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The REACH baseline study 5 years update

Comprehensive study report

2012 edition

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This publication was prepared under the responsibility of Rainer Muthmann, Head of Unit – Environment and forestry – European Commission – Eurostat.

Publication editors:

Christian Heidorn, Lene Bochaton – European Commission – Eurostat

Project management and contact:

Christian Heidorn
European Commission – Eurostat - Environment and forestry statistics
mailto:Christian.Heidorn@ec.europa.eu

Consultants:

Öko-Institut e.V.
Institut für angewandte Ökologie
Institute for Applied Ecology

Dirk Bunke
Rita Groß
Wolfgang Jenseit
Lothar Rausch

INERIS

Sandrine Andres
Laure Geoffroy
Vincent Grammont

FoBiG
Forschungs- und Beratungsinstitut Gefahrstoffe GmbH

Fritz Kalberlah
Jan Oltmanns

DHI
WATER & ENVIRONMENT

Michael Jakob Anderson
Dorte Rasmussen

Steering Committee:

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Further information:

Eurostat Website

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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

Executive summary / Key findings

REACH, the European Union Policy on chemicals, includes several reporting obligations for Member States, the European Chemicals Agency and the Commission. The first general report of the Commission on the experience acquired with the operation of this Regulation shall be published in 2012 (REACH Art. 117 (4)).

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

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

In 2007, in a so-called 'first snapshot' a representative set of 237 randomly selected reference substances have 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 main objective of the 5 years update of the REACH baseline study 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 of 2007.

Key findings of the 5 years update are described in this report and summarised as follows:

Key question 1:

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. The 5 years update of the REACH baseline study found a marked decrease in the Risk Scores for the aggregated evaluation of 62 substances (46 HPV chemicals and 16 SVHC)([1]).
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 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 reflecting changes in the knowledge about the substances.

Conclusion 1: The results of the 5 years update show a marked decrease in the nominal risk associated with the registered reference substances which is largely believed to be due to REACH.

Key question 2:

Does REACH lead to an improvement of the quality of data?

Development of the Quality Scores

1. The quality of the underlying data improves considerably, expressed in a reduction of the Total Quality Score from 2007 to 2011.
2. The improvement in quality is evident in all four impact areas.
3. For the majority of HPV chemicals and SVHC, the quality of the data underlying the exposure estimate (Quality Score Toxicity) and the toxicity estimate (Quality Scores Exposure) improve.
4. For the first time, some of the reference substances reach the best quality possible (Quality Score equal to 1) in some impact areas.
5. Due to the registration, DNELs, PNECs and more detailed information on uses become available for a large number of substances.

Conclusion 2: The results of the 5 years update show a marked increase in the quality of the data, which are available for the chemical assessment of the registered reference substances.

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

Additional findings

1. In 2011, a remarkable number of reference substances still show RCRs above 1. This is mainly due to three 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.
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 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 (e.g. derivation of DMELs for SVHC). They are described for each impact area in the related subchapters 'Summary and conclusion'.

1 Background

REACH, the European Union Policy on chemicals, includes several reporting obligations for Member States, the European Chemicals Agency and the Commission. The first general report of the Commission on the experience acquired with the operation of this Regulation shall be published in 2012 (REACH Art. 117 (4)).

In the REACH baseline study, a set of indicators has been developed to monitor the performance of REACH and its central elements ([2]). 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, a specific, 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:

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

In 2007, in a so-called 'first snapshot' a representative set of 237 randomly selected reference substances have 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 underlying methodology has been discussed intensively with the Steering Committee of the study and has been documented in four methodology papers. The results of the first assessment have been published in The REACH baseline study in 2009 (EUROSTAT 2009), which also discusses the concepts (e.g. nominal risk) used in this study.

Regarding the REACH review process scheduled for 2012, EUROSTAT has been asked by the Commission to prepare a 5 years update of the REACH baseline study. This update (which is called 'the second snapshot') 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 of the REACH baseline study 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 of 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 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 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).

([2]) The REACH baseline study has been commissioned by Eurostat in cooperation with the services responsible for environment and industry of the European Commission.

1 Background

Risk Scores and Quality Scores for HPV chemicals and SVHC have been determined for all four impact areas of the REACH baseline study:

- impact on **workers**,
- impact on the **environment**,
- direct impacts on **consumers** and
- impacts on **humans via the environment**.

The results are described in chapter 3.2 for each of the impact areas, with the detailed evaluation providing different levels of detail:

- The **summary level** evaluates all substances together in relation to Risk Scores and overall Quality Scores. It is the most aggregated level of analysis.
- The **profile level** provides more detail on Risk Scores and overall Quality Scores for HPV chemicals and SVHC separately.
- The **analysis level** is the most detailed level and also evaluates HPV chemicals and SVHC separately. It goes down to an analysis of the different components, such as RCRs, exposure and toxicity estimates and Quality Scores for the exposure and toxicity estimates.

Before presenting the results of the 5 years update, we give a brief summary of methodological issues relevant for understanding the REACH baseline study and its update.

2 Methodology

Risk Scores and Quality Scores: Principally, the methodology used in the REACH baseline study to calculate the nominal risk 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 (RCRs) 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 and the Quality Score for the toxicity data are multiplied to give the total Quality Score. The total Quality Score ranges from 1 (best quality) to 100 (lowest quality). For each of the four impact areas, the approach used is documented in a detailed technical report (methodology annexes I – IV).

Adaptation of 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 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. Some of the adaptations are relevant for all four impact areas; some are specific for a certain impact area. Changes range from simple re-phrasing and inclusion of new sources (most notably technical dossiers (IUCLID5) and chemical safety reports (CSRs)) to adaptations involving more comprehensive issues. Discussion of the proposed adaptations confirmed that these adaptations do not lead to any form of bias in the assessment: the principle approach and the key elements of the assessment remain unchanged. A detailed description of the methodology (including the adaptations) has been documented as updated versions of the methodology annexes I – IV.

Reference substances which have not been registered: In 2007, 65 HPV chemicals and 25 SVHC have been selected as reference substances (3 substances are included both in the HPV chemicals and the SVHC, so the actual number of different chemicals was 87). Registration of these substances has been expected by 30 November 2010.

However, only 62 of these 87 reference substances were registered by that deadline. 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 5.000 substances were not registered by the first deadline ([3]).

What happened to the remaining 25 reference substances? According to the analysis published by 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 also chapter 4.2).

Evaluation of data from registration dossiers: Detailed information on substance properties and safe use of chemicals have 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, assessed in Chemical Safety Reports (CSRs),
- the basis for these data in order to assess the quality,
- tonnage and detailed use information.

([3]) 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)

Not all of these data are publicly available. For example, detailed data on tonnages and uses as well as exposure data are only contained in the CSRs, which are not publicly available ([4]). 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.

After agreement of the proposed procedures by Eurostat and the other Commission services involved and 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. 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 full evaluation. Tonnage information was estimated by ECHA on the basis of all dossiers.

Assessment of the quality of the registration dossiers as such has not been in 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. Quality Scores of the REACH baseline study refer to these elements of the registration dossiers only.

([4]) Information on the identity of manufacturers/importers has not been required for the assessment.

3 Results and discussion

3.1 The 2011 sample

3.1.1 Introduction

Overall, information from REACH registration dossiers was retrieved for 71 substances. The following table summarises the distribution between the different tonnage bands. Due to the nature of REACH, with different registration deadlines for different tonnage bands, the evaluation by and large captures changes in high production volume (HPV) substances and substances of very high concern (SVHC). This is evident in the percentage of these substances in the 2011 sample, together accounting for 88% of the total number compared to 37% at baseline (Table 3.1).

Table 3.1: Characteristics of the sample compared to the baseline set

	Baseline sample		Sample 2011	
	No.	% of total	No.	% of total
HPV	65	27	46	62
MPV	45	19	4	5.4
LPV	105	44	5	6.7
SVHC	25	10	19	26
Total	240*		74*	

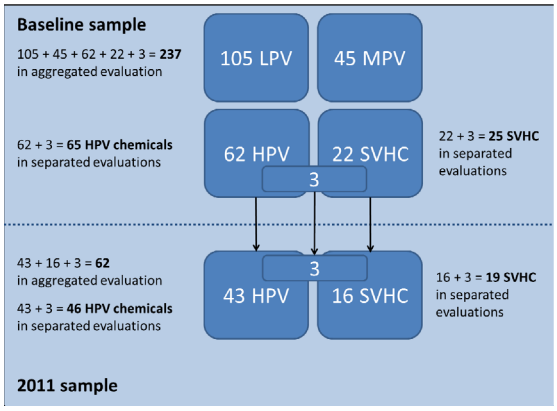
* includes 3 substances also included in the respective tonnage band; i.e. 237 and 71 different substances were evaluated, respectively.

Source: Author's compilation

In the detailed evaluation of the risk and quality indicator presented in Chapter 3.2, only HPV chemicals and SVHC are considered. The 5 LPV substances and 4 MPV substances are excluded from this evaluation, since the numbers are so small that any meaningful analysis of changes from baseline to 2011 appears impossible. However, some preliminary trends on these substances are described in Chapter 3.3.

Overall, the following graph shows the numbers of substances evaluated at baseline and in 2011. In both evaluations, there are 3 substances belonging to both HPV chemicals and SVHC. In the aggregated analysis at summary level (see Chapter 3.2.1) 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 3.1: Summary of sample sizes: baseline and 2011 evaluation



Source: Author's compilation

3.1.2 Checking the 2011 sample

Additional calculations were performed using the data of the baseline evaluation, to get an idea if the 'missing' substances introduce a systemic bias or error in any comparison. For example, it is conceivable that substances

with a high Risk Score in 2007 were not registered in 2010 (e.g. due to decreased production). All calculations in this section refer to the impact area of workers, which was chosen for this analysis.

Basically, this evaluation involves a comparison **completely on the basis of the 2007 data** of:

- the 46 HPV chemical evaluated in 2011 with the 65 HPV substances at baseline;
- the 19 SVHC evaluated in 2011 with the 25 SVHC evaluated at baseline.

Statistical descriptors for HPV substances and SVHCs, analysed separately both at baseline 2007 and in the sample 2011, are shown in Table 3.2. The 46 HPV substances in the sample 2011 do not appear to differ much from the 65 baseline HPV substances. While there are some differences in the percentiles, the medians and GMs for the Risk Score are (almost) identical. A slightly different picture emerges for SVHCs, for which the median and GM Risk Score is lower in the 2011 sample (GM: 1297 vs. 2100, factor 1.6). This is primarily the consequence of a lower RCR (GM: 220 vs. 330, factor 1.5). It must be stressed, however, that the values are still in the same order of magnitude.

In relation to the overall Quality Score, a slightly better quality is observed in the sample 2011, especially for the median QS_{total} for SVHC.

Table 3.2: Statistical descriptors for HPV substances and SVHCs in the baseline set 2007 and in the sample 2011 (rounded to two significant figures)

	RCR		PRM		RISKSCORE		QS_{total}	
	2007	**2011**	**2007**	**2011**	**2007**	**2011**	**2007**	**2011**
HPV								
n	65	46	65	46	65	46	65	46
Median	**0.83**	**0.86**	**5.0**	**5.0**	**4.0**	**4.5**	**32**	**30**
GM	**2.5**	**2.5**	**5.3**	**5.5**	**13**	**14**	**25**	**21**
10th P	0.068	0.15	4.0	4.0	0.43	0.79	8.4	4.0
25th P	0.25	0.45	4.0	4.0	2.0	2.2	16	16
75th P	6.7	9.6	7.0	7.0	34	83	48	35
90th P	304	73	8.0	8.0	1200	400	58	55
MIN	0.013	0.028	3.0	4.0	0.066	0.11	2.0	2.0
MAX	480000	480000	10	10	2400000	2400000	100	100
SVHC								
n	25	19	25	19	25	19	25	19
Median	**670**	**670**	**6.0**	**6.0**	**3300**	**3300**	**40**	**24**
GM	**330**	**220**	**6.2**	**5.9**	**2100**	**1300**	**27**	**21**
10th P	0.31	0.17	4.4	3.8	1.3	0.74	4.0	4.0
25th P	15	10	5.0	5.0	75	55	12	9.0
75th P	1800	1800	9.0	7.5	16000	14000	60	48
90th P	480000	480000	10	9.2	3500000	2800000	92	84
MIN	0.11	0.11	3.0	3.0	0.39	0.39	4.0	4.0
MAX	1200000	1200000	10	10	6000000	6000000	100	100

Source: Author's compilation

RCR distribution

A similar picture emerges when the distribution of RCRs above, below and equal to 1 is compared. Again, the sample 2011 of 46 HPV chemicals and 19 SVHC appears to be quite similar to the distribution in the baseline dataset of 65 HPV substances and 25 SVHC (Table 3.3).

Table 3.3: RCR distribution in HPV substances and SVHC evaluated separately

	HPV 2007		HPV 2011		SVHC 2007		SVHC 2011	
	n	% of total	n	% of total	n	% of total	N	% of total
RCR>1	26	40	21	46	21	84	15	79
RCR<1	36	55	24	52	4	16	4	21
RCR=1	3	4.6	1	2.2	0	-	0	-
Total	65		46			25	19	

Source: Author's compilation

Conclusions

Overall, this comparison of the 2011 sample with the baseline set indicates that the sample can be considered representative of the baseline HPV and SVHC data. The differences observed, namely:

- slightly lower RCRs and Risk Scores for SVHC and
- slightly lower overall Quality Scores for HPV chemicals and SVHC,

occur in the same direction as observed on the basis of the 2011 evaluation (see Chapter 3.2.2). For example, the median QS_{total} was 40 for the 25 SVHC evaluated at baseline, 24 for the 19 SVHC evaluated on the basis of the baseline data and further decreased to 12 for the these same substances when evaluated with the 2011 data (Chapter 3.2.2, SHVC).

3.2 Risk and quality indicators for HPV chemicals and SVHC

3.2.1 Introduction

The following chapters include a detailed evaluation for the different impact areas at different levels of analysis, providing different levels of detail:

- The **summary level** evaluates all substances together in relation to Risk Scores and overall Quality Scores. It is the most aggregated level of analysis.
- The **profile level** provides more detail on Risk Scores and overall Quality Scores for HPV chemicals and SVHC separately.
- The **analysis level** is the most detailed level and also evaluates HPV chemicals and SVHC separately. It goes down to an analysis of the different components, such as RCRs, exposure and toxicity estimates and Quality Scores for the exposure and toxicity estimates.

3.2.2 Impact area: Workers

As indicated in Chapters 2 and 3.1, a total of 62 substances (46 HPV chemicals and 16 SVHC) could be evaluated in the 5 years update. These 62 substances were aggregated at the summary level (Chapter 3.2.2.1), but were evaluated separately (HPV chemicals and SVHC) at the profile and analysis levels (Chapters 3.2.2.2 and 3.2.2.3). In these latter evaluations, 3 HPV substances are also included in the SVHC group (leading to 19 SVHC), an approach that was also taken at baseline.

It must be stressed that the same HPV chemicals and SVHC are compared, i.e. when RCRs, toxicity estimates and Quality Scores are reported below for baseline and 2011, identical substances are compared.

3.2.2.1 Summary level

The summary level describes the results for the Risk Score and the Quality Score aggregated across all substances. At baseline in 2007, these values were aggregated across all LPV, MPV and HPC chemicals as well as SVHC. In the 5 years update, only HPV substances and SVHC are evaluated.

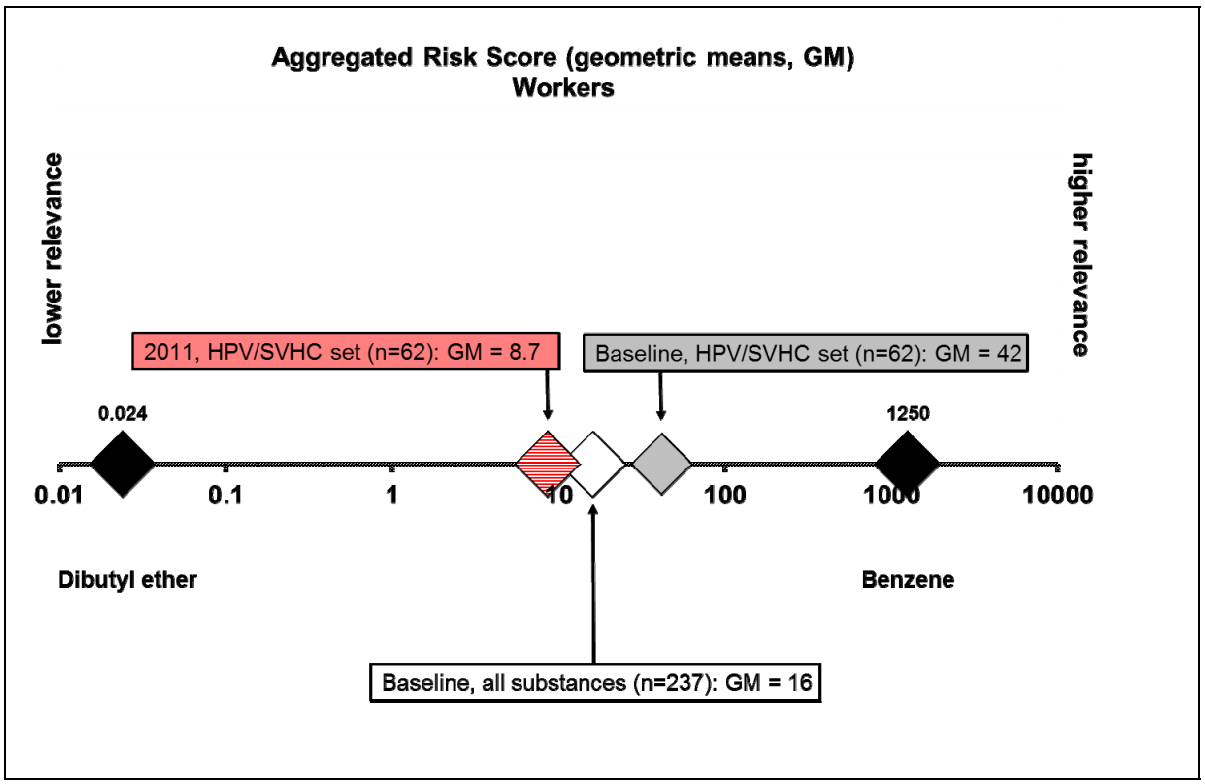
To account for this difference, Risk Scores and Quality Scores of the 2011 sample (i.e. the 62 substances evaluated) were also calculated on the basis of the baseline figures. The respective values then describe the change for the identical set of substances and are thus more helpful than a comparison between the entire baseline set and the sample 2011.

Figure 3.2 shows the aggregated Risk Scores:

- for all substances at baseline: GM = 16
- for the 62 substances on the basis of the baseline data: GM = 42
- for the 62 substances in the 5 year update: GM = 8.7

As in the REACH baseline study, the Risk Scores for dibutyl ether and benzene are shown as reference points for ranking these values (see (The REACH baseline study - Eurostat 2009 for details).

Figure 3.2: Aggregated Risk Scores (workers) at baseline and in 2011



Source: Author's compilation

These data show that the 2011 sample had a higher Risk Score at baseline than the overall set evaluated (GM 42 compared to 16). This is not an unexpected finding, since the 62 substances of the 2011 sample include a much higher fraction of SVHC than the entire set (26% compared to 10%) and since the baseline Risk Score for SVHC was about two orders of magnitude higher than the ones observed for LPV, MPV or HPV (The REACH baseline study - Eurostat 2009).

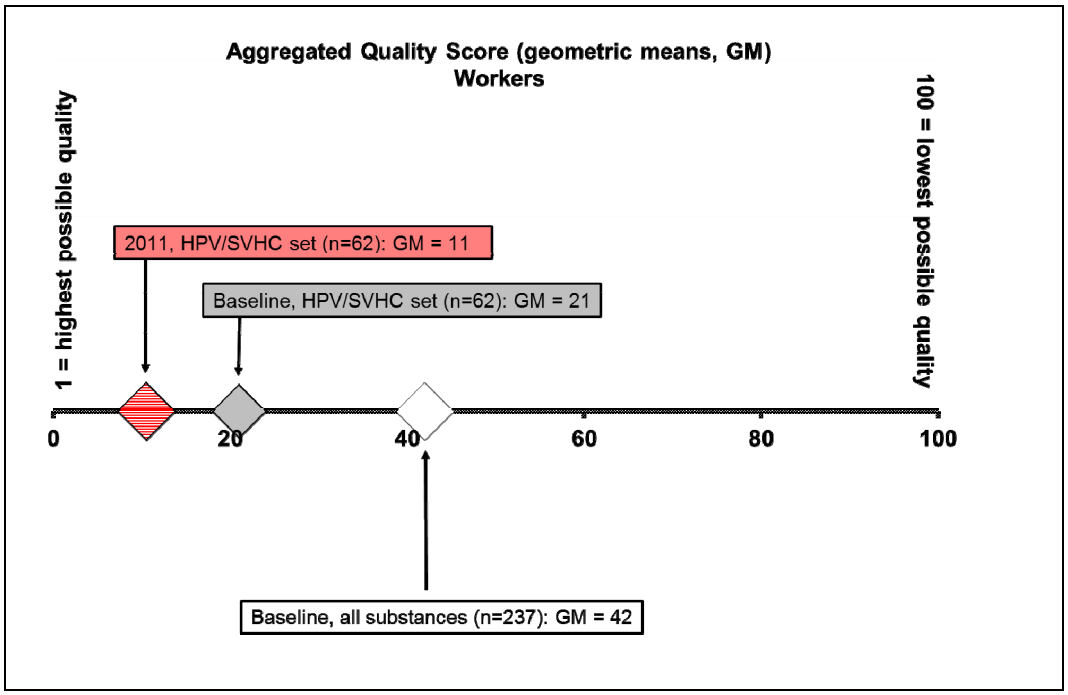
The 5 years update indicates an almost 5-fold decrease in the aggregated Risk Score for the 62 substances evaluated: from 42 in 2007 (baseline) to 8.7 in 2011 (based on GMs). This is mostly due to the pronounced decrease in Risk Scores observed for SVHC, which is reduced by about two orders of magnitude; 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). As a consequence of this pronounced decline in SVHC Risk Scores, the absolute value of the aggregated Risk Score in 2011 is even lower than the one at baseline (8.7 compared to 16), despite the high fraction of SVHC in the 2011 sample.

Figure 3.3 shows the results for the identical evaluation of the aggregated Quality Scores, again including results:

- for all substances at baseline: GM = 42
- for the 62 substances on the basis of the baseline data: GM = 21
- for the 62 substances in the 5 years update: GM = 11

For an interpretation of Quality Scores, it is important to stress that a better quality is assigned lower Quality Scores in the evaluations (The REACH baseline study - Eurostat 2009). No reference points are provided for the Quality Score, which is scaled between 1 and 100 (highest vs. lowest possible quality).

Figure 3.3: Summary level: Aggregated Risk Scores (workers)



Source: Author's compilation

At baseline, HPV substances and SVHC had a better quality than LPV and MPV (the REACH baseline study - Eurostat 2009). Since the 2011 sample only consists of HPV substances and SVHC, the Quality Score is much better in this sample compared to the entire baseline set (GM: 21 compared to 42). The quality of the data (with a GM of 21 already quite good in 2007 for the 62 substances) further increases in 2011, as evidenced by a decrease of the Quality Score to a GM of 11. As will be shown in the following chapters, this decrease is observed for both HPV chemicals and SVHC.

The change in Risk Score and Quality Scores from baseline to 2011 is summarised in Table 3.4. Median values are included in addition to the GMs and confirm the trend of decreasing Risk and Quality Scores.

Table 3.4: Summary of aggregated Risk and Quality Scores

	Risk Score		Quality Score	
	Baseline	2011	Baseline	2011
n	62	62	62	62
GM	42	8.7	21	11
Median	15	5.7	30	14

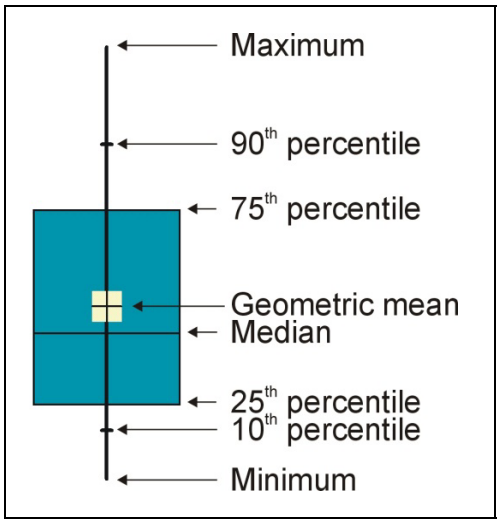
Source: Author's compilation

3.2.2.2 Profile level

HPV substances and SVHC are separated at profile level and within each group values are compared on the basis of the baseline evaluation and the 2011 evaluation.

The profile level presents results as whisker plots and Figure 3.4 shows the various statistical descriptors contained in this type of graph.

Figure 3.4: Legend to whisker plots



Source: Author's compilation

HPV Chemicals

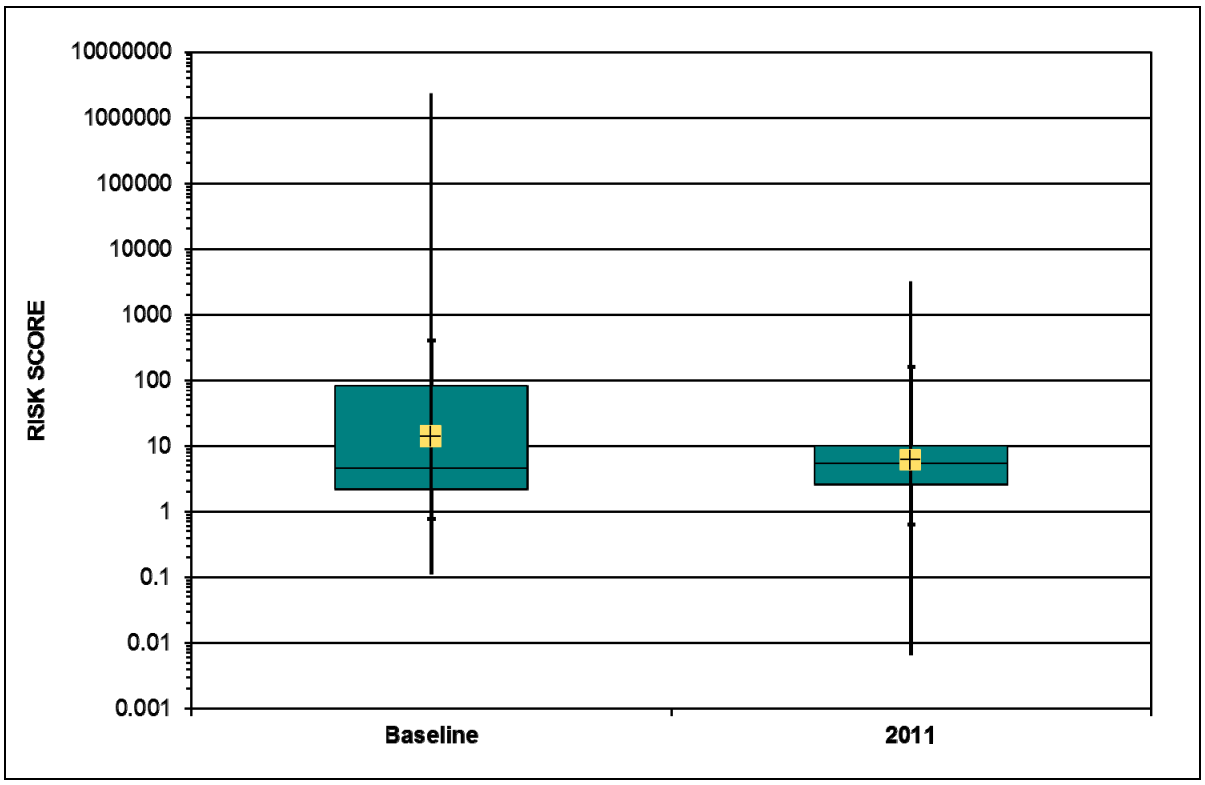
Figure 3.5 presents the changes in Risk Scores from baseline to 2011 for the 46 HPV chemicals evaluated. Detailed descriptive statistics are presented in Table 3.5 below.

The whisker plot identifies some important aspects:

- There is a general downward trend of Risk Scores, i.e. maximum and minimum values as well as the upper percentiles are lower in 2011 compared to baseline.
- A decrease in Risk Scores is also evident in the GM, but not in the median values, the latter in fact showing a slight increase.
- The IQR (interquartile range, i.e. the 25th–75th percentile range) is substantially reduced in 2011, which is by and large due to a considerable decrease in the 75th percentile.

Overall, this evaluation shows that fewer HPV substances show extreme Risk Scores and that there is a general downward shift of Risk Scores. Average Risk Scores are much less affected, but the IQR is substantially reduced and the 'middle fifty' spans a narrow range of 2.6-10 in 2011 (instead of 2.2-83 at baseline).

Figure 3.5: Comparison of baseline and 2011 Risk Scores for HPV chemicals (n=46)



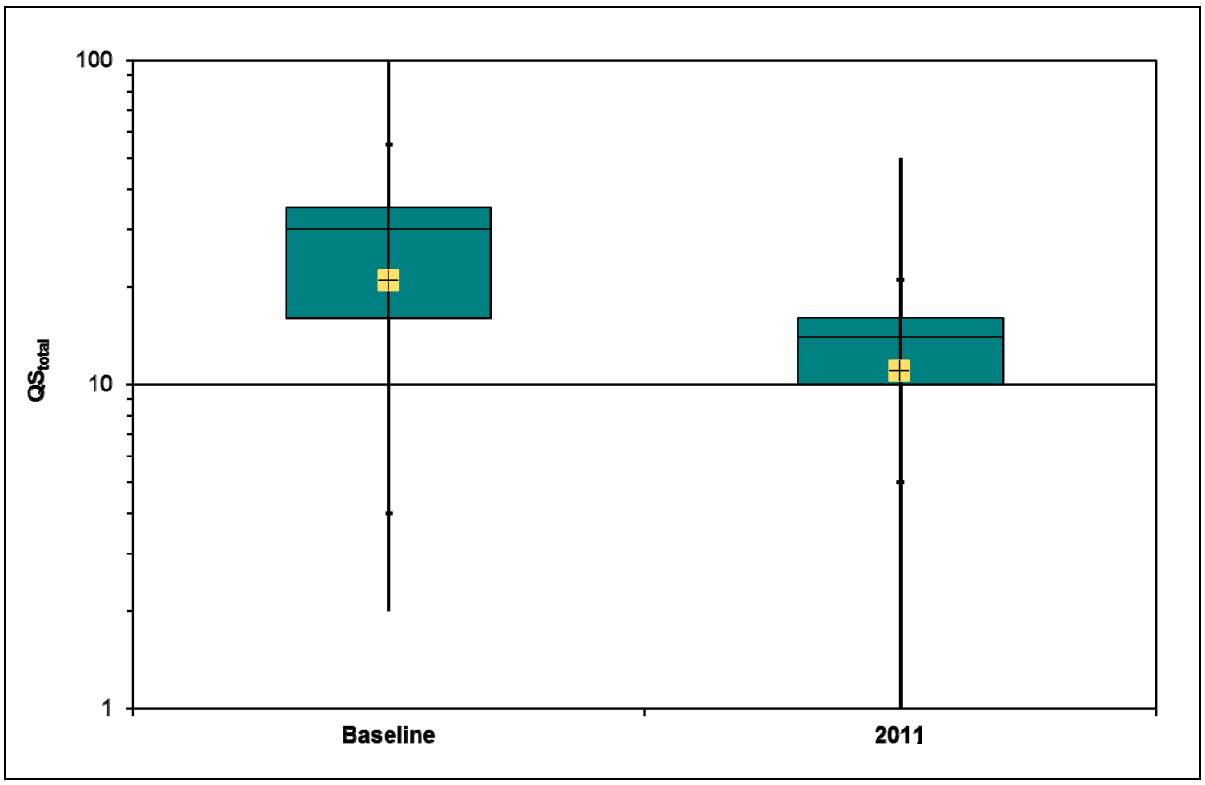
Source: Author's compilation

The evaluation of the Quality Score (QS_{total}) presented in the whisker plot (Figure 3.6) generally shows a similar picture as the Risk Score evaluation:

- QS_{total} shows a general downward trend from baseline to 2011.
- In fact, while the highest quality possible (QS_{total} = 1) was not achieved at baseline, this was the case in 2011 (2/46 substances, 4.3%).
- Similarly, the poorest quality assigned to any substance in 2011 was QS_{total} = 50, a value that was exceeded by 6/46 of the HPV chemicals (13%) at baseline (see 90th percentile in Figure 3.6 and Figure 3.7).
- In contrast to the changes in Risk Scores, however, a clearer decline in the mean QS_{total} (i.e. an increase in quality) is evident in 2011 compared to the baseline level.
- Also somewhat different is the movement of the IQR, since both the 25th and the 75th percentiles are lower in 2011 than at baseline. As a consequence, the 25th percentile of QS_{total} = 16 at baseline is the 75th percentile in 2011. Expressed verbally this means that 75% of the substances had a poorer quality (than this value) at baseline, while this was only true for 25% of the substances in 2011.

Again, descriptive statistics are presented in 3.6 below.

Figure 3.6: Comparison of baseline and 2011 Quality Scores (QS_{total}) for HPV chemicals (n=46)



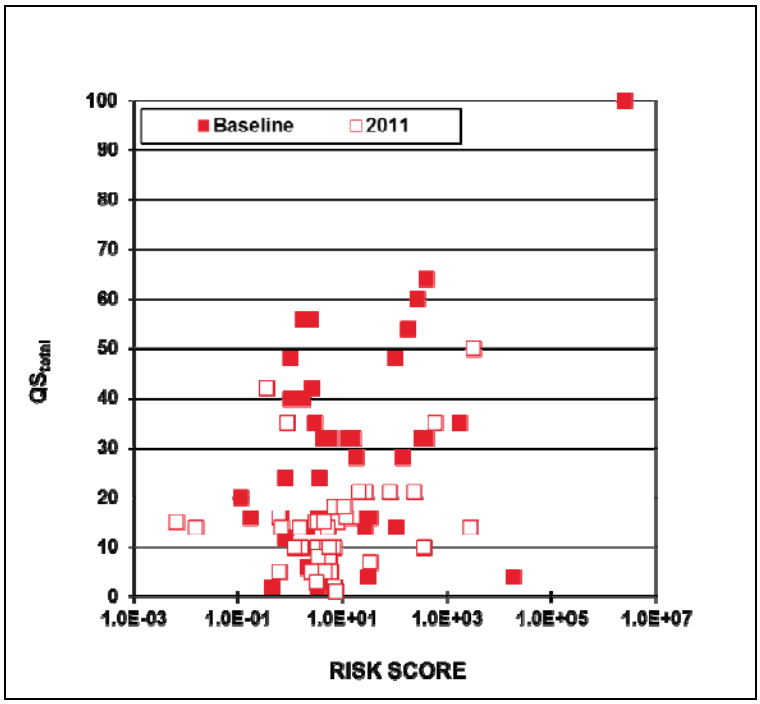
Source: Author's compilation

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 at analysis level (Chapter 3.2.2.3).

The scatter plot in Figure 3.7 for HPV chemicals shows a general movement of the data points towards the lower left corner (i.e. lower Risk Score, better quality) in 2011. The decline of QS_{total} is somewhat more eye-catching in the scatter plot than the decline in the Risk Score, an observation in line with the statistical data.

Figure 3.7 also suggests that there is a cluster of high quality ($QS_{total} < 20$) data points at Risk Scores of approximately 0.1-10. This observation will be treated in detail at the analysis level (Chapter 3.2.2.3).

Figure 3.7: Risk/QS_{total} scatter plot for HPV chemicals (n=46): baseline – 2011 comparison



Source: Author's compilation

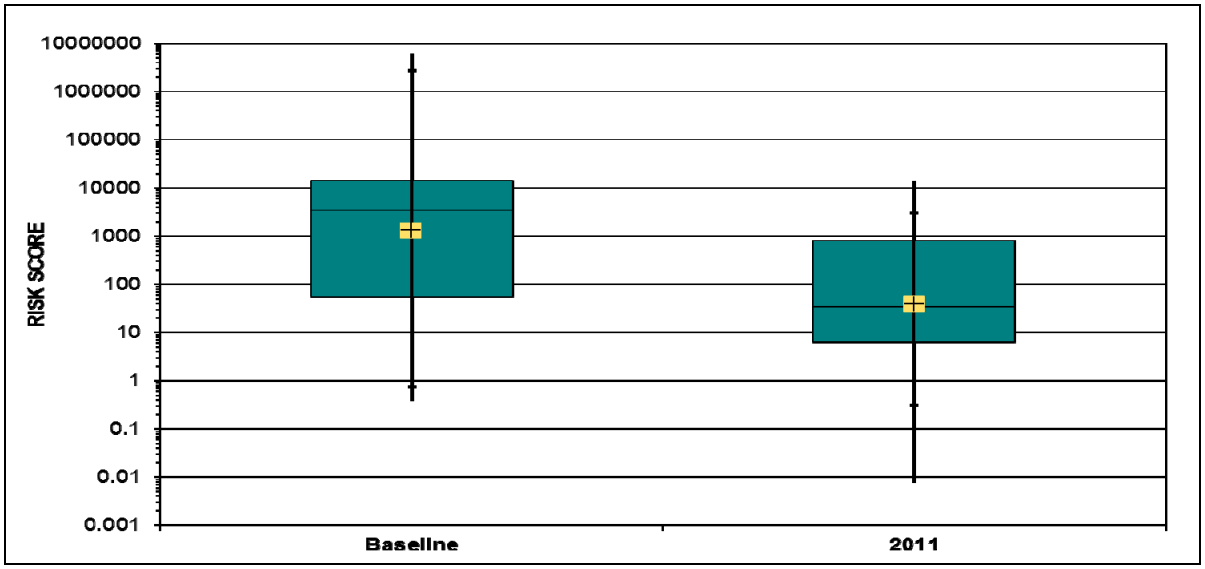
Substances of very high concern (SVHC)

Figure 3.8 and Figure 3.9 show the changes Risk and Quality Scores from baseline to 2011 for the 19 SVHC evaluated. In general, the changes are quite similar to the ones described above for HPV chemicals, in particular the downward trend in both Risk and Quality Scores. In addition, the poorest quality assigned in 2011 (QS_{total} = 50, same as for HPV) was exceeded by 4/19 at baseline, i.e. 21% of the SVHC had a poorer quality. At the other end of the scale 2/19, SVHC (11%; 4.3% for HPV) were assigned the best quality possible (QS_{total} = 1) and such a maximum quality was never assigned at baseline.

Some notable differences between HPV chemicals and SVHC include:

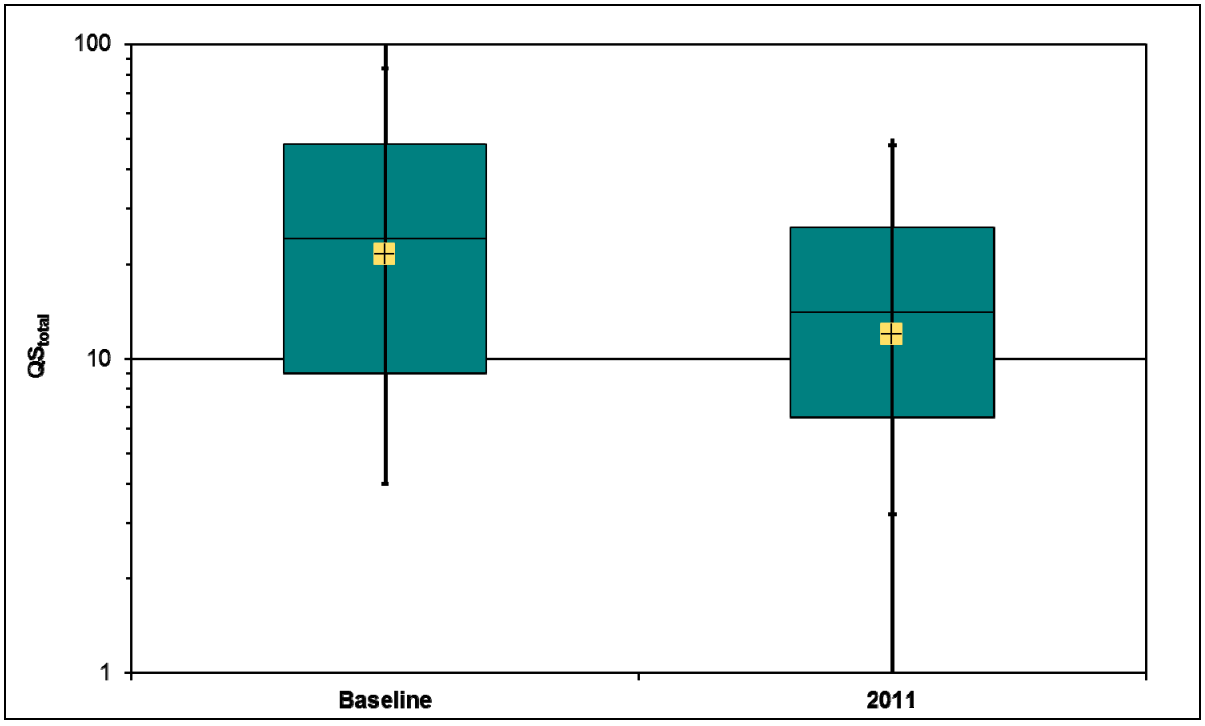
- GM and median Risk Scores are more clearly reduced in 2011 in the case of SVHC (only a small or no decline for HPV). In fact, this decline of SVHC Risk Scores is very substantial by about two orders of magnitude (Table 3.5).
- In this context, almost 50% of the SVHC had a Risk Score above 3000 at baseline, while this was only the case for 10% of the SVHC in 2011 (compare baseline median and 2011 90th percentile in Figure 3.8).
- The IRQ of the Risk Score declines as a whole (while only the 75th percentile was reduced in the case of HPV). As a consequence, the 'narrowing' of the IRQ is not as pronounced as in the case of HPV substances.
- Compared to HPV substances, QS_{total} for SVHC declines by a similar degree (GM and median), but the downward shift of the IRQ is less pronounced, with quite some overlap between baseline 25th percentile and the 75th percentile in 2011 (compare Figure 3.6 and Figure 3.9).

Figure 3.8: Comparison of baseline and 2011 Risk Scores for SVHC (n=19)



Source: Author's compilation

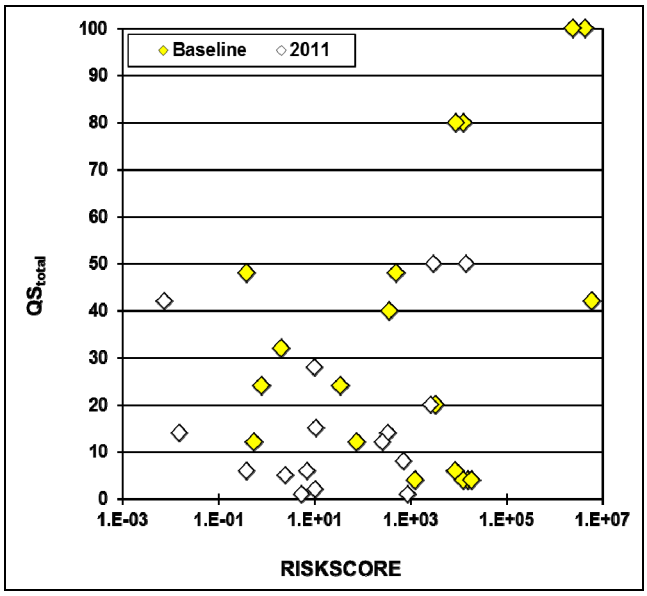
Figure 3.9: Comparison of baseline and 2011 Quality Scores (QS_{total}) for SVHC (n=19)



Source: Author's compilation

As for HPV substances, the SVHC scatter plot (Figure 3.10) shows a general movement of the data points towards the lower left (i.e. lower risk score, better quality) in 2011. The leftward movement of the Risk Scores (i.e. decreasing Risk Scores) is more evident than for HPV substances. The clustering of values observed for HPV chemicals is not found for SVHC, though this might entirely be due to the substantially lower number of data points.

Figure 3.10 Risk/QS_{total} Quality Score scatter plot for SVHC (n=19): baseline – 2011 comparison



Source: Author's compilation

Conclusions on the profile level evaluation

Descriptive statistics of the evaluation at the profile level are presented in Table 3.5 below. Together with the whisker and scatter plots presented above, the following general conclusions can be drawn:

- Risk Scores and QS_{total} decrease in 2011.
- This decreasing trend is visible in most, though not all statistical descriptors (e.g. median Risk Score for HPV chemicals). However, it is clearly evident in the whisker plots considering the entire distribution of values.
- The decline in Risk Scores is more dramatic for SVHC than for HPV substances.
- As a consequence, Risk Scores for HPV chemicals and SVHC have moved closer together in 2011. While SVHC Risk Scores (GM, median) at baseline were about 2-3 orders of magnitude higher than the respective Risk Scores for HPC chemicals, the difference is only about one order of magnitude in 2011 (Table 3.5).
- Extreme Risk Scores remain, but these are considerably lower than at baseline.
- The decrease in QS_{total} (i.e. improvement in quality) is similar for HPV substances and SVHC.
- As a verbal interpretation of the statistical information, it is useful to note that:
  - none of the HPV chemicals and SVHC had a $QS_{total} > 50$ in 2011
  - 13% of the HPV chemicals and about 21% of the SVHC had a poorer quality ($QS_{total} > 50$) at baseline.

Table 3.5: Summary descriptive statistics for HPV chemicals: Risk Score and QS_{total} (rounded to two significant figures)

	HPV chemicals				SVHC			
	Risk Score		QS_{total}		Risk Score		QS_{total}	
	Baseline	2011	Baseline	2011	Baseline	2011	Baseline	2011
n	46	46	46	46	19	19	19	19
Median	4.5	5.4	30	14	3300	33	24	12
GM	14	6.0	21	11	1300	38	21	10
10^{th} percentile	0.79	0.64	4.0	5.0	0.74	0.31	4.0	1.8
25^{th} percentile	2.2	2.6	16	10	55	6.2	9.0	6.0
75^{th} percentile	83	10	35	16	14000	790	48	24
90^{th} percentile	400	160	55	21	2800000	3000	84	50
MIN	0.11	0.0064	2.0	1.0	0.39	0.0075	4.0	1.0
MAX	2400000	3200	100	50	6000000	14000	100	50
IQR	81	7.3	19	6.0	14000	790	39	18

Source: Author's compilation

The findings obtained at profile level will be discussed in more detail in the following section, analysing the various inputs into the Risk Score and the components of QS_{total}, i.e. the Quality Score for the toxicity estimate (QS_{tox}) and the Quality Score for the exposure estimate (QS_{exp}).

3.2.2.3 Analysis level

The main purpose of the analysis level is to provide an additional level of detail and help to identify the parameters that have an important impact on the changes described above. To this end, the analysis is extended to the individual components, namely (see The REACH baseline study - Eurostat 2009 for additional details):

- for the Risk Score
  - the population risk modifier (PRM)
  - the risk characterisation ratio (RCR), calculated from:
    - the estimated exposure
    - the toxicity estimate (DNEL, DMEL, OEL or $OEL_{analogue}$)
- for the Quality Score (QS_{total})
  - the Quality Score for the toxicity estimate (QS_{tox})
  - the Quality Score for the exposure estimate (QS_{exp})

The individual components will be discussed in this section, with a special emphasis on the discussion of RCR values obtained.

Population Risk Modifier (PRM)

The methodology for PRM calculation had to be adapted due to several changes. For example, PRM calculation at baseline involved the 'old' descriptor system of the TGD (EC 2003) with 'use categories', 'industrial categories' etc., while the 'new' REACH descriptor system was used in 2011. For other PRM input parameters (number of manufacturers and tonnage band information), detailed data were extracted by ECHA from registration dossiers specifically for this project. These data are considered more up-to-date than some of the information collected at baseline (e.g. the number of manufacturers/importers).

An evaluation of the PRM shows no substantial differences between the baseline data and 2011 (Table 3.6).

If at all, there is a trend towards slightly higher PRM values for HPV chemicals and towards slightly lower values for SVHC. It is impossible to judge, whether these slight changes are due to the adaptations in the methodology mentioned or reflect real changes.

Table 3.6: Summary descriptive statistics for the Population Risk Modifier (rounded to two significant figures)

	HPV chemicals		SVHC	
	Baseline	**2011**	**Baseline**	**2011**
n	46	46	19	19
Median	5.0	7.0	6.0	6.0
GM	5.5	6.0	5.9	5.2
10^{th} percentile	4.0	4.0	3.8	2.8
25^{th} percentile	4.0	5.0	5.0	4.0
75^{th} percentile	7.0	8.0	7.5	7.5
90^{th} percentile	8.0	8.5	9.2	8.2
MIN	4.0	3.0	3.0	2.0
MAX	10	9.0	10	9.0
IQR	3.0	3.0	2.5	3.5

Source: Author's compilation

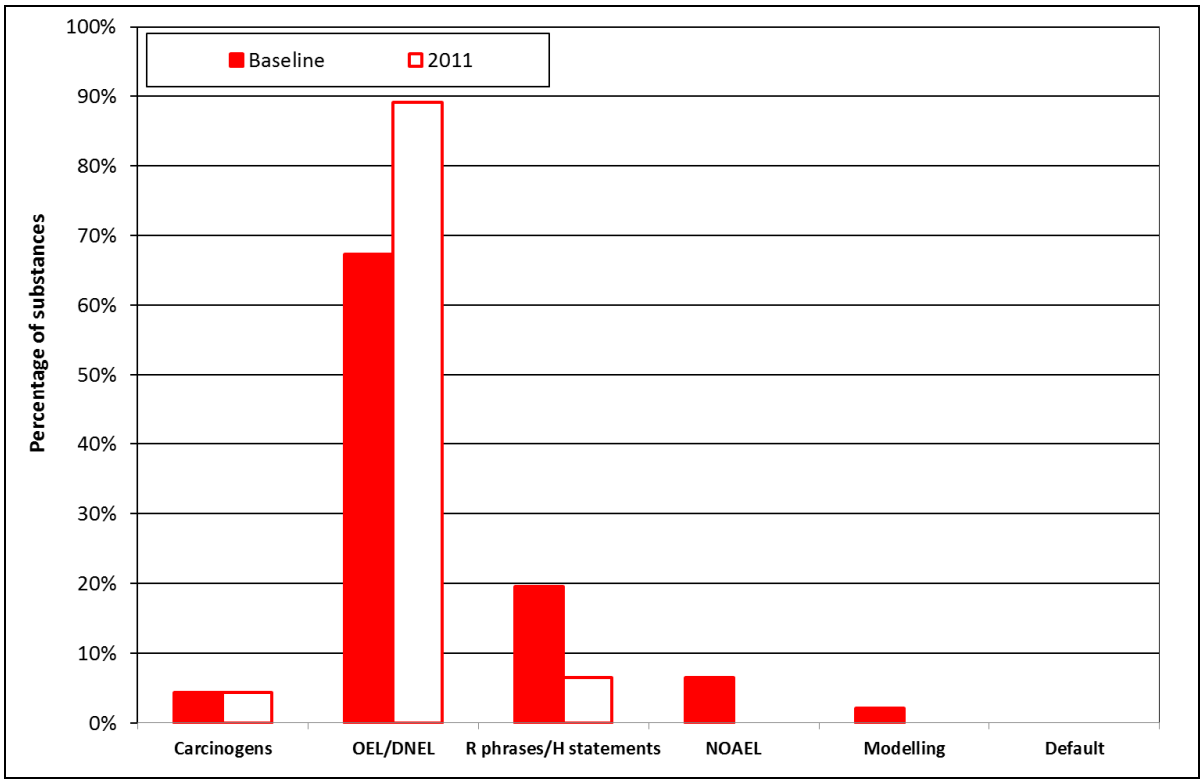
Since the Risk Score is the product of the RCR and the PRM, the absence of pronounced changes in the PRM suggests that the changes observed in the Risk Scores is primarily due to changes in the RCR. This will be discussed for HPV chemicals and SVHC more in detail later in this chapter.

Data availability

Before RCRs and their components will be analysed in detail, a brief evaluation of the data basis is helpful. In the REACH baseline study, OELs were available for almost 60% of the 65 HPV substances evaluated (The REACH baseline study - Eurostat 2009). It must be stressed that the baseline evaluation already included 'company OELs' reported in the IUCLID4 files and did not solely rely on "official" national or EU OELs. This fact explains the relatively high fraction of OELs available at baseline.

For the 2011 sample of 46 HPV substances, this figure was slightly higher (67%) at baseline and increased in the 2011 evaluation to almost 90% (Figure 3.11).

Figure 3.11: Data availability analysis for toxicity data of HPV chemicals (n=46): baseline – 2011 comparison



Source: Author's compilation

This increase is primarily due to the availability of DNELs (workers) for substances, for which an OEL was not available at baseline. As a consequence of increased DNEL availability, the toxicity estimate on the basis of risk phrases or hazard statements was less often used and the even less reliable methods (use of a NOAEL or modelling) was never used in the 2011 evaluation. Default toxicity estimates were neither used at baseline nor in 2011 for HPV substances, which is in line with the complete baseline set of 65 HPV chemicals (The REACH baseline study - Eurostat 2009).

For SVHC, the toxicity estimate is primarily based on the carcinogenic properties and this did not change from baseline to 2011 (12 of the 19 SVHC are classified as carcinogens (category 1A or 1B under CLP)). Little change is observed for the remaining 7 SVHC: for one substance, for which the toxicity estimate had to be based on the risk phrase, a DNEL was available in 2011.

The primary focus is therefore on the 12 carcinogenic SVHC, for which the evaluation found that:

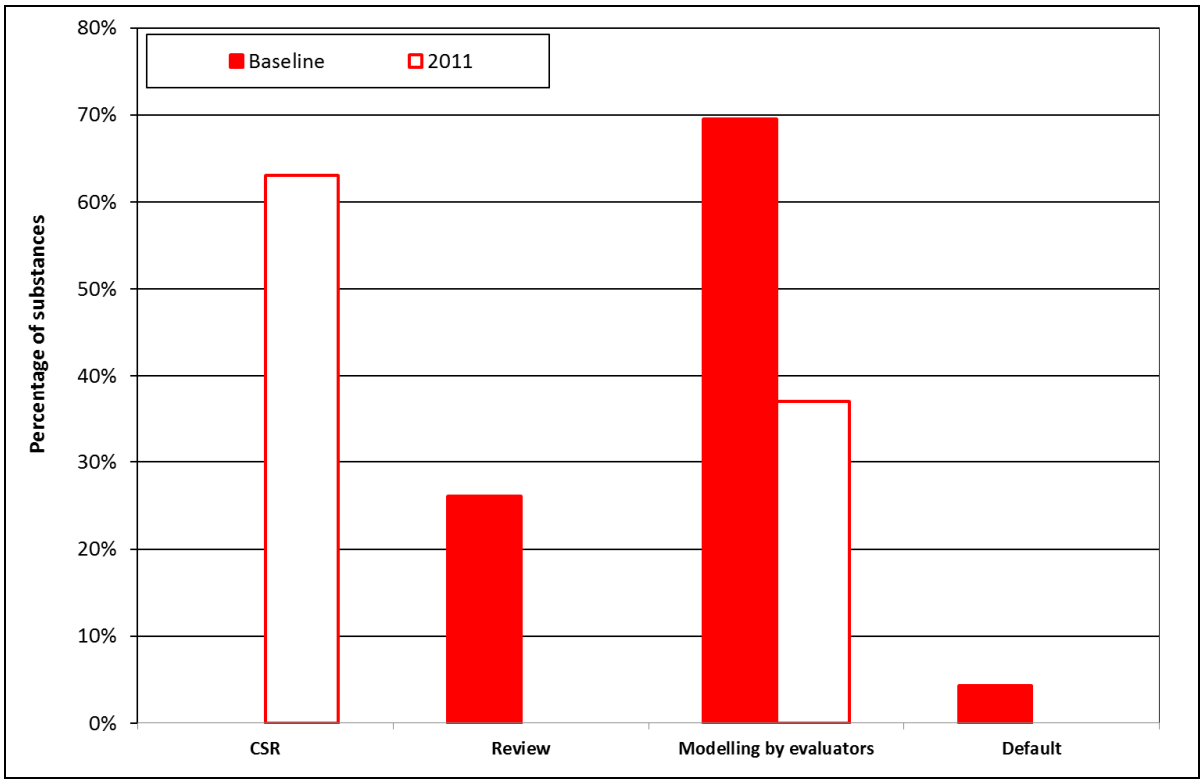
- DMELs were only derived for 6 substances (50%).
- For many of the carcinogenic SVHC without a DMEL, DNELs were given and sometimes a justification for not deriving a DMEL is presented (e.g. lack of dose-response information).
- There is no harmonised understanding by registrants which risk level (extra risk due to occupational exposure) should be assigned to the DMEL.

The question of the actual values for DMELs is discussed in detail below in the context of RCRs for SVHC (see Analysis Box 3.4, below).

Overall, DMELs were only derived for half of the carcinogenic SVHC, a finding that is in agreement with observations made by others. Analysing REACH registration dossiers, Rouw (2011) found that DMELs were derived for about 40 carcinogens, while there were 60 additional carcinogens without a DMEL. In addition, and also in agreement with our findings, DMELs corresponding to quite different risk levels ranging from 1:1.000 to 1:1.000.000 were found in the evaluation by Rouw (2011).

In relation to the exposure estimate, Figure 3.12 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 (Table 3.7).

Figure 3.12: Data availability analysis for exposure data of HPV chemicals (n=46): baseline – 2011 comparison



Source: Author's compilation

The lack of using data from reviews in 2011 is somewhat misleading since monitoring data reported in CSRs are sometimes the same or very similar to the ones reported in reviews. For example, European Union Risk Assessment Reports frequently report monitoring results obtained from industry (e.g. companies or sector associations). These data may now be included in CSRs as monitoring results. However, our evaluation also found some registrants used modelling approaches rather than exposure data available from reviews with the consequence of a poorer quality see (Chapter **chemicals**).

Modelling by the evaluators had to be used for 17 of the 46 HPV chemicals (37%) in 2011 (Figure 3.12), since an exposure estimate was not available for these substances (see Table 3.7). Lacking exposure estimation for these 17 HPV chemicals is primarily due to two reasons:

- A CSR is legally not required, e.g. if the registration dossier is for an isolated intermediate handled under strictly controlled conditions (n=7)
- A CSR exists, but the substance is not classified and an exposure estimation and risk characterisation is therefore not required (n=7)
- The remaining 3 substances are either not classified for human health endpoints or exposure is only addressed qualitatively (e.g. for endpoints such as corrosion).

The consequences of lacking exposure estimates are discussed in the context of RCRs below.

Table 3.7: Methods for exposure estimation used in CSRs for 46 HPV chemicals (rounded to two significant figures)

Method of exposure estimation	Percentage	
	of all 46 HPV chemicals	of those with estimate
ECETOC TRA modelling	48%	76%
Higher tier modelling	4.3%	6.9%
Monitoring	11%	17%
No exposure estimation available	37%	N/A

Source: Author's compilation

Overall, 83% of all available exposure estimates for HPV chemicals were derived from modelling approaches (primarily ECETOC TRA) and 17% were based on monitoring data.

The situation for exposure estimates for SVHC is quite similar to the one observed for HPV chemicals. One of the main differences is that a higher fraction of 53% of exposure estimates at baseline came from reviews (26% for HPV chemicals). This is not surprising since SVHC can be expected to have been included in reviews by national and international organisations more often. Consequently, modelling exposure was only required in 37% of SVHC at baseline (70% for HPV chemicals).

However, this figure remained stable in 2011 and modelling had to be conducted for 7 of the 19 SVHC (37%). Similar to HPV substances, lacking exposure estimates were mostly due to the fact that a CSR was not required (n=4). The other 3 cases primarily involved qualitative instead of quantitative assessments.

The exposure estimates for SVHC available in CSRs were largely conducted with ECETOC TRA (40%) or based on monitoring data (40%), with the remainder carried out with higher tier modelling tools. The main difference to HPV chemicals therefore is the higher fraction of monitoring data used in exposure estimation. The type of monitoring data ranged from briefly reporting data from reviews to extensive in-house data with statistical evaluation to derive exposure estimates.

Default exposure estimates, which were required for 2/19 SVHC at baseline, were no longer required in 2011.

Overall, more data became available between the baseline in 2011. This is particularly evident for HPV chemicals, but less so for SVHC. In the latter case, DMELs were not derived for half of the carcinogens included in this group.

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 in the following sections.

HPV chemicals in detail

RCR overview

As mentioned earlier, the Risk Score is obtained by multiplying the Risk Characterisation Ratio (RCR) with the Population Risk Modifier (PRM). The data for the PRM (Table 3.6, also included in Table 3.8 below for ease of comparison) show little change between baseline and 2011, with possibly slightly higher PRM values for HPV chemicals in 2011. The evaluation at profile level (Chapter 3.2.2.2) showed a general downward trend of HPV Risk Scores, and a decrease was evident in the GM, but not at the median (showing a slight increase). From these data, it can be assumed that the RCR should also display a similar pattern. The summary statistics reported in Table 3.8 indeed show that:

- the GM RCR decreases from baseline to 2011, which translates into a lower Risk Score due to similar PRM,
- the median RCR only shows a small decrease in 2011 and the slightly increased Risk Score is completely due to the increased PRM,
- the general decrease in Risk Scores in 2011 (evident e.g. in the upper percentiles, minimum and maximum values) is primarily due to diminished RCRs since the PRM values do not change much,
- both the median and GM RCRs are below 1 in 2011, while this was only the case for the median at baseline and

- the 'narrowing' of the Risk Scores results from a 'narrowing' of the RCRs and is solely due to a decrease in the 75th percentile of the RCR

The descriptive statistics can be translated in the somewhat more intuitive statement that the 'middle fifty' in 2011 had an RCR in the range of 0.43-1.5 in 2011, while at baseline the range was 0.45-9.6.

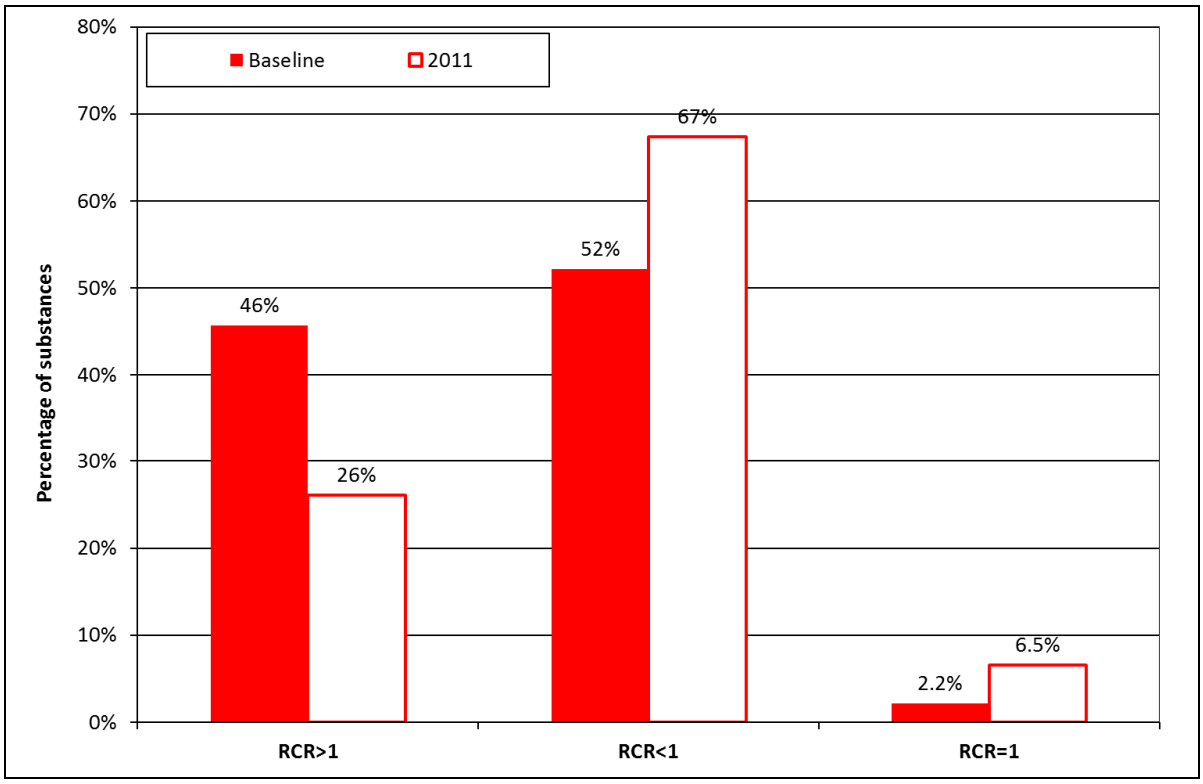
Table 3.8: Summary descriptive statistics for RCR, PRM and Risk Score for HPV chemicals (n=46): baseline – 2011 comparison (rounded to two significant figures)

	RCR		PRM		Risk Score	
	Baseline	2011	Baseline	2011	Baseline	2011
n	46	46	46	46	46	46
Median	0.86	0.78	5.0	7.0	4.5	5.4
GM	2.5	0.99	5.5	6.0	14	6.0
10th percentile	0.15	0.13	4.0	4.0	0.79	0.64
25th percentile	0.45	0.43	4.0	5.0	2.2	2.6
75th percentile	9.6	1.5	7.0	8.0	83	10
90th percentile	73	22	8.0	8.5	400	160
MIN	0.028	0.0013	4.0	3.0	0.11	0.0064
MAX	480000	470	10	9.0	2400000	3200
IRQ	9.2	1.1	3.0	3.0	81	7.3

Source: Author's compilation

Another way of presenting these results is by differentiation of RCRs above, below and equal to 1. Figure 3.13 shows the distribution of RCRs according to this differentiation and identifies a decline of the fraction of HPV chemicals with RCRs > 1 in 2011 with a corresponding increase in with RCRs below or equal to 1.

Figure 3.13: Distribution of RCRs for HPV chemicals (n=46), above, below or equal to 1: baseline – 2011 comparison (rounded to two significant figures)



Source: Author's compilation

Analysis Box 3.1: RCRs equal to 1

As shown in Figure 3.13, the fraction of substances with an RCR = 1 triples from baseline to 2011. While only few substances are concerned in our sample, it is expected that many CSRs with RCRs = 1 for some uses will be encountered. In this context, it is worth noting that some of ECHA's guidance documents contain some form of re-interpretation of the text of the REACH Regulation.

Annex I, No. 6.4 of the REACH Regulation stipulates that "*the risk to humans and the environment can be considered to be adequately controlled [.] if the exposure levels […]* ***do not exceed*** *the appropriate DNEL or the PNEC"* (our emphasis). In our opinion, this clearly implies that an RCR = 1 (i.e. exposure level and DNEL are equal) indicates adequate control of risk according to the Regulation.

Part E of ECHA's Guidance on Information Requirements and Chemical Safety Assessment, gives the following interpretation: "*REACH Annex I, 6.4 states that for any exposure scenario the risk to humans can be considered to be controlled if* ***exposure levels do not exceed the appropriate DNEL****, i.e. if the* ***RCR <1***" (our emphasis). In our opinion, the term should rather read "RCR ≤ 1".

ECHA's "Guidance in a nutshell: Chemical Safety Assessment" goes one step further: *"Risks are regarded as controlled under REACH when the* ***exposure levels to the substance are below the threshold levels*** *considered as safe, both for humans and for the environment"* (our emphasis), with threshold levels being defined as "*DNEL/DMEL or PNEC*" in the same document. This implies that an RCR < 1 is required, but the text deviates from the Regulation.

While these issues may seem minor, unambiguous and consistent definitions in Guidance documents that are in agreement with the Regulation are warranted. In addition, RCRs = 1 should be treated as indicating adequate control of risk. As a consequence, in the grouping conducted in this report, substances with RCRs < 1 and those with RCRs = 1 are evaluated together.

The more detailed data in the following table also identify a more significant decline in 2011 of the number of substances with RCR > 10, with only 5 substances displaying an RCR > 10.

Finally, the number of substances with RCR = 1 increases, possibly reflecting the fact that some registrants consider an RCR of 1 as demonstrating safe use. 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.

Table 3.9: Distribution of RCRs for HPV chemicals (n=46): baseline – 2011 comparison (rounded to two significant figures)

	Baseline			2011		
	n	% of total number of substances	% of those with RCR >1	n	% of total number of substances	% of those with RCR >1
RCR<1	24	52%		31	67%	
RCR>1	21	46%		12	26%	
RCR>10	12	26%	57%	5	11%	42%
RCR=1	1	2.2%		3	6.5%	

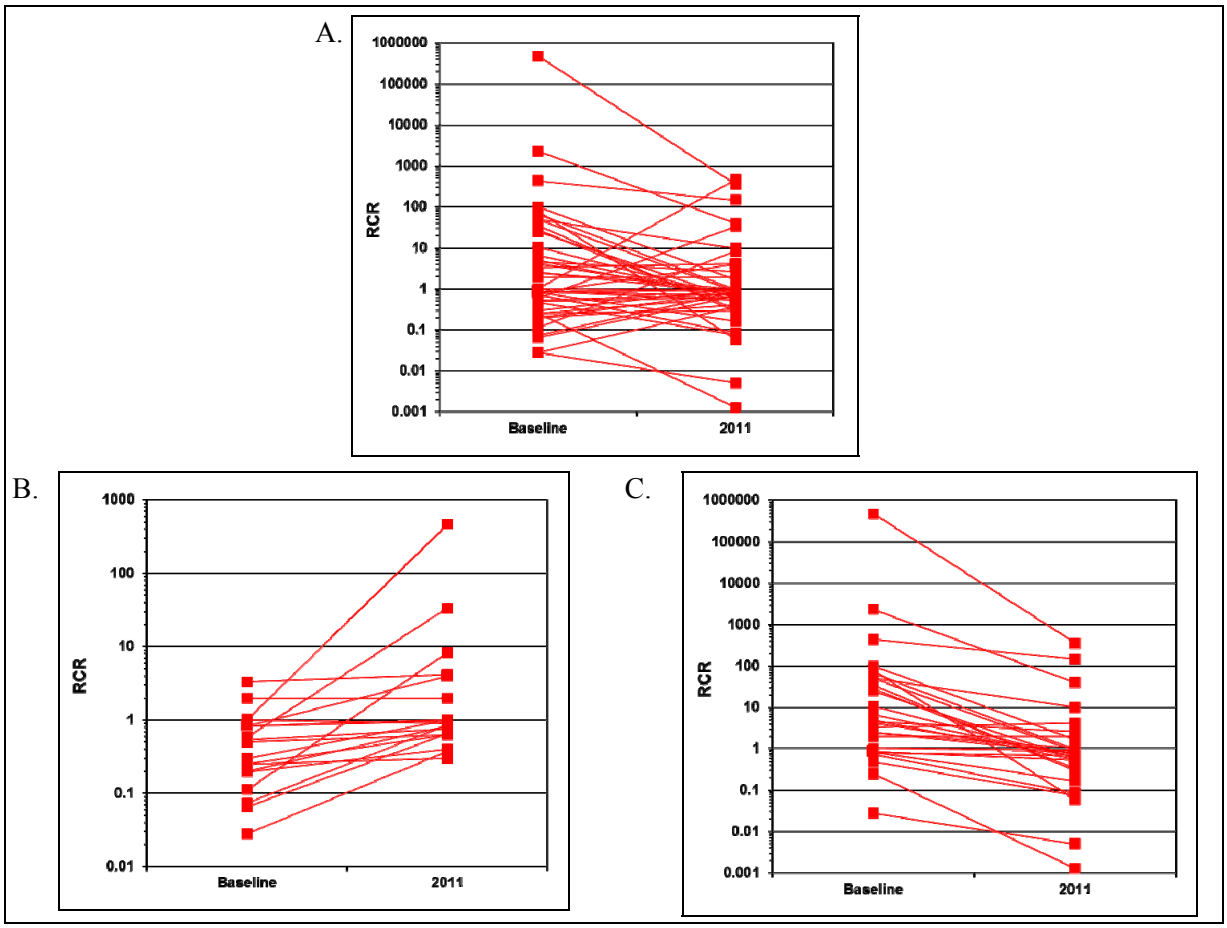
Source: Author's compilation

RCR shifts from baseline to 2011

These data provide an overall picture of RCR distribution, but do not show shifts at the individual substance level. Such an analysis is shown in Figure 3.14 and the following changes from baseline to 2011 were observed:

- 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%).

Figure 3.14: Shift of RCRs at the individual substance level for 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 main changes in this figure and the underlying data can be described as follows:

- The graph again highlights the 'narrowing' effect: while many substances were concentrated between RCRs in the 0.1-100 range at baseline, the bulk moved to the 0.1-10 range in 2011. The figure illustrates the decrease in upper percentiles (but not lower percentiles) reported in Table 3.8.
- There is an apparent cluster of RCRs just below 1 in 2011 that was not evident at baseline. Many substances appear to be moving from RCRs either above or below 1 at baseline to an RCR just below 1 in 2011. This type of 'movement' is only evident in this type of chart as discussed in Analysis Box 3.2.
- It is evident that an increase in RCR does not necessarily lead to an RCR > 1. Conversely, an RCR decrease will not always result in an RCR ≤ 1 (see Figure 3.14-B and Figure 3.14-C). In particular, very high baseline RCRs (>100), while decreasing, are still clearly above 1 in 2011.

Analysis Box 3.2: RCR cluster just below 1

The observation that RCRs in 2011 tend to cluster at values just below 1 deserves special attention. This observation relates to all HPV substances, i.e. those which had an RCR > 1 or an RCR < 1 at baseline.

One possible interpretation of this observation relates to the process of risk characterisation under REACH. We suggest that the cluster is inherently related to the tiered approach of exposure estimation and risk characterisation under REACH, in which the RCR is not so much a figure related to "true risk", but rather a tool to identify risk management measures necessary to ensure safe use of the substance.

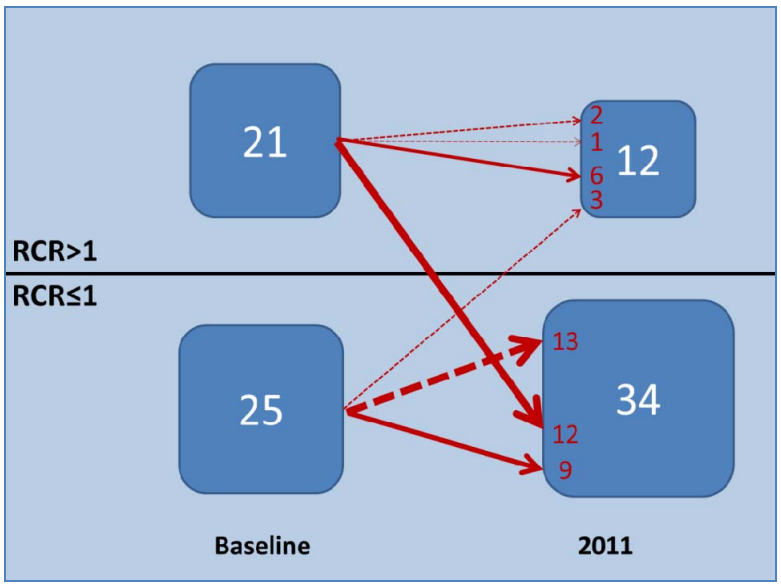
For occupational exposure, ECETOC TRA modelling is usually conducted as a Tier 1 approach. If safe use can be demonstrated (i.e. RCR ≤ 1), the exposure estimation is usually finished and no further refinement is carried out. Consequently, RCR values tend to cluster just below 1. This is also true for HPV substances that had an RCR clearly below 1 (e.g. 0.01-0.1, see Figure 3.14-B) at baseline, which have an increased RCR slightly below 1 in 2011. In most of these cases, the toxicity estimate in 2011 is the same as at baseline, but the exposure estimate is higher, supporting the suggestion above. There are individual examples, where the baseline exposure estimate was based on monitoring data from reviews (sometimes of poor quality, sometimes higher quality), but the 2011 exposure estimate was based on ECETOC TRA modelling, resulting in higher values for the reason given above. This shift from monitoring data to modelled exposure estimates is also responsible for a poorer quality (higher QS_{exp} in 2011) for some of the substances.

This tiered approach taken by registrants is completely in line with REACH philosophy and Guidance provided by ECHA. However, it should always be remembered that the aim is to demonstrate safe use and not necessarily to generate a realistic exposure estimate.

The changes shown in Figure 3.14 also indicate that – although there is a cluster at RCR values just below 1 in 2011 – not all RCRs are e.g. in the 0.7-1 range. Again, this is inherent in the approach to exposure estimation under REACH. For the occupational setting, both inhalation and dermal exposure have to be considered. If, for example, an RCR for dermal exposure of 0.49 is derived, the inhalation exposure RCR can only be up to 0.51. Since we only deal with inhalation exposure in the context of this evaluation, there are many RCRs in the 0.1-1.0 range and not just in the upper end towards 1.

The shifts in RCRs for individual substances shown in Figure 3.14 are summarised in the following figure, this time with an emphasis on changes in relation to the 'critical' level of an RCR of 1. The figure approximates the number of substances in the relative size of the squares and the relative width of the arrows, thus highlighting the most important shifts.

Figure 3.15: Summary of RCR shifts for HPV chemicals (n=46; arrow width and areas approximate the number of substances and arrow orientation shows RCR increases or decreases, with 1 RCR remaining equal)



Source: Author's compilation

The main changes from baseline to 2011 can be summarised as follows:

- Of the 21 HPV chemicals with an RCR > 1 at baseline, 12 (57%) have an RCR ≤ 1 in 2011, while the remaining 9 (43%) chemicals remain in the RCR > 1 group.
- While the RCR increases for 16/25 HPV chemicals with an RCR ≤ 1 at baseline, the vast majority of these (13/16, 81%) still have an RCR ≤ 1 in 2011.
- The RCR for the remaining 9/25 HPV chemicals with an RCR ≤ 1 at baseline further decreases in 2011.
- Taken together, 22/25 HPV chemicals (88%) remain in the RCR ≤ 1 group, a fact that underlines the notion that the baseline estimates were reasonably well founded.

Another important finding from this analysis is that only 3 HPV chemicals (6.5%) move from an RCR ≤ 1 at baseline to an RCR > 1 in 2011. These substances were analysed in detail to ascertain the origin of this shift. Since the substances included in the REACH baseline study and its updates are confidential, the figures in Table 3.10 were somewhat altered to prevent tracking the substances in question. However, the data basis and values represent the true picture.

Table 3.10: Substances with RCRs ≤ 1 at baseline and > 1 in 2011

Substance	Estimate*	Baseline	2011
Substance A (classified as corrosive, no quantitative exposure estimate)	EXP	0,5 mg/m^3 (modelled)	500 mg/m^3 (PROC 11)
	TOX	1 mg/m^3 (OEL$_{analogue}$)	20 mg/m^3 (DNEL)
	RCR	0.5	25
Substance B (not classified, no exposure estimate)	EXP	5 mg/m^3 (modelled)	20 mg/m^3 (PROC11)
	TOX	5 mg/m^3 (OEL)	5 mg/m^3 (DNEL)
	RCR	1	4
Substance C (CSR not required)	EXP	2 mg/m^3 (modelled)	6 mg/m^3 (PROC3)
	TOX	20 mg/m^3 (OEL)	1.5 mg/m^3 (DNEL)
	RCR	0.1	4

* EXP: Exposure estimate, TOX: toxicity estimate; "modelled" refers to modelling carried out by evaluators at baseline, generally without consideration of the specific use (information usually not available); in 2011 all exposure estimates were also modelled, but based on PROCs given in the dossier and the PROC used in modelling is given.

Source: Author's compilation

This summary shows that an exposure estimate was lacking for all substances for the reasons described in Chapter 3.2.2.3. Therefore, modelling was employed on the basis of PROCs assigned for the respective substance. In all cases, this led to higher exposure estimates compared to baseline. For substances A and C, a low vapour pressure led to a comparatively low exposure estimate at baseline. In 2011, however, PROC11 (non-industrial spraying) with potential aerosol exposure increased the estimate. The toxicity estimates display all possible shifts (increase, decrease or unchanged). It has only a pronounced influence for substance C, i.e. the baseline exposure estimate (2 mg/m³) and the 2011 DNEL (1.5 mg/m³) result in an RCR > 1. In the two other cases, the increased exposure estimate is the driving force. In this context, however, it must be stressed that modelling by the evaluators not always leads to higher exposure estimates (see discussion below).

Overall, this evaluation of changes in the RCR shows:

- The number of HPV substances with an RCR ≤ 1 increases from 25 (54%) at baseline to 34 (74%) in 2011.
- This is largely brought about by an RCR decrease from > 1 to ≤ 1 for 12 substances, counteracted somewhat by an RCR increase from ≤ 1 to > 1 for 3 HPV chemicals.
- The baseline estimates were not overly conservative; otherwise, one would have expected a much higher fraction of RCR decreases in 2011. In addition, Figure 3.14 shows that a substantial number of RCRs do not change dramatically.
- RCR changes occur in all directions, with about 60% showing a decrease and about 40% of the HPV chemicals showing an increase in RCRs.

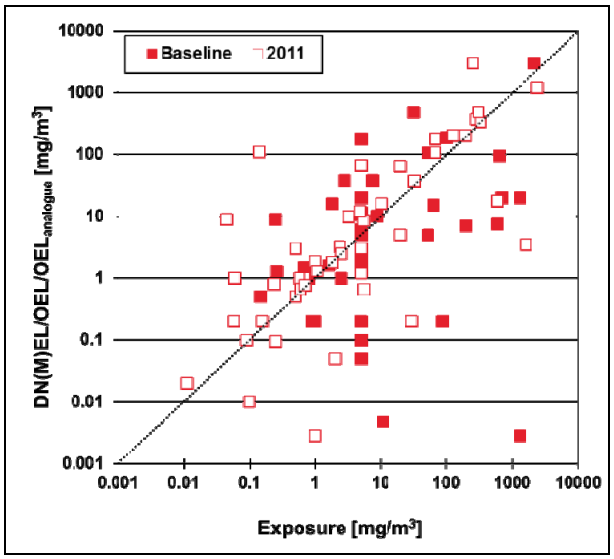
Shifts of the exposure estimate and the toxicity estimate

Since the RCR is calculated from the exposure estimate and the toxicity estimate, it is worth looking at the exposure and toxicity estimates at baseline and in 2011. The following figure presents the respective value as a scatter plot, with all data points above the dashed line indicating RCRs < 1 and all data points below it indicating RCRs > 1. Apart from the RCR cluster at or slightly below 1, the figure suggests that

- there is a trend to the left, i.e. towards lower exposure estimates in 2011 compared to baseline,
- there is no clear downward trend, i.e. toxicity estimates do not appear to change considerably.

This is also evident in the descriptive statistics shown in Table 3.11, with decreasing toxicity estimates only identifiable for some of the parameters.

Figure 3.16: Scatter plot of exposure estimate and reference value for HPV chemicals (n=46): baseline – 2011 comparison



Source: Author's compilation

Table 3.11: Summary descriptive statistics for exposure and toxicity estimates for HPV chemicals (n=46): baseline – 2011 comparison (rounded to two significant figures)

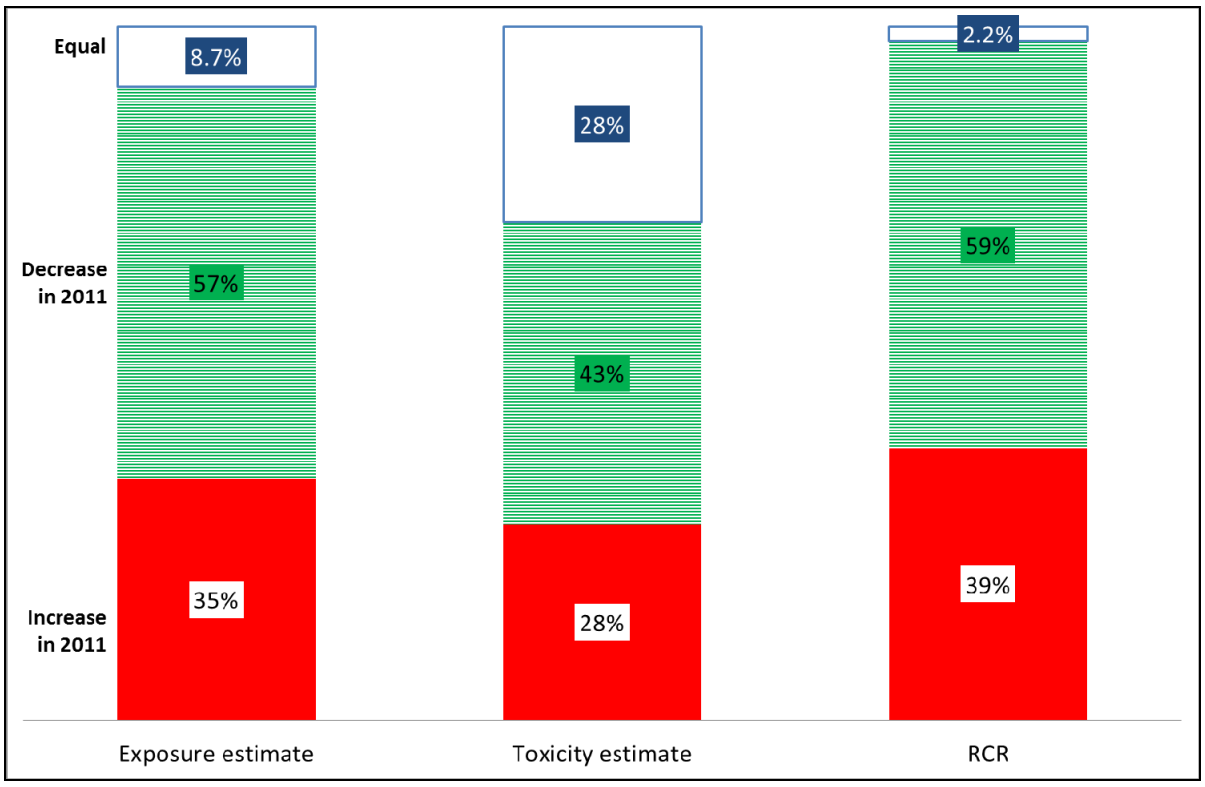
	Exposure estimate [mg/m^3]		DN(M)EL/OEL/OEL$_{analogue}$ [mg/m^3]	
	Baseline	**2011**	**Baseline**	**2011**
n	46	46	46	46
Median	5.0	2.9	6.0	3.0
GM	11	4.0	4.4	4.1
10th percentile	0.76	0.094	0.15	0.097
25th percentile	3.4	0.52	1.0	0.68
75th percentile	53	32	20	58
90th percentile	670	300	140	270
MIN	0.15	0.011	0.0028	0.0028
MAX	2400	2400	3000	3000
IRQ	50	31	19	57

Source: Author's compilation

Again, these descriptions do not assess the behaviour of individual substances. This is only possible by tracking changes for each substance separately. If an analysis identical to the one carried out for RCRs (see Figure 3.14 and the analysis around it) is carried out for exposure and toxicity estimates, the following picture emerges (Figure 3.17, RCRs shown for comparison):

- The exposure estimate is higher in 2011 than at baseline for 35% of the HPV chemicals, which is partly due to the tiered approach of exposure estimation under REACH (see Analysis Box 3.2, above). In addition, there is still a substantial number of HPV chemicals for which modelling had to be conducted in this evaluation due to lacking exposure estimates (e.g. if an exposure estimation is not required under REACH; see Figure 3.12 and discussion above). As exemplified by the three substances above (see Table 3.10 above), the baseline exposure estimation assumed relatively low inhalation exposures, e.g. based on a very low vapour pressure. The registration dossiers provided additional information for the 2011 evaluation, especially in relation to process categories (PROC). If, for example, a substance is used in non-industrial spraying processes (PROC 11) with possible aerosol formation, comparatively high exposure estimates are obtained even for low volatility substances.
- For the 10 substances, for which a CSR exists but an exposure estimation and risk characterisation was not conducted, the modelled exposure usually increases in 2011 (n=5) or remains the same as at baseline (n=4).
- The exposure estimate is lower in 2011 compared to baseline for 57% of the HPV substances. In most cases, ECETOC TRA modelling carried out within the framework of CSRs considered risk management measures (RMMs) and conditions of use (e.g. concentration of the substance in products) and therefore resulted in lower exposure estimates than baseline modelling without consideration of RMMs. In addition, some HPV chemicals were registered as isolated intermediates under strictly controlled conditions (exposure estimation is therefore not required). In these cases, the exposure estimate in 2011 was very low due to this information on the use pattern, which was often not available at baseline.
- As stated above, a CSR was not required for 7/46 HPV chemicals (usually isolated intermediates handled under strictly controlled conditions). For all but one of these substances, the 2011 exposure estimate is (often substantially) lower than the baseline estimate, primarily because information on the use as an intermediate could be considered in the 2011 estimate.
- More than one fourth of the toxicity estimates do not change. This is not unexpected, since many registrants haven chosen an existing OEL as the DNEL for workers. In addition, this group also includes substances for which DNELs were not derived and an OEL or $OEL_{analogue}$ was used. This was often the same value as at baseline.
- Decreases in the toxicity estimate reflect the fact that registrants have sometimes derived DNELs that are lower than existing OELs. This may in part be due to unpublished industry data being used in DNEL derivation, which were not available to national or international agencies deriving OELs. These studies were not necessarily conducted due to REACH information requirements (i.e. after 2006), but may have been conducted a long time ago, but were only now assessed as a source for DNEL derivation. In addition, the methodology for DNEL derivation involves application of assessment factor, a methodology not used by all agencies deriving OELs. Finally, some of the baseline toxicity values were $OEL_{analogues}$, i.e. were estimated from risk phrases or on the basis of published toxicity studies. In some of these cases, although not all (see below), a DNEL derivation may have resulted in lower values.
- Higher DNELs compared to baseline OELs/$OEL_{analogues}$ were observed for 28% of HPV chemicals. As mentioned above, $OEL_{analogues}$ derived at baseline may have been conservative and DNEL derivation resulted in higher values. This applies e.g. to corrosive substances that yielded a comparatively low $OEL_{analogue}$ of 1 mg/m^3 at baseline. Under REACH, corrosive effects are often dealt with in a qualitative risk characterisation and the DNEL derived for quantitative risk characterisation may thus be higher (see substance A in Table 3.10 above).

Figure 3.17: Changes in exposure estimates, toxicity estimates and RCRs for individual HPV substances (n=46) from baseline to 2011



Source: Author's compilation

Impact of the exposure estimate and the toxicity estimate on RCRs

While Figure 3.17 is instructive in relation to the changes observed, it does not allow analysing the impact of changes in exposure and toxicity estimates on the changes observed in the RCR. Therefore, a detailed matrix summarising the substance-specific changes differentiated by RCR (increases and decreases, one substance without change in the RCR was neglected) was developed. Table 3.12 shows the number of substances in each matrix cell and gives the number of substances with an RCR > 1 in parentheses.

Table 3.12: Matrix of changes in exposure and toxicity estimates differentiated by RCR changes for HPV chemicals (n=45, one substance with no RCR change excluded):

Increase: higher values in 2011 than at baseline
Decrease: lower values in 2011 than at baseline
Number of substances with RCR > 1 in parentheses

RCR increase	Exposure estimate			
Toxicity estimate	**Increase**	**Decrease**	**Equal**	**Total**
Increase	4 (2)	0	0	**4 (2)**
Decrease	4 (2)	3 (0)	1 (1)	**8 (3)**
Equal	6 (0)	0	0	**6 (0)**
Total	**14 (4)**	**3 (0)**	**1 (1)**	**18 (5)**
RCR decrease	**Exposure estimate**			
Toxicity estimate	**Increase**	**Decrease**	**Equal**	**Total**
Increase	2 (0)	5 (1)	2 (1)	9 (2)
Decrease	0	12 (2)	0	12 (2)
Equal	0	6 (2)	0	6 (2)
Total	**2 (0)**	**23 (5)**	**2 (1)**	**27 (6)**

Source: Author's compilation

First of all, it is worth noting that the substances with an RCR > 1 in 2011 are about equally distributed in the two groups (n=5 and n=6), i.e. the RCR increased or decreased from baseline. There is one additional substance with an RCR > 1, which showed no changes from baseline (see Figure 3.15).

It is evident from this analysis that the changes in the exposure estimate have a much stronger influence on the RCR changes than the changes in the toxicity estimate. Therefore, changes in the exposure estimate were analysed in more detail in relation to RCR changes (Figure 3.18 and Figure 3.20). These figures display much of the information from Table 3.12, but add additional information in RCR shifts from baseline to 2011 and may be somewhat easier to read than the matrix analysis above.

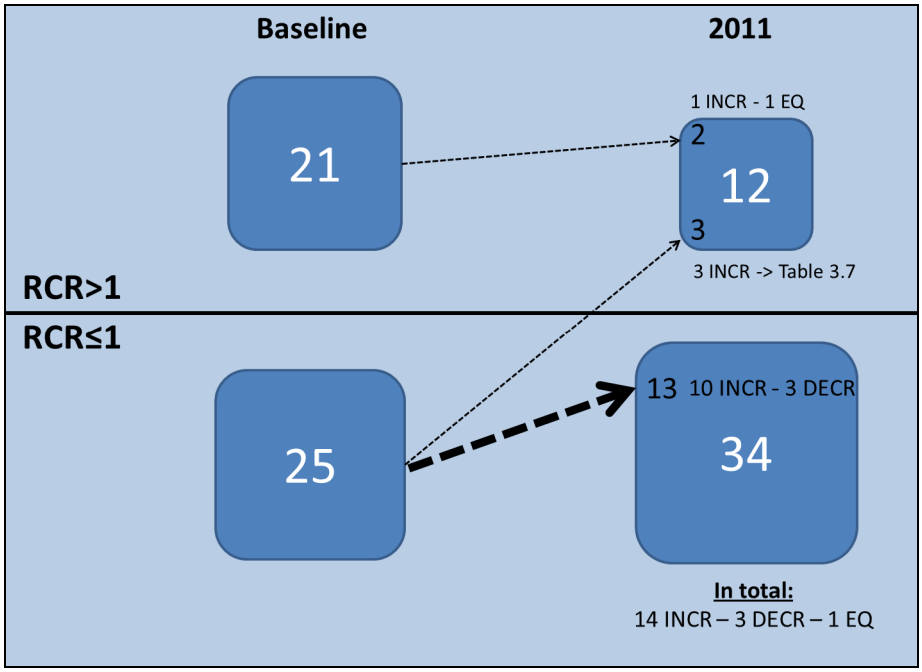
Detailed evaluation of HPV chemicals with increased RCRs

The three substances in Figure 3.18 that move from an RCR ≤ 1 at baseline to an RCR > 1 in 2011 were already discussed in detail in Table 3.10. All three have an increased exposure estimate, based on modelling by the evaluators due CSRs or lacking exposure assessment in the CSRs. Two substances remain in the RCR > 1 group and again, an exposure assessment was not available in the CSR.

The main group in this subset, however, had RCRs ≤ 1 both at baseline and in 2011. Of the 13 HPV chemicals showing RCR increase in this group, 10 had an increased exposure estimate and this comparatively large group was therefore assessed in detail (Table 3.13). In this evaluation, ratios of exposure estimates and RCRs are given, partly to avoid identification of the substances, which would be possible with the values for exposure estimates and RCRs.

In the 'ratio 2011/baseline' for the exposure estimates, the figure gives the factor by which the exposure estimate in 2011 was higher than at baseline (since the table lists substances with higher exposure estimates in 2011, these factors are all above 1). In the 'ratio' column for RCRs, the respective factors for the RCRs are given. Taking substance E as an example, the exposure estimate in 2011 was 2.8-times higher than at baseline. The RCR ratio indicates that the RCR in 2011 was only 1.4-times higher, therefore by definition stating that the DNEL was 2-times higher in 2011.

Figure 3.18: Changes in exposure estimates and RCRs for HPV chemicals with increased RCRs (INCR: 2011 exposure estimate higher than at baseline; DECR: exposure estimate lower; EQ: exposure estimate equal; total number of substances taken from Figure 3.15)



Source: Author's compilation

Table 3.13: HPV chemicals with increased RCRs, increased exposure estimates and RCRs ≤ 1 both at baseline and in 2011 (modelling refers to ECETOC TRA modelling by the evaluators; TRA refers to ECETOC TRA modelling in CSRs, usually considering RMMs)

	Exposure estimate			RCR	
	Basis		Ratio 2011/ Baseline	Ratio 2011/ Baseline	RCR increase influenced by
	Baseline	2011			
D	Review	TRA	12	12	exposure only
E	Review	TRA	2.8	1.4	additional DNEL impact
F	Modelling	TRA	2.0	2.5	additional DNEL impact
G	Modelling	TRA	1.2	1.2	exposure only
H	Modelling	TRA	13	13	exposure only
I	Review	TRA	3.3	3.3	exposure only
J	Modelling	TRA	65	1.2	additional DNEL impact
K	Modelling	Modelling	10	10	exposure only
L	Modelling	Monitoring	4.1	4.1	exposure only
M	Review	Monitoring	1.0*	2.0	additional DNEL impact

** Rounded value, actual value is very slightly above 1*

Source: Author's compilation

This evaluation and the raw data extracted from dossiers allow the following conclusions to be drawn:

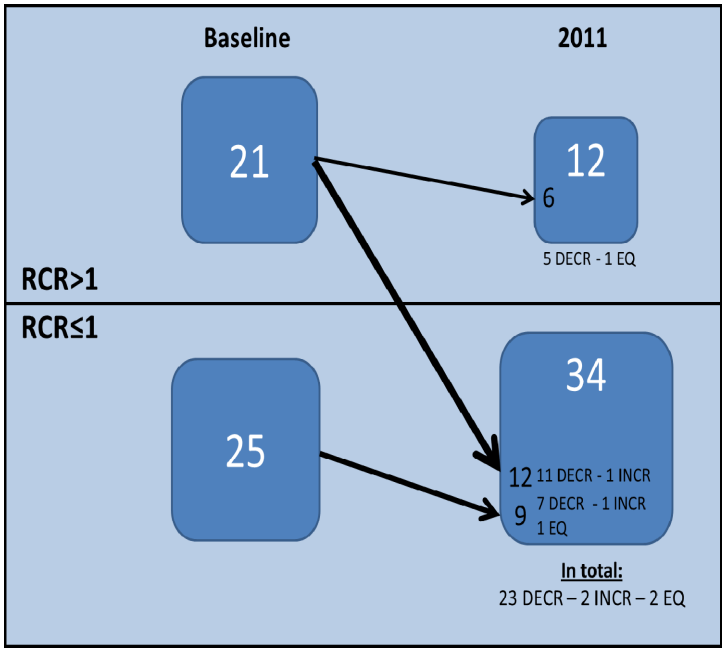
- The RCR increase can be entirely explained by increases in the exposure estimate for 6/10 substances.
- For the 4 substances with an additional DNEL impact, this is usually small (factor 1-2), with only one exception (substance J) and occurs equally in both directions (DNEL increase and DNEL decrease).
- There is no systematic pattern in relation to the basis of exposure estimation: the fact TRA modelling or monitoring data gave higher exposure estimates than modelling at baseline for 5/10 substances (F-H, J, L) further confirms that baseline exposure estimates were not grossly over-conservative.
- The 2011 RCR for these 10 HPV chemicals range between 0.4 and 1 and these substances represent the cluster already referred to above (see also Figure 3.14-B). Their mean values (almost identical AM, GM and median of about 0.7-0.8) are higher than the corresponding baseline value (means of 0.2-0.3).
- Most of these were obtained by ECETOC TRA modelling in the context of CSRs, further adding evidence to the suggestion that the tiered approach of exposure assessment and risk characterisation under REACH is responsible for this cluster (see Analysis Box 3.1).
- TRA modelling was used instead of available monitoring data from reviews in 3/10 cases. This may seem unusual at first sight, but there is a rationale behind it: ECETOC TRA modelling allows the specification of RMMs and conditions of use to be communicated within the supply chain. In the case of monitoring data from reviews, it appears impossible to specify the RMMs and conditions of use associated with these data in almost all cases.

Overall, increased exposure estimates lead to increased RCRs in a substantial number of cases, but the resulting RCR is rarely above 1.

Detailed evaluation of HPV chemicals with decreased RCRs

Of the 6 HPV substances with decreased RCRs, but RCRs > 1 at baseline and in 2011, 5 substances also have decreased exposure estimates (Figure 3.19). The two main groups, however, are substances remaining in the RCR ≤ 1 group (n=9) and substances moving from the RCR > 1 group to the RCR ≤ 1 group (n=12). Again, reduced exposure estimates were obtained for the vast majority of these substances and they will therefore be analysed in more detail.

Figure 3.19: Changes in exposure estimates and RCRs for HPV chemicals with decreased RCRs (INCR: 2011 exposure estimate higher than at baseline; DECR: exposure estimate lower; EQ: exposure estimate equal; total number of substances taken from Figure 3.15)



Source: Author's compilation

There are 7 substances showing a reduced exposure estimation and, as a result, a further reduction of the RCR within the RCR ≤ 1 group. For most of these substances, the 2011 exposure estimate is only about 10-20% of the baseline estimate. This can easily be explained in cases where modelling was conducted at baseline by the application of RMMs in 2011. For example, many solids yielded an exposure estimate of 5 mg/m^3 at baseline (if no exposure data were available), a value that is also obtained in ECETOC TRA for many PROCs. If, however, local exhaust ventilation is integrated in the estimation, this value often declines to 0.5 (industrial setting), i.e. to 10% of the baseline estimate (see substances Q, R and T in Table 3.14).

Compared with the substances with increased RCRs, an additional DNEL impact is observed for a higher fraction of substances. In three of these four cases, however, the DNEL was lower than the baseline toxicity estimate (as evidenced by a higher RCR ratio 2011/baseline than exposure estimate ratio). This means that the decrease in the exposure estimate leads to a decline in RCRs, despite the fact that DNELs decrease as well (which would lead to an RCR increase). For these substances and substance O, 2011 RCR values are in the range of 0.2-0.9, while RCRs are substantially lower for the other 3 substances (N, R, S; RCRs 0.09 or lower).

Table 3.14: HPV chemicals with decreased RCRs, decreased exposure estimates and RCRs ≤ 1 both at baseline and in 2011 (modelling refers to ECETOC TRA modelling by the evaluators; TRA refers to ECETOC TRA modelling in CSRs, usually considering RMMs)

	Exposure estimate			RCR	
	Basis		Ratio 2011/ Baseline	Ratio 2011/ Baseline	RCR decrease influenced by
	Baseline	2011			
N	Review	Modelling	0.2	0.2	exposure only
O	Review	Advanced*	0.9	0.9	exposure only
P	Review	Modelling	0.1	0.6	additional DNEL impact
Q	Modelling	TRA	0.1	0.9	additional DNEL impact
R	Modelling	TRA	0.1	0.1	exposure only
S	Modelling	TRA	0.03	0.01	additional DNEL impact
T	Modelling	Modelling	0.1	0.2	additional DNEL impact

** Advanced (Tier 2 or similar) modelling*

Source: Author's compilation

The fact that ECETOC TRA or Tier 2 modelling or even modelling by the evaluators results in lower exposure estimates in 2011 than taken from reviews at baseline (substances N-P) is also interesting. Two of these three substances are handled under strictly controlled conditions or in closed systems, explaining the low estimate in 2011. This corroborates the finding that modelling by the evaluators does not necessarily increase the exposure estimate and does not necessarily lead to increased RCRs.

The following table shows the results of this analysis for the 11 HPV substances with decreased RCRs and decreased exposure estimates, which actually moved from the RCR > 1 to the RCR ≤ 1 group. Except substance AE, all show an additional DNEL impact. However, DNELs decrease for 7/10 substances (as evidenced by a higher RCR ratio 2011/baseline than exposure estimate ratio). As for the substances in Table 3.14, the substantial decline in exposure estimates leads to an RCR decrease although the DNEL decreases as well (see also Analysis Box 3.3).

Table 3.15: HPV chemicals with decreased RCRs, decreased exposure estimates and RCRs > 1 at baseline and ≤ 1 in 2011 (modelling refers to ECETOC TRA modelling by the evaluators; TRA refers to ECETOC TRA modelling in CSRs, usually considering RMMs)

	Exposure estimate			RCR	
	Basis		Ratio 2011/ Baseline	Ratio 2011/ Baseline	RCR increase influenced by
	Baseline	2011			
U	Modelling	TRA	0.02	0.01	additional DNEL impact
V	Modelling	TRA	0.01	0.02	additional DNEL impact
W	Review	TRA	0.04	0.18	additional DNEL impact
X	Review	TRA	0.01	0.10	additional DNEL impact
Y	Review	TRA	0.06	0.18	additional DNEL impact
Z	Modelling	Advanced	0.12	0.02	additional DNEL impact
AA	Modelling	Modelling	0.0001	0.001	additional DNEL impact
AB	Modelling	TRA	0.36	0.40	additional DNEL impact
AC	Modelling	Modelling	0.0001	0.01	additional DNEL impact
AD	Default	TRA	0.14	0.01	additional DNEL impact
AE	Modelling	Monitoring	0.02	0.02	exposure only

Source: Author's compilation

Analysis Box 3.3: Examples and generalisation

Data for substance V from Table 3.15 are presented in detail to exemplify the shifts observed. Again, the original data are somewhat distorted to prevent identification of this substance.

This substance had an exposure estimate at baseline of 140 mg/m^3 based on the relatively high vapour pressure. An OEL/OEL$_{analogue}$ of 20 mg/m^3 resulted in an RCR of 7 at baseline. In 2011, a lower DNEL of 10 mg/m^3 was derived and the exposure estimate was reduced to 1.4 mg/m^3 based on ECETOC TRA modelling within a CSR (1.4/140 = 0.01 as shown in

Table 3.15). This modelling took the type of use (PROCs) and RMMs into account, i.e. information that was not available at baseline. Overall the 2011 evaluation resulted in an RCR of 0.14 (0.14/7 = 0.02 as shown in

Table 3.15).

It should be noted that the baseline exposure estimate of 140 mg/m^3 was not over conservative. For example, many PROCs in ECETOC TRA result in similar exposure estimate for substances of medium volatility. It is the only application of RMMs and specific conditions of use (e.g. less than full shift exposure, substances in products) that lead to a significant reduction and are included in the exposure assessment. Of all substances evaluated here, ECETOC TRA modelling in 2011 always involved application of RMMs.

The other important message is that reduced exposure estimates lead to a decline in the RCR even though DNELs decline as well for the majority of substances. In the example above, the exposure estimate is reduced by a factor of 100, while the DNEL declines only by a factor of 2.

More generally, a higher reduction for exposure estimates than for DNELs can also be expected, since the exposure estimate depends on RMMs and conditions of use, i.e. factors that can be managed and are not an inherent property of the substance. Consequently, application of local exhaust ventilation (LEV) alone often leads to a tenfold reduction in the exposure estimate (and even higher reductions are achieved if more RMMs and specific conditions of use are applied). DNELs, in contrast reflect properties that are inherent of the substance and although they might change, the difference is not expected to be as pronounced.

These issues ultimately explain the fact that changes in the exposure estimate have a larger impact on the RCR than changes in the toxicity estimate for HPV chemicals.

With the exception of substance AA (an isolated intermediate handled under strictly controlled conditions), all RCRs for the substances in Table 3.15 are in a range slightly below 1 (0.3-1). Again, this is by and large explained by the tiered approach of exposure assessment under REACH, where modelling approaches (ECETOC TRA or advanced tools) are used to ensure safe use rather than to get a 'true' exposure estimate (see Analysis Box 3.1). These substances reflect the cluster of HPV chemicals shown in Figure 3.14-C.

This evaluation for HPV chemicals with decreased RCRs and decreased exposure estimates can be summarised as follows:

- The RCR decrease can be explained by decreases in the exposure estimate for the majority of substances. While an additional impact of the toxicity estimate is observed for 14/18 substances analysed in detail in Table 3.14 and Table 3.15, the toxicity estimate decreases for 10 of these, i.e. the toxicity estimate would rather increase the RCR.
- Again, there is no systematic pattern in relation to the basis of exposure estimation: in fact, modelling conducted by the evaluators led to the most pronounced reduction in exposure estimates for substances presented in Table 3.15. This is due to the fact that these substances are handled as isolated intermediates under strictly controlled conditions, information that was reported in the dossiers and could therefore be considered in exposure estimation.
- Very similar to substances with increased exposure estimates and increased RCRs, TRA modelling was used instead of higher monitoring data from reviews in 3/11 cases (see comments above).

Finally, an evaluation of the 12 substances with an RCR > 1 in 2011 shows the following (see Figure 3.18 and Figure 3.19):

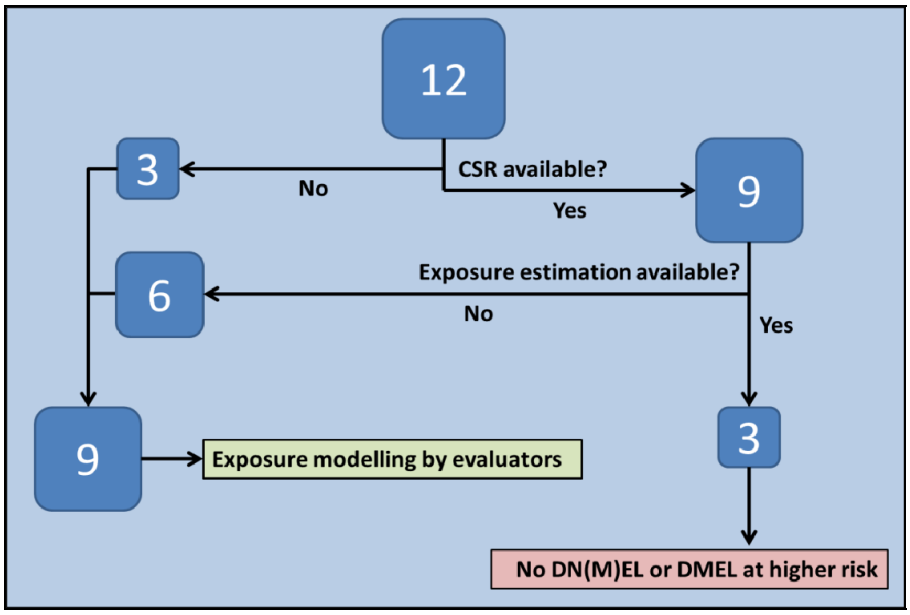
- Most of these (n=9) already had an RCR > 1 at baseline and for these substances, the RCR remains equal (n=1, not shown in the figures), increases (n=2) or decrease (n=6), the latter again largely due to a decrease in the exposure estimate.
- The other three substances move from an RCR ≤ 1 at baseline to an RCR > 1 in 2011 and are discussed in detail in Table 3.10.
- For the majority of substances (n=9, not identical to the 9 substances mentioned above), an exposure estimate was not available either because a CSR was not required or an exposure estimate within a CSR was lacking (see Figure 3.20). Exposure therefore had to be modelled by the evaluators. This led to increased exposure estimates in 4 cases (3 substances not classified, 1 without a CSR) and decreased exposure estimates in 2 cases (substances without a CSR), with RCRs developing in the same direction. The toxicity estimate in these cases again changed in different directions. Exposure estimates remained at the baseline value for the remaining 3 substances (all not classified), in which the toxicity estimate directed the change of the RCR (1 increase, 1 decrease, 1 remaining equal). This underlines the notion that the exposure estimate has a high impact on the RCR changes observed.
- For the substances without a CSR, the available dossier for one substance was for a registration in the 1-10 t/a band, not requiring a CSR. Dossiers available to the evaluators for the other two substances concerned use as an isolated intermediate under strictly controlled conditions. However, the available information indicates that these substances are also used as isolated intermediates by others not under strictly controlled conditions or in non-intermediate uses. Therefore, these substances were not evaluated as being used exclusively under strictly controlled conditions.
- However, there might well be other dossiers with CSRs (including exposure estimation and risk characterisation) for these substances, which were not available to the evaluators. As a consequence, the evaluation in relation to these substances must be considered preliminary.
- The 3 substances, for which CSRs with exposure assessments were available, deserve special attention. The exposure estimate was taken from the CSR in these cases, but the toxicity estimate was adapted. Two of these substances are carcinogens and DMELs were re-calculated to correspond to a risk of 5:100.000 (see the extended discussion for SVHC below, Analysis Box 3.4). For one additional substance, the CSR did not contain a DNEL for workers.
- Ultimately, the 6 substances in this group that have no exposure estimation for workers are seen as the most problematic group. Of these,
  - 3 are not classified,
  - 2 are classified but not for human health endpoints (1 for physico-chemical properties only and 1 for environmental effects only) and
  - 1 is classified for local effects (corrosive properties) only

  Note that 3 of these substances (1 from each sub-group) are discussed in Table 3.10.

They represent the only 3 chemicals that move from the RCR ≤ 1 group at baseline to the RCR > 1 group in 2011.

It is beyond the scope of this evaluation to discuss in detail on the appropriateness of the approach chosen by registrants in relation to the scope of exposure assessment (but see also discussion below). In this context, our evaluation also found that several registrants chose a different approach and conducted exposure estimation and risk characterisation for substances not classified for human health endpoints or classified only for 'quantitative endpoints'. The problems identified above thus refer to the approach taken only by some registrants.

Figure 3.20: HPV chemicals with RCRs > 1 in 2011: available information



Source: Author's compilation

In summary, the analysis for HPV substances shows that changes between baseline and 2011 occur in many directions. Nonetheless, the following main findings are important:

- RCRs are lower in 2011 compared to baseline for almost 60% of HPV chemicals. As a consequence, 74% of all HPV chemicals show an RCR ≤ 1 in 2011 compared to 57% at baseline.
- The vast majority of HPV substances with RCRs increased in 2011 compared to baseline also show an increased exposure estimate and the vast majority of HPV substances with decreased RCRs in 2011 also have decreased exposure estimates. In both cases, toxicity estimates change about equally in all directions. Interestingly, decreased exposure estimates still result in decreased RCRs despite a concomitant decrease in toxicity estimates for a substantial number of substances.
- Overall, the changes in exposure estimates therefore have a more pronounced and often decisive impact on the RCR than changes in the toxicity estimate. This finding is not unexpected, since exposure estimates are subject to modifications that are substance-independent (e.g. application of LEV) and affect large reductions, while the toxicity estimates represent an inherent property of the substance and are generally not expected to change to such an extent.
- RCR values > 1 are observed for 12 substances (26%) in 2011, 9 of which already had RCR values > 1 at baseline. In 2011, RCR values above 1 are primarily the result of lacking exposure estimates.
- Exposure modelling by the evaluators was necessary for 17/46 HPV chemicals, primarily because
  - a CSR was not required (n=7): this usually resulted in a decline in the exposure estimate and a decline in the RCR. However, the RCR is above 1 for 3 of these substances, which all have very low DNELs.
  - exposure estimation was not performed in the CSR (n=7): this typically increased the exposure estimate or it remained at the baseline level. The 3 HPV chemicals with an RCR ≤ 1 at baseline, increasing to an RCR > 1 in 2011 belong to this group as well as the two substances with increased RCR remaining in the RCR > 1 group (see Figure 3.18).

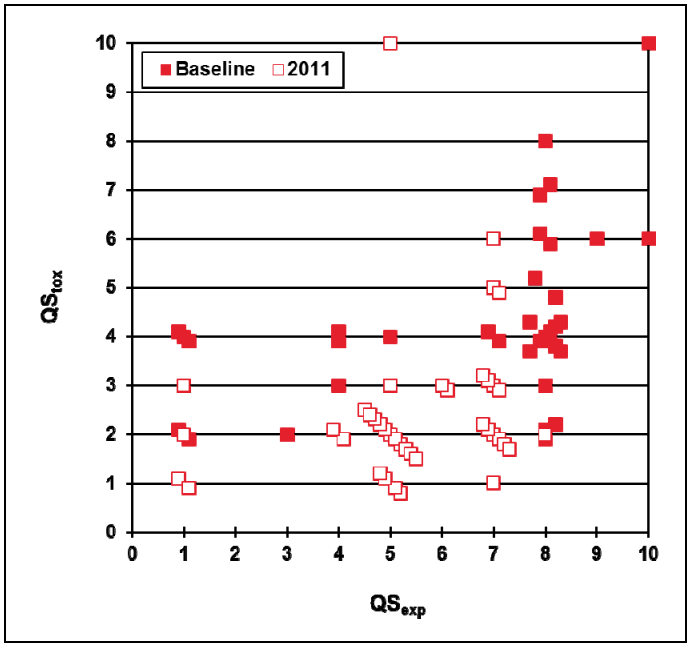
Overall, the result for the 17 substances, for which exposure modelling was conducted by the evaluators, is as follows:

- RCR > 1 in 2011 for 9 substances (the majority of the 12 substances with an RCR > 1 in 2011), of which
  - 3 substances moved up from the RCR ≤ 1 group (see Table 3.10)
  - 6 substances already had an RCR > 1 at baseline
- RCR ≤ 1 in 2011 for 8 substances, of which
  - 2 substances had an RCR > 1 at baseline
  - 6 substances already had an RCR ≤ 1 at baseline

As noted at profile level, the **Quality Score (QS_{total})** decreases from baseline to 2011, indicating a better quality of the 2011 data. 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 decline in QS_{total} is due to a decline in one of these components or both.

Figure 3.21 shows a QS_{exp}/QS_{tox} scatter plot for HPV substances. Since QS by definition are integers and some substances have exact the same values, there would be considerable overlay in the scatter plot, showing only a fraction of the substances. Therefore, a shift in the original values was manually introduced to visualise more clearly the changes (e.g. for the many baseline data points QS_{exp} = 8 and QS_{tox} = 4, values were changed to 8.2/3.8, 8.1/4.1 etc.).

Figure 3.21: Quality Score scatter plot for HPV chemicals (n=46): baseline – 2011 comparison



Source: Author's compilation

The scatter plot clearly shows a decline in both Quality Scores and visualises several additional aspects:

- At baseline, there is an apparent cluster with data points at QS_{exp} = 8 / QS_{tox} = 4 (in fact, these values constitute the medians at baseline, see Table 3.16). These data points reflect the fact that
  - exposure generally had to be modelled at baseline, usually without any additional information, resulting in QS_{exp} = 8.
  - many toxicity estimates were based on OELs or $OEL_{analogues}$ derived from risk phrases (Eurostat 2009), which often gave QS_{tox} = 4 (depending on the availability of testing data).
- In 2011, at least two new clusters emerge:
  - One at QS_{exp} = 5 / QS_{tox} = 2, which reflects ECETOC TRA exposure modelling with consideration of RMMs (usually conducted in CSRs) combined with an OEL/DNEL for the toxicity estimate. There is a subset of substances with QS_{tox} = 1, which was assigned if a DNEL was identical to an OEL.
  - A second (smaller) cluster at QS_{exp} = 7 / QS_{tox} = 2, which again results from the increased availability of DNELs. For these substances, however, ECETOC TRA modelling had to be performed during the evaluation since a CSR or an exposure assessment was not required (isolated intermediates, substances not classified etc., see Chapter 3.3.2.3.2, above). While the use pattern was usually known from the PROCs assigned by registrants, no information on RMMs was available, resulting in a lower quality than ECETOC TRA modelling carried out in the context of CSRs. Again, there is a subset with QS_{tox} = 3, reflecting substances without complete testing (e.g. if a 90d toxicity study was not available but marked as planned or data were not available for specific endpoints in the case of isolated intermediates. While in the latter case, registrants conform to REACH requirements, these data are lacking for a full evaluation and therefore the quality was lower (this approach was also taken at baseline)).

The improvement in the quality of both exposure and toxicity estimates (i.e. the decline in QS_{exp} and QS_{tox}) is also evident in the statistical evaluation presented in Table 3.16 (QS_{total} included for comparison).

Table 3.16: Summary descriptive statistics for Quality Scores for HPV chemicals (n=46): baseline – 2011 comparison (rounded to two significant figures)

	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

Again, a substance-specific analysis similar to the one conducted for RCRs is performed for the Quality Scores to identify substance-specific changes and the impact of the individual QS component(s). The analysis presented in Table 3.17 (excluding one HPV substances with no change in QS_{total}) allows the following conclusions to be drawn:

- Only 7/45 (16%) HPV chemicals show an increase in QS_{total}, which is largely due to increased QS_{exp}.
  - This QS_{exp} increase is primarily due to the fact that some registrants decided to model occupational exposure with ECETOC TRA in the CSRs, while monitoring results from reviews were available at baseline (the quality of which varied but was usually rated better than modelling according to the methodology applied).
  - As already stated above, this approach taken by registrants is plausible since only ECETOC TRA modelling allows the specification of RMMs and conditions of use to be communicated within the supply chain.
- The majority of HPV chemicals shows a decrease in QS_{total} (i.e. an increased quality), which is due to decreases in both Quality Score components.
- More than half of the HPV chemicals with a decline in QS_{total} display decreases in both Quality Score components (21/38, 55%), largely reflecting
  - the availability of DNELs (see Figure 3.11), assigned a high quality and
  - ECETOC TRA modelling of exposure under consideration of risk management measures in CSRs, which is assigned a higher quality than modelling without risk management measures at baseline (see Figure 3.12).
- Overall, the data show 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.

Table 3.17: Matrix of changes in Quality Scores for HPV chemicals (n=45, one substance with no changes excluded):

Increase: higher values in 2011 than at baseline
Decrease: lower values in 2011 than at baseline; zero values not shown

QS_{total} increase	QS_{exp}			
QS_{tox}	Increase	Decrease	Equal	Total
Increase		1		**1**
Decrease	4			**4**
Equal	2			**2**
Total	**6**	**1**		**7**
QS_{total} decrease	QS_{exp}			
QS_{tox}	Increase	Decrease	Equal	Total
Increase		1		**1**
Decrease	4	21	6	**31**
Equal		6		**6**
Total	**4**	**28**	**6**	**38**

Source: Author's compilation

Overall, the quality of the exposure estimate, the toxicity estimate and the overall quality improves considerably from baseline to the 2011 evaluation.

SVHC in detail

As mentioned earlier, the Risk Score is obtained by multiplying the Risk Characterisation Ratio (RCR) with the Population Risk Modifier (PRM). The data for the PRM (Table 3.6, also included in Table 3.18 below for ease of comparison) show little change between baseline and 2011, with possibly slightly lower PRM values for SVHC in 2011. However, the data in Table 3.18 clearly show that the substantial decline in GM and median Risk Scores in 2011 is almost entirely due to decreases in the RCR.

Table 3.18: Summary descriptive statistics for RCR, PRM and Risk Score for SVHC (n=19): baseline – 2011 comparison (rounded to two significant figures)

	RCR		PRM		Risk Score	
	Baseline	2011	Baseline	2011	Baseline	2011
n	19	19	19	19	19	19
Median	670	8.3	6.0	6.0	3300	33
GM	220	7.4	5.9	5.2	1300	38
10^{th} percentile	0.17	0.15	3.8	2.8	0.74	0.31
25^{th} percentile	10	1.3	5.0	4.0	55	6.2
75^{th} percentile	1800	99	7.5	7.5	14000	791
90^{th} percentile	480000	480	9.2	8.2	2800000	3000
MIN	0.11	0.0019	3.0	20	0.39	0.0075
MAX	1200000	1800	10	9.0	6000000	14000
IRQ	1800	98	2.5	3.5	14000	790

Source: Author's compilation

Similar to HPV chemicals, the results can be differentiated by RCR bands (> 1, < 1 etc.). The following table shows that

- despite the considerable decrease in absolute RCRs in 2011 compared to baseline, the majority of SVHC still have an RCR > 1 (79% at baseline and 74% in 2011).
- the fraction of SVHC with RCRs > 10 more clearly declines from 74% at baseline to 47% in 2011 (this same information is evident in Table 3.18, where the baseline 25^{th} percentile roughly becomes the median in 2011).

Table 3.19: Distribution of RCRs for SVHC (n=19): baseline – 2011 comparison (rounded to two significant figures)

	Baseline			2011		
	n	% of total number of substances	% of those with RCR >1	n	% of total number of substances	% of those with RCR >1
RCR<1	4	21%		5	26%	
RCR>1	15	79%		14	74%	
RCR>10	14	74%	93%	9	47%	64%
RCR=1	0			0		

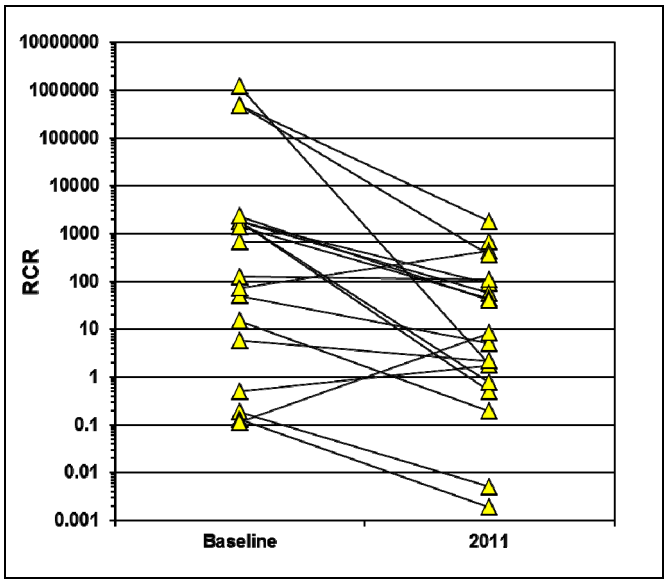
Source: Author's compilation

At the individual substance level, Figure 3.22 clearly shows that – in contrast to HPV chemicals – the vast majority of SVHC shows a decrease in the RCRs in 2011 compared to baseline, with only few showing an RCR increase:

- 1 SVHC shows no change in the RCR (5.3%; 2.2% for HPV chemicals),
- 3 SVHC show an increase in the RCR (16%; 39% for HPV chemicals) and
- 15 SVHC show a decrease in the RCR (79%; 59% for HPV chemicals).

The cluster at RCR values just below 1 that was identified above for HPV chemicals is not observed for SVHC, but this could be due to the smaller sample size.

Figure 3.22: Shift of RCRs at the individual substance level for SVHC (n=19)



Source: Author's compilation

This figure also illustrates that of the 4 SVHC with an RCR ≤ 1 at baseline, 2 remain in this group in 2011, while 2 chemicals show an RCR increase to values between 1 and 10.

As already mentioned, most of the SVHC (12/19, 63%) are carcinogens so that an evaluation of the cancer risk is very relevant for these SVHC in the context of this evaluation. The absolute RCR values for SVHCs are directly linked to the cancer risk on which the DMELs are based. In this context, the methodology applied in this study inherently leads to higher RCRs than would be seen in CSRs (see Analysis Box 3.4).

Analysis Box 3.4: DMELs and risk

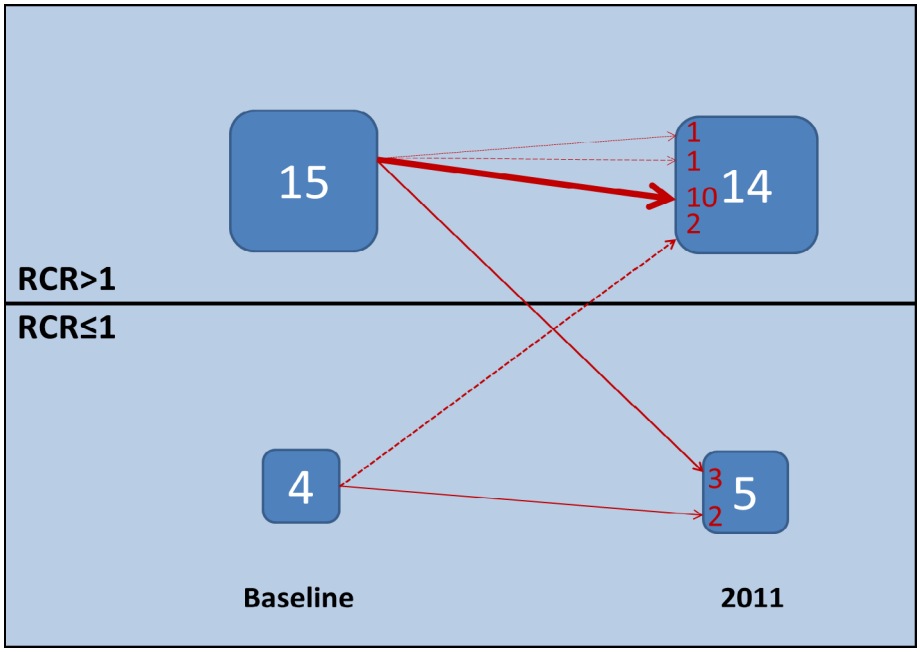
The methodology applied in this study (both at baseline and in 2011) uses a cancer risk of 5:100.000, which is lower than the risks usually applied for occupational settings. In Germany, a "tolerable risk" of 4:1000 and an "acceptable risk" of 4:10.000 form the basis for the evaluation of carcinogens at the workplace. The latter, however, is only valid provisionally and has to be substituted by a risk of 4:100.000 by 2018 at the latest (AGS, 2008; 2010). Thus, our approach of using a risk of 5:100.000 – while not being current practice in most countries – reflects the principle of minimising exposure to carcinogenic substances at the workplace.

In agreement with the approaches described above, DMELs for SVHC were often derived on the basis of a risk of about 1-5:1.000. This is also in agreement with an analysis performed by others. Out of 23 dossiers with DMELs analysed, 9 (39%) were related to a risk of 1-5:1.000, 4 (17%) were related to a risk of 1-5:10.000 and 9 (39%) were related to a risk of 1-5:100.000 (as employed in this study). Interestingly, the risk associated with a DMEL was not quantified for another 7 carcinogens (Rouw, 2011). In our study, DMELs were divided by the appropriate factor to correspond to a risk of approximately 5:100.000 since this risk formed the basis of the baseline evaluation (when DMELs were not available). As a direct consequence, many RCRs are above 1 for SVHC.

The shifts in RCRs for individual substances shown in are summarised in the following figure, this time with an emphasis on changes in relation to the 'critical' level of an RCR of 1. The figure approximates the number of

substances in the relative size of the squares and the relative width of the arrows, thus highlighting the most important shifts.

Figure 3.23: Summary of RCR shifts for SVHC (n=19; arrow width and areas approximate the number of substances and arrow orientation shows RCR increases or decreases, with 1 RCR remaining equal)



Source: Author's compilation

The main changes from baseline to 2011 can be summarised as follows:

- While the data in
- Table 3.19 may suggest that one SVHC moves from the RCR > 1 to the an RCR ≤ 1 group, the figure illustrates that such a movement occurs with 3 SVHC but is counteracted by an 'upward' movement from the RCR ≤ 1 to the RCR > 1 group by 2 substances.
- The main shift is an RCR decrease within the RCR > 1 group for 10 SVHC. Within this group, 9 substances had an RCR > 10 at baseline and this fraction was reduced to 7 substances in 2011. Thus, the RCR decline in the group led to a reduction from RCRs > 10 to RCRs of 1-10 only in the case of 2 substances.

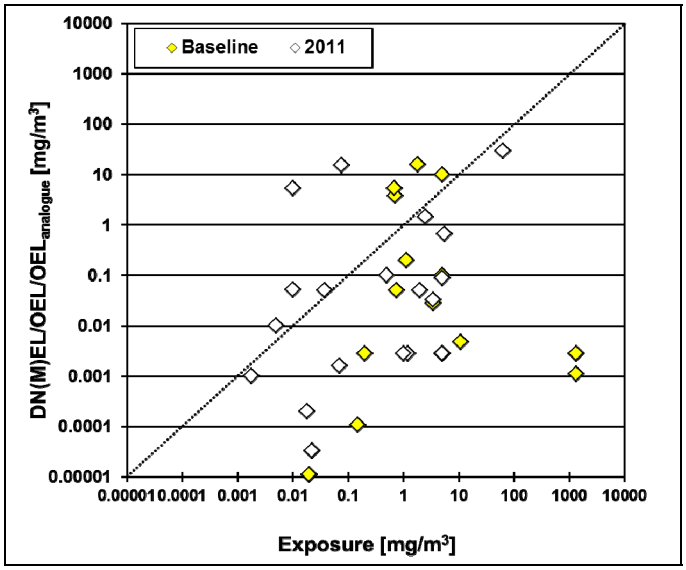
Again, the 2 substances that move up to the RCR > 1 group deserve special attention. Both are non-carcinogens and have a DNEL that is about an order of magnitude lower than the toxicity estimate used at baseline. The exposure estimate was 50% of the baseline estimate in one case. This was based on extensive monitoring data reported in the CSR and an existing review. Upon investigation of the review data, the evaluators decided to use a different exposure value than selected in the CSR, resulting in an RCR value slightly above 1. For the second substance, the exposure estimate had to be modelled by the evaluators and increased slightly compared to baseline due to PROCs mentioned in the dossier. Together with the considerable decline in the DNEL, this results in an RCR in the 1-10 range.

Similar to HPV chemicals, the individual components of RCRs, i.e. the exposure estimate and the toxicity estimate, provide additional insight into the changes seen between baseline and 2011. Again, the data points above the dashed line in Figure 3.24 indicate RCRs < 1 and data points below it indicate RCRs > 1. The data in this figure suggests that

- there is a trend to the left, i.e. towards lower exposure estimates in 2011 compared to baseline,
- a clear trend in the toxicity estimates is not evident.

The descriptive statistics shown in Table 3.20 generally support these conclusions. However, the median and the different percentiles presented in this table suggest an increase in the toxicity estimate, a finding also supported by the substance-specific shifts discussed below (see Figure 3.25).

Figure 3.24: Scatter plot of exposure estimate and reference value for SVHC (n=19): baseline – 2011 comparison



Source: Author's compilation

Table 3.20: Summary descriptive statistics for exposure and toxicity estimates for SVHC (n=19): baseline – 2011 comparison (rounded to two significant figures)

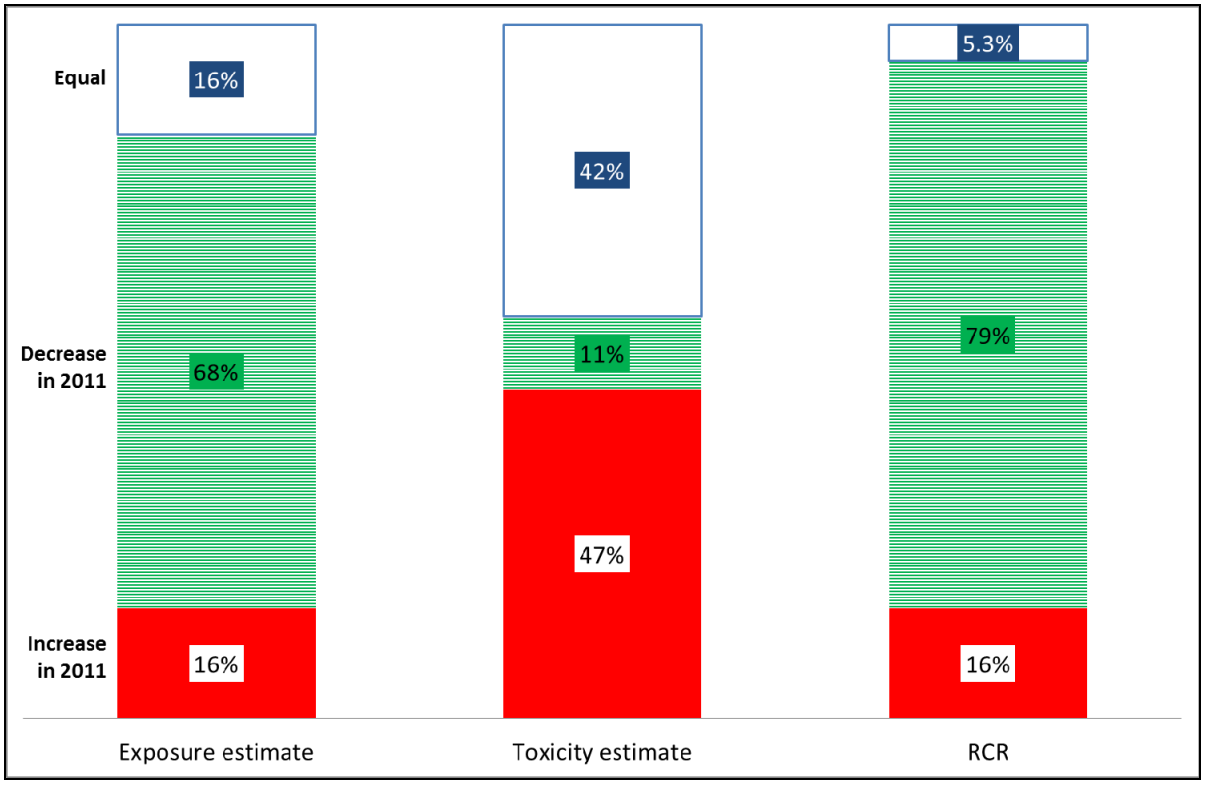
	Exposure estimate [mg/m^3]		DN(M)EL/OEL/OEL$_{analogue}$ [mg/m^3]	
	Baseline	**2011**	**Baseline**	**2011**
n	19	19	19	19
Median	1.8	0.50	0.0028	0.050
GM	2.4	0.26	0.011	0.035
10th percentile	0.022	0.0090	0.000029	0.00084
25th percentile	0.45	0.020	0.0020	0.0028
75th percentile	5.0	3.0	0.15	0.38
90th percentile	1300	5.1	6.2	7.3
MIN	0.020	0.0018	0.000011	0.000034
MAX	1300	63	16	29
IRQ	4.6	3.0	0.15	0.38

Source: Author's compilation

At the substance-specific level, the changes observed for SVHC are similar to the ones described above for HPV chemicals with some notable exceptions (Figure 3.25):

- Overall, there is generally a higher fraction of substances with equal estimates at baseline and in 2011 compared to HPV chemicals.
- The exposure estimate is higher in 2011 than at baseline for only 3/19 (16%) of the SVHC (35% for HPV chemicals), which is completely due to the reasons already identified above for HPV chemicals: the tiered approach of exposure estimation under REACH may lead to "safe" exposure levels rather than realistic ones (see Analysis Box 3.2, above). In two of the three cases, the exposure estimate at baseline was taken from reviews (modelled or monitoring data), while exposure was modelled using ECETOC TRA or other tools in 2011. In the third case, exposure had to be modelled both at baseline and in 2011 and this led to a somewhat higher estimate in 2011 due to available information on PROCs.
- The exposure estimate is lower in 2011 compared to baseline for 13/19 SVHC (68%). There is no clear trend in relation to the causes: exposure estimates that are lower in 2011 than at baseline were based on ECETOC TRA or higher tier modelling in CSRs (4/13), on monitoring data reported in CSRs (4/13) or were derived by the evaluators because no CSR was available (5/13; these were based on modelling or extracted from existing reviews).
- Almost half of the toxicity estimates (42%) do not change and this is primarily due to the following factors: DMELs were not derived for a substantial number of carcinogenic SVHC (see Chapter 3.2.2.3). In most of these cases, the baseline (risk-based) estimates were used. In addition, DMELs derived in CSRs were in some cases (after conversion to a risk of 5:100.000, see Analysis Box 3.4) identical to the (risk-based) estimates derived at baseline. This is not unexpected since for any given substance, there are often only few reliable carcinogenicity studies available and the chance of deriving an identical value is therefore high.
- Decreases in the toxicity estimate have only been observed for two substances. Both are not classified as carcinogens and lower DNELs were derived compared to the baseline toxicity estimate. These are the two substances already discussed above that move from the RCR ≤ 1 group at baseline to the RCR > 1 group in 2011 (see also Figure 3.23).
- Quite different to HPV chemicals (28%), higher DN(M)ELs compared to baseline OELs/$OEL_{analogues}$ were observed for 9/19 (47%) of SVHC. This relates to higher DNELs in 2011 for 2 non-carcinogens. The other 7 SVHC are all carcinogens, for which a low value was derived at baseline on the basis of available risk estimates or using the default figure. In 2011, a higher DMEL (or risk-based $OEL_{analogue}$ if a DMEL was not available) was derived in 2011 (even after correction to a risk of 5:100.000, see Analysis Box .3.4). It is beyond the scope of this study to evaluate the DMEL derivation in CSRs in detail and the validity of DMELs can therefore not be judged. However, it must be stressed that baseline estimates were not necessarily over conservative, but there is also the possibility that DMELs were not derived correctly. For example, in an analysis of 33 dossiers, Rouw (2011) observed that 21% of the DMELs were not derived correctly or are at least doubtful. The same author noted that for an additional 18% DNELs rather than DMELs were derived, confirming the findings of the present study (see point c) above).
- For the 7 carcinogenic SVHC with increased toxicity estimates, the 2011 value is typically about one order of magnitude higher than the baseline figure (even if the latter was based on a default value). This is a small difference given the uncertainties involved in the derivation of cancer risk figures and further supports the notion that the baseline estimates were not grossly overprotective.
- Taken together, decreased toxicity estimates are only observed for non- carcinogenic SVHC, while increased toxicity estimates are primarily observed for carcinogenic SVHC (see also an additional analysis in Table 3.21).

Figure 3.25: Changes in exposure estimates, toxicity estimates and RCRs for individual SVHC (n=19) from baseline to 2011



Source: Author's compilation

Table 3.21: Changes of the toxicity estimate for SVHC (n=19) differentiated by carcinogenic and not carcinogenic SVHC: baseline – 2011 comparison (rounded to two significant figures)

2011 compared to baseline	n	All SVHC	n	Not carcinogenic	n	Carcinogenic
Increased toxicity estimate	9	47%	2	29%	7	58%
Decreased toxicity estimate	2	11%	2	29%	0	
Equal toxicity estimate	8	42%	3	43%	5	42%

Source: Author's compilation

Table 3.22 presents the substance-specific matrix analysis for SVHC, again showing the number of substances in each matrix cell and giving the number of substances with an RCR > 1 in parentheses. This analysis allows the following conclusions to be drawn:

- SVHC with RCRs increased in 2011 compared to baseline
  - The limited number of only three substances in this group prevents a more detailed analysis or reliable conclusions.
  - It should be noted that all three substances have RCRs > 1 and that this was the case only for one of these three substances at baseline.
- SVHC with RCRs decreased in 2011 compared to baseline
  - The majority of SVHC with decreased RCRs also have lower exposure estimates in 2011 (12/15, 80%), a situation very similar to HPV chemicals (85%). In contrast to the latter (22%), however, 7/12 (58%) still have an RCR > 1.
  - For substances with decreased exposure estimates, the toxicity estimate either does not change at all or increases, thus amplifying the RCR decrease. This is quite different to HPV chemicals, for which

RCR decreases were observed in this group despite decreases in the toxicity estimate (this does not occur at all for SVHC).

– Overall, both decreases in exposure estimates and increases in toxicity estimates appear to be roughly equally important for the decline in RCRs. This is quite different from HPV chemicals, for which the exposure estimate appears to have a higher impact than the toxicity estimate on the declining RCRs.
– Nonetheless, only the decrease in the exposure estimate is responsible for RCR ≤ 1. An increase in the toxicity estimate – while leading to RCR decreases, only results in RCR ≤ 1, if the exposure estimate decreases.

Table 3.22: Matrix of changes in exposure and toxicity estimates differentiated by RCR changes for SVHC (n=18, one substance with no RCR change excluded):

Increase: higher values in 2011 than at baseline
Decrease: lower values in 2011 than at baseline
Number of substances with RCR > 1 in parentheses

RCR increase	**Exposure estimate**			
Toxicity estimate	**Increase**	**Decrease**	**Equal**	**Total**
Increase	0	0	0	**0**
Decrease	1 (1)	1 (1)	0	**2 (2)**
Equal	1 (1)	0	0	**1 (1)**
Total	**2 (2)**	**1 (1)**	**0**	**3 (3)**
RCR decrease	**Exposure estimate**			
Toxicity estimate	**Increase**	**Decrease**	**Equal**	**Total**
Increase	1 (1)	6 (3)	2 (2)	**9 (6)**
Decrease	0	0	0	**0**
Equal	0	6 (4)	0	**6 (4)**
Total	**1 (1)**	**12 (7)**	**2 (2)**	**15 (10)**

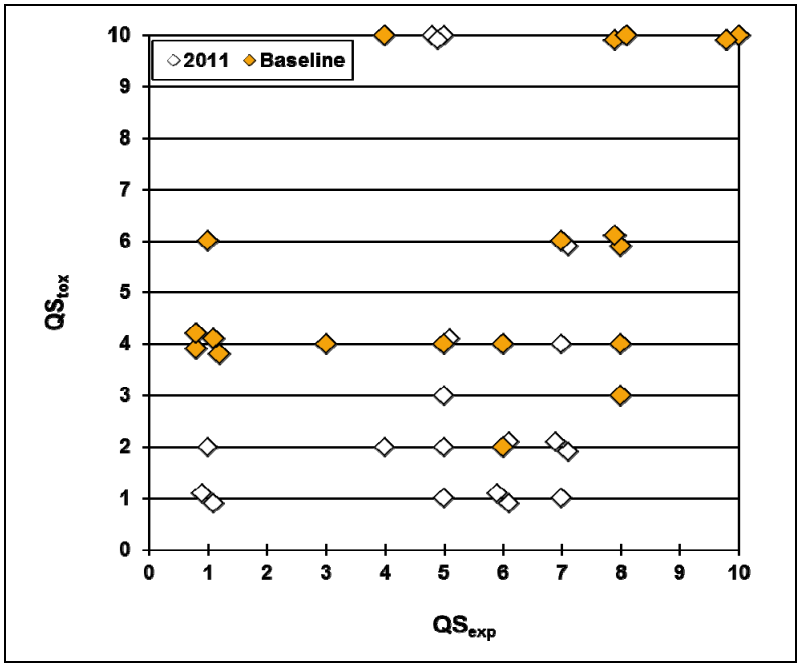
Source: Author's compilation

In summary, the analysis for SVHC shows that changes between baseline and 2011 occur in many directions. Nonetheless, the following main findings are important:

- For the majority of SVHC (79%), RCRs are lower in 2011 compared to baseline.
- Despite this decrease in RCRs, 74% of all SVHC still have an RCR > 1 in 2011 compared to 79% at baseline.
- While the fraction of SVHC with RCR > 1 did not change much, the fraction of SVHC with RCR > 10 declined from 74% at baseline to 47% in 2011.
- The main reason for the high number of substances with RCRs > 1 is inherent in the methodology applied: a cancer risk at the workplace of 5:100.000, which is considerably lower than cancer risks typically applied in many countries, leads to very low toxicity estimates and therefore high RCRs.
- As a consequence, the decline of RCRs observed for 79% of the SVHC is more important than absolute RCR figures.
- In contrast to HPC chemicals, the decline in RCRs appears to be driven by both increases in toxicity estimates and decreases in exposure estimates, but only the latter leads to RCR values ≤ 1.

As noted at profile level, the **Quality Score (QS_{total})** for SVHC decreases from baseline to 2011, indicating a better quality of the 2011 data. Figure 3.26 shows the QS_{exp}/QS_{tox} scatter plot for SVHC, identifying the changes of these individual components of QS_{total}. Again, a shift was introduced to prevent overlay in the scatter plot, but all QS values are integers.

Figure 3.26: Quality Score scatter plot for SVHC (n=19): baseline – 2011 comparison



Source: Author's compilation

The scatter plot clearly shows an improvement in the quality of both exposure and toxicity estimates (i.e. the decline in QS_{exp} and QS_{tox}), although the decrease appears to be more evident for QS_{tox}. While specific clusters were observed for HPV chemicals (see Figure 3.21), this is not as evident for SVHC either at baseline or in 2011, most probably due to the smaller sample size. The descriptive statistics for QS_{tox} and QS_{exp} presented in Table 3.23 (QS_{total} included for comparison) also support the notion of a more pronounced change for QS_{tox}. For QS_{exp}, the main change appears to be a downward shift of the upper percentiles and a marked 'narrowing' effect: the "middle fifty" now have a QS_{exp} of 5.0-6.5, while this was 2.0-8.0 at baseline.

Table 3.23: Summary descriptive statistics for Quality Scores SVHC chemicals (n=19): baseline – 2011 comparison (rounded to two significant figures)

	QS_{exp}		QS_{tox}		QS_{total}	
	Baseline	**2011**	**Baseline**	**2011**	**Baseline**	**2011**
n	19	19	19	19	19	19
Median	6.0	5.0	4.0	2.0	24	12
GM	4.1	4.3	5.3	2.4	21	10
10^{th} percentile	1.0	1.0	3.8	1.0	4.0	1.8
25^{th} percentile	2.0	5.0	4.0	1.0	9.0	6.0
75^{th} percentile	8.0	6.5	8.0	4.0	48	24
90^{th} percentile	8.4	7.0	10	10	84	50
MIN	1.0	1.0	2.0	1.0	4.0	1.0
MAX	10	7.0	10	10	100	50
IRQ	6.0	1.5	4.0	3.0	39	18

Source: Author's compilation

The matrix analysis for the Quality Scores presented in Table 3.24 shows somewhat less pronounced changes for SVHC compared to HPV chemicals (see Table 3.17).

- About twice as many SVHC (6/18, 33%) show an increase in QS_{total} (HPV chemicals, 16%), which is completely due increases in QS_{exp}.
- In all these cases, exposure data from reviews (RARs, EHCs or similar documents) were available at baseline, while in 2011 either
  - no CSR was available or exposure was estimated from poorly documented data (3/6); in these cases, modelling by the evaluators and poorly documented data from a CSR were used, because they resulted in considerably lower exposure estimates for the main use than the data from reviews; exposure estimates were thus lower but of a poorer quality or
  - ECETOC TRA or higher tier modelling was performed (3/6).
- The majority of SVHC show a decrease in QS_{total} (i.e. an increased quality), which is due to decreases in both Quality Score components.
- More than half of the SVHC with a decline in QS_{total} display decreases in both Quality Score components (7/12, 58%), largely reflecting
  - the availability of DN(M)ELs (see Figure 3.11), assigned a high quality and
  - use of high quality monitoring data or higher tier modelling in 2011 (n=3); however, exposure estimates were not available in 4 of these cases and modelling had to be conducted by the evaluators. This nonetheless led to a higher quality, since modelling could be based on more specific information (PROCs as well as use as isolated intermediate under strictly controlled conditions) than at baseline.
- Overall, the data show that
  - the quality of the toxicity estimate improves for 13/18 (72%, HPV chemicals: 78%),
  - the quality of the exposure estimate improves for 10/18 (56%, HPV chemicals: 64%) and
  - the overall quality improves for 12/18 SVHC (67%, HPV chemicals: 84%)

Table 3.24: Matrix of changes in Quality Scores for SVHC (n=18, one substance with no changes excluded):

Increase: higher values in 2011 than at baseline
Decrease: lower values in 2011 than at baseline; zero values not shown

QS_{total} increase	QS_{exp}			Total
QS_{tox}	Increase	Decrease	Equal	
Increase				
Decrease	4			4
Equal	2			2
Total	6	0	0	6
QS_{total} decrease	QS_{exp}			Total
QS_{tox}	Increase	Decrease	Equal	
Increase				
Decrease	1	7	1	9
Equal		3		3
Total	1	10	1	12

Source: Author's compilation

In summary, the quality of the exposure estimate, the toxicity estimate and the overall Quality Score improves for the majority of substances. However, the quality of the exposure estimate is poorer in 2011 than at baseline for about one third of SVHC, because available exposure data from reviews were not used.

3.2.2.4 Summary and conclusions

The 5 years update of the REACH baseline study found a marked decrease in the Risk Scores for the aggregated evaluation of 62 substances (46 HPV chemicals and 16 SVHC) from a GM of 42 at baseline to 8.7 in 2011. At the same time, the quality of the underlying data improves considerably from GM of 21 at baseline to 11 in 2011.

With little change in the Population Risk Modifier, the analysis of HPV chemicals and SVHC reveals that the decline in Risk Scores is almost entirely due to decreases in Risk Characterisation Ratios. RCRs decrease for about 60% of HPV chemicals and about 80% of SVHC. However, for the latter this decline primarily reduces the percentage of substances with RCRs above 10. In contrast, the decline in RCRs leads to a pronounced reduction of the fraction of HPV substances with RCRs above 1 (Table 3.25). This difference between HPV chemicals and SVHC can be largely explained by the methodology of this study, which bases the toxicity estimate for carcinogens (predominant in the SVHC group) on a low risk of 5:100.000 and therefore leads to higher RCRs than derived in CSRs (which typically employ a risk at the workplace of 1-5:1.000 in agreement with many national approaches). Our approach reflects the principle of minimising exposure to carcinogenic substances at the workplace and thus identifies the need for further action. It should also be stressed that the ECHA Guidance on Information Requirements and Chemical Safety Assessment (Part E, 2008) states that cancer risk levels of 1:100.000 *'could be seen as indicative tolerable risks levels when setting DMELs for workers'*. This risk level, however, appears to have rarely been used in the CSRs.

Table 3.25: Summary of the change in RCR distribution from baseline to 2011 (rounded to two significant figures)

	HPV chemicals		SVHC	
	Baseline	2011	Baseline	2011
RCR≤1	54%	74%	21%	26%
RCR>1	46%	26%	79%	74%
RCR>10	26%	11%	74%	47%

Source: Author's compilation

Both RCR increases and decreases for HPV chemicals are large driven by increases and decreases in the exposure estimates, respectively. For example, of the 18 substances showing an RCR increase, 14 also show an increase in the exposure estimate, while the toxicity estimate does not show a specific pattern. However, it must be stressed that an RCR increase does not necessarily result in RCR values above 1. In fact, 13/18 substances remain in the RCR ≤ 1 group and 10 of these show an increase in the exposure estimate (these are discussed in the next paragraph). Quite similarly, of the 27 HPV chemicals with a decreased RCR, 23 show a decline in the exposure estimate, again with the toxicity estimate displaying no specific pattern.

One of the interesting findings of this study is the fact that RCRs – no matter if they increase or decrease – tend to cluster at values slightly below 1 in 2011. This is also evident in the narrowing of the interquartile range (i.e. the "middle fifty" of all substances) from 0.45-9.6 at baseline to 0.43-1.5 in 2011. The cluster at RCR values just below 1 is explained by the tiered approach to exposure estimation under REACH, which primarily serves the purpose to ensure safe use and not so much to derivate more or less realistic exposure estimates. As a consequence, exposure modelling is usually taken to the point where RCR < 1 is achieved, without further refinement. For example, the mean (AM, GM and median) RCR values in 2011 were about 0.7-0.8, while they were 0.2-0.3 at baseline for the 10 substances with increased RCRs and increased exposure estimates (but RCR ≤ 1, discussed in the previous paragraph). In the majority of these cases, exposure estimation was conducted using ECETOC TRA. In this context, it is important to realise that in our sample – 83% of all available exposure estimates in CSRs for HPV chemicals were derived from modelling approaches (primarily ECETOC TRA).

Another important result of this study is the finding that exposure estimates are not available for a substantial fraction of HPV chemicals (n=17, 37%). Exposure estimates are lacking primarily for two equally important reasons:

- A CSR was not required (primarily isolated intermediates handled under strictly controlled conditions).
- Exposure estimation was not performed in the CSR (primarily because the substance was not classified or not classified for human health endpoints).

In 9 of these cases (6 substances not classified, 3 without a CSR), the RCR in 2011 was above 1. In fact, these substances form the majority of the 12 substances with an RCR > 1 in 2011. It cannot be simply assumed that the exposure modelled by the evaluators is overprotective because:

- The substances without a CSR all have very low DNELs and the modelled exposure is not extreme: it was based on PROCs given in the dossiers and assumed low fugacity in all three cases based on the properties of the substance as described in the dossier.
- 4 of the 6 substances without exposure estimation in the CSR have low DNELs. Again, the exposure estimates are based on PROCs assigned in the dossiers and consider the fugacity of the substance.

For the 3 substances without a CSR, other dossiers (not available to the evaluators) may exist that contain a CSR with exposure estimation and risk characterisation, since in most cases only the dossier for use as an isolated intermediate under strictly controlled conditions was available.

The 6 cases where an exposure estimation and risk characterisation for human health was missing are therefore considered the most problematic ones. These cases largely reflect the fact that – while DNELs are derived for the majority of 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.

While it is beyond the scope of this study to judge on the appropriateness of the approaches chosen by registrants in this respect, the different interpretations might be due to the fact that the respective Guidance on the scope of exposure assessment was published in its final version long after the 2010 registration deadline (August 2011).

More generally, however, the REACH Regulation itself leads to the problems encountered for the 3 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, the following considerations should be taken into account:

- The DNELs for these 3 substances are not extremely high, but are in the range of the median/GM for DNELs in this evaluation of HPV chemicals (about 3-4 mg/m^3, see Table 3.11).
- A DNEL in this range can be derived from a standard 90-day oral repeated dose toxicity study in rodents with N/LOAELs not requiring classification for specific target organ toxicity.
- ECETOC TRA modelling without application of RMMs results in higher values for many PROCs (only low dustiness solids are an exception). Many of the HPV substances considered here are used in PROC11 (non-industrial spraying) applications, which even for low fugacity substances results in a high exposure estimate, since aerosol formation is assumed.

The outcome is that RMMs ensuring safe use do not have to be established for non-classified substances, while this is the case for classified substances. This is illustrated by comparing two HPV chemicals from the sample. Again, the original figures were altered to prevent tracking the substances in question (Table 3.26).

Substance B was already discussed in Table 3.10 above. The substance is not classified and exposure estimation was therefore not performed, which is in agreement with the REACH Regulation (but see discussion below). The substance is used in non-industrial spraying processes (PROC11), which led to a higher exposure estimate in the modelling performed by the evaluators and a higher risk characterisation ratio. Since this substance is a solid, it may well be the case that it is only used in products, possibly with a low concentration in the product. This alone would reduce the exposure estimate, but is not known and not communicated in the supply chain (e.g. to be used only in products containing no more than 5% of substance B). But still, in light of the DNEL, RMMs such as LEV would probably be required to demonstrate safe use of the substance in non-industrial spraying applications. Again, this is not communicated in the supply chain, because under REACH, it does not have to be.

In contrast, substance AF is classified and a full exposure estimation and risk characterisation is required. Note that the DNEL is actually higher than the one for substance B (indicating a lower toxicity in relation to long-term exposure of workers). ECETOC TRA modelling by registrants included the application of RMMs (to be communicated in the supply chain) and resulted in a much lower exposure estimate than at baseline with the consequence of an RCR below 1.

Table 3.26: Comparison of two HPV chemicals: classified versus non-classified

Substance	Estimate*	Baseline	2011
Substance B (not classified; from Table **3.10**)	EXP	5 mg/m^3 (modelled)	20 mg/m^3 (PROC11)
	TOX	5 mg/m^3 (OEL)	5 mg/m^3 (DNEL)
	RCR	1	4
Substance AF (classified)	EXP	200 mg/m^3 (modelled)	5 mg/m^3 (TRA)
	TOX	10 mg/m^3 (OEL)	10 mg/m^3 (DNEL)
	RCR	20	0.5

Source: Author's compilation

Control of risk and safe use are thus only demonstrated for classified substances. The recent final ECHA Guidance on the scope of exposure assessment (August 2011) states that '*the registrant **should** consider adverse effects not leading to* classification' (our emphasis) and that an exposure assessment may also be necessary for '*any other adverse effects seen for which a DNEL can be derived but which do not lead to classification*'. This would apply to many of the substances without an exposure estimate discussed above. However,

- this final Guidance was not available before the 2010 registration deadline,
- the draft Guidance available at the time, while pointing out that an exposure estimate may be necessary for non-classified substances, contained a flow chart that can easily be interpreted in a different direction, namely that exposure assessment and risk characterisation are only required for classified substances,
- it may well be questioned legally, whether Article 14(4) of the REACH Regulation actually requires such an exposure assessment and risk characterisation for non-classified substances as identified in the Guidance, i.e. whether it is a legal requirement or one (of many) interpretation(s).

More generally, this evaluation points to the importance of the exposure estimate in the identification and control of risk. Despite the general risk-based approach of REACH, much more emphasis, however, is placed on toxicity-related parameters and these ultimately drive the need to perform exposure estimation and risk. The emphasis on toxicity-related parameters is also evident in the fact that only the latter are disseminated in ECHA's public database. While the classification of a substance and the DNELs are readily accessible, no information on the exposure estimate and the risk is disseminated.

It must also be remembered that the toxicity estimate relates to an inherent property of the substance. While it may change over the years with more data becoming available, the changes are usually small, especially for the relatively well studies HPV chemicals. The exposure estimate, in contrast, is less dependent on the properties of the substance (although it influences fugacity) and is more related to RMMs and conditions of use. For example, ECETOC TRA calculates an exposure of 500 ppm for PROC11 for a substance of medium fugacity without any RMMs and specific conditions of use. With LEV, limiting exposure to 1-4 hours a day and limiting the concentration of the substance in the product to 1-5%, the exposure estimate can be reduced to 12 ppm. There are not many substances, for which the toxicity estimate can exhibit such differences.

For SVHC this evaluation shows that:

- RCRs are lower than at baseline for almost 80%,
- the reduction in RCRs primarily affects the fraction of SVHC with an RCR > 10, which declines from 74% at baseline to 47% in 2011, while 74% still have an RCR > 1 (not much change from baseline),
- the high number of substances with RCRs > 1 is the result of the methodology applied: a cancer risk at the workplace of 5:100.000, which is considerably lower than cancer risks typically applied in many countries, leads to very low toxicity estimates and therefore high RCRs,
- as a consequence, the decline of RCRs observed for 79% of the SVHC is more important than absolute RCR figures,
- in contrast to HPV chemicals, the decline in RCRs appears to be driven by both increases in toxicity estimates and decreases in exposure estimates, but only the latter leads to RCR values ≤ 1.

The majority of SVHC are classified carcinogens and this property and the associated risk are crucial in many cases. Therefore, DMEL derivation in CSRs is of critical importance. The finding of this evaluation that DMELs were not derived for about half of the carcinogenic SVHC is confirmed by an evaluation of Rouw (2011). For those substances, for which a DMEL was derived, this author reported a substantial number of incorrect or doubtful DMEL derivations and/or DMEL derivation without identification of the associated risk level.

These problems may partly be the result of lacking Guidance on DMEL derivation. If relevant and reliable human data on the carcinogenic potential are available, the DMEL may be derived from human data. Again, the final version of ECHA's Guidance on derivation of DNELs/DMELs from human data only became available after the 2010 registration deadline (December 2010).

Many of the other issues identified in the evaluation of SVHC are quite similar to the ones for HPV chemicals. For example, the fraction of SVHC for which exposure had to be modelled by the evaluators is the same as for HPV chemicals (37%). The reason, however, lies less in non-classified substances (since the vast majority of SVHC is classified) but mostly in the fact that CSRs are not required.

For the majority of HPV chemicals and SVHC, the quality of the data underlying the exposure estimate and the toxicity estimate improves (Table 3.27). The change in GM from baseline to 2011 in this table only reflects part of the improved quality. For example, there is no change in the GM for the exposure estimate of SVHC, but the data presented above clearly indicate a decline in upper percentiles (i.e. less 'bad' estimates in 2011 than at baseline). The overall improvement is practically identical for both HPV chemicals and SVHC.

Table 3.27: Summary of changes in the quality from baseline to 2011(rounded to two significant figures)

Parameter	Quality improves for		QS (GM changes baseline -> 2011)	
	HPV chemicals	SVHC	HPV chemicals	SVHC
Exposure estimate	64%	56%	5.5 -> 5.0	4.1 -> 4.3
Toxicity estimate	78%	72%	3.8 -> 2.2	5.3 -> 2.4
Overall	84%	67%	21 -> 11	21 -> 10

Source: Author's compilation

The final issue to be addressed relates to the 'success of REACH', i.e. are all the changes observed due to REACH or can other impacts be suspected. For the impact area of workers, the following results of this evaluation can be seen as REACH-related:

- 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 exits.
- 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, this evaluation revealed individual cases, where a substantially lower DNEL for workers was derived compared to existing OELs. While it may be assumed that these data could potentially also lead to a lower OEL (in fact, for one substance a lower OEL in 2011 than at baseline was observed), the process of OEL revision is a long one, often taking many years before changes take effect.
- If differences between DNELs and OELs are observed, this also points to a lacking harmonisation in the toxicological assessment of the substances (one of the intentions of REACH) and this is accounted for by a slightly lower quality.
- Improved exposure assessments can also be seen as a result of REACH. Although problems associated with the scope of 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. It is well known that many registrants put much effort in the identification of supply chains and downstream uses, which were sometimes unknown to them prior to REACH. 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.

  In the methodology applied, this does not necessarily lead to a better Quality Score. Sometimes, monitoring data from reviews were used at baseline, which usually yielded better QS than ECETOC TRA modelling performed in the context of a CSR in 2011. Therefore, the better quality is not readily evident

in some of the statistical descriptors (see e.g. GM in Table 3.27). However, from the perspective of registrants, monitoring data are often not appropriate, because they do not allow specification of RMMs and conditions of use necessary to ensure safe use of the substance. In addition, monitoring data may be available for some, but typically not for all uses of a substance, especially if there are many different uses to be assessed.

- Apart from exposure assessments performed in the context of CSRs, the information gathered by registrants on the different uses of a substance are 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 evaluators (37% of substances). For example, some substances were registered as isolated intermediates under strictly controlled conditions without any other uses. In these cases, the exposure estimated by the evaluators was usually very much lower than the baseline estimate (when this information was usually 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). Many of these substances are those with an RCR > 1 in 2011, an issue that was discussed in detail above.
- As a consequence of these REACH-related changes, RCRs and Risk Scores decrease from baseline to 2011, 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 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 another evaluation of registration dossiers (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. For example, the occupational risk characterisation for the carcinogenic effects of benzene (a substance included as a reference point in Figure 3.2) in the European Union Risk Assessment Report is based on a '*preliminary critical exposure level*' of 0.1 ppm (ECB 2008). Similarly, the European Union Binding Occupational Exposure Limit Value for this substance (1 ppm) lacks a clearly specified risk associated with this exposure level, but has been considered to be related to a risk of about 1-5:1.000 (Nies et al. 2002).
- Some of these problems appear to be related to the fact, that the respective final Guidance documents only became available after the 2010 registration deadline. Since these documents are now available, it may be assumed that these problems will be resolved in the future.
- However, the interpretations in relation to the requirements for exposure assessment and risk characterisation may remain an issue. This ultimately points to the more general issue of potential differences between the legal requirements (i.e. the REACH Regulation) and the interpretations of legal requirements as given in Guidance documents.
- This is also apparent in the issue of RCR values equal to 1 (see Analysis Box 3.1). While as such, it only relates to a minor issue, this issue nonetheless highlights the need for unambiguous and consistent definitions in Guidance documents that are in agreement with the Regulation.

3.2.3 Impact area: Environment

As mentioned before, a total of 62 substances (46 HPV chemicals and 16 SVHC) could be evaluated in the 5 years update. These 62 substances were aggregated at the summary level (Chapter 3.2.3.1), but were evaluated separately (HPV chemicals and SVHC) at the profile and analysis levels (Chapters 3.2.3.2 and 3.2.3.3). In these latter evaluations, 3 HPV substances are also included in the SVHC group (leading to 19 SVHC), an approach that was also taken at baseline.

It must be stressed that the same HPV chemicals and SVHC are compared, i.e. when RCRs, toxicity estimates and Quality Scores are reported below for baseline and 2011, identical substances are compared.

Because there is a significant uncertainty in the tonnages, the comparison has been carried out on two levels: a) a comparison where the actual tonnages for 2007 and 2011 respectively are used (not normalised) and b) comparison, where the exposure and risk scores are normalised with respect to the 2007 tonnage (normalised).

3.2.3.1 Summary level

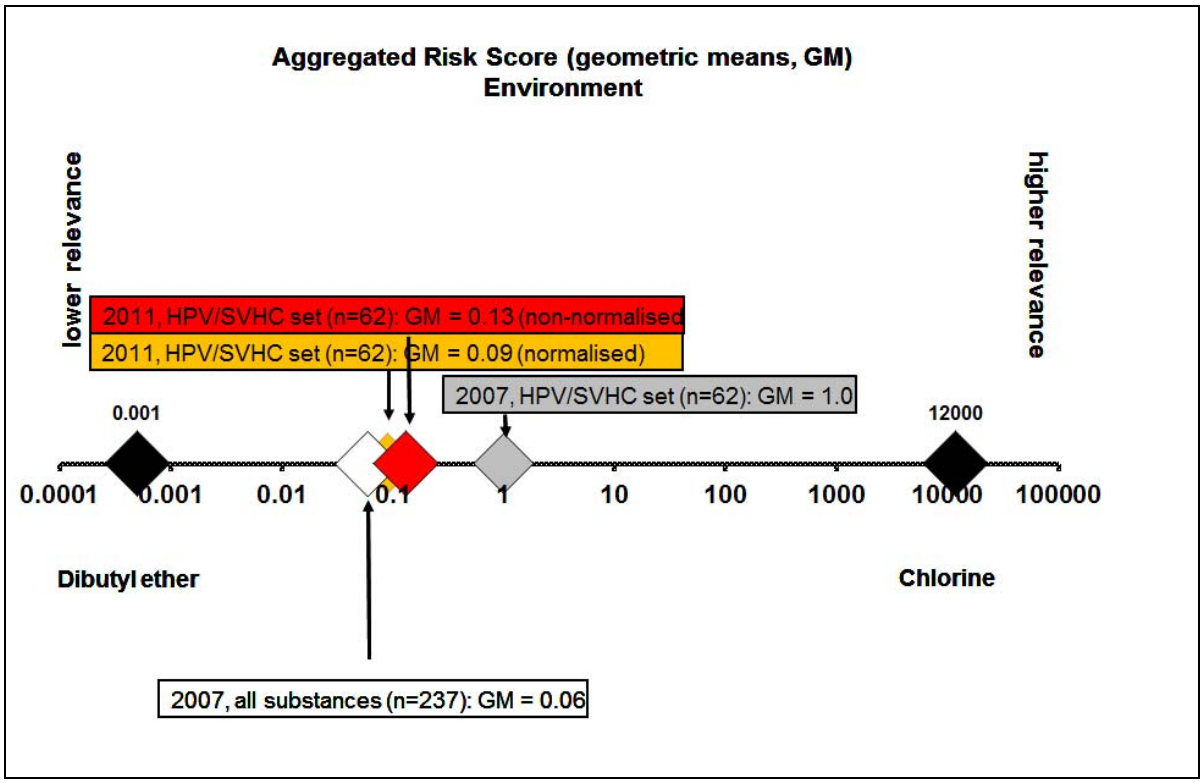
The summary level describes the results for the Risk Score and the Quality Score aggregated across all substances. At baseline in 2007, these values were aggregated across all LPV, MPV and HPC chemicals as well as SVHC. In the 5 years update, only HPV substances and SVHC are evaluated.

To account for this difference, Risk Scores and Quality Scores of the 2011 sample (excluding the LPV and MPV) were also calculated on the basis of the baseline figures. The respective values then describe the change for the identical set of substances and are thus more helpful than a comparison between the entire baseline set and the sample 2011.

Figure 3.27 shows the aggregated Risk Scores:

- for all substances at baseline: GM = 0.06
- for the substances on the basis of the baseline data: GM = 1.0
- for the substances in the 5 years update: GM = 0.09 (non-normalised tonnage data) respectively GM =0.13 (normalised tonnage data)

Figure 3.27: Aggregated Risk Scores (environment) at baseline and in 2011



Source: Author's compilation

As in the REACH baseline study, the Risk Scores for dibutyl ether and chlorine (using 2007 baseline data) are shown as reference points for ranking these values (see Eurostat 2009 for details).

These data show that the Risk Score for the 62 substances at baseline is approximately 10 times higher than Risk Score for the same 62 substances in the 2011 update. This indicates that the overall Risk Score has decreased from 2007 to 2011. Recalling that the Risk Scores for SVHC and HPV substances were two to three orders of magnitude higher than the Risk Scores observed for LPV and MPV in the baseline study (Eurostat 2009), it is not so surprising that the 2011 sample does not have a much higher Risk Score (GM) than the Risk Score (GM) for 2011. The baseline sample included both LPV, MPV, HPV and SVHC substances, whereas the 62 substances in the 2011 sample are all SVHC or HPV substances. It is also seen that the normalised Risk Scores (GM 0.09) are lower but very comparable to the non-normalised Risk Scores (GM 0.13).

The result of the 5 years update indicates an around 10-fold decrease in the aggregated Risk Score for the 62 substances evaluated: from 1.0 in 2007 (baseline) to 0.13 (not normalised) and 0.09 (normalised) in 2011 (based on GMs). This is mostly due to the pronounced decrease in Risk Scores observed for SVHC, which is reduced

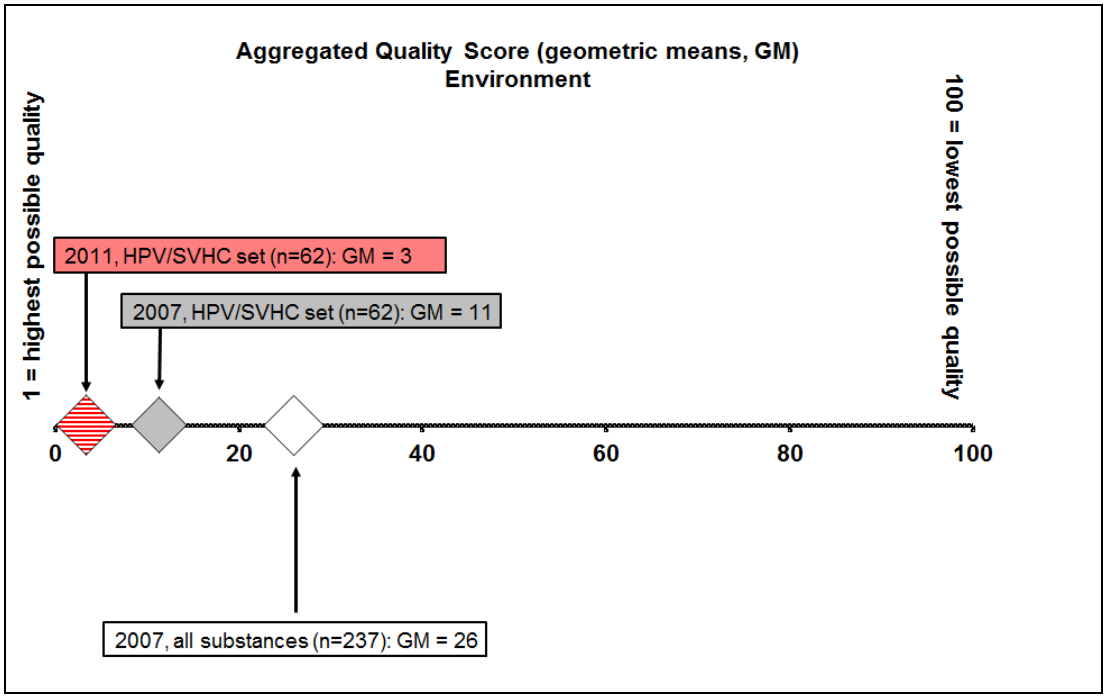
by about two orders of magnitude, while the Risk Score for HPV chemicals declined by a factor of 2-3 based on GM (these changes will be discussed in detail in the following sections).

Figure 3.28 shows the results for the similar evaluation of the aggregated Quality Scores, again including results:

- for all substances at baseline: GM = 26
- for the HPV and SVHC substances on the basis of the baseline data: GM = 11
- for the HPV and SVHC substances in the 5 years update: GM = 3

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

Figure 3.28: Summary level: Aggregated Quality Scores (environment)



Source: Author's compilation

At baseline, HPV substances and SVHC had a better quality than LPV and MPV (Eurostat 2009). Since the evaluated 2011 sample only consists of HPV substances and SVHC, the Quality Score is much better in this sample compared to the entire baseline set (GM: 11 compared to 26). The quality of the data (with a GM of 11 already quite good in 2007 for the 62 substances) further increased in 2011, as evidenced by a decrease of the Quality Score to a GM of 3. As will be shown in the following chapters, this decrease in the Quality Score is observed for both HPV chemicals and SVHC.

The change in Risk Score and Quality Scores from baseline to 2011 is summarised in Table 3.28. Median values are included in addition to the GMs and confirm the trend of decreasing Risk and Quality Scores.

Table 3.28: Summary of aggregated Risk and Quality Scores

Parameter	Risk Score			Quality Score	
	Baseline	2011		Baseline	2011
		normalised	not normalised		
n	62	62	62	62	62
GM	1.0	0.09	0.13	11.4	3.4
Median	0.6	0.07	0.10	9.9	3.8

Source: Author's compilation

3.2.3.2 *Profile level*

HPV substances and SVHC are separated at profile level and values are compared on the basis of the baseline evaluation and the 2011 evaluation within each group.

Similar to the other impact areas, the profile level presents results as whisker plots.

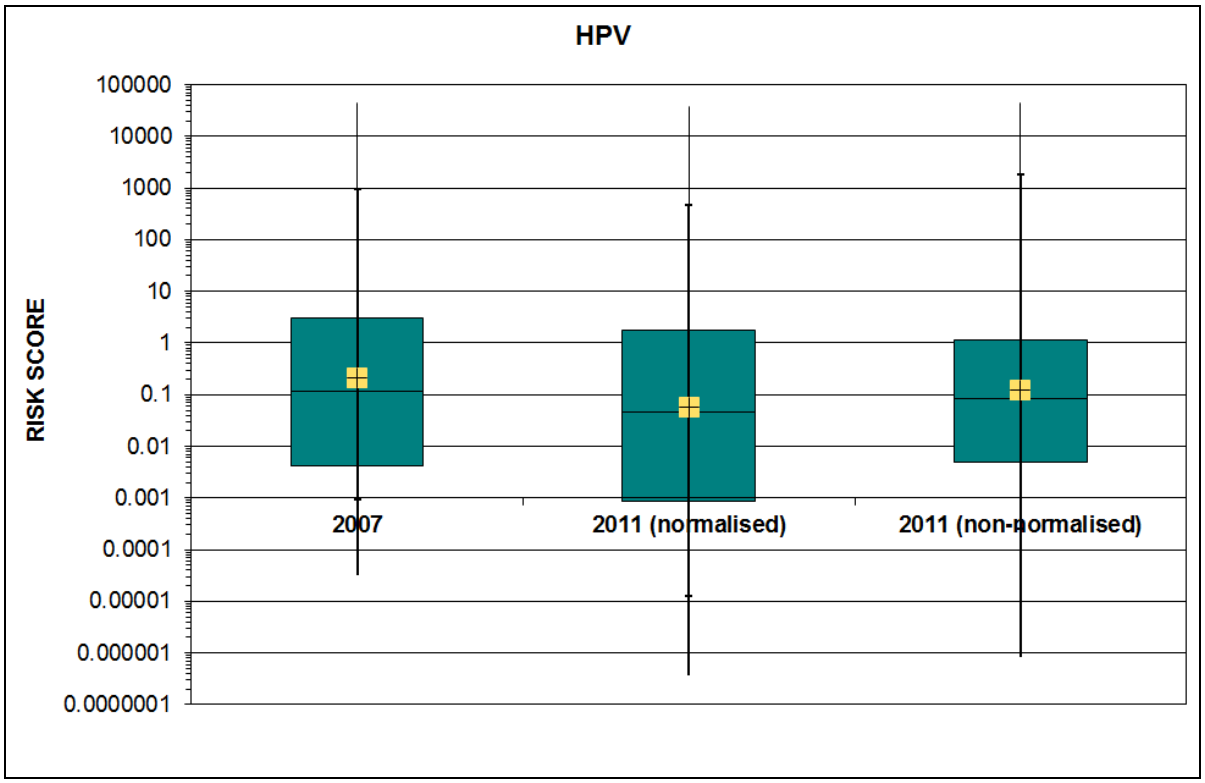
HPV chemicals

Figure 3.29 presents the changes in Risk Scores from baseline to 2011 for the 46 HPV chemicals evaluated. Detailed descriptive statistics are presented in Table 3.29. The whisker plot identifies some important aspects:

- There is a general (but only slight) downward trend of Risk Scores, i.e. maximum and minimum values as well as the upper percentiles are lower in 2011 compared to baseline.
- A decrease in Risk Scores is also found for the GM and the median values.
- The IQR interval (25^{th}–75^{th} percentile) (in logarithm units) based on the 2007 tonnage (normalised Risk Scores) has become wider, whereas the IQR for Risk Scores based on the 2011 tonnage (non-normalised Risk Scores) has become narrower.

Overall, this evaluation shows a general but small downward shift of Risk Scores.

Figure 3.29: Comparison of baseline and 2011 Risk Scores for HPV chemicals (n=46)



Source: Author's compilation

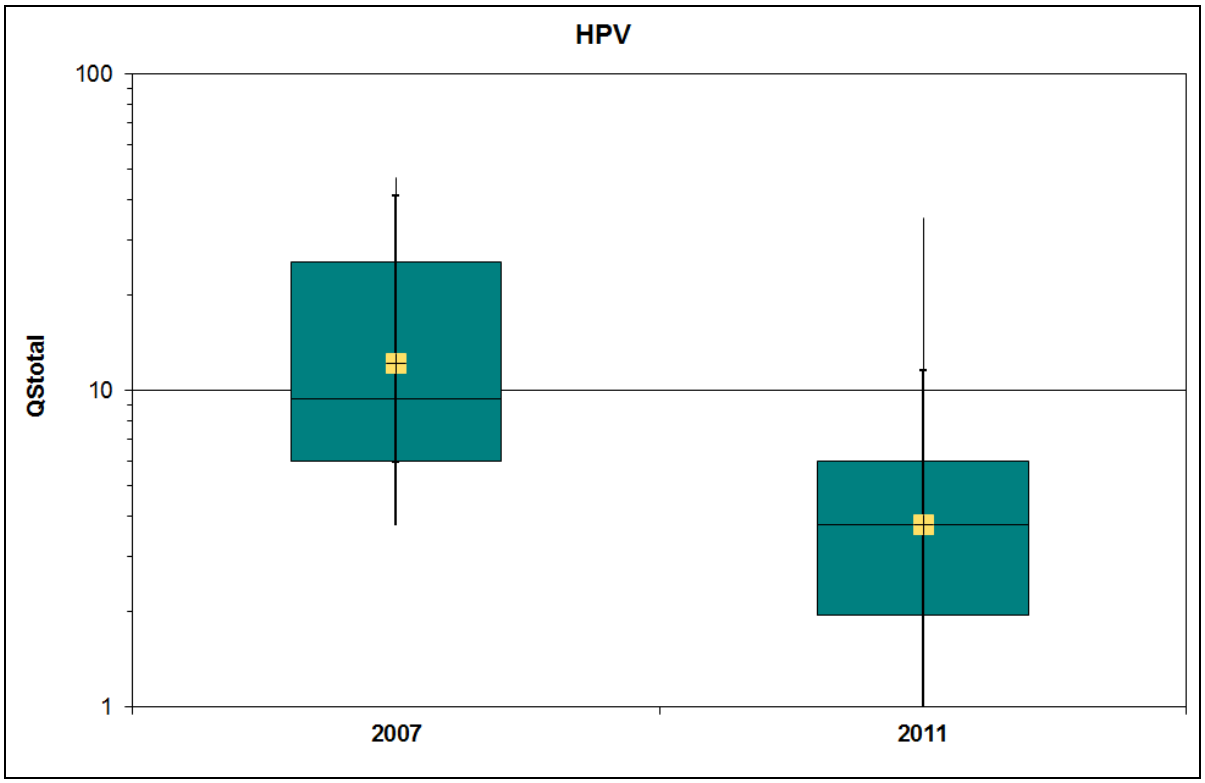
The evaluation of the Quality Score (QS_{total}) presented in the whisker plot (Figure 3.30) generally shows a similar picture as the Risk Score evaluation:

- QS_{total} shows a general downward trend from baseline to 2011.
- In fact, while the highest quality possible (QS_{total} = 1) was not achieved at baseline, this was the case in 2011 (6/46 substances, 13%).
- Similarly, the poorest quality assigned to any substance in 2011 was QS_{total} = 35, a value that was exceeded by 8/46 of the HPV chemicals (17%) at baseline.
- There is a clear decline in the QS_{total} (i.e. an increase in quality) in 2011 compared to the baseline level.
- The IQR has significantly decreased from 2007 to 2011. Actually, both the 25^{th} and the 75^{th} percentiles in 2011 are lower than or at the same levels as the 25^{th} percentile at baseline. The 25^{th} percentile of QS_{total} =

6 at baseline is equal to the 75th percentile in 2011. Expressed verbally this means that 75% of the substances had a poorer quality (than this value of 6) at baseline, while this was only true for 25% of the substances in 2011.

Descriptive statistics are presented in Table 3.30.

Figure 3.30: Comparison of baseline and 2011 Quality Scores (QS_{total}) for HPV chemicals (n=46)

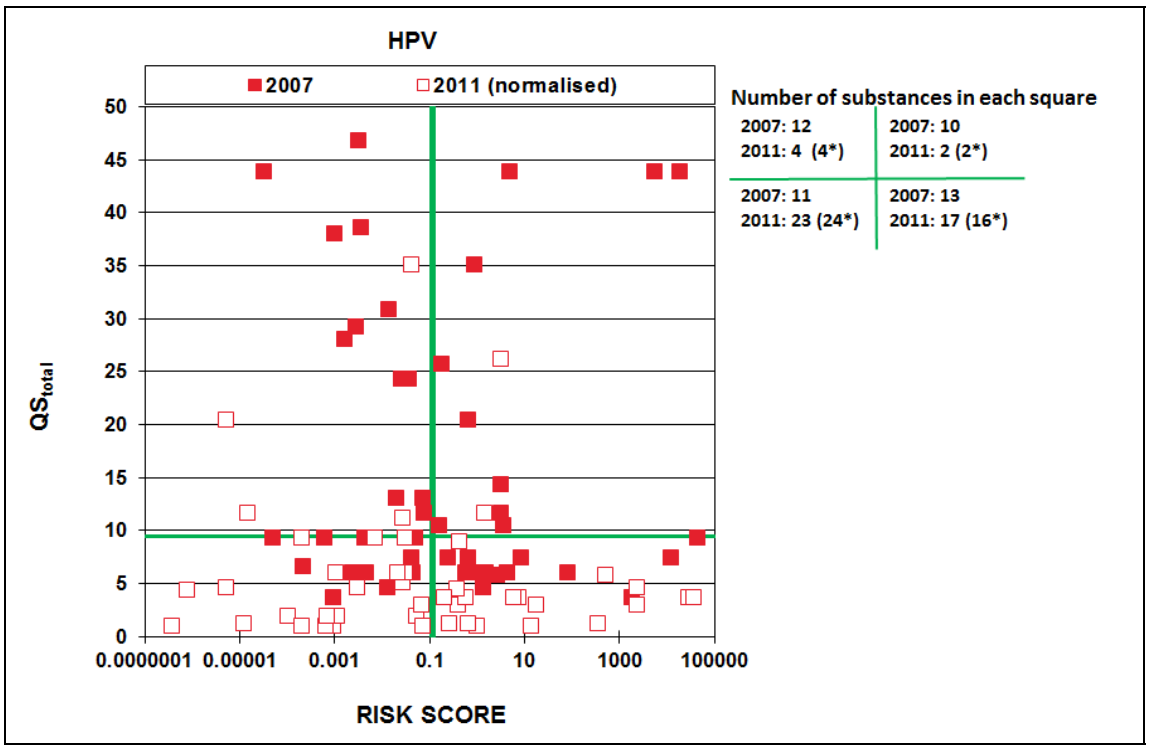


Source: Author's compilation

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. Such an evaluation will be presented at analysis level (Chapter 3.2.3.3).

The scatter plot in Figure 3.30 for HPV chemicals shows a general movement of the data points towards the lower part (better quality) especially lower left corner (i.e. lower Risk Score, better quality) in 2011. The decline of QS_{total} is more pronounced in the scatter plot than the decline in the Risk Score, an observation in line with the statistical data.

Figure 3.31: Risk-QS_{total} scatter plot for HPV chemicals (n=46): baseline – 2011 comparison.



*: not normalised Risk Scores

Source: Author's compilation

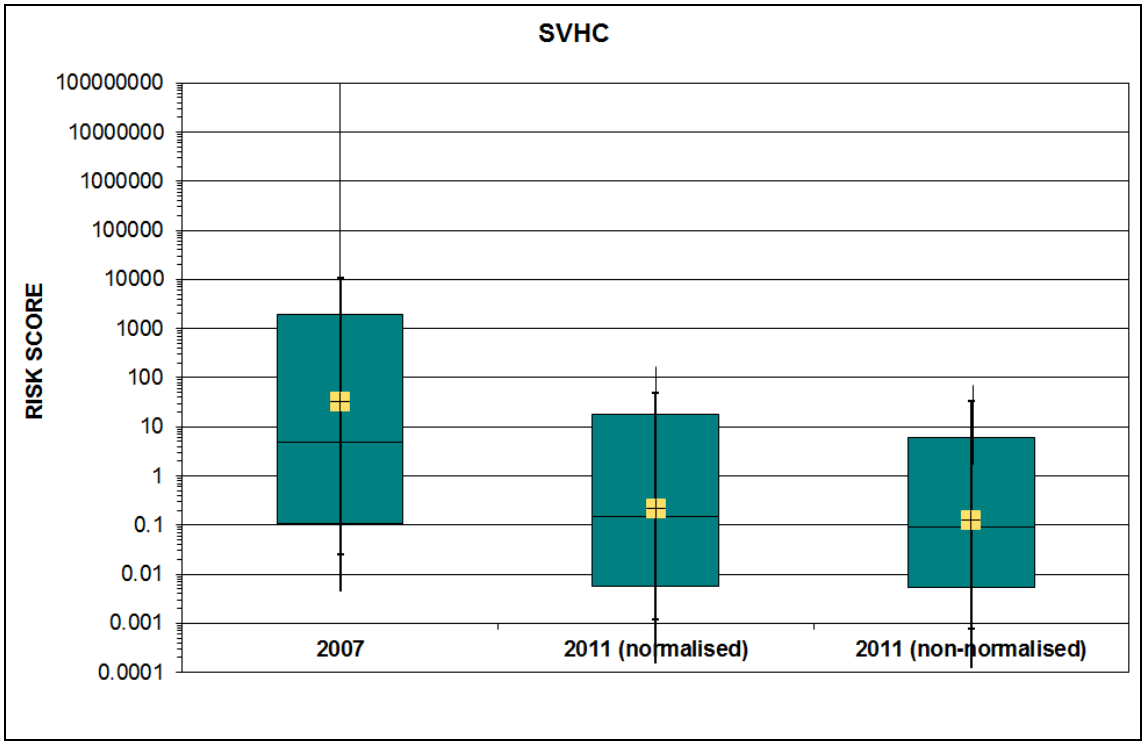
Substances of very high concern (SVHC)

Figure 3.32 and Figure 3.33 show the changes Risk and Quality Scores from baseline to 2011 for the 19 SVHC evaluated. In general, the changes are quite similar to the ones described above for HPV chemicals, in particular the downward trend in both Risk and Quality Scores. In addition, the poorest quality assigned in 2011 (QS_{total} = 35, same as for HPV) was exceeded by 3/19 at baseline, i.e. 16% of the SVHC had a poorer quality. At the other end of the scale, 3/19 SVHC (16%; 13% for HPV) were assigned the best quality possible (QS_{total} = 1) and such a maximum quality was never assigned at baseline.

Some notable differences between HPV chemicals and SVHC include:

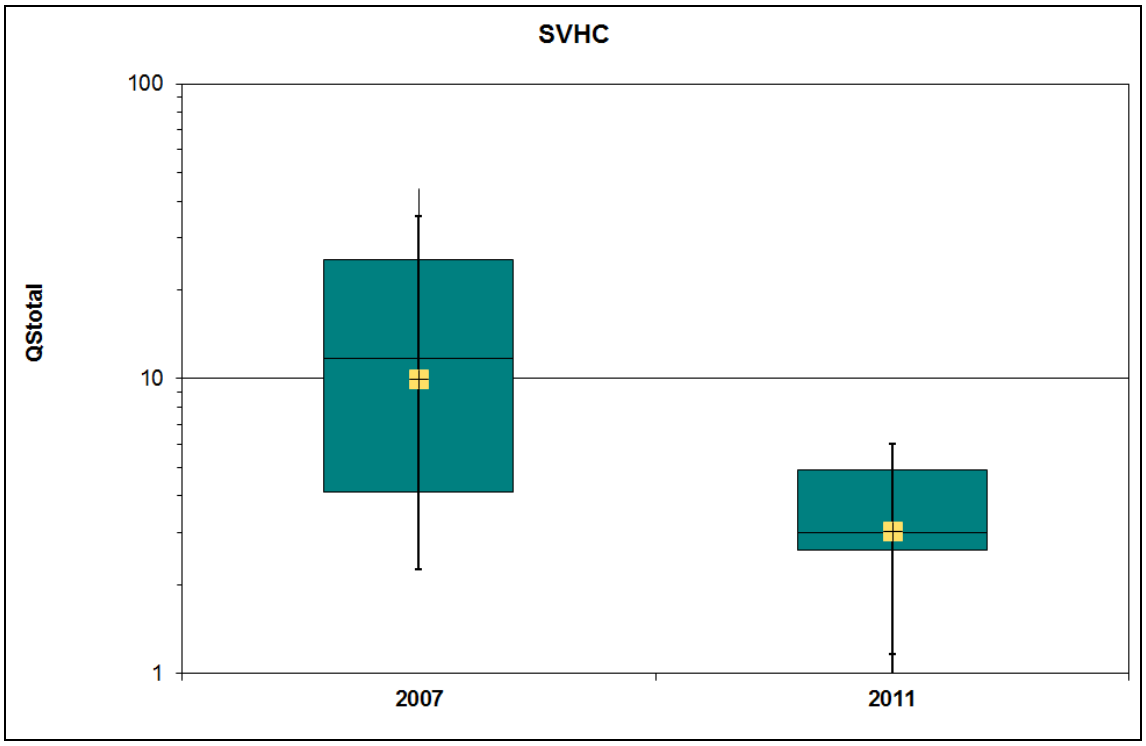
- GM and median Risk Scores are reduced in 2011 by two orders of magnitude in the case of SVHC, while the GM was reduced by a factor of only 2-4 for the HPV chemicals (Table 3.5).
- 50% of the SVHCs had a Risk Score above 4.8 at baseline. This was the case for 7/19 (36%, normalised) and 5/19 (26%, not normalised) of the SVHC in 2011.
- QS_{total} for SVHC declines by a similar degree (GM and median) to HPV. The downward shift of the IRQ of the QS_{total} for the HPV and the SVHC are similar.

Figure 3.32: Comparison of baseline and 2011 Risk Scores for SVHC (n=19)



Source: Author's compilation

Figure 3.33: Comparison of baseline and 2011 Quality Scores (QS_{total}) for SVHC (n=19)

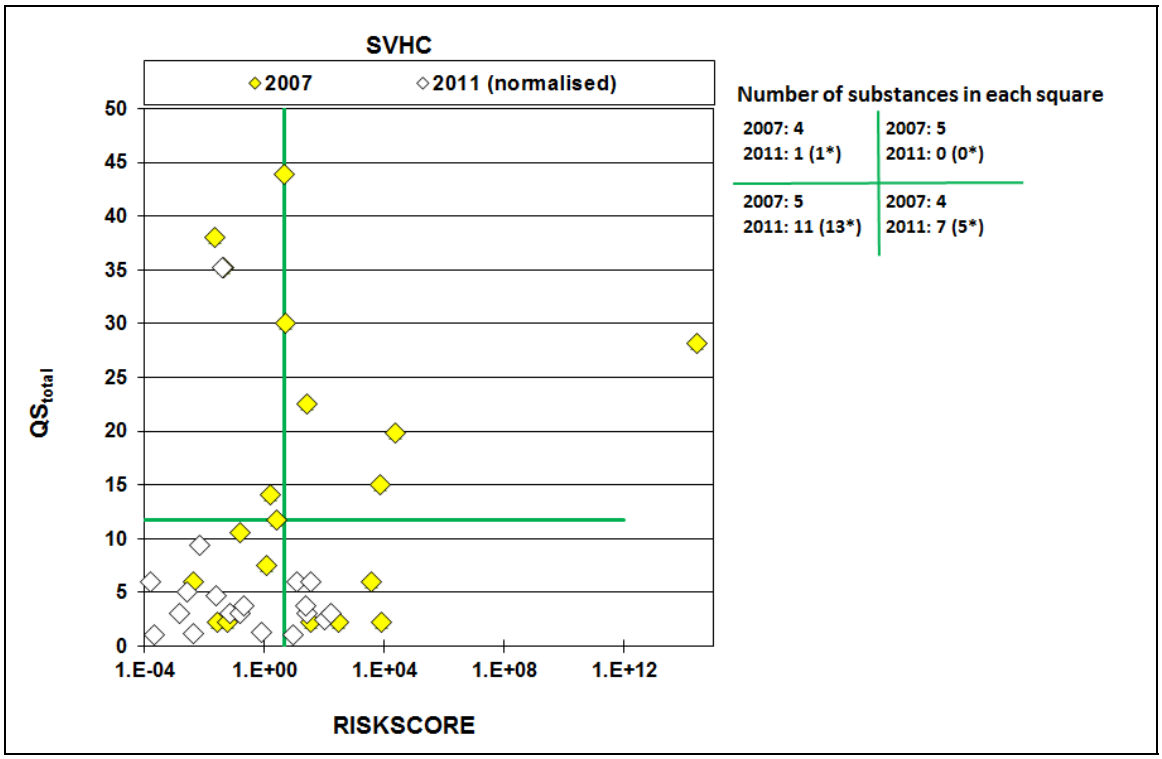


Source: Author's compilation

As for HPV substances, the SVHC scatter plot (Figure 3.34) shows a general movement of the data points towards the lower left (i.e. lower risk score, better quality) in 2011. The leftward movement of the Risk Scores (i.e. decreasing Risk Scores) is more evident than for HPV substances.

Figure 3.34: Risk/QS_{total} Quality Score scatter plot for SVHC (n=19): baseline – 2011 comparison.

*: not normalised Risk Scores



Source: Author's compilation

Conclusions on the profile level evaluation

Descriptive statistics of the evaluation at the profile level are presented in Table 3.29 below. Together with the whisker and scatter plots presented above, the following general conclusions can be drawn:

- Risk Scores and QS_{total} decreased in 2011.
- This decreasing trend is visible in most statistical descriptors and it is clearly evident in the whisker plots considering the entire distribution of values.
- The decline in Risk Scores is more pronounced for SVHC than for HPV substances.
- As a consequence, Risk Scores for HPV chemicals and SVHC have moved closer together in 2011. While SVHC Risk Scores (GM, median) at baseline were about 150 times higher than the respective Risk Scores for HPV chemicals, the ratio was around 2-4 in 2011 (Table 3.5).
- Extreme Risk Scores remain, but these are considerably lower than at baseline.
- The decrease in QS_{total} (i.e. improvement in quality) is similar for HPV substances and SVHC.
- The normalised risk scores have a larger span than the non-normalised risk scores. This could indicate that the 2011 tonnages have a smaller span than the applied 2007 tonnages.

Table 3.29: Summary descriptive statistics for HPV chemicals and SVHC: Risk Score and QS_{total} (rounded to one significant figure)

	HPV chemicals					SVHC				
	Risk Score			QS_{total}		Risk Score			QS_{total}	
	Base-line	2011 (norm.)	2011 (no norm.)	Base-line	2011	Base-line	2011 (norm.)	2011 (no norm.)	Base-line	2011
n	46	46	46	46	46	19	19	19	19	19
Median	1.2E-01	4.7E-02	8.6E-02	9.4	3.8	4.8	1.5E-01	9.2E-02	11.7	3.0
GM	2.1E-01	5.8E-02	1.2E-01	12.2	3.8	3.2E+01	2.2E-01	1.3E-01	9.9	3.5
10^{th} percentile	9.6E-04	1.3E-05	2.5E-04	5.9	1.0	2.6E-02	1.2E-03	7.6E-04	2.3	1.1
25^{th} percentile	4.3E-03	8.6E-04	4.9E-03	6.0	2.0	1.1E-01	5.6E-03	5.4E-03	4.1	2.8
75^{th} percentile	3.0	1.8	1.1	25.4	6.0	1.9E+03	1.7E+01	6.1	25.3	5.5
90^{th} percentile	9.6E+02	4.7E+02	1.9E+03	41.3	11.6	1.1E+04	4.8E+01	3.3E+01	35.7	6.7
MIN	3.3E-05	3.8E-07	8.2E-07	3.8	1.0	4.4E-03	1.5E-04	1.2E-04	2.3	1.0
MAX	4.4E+04	3.7E+04	4.3E+04	46.9	35.2	2.8E+14	1.6E+02	7.9E+01	43.9	35.2
IQR*	2.8*	3.3*	2.4*	19.4	4.0	4.2*	3.5*	3.1*	21.2	2.8

* values as difference in log-units

Source: Author's compilation

The findings obtained at profile level will be discussed in more detail in the following section, analysing the various inputs into the Risk Score and the components of QS_{total}, i.e. the Quality Score for the toxicity estimate (QS_{tox}) and the Quality Score for the exposure estimate (QS_{exp}).

3.2.3.3 Analysis level

The main purpose of the analysis level is to provide an additional level of detail and help to identify the parameters that have an important impact on the changes described above. Therefore, the analysis is extended to the individual components, namely (see The REACH baseline study - Eurostat (2009) for additional details):

- for the Risk Score, which is the product of the RCR, severity modifier and the PRM:
  - the population risk modifier (PRM)
  - severity modifier
  - the risk characterisation ratio (RCR), calculated from:
    - the estimated exposure
    - the toxicity estimate
- for the Quality Score (QS_{total})
  - the Quality Score for the toxicity estimate (QS_{tox})
  - the Quality Score for the exposure estimate (QS_{exp})

The individual components will be discussed in this section, with a special emphasis on the discussion of obtained RCR values.

Population Risk Modifier (PRM)

The PRM was calculated by (both in 2007 and in 2011):

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

The methodology for PRM calculation had to be slightly adapted due to several changes. For example, PRM calculation at baseline involved the 'old' descriptor system of the TGD (EC 2003) with 'use categories', 'industrial categories' etc., while the 'new' REACH descriptor system was used in 2011. The decision of whether a use is wide dispersive or not in the 2011 study was determined from the ERC associated to the use. The tonnage associated to each use – if not informed in the dossier – was estimated by the default fractions of tonnages associated to each ERC.

An evaluation of the PRM shows a significant difference between the baseline and 2011 data (Table 3.30) especially regarding the SVHC substances. The PRM has significantly decreased in 2011 compared to 2007 meaning that the uses are more related to industrial uses than professional/consumer uses. It may partly be a result of the change in calculation of PRM, however it may also be a result of the fact that most registered uses – especially the SVHC – are related to industrial uses and not so much to consumer and professional uses. Actually, only 56% of the HPV substances and 32% of the SVHC substances had one or more consumer/professional uses.

In conclusion, a fraction of the observed change in the Risk Score is assigned to the decrease in the PRM.

Table 3.30: Summary descriptive statistics for the Population Risk Modifier

	HPV chemicals		SVHC	
	Baseline	2011	Baseline	2011
n	46	46	19	19
Median	2.3	1.0	3.7	1.0
GM	2.5	1.9	3.0	1.3
10^{th} percentile	1.0	1.0	1.0	1.0
25^{th} percentile	1.0	1.0	1.0	1.0
75^{th} percentile	5.8	4.5	5.3	1.3
90^{th} percentile	8.5	6.2	6.7	2.7
MIN	1.0	1.0	1.0	1.0
MAX	10.0	6.7	10.0	4.1
IQS	4.8	3.5	4.3	0.3

Source: Author's compilation

Severity modifier

No changes in the values assigned to the severity modifier have been made in the 2011 study. Therefore, the observed change in the Risk Score is not assigned to a change in the severity modifier.

Data availability

Before RCRs and their components will be analysed in detail, a brief evaluation of the data basis is helpful.

Table 3.31 gives a brief overview of the data sources for some of the most essential data:

- related to exposure: vapour pressure (P^{sat})/water solubility (S_w), logKow, biodegradation;
- related to toxicity: ecotoxicity data.

It is seen from the table that the use of QSAR/Read-Across/Guestimates to derive at property values was decreased in 2011 compared to the baseline study. This has an impact on the Quality Scores as also illustrated in Table 3.32.

Table 3.31: Data availability analysis for environmental exposure and toxicity data – baseline – 2011 comparison

Data source	Exposure		logKow		P^{sat}/S_w		Biodegrada-tion		Ecotoxicity data	
	2007	2011	2007	2011	2007	2011	2007	2011	2007	2011
From CSR (only exposures considered.)	-	46%	-	-	-	-	-	-	-	-
Measured	-	4%	56%	57%	49%	68%	45%	76%	31%	67%
QSAR/Read-Across/estimate	-	-	44%	43%	35%	16%	35%	4%	60%	33%
Default	-	-	-	-	16%	16%	20(1)	20(1)	9%	

(1):Inorganic.

Source: Author's compilation

Table 3.32: Summary of changes in the quality from baseline to 2011

	Quality improvements for		
	Exposure estimate	Toxicity estimate	Overall
HPV chemicals	46%	72%	91%
SVHC	53%	53%	84%

Source: Author's compilation

HPV chemicals in detail

As mentioned earlier, the Risk Score is obtained by multiplying the Risk Characterisation Ratio (RCR) with the Population Risk Modifier (PRM) and severity modifier. The data for the PRM (Table 3.30 also included in Table 3.33) below for comparison) show a change between baseline and 2011, with higher PRM values for HPV chemicals in 2007. The evaluation at profile level (Chapter 3.2.3.2) showed a general slightly downward trend of HPV Risk Scores. From these data, it can be assumed that the RCR should also display a similar pattern. The summary statistics reported in Table 3.33 indeed show that:

- the GM and median RCR decreased from baseline to 2011, which results in a lower Risk Score as also the PRM reduced from baseline to 2011,
- the general decrease in Risk Scores in 2011 (evident e.g. in the upper percentiles, minimum and maximum values) is both due to a decrease in RCRs and a decrease in the PRM values.

Table 3.33: Summary descriptive statistics for RCR, PRM and Risk Score for HPV chemicals (n=46): baseline – 2011 comparison (rounded to two significant figures)

	RCR			PRM		Risk Score		
	Baseline	2011 (norm.)	2011 (no norm.)	Baseline	2011	Baseline	2011 (norm.)	2011 (no norm.)
n	46	46	46	46	46	46	46	46
Median	5.8E-02	1.9E-02	2.2E-02	2.3	1.0	1.2E-01	4.7E-02	8.6E-02
GM	8.4E-02	2.8E-02	5.9E-02	2.5	1.9	2.1E-01	5.8E-02	1.2E-01
10^{th} percentile	6.0E-04	8.0E-06	2.5E-04	1.0	1.0	9.6E-04	1.3E-05	2.5E-04
25^{th} percentile	3.3E-03	6.7E-04	4.0E-03	1.0	1.0	4.3E-03	8.6E-04	4.9E-03
75^{th} percentile	1.2	1.6	1.1	5.8	4.5	3.0	1.8	1.1
90^{th} percentile	1.5E+02	2.9E+02	4.8E+02	8.5	6.2	9.6E+02	4.7E+02	1.9E+03
MIN	3.3E-05	3.8E-07	4.2E-07	1.0	1.0	3.3E-05	3.8E-07	8.2E-07
MAX	2.4E+04	9.9E+03	1.1E+04	10.0	6.7	4.4E+04	3.7E+04	4.3E+04
IRQ	2.5*	3.4*	2.4*	4.8	3.5	2.8*	3.3*	2.4*

Source: Author's compilation

Another way of presenting these results is by differentiation of RCRs 'above' and 'below or equal to 1'. Figure 3.35 shows the distribution of RCRs according to this differentiation and identifies a small decline of the fraction of HPV chemicals with RCRs > 1 in 2011 with a corresponding increase in with RCRs below 1. Please note that no environmental RCRs equalled 1.

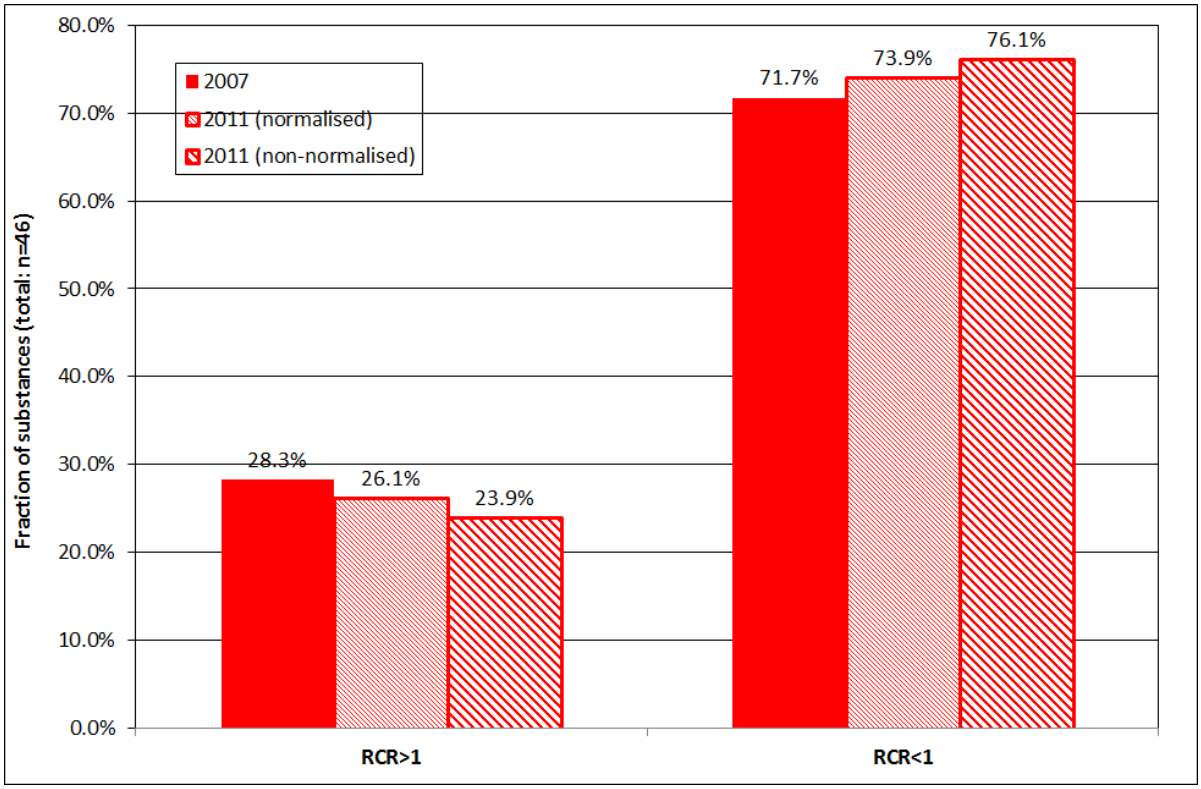
An RCR > 1 indicates a risk to the environment, and it means safe use cannot be demonstrated. In principle, you cannot have an CSR showing RCRs > 1. This issue is discussed in Box 3.1.

Box 3.1 RCR > 1

There can be several reasons why the calculation came up with an RCR > 1:

- For several of the calculations with no CSR then the emission fractions were either calculated from the SPERC (if assigned) or the ERCs. In the case of the latter then no Risk Management are included. This means that in the real world, then RMM limiting the releases and thus the exposure would be introduced. In addition, emissions calculated from the ERCs are very conservative.
- No actual PNECs have been applied. Only pseudo-PNEC values are applied. These are found simply by taking the lowest long term NOEC (or EC10) and dividing it by 100.
- Actually, we found CSRs concluding an RCR >>1. It was then argued in the CSR that the background level was so much higher than the contribution from the use of the substance, so it in reality do not exhibit a risk.

Figure 3.35: Distribution of RCRs for HPV chemicals (n=46), above or below 1: baseline – 2011 comparison



Source: Author's compilation

The following table shows both the minor decline in number of HPV with RCRs > 1. It also shows that the number of HPV in 2011 with an RCR > 10 is at the same level or even higher than at baseline (13% at baseline, 13–15% in 2011).

Table 3.34: Distribution of RCRs for HPV chemicals (n=46): baseline – 2011 comparison

	Baseline			2011 – normalised			2011 – not normalised		
	n	% of total number of substances	% of those with RCR >1	n	% of total number of substances	% of those with RCR >1	n	% of total number of substances	% of those with RCR >1
RCR<1	33	72%		34	74%		35	76%	
RCR>1	13	28%		12	26%		11	24%	
RCR>10	6	13%	46%	6	13%	50%	7	15%	64

Source: Author's compilation

These data provide an overall picture of RCR distribution, but do not show shifts at the individual substance level. Such an analysis is shown in Figure 3.36 and the following changes from baseline to 2011 were observed:

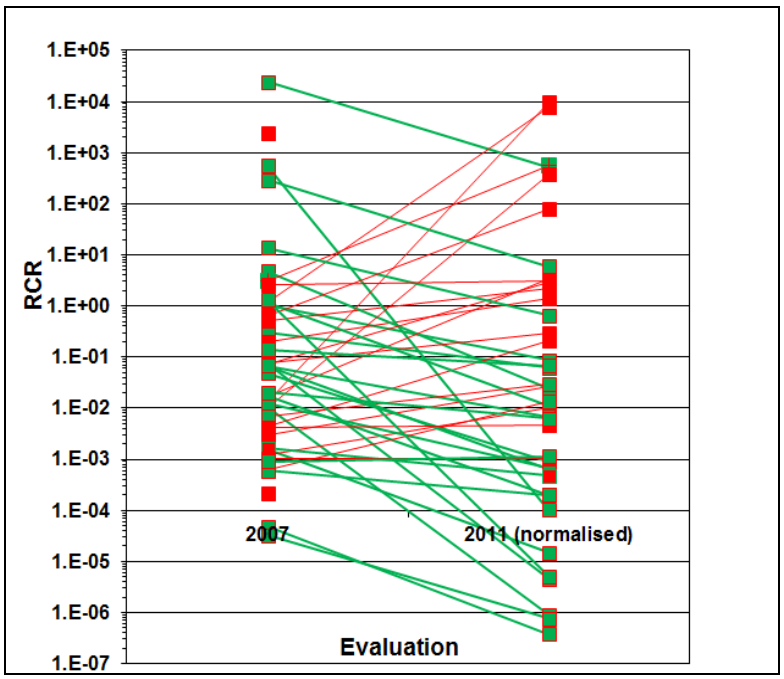
Based on normalised tonnages:

- 20 HPV chemicals show an increase in the RCR (43%) and
- 26 HPV chemicals show a decrease in the RCR (56%).

Based on non-normalised tonnages:

- 21 HPV chemicals show an increase in the RCR (45%) and
- 25 HPV chemicals show a decrease in the RCR (54%).

Figure 3.36: Shift of RCRs at the individual substance level for HPV chemicals (n=46): Green: decrease in RCR from baseline to 2011. Red: Increase in RCR from baseline to 2011.
Based on normalised tonnages.



Source: Author's compilation

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

- A wider range of RCR is observed in 2011 compared to baseline.
- Significant changes in the RCRs are observed; 43-45% of RCRs are increased and 54-56% are decreased compared baseline to 2011.
- The minimum RCRs are significantly decreased in 2011 compared to baseline, and the maximum RCRs are slightly decreased in 2011 compared to baseline.
- A tendency of a general decrease in the highest RCRs in 2011 compared to baseline for the HPV can be observed.

Overall, this evaluation shows:

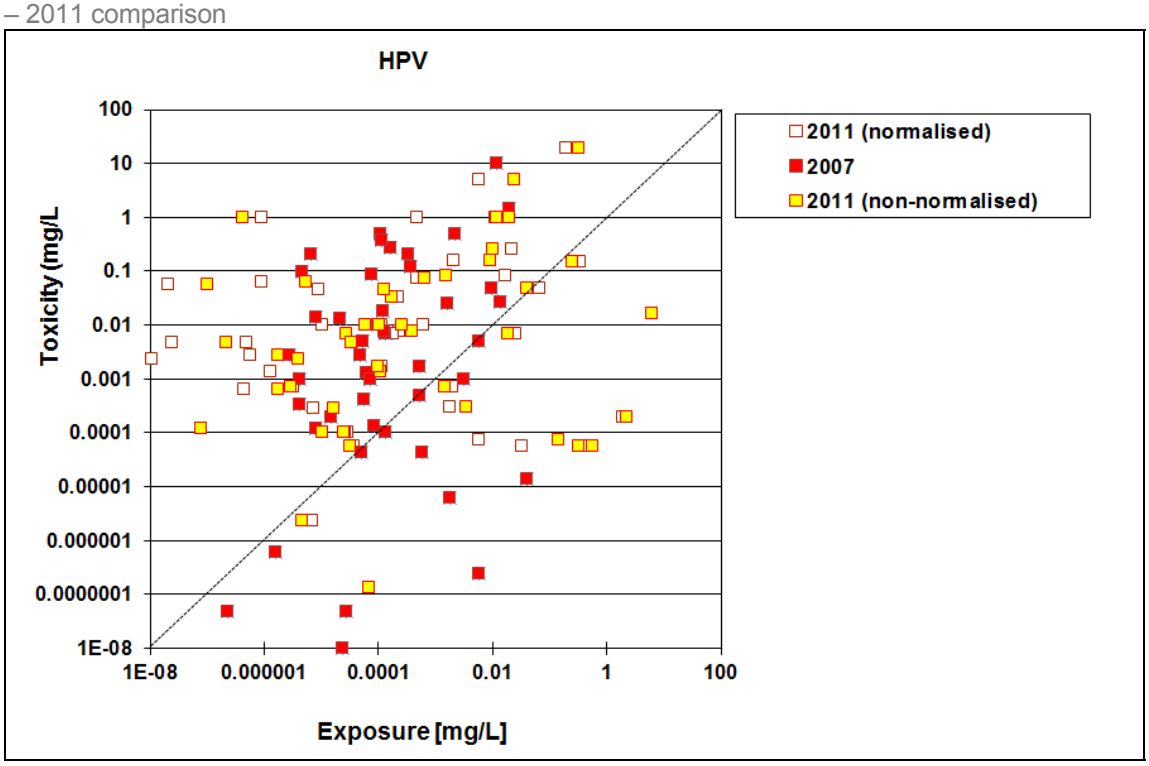
- The number of HPV chemicals in 2011 with an RCR > 1 is similar at baseline (25% at baseline, 21-26% in 2011).
- The number of HPV substances in 2011 with an RCR > 10 is at the same level than at baseline (13% at baseline, 13-15% in 2011).
- The baseline estimates were not overly conservative; otherwise, one would have expected a much higher fraction of RCR decreases in 2011
- RCR changes occur in all directions, with about 57% (normalised) respectively 54% (not-normalised) showing a decrease and about 43% (normalised) respectively 46% (not-normalised) of the HPV chemicals showing an increase in RCRs.

Since the RCR is calculated from the exposure estimate and the toxicity estimate, it is worth looking at the exposure and toxicity estimates at baseline and in 2011. The following figure presents the respective value as a scatter plot, with all data points above the dashed line indicating RCRs < 1 and all data points below the line indicating RCRs > 1. The figure supported by the numbers in Table 3.35 suggests that

- there is wider distribution in the exposure estimate in 2011
- the toxicity estimates tend to have increased slightly from 2007 to 2011

This is also evident in the descriptive statistics shown in Table 3.35, with decreasing toxicity estimates only identifiable for some of the parameters.

Figure 3.37: Scatter plot of exposure estimate and reference value for HPV chemicals (n=46): baseline – 2011 comparison



Source: Author's compilation

Table 3.35: Summary descriptive statistics for exposure and toxicity estimates for HPV chemicals (n=46): baseline – 2011 comparison (rounded to two significant figures)

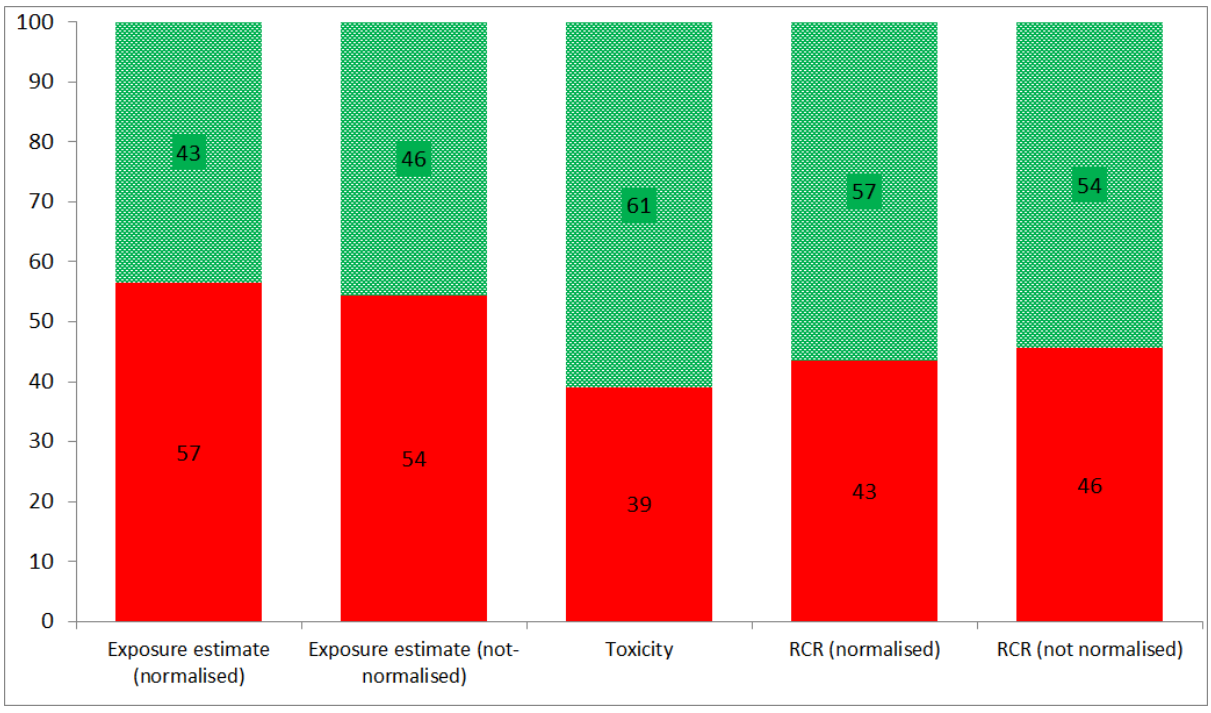
	Exposure estimate [mg/L]			Toxicity [mg/L]	
	Baseline	2011 – normalised	2011 – not normalised	Baseline	2011
n	46	46	46	46	46
Median	1.1E-04	1.5E-04	1.2E-04	2.7E-03	5.9E-03
GM	1.4E-04	1.3E-04	2.6E-04	1.6E-03	4.4E-03
10th percentile	4.4E-06	2.2E-08	1.6E-07	2.8E-06	6.0E-05
25th percentile	2.7E-05	7.1E-06	7.5E-06	1.4E-04	3.0E-04
75th percentile	1.8E-03	1.9E-02	2.2E-02	9.7E-02	9.1E-02
90th percentile	1.3E-02	4.2E-01	5.2E-01	5.0E-01	1.0E+00
MIN	2.3E-07	3.8E-10	4.0E-10	1.0E-08	1.3E-07
MAX	4.0E-02	6.1E+00	6.2E+00	1.0E+01	1.9E+01
IRQ	1.8	3.4	3.5	2.8	2.5

Source: Author's compilation

Again, these descriptions do not assess the behaviour of individual substances. This is only possible by tracking changes for each substance separately. If an analysis identical to the one carried out for RCRs is carried out for exposure and toxicity estimates, the following picture emerges (Figure 3.38, RCRs shown for comparison):

- The exposure estimate is higher in 2011 than at baseline for 57% (normalised) and 54% (not normalised) of the HPV chemicals – corresponding to that the exposure estimate is lower in 2011 than at baseline for 43% (normalised) and 46% (not normalised) of the HPV chemicals.
- The toxicity estimate is higher in 2011 than at baseline for 39% of the HPV chemicals – corresponding to that the toxicity estimate is lower in 2011 than at baseline for 61% of the HPV. It is believed to be a consequence of larger availability of experimental ecotoxicity data.

Figure 3.38: Changes in exposure estimates, toxicity and RCRs for individual HPV substances (n=46) from baseline to 2011; ■: increase. ■: decrease



Source: Author's compilation

While this chart is instructive in relation to the changes observed, it does not allow analysing the impact of changes in exposure and toxicity estimates on the changes observed in the RCR. Therefore, a detailed matrix summarising the substance-specific changes differentiated by RCR (increases and decreases) was developed. Table 3.36 shows the number of substances in each matrix cell and reveals (together with the underlying raw data) the following:

- HPV substances with RCRs increased in 2011 compared to baseline (note that the numbers for normalised are given in green and for not-normalised are given in [blue]):
  - 85% [86%] of substances with an RCR increased in 2011 (17/20 = 85% [18/21 = 86%]) show an increase in the exposure estimate
  - For substances with increased exposure estimates, the toxicity estimate changed about equally in all directions.
  - The toxicity increased for 13/20 (35%) [12/21 (57%)] of substances (i.e. the PNEC decreased), potentially causing an RCR increase. For 10/20 (50%) [9/21 (43%)] of these, the exposure estimate also increased.
  - The combined effect of increased exposure estimates and increased toxicity is therefore observed for 10 [9] substances
  - Overall, 10/20 (50%) [9/21 (45%)] of these substances have an RCR > 1 in 2011.
  - The combined effect of increased exposure estimates and increased toxicity, potentially leading to the highest RCR increase is only shown for around 22% [20%] of substances.
- HPV substances with RCRs decreased in 2011 compared to baseline
  - Decreased RCRs appear to result from decreased exposure estimates (17/26, 69%) [13/24, 52%], and decreased toxicity (21/26, 81% [19/25, 76%]) and only few of these have an RCR > 1 (8%).
  - For substances with decreased exposure estimates, the toxicity changed in all directions but primarily they have decreased. Within this subset, only 1 substance has an RCR > 1.
  - Overall, only 2/26 (8%) of these substances have an RCR > 1.

Table 3.36: Matrix of changes in exposure and toxicity differentiated by RCR changes for HPV chemicals (n=45, one substance with no RCR change excluded):
Increase: higher values in 2011 than at baseline,
Decrease: lower values in 2011 than at baseline;
Number of substances with RCR > 1 in parentheses

Normalised Exposure and RCR-scores			
RCR increase	**Exposure estimate**		
Toxicity	**Increase**	**Decrease**	**Total**
Increase*	10	3	**13**
Decrease*	7	0	**7**
Total	**17**	**3**	**20**
RCR decrease	**Exposure estimate**		
Toxicity	**Increase**	**Decrease**	**Total**
Increase	0	5	**5**
Decrease	9	12	**21**
Total	**9**	**17**	**26**
Non-normalised Exposure and RCR-scores			
RCR increase	**Exposure estimate**		
Toxicity	**Increase**	**Decrease**	**Total**
Increase	9	3	**12**
Decrease	9	0	**9**
Total	**18**	**3**	**21**
RCR decrease	**Exposure estimate**		
Toxicity	**Increase**	**Decrease**	**Total**
Increase	0	6	**6**
Decrease	12	7	**19**
Total	**12**	**13**	**25**

** toxicity increase refers to a decrease in the pseudo-PNEC and toxicity decrease refers to an increased pseudo-PNEC*

Source: Author's compilation

It is evident from this analysis that the changes in the RCRs are both a result of changes in the exposure estimate and in the toxicity estimate.

In summary, the analysis for HPV substances shows that changes between baseline and 2011 occur in many directions. Nonetheless, the following main findings are important:

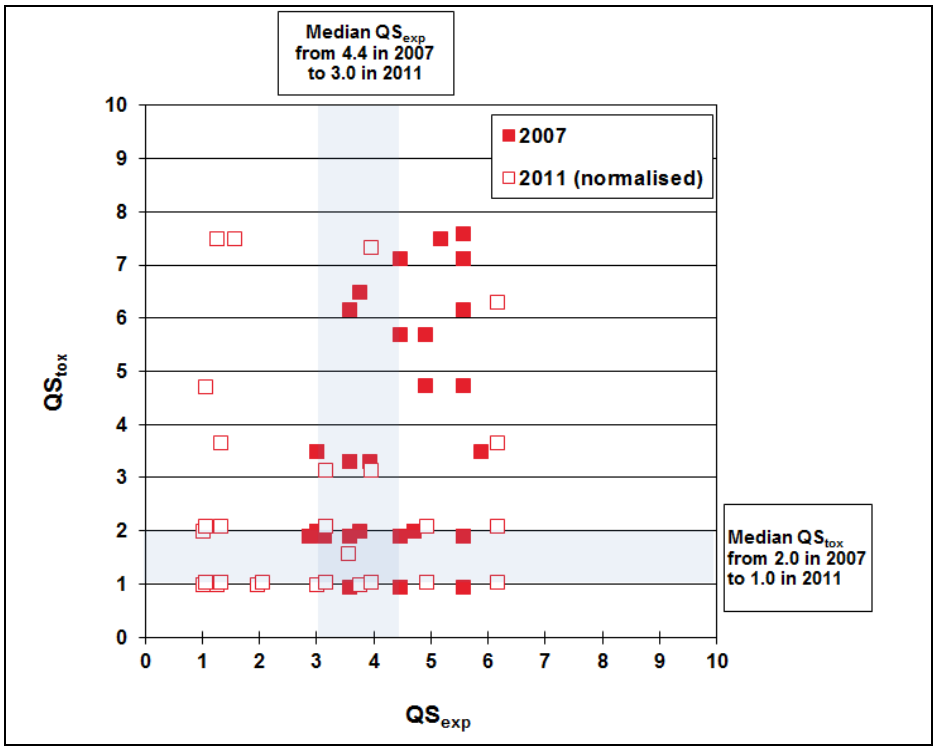
- For the majority of HPV chemicals (57% [54%]), RCRs are lower in 2011 compared to baseline.
- 67% [67%] of all HPV chemicals show an RCR ≤ 1 in 2011 compared to 63% at baseline.
- RCR values > 10 are observed for 6 [7] substances (11% [13%]) in 2011, 6 of which already had RCR values > 1 at baseline.
- The shifts in RCR are driven both by the changes in exposure estimates and changes in the toxicity estimates.
- the data basis and changes from baseline to 2011 are very diverse with RCR values > 1 not being the result of a systematic pattern.

As noted at profile level, the **Quality Score (QS_{total})** decreases from baseline to 2011, indicating a better quality of the 2011 data. 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 decline in QS_{total} is due to a decline in one of these components or both.

Figure 3.39 shows a QS_{exp}/QS_{tox} scatter plot for HPV substances. Since QS for some of the substances have exactly the same values, there is considerable overlay in the scatter plot, showing only a fraction of the substances.

Since many substances have exact the same QS-values, there would be considerable overlay in the scatter plot, showing only a fraction of the substances. Therefore, a shift in the original values was manually introduced to visualise more clearly the changes (baseline data was multiplied with 0.95 and 2011 data was multiplied with 1).

Figure 3.39: Quality Score scatter plot for HPV chemicals (n=46): baseline – 2011 comparison



Source: Author's compilation

The scatter plot clearly shows a decline in both Quality Scores. Furthermore, at baseline, a tendency that substances with high QS_{tox} also had high QS_{exp} (correlation coefficient 0.5) could be observed, whereas in 2011, no relationship appears between QS_{tox} and QS_{exp} (correlation coefficient -0.0).

The improvement in the quality of both exposure and toxicity estimates (i.e. the decline in QS_{exp} and QS_{tox}) is also evident in the statistical evaluation presented in Table 3.37Table 3.16 (QS_{total} included for comparison).

Table 3.37: Summary descriptive statistics for Quality Scores for HPV chemicals (n=46): baseline – 2011 comparison (rounded to two significant figures)

	QS_{exp}		QS_{tox}		QS_{total}	
	Baseline	**2011**	**Baseline**	**2011**	**Baseline**	**2011**
n	46	46	46	46	46	46
Median	4.4	3.0	2.0	1.0	9.4	3.8
GM	4.2	2.3	2.9	1.6	12	3.8
10^{th} percentile	3.0	1.0	1.4	1.0	5.9	1.0
25^{th} percentile	3.8	1.3	2.0	1.0	6.0	2.0
75^{th} percentile	5.9	3.8	6.0	2.0	25	6.0
90^{th} percentile	5.9	5.9	7.5	4.3	41	12
MIN	3.0	1.0	1.0	1.0	3.8	1.0
MAX	5.9	5.9	8.0	7.5	47	35
IRQ	2.1	2.5	4.0	1.0	19	4.0

Source: Author's compilation

Again, a substance-specific analysis similar to the one conducted for RCRs is performed for the Quality Scores to identify substance-specific changes and the impact of the individual QS component(s). The analysis presented in Table 3.38 (excluding one HPV substances with no change in QS_{total}) allows the following conclusions to be made:

- Only 4/46 (9%) HPV chemicals show an increase in QS_{total}, which is largely due increases in QS_{exp}.
  - This QS_{exp} increase is due to the lower data quality of the substance data needed for the exposure calculations, i.e. vapour pressure, water solubility, log K_{OW}, (bio)degradability
- The majority of HPV chemicals shows a decrease in QS_{total} (i.e. an increased quality), which is due to decreases in both Quality Score components (42/46, 91%).
- Half of the HPV chemicals with a decline in QS_{total} display decreases in both Quality Score components (21/42, 50%),
- Overall, the data show that
  - the quality of the toxicity estimate improves for 33/46 (72%),
  - the quality of the exposure estimate improves for 31/46 (67%) and
  - the overall quality improves for 42/46 (91%) HPV chemicals.

Table 3.38: Matrix of changes in Quality Scores for HPV chemicals (n=46: increase: higher values in 2011 than at baseline decrease: lower values in 2011 than at baseline; zero values not shown

QS_{total} increase	**QS_{exp}**		
QS_{tox}	**Increase**	**Decrease**	**Total**
Increase	3	1	**4**
Decrease	0	0	**0**
Total	**3**	**1**	**4**
QS_{total} decrease	**QS_{exp}**		
QS_{tox}	**Increase**	**Decrease**	**Total**
Increase	0	9	**9**
Decrease	12	21	**33**
Total	**12**	**30**	**42**

Source: Author's compilation

Overall, the quality of the exposure estimate, the toxicity estimate and the overall quality improves considerably from baseline to the 2011 evaluation. In summary, the analysis for HPV substances shows that changes between baseline and 2011 occur in many directions.

In summary for the HPV chemicals: For the majority of HPV chemicals, RCRs are lower in 2011 compared to baseline. This is primarily explained by a decrease in toxicity (or increase in the toxicity estimate). Overall, the quality of the exposure estimate, the toxicity estimate and the overall quality improves considerably from baseline to the 2011 evaluation.

SVHC in detail

As mentioned earlier, the Risk Score is obtained by multiplying the Risk Characterisation Ratio (RCR) with the Population Risk Modifier (PRM). The data for the PRM (Table 3.30, also included in

Table **3.39** for ease of comparison) show little change between baseline and 2011, with lower PRM values for SVHC in 2011. The data in

Table **3.39** clearly show that the substantial decline in mean and median Risk Scores in 2011 is due to decreases in the RCR and to a small degree explained by the decrease in PRM.

Table 3.39: Summary descriptive statistics for RCR, PRM and Risk Score for SVHC (n=19): baseline – 2011 comparison (rounded to two significant figures)

	RCR			PRM		Risk Score		
	Baseline	2011 – normalised	2011 – not normalised	Baseline	2011	Baseline	2011 – normalised	2011 – not normalised
n	19	19	19	19	19	19	19	
Median	1.6E+00	1.5E-01	5.6E-02	3.7	1.0	4.8E+00	1.5E-01	9.2E-02
GM	1.0E+01	1.6E-01	9.0E-02	3.0	1.3	3.2E+01	2.2E-01	1.3E-01
10^{th} percentile	1.6E-02	3.2E-04	7.6E-04	1.0	1.0	2.6E-02	1.2E-03	7.6E-04
25^{th} percentile	4.7E-02	5.6E-03	3.9E-03	1.0	1.0	1.1E-01	5.6E-03	5.4E-03
75^{th} percentile	1.9E+02	1.1E+01	1.4E+00	5.3	1.3	1.9E+03	1.7E+01	6.1E+00
90^{th} percentile	1.6E+03	2.9E+01	3.3E+01	6.7	2.7	1.1E+04	4.8E+01	3.3E+01
MIN	4.4E-03	1.5E-04	1.2E-04	1.0	1.0	4.4E-03	1.5E-04	1.2E-04
MAX	5.6E+13	1.1E+02	7.9E+01	10.0	4.1	2.8E+14	1.6E+02	7.9E+01
IRQ	3.6	3.3	2.6	4.3	0.3	4.2	3.5	3.1

Source: Author's compilation

Similar to HPV chemicals, the results can be differentiated by RCR bands (> 1, < 1 etc.). Table 3.40 shows that

- at baseline the ratio between number of SVHC with RCR ≤ 1 and RCR >1 was almost 1:1. In 2007 the ratio has changed to around 2:1
- the fraction of SVHC with RCRs > 10 declines from 37% at baseline to 26% (normalised) respectively 21% (not-normalised) in 2011.

Table 3.40: Distribution of RCRs for SVHC (n=19): baseline – 2011 comparison (rounded to two significant figures)

	Baseline			2011 – normalised			2011 – not normalised		
	N	% of total number of substances	% of those with RCR >1	N	% of total number of substances	% of those with RCR >1	N	% of total number of substances	% of those with RCR >1
RCR≤1	9	47%		12	63%		13	68%	
RCR>1	10	53%		7	37%		6	32%	
RCR>10	7	37%	70%	5	26%	71%	4	21%	67%

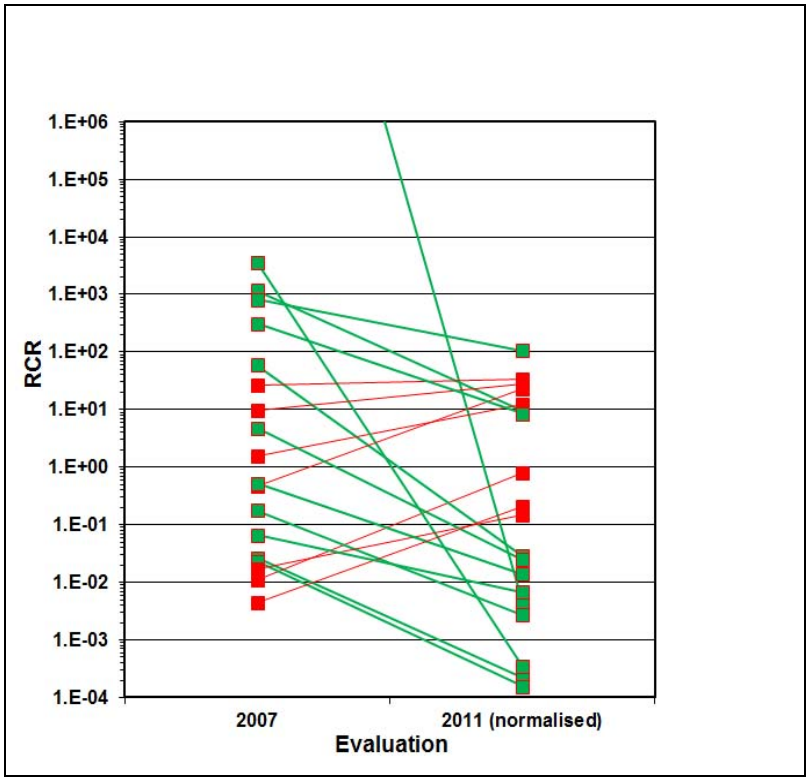
Source: Author's compilation

For a discussion of why RCRs> 1 is observed see Box 3.1.

At the individual substance level, Figure 3.40 shows that the majority of SVHC has a decrease in the RCRs in 2011 compared to baseline. The change is larger than for the HPV chemicals:

- 7 [6] SVHC show an increase in the RCR (37% [32%]; 43% [46%] for HPV chemicals) and
- 12 [13] SVHC show a decrease in the RCR (63% [68%]; 57% [54%] for HPV chemicals).

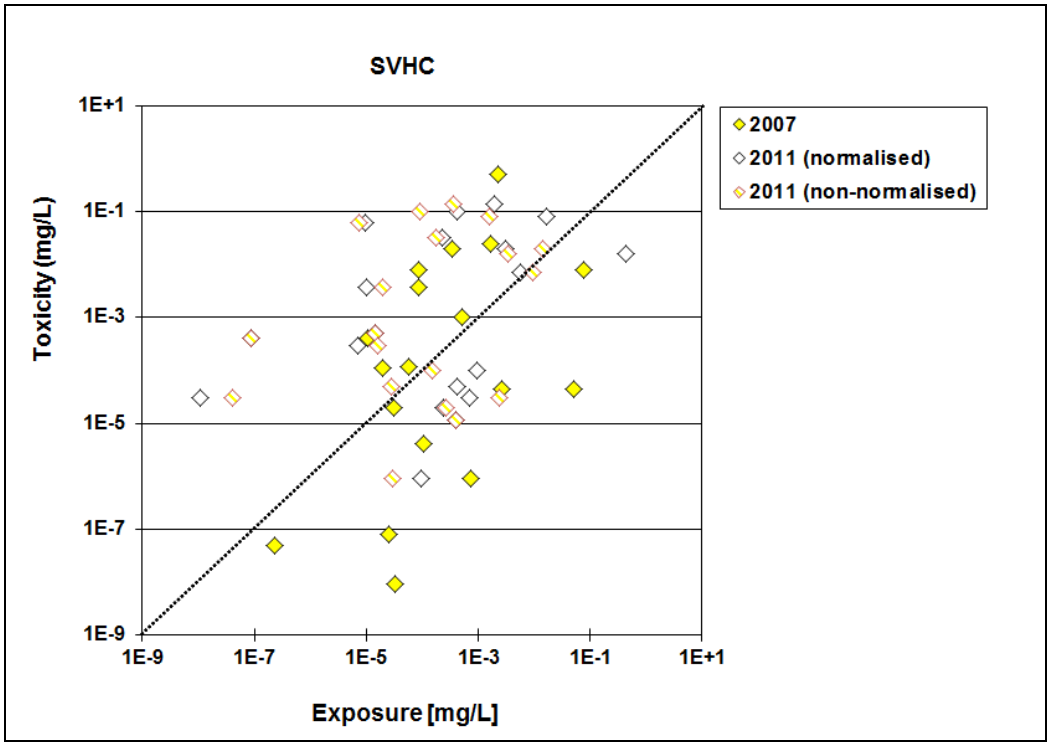
Figure 3.40: Shift of RCRs at the individual substance level for SVHC (n=19)



Source: Author's compilation

Similar to HPV chemicals, the individual components of RCRs, i.e. the exposure estimate and the toxicity estimate, provide additional insight into the changes seen between baseline and 2011. Again, the scatter plot shown in Figure 3.41 includes data points above the dashed line indicating RCRs < 1 and data points below the line indicating RCRs > 1. The data in this figure suggests that there is a trend to the left, i.e. towards lower exposure estimates and higher toxicity estimates in 2011 compared to baseline. This is also evident in the descriptive statistics shown in Table 3.41.

Figure 3.41: Scatter plot of exposure estimate and reference value for SVHC (n=19): baseline – 2011 comparison



Source: Author's compilation

Table 3.41: Summary descriptive statistics for exposure and toxicity estimates for SVHC (n=19): baseline – 2011 comparison

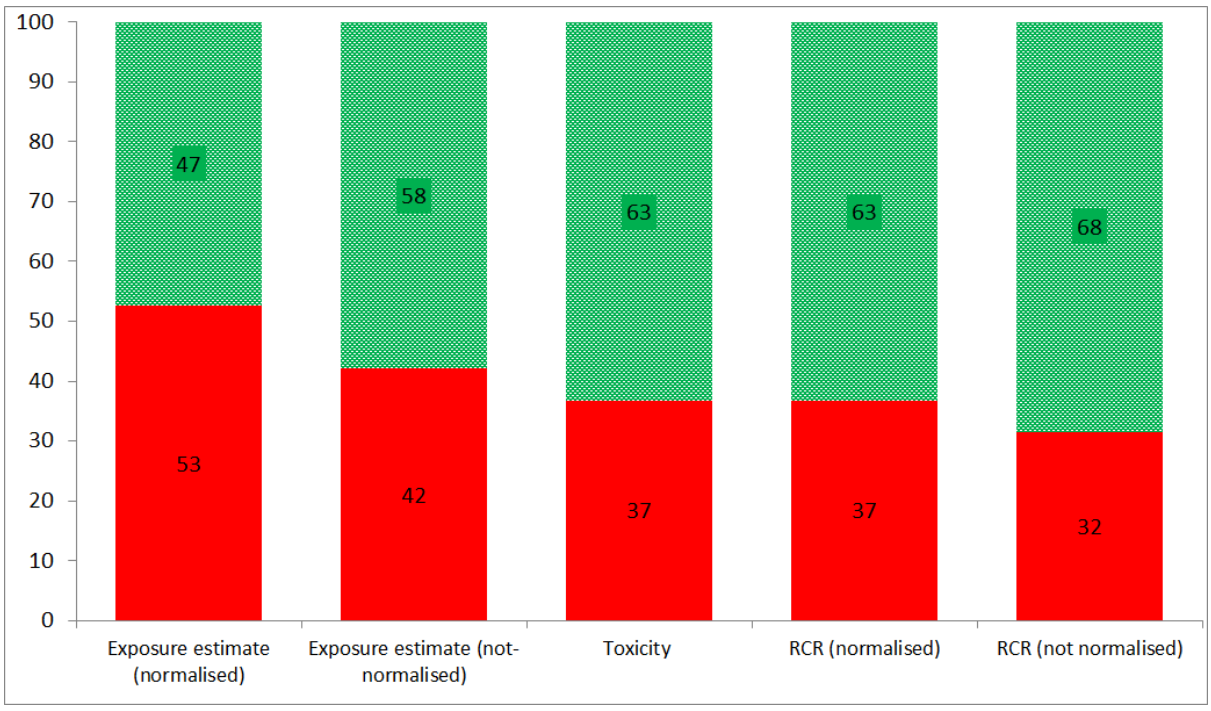
	Exposure estimate [mg/L]			Toxicity [mg/L]	
	Baseline	2011 – normalised	2011 – not normalised	Baseline	2011
n	19	19	19	19	19
Median	1.1E-04	4.0E-04	1.5E-04	1.2E-04	5.0E-04
GM	2.7E-04	1.6E-04	1.0E-04	9.8E-05	6.9E-04
10th percentile	1.8E-05	5.8E-06	5.8E-06	6.6E-08	9.5E-06
25th percentile	3.2E-05	1.2E-05	1.7E-05	1.2E-05	3.1E-05
75th percentile	1.9E-03	1.4E-03	1.4E-03	7.9E-03	2.3E-02
90th percentile	5.3E-02	7.9E-03	1.0E-02	1.8	1.1E-01
MIN	2.3E-07	1.1E-08	4.2E-08	1.0E-15	4.8E-08
MAX	7.7E-02	4.4E-01	1.7E-02	5.9	5.0E-01
IRQ	1.8	2.1	1.9	2.8	2.9

Source: Author's compilation

At the substance-specific level, the changes observed for SVHC are similar to the ones described above for HPV chemicals with some notable exceptions:

- The exposure estimate is higher in 2011 than at baseline for 53% [42%] of the SVHC (57% [54%] for HPV chemicals. The exposure estimate is lower in 2011 compared to baseline for 47% [58%] of the SVHC.
- Decreases in the toxicity are observed for 63% of the SVHC (61% of the HPV).
-

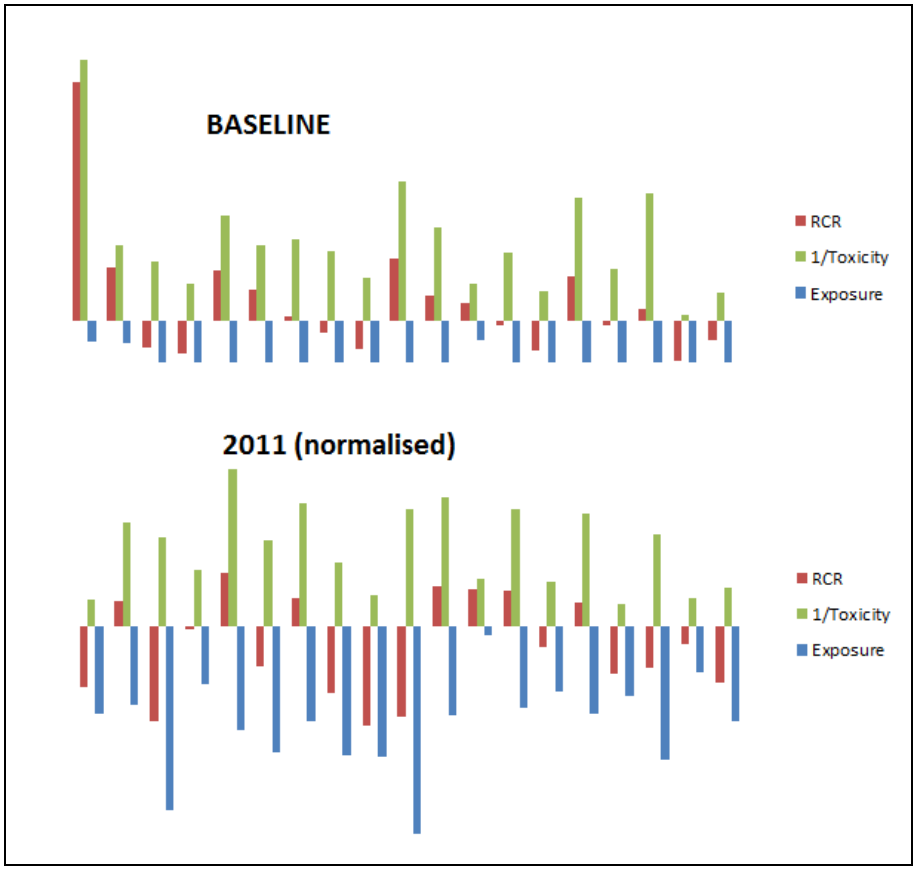
Figure 3.42: Changes in exposure estimates, toxicity and RCRs for individual SVHC (n=19) from baseline to 2011; ■: increase, ■: decrease



Source: Author's compilation

Figure 3.43 shows the changes in contribution from the toxicity and exposure estimates to the overall RCR. By comparing the upper figure (baseline) with the lower figure (2011), the changes in the contribution from the toxicity respectively exposure as well the total changes can be observed. As an example, the first substance at baseline had a very low toxicity estimate contributing very significantly to the RCR, whereas the contribution from the exposure estimate is very low. In 2011 this picture has changed significantly for the substance, as contribution from the toxicity to the RCR has decreased significantly (lower toxicity), and the contribution from the exposure has decreased as well. Overall the RCR has decreased significantly for this substance. From Figure 3.43, it can be seen that in general, it is primarily decreases in the exposure estimates that causes overall changes to the RCRs.

Figure 3.43: Changes in exposure estimates, toxicity estimates and RCRs for individual SVHC (n=19) from baseline to 2011



Source: Author's compilation

Table 3.42 presents the substance-specific matrix analysis for SVHC, again showing the number of substances in each matrix cell. The result of this analysis allows the following conclusions to be made:

- SVHC with RCRs increased in 2011 compared to baseline
  - The increase in the RCRs is primarily explained by an increase in the exposure estimate.
- SVHC with RCRs decreased in 2011 compared to baseline
  - 9/12, 75% [10/13, 83%] of SVHC with decreased RCRs have lower exposure estimates in 2011. These percentages are higher than for the HPV chemicals (65% [52%]).
  - For substances with decreased exposure estimates, the toxicity has increased for 2, 22% [2, 20%] of the SVHC. For these, the decrease in exposure has counteracted the increase in toxicity, so overall the RCR has decreased.
  - Overall, both a decrease in the exposure estimate and an increase in the toxicity estimate appear to be roughly equally important for the decline in RCRs.

Table 3.42: Matrix of changes in exposure estimates and toxicity differentiated by RCR changes for SVHC (n=19). Increase: higher values in 2011 than at baseline, decrease: lower values in 2011 than at baseline

Normalised Exposure and RCR scores			
RCR increase	**Exposure estimate**		
Toxicity	**Increase**	**Decrease**	**Total**
Increase*	4	1	**5**
Decrease*	2	0	**2**
Total	**6**	**1**	**7**
RCR decrease	**Exposure estimate**		
Toxicity	**Increase**	**Decrease**	**Total**
Increase	0	2	**2**
Decrease	3	7	**10**
Total	**3**	**9**	**12**
Non-normalised Exposure and RCR scores			
RCR increase	**Exposure estimate**		
Toxicity	**Increase**	**Decrease**	**Total**
Increase	1	0	**1**
Decrease	4	1	**5**
Total	**5**	**1**	**6**
RCR decrease	**Exposure estimate**		
Toxicity	**Increase**	**Decrease**	**Total**
Increase	0	2	**2**
Decrease	3	8	**11**
Total	**3**	**10**	**13**

* toxicity increase refers to a decrease in the pseudo-PNEC and toxicity decrease refers to an increased pseudo-PNEC

Source: Author's compilation

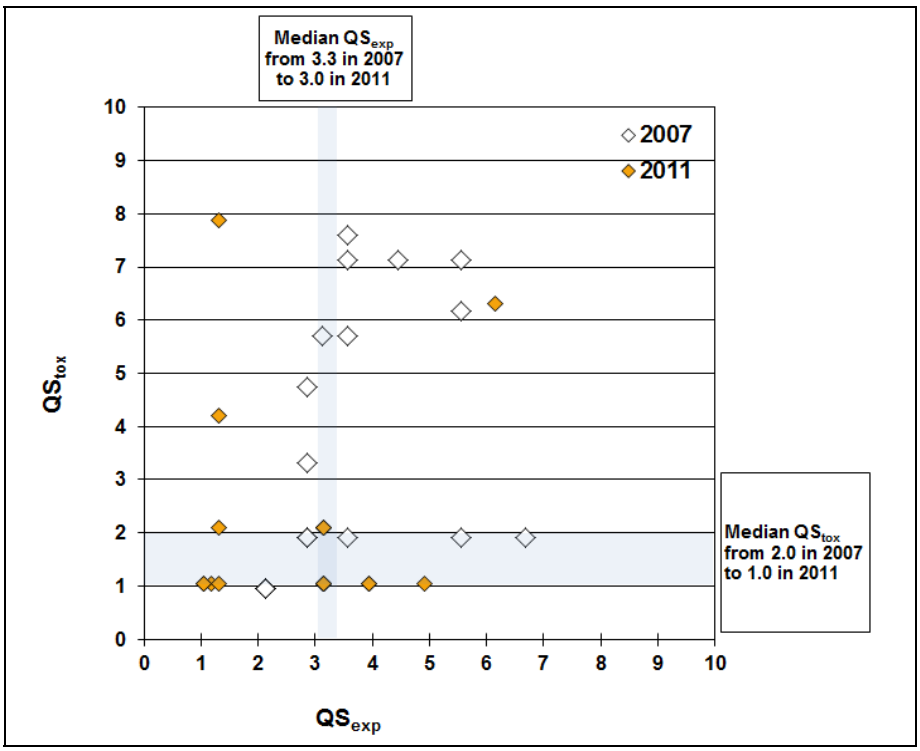
In summary, the analysis for SVHC shows that changes between baseline and 2011 occur in many directions. Nonetheless, the following main findings are important:

- For the majority of SVHC (63% [68%]), RCRs are lower in 2011 compared to baseline.
- Despite this decrease in RCRs, 26% [21%] of all SVHC still have an RCR > 1 in 2011 compared to 70% at baseline.
- The fraction of SVHC with RCR > 10 declined from 37% at baseline to 26% [21%] in 2011.
- The decline in RCRs appears to be driven both by decreases in exposure estimates and toxicity. However, it also appears as if the changes in exposure estimates had the largest quantitative contribution to the changes in the RCRs.

As noted at profile level, the **Quality Score (QS_{total})** for SVHC decreases from baseline to 2011, indicating a better quality of the 2011 data.

Figure 3.44 shows a QS_{exp}/QS_{tox} scatter plot for SVHC, identifying the changes of these individual components of QS_{total}.

Figure 3.44: Quality Score scatter plot for SVHC (n=19): baseline – 2011 comparison



Source: Author's compilation

The scatter plot clearly shows a decline in both Quality Scores (i.e. increase in quality). The improvement in the quality of both exposure and toxicity estimates (i.e. the decline in QS_{exp} and QS_{tox}) is also evident in the statistical evaluation presented in Table 3.43 (QS_{total} included for comparison).

Table 3.43: Summary descriptive statistics for Quality Scores SVHC chemicals (n=19): baseline – 2011 comparison (rounded to two significant figures)

	QS_{exp}		QS_{tox}		QS_{total}	
	Baseline	**2011**	**Baseline**	**2011**	**Baseline**	**2011**
n	19	19	19	19	19	19
Median	3.3	3.0	2.0	1.0	12	3.0
GM	3.5	2.3	2.9	1.5	9.9	3.5
10^{th} percentile	2.3	1.1	1.0	1.0	2.3	1.1
25^{th} percentile	2.6	1.3	1.5	1.0	4.1	2.8
75^{th} percentile	4.2	3.0	6.3	2.0	25	5.5
90^{th} percentile	5.9	3.9	7.5	4.4	36	6.7
MIN	2.3	1.0	1.0	1.0	2.3	1.0
MAX	7.0	5.9	8.0	7.5	44	35
IRQ	1.6	1.8	4.8	1.0	21	2.8

Source: Author's compilation

The matrix analysis for the Quality Scores presented in Table 3.44 shows somewhat less pronounced changes for SVHC compared to HPV chemicals (see Table 3.38).

- 3/19, 16% of the SVHC show an increase in QS_{total} (HPV chemicals, 9%), which is completely due increases in QS_{exp}.
- The majority of SVHC show a decrease in QS_{total} (i.e. an increased quality), which is due to decreases in both Quality Score components.
- 25% of the SVHC with a decline in QS_{total} display decreases in both Quality Score components (4/16)
- Overall, the data show that
  - the quality of the toxicity estimate improves for 10/19 (53%, HPV chemicals: 71%),
  - the quality of the exposure estimate improves for 10/19 (53%, HPV chemicals: 65%) and
  - the overall quality improves for 16/19 SVHC (84%, HPV chemicals: 91%)

Table 3.44: Matrix of changes in Quality Scores for SVHC: increase: higher values in 2011 than at baseline, decrease: lower values in 2011 than at baseline; zero values not shown

QS_{total} increase	**QS_{exp}**		
QS_{tox}	**Increase**	**Decrease**	**Total**
Increase	3	0	**3**
Decrease	0	0	**0**
Total	**3**	**0**	**3**
QS_{total} decrease	**QS_{exp}**		
QS_{tox}	**Increase**	**Decrease**	**Total**
Increase	0	6	**6**
Decrease	6	4	**10**
Total	**6**	**10**	**16**

Source: Author's compilation

In summary, the quality of the exposure estimate, the toxicity estimate and the overall Quality Score improves for the majority of substances. The quality of the exposure estimate and the quality of the toxicity estimate is poorer in 2011 than at baseline for about 47% of the SVHC.

In summary for the SVHC chemicals: In summary, the analysis for SVHC shows that changes between baseline and 2011 occur in many directions. Nonetheless, the following main findings are important: For the majority of SVHC, RCRs are lower in 2011 compared to baseline. The decline in RCRs appears to be driven both by decreases in exposure estimates and toxicity. However, it also appears as if the changes in exposure estimates had the largest quantitative contribution to the changes in the RCRs. The quality of the exposure estimate, the toxicity estimate and the overall Quality Score had improved from 2007 to 2011 for the majority of substances.

3.2.3.4 Summary and conclusions

The result of the 5 years update indicates an around 10-fold decrease in the aggregated Risk Score for the 65 substances evaluated. This is found to be 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 declined by a factor of 2-3 (based on GM). As a consequence, Risk Scores for HPV chemicals and SVHC have moved closer together in 2011.

At baseline, HPV substances and SVHC had a better quality than LPV and MPV. Since the evaluated 2011 sample only consists of HPV substances and SVHC, the Quality Score is much better in this sample compared to the entire baseline set. The quality of the data further increased in 2011. It was found that the use of QSAR/Read-Across/Guestimates to derive at property values had decreased in 2011 compared to the baseline study. It was found that the quality of the exposure estimate, the toxicity estimate and the overall quality improves considerably from baseline to the 2011 evaluation. The improvement in quality is similar for HPV substances and SVHC.

The risk scores decreased both as a result of a decrease in the PRM and a decrease in the RCR.

An evaluation of the PRM showed a significant difference between the baseline and 2011 data especially regarding the SVHC substances. The PRM has significantly decreased in 2011 compared to 2007 indicating that the uses are more related to industrial uses than professional/consumer uses. Only 56% of the HPV substances and 32% of the SVHC substances had one or more consumer/professional uses.

The changes in the RCRs are found to be both a result of changes in the exposure estimate and in the toxicity estimate for the HPV. The decline in RCRs of the SVHC appeared also to be driven both by decreases in exposure estimates and toxicity. However, it also appears that the changes in exposure estimates had the largest contribution to the changes in the RCRs.

As there is a significant uncertainty in the tonnages, the comparison has been carried out on two levels: a) a comparison where the actual tonnages for 2007 and 2011 respectively are used (not normalised) and b) comparison, where the exposure and risk scores are normalised with respect to the 2007 tonnage (normalised). It was found that the applied tonnage had some impact on the derived numbers, however not on the overall conclusions.

3.2.4 Impact area: Consumers

As described in chapter 3.1, data have been analysed for 62 substances from registration dossiers (IUCLID files and/or CSRs) and other sources (e.g. RAR).

As a result and for statistical and graphical purposes, the substances for which exposure is estimated to be null are not included in the exposure estimate, RCR, and Risk Score levels of analysis. It is the case for 40 substances not intended to be used by general public, and without identified exposure, in 2011. The number of substances considered is indicated at each step in the analysis.

All 62 substances are included for the Quality Score level of analysis and for the analysis of the sources of the estimates.

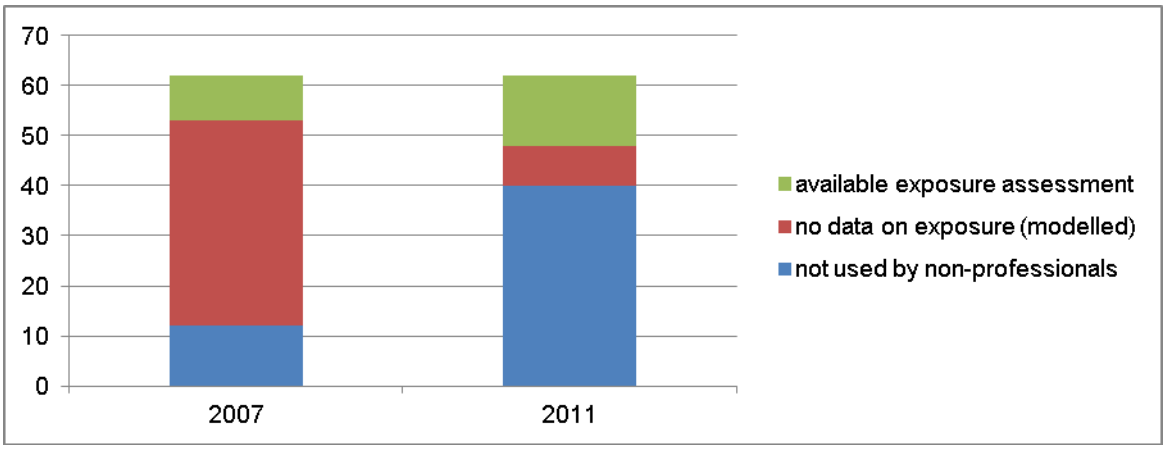
3.2.4.1 Summary level

Data on uses and available exposure assessments

In the 62 consulted registration dossiers (IUCLID files and/or CSRs), use by the general public is intended for only 22 substances. The other (40) substances should not be incorporated in consumer products and exposure to non-professional users is not anticipated. For the 22 ‘used’ substances, exposure estimates are provided in CSRs for 14 substances.

In 2007, exposure to 41 of the 62 substances was modelled because no estimation was available. 12 were not intended to be used by consumers. Exposure estimates were available for 9 substances only. Data on uses (except when RAR were available) were often incomplete, with very low details. Among the 40 ‘not used’ substances, 10 substances were already not intended to be used by non-professional users in 2007. Exposure to general public (directly or indirectly) was available (e.g. in RAR) for 8 of these. For the 22 remaining substances, exposure was modelled but uses by non-professionals were often not clearly defined.

Figure 3.45: Comparison of available information on uses and exposure (62 substances).

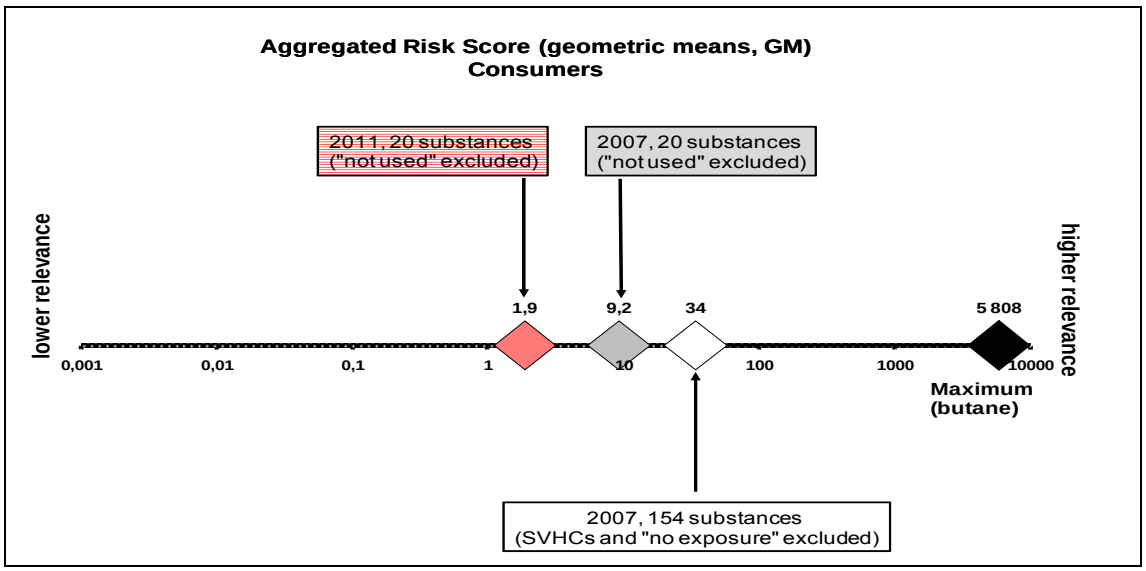


Source: Author's compilation

At the summary level for the impact area of consumers in the year 2011, the geometric means of Risk Score is **1.9** (for 20 substances, the 'not used' being excluded) and of Quality Score is **6** (for 67 substances). Figure 3.46 and Figure 3.47 show these scores.

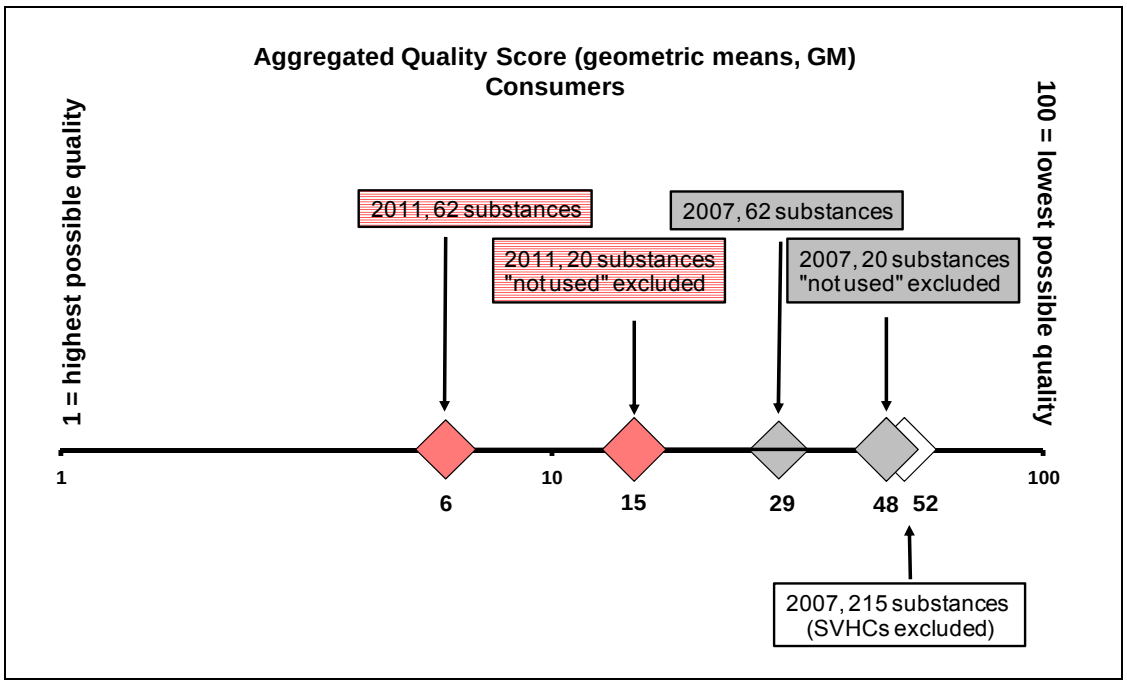
The comparison with the respective scores estimated in 2007 (for the same substances) shows a lower estimated risk (9.2 to 1.9) and a better quality (29 to 6) of the data.

Figure 3.46: Summary level: Aggregated Risk Scores (consumers)



Source: Author's compilation

Figure 3.47: Summary level: Aggregated Quality Scores (consumers)



Source: Author's compilation

3.2.4.2 Profile level

This profile levels provide further details for the comparison of the Risk and Quality scores between 2007 and 2011.

Results of Risk Score and Quality Score are given in Table 3.45, for 20 common substances ('not used' excluded). The results are also shown in whisker plots and cloud in following figures.

Figure 3.48 shows the decrease of Risk Score between 2007 and 2011 by a factor 6 for geometric mean and 9 for median value. The shape of the distribution is not visibly different.

Figure 3.49 shows the decrease of Quality Score between 2007 and 2011 by a factor 3 for geometric mean and 5 for median value. The shape of the distribution is visibly narrower (80% of the scores are between 8 and 21).

The cloud, Figure 3.50, shows the visible shift toward better quality and lower risk.

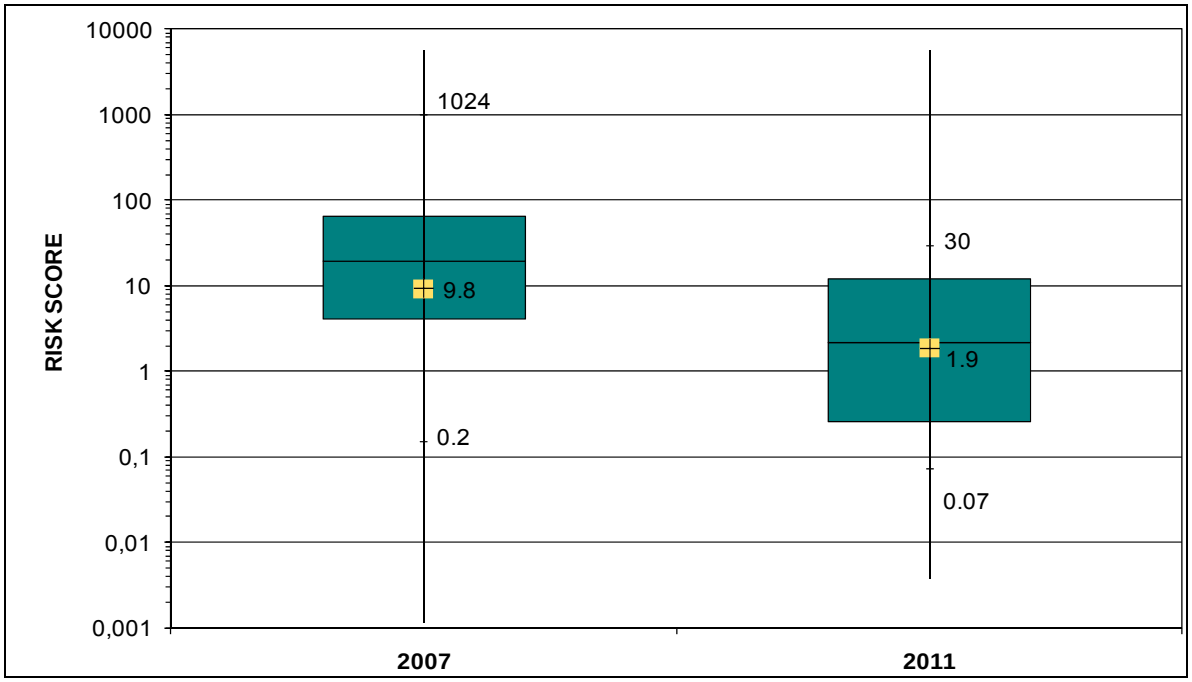
Table 3.45: Results of Risk Scores and Quality Scores for 20 substances ("not used" excluded) in 2007 and 2011, distribution data

		2007	2011
RISK SCORE Consumers (n=20)	Median	19	2.2
	GM	9.8	1.9
	10th percentile	0.2	0.07
	25th percentile	4.1	0.26
	75th percentile	65	12
	90th percentile	1024	30
	MIN	0.001	0.004
	MAX	5 808	5 808

		2007	2011
QUALITY SCORE Consumers (n=20)	Median	64	14
	GM	48	15
	10th percentile	16	8
	25th percentile	48	12
	75th percentile	74	16
	90th percentile	80	21
	MIN	6	7
	MAX	80	56

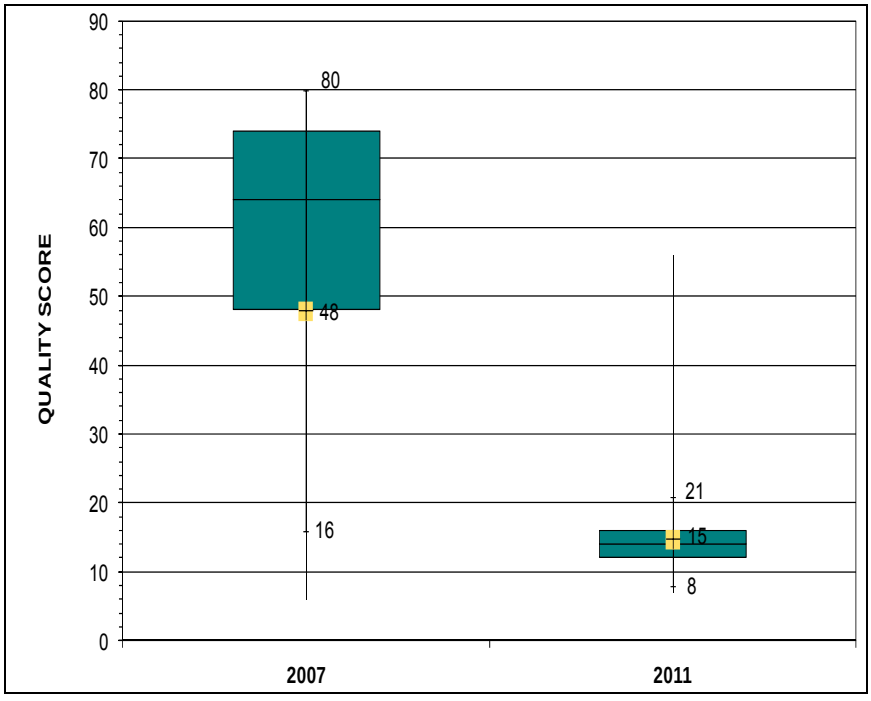
Source: Author's compilation

Figure 3.48: Risk Score Profile (consumers). Numerical values given for geometric mean, 10th percentile and 90th percentile (20 substances; RS = 0 excluded)



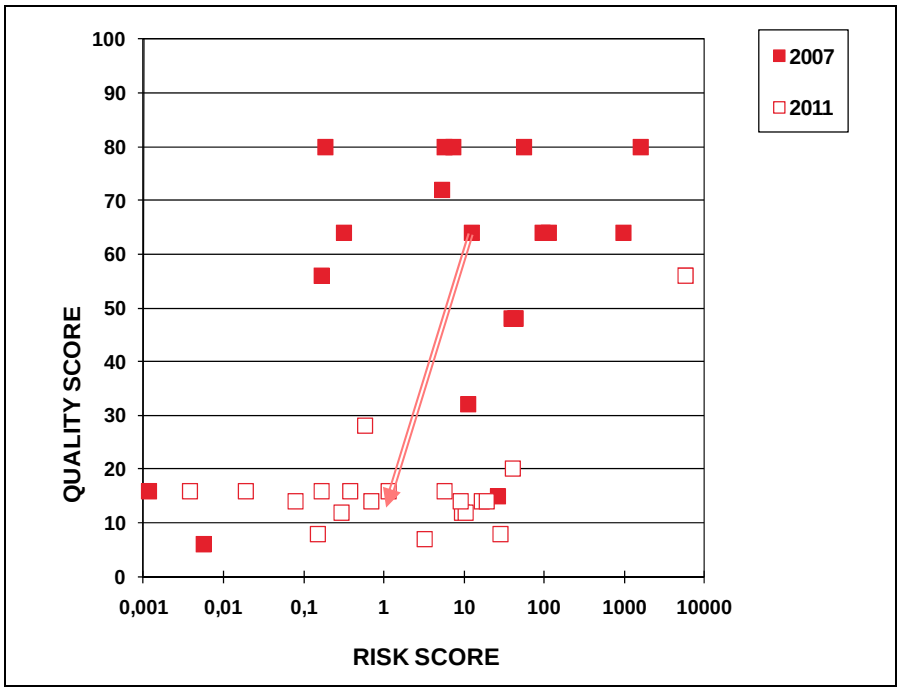
Source: Author's compilation

Figure 3.49: Quality Score Profile (consumers). Numerical values given for geometric mean, 10th percentile and 90th percentile (20 substances; RS = 0 excluded)



Source: Author's compilation

Figure 3.50: Risk and *Quality Scores presented as a cloud (20 substances; RS = 0 excluded)*



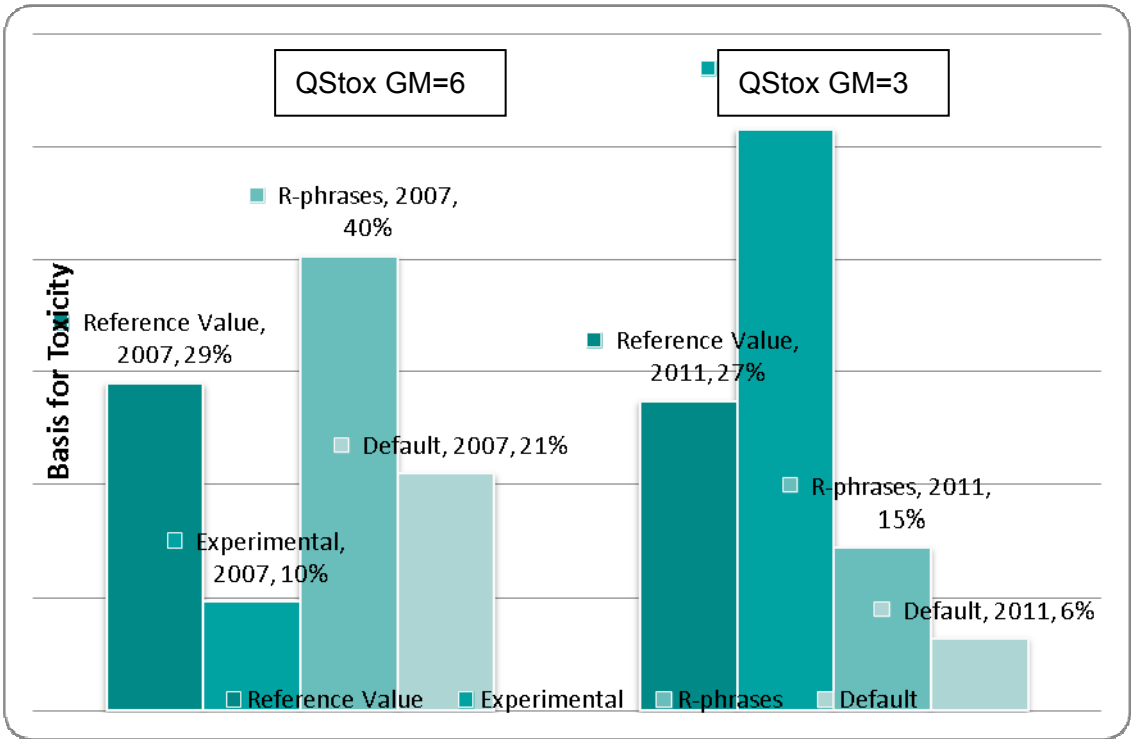
Source: Author's compilation

3.2.4.3 Analysis level

Basis and quality of data

Figure 3.51 and Figure 3.52 provide detailed information about data availability for toxicity and exposure. These statistics are calculated for the set of 62 substances.

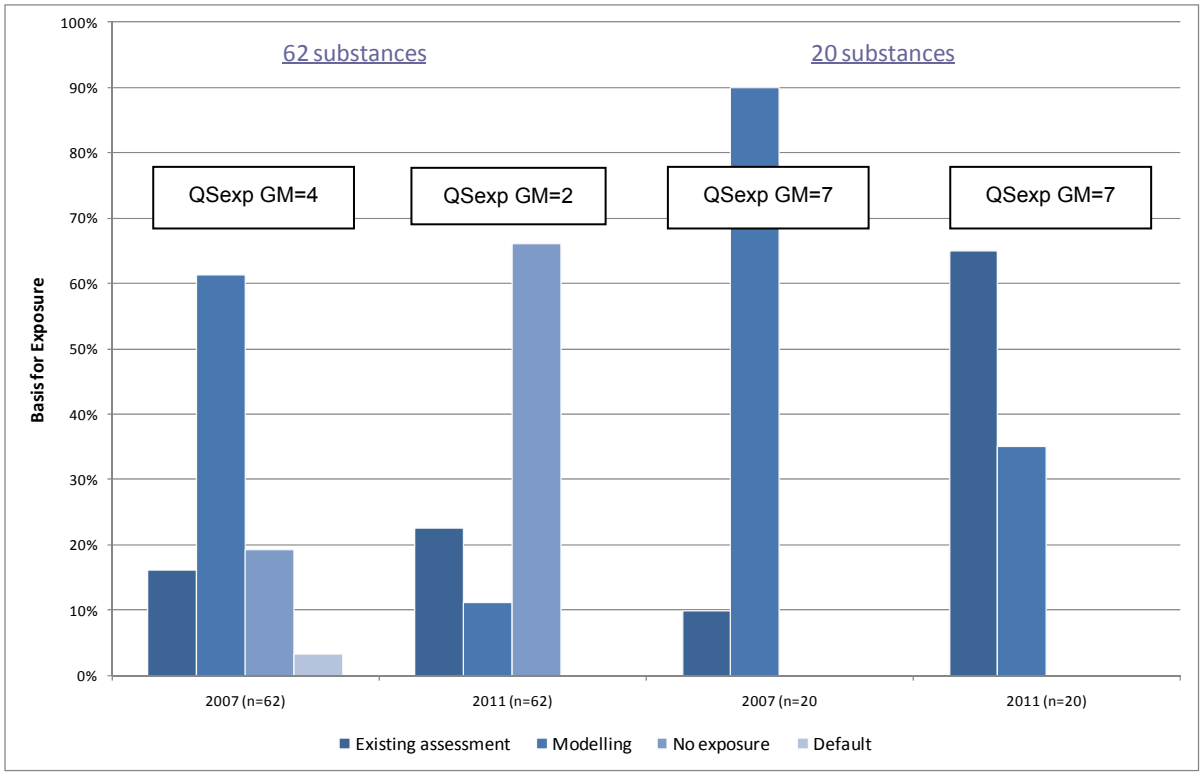
Figure 3.51: Data availability analysis for toxicity (consumers) and geometric mean of Quality Score for toxicity (62 substances)



Source: Author's compilation

The ratio of toxicity estimates based on reference values (e.g. RfD) or experimental data (e.g. NOAEL and DNEL) increases strongly from 39% 2007 to 79% 2011. In many cases, DNEL estimated in CSRs replaced scores based on R-phrases or default values. This fact, and the respective improvement of the data quality (Geometric mean of QStox from 6 to 3), is directly linked to the calculation of DNELs in the REACH registration dossiers.

Figure 3.52: Data availability analysis for exposure estimates (consumers) and geometric mean of Quality Score for toxicity estimate (62 and 20 substances)



Source: Author's compilation

Between 2007 and 2011, the rate of substances with no exposure is tripled to 66%. Indeed, in the set of 62 substances, the use by the general public is intended in only 20 dossiers. The rate of existing assessments (in RAR or REACH dossiers) slightly increases from 16% to 23%. Consequently, the need for modelling or default values to calculate the exposure estimates is reduced to 11% of the substances in 2011 instead of 61% in 2007.

In 2011, exposure is estimated in the CSRs for 65% of the substances intended to be used by the general public. For the other 35%, the same model as in 2007 has been used for the calculation of exposure estimates.

Exposure and Toxicity Estimates

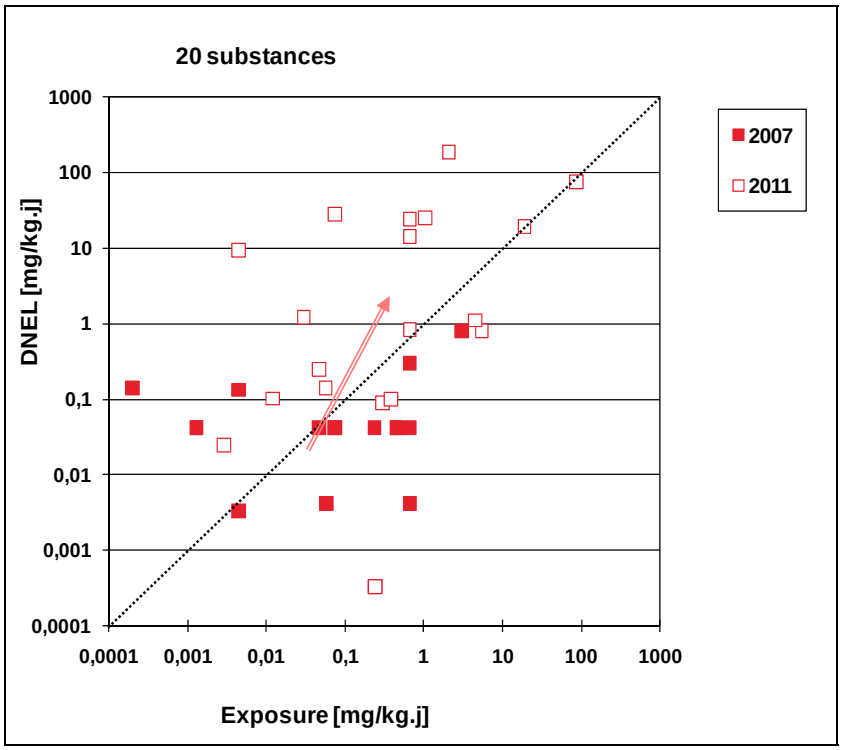
For the 20 substances with potential exposure to general public, results of the estimates of exposure and toxicity (DNEL or analogue) are presented in Table 3.46 and Figure 3.53.

Table 3.46: Exposure and Toxicity estimates (mg/(kg.j)) for consumers (20 substances)

	Exposure		DNEL (or analogue)	
	2007	2011	2007	2011
GM	0.05	0.4	0.03	1.6
MIN	0.000004	0.003	0.0003	0.0003
10th percentile	0.001	0.01	0.004	0.08
25th percentile	0.004	0.05	0.02	0.13
Median	0.16	0.52	0.04	1.2
75th percentile	0.6	2.7	0.04	24
90th percentile	0.7	25.8	0.16	75
MAX	3	87	0.8	184

Source: Author's compilation

Figure 3.53: Analysis of the Exposure and Toxicity estimates (mg/(kg.j) for consumers (20 substances))



Source: Author's compilation

An increase of the estimates of the DNEL (or analogue) by a factor about 50 (for GM) is visible. This increase can be explained by a better quality of available data: the use of experimental data in the CSRs in 2011 compared to scores based on R-phrases or default values in 2007.

The shift toward higher exposure estimates is not so significant (factor 8 for GM; 3 for median). This may be due to changes in the models used to estimate exposure: the new version (2010) of TRA tool for consumers is known to be generally more conservative compared to the older version ([5]). This shift does not seem to be linked neither to a better quality of data nor to a real increase of the exposure.

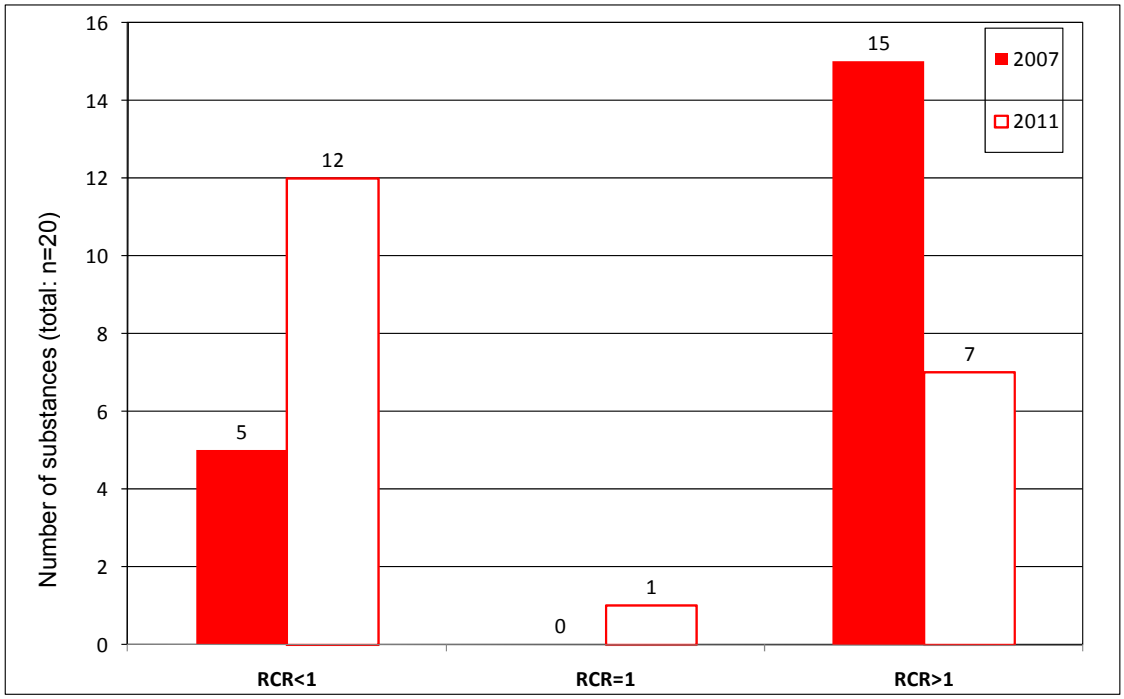
Risk Characterisation Ratios

In Figure 3.53, the points below the line show Risk Characterisation Ratios above 1 (exposure > DNEL). Between 2007 and 2011, the number of RCR above 1 decreased from 15 to 7. This evolution to lower RCR is illustrated in Figure 3.54 and Figure 3.55.

RCR above 1 in this exercise does not mean that they are above 1 in the CSRs because they are recalculated in this exercise with route-to-route extrapolation (not done in the CSRs).

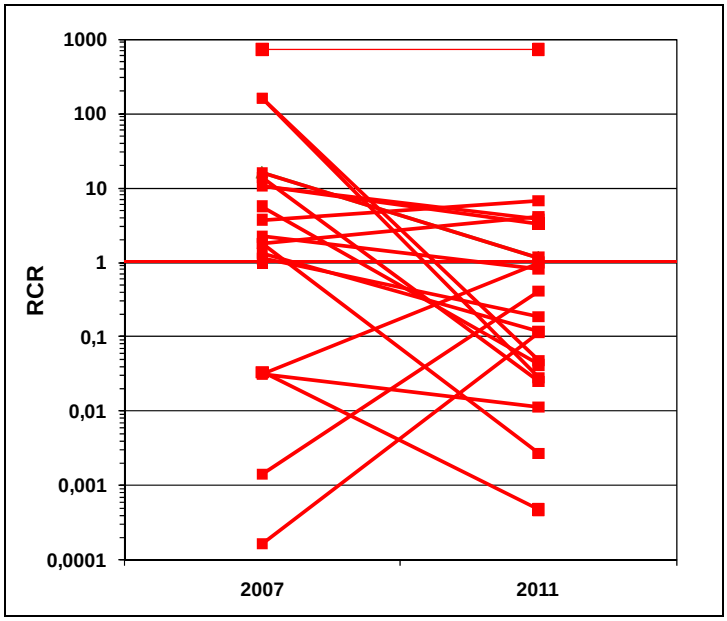
(5) assumed at the ECETOC Workshop, 15th May 2009.

Figure 3.54: Numbers of substances with Risk Characterisation Ratios below or above 1 (20 substances)



Source: Author's compilation

Figure 3.55: Evolution of RCR between 2007 and 2011 (22 substances)



Source: Author's compilation

The decrease of RCR values may be understood as an apparent decrease of the risk, but it is more probably due to the better estimate of DNELs and exposure doses. As RCR = exposure/DNEL, and DNEL increase more than exposure, the ratio decrease.

3.2.4.4 Summary and Conclusions

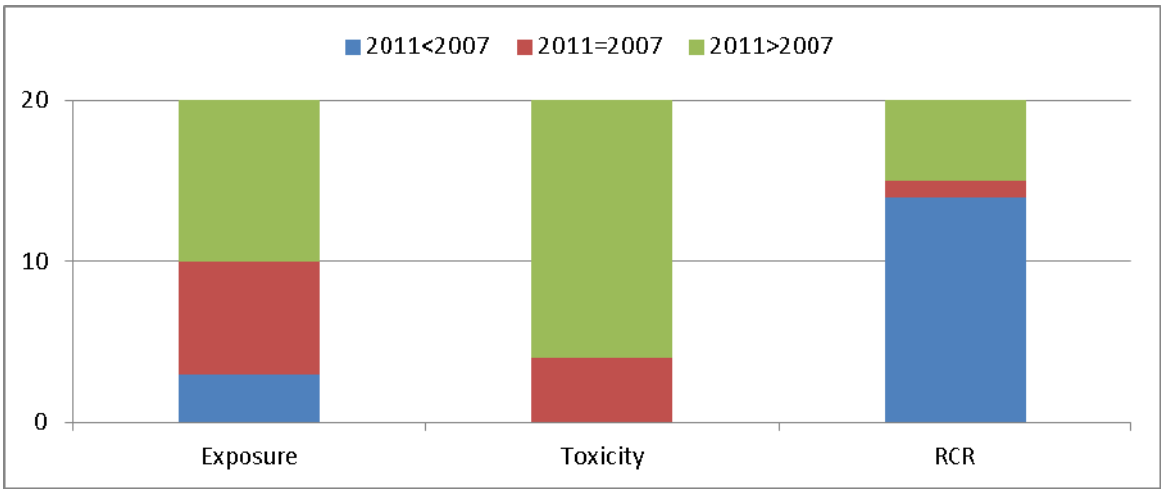
Among the 62 reference substances registered in 2011, exposure to consumers is assumed only for 20 substances. The others are not intended to be used by general public, hence risk for consumers is anticipated to be null. There is no data on indirect exposure to general public (e.g. by leaching from material) in CSRs, and very few from other sources. Therefore it has not been assumed even if it cannot be excluded.

Assessment of exposure was available for only 2 of the 20 substances with exposure in 2007 (e.g. in RAR) and for 13 in 2011 (in CSRs). The estimates are globally higher in 2011 than in 2007 (for 10 substances), mainly because of changes in the TRA model (more conservative for consumers in the new version).

Assessment of toxicity (DNEL or analogue) is clearly of better quality in 2011 than in 2007 (Geometric mean of QStox from 6 to 3), thanks to the determination of DNEL from experimental data in the CSRs. In 2011, DNEL and/or reference values are available for 79% of the substances. Moreover, the improvement of the data availability globally leads to higher toxicity scores (for 16 of 20 substances).

A decrease of the RCR is observed for 14 of 20 substances, mainly linked to the increase of the DNELs.

Figure 3.56: Evolution of Exposure and Toxicity estimates and RCR



Source: Author's compilation

3.2.5 Impact area: Humans via the environment

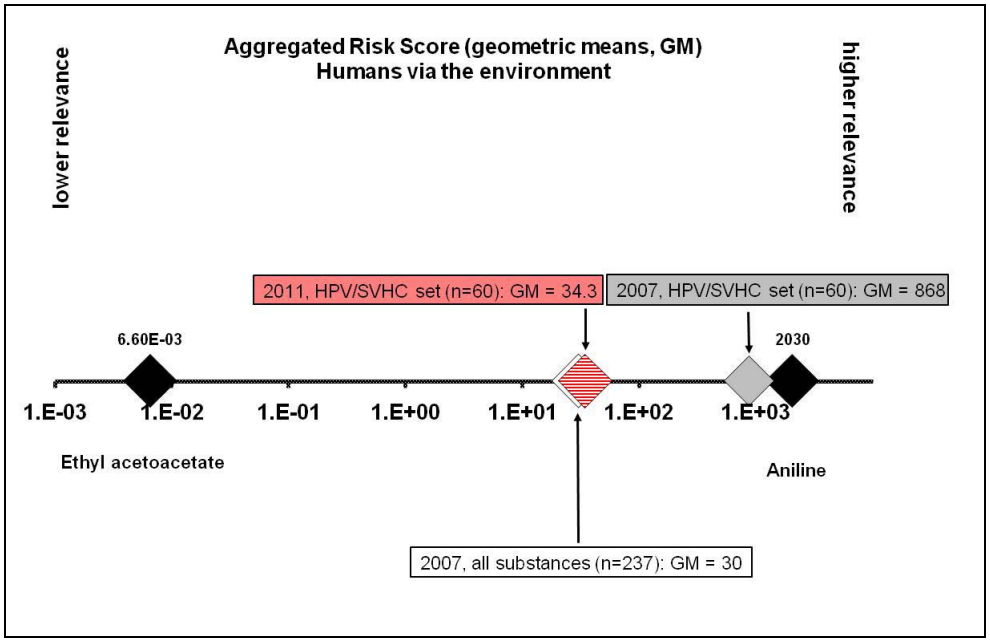
As described in chapter 3.1, a total of 62 substances (46 HPV chemicals and 19 SVHC) could be evaluated in the 5 years update. For statistical and graphical purposes, two substances with no exposure for humans via the environment are not included in the analysis on summary level.

3.2.5.1 Summary level

At the summary level for area of Humans via the environment in 2011, the geometric means of Risk Score and of Quality Score, presented in Figure 3.57 and Figure 3.58, is **34.3** and **15 respectively** (for 60 substances).

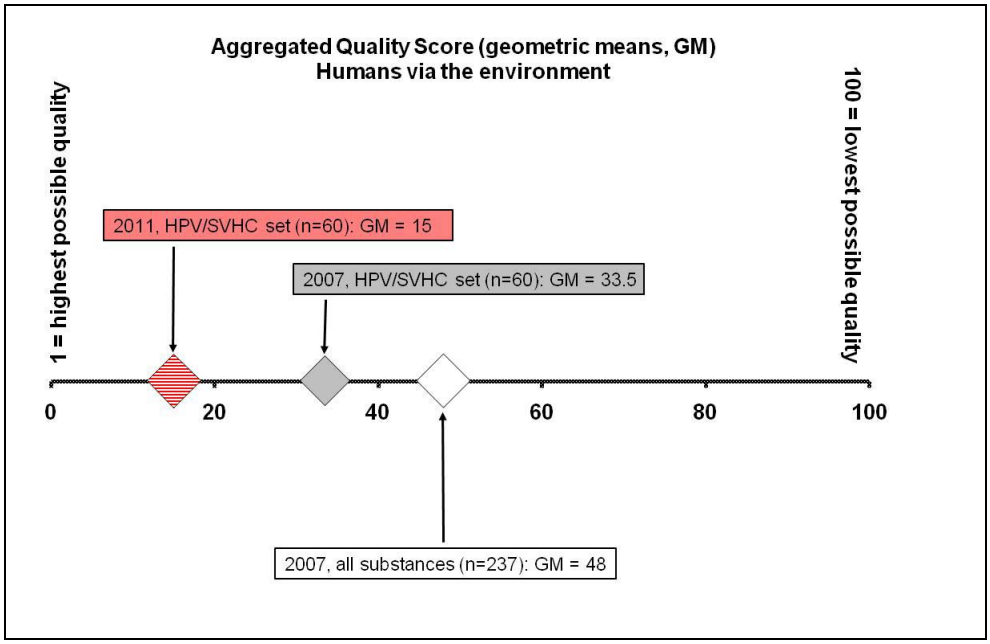
For the same substances in 2007, the geometric means of Risk Score and Quality Score were thirty times and two times higher respectively.

Figure 3.57: Summary level: Aggregated Risk Scores (Humans via the environment) at baseline and in 2011



Source: Author's compilation

Figure 3.58: Summary level: Aggregated Quality Scores (Humans via the environment) at baseline and in 2011



Source: Author's compilation

The change in Risk Score and Quality Scores from baseline to 2011 is summarised in Table 3.47. Median values are included in addition to the GMs and confirm the trend of decreasing Risk and Quality Scores.

Table 3.47: Summary of aggregated Risk and Quality Scores

	Risk Score		Quality Score	
	Baseline	2011	Baseline	2011
n	60	60	60	60
GM	868	34.3	33	15
Median	490	33.7	37	13

Source: Author's compilation

3.2.5.2 Profile level

This profile levels provide further details for the comparison of the Risk and Quality scores between 2007 and 2011. Among the different types of substances (HPV, MPV, LPV, SVHC), only SVHC and HPV are considered in the further analysis due to the low number of LPV/MPV in the set which is too low to be statistically significant.

For HPV substances

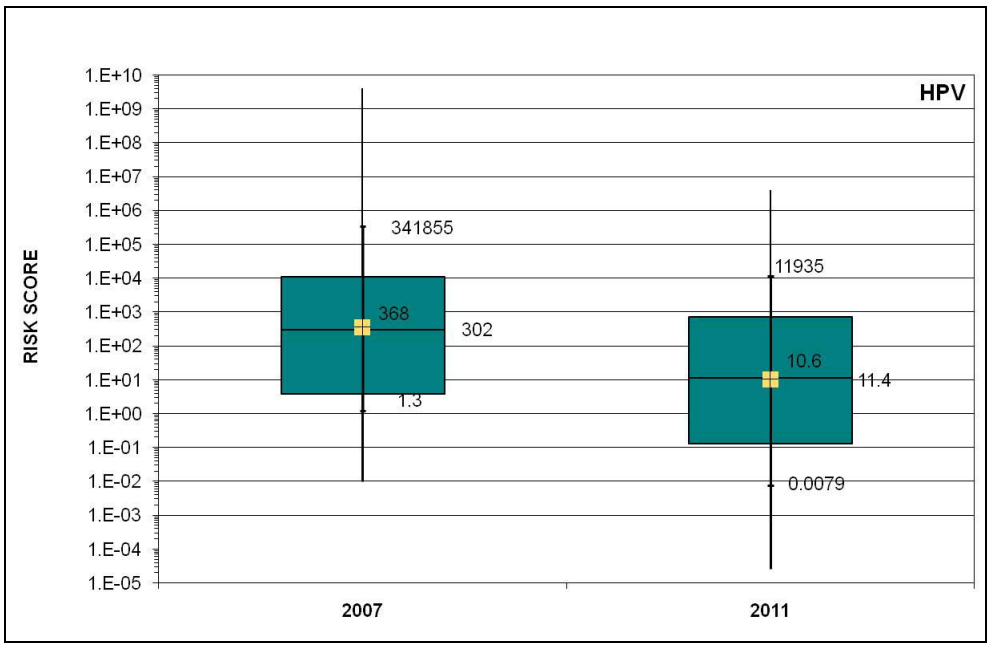
Results of Risk Score and Quality Score are given in Table 3.48, for HPV substances and in for SVHC substances. The results are also presented in whisker plots in following figures (Figure 3.59 and Figure 3.60).

Table 3.48: Distribution results of Risk Scores and Quality Scores for 44 HPV substances in 2007 and 2011

		2007	2011
Distribution of Risk Scores for HPV substances (n=44)	Median	302	11.4
	GM	368	10.6
	10^{th} percentile	1.3	0.0079
	25^{th} percentile	3.9	0.14
	75^{th} percentile	11221	727
	90^{th} percentile	341855	11935
	MIN	0.01	0.00003
	MAX	4060913706	3913142
		2007	**2011**
Distribution of Quality Scores for HPV substances (n=44)	Median	37	13
	GM	34	15
	10^{th} percentile	21	7
	25^{th} percentile	26	9
	75^{th} percentile	45	26
	90^{th} percentile	63	36
	MIN	9	5.9
	MAX	79	69

Source: Author's compilation

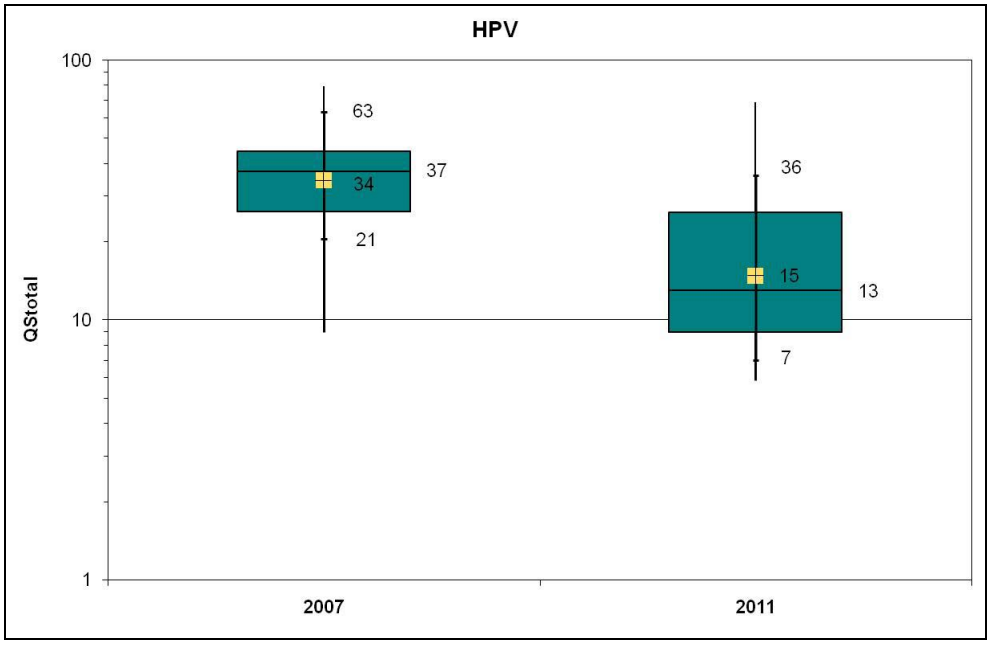
Figure 3.59: Comparison of baseline and 2011 Risk Scores for HPV chemicals (n=44)



Source: Author's compilation

The variation of the Risk Score from baseline to 2011 for the 44 HPV substances is presented in figure 5.3. The whisker plot emphasizes the decrease in Risk Scores which is confirmed by the decrease of the geometric mean and the median. Nevertheless, the interquartile range remained in the same range as it is shown by the constant width of the baseline and 2011 whisker box.

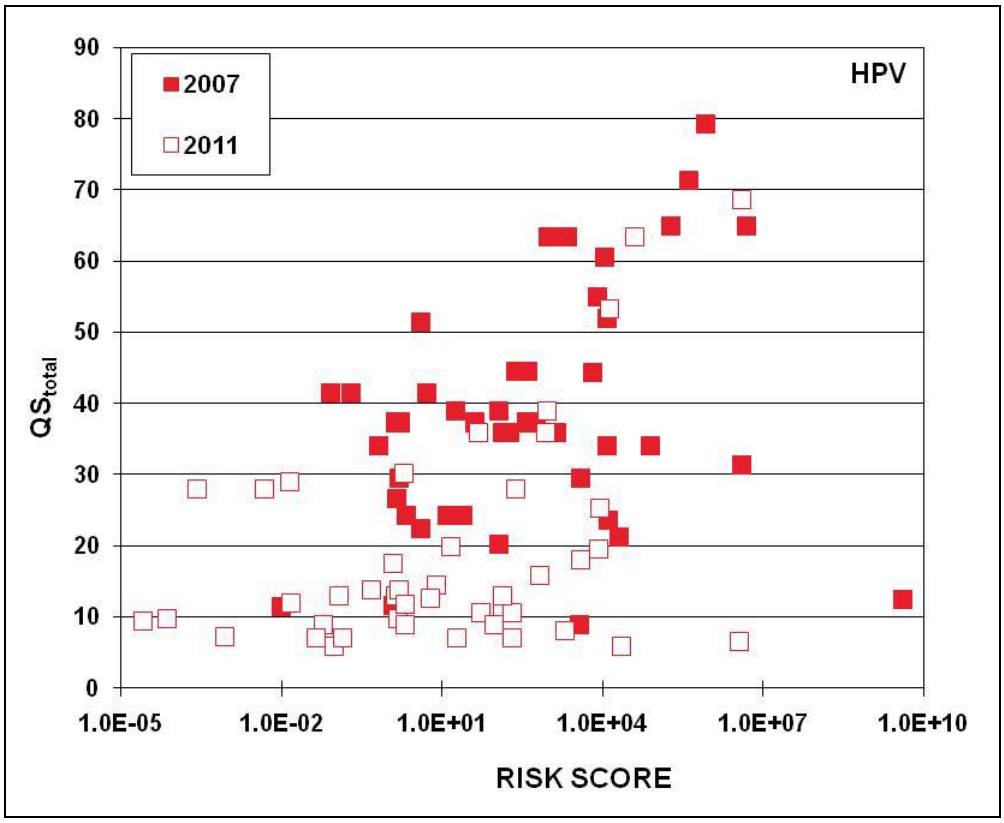
Figure 3.60: Comparison of baseline and 2011 Quality Scores for HPV chemicals (n=44)



Source: Author's compilation

The evaluation of the Quality Score (QS_{total}) presents in the whisker plot (figure 5.4) showed a similar downward trend of the scores compared to baseline. The geometric mean and the median decreased significantly.

Figure 3.61: Risk/QS_{total} scatter plot for HPV chemicals (n=44): 2007 baseline-2011 comparison



Source: Author's compilation

Figure 3.61 shows a shift toward better quality and lower risk.

For SVHC substances

For SVHC evaluation, 16 substances are taken into account. Distribution of Risk and Quality Scores are presented in Table 3.49. As is shown for HPV substances, the decrease in Risk and Quality scores are observed for SVHC substances. The median and the geometric mean of Risk Score are almost 6 and 10 times respectively lower in 2011 compared with the value obtained for the baseline of 2007. For the Quality Score, the median and the geometric mean are almost 2 times lower for both.

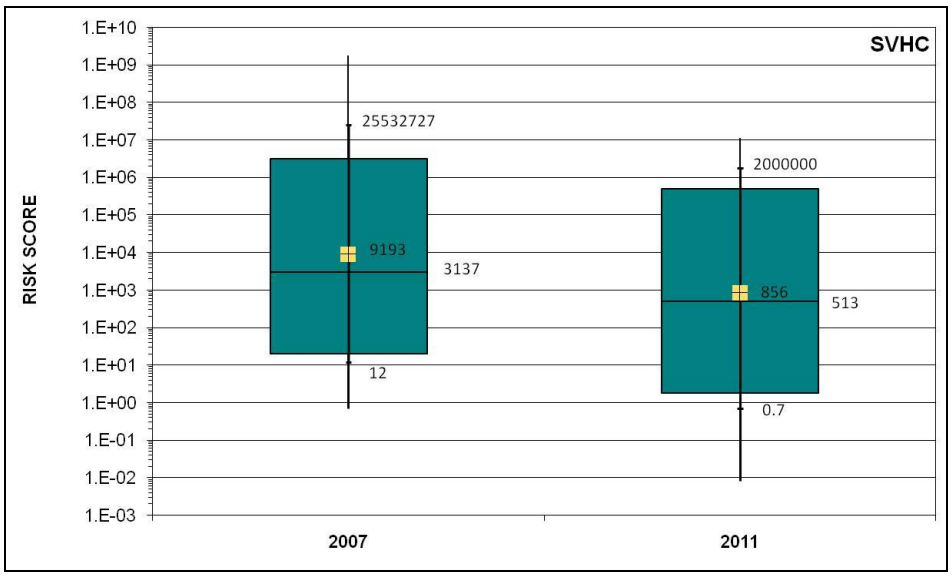
Table 3.49: Distribution results of Risk Scores and Quality Scores for 16 SVHC substances in 2007 and 2011

		2007	2011
Distribution of Risk Scores for SVHC substances (n=16)	Median	3137	513
	GM	9193	856
	10th percentile	12	0.7
	25th percentile	20	1.9
	75th percentile	3275645	502567
	90th percentile	25532727	2000000
	MIN	0.72	0.0084
	MAX	1811042746	10000000
		2007	**2011**
Distribution of Quality Scores for SVHC substances (n=16)	Median	27	14
	GM	31	16
	10th percentile	16.2	6.8
	25th percentile	17	12.5
	75th percentile	55	22
	90th percentile	61	40
	MIN	13	4.5
	MAX	69	58.5

Source: Author's compilation

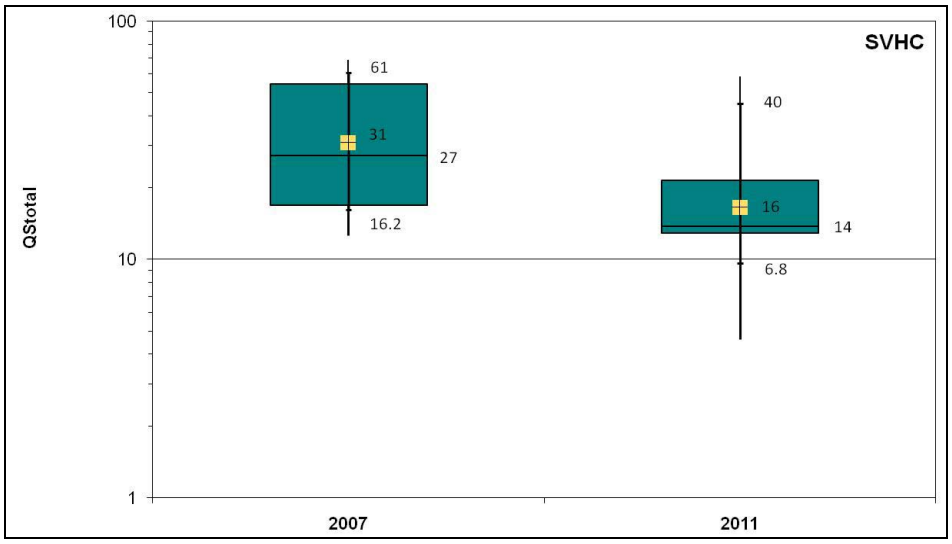
Whisker plots are presented in Figure 3.62 for the comparison of baseline and 2011 Risk Scores and in Figure 3.63 for the comparison of baseline and 2011 Quality Scores (Q_{Stotal}). This figure shows an improvement in average and median values of the risk score, however, the dispersion of the points highlighted by intercentiles space shows that the extent and the inequality of risk scores is equivalent to that observed for the baseline in 2007.

Figure 3.62: Comparison of baseline and 2011 Risk Scores for SVHC chemicals (n=16)



Source: Author's compilation

Figure 3.63: Comparison of baseline and 2011 Quality Scores for SVHC chemicals (n=16)

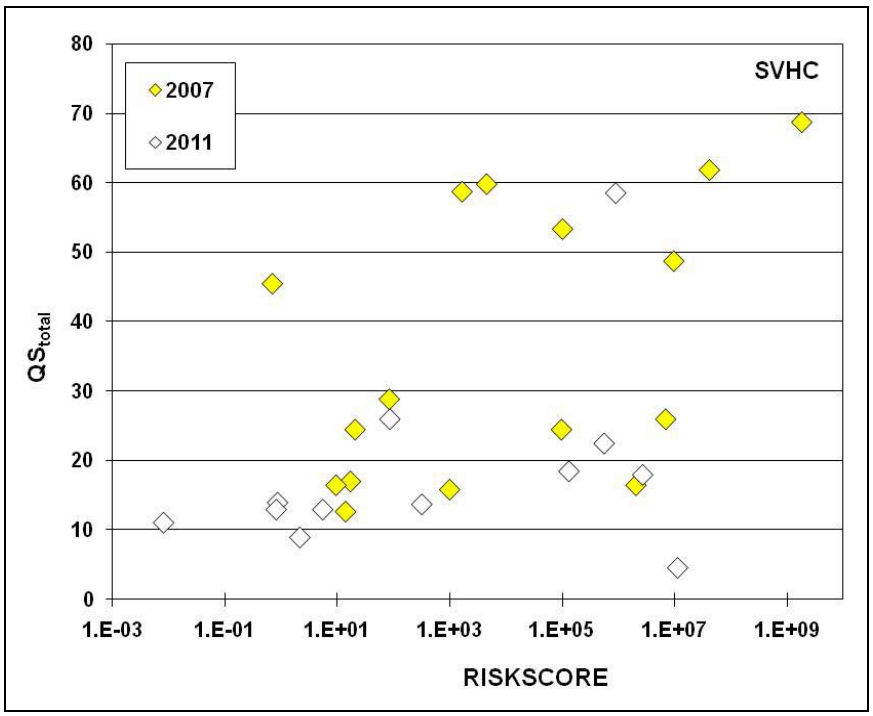


Source: Author's compilation

With regard to the Quality Scores, lower values of the median and the geometric mean shows an increase in data quality. In addition, the quality of the data is more homogeneous than those of 2007 since the thickness of the box plot was halved in 2011.

The scatter plot presented in Figure 3.64 shows a general movement of the data points towards the lower Risk Score and better quality in 2011 as for HPV substances.

Figure 3.64: Risk/QStotal scatter plot for SVHC chemicals (n=16): 2007 baseline-2011 comparison



Source: Author's compilation

3.2.5.3 Analysis level

For humans via the environment, this analysis is based on the analysis done in the consumer impact area for toxicity estimates and in the environment impact area for exposure estimate determination.

Among the 60 dossiers, an evaluation of risk for humans via the environment is presented only for 10 of them. Adequate monitoring data have not been found for any of them and the data concerning the exposure are obtained by modelling.

Basis and quality of data

For this area, the calculation of the total quality score is based on toxicity score obtained for consumer area. In this Chapter, an increase from 8% to 52 % of experimental data is underlined. This rise is directly linked to the DNELs in the REACH registration dossiers.

The quality score for exposure (QSexp) is linked to the exposure quality score of the environment area and the second term is specifically based on the quality of data available for the assessment of exposure of humans via the environment. In the absence of specific information, this parameter is based on the log Kow of the substance and the validity domain of the model used.

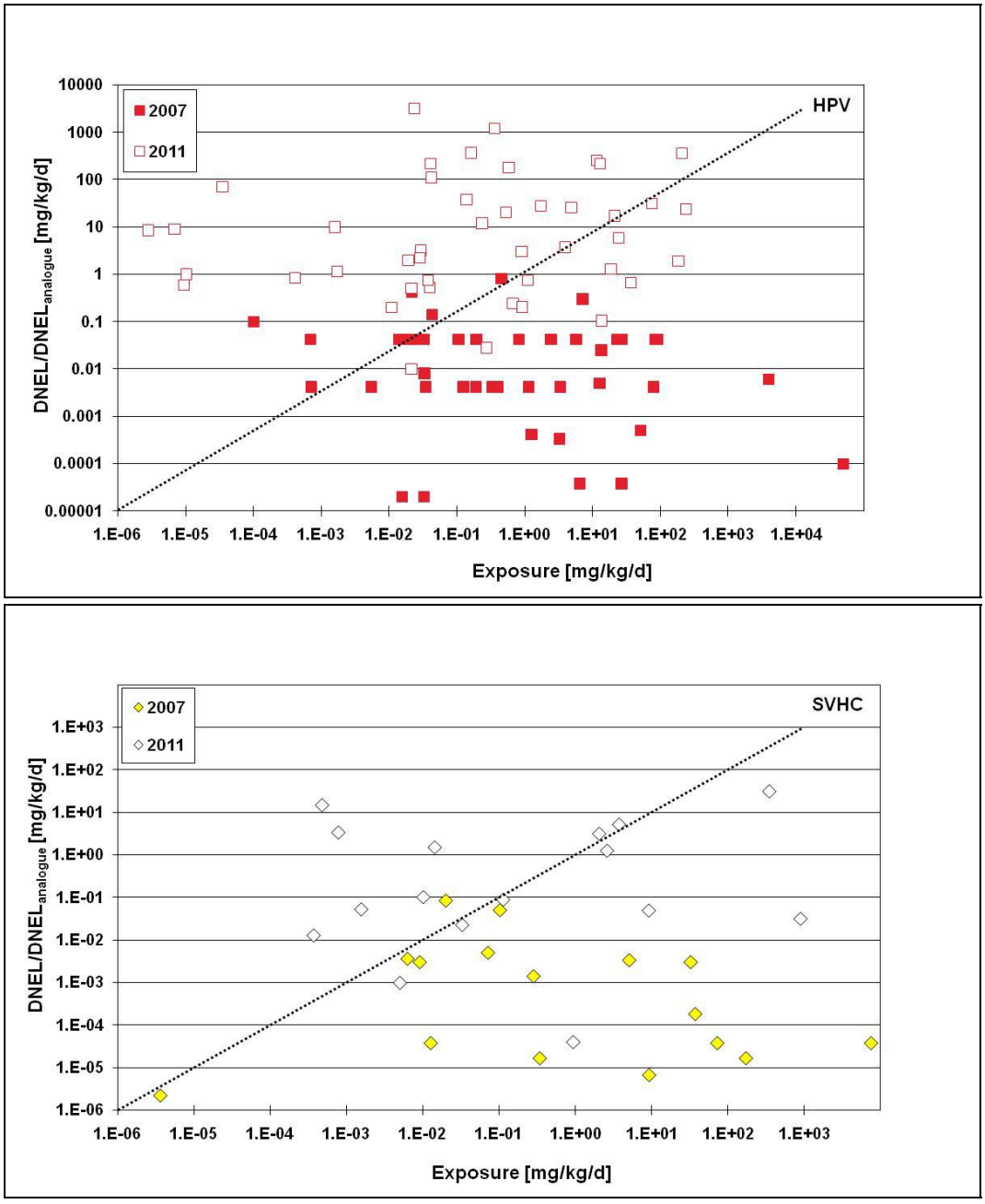
Table 3.50 presents the comparison of the distribution of QSexp between the baseline and 2011. Consequently, the increase of QSexp could be explained with the improvement of the quality data as Kow linked to the registration dossier.

Table 3.50: Distribution of QSexp: Baseline – 2011 comparison

		2007	2011
Distribution of Quality Scores for exposure (n=60)	Median	5.7	4.9
	GM	5.6	4.8
	10^{th} percentile	4.5	3.5
	25^{th} percentile	4.9	3.6
	75^{th} percentile	6.5	6.1
	90^{th} percentile	7.6	6.5
	MIN	2.5	1.625
	MAX	8.5	7.9

Source: Author's compilation

Figure 3.65: Analysis of the exposure and toxicity estimates (mg/kg/d) for humans via environment area. HPV and SVHC substances



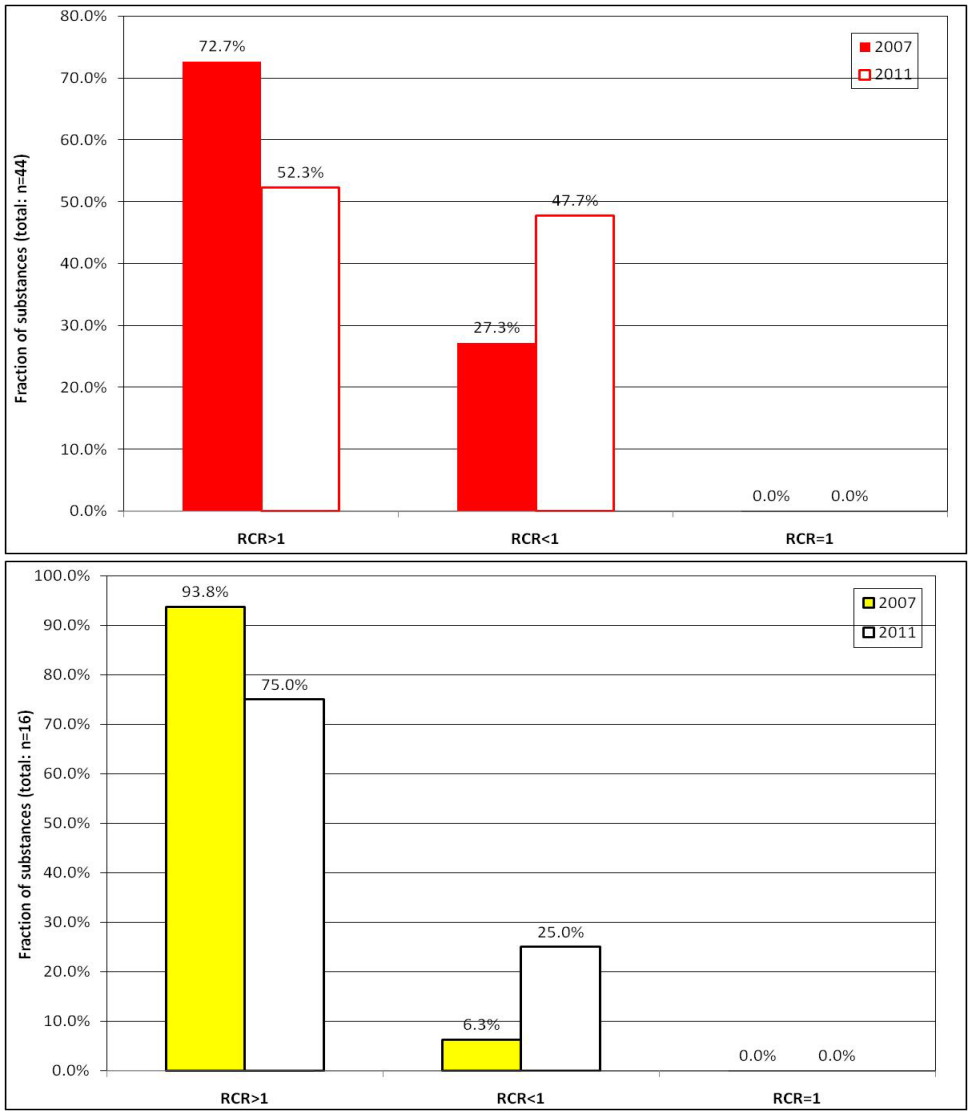
Source: Author's compilation

Figure 3.65 shows the assumed exposure concentration on the x-axis and the assumed safe concentration (as expressed by the DNEL (or analogues) on the y-axis for HPV in the first figure and SVHC in the second one. The dashed diagonal line discriminates exposure higher or lower than DNEL or analogue. A main part of HPV and SVHC considered in 2011 is above the dashed line. For this figure a shift is clearly visible towards RCRs lower than one (to the upper left-hand triangle in fig. 3.65). This decrease of RCR seems to be a direct consequence of the increase of DNEL values observed.

Risk Characterisation Ratios

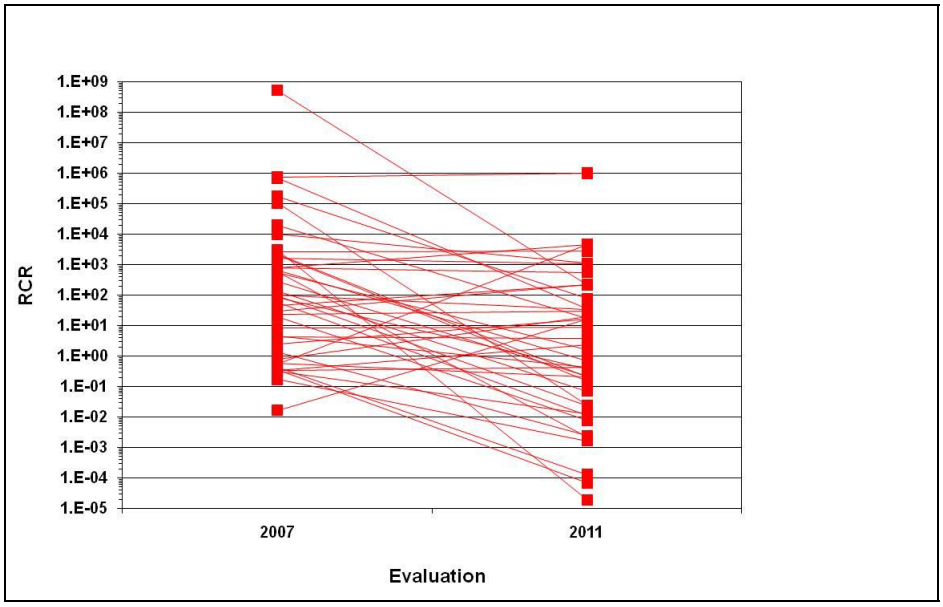
In Figure 3.65, the points below the line show Risk Characterisation Ratios above 1 (exposure > DNEL). Between 2007 and 2011, the number of RCR above 1 decreased from 72.7 to 52.3% and from 93.8 to 75% for HPV and SVHC chemicals respectively (see Figure 3.66). Consequently, the number of RCR below 1 decreased from 27.3 to 47.7 and from 6.3 to 25% for HPV and SVHC respectively. As mentioned earlier, the decrease of RCR is linked with the increase of DNELs.

Figure 3.66: Fractions of Risk Characterisation Ratios below or above 1 for HPV and SVH chemicals



Source: Author's compilation

Figure 3.67: Shift of RCR between 2007 and 2011 at the individual level



Source: Author's compilation

For the baseline, 47 substances had a RCR above 1 and 13 below 1. In 2011, for 35 substances the RCR is above 1 and 25 below 1. In 3.67, the extent of the range of RCR remains unchanged in 2011 compared to the baseline even if RCR decrease. Most of RCR decrease and the minimum RCR significantly decrease in 2011 compared to baseline.

3.2.5.4 Summary and Conclusions

Among the reference substances registered in 2011, reported in 2011 and evaluated in this report, no specific data on exposure for humans via environment is reported. All data are calculated by modelling.

The quality of toxicity assessment (DNEL or analogue) is clearly better quality in 2011 than in 2007 (median of QStox from 7 to 5), thanks to the determination of DNEL from experimental data in the CSRs.

The aggregated Risk Scores (for 60 substances) are globally lower in 2011 than in 2007 (GM from 437 to 16.3), and the quality is improved (GM of Qscore from 33.7 to 15.2). This shift is mainly explained by the improvement of data availability for toxicity leading to higher DNEL.

In 2011, the rate of substances with RCR above 1 decreased by 22% compared to the baseline. This reduction is mainly due to the increase of the DNEL or analogue.

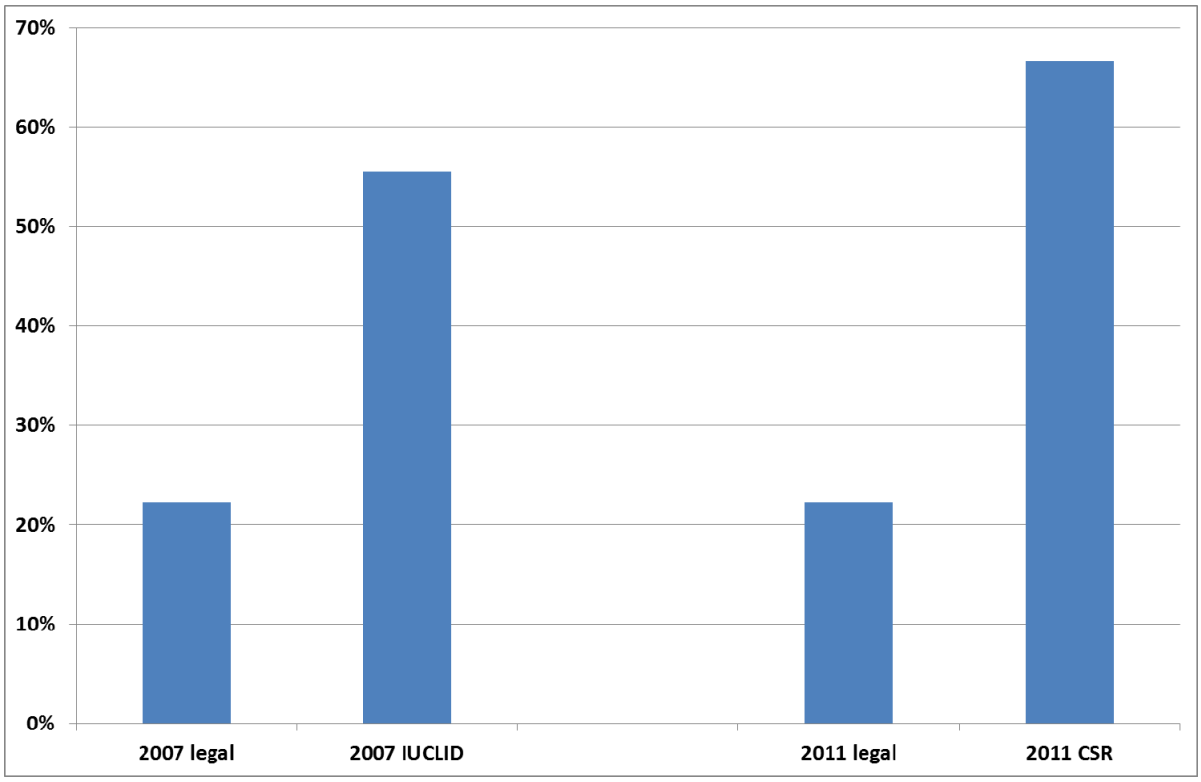
3.3 LPV and MPV chemicals – some initial trends

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 entering 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.

Figure 3.68: Changes in classification between the baseline (2007) and the 2011 evaluation: Percentage of substances for which information on classification was available



Source: Author's compilation

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.

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.

4 Further aspects

4.1 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 analysis by ECHA shows withdrawing from the market as 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 by May 2018.

4.2 Changes in the tonnage band of the reference substances

In 2011, data from the registration dossiers confirmed the assumed 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. For one HPV chemical, a 100-1000 t registration dossier was evaluated and the tonnage was given as < 1000 t/a. However, 'intermediate' registration dossiers > 1000 t/a exist for this substance, so that this substance can be classified as HPV. In another case, ECHA extracted an estimated tonnage of just below 1000 t/a although the substance was registered as a transported isolated intermediate above 1000 t/a. ECHA stated that their data extraction might be missing some of the 'intermediate tonnages', so that this substance can be classified as HPV as well. 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.

The other group of substances (SVHC) has not been selected in relation to tonnage bands and was therefore not analysed in relation to shifts.

4.3 Relevance of additional company specific data

One objective of the REACH baseline study is to analyse whether REACH leads to an improvement in the knowledge on the properties of a substance and to a reduction of the risks associated with substances regulated under REACH. This requires 'measuring' indicators for the quality of the data and for the risks associated with the reference substances of the study. In order to generate robust results, the methodology has to be applied to a group of substances which is large enough to represent the whole group of REACH related substances.

To generate an indicator for the quality of the data available at a given point in time, a documentation and assessment of the available data is required. The methodology for this step should allow repetition of the assessment at a later point in a reproducible manner.

For a given substance, data on inherent properties can be distributed among a wide range of sources. Apart from data which are publicly available, companies can have additional data, e.g. from unpublished toxicological studies. Early analysis of publicly available data has shown that for many substances data on substance properties have been missing. At present it is unknown for the public to which extent chemical industry in Europe has been the owner of additional studies on substance properties reducing the lack of data stated in literature.

For the REACH baseline study it was necessary to make a clear decision which data sources have to be analysed in order to determine which data are available for a reference substance.

It has not been the objective of the study to make a substance specific toxicological and eco toxicological risk assessment, including the development of new occupational exposure levels. For such a purpose it would be necessary to take into account as much studies as possible, to include studies owned by companies and discuss the results with the interested parties.

Far away from the aim to make a substance-specific risk assessment, it has been the aim of the REACH baseline study to characterise for a large number of substances which data has been 'publicly available' in 2007,

supplemented by data from IUCLID 4 dossiers which have been made available for the assessment by EUROSTAT. There are five reasons for this decision:

- Based on the experience from the members of the project team, the main data sources used for the study are expected to give a sufficient picture on data availability for the purpose of the study. Data sources selected for the study include IUCLID 4 files which intended to collect the knowledge of companies on 'their' substances. They include the results classification and labelling which took place on the base of the knowledge companies had on substances.
- It would be very time-consuming to screen all known potential data sources (substance properties, exposure situations) for additional data on more than 200 substances.
- Including all data sources would make it more difficult to do the analysis in an 'objective' manner. Individual knowledge of the assessor how to find further data could influence the result of the assessment in a non-reproducible way.
- Including non-reviewed studies from different sources requires additional expert judgement regarding reliability of the studies.
- Typical additional company specific data (e.g. the VCI minimal data set or a specific toxicological study) would have only minor effect on the Quality Score of the reference substance. Major changes in the Quality Score can be achieved only by peer-reviewed data e.g. an SIDS document or a EU RAR, by changes in an OEL or a deviating R phrase. These kinds of data are covered by the REACH baseline study.

4.4 Consideration of risk management measures and data on real exposures

In some discussions, industry associations assumed that the exposure estimates of the REACH baseline study overestimate the real exposure situation. Companies may have additional risk management measures in place which are not publicly documented. These measures are communicated in the supply chains in the safety data sheets. They would lead to lower exposures than assumed in the REACH baseline study. Calculated exposure estimates of the REACH baseline study would be too high.

In order to clarify this point, we analysed the methodology applied in the REACH baseline study to derive the exposure estimate regarding the question of taking into account risk management measures. (The methodology to derive the exposure estimates for work places has been described in detail in Annex I of the REACH baseline study).

The analysis leads to the following findings:

- The aim of the exposure assessment within the REACH baseline study is 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. These measured data take into account the risk management measures which are in place in the companies involved.
- Preferred data sources for the derivation of the exposure estimate have been European Risk Assessment Reports and comparable documents, e.g. Environmental Health Criteria, SIDS, CICAD. These reports take into account the current practice of risk management in the companies.

As far as measured exposure data have been used for the calculation of the toxicity estimates, it can be assumed that the applied RMMs are taken into account adequately.

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 cases estimation is derived from average values. The upper limit has been set to 50% of the maximum exposure which has been measured (Annex I, p. 13).
- If only ranges are available, 0,5 x maximum is used to derive the exposure estimate.
- Exposure values reported 20 years ago or before are not taking into account, if more recent data are available. (Annex I, p.13).
- 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 is derived from modelling approaches. The methodology for the impact area workers is described in chapter 3.4 of annex I. Also in this case, risk management measures are partly taken into account.

Most importantly, the 5 years update shows that the baseline exposure estimates for the impact area of workers were not over conservative. While there is a moderate decrease in statistical descriptors of exposure estimates in 2011 compared to baseline (median 5.0 mg/m3 -> 2.9 mg/m3; GM 11 mg/m3 -> 4.0 mg/m3), the substance-specific evaluation shows that the exposure estimate actually increases in 2011 for 35% of the substances and remains equal for almost 9% (Chapter 3.2.2.3). In fact, there are several substances, for which baseline modelling resulted in lower exposure estimates than ECETOC TRA modelling reported in CSRs in 2011 (but the latter still ensures RCRs < 1).

4.5 Authorisation and restriction of reference substances

Since the first assessment in 2007, reference substances of very high concern 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.

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