1. This is mainly due to four reasons: 1) the REACH Regulation does not require a chemical safety assessment (intermediates); 2) the REACH Regulation does not require an exposure assessment and risk characterisation (non-classified substances); 3) limited scope of exposure assessment by some registrants 4) lack of reliable DMELs for SHVC.
2. These findings highlight the fact that appreciable risks can be associated with substances, which are not classified.
3. In most of the CSRs analysed, no detailed quantitative risk assessments have been made for the impact areas consumers and humans via the environment.

Many additional findings are specific for individual impact areas. They are described for each impact area in the subchapters 'Summary and conclusion' of the comprehensive report.

Conclusions. The 5 years update of the REACH baseline study found clear indications that registration due to REACH leads to a significant improvement of our knowledge on substance properties. For the first time, for many substances existing data have been used to derive toxicity estimates such as DNELs, DMELs and PNECs, and to perform exposure estimations and risk characterisations. In addition, for a relevant part of the substances analysed the RCRs show a clear decrease. The fraction of reference substances with RCRs at or below 1 increases. This can be seen as an indication for a better control of risks due to the chemical safety assessments required by REACH.

The main difference in the data sources in our analysis 2007 and 2011 have been the availability of registration dossiers in 2011. The changes in the Risk Scores and Quality Scores origin from the data in these documents (to a minor extent additional information came from REACH documents for SVHC due to authorization and restriction). Therefore, it is reasonable to state that the registration obligation under REACH leads to the improvements of data availability and the reduction of the RCRs, which have been found in the REACH baseline 5 years update for registered reference substances.

Details from the analysis in the different impact areas support these overall conclusions:

- The **higher availability of DNELs** compared to OELs at baseline is clearly linked to REACH, since the Regulation introduced this instrument.
- Apart from DNEL availability itself, this instrument also leads to a **confirmation (or lack of it) of existing OELs**. The 2011 analysis revealed individual cases, where a substantially lower DNEL for workers was derived compared to existing OELs.
- For the impact area consumers, data on uses, toxicity and exposure were very incomplete in 2007. In 2011, the first improvement has been a clarification of intended uses. Also in this impact area, toxicity estimates (DNELs or analogues) are clearly of better quality in 2011 than in 2007 thanks to DNEL derivation from experimental data in the CSRs.
- **Improved exposure assessments** can also be seen as a result of REACH. Although problems associated with the exposure assessment remain, many registrants have put much effort in performing exposure assessments and risk characterisations, resulting in a detailed description of risk management measures (RMMs) and specific conditions of use necessary to ensure control of risk and safe use. This information was not available at baseline and can thus be attributed to REACH.
- Many registrants put much effort in the **identification of supply chains and downstream uses**, which were sometimes unknown to them prior to REACH.
- Apart from exposure assessments performed in the context of CSRs, the **information gathered by registrants on the different uses** of a substance is valuable as such. This became evident in the case of substances, for which an exposure estimate was not available and had to be modelled by the authors of this 5 years update (37% of substances for the impact area workers).
- Similar to the findings for workers, analysis in the impact area environment has shown a better knowledge on the uses of chemicals (e.g. less wide dispersive uses), better exposure assessments and improved toxicity estimates for substances for which a CSR was required.
- As a consequence of these REACH-related changes, RCRs and Risk Scores decrease from baseline to 2011, while the quality of the underlying data generally improves at the same time, ultimately pointing to a better control of risk.

While many of the changes observed in this evaluation can therefore be considered REACH-related, the evaluation also allowed the identification of potential problems.

- Lacking exposure estimates and their consequences are discussed in detail in the comprehensive report. These cases point to the fact that – even after REACH taking effect – relevant exposure to chemicals may exist in situations, in which the Regulation does not require exposure estimation and risk characterisation (or was interpreted by some registrants in such a way).
- Major problems are associated with DMEL derivation, a finding that has also been made in other evaluations of registration dossiers using different sets of carcinogens (Püringer 2011; Rouw 2011).

Apart from registration, some of the reference substances are subject to REACH Authorisation and Restriction procedures. This shows that both elements of REACH have been able to identify relevant substances of the reference group of the REACH baseline study.

Not all of the reference substances expected for registration by the end of November 2010 have been registered. However, there are no indications that these substances are no longer on the market. It is reasonable to assume that they will be registered in the second and third registration phase.

In the 5 years update, the detailed analysis of the development of the risk and quality scores had to be restricted to HPV chemicals and SVHC. In the second and third registration phase, registrations of substances with medium and low production volumes take place. A preliminary analysis of the small number of registered MPV and LPV chemicals indicates improved data availability already.

The methodology developed in the REACH baseline study allows analysing in the 10 years update and the 15 years update, whether the findings of the first update can be confirmed for medium and low production volume chemicals.

1 Background

The REACH baseline study: In the REACH baseline study, a set of indicators has been developed to monitor the performance of REACH and its central elements ([3]). Inter alia, this study presented a baseline estimation of the risk caused by chemicals and of the quality of underlying substance-specific data, which were available when REACH came into force in June 2007. For this purpose, the so-called 'Risk and Quality Indicator System' has been developed. It allows assessing risk and quality at different points in time.

The 'Risk and Quality' Indicator System of the study tracks two major goals of REACH:

- Improvement in the quality of publicly available data for the safety assessment of chemicals and
- reduction in the risk of chemicals to humans and the environment.

Risk Scores and Quality Scores: Principally, the methodology used in the REACH baseline study to calculate the nominal risk of the reference substances has the same structure as the chemical safety assessment under REACH. Exposure estimates and toxicity estimates are the key parameters to calculate the risk characterisation ratios (**RCR**s) and **Risk Scores** for the reference substances. A specific ranking system has been developed to assess the quality of the toxicity data and the exposure data. Data of high quality have a **Quality Score** of 1, data of low quality have a Quality Score of up to 10. The Quality Score for the exposure data ($\mathbf{QS_{exp}}$) and the Quality Score for the toxicity data ($\mathbf{QS_{tox}}$) are multiplied to give the (total) Quality Score $\mathbf{QS_{total}}$, the latter ranging from 1 (best quality) to 100 (lowest quality).

The four impact areas: Risk Scores and Quality Scores are determined for the following four impact areas: **workers**, **environment**, **consumers** and **humans via the environment**.

For each of the four impact areas, the approach used (discussed intensively with the Steering Committee of the study) is documented in a detailed technical report (methodology annexes I–IV). The same principal approach has been applied in all impact areas. Some details of the methodology differ between the impact areas. Therefore, it is possible to compare the impact areas regarding general trends. They should not be compared regarding individual figures (e.g. geometric means of the risk cores).

The baseline – 2007: In 2007, a representative set of 237 randomly selected reference substances has been assessed in the 'Risk and Quality Indicator System'. The nominal risk and the quality of the data available for these substances have been determined and expressed as 'Risk Scores' and 'Quality Scores'. The results of the first assessment have been published in the REACH baseline study (EUROSTAT 2009), which also discusses the concepts (e.g. nominal risk) used in this study.

The 5 years update – 2011: Regarding the REACH review process scheduled for 2012, EUROSTAT has been asked by the European Commission Directorates General for the Environment and for Enterprises and Industry to prepare a 5 years update of the study. This update analyses the changes occurring in the nominal risk associated with the selected reference substances and in the quality of the available data.

The main objective of the 5 years update is to calculate the Risk Scores and the Quality Scores (and the related figures) for the situation in 2011 – and to compare them with the figures for 2007. The conclusions from this comparison should allow answering the following two questions:

- Does REACH lead to an improvement of the quality of data, which are publicly available for the chemical safety assessment of chemicals?
- Does REACH lead to a reduction of the risks, which are posed by chemicals to humans and the environment?

Causal link between detected changes and REACH: Changes in the quality of the data and in the risk associated with chemicals can be caused by several activities. Not all of them are necessarily REACH-related, but can be the effect of other existing legislations or other changes.

Therefore, the 5 years update sets its focus on the group of reference substances for which major changes due to REACH are expected to be already noticeable: high production volume (HPV) substances and substances with specific hazardous properties (substances of very high concern, SVHC), which had to be registered by the end of November 2010. For them, a direct relationship between changes in the Risk Scores and Quality Scores and REACH-related documents (registration dossiers, dossiers from the authorisation and restriction procedures) can be assumed. A small number of the medium and low production reference substances has already been registered, but their number is too small to allow conclusions for the groups of medium and low production

([3]) EUROSTAT 2009: The REACH baseline study. Eurostat Methodologies and Working Papers. Luxembourg 2009. The REACH baseline study has been commissioned by Eurostat in cooperation with the services responsible for environment and industry of the European Commission.

reference substances. Therefore, Risk Scores and Quality Scores have not been re-calculated for these substances. However, a preliminary analysis has been made for these substances in relation to changes in classification and the availability of toxicity estimates (see chapter 3.3).

Methodological issues, which support a deeper understanding of the REACH baseline study, and its updates are described later – in chapter 6. These issues refer to:

- the evaluation of data from registration dossiers;
- adaptations of methodology;
- the 2011 sample;
- consideration of risk management measures and data on real exposures;
- relevance of additional company specific data and
- changes in the tonnage band of the reference substances.

In the following chapter 2 we start with a **description of the key findings** of the 5 years update. **Further findings** are presented in chapter 3. **Conclusions** are documented in Chapter 4. Supporting information on the **characteristics of the 5 years update** can be found in Chapter 5. As already mentioned above, for **methodological issues** see Chapter 6.

2 Key findings of the 5 years update

In this chapter, the key findings of the study are described at **three levels of analysis**.

- The **summary level** evaluates all 62 substances together.
- The **profile level** provides more details for the group of HPV chemicals and the group of SVHC separately.
- The **analysis level** is the most detailed level. It goes down to an analysis of the different components of the indicator system, such as RCRs, exposure and toxicity estimates and Quality Scores for the exposure and toxicity estimates. The main purpose is to understand the changes found for individual substances.

In the comprehensive report, the results are presented systematically for each of the impact areas. The key findings are illustrated by selected figures and tables from the different impact areas below.

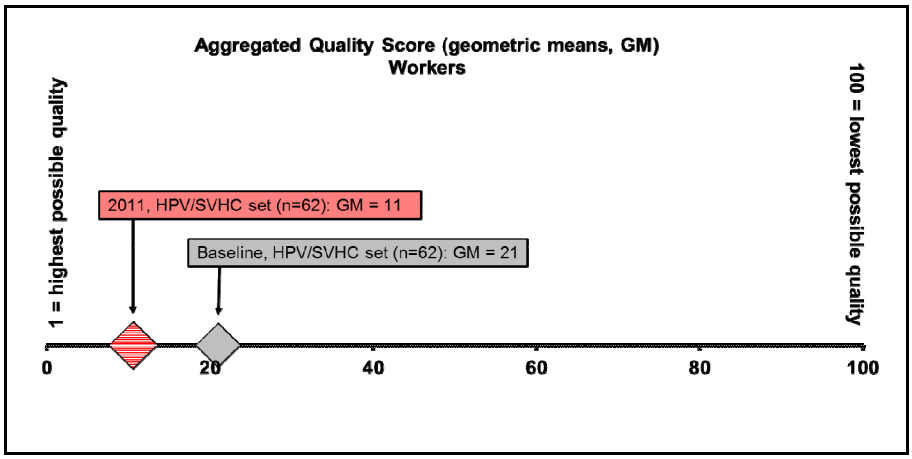
2.1 Development of the quality of the data

The quality of the data available for the assessment of the reference substances improves considerably, indicated by a reduction of the Quality Score from 2007 to 2011.

For an interpretation of Quality Scores, it is important to stress that a better quality is assigned lower Quality Scores in the evaluations (Eurostat 2009).

The following figure shows the development of the Quality Score for the 62 reference substances in the impact area workers. The figure shows a decline of the geometric mean of the Quality Score for this impact from 21 in 2007 to 11 in 2011.

Figure 2.1: Aggregated Quality Score. Comparison 2007 – 2011. Impact area workers (n=62)



Source: Author's compilation

This decrease in the Quality Score (improvement in quality) is also observed if the analysis is made separately for HPV chemicals and SVHC.

The improvement in quality of the data has been seen in all four impact areas.

The change in the total Quality Scores from 2007 to 2011 is summarised for the four impact areas in Table 2.1. Median values are included in addition to the geometrics means and confirm the trend of decreasing Quality Scores. This indicates a clear increase in the quality of the data available for the assessment of the 62 reference substances (HPVCs and SVHC).

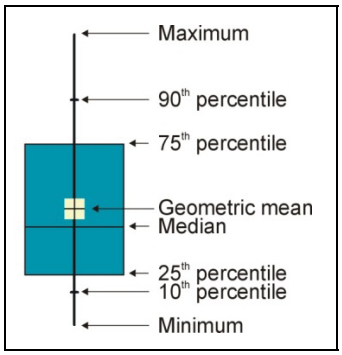
Table 2.1: Summary of aggregated Quality Scores. Comparison 2007 – 2011 (n = 62)

Impact area	Quality Score, Geometric mean		Quality Score, Median	
	2007	2011	2007	2011
Workers	21	11	30	14
Environment	11	3	10	4
Consumers	48	15	64	14
Humans via the Environment	33	15	37	13

Source: Author's compilation

Changes of the quality of the available data have been analysed in more detail for the HPVCs and the SVHCs separately. The results are presented as whisker plots, and Figure 2.2 shows the various statistical descriptors contained in this type of graph.

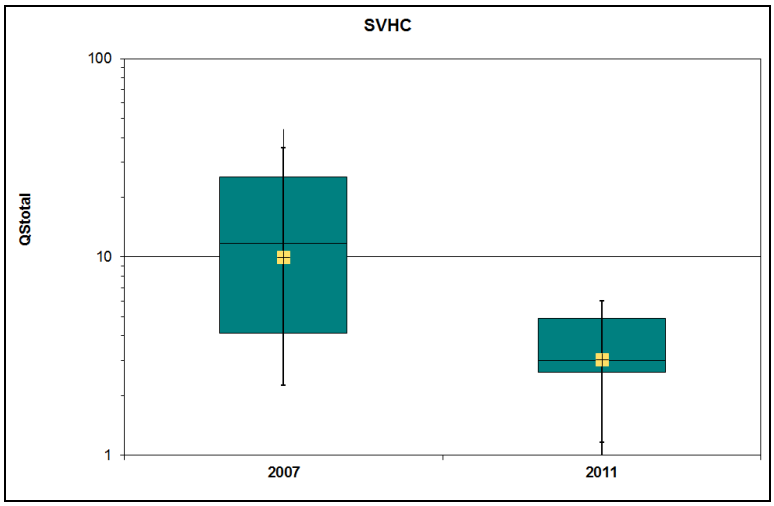
Figure 2.2: Legend to whisker plots



Source: Author's compilation

As an example, the changes in the quality of available data are shown in Figure 2.3 for SVHC in the impact area environment. A clear improvement of the quality of the data is shown by several of the statistical parameters. In addition, the poorest quality in 2011 was a QS_{total} of 35 that was exceeded by 3/19 substances in 2007. This means that 16% of the SVHC had a poorer quality in 2007 than the worst quality assigned in 2011. QS_{total} for SVHC declines by a similar degree (GM and median) to HPV (see comprehensive report for further details).

Figure 2.3: Quality Scores (QS_{total}). Comparison 2007 – 2011. Impact area environment. SVHC (n=19)



Source: Author's compilation

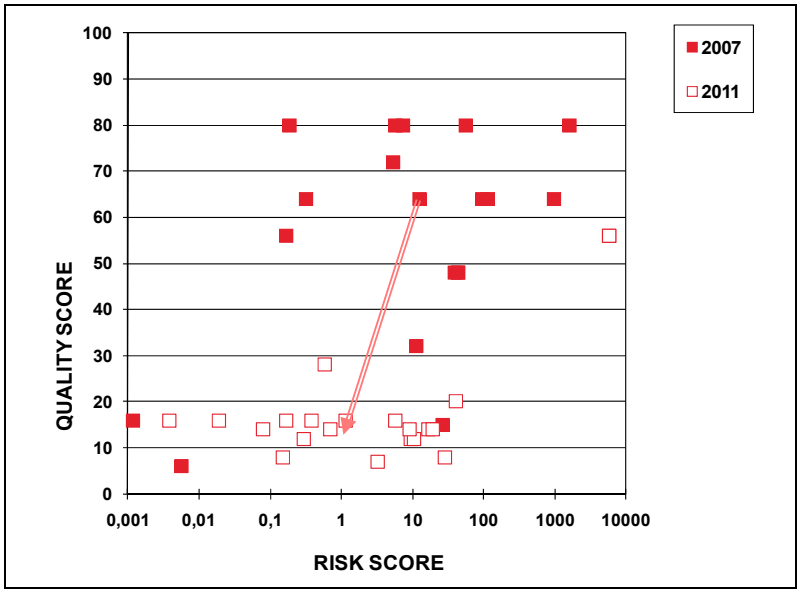
For the first time, some of the reference substances reach the best quality possible (QS_{total} equal to 1) in some impact areas.

The detailed analysis of the quality scores for SVHC also documents that 16% of the reference substances were assigned the best quality possible (QS_{total} = 1) for the impact area environment. Such a maximum quality was never assigned in 2007.

Whisker plots contain a wealth of statistical information and give an idea of the distribution of the respective values. However, they do not show the distribution of individual values. As in the REACH baseline study (Eurostat 2009), Risk Score/Quality Score (QS_{total}) scatter plots are used for this purpose at profile level. These scatter plots do not contain additional data, but rather provide a different view of the same data. Note that the scatter plots presented here do not allow identification of the movement of a particular substance. However, such an evaluation will be presented later at analysis level.

As an example, Figure 2.4 shows the scatter plot of Risk Score / Quality Score for the HPV substances, impact area consumers. A general movement of the data points towards the lower left corner can be seen. The lower left corner indicates a better quality of the available data and a lower risk associated with the reference substances in 2011 compared to 2007.

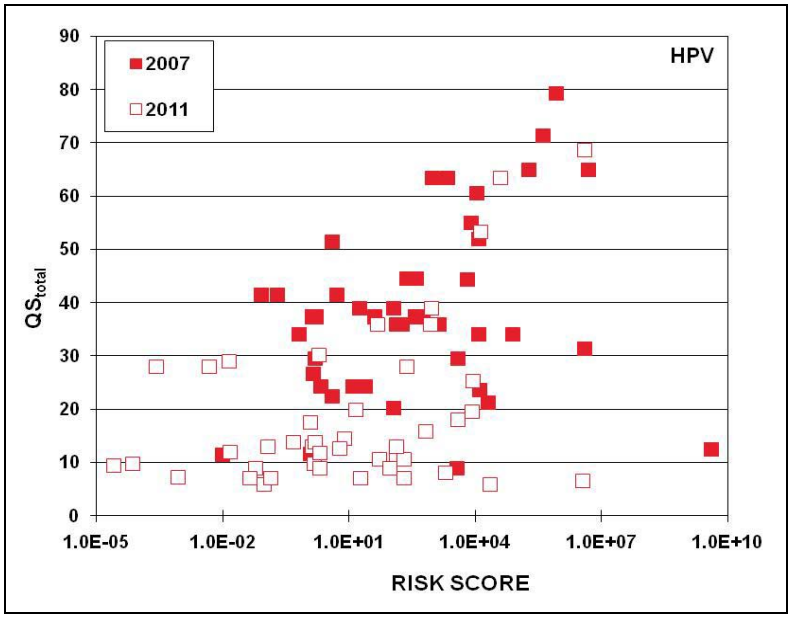
Figure 2.4: Risk Score/QS_{total} scatter plot. Comparison 2007 – 2011. Impact area consumers. HPV reference substances (n=20)



Source: Author's compilation

As a second example, Figure 2.5 shows the scatter plot analysis for the HPV substances for the impact area humans via the environment. In this case, a shift toward better quality and lower risk can also be seen.

Figure 2.5: Risk Score/QS_{total} scatter plot. Comparison 2007–2011. Impact area Humans via the environment. HPV reference substances (n=44)



Source: Author's compilation

Such scatter plots are given in the comprehensive report for all four impact areas. More details on the key findings for the risk scores are given later in Chapter 3.2.

For the majority of HPV chemicals and SVHC, the quality of the data underlying the exposure estimate (QS_{exp}) and the toxicity estimate (QS_{tox}) improve.

As noted above already, the total quality of the available data increases from 2007 to 2011. The related element of the indicator system (QS_{total}) is composed of the individual Quality Scores for the exposure estimate (QS_{exp}) and the toxicity estimate (QS_{tox}). It is therefore interesting to analyse whether the improvement in the quality is due to an improvement in one of these components or both.

A statistical evaluation shows that both elements contribute to the improvement of the total Quality Score (Table 2.2.).

Table 2.2: Summary descriptive statistics for Quality Scores. Comparison 2007 – 2011. Impact area workers. HPV chemicals (n=46)

	QS_{exp}			QS_{tox}			QS_{total}	
	Baseline	**2011**		**Baseline**	**2011**		**Baseline**	**2011**
n	46	46		46	46		46	46
Median	8.0	5.0		4.0	2.0		30	14
GM	5.5	5.0		3.8	2.2		21	11
10^{th} percentile	1.0	4.0		2.0	1.0		4.0	5.0
25^{th} percentile	5.5	5.0		3.0	2.0		16	10
75^{th} percentile	8.0	7.0		5.0	3.0		35	16
90^{th} percentile	8.0	7.0		6.0	3.0		55	21
MIN	1.0	1.0		2.0	1.0		2.0	1.0
MAX	10	8.0		10	10		100	50
IRQ	2.5	2.0		2.0	1.0		19.0	6.0

Source: Author's compilation

The detailed analysis of the data for the impact area workers (on the basis of 45 substances; one substance without any changes excluded) shows that

- the quality of the toxicity estimate improves for 35/45(78%),
- the quality of the exposure estimate improves for 29/45 (64%) and
- the overall quality improves for 38/45(84%) HPV chemicals.

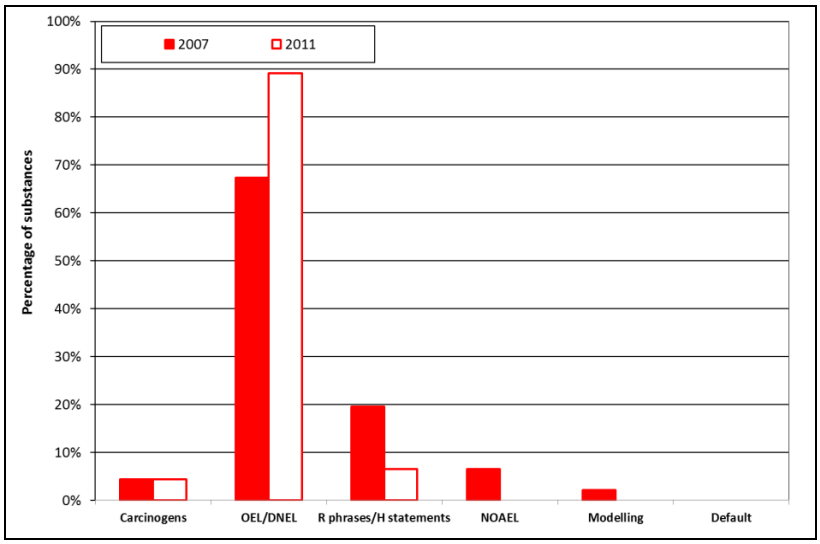
What are the main reasons for these improvements in quality? At baseline, occupational exposure generally had to be modelled, usually without any additional information, resulting in QSexp = 8. Many toxicity estimates were based on OELs or OELanalogues derived from risk phrases (Eurostat 2009), which often gave QStox = 4 (depending on the availability of testing data). In 2011, ECETOC TRA exposure modelling with consideration of RMMs (usually conducted in CSRs) combined with an OEL/DNEL for the toxicity estimate in many cases. This results in a QS_{exp} of 5 (instead of 8) and a QS_{tox} of 2 (instead of 4). There is a subset of substances with QStox = 1, which was assigned if a DNEL was identical to an OEL.

Due to the registration, DNELs, PNECs and more detailed information on uses and exposures become available for a large number of substances.

The increase in quality of the data available for the assessment of the reference substances described above is reflected in another finding of the 5 years update: the data sources for the toxicity estimate and for the exposure estimate change to a large extent. This is illustrated below for HPV substances for the impact area workers. Additional findings from the other impact areas are added.

At the 2007 baseline, the main source for the toxicity estimate was occupational exposure limit values (OELs). They were available for almost 67% of the 46 HPV substances – including 'company OELS' reported in IUCLID 4 files. In 2011, DNELs become available for almost 90% of the HPV substances. As a consequence of increased DNEL availability, the toxicity estimate on the basis of risk phrases or hazard statements was less often used and even less reliable methods (use of a NOAEL or modelling) were never used in the 2011 evaluation. **Figure 2.6** shows the change in the data availability for the toxicity estimate. Similar to the findings in the impact area workers, increased availability of DNELs has been found for the impact area consumers (and humans via the environment). Increased availability of PNECs has been a result of registration for the impact area environment.

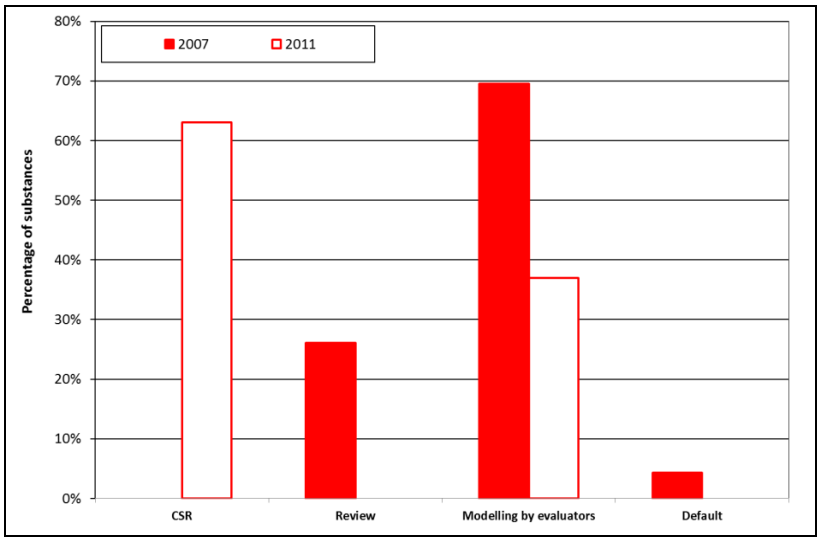
Figure 2.6: Data availability analysis for toxicity data. Comparison 2007 – 2011. Impact area workers. HPV chemicals (n=46)



Source: Author's compilation

In relation to the exposure estimate, Figure 2.7 shows the expected finding that most of these (63%) could be taken from CSRs. The figure also shows that – as a consequence – modelling had to be used much less. In this context it must be stressed that 'modelling' refers to exposure modelling carried out by the evaluators. In fact, modelling using the ECETOC TRA tool or (much less often) more advanced tools is carried out for about 50% of all 46 HPV chemicals and for more than 80% of the substances, for which exposure estimates were carried out in CSRs.

Figure 2.7: Data availability analysis for exposure data. Comparison 2007 – 2011. Impact area workers. HPV chemicals (n= 46)



Source: Author's *compilation*

The data availability analysis also highlights the fact that exposure estimates are lacking for more than one third of the chemicals and in the vast majority of these cases exposure estimates are not required under REACH. The consequences of this fact will be discussed later.

2.2 Development of the Risk Scores

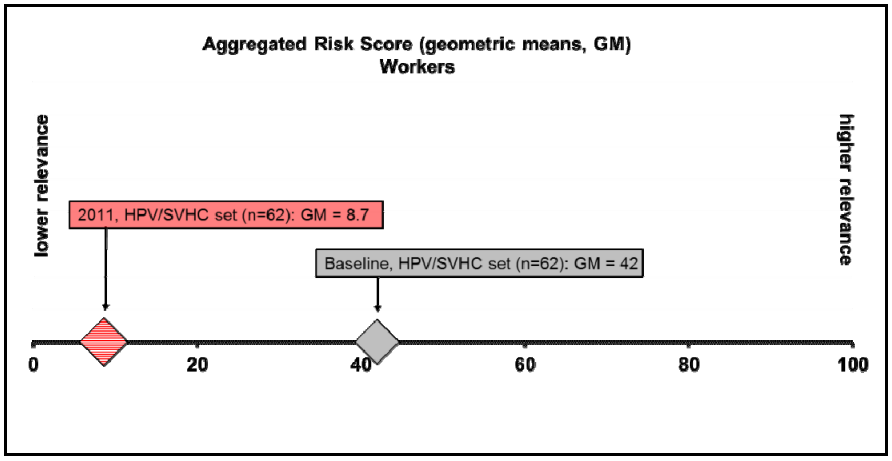
In the analysis 2011 a marked decrease in the Risk Scores has been found for the aggregated evaluation of 62 substances (46 HPV chemicals and 16 SVHC)([4]).

The Risk Scores are an indication for the nominal risks associated with the reference sample. They are based on a calculation of the risk characterisation ratios (RCRs) for the substances. In line with the chemical substance evaluation under REACH, RCRs are defined as the ratio of the exposure estimate to the toxicity estimate. The Risk Scores are calculated by multiplying the RCR by an additional factor, the Population Risk Modifier. This factor indicates whether a low or a high number of persons / organisms are expected to be exposed. It ranges from 1–10, with the higher figure indicating a higher exposure potential.

Different from the Quality Scores (which by definition can assume values between 1 and 100 only), Risk Scores are not restricted to a given range of values. The Risk Score does not intend to give an exact numerical value for real risks associated with a reference substance, but is primarily used for an assessment of the shifts associated with a substance or the entire sample.

The 5 years update found a significant decrease in the Risk Scores for all impact areas. As an example, the following figure for the impact area workers shows the shift of the geometric mean of the Risk Scores for the whole set of 62 high HPVCs and SVHC.

Figure 2.8: Aggregated Risk Scores. Comparison 2007 and 2011. Impact area workers (n= 62)



Source: Author's compilation

The 5 years update indicates an almost 5-fold decrease in the aggregated Risk Score for the 62 substances evaluated for the impact area workers: from 42 in 2007 (baseline) to 8.7 in 2011 (based on GMs). This is mostly due to the pronounced decrease in Risk Scores observed for SVHC, which is reduced by about two orders of magnitude; while the Risk Score for HPV chemicals declines by only a factor of 2 based on GM (these changes will be discussed in detail in the following sections).

A similar development can be seen for the other three impact areas. The change in the Risk Scores from 2007 to 2011 is summarised for the four impact areas in Table 2.3. Median values are included in addition to the geometric means and confirm the trend of decreasing Risk Scores. This indicates a clear reduction in the risks which are associated with the 62 reference substances (HPVCs and SVHC).

([4]) Three of the HPV chemicals were also evaluated in the SVHC group analysed separately, leading to a total number of SVHC of 19.

Table 2.3: Summary of aggregated Risk Scores. Comparison 2007 – 2011 (n= 62)

Impact area	Risk Score, Geometric mean		Risk Score, Median	
	2007	2011	2007	2011
Workers	42	9	15	6
Environment	1	0,1	0.6	0.1
Consumers	10	2	19	2
Humans via the Environment	868	34	37	13

Source: Author's compilation

The decline in Risk Scores is almost entirely due to decreases in Risk Characterisation Ratios.

At the summary level, Risk Scores have been calculated for all 62 substances together. At the profile level, the development of the Risk Scores has been analysed in more detail for the group of HPV chemicals and SVHC separately. A comparison of the Population Risk Modifier revealed little change between 2007 and 2011. Therefore, the decline in Risk Scores results directly from a decline of the RCRs of the reference substances.

The analysis shows a pronounced reduction of the fraction of substances with RCRs above 1 and/or RCRs above 10 in all four impact areas.

In all impact areas, the number of substances with RCRs > 1 decreases from 2007 to 2011. The following table shows the figures for the impact area workers. Overall, the percentage of HPV chemicals with RCRs at or below 1 increases by 20% from (25/46 =) 54% at baseline to (34/46 =) 74% in 2011.It was also possible to identify a significant decline in 2011 of the number of substances with RCR > 10, with only 5 substances displaying an RCR > 10 (instead of 12 in 2007).

Table 2.4: Distribution of RCRs. Comparison 2007 – 2011. Impact area workers. HPV chemicals (n= 46)

	2007		2011	
	n	% of total number of substances	n	% of total number of substances
RCR ≤ 1	**25**	**54 %**	**34**	**74%**
RCR < 1	24	52 %	31	67 %
RCR = 1	1	2,2 %	3	6,5 %
RCR > 1	21	46 %	12	26%
RCR > 10	12	26 %	5	11%
total	46	100 %	46	100 %

Source: Author's compilation

Figures as given in the table above provide an overall picture of RCR distribution, but do not show shifts at the individual substance level. Such an analysis is shown in Figure **2.9** and the following changes from baseline to 2011 were observed for the impact area workers:

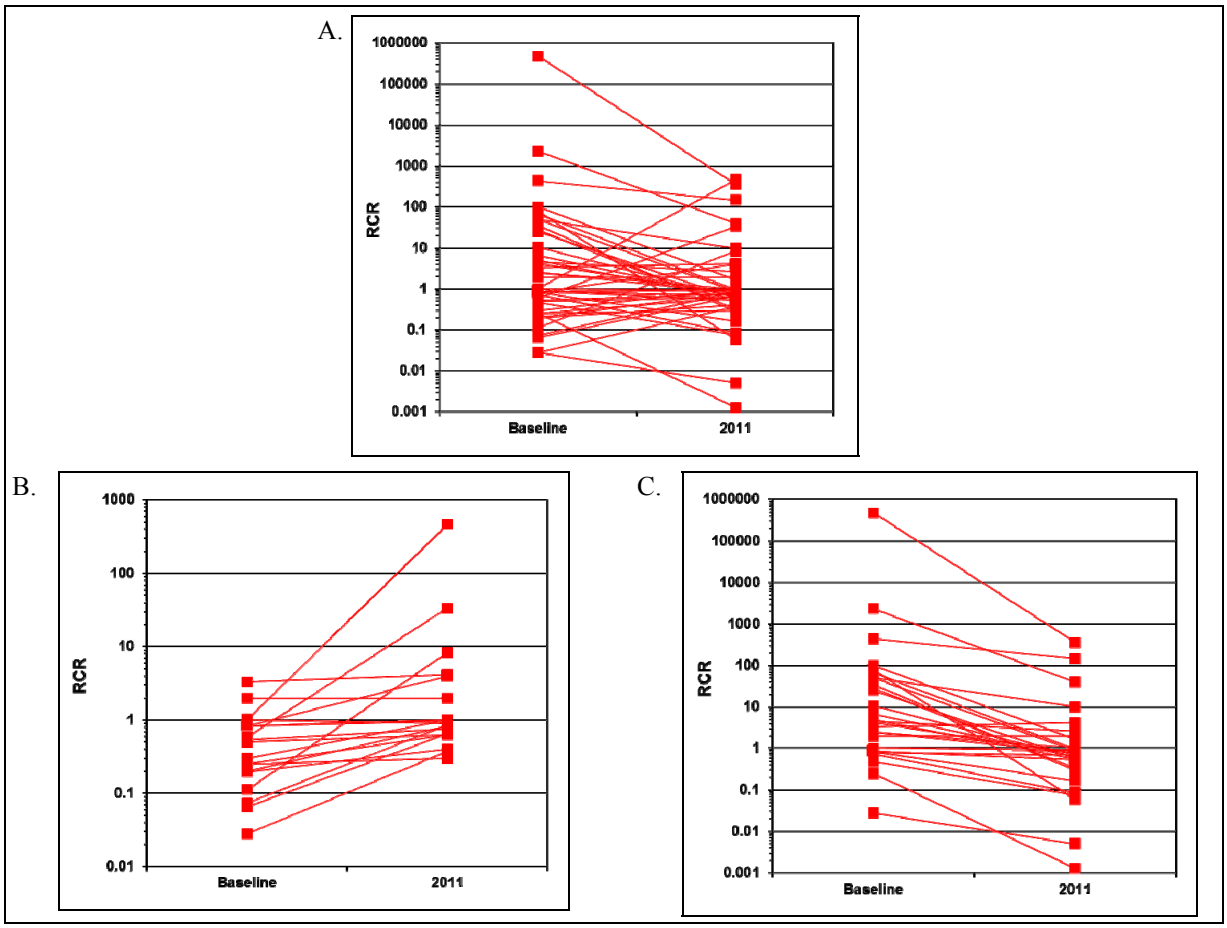
- 1 HPV chemical shows no change in the RCR (2,2%),
- 18 HPV chemicals show an increase in the RCR (39%) and
- 27 HPV chemicals show a decrease in the RCR (59%).

The main changes in this figure and the underlying data can be described as follows:

- The graph highlights the "narrowing" effect: while many substances were concentrated between RCRs in the 0.1-100 range in 2007, the bulk moved to the 0.1–10 range in 2011.
- There is an apparent cluster of RCRs just below 1 in 2011 that was not evident in 2007. Many substances appear to be moving from RCRs either above or below 1 in 2007 to a RCR just below 1 in 2011 (this pattern is discussed in detail in Analysis Box 3.2 in the comprehensive report).
- It is evident that an increase in RCR does not necessarily lead to a RCR > 1. Conversely, a RCR decrease will not always result in an RCR ≤ 1 (see Figure **2.9**-B and -C). In particular, very high RCRs (>100) in 2007, while decreasing, are still clearly above 1 in 2011.

Figure 2.9: Shift of RCRs at the individual substance level. Comparison 2007 – 2011. Impact area workers. HPV chemicals (n=46):

A – All substances
B – Substances showing no change or increases in RCRs
C – Substances showing decreases in RCRs (note the different scales)



Source: Author's compilation

The development of RCRs of individual substances has been analysed in the other impact areas too.

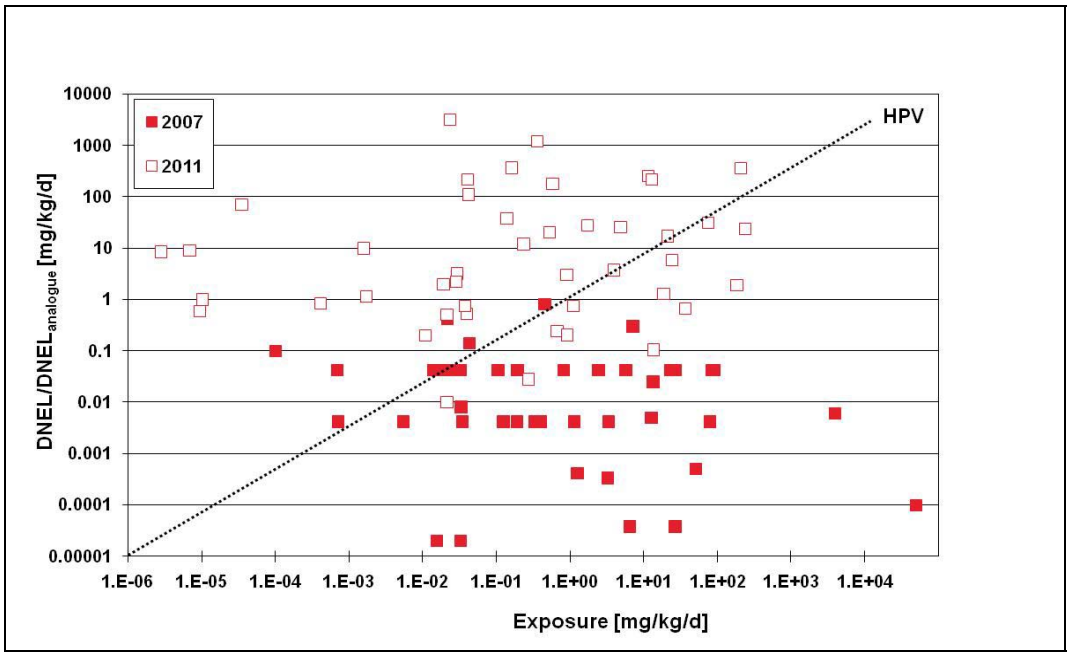
Since the RCR is calculated from the **exposure estimate** and the **toxicity estimate**, it is worth looking at the exposure and toxicity estimates in 2007 and in 2011.

Figure 2.10 shows the exposure estimate on the x-axis and the assumed safe level (as expressed by the DNEL (or analogues), toxicity estimate) on the y-axis. The example refers to HPV chemicals and the impact area humans via the environment. The dashed diagonal line discriminates exposure higher or lower than DNEL or analogue. In other words: all data points above the dashed line indicating RCRs < 1 and all data points below it indicating RCRs > 1.

The majority of HPV substances analysed in 2011 is above the dashed line. Compared to the situation in 2007, a shift is clearly visible towards RCRs lower than one (to the upper left-third of the

Figure **2.10**). For the impact area humans via the environment, this decrease of RCR seems to be a direct consequence of the increase of DNEL values observed.

Figure 2.10: Analysis of the exposure and toxicity estimates (mg/kg/d). Comparison 2007 – 2011. Impact area Humans via the environment. HPV substances (n= 46)

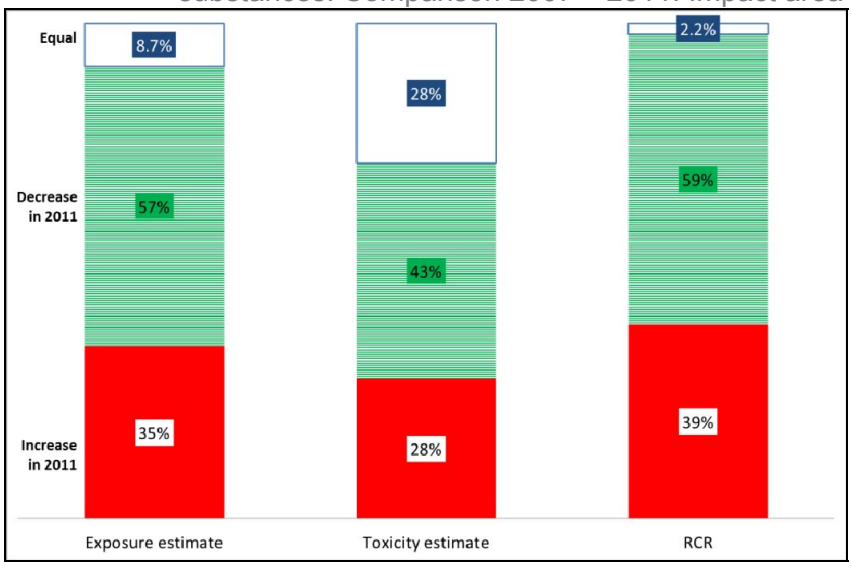


Source: Author's compilation

For almost all substances, changes in at least one of the key input parameters for the RCR (toxicity estimate, exposure estimate) took place indicating changes in the knowledge about the substances.

Scatter plots of toxicity estimates and exposure estimates as presented above do not allow assessing the behaviour of individual substances. This is only possible by tracking changes for each substance separately. Such an analysis, identical to the one carried out for RCRs (see Figure 2.9 and the analysis around it) has been carried out for exposure and toxicity estimate. For the impact area workers, the following picture emerges (Figure 2.11, RCRs shown for comparison):

Figure 2.11: Changes in exposure estimates, toxicity estimates and RCRs for individual substances. Comparison 2007 – 2011. Impact area workers. HPVC (n= 46)



Source: Author's compilation

Changes in the exposure estimate have been found for almost 92% of the substances and changes in the toxicity estimate for about 71% and decreases of the estimate dominate in both cases.

(More details on this are given in the comprehensive report in Chapter 3.2.2.3).

2.3 Additional key findings

In 2011, a remarkable number of reference substances still show RCRs above 1.

In the majority of the cases with RCRs above 1, exposure estimates have not been available in the registration dossiers for these substances. While DNELs are derived for the majority of the substances, an exposure estimation and risk characterisation is only performed under certain circumstances, i.e. if the substance is classified. But even for classified substances, some registrants have chosen not to perform an exposure estimation and risk characterisation for human health, e.g. if the substance was not classified for human health endpoints.

In the impact area workers, exposure estimates are lacking mainly due to three reasons: 1) for some of the reference substances the REACH Regulation does not require a chemical safety assessment (primarily isolated intermediates handled under strictly controlled conditions); 2) the REACH Regulation does not require an exposure assessment and risk characterisation of non-classified substances); 3) limited scope of exposure assessment by some registrants in case of substances which have been classified only for a specific endpoint. In all these cases, exposures have been modelled by the evaluators. For SVHC, a further reason for RCRs above 1 has been the lack of reliable DMELs (for details see Analysis Box 3.4 and Chapter 3.2.2.9 of the comprehensive report).

These findings highlight the fact that appreciable risks can be associated with substances, which are not classified.

More generally, however, the REACH Regulation itself leads to the findings for the substances that are not classified. While the general approach of REACH is risk-based, the provision that an exposure estimation and risk characterisation is only required for substances that are classified, introduces a hazard element. This may well be justified since it can be assumed that toxic substances should have a classification (e.g. for specific target organ toxicity). However, non-classification does not automatically mean that DNELs for these substances are very high. In the case of 3 non-classified reference substances, the DNELs are not extremely high. They are in the range of the median values or DNELs of all analysed HPV chemicals (about 3-4 mg/m^3, see Chapter 3.2.2.4 of the comprehensive report). Such a DNEL can be derived from a standard repeated-dose toxicity study with N/LOAELs, which do not result in a classification.

Many of the non-classified substances considered here are used in non-industrial spraying applications, which often results in a high exposure estimate, since aerosol formation is assumed. In practice, risk management measures ensuring safe use do not have to be established for non-classified substances, while this is the case for classified substances.

Overall, the combination of ‘moderate’ DNELs and high exposure estimates for non-classified substances lead to RCRs above 1 and indicate possible risks.

In most of the CSRs analysed, no detailed quantitative risk assessments have been made for the impact areas consumers and humans via the environment.

Of the 62 reference substances included in the analysis, consumer uses have been identified for only 22 substances. For 14 of these 22 substances, exposure estimates for consumers have been provided in the CSRs. Exposure of the general public during service life, e.g. by leaching from materials, have not been discussed in detail in the CSRs. In most cases, exposure estimates had to be calculated by the evaluators in order to calculate the Risk Scores.

Similar, for the impact area humans via the environment data have been very limited in in the CSRs which were evaluated. For all reference substances the risk scores had to be calculated by modelling by the evaluators.

3 Further aspects

3.1 Availability of the reference substances on the market

Overall, 46 of the 65 HPV chemicals and 19 of the 25 SVHC selected as reference substances have been registered. This is taken as an indication for placing these substances on the market. For the reference substances, which have not been registered, there are no indications that their availability on the market changed from 2007 to 2011. They do not belong to the group of substances for which an analysis by ECHA shows withdrawal from the market as a reason for non-registration. It is reasonable to assume that these substances are still manufactured, with lower production volumes than assumed in 2007, and will be registered in the second registration phase by end of May 2013 or in the third phase (May 2018).

3.2 Authorisation and restriction of reference substances

Since the first assessment in 2007, reference substances of very high concern (SVHC) have been proposed for the candidate list, included in the candidate list, recommended for inclusion in Annex XIV and/or included in Annex XIV. In total, 10 of the 25 SVHC became subject of one of the different elements of the authorisation procedure. These results show that the REACH authorisation procedure has been able to identify some SVHC from the set of reference substances. For each of them the authorisation procedure leads to documents with additional information on substance properties, use pattern and availability of substitutes. This information has supplemented the information from the registration dossiers when re-calculating the Risk and Quality Scores of the reference substances.

Due to the limited number of SVHC, any additional information on the reference SVHC would reveal their identity and can therefore not be given here. These data were provided to EUROSTAT in a separate report.

3.3 LPV and MPV chemicals – some initial trends

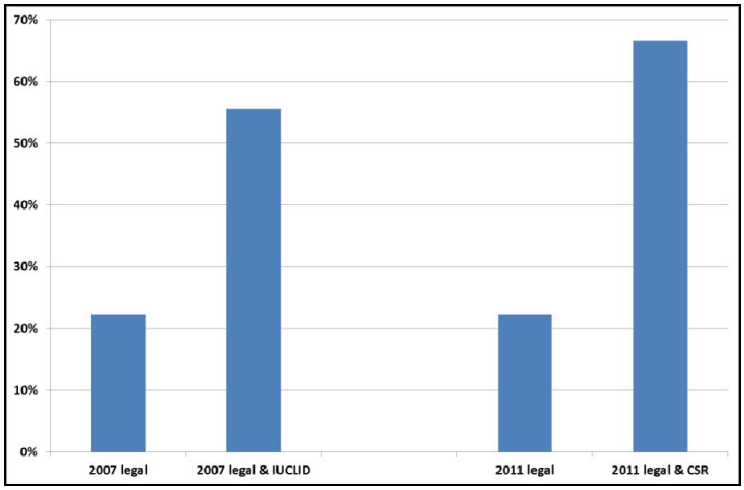
As has been stated earlier, LPV and MPV have been excluded from a detailed evaluation within the 5 years update, due to the (expected) very small number of registration dossiers (only 9 for LPV and MPV together). However, these substances were checked for changes in relation to classification information.

The following figure shows that 2/9 (22%) substances were classified according to the then current legislation ("legal") in 2007 and this figure did not change in 2011. An additional 3 substances were self-classified by manufacturers in 2007, so that the total number rose to 5/9 (55%) in 2007. In 2011, this figure increases to 67% (6/9 substances) due to additional classification information for 1 substance from a CSR.

This substance is classified for aquatic hazards and the underlying information seems to have been generated after the entry into force of REACH. It thus appears that data requirements under REACH led to a study being conducted that in turn resulted in a classification of a previously non-classified substance.

While this difference may appear small, it is based on only 9 substances. If this finding of additional classification information for 1/9 (11%) is representative, this points to a large number of chemicals for which such additional information will become available in the future.

Figure 3.1: Changes in classification. Percentage of substances for which information on classification was available. Comparison 2007 – 2011.
MPV and LPV chemicals (n = 9)



Source: Author's compilation

In relation to DNELs for workers, the difference is even more pronounced. Of the 9 substances, none had a 'legal' OEL in 2007, but 2 had a company OEL reported in the IUCLID datasets evaluated at baseline. A DNEL was available for a total of 5 substances (including the 2 that previously had a company OEL). Thus, additional information was generated due to REACH for 3/9 (33%) substances. Again, if this figure is representative, such additional information will probably become available for hundreds, if not thousands, of chemicals. This hypothesis can be verified in future updates of the REACH baseline study.

4 Conclusions

The 5 years update of the REACH baseline study found clear indications that registration due to REACH lead to a significant improvement of our knowledge on substance properties. For the first time, for many substances existing data have been used to derive toxicity estimates such as DNELs, DMELs and PNECs, and to perform exposure estimations and risk characterisations. In addition, for a relevant part of the substances analysed the risk characterization ratios show a clear decrease. The fraction of reference substances with risk characterization ratios at or below 1 increases.

The main difference in the data sources in our analysis 2007 and 2011 have been the availability of registration dossiers in 2011. The changes in the Risk Scores and Quality Scores origin from the data in these documents (to a minor extent additional information came from REACH documents for SVHC due to authorization and restriction). Therefore, it is reasonable to state that the registration obligation under REACH leads for the reference substances which have been registered to the improvements of data availability and the reduction of the risk characterization ratios which have been found in the REACH baseline study 5 years update.

Details from the analysis in the different impact areas support these conclusions.

- The **higher availability of DNELs** compared to OELs at baseline is clearly linked to REACH, since the Regulation introduced this instrument. Thus, DNELs are now available for 10 substances (out of the 46 HPV chemicals), for which no OEL existed at baseline.
- Apart from DNEL availability itself, this instrument also leads to a **confirmation (or lack of it) of existing OELs**. If registrants decide to use an existing OEL as DNEL, they will check the appropriateness against the toxicity data they included in their dossier. If data requirements under REACH reveal additional information, a deviation from an existing OEL may become necessary. For example, for the impact area workers this evaluation revealed individual cases, where a substantially lower DNEL was derived compared to existing OELs.
- For the impact area consumers, data on uses, toxicity and exposure were very incomplete in 2007. The first improvement in 2011 has been the identification of relevant uses. In addition, also in this impact area the toxicity estimates (DNEL or analogue) are clearly of better quality in 2011 than in 2007 thanks to the determination of DNEL from experimental data in the CSRs.
- **Improved exposure assessments** can also be seen as a result of REACH. Although problems associated with the exposure assessment remain (see discussion above), many registrants have put much effort in performing exposure assessments and risk characterisations, resulting in a detailed description of RMMs and specific conditions of use necessary to ensure control of risk and safe use. This information was not available at baseline and can thus be attributed to REACH.

  It may be argued that these RMMs were already in place prior to REACH. While this may be true for the manufacture of the substance and some of the main uses by large companies, it can well be questioned whether this also applies to all downstream uses. Many registrants put much effort in the **identification of supply chains and downstream uses**, which were sometimes unknown to them prior to REACH. This not only refers to the uses as such, but also to the processes involved. For example, the high fraction of HPV substances used in non-industrial spaying processes (PROC11), testifies to the detailed data generated by REACH for downstream uses. **Exposure estimates as well as the specification of RMMs and conditions of use for these downstream uses – we believe – only became available due to REACH**.
- Apart from exposure assessments performed in the context of CSRs, the **information gathered by registrants on the different uses** of a substance is valuable as such. This became evident in the case of substances, for which an exposure estimate was not available and had to be modelled by the authors of this 5 years update (37% of substances). For example, some substances were registered as isolated intermediates under strictly controlled conditions with no other uses. In these cases, the exposure estimated by the evaluators was usually much lower than the baseline estimate (when this information was often not available). At the other extreme, several substances for which no exposure estimate was available were identified as being used in non-industrial spraying processes (PROC11), which led to a high exposure estimate (often higher than at baseline, when this information was not available).
- For the impact area environment, a decline in the Population Risk Modifier indicates that the uses are more related to industrial uses than to professional or consumer uses.
- Similar to the findings for the impact area workers, analysis in the impact area environment has shown a better knowledge on the uses of chemicals; less wide disperse uses, better exposure assessments and improved toxicity estimates, for substances for which a chemical safety report was required.

- As a consequence of these REACH-related changes, RCRs and Risk Scores decrease from baseline to 2011, while the quality of the underlying data generally improves at the same time, ultimately pointing to a better control of risk.

While many of the changes observed in this evaluation can therefore be considered REACH-related, the evaluation also allowed the identification of potential problems.

- Lacking exposure estimates and their consequences are discussed in detail above. It must be stressed that for the majority of substances showing an RCR > 1 in 2011, an exposure estimation and risk characterisation in the dossiers evaluated was lacking.

  More generally, these cases point to the fact that – even after REACH taking effect – relevant exposure to chemicals may exist in situations, in which the Regulation does not require exposure estimation and risk characterisation (or was interpreted by some registrants in such a way).
- Major problems are associated with DMEL derivation, a finding that has also been made in other evaluations of registration dossiers using different sets of carcinogens (Püringer 2011; Rouw 2011). However, it must be stressed that these problems (e.g. lacking DMEL, unclear specification of risks associated with DMELs) are not solely related to REACH registration dossiers. Nonetheless, this evaluation shows that more detailed guidance for DMEL derivation – e.g. with specific case studies – is required.

Not all of the reference substances expected for registration by End of November 2010 have been registered. However there are no indications that these substances are no longer on the market. It is reasonable to assume that they will be registered in the second and third registration phase.

Apart from registration, some of the reference substances became involved in the REACH Authorisation and Restriction procedures. This shows that both elements of REACH have been able to identify relevant substances of the reference group of the REACH baseline study.

Although excluded from further analysis in the 5 years update due to their limited number a preliminary analysis of the registered MPVC and LPVC indicate an improvement in the data availability for these substances already now.

In the 5 years update, the detailed analysis of the development of the risk and quality scores had to be restricted to high production volume chemicals and substances of very high concern. In the second and third registration phase, registrations of substances with medium and low production volumes take place. In the REACH baseline study, risk and quality scores for reference substances from these groups have been documented.

The findings for the HPV and SVHC chemicals may not be completely similar for the chemicals to be registered in 2013 and 2018, as

- It is observed that the changes in the RCRs are most significant for the chemicals with a CSR. Therefore, we do not expect the exact same pattern for the 2013 and 2018 registration chemicals (MPV, LPV), as the fraction of chemicals requiring a CSR is expected to be lower for the MPV and LPV chemicals than for the HPV and SVHC chemicals
- R50/53 chemicals with a tonnage above 100 tonnes/year were to be registered in 2011. Therefore, the chemicals exhibiting the highest risk to the environment due to a combination of high tonnage and as being the most environmentally hazardous should be covered by the 2011 registration
- As the RCRs for the impact area environment are directly proportional to the tonnage, it is expected to be more straightforward to demonstrate environmental safe use for the lower tonnage chemicals than the HPV and SVHC chemicals. Therefore, the uses of these chemicals are expected to be less restricted compared to the HPVC and SVHC

The analysis in 2007 found that the availability of data for HPVC and SVHC was better than for LPV and MPV chemicals; a number of data was based on QSAR or similar estimates. Even though that the data requirements for the LPV and MPV chemicals are not so comprehensive as for the HPV chemicals, the quality of the data for the LPV and MPV chemicals may increase even more than for the HPV and SVHC chemicals, because that no experimental data was available for many of the LPV and MPV chemicals at baseline.

The methodology developed in the REACH baseline study allows analysing in the 10 years update and the 15 years update, whether the findings of the 5 years update can be confirmed for medium and low production volume chemicals. Within a few years the approach of the study allows to analyse the fate of a representative set of substances under REACH.

5 Characteristics of the 5 years update

Focus on High Production Volume substances and substances of very high concern. Changes in the quality of the data and in the risk associated with chemicals can be caused by several activities. Not all of them are necessarily REACH-related, but can be the effect of other existing legislations or other changes. Therefore, the 5 years update sets its focus on the group of reference substances for which major changes due to REACH are expected to be already noticeable: **high production volume (HPV) substances** and **substances of very high concern (SVHC**), which had to be registered by the end of November 2010. For them, a direct relationship between changes in the Risk Scores and Quality Scores and REACH-related documents (registration dossiers, dossiers from the authorisation and restriction procedures) can be seen.

Evaluation of data from registration dossiers: Detailed information on substance properties and safe use of chemicals has been expected in the REACH registration dossiers delivered by manufacturers and importers by 30 November 2010. The Risk and Quality Indicator System is basically based on

- information on toxicity data: usually reference doses/concentrations (DNELs and PNECs) or classification and labelling information
- exposure data for the four impact areas as derived in CSRs,
- the basis for these data in order to assess the quality,
- tonnage and detailed use information.

Not all of these data are publicly available. In order to fully cover the data generated by REACH in the 5 years update of the REACH baseline study, access to the registration dossiers, and CSRs in particular, has been crucial. Under consideration of the required measures to assure confidential treatment of the information, evaluations of the registration dossiers of the reference substances took place on the premises of EUROSTAT (for details see Chapter 6.1).

The 2011 sample. In 2007, 65 HPV chemicals and 25 SVHC have been selected as reference substances (3 substances are included both in the HPVCs and the SVHC, so the actual number of different chemicals was 87). Registration of these 87 substances has been expected by 30 November 2010. However, only 62 of these 87 substances were registered by that deadline (46 of 65 HPVCs and 19 of 25 SVHC). In addition, four substances with medium production volumes and five substances with low production volumes have been registered. Overall, information from REACH registration dossiers was retrieved for 71 substances.

In the detailed evaluation of the Risk % Quality Indicator in 2011, only HPV chemicals and SVHC are considered. All comparisons between the first assessment 2007 and the second assessment 2011 refer to the identical set of 46 HPV chemicals and 19 SVHC (this sample is called the "2011 sample"). Additional analysis has shown that the 2011 sample is representative for the group of HPVCs and SVHC selected in 2007 ('baseline sample') (see Chapter 3.1.2 of the comprehensive report for details). The 5 LPV substances and 4 MPV substances are excluded from the evaluation in 2011, since the numbers are so small that no meaningful analysis of changes from baseline to 2011 appears possible. Some preliminary trends on these substances are described in Chapter 3.3.

What happened to the remaining 25 reference substances? As mentioned above, only 62 of 87 reference substances were registered by the deadline of the first registration phase. In this respect, the Baseline set of reference substances shows a similar behaviour as the whole group of substances, which were expected to be registered by the first deadline: according to a recent analysis published by ECHA, 1500 of 5000 substances were not registered by the first deadline ([5]). According to ECHA, there are no indications that these substances are no longer available on the market. Therefore, it is assumed that these substances will be registered in the second or third registration phase (see Chapter 4.1 for details).

([5]) The analysis of Substances intended to be registered by 2010, but which were not registered, has been published by ECHA (http://echa.europa.eu/chem_data/list_registration_2010_en.asp#download)

6 Methodological issues

For details on methodology, see methodology papers. Some aspects important for the 5 years update are mentioned here.

6.1 Evaluation of data from registration dossiers

As already mentioned above, not all of the data required for the calculation of the Risk and Quality Scores are publicly available. Evaluations of the registration dossiers have been a crucial element of the analysis made for the 5 years update. While for a given substance, several dossiers may have been submitted, the most relevant registration dossiers (usually the lead dossier) has been identified by ECHA and provided for analysis. Tonnage information was estimated by ECHA on the basis of all dossiers. Note that an assessment of the quality of the registration dossiers as such has not been within the scope of the 5 years update study. Only the quality of the data for the toxicity estimate and for the exposure estimate was assessed on the basis of the methodology of the REACH baseline study. For example, a DNEL for the impact area workers is assigned a higher Quality Score than a toxicity estimate derived from risk phrases/hazard statements. However, the Quality Score makes no quality statement in relation to the DNEL derived (e.g. in relation to appropriate use of assessment factors).

6.2 Adaptation of the methodology

For a sound comparison of pre-REACH and REACH data it is crucial that the general methodology is not altered and that any adaptations are transparent and discussed beforehand. Therefore, for the 5 years update of the REACH baseline study, Risk Scores and Quality Scores have been calculated using the same methodology as in 2007. However, some adaptations of the methodology were necessary because REACH and other legislation introduced some new elements, e.g. DNELs as new toxicity estimates; use patterns are characterised by the new Use Descriptor System; hazard statements according to the CLP Regulation, replacing the risk phrases according to Directive 67/548/EEC

Details of adaptations have been discussed for all impact areas. Changes range from simple re-phrasing and inclusion of new sources (most notably technical dossiers (IUCLID5) and chemical safety reports) to adaptations involving more comprehensive issues. Discussion of the proposed adaptations confirmed that no bias has been introduced and the key elements of the assessment remain unchanged (for details see methodology annexes I – IV). In fact, the largest changes probably affected the Population Risk Modifier (new Use Descriptor System, more detailed information on tonnages, more detailed information on the number of manufacturers/importers than at Baseline), which, however, only showed little change between 2007 and 2011.

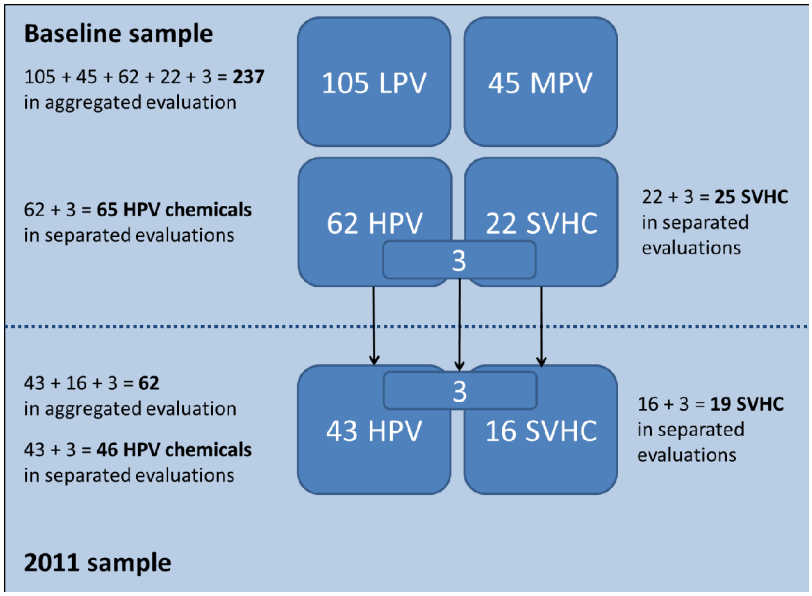
6.3 The 2011 sample

The following graph shows the numbers of substances evaluated at baseline and in 2011.

In 2007, 237 reference substances have been analysed. For the 5 years update, information from REACH registration dossiers was retrieved for 71 substances.

In both evaluations, there are 3 substances belonging to both HPV chemicals and SVHC. In the aggregated analysis at summary level these 3 substances are only counted once, but at all other levels of analyses, they are evaluated both as HPV chemicals and SVHC. This approach had to be chosen to be consistent with the baseline methodology.

Figure 6.1: Summary of sample sizes: baseline and 2011 evaluation



Source: Author's compilation

Due to the nature of REACH, with different registration deadlines for different tonnage bands, the evaluation 2011 captures changes in HPV substances and SVHC. Additional calculations were performed using the data of the baseline evaluation (2007), to get an idea if the 'missing' substances not assessed in 2011 introduce a systemic bias or error in any comparison. A detailed description of this comparison is given in Chapter 3.1 of the comprehensive report. It has been shown that the 62 reference substances, which build the 2011 sample, are representative for the HPV and SVHC substances in 2007.

6.4 Consideration of risk management measures and data on real exposures

The exposure assessment within the REACH baseline study aimed to derive a real worst case estimate for the main use of the reference substances. According to the TGD 2003, this should be the 90th or 95th percentile of exposure values. As far as possible, measured exposure data have been used to derive the exposure estimate. They take into account the risk management measures being in place in the companies involved.

Preferred data sources for the derivation of the exposure estimate have been European Union Risk Assessment Reports and comparable documents, e.g. Environmental Health Criteria, SIDS, CICAD, including the current practice of risk management in the companies. In addition, the applied methodology includes some elements to avoid overestimation of exposures.

- If monitoring results do not provide 90th/95th percentiles, a realistic worst case estimation is derived from average values. The upper limit has been set to 50% of the maximum exposure which has been measured.
- Exposure values reported 20 years ago or before are not taken into account, if more recent data are available. Old exposure data are not used if the mean concentration is above the current occupational exposure limit. It can be assumed, that current exposure is below these values in almost all cases.

If no adequate exposure data are available, the exposure estimate was derived from modelling. Also in this case, risk management measures are partly taken into account. The results of the 5 year update show that the 2007 exposure estimates were not over-conservative.

6.5 Relevance of additional company specific data

Apart from data which are publicly available, companies can have additional data, e.g. from unpublished toxicological studies. In order to characterise for a large number of substances which data has been 'publicly available' in 2007, a defined set of reference sources has been analysed (see methodology description). Based on the experience of the project team, these main data sources give a sufficient picture on data availability for the purpose of the study. In addition, IUCLID 4 files have been made available by EUROSTAT, to include the knowledge of companies on 'their' substances, e.g. results of classification and labelling as well as company-specific OELs. Typical additional company specific data (e.g. a single specific toxicological study) would have only minor effect on the Quality Score of the reference substance. Major changes can be achieved only by peer-reviewed data e.g. an SIDS document or an EU RAR, by changes in an OEL or a deviating R phrase. These kinds of data are covered by the REACH baseline study.

6.6 Changes in the tonnage band of the reference substances

In 2011, data from the registration dossiers confirmed the 2007 tonnage band for 43 of the 46 HPV substances. Only for 3 of the HPV reference substances, tonnages were estimated to be below 1000 t. There are indications for some of these substances that overall tonnages may be > 1000 t/a. For example, full registration dossiers were provided by ECHA when available, since these usually contain more information than registration dossiers for isolated intermediates. In the light of the overall uncertainties in estimating tonnages, we believe that the differences observed are small and do not point to any substantial shift in tonnage band for HPV chemicals.

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