6. Results and discussion

The aim of this study was to test a number of indicators and different other information which have been proposed for measuring and evaluating the impact of the authorisation process.

These indicators have been elaborated in the Risk Management Expert Group established by ECHA (1) with the intention to specifically answer questions of political relevance in the discussion of authorisation under REACH such as:

- Has the objective of substitution worked?
- Are there less articles containing SVHCs on the market or has production and uses of SVHCs just been shifted outside Europe?
- What are the major substitutes for SVHCs and are these alternates safer?
- Have authorisation decisions led to better control of risks?
- Is the authorisation as such or parts thereof a cost-effective policy for protecting man and environment?
- Does authorisation work better for certain types of substances than for others and would this help to make more appropriate choices on SVHC candidates?
- What other modifications should be considered to improve the workability and efficiency of the authorisation instrument or individual steps thereof?

The comprehensive results obtained for the substances investigated in this project can be found in the Annex I. Annex I contains the results for indicators based on registration data, the SPIN database, EUROSTAT and a market study on phthalates, and are presented by substance groups. For those substances which have not been registered, there is only very limited data available, most of which are based on the SPIN database. Monitoring data such as data from the European Pollutant Release and Transfer Register (E-PRTR) or data from European ambient monitoring programmes are available for only few parameters of interest are included in the Annex where relevant.

Of a total of 34 SVHCs considered in this study, 23 had been registered in IUCLID. For 26 substances data are available in the SPIN-database, for three substances Eurostat information and for four substances E-PRTR data are available. The market study specifically addressed only the group of phthalates.

The assessment of indicators was supplemented by a survey of registrants, authorisation holders and potential downstream users of the 34 SVHCs of interest, targeting their experiences with the authorisation under REACH. The applied questionnaires and the results of the survey can be found in Annex II.

For any technical and numerical details on the raw data and the manipulation thereof the reader is referred to the comments provided in the Annexes.

The following discussion is organised as follows. Section 6.1 presents representative or typical results obtained for the proposed indicators and other information’s and critically examines the appropriateness and usability of these data for the monitoring of the potential impacts of authorisation under REACH.
Section 6.2 provides a condensed summary of the findings in a slightly different presentational approach: The results are discussed as per substance group, considering the following relevant substance groups: phthalates, glymes, lead compounds, halocarbons, aromatic amines, organophosphorous compounds, arsenic compounds and ADCA.

6.1. Summary of the results obtained for indicators and collected information

This section aims at a critical discussion of the usability and appropriateness of the proposed indicators and other type of information. Generally it was found that many of the collected raw data had certain biases, gaps or flaws which limit their applicability. The reasons for this and the consequence for the interpretation of the data are discussed below.

6.1.1. Number of registrations and spontaneous updates

The numbers of registrations and spontaneous updates were collected from the IUCLID database. The presumption was that the authorisation process would have a direct impact on the number of registrations and spontaneous updates. Especially for those substances for which alternatives are available on the European market, it can be assumed that registrants decided to decrease or stop their manufacturing/importing activity within the EU in order to avoid cost-bearing activities. Such changes should be visible in decreasing numbers of registrations and an increasing intensity of registration updates, presumably linked to specific milestones in the authorisation process. This reaction is expected to be at the sunset date, as only then the registrants have to stop using the concerning SVHCs. If there is a clear decline in the number of uses or spontaneous updates before the sunset date, it could be an indication to reduce the priority of the substance for inclusion in A.XIV An overview of the number of full and still active registrations over the timeline can be seen Figure 8 shows those registered SVHCs which have already been included in Annex XIV. For those substances the first registration date occurred only after their inclusion in the candidate list. Figure 9 contains the other registered SVHCs.

Starting with the assumptions that the inclusion of a substance in the candidate list may have an impact on the number of registrations, it turned out that such an effect was not observed. For some substances this assumption could not be tested simply because the date for the inclusion in the candidate list was prior to the first registration date (FRD) and, therefore, no or only few registrations were available at the early stage of the authorisation time line. For those substances which were registered at or before the time of inclusion into the candidate list (Figure 9), clearly no decline in the number of registrations has been observed.

The most remarkable change following the inclusion in the candidate list of the registered SVHCs is a slight increase of the number of registrations at the next milestone, either the inclusion in Annex XIV (Figure 8) or the recommendation for inclusion in Annex XIV (Figure 9). The reason for these increases is probably because of the pressure from ECHA due to their priority assessment.

For most substances depicted in Figure 8, there are also slight changes in the numbers of registrations observed at the latest application date (LAD) and/or the sunset date. The observed effect was, not unexpectedly a decrease in the number of registrations as some registrations had been inactivated. However, for some substances, as for example MDA and
diarsenic trioxide, the number of registrations increased and for others such as diglyme and BBP the number of registrations did not change at all.

Figure 8: Number of all active registrations for the substances included in Annex XIV. The graph on the left depicts DEHP = bis(2-ethylhexyl)phthalate, DBP = dibutyl phthalate, DIBP = diisobutyl phthalate, Tris = tris(2-chloroethyl) phosphate, Ditri = Diarsenic trioxide, MDA= 4,4'-diaminodiphenylmethane, TCE = trichloroethylene and BBP = Benzyl butyl phthalate. The Milestones A and B are for Ditri and TCE the FRD and the final A.XIV recom., respectively and for the other substances it is the other way around. The graph on the right side depicts Diglyme = bis(2-methoxyethyl)ether, Form = formaldehyde oligomeric reaction products with aniline, MOCA = 2,2'-dichloro-4,4'-methylenedianiline and EDC = 1,2-dichloroethane

Figure 9: Number of all active registrations for the substances included on the candidate list but not yet on Annex XIV. The Milestones A, B, C and D are the milestones FRD, RoI SVHC, Candidate List and Final A.XIV Recom. for the substances: DIPP = diisopentyl phthalate, Trix = trixylyl phosphate, PBO = lead monoxide, orange lead, PLTS = pentalead tetraoxide sulphate, TLS = tetralead trioxide sulphate, EGDME = 1,2-dimethoxyethane, TEGDME = tetraethylene glycol dimethyl ether, ADCA = diazene-1,2-dicarboxamide (C,C'-azodi(formamide)), BCA= 1,2-benzenedi-carboxylic acid, di-C6-10-alkyl esters. In case of the substances EGME = 2-Methoxyethanol and EGEE = 2-Ethoxyethanol the milestones stand for RoI SVHC, Candidate List and FRD, respectively.
A general conclusion from this analysis is that candidate listing does not seem to have any significant impact on the number of registrations for the tested SVHCs. The causes for the observed slight increase of the numbers of registrations at the following milestone (inclusion in Annex XIV or recommendation for inclusion) is probable because of the pressure from ECHA due to their priority assessment.

A relatively similar behaviour is found in the results for the number of registrations which were spontaneously updated (Figure 10 and Figure 11). Only for DEHP, for the lead compounds, and for ADCA remarkable increases for this indicator are observed. For DEHP the most significant increase of the number of spontaneous updates is observed from inclusion in Annex XIV to the LAD, while for the lead compounds and for ADCA the most remarkable increase in updates was from candidate listing to the decision of ECHA to recommend the inclusion in Annex XIV of these substances.

It is noted that spontaneous updates are those updates which are made by registrants on their own initiative and not caused by interventions by authorities. It was not possible within the scope of this project to analyse the motivations of the updates by registrants. In particular for the lead compounds it can be speculated that one reason of updates may have been the clarification about the status of those compounds as either being substances, mixtures or articles. In this case the authorisation process can be envisaged as having an indirect effect by clarifying an interpretative issue.

Figure 10: Number of spontaneous updates for the substances included in Annex XIV. The graph on the left depicts DEHP = bis(2-ethylhexyl)phthalate, DBP = dibutyl phthalate, DIBP = diisobutyl phthalate, Tris = tris(2-chloroethyl) phosphate, Ditri = Diarsenic trioxide, MDA= 4,4’- diaminodiphenylmethane, TCE = trichloroethylene and BBP = Benzyl butyl phthalate. The Milestones A and B are for Ditri and TCE the FRD and the final A.XIV recom., respectively and for the other substances it is the other way around. The graph on the right side depicts Diglyme = bis(2-methoxyethyl)ether, Form = formaldehyde oligomeric reaction products with aniline, MOCA = 2,2’-dichloro-4,4’-methylxedianiline and EDC = 1,2-dichloroethane.
Substances on CD

Figure 11: Number of spontaneous updates for the substances included on the candidate list but not yet in Annex XIV. The Milestones A, B, C and D are the milestones FRD, RoI SVHC, Candidate List and Final A.XIV Recom. for the substances: TRIX = trixylyl phosphate, PBO = lead monoxide, Orange Lead, PLTS = pentalead tetraoxide sulphate, TLS = tetralead trioxide sulphate, EGEE = 2-ethoxyethanol, ADCA = diazene-1,2-dicarboxamide (C,C'-azodi(formamide)) and BCA = 1,2-benzenedi-carboxylic acid, di-C6-10-alkyl esters. For the substance EGME = 2-Methoxyethanol, the Milestones are: RoI SVHC, Candidate List and FRD. For the other substances on CD there were no spontaneous updates.

As a general conclusion regarding the substances depicted in Figure 10 the period between the inclusion in Annex XIV and the LAD seems to have the most remarkable impact on registration updates but this is true only for some SVHCs while for others the number of updates is not or only very little increased. The precise causes for these impacts remain to be explained but it can be probably assumed that registrants who are interested in applying for an authorisation will have a strong motivation to improve their dossiers prior to the latest application date, specifically for the downstream uses and use scenarios which they aim to defend in their authorisation application. This effect while not being easy to interpret can probably be considered as a trigger for dossier improvements which is a positive impact. The remarkable increase of dossier updates for the lead compounds is probably an artefact which is associated with a clarification of the status of those compounds as either being substances, mixtures or articles but could also be the motivation to reduce priority of the substance for inclusion in A.XIV

As additional information Table summarises the average number of (full) registration updates per dossier for those SVHCs which have already reached the latest application date (LAD) in the authorisation process. This figure is defined as the number of spontaneous updates at the LAD (as measured from the previous step in the authorisation time line which is the inclusion in Annex XIV) divided by the number of active dossiers. This number could be roughly considered as a measure of the intensity of dossier updates. Of course, this indicator must be

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7 Note that the IUCLID data for this study refers to the date October 2015. The table does not contain three further substance because they have reached the LAD only after this date (EDC, MOCA, Form).
considered with care as a high value of the average number of updates may not necessarily be representative for the update intensity of all dossiers. If one or only few of the dossiers were intensively updated (for whatever reason) while most of the other dossiers were not, the average update per dossier would be high but relatively meaningless as an indicator for the dossier updating intensity. With this caution in mind, Table clearly shows that the number of updates at the latest application date were for most SVHCs significantly below one, indicating that the majority of dossiers have not at all been spontaneously updated while approaching the LAD.

Table 10: Number of spontaneous updates of dossiers by registrants between the inclusion in Annex XIV and the latest application date (LAD)

<table>
<thead>
<tr>
<th>Substance</th>
<th>No. of spontaneous updates n at LAD</th>
<th>No. of dossiers M at LAD</th>
<th>n/M</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tris</td>
<td>2</td>
<td>2</td>
<td>1,0</td>
</tr>
<tr>
<td>Ditri</td>
<td>2</td>
<td>2</td>
<td>1,0</td>
</tr>
<tr>
<td>DEHP</td>
<td>7</td>
<td>21</td>
<td>0,7</td>
</tr>
<tr>
<td>DIBP</td>
<td>1</td>
<td>2</td>
<td>0,5</td>
</tr>
<tr>
<td>DBP</td>
<td>2</td>
<td>6</td>
<td>0,2</td>
</tr>
<tr>
<td>MDA</td>
<td>2</td>
<td>8</td>
<td>0,3</td>
</tr>
<tr>
<td>TCE</td>
<td>1</td>
<td>6</td>
<td>0,2</td>
</tr>
<tr>
<td>BBP</td>
<td>0</td>
<td>1</td>
<td>0,0</td>
</tr>
</tbody>
</table>

The results in Table 10 bring the observations made in Figure 10 in a better perspective. Only for three SVHCs (Tris, Ditri, DEHP) the average number of updates is above 0.5, meaning that for all other substances less than every second dossier had been updated in the period from inclusion in Annex XIV to the LAD. This shows that even though this point in the timeline of authorisation has an observable impact, the updating intensity is generally low.

As a more general conclusion, the indicators based on the number of registrations or on the number of spontaneous dossier updates generally do not exhibit significant change at any of the stages of the authorisation process and thus do not seem to be reliable indicators for measuring impacts from the authorisation process. In particular, candidate listing does not have measurable or interpretable effects on the number of registrations. The most remarkable changes for some of the selected SVHCs have been seen in increases of registration updates in the period between inclusion in Annex XIV and the latest application date (LAD) and for others after the inclusion on the candidate list. Both effect were only observed for some SVHCs and did not occur with significant updating intensity for most SVHCs. While it was not possible in this project to explore the motivation of registrants for their registration updating it can be speculated that probably the most significant impact of the authorisation process on registration updating is caused by a general raising of awareness of registrants but also of their downstream users which may lead to an intensification of information exchange along the supply chain and a resulting motivation to correcting errors or clarifying misinterpretations, and thus result in dossier improvements. The high intensity of updating after the candidate list is probable because of the pressure due to the priority assessment by ECHA. From the data shown in this study, the most significant dossier updates occurred for substances with a latest application date in the time period which followed the inclusion in Annex XIV, lasting until the latest application date and for the substances without a latest application date it was after the inclusion on the candidate list.
6.1.2. Use-Profiles

The second type of indicators which have been investigated in this project refers to the downstream uses which are described in detail in the exposure scenarios included in the chemical safety reports of registration dossiers. The motivation for studying those indicators was the expectation that the authorisation process would motivate registrants to carefully review and revise the downstream uses by selecting those which they intend to defend in an authorisation procedure while abandoning other less relevant uses. Even in cases where a full substitution was not possible, this revision could potentially lead to an improvement of dossier quality as the information contained in the dossiers better reflect the real situation. If this actually was the case here is one of the questions specifically considered in the following discussion. The specified uses for the different substances have been extracted from the IUCLID database. IUCLID applies a number of different use descriptors which have been summarised in section 2 and Annex III. They can be roughly divided into four groups of indicators:

- Use descriptors: Indicators which describe the uses of the substance on the market, including the sector of use category (SU), the chemical product category (PC) and the article category (AC)
- LCS-descriptors: Indicators which describe the life-cycle stage to which the substance can be assigned to (such as manufacture, formulation or re-packing, professional end-use, industrial end use, consumer end use or (article) service life)
- Process descriptors: Indicators which describe the manipulative process (PROC) or the technical function (TF) in which the substance is applied
- Exposure descriptors: Indicators which describe for each use the contributing activities, including the process category (PROC) related to workers exposure, the product category (PC) and article category (AC) related to consumers exposure and the environmental release category (ERC) related to environmental exposure

There are essentially two ways for calculating the indicators of the use-profile. One is to simply sum up the uses assigned to a certain category for all use scenarios of all registrations. This clearly leads to double-counting of uses falling into the same use category. The other option is to count each use category only once. While the first option provides a measure of the intensity of a certain use category, the second option is a sensitive measure of changes in the use spectrum (changes in the number of different use categories reflect either the abandoning of previous use categories or the introduction of new ones). The focus in this discussion lies on the impact of the authorisation process on the use spectrum, so for the following figures, option 2 was selected (in Annex I data for both options are provided).

It is noted here that use-profiles should be generally handled with some care as there may be misattributions after software updates of IUCLID. Additionally there are two more limitations which should be noted: Firstly, among registrants there is a lack of common understanding of the use descriptors, particularly at the start of REACH, which has led to many updates/refinements and secondly, there are cases where registrants simply ticked wrong use descriptors.

A comprehensive presentation of the results on indicators based on use-profiles is provided in the Annex I for each substance group. As can be seen there, the most significant changes in

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8 This information was communicated by ECHA
the use-profile indicators were observed at the inclusion of a substance in Annex XIV or at the latest application date. This is not surprising in view of the results obtained for registration updates in section 7.1.1. In view of these results, the following figures include only those substances which are on Annex XIV and for which the latest application date has passed before the project deadline (substances labelled with “LADP” in Table 4). As the event of candidate listing had little impact on registrations (registration updates), only the following four steps in the authorisation process are depicted in the following five Figures: the two most important milestones, inclusion in Annex XIV (Annex XIV) and the latest application date (LAD) and the step prior to Annex XIV (termed “milestone X”) and the step following LAD (termed “milestone Y”)

Figure 12 shows the indicator for the use descriptors, i.e. the number of uses for the sector of use category (SU), the chemical product category (PC) and the article category (AC) over the time-line (unique category counting).

![Category of use: AC, PC and SU](image)

Figure 12: shows the indicators for the sector of use category (SU), the product category (PC) and the article category (AC) for all selected substances over the time-line (applying the option of unique category counting). DEHP = bis(2-ethylhexyl)phthalate, Tris = tris(2-chloroethyl) phosphate, Ditri = diarsenic trioxide, DIBP = diisobutyl phthalate, DBP = dibutyl phthalate, MDA = 4,4'-diaminodiphenylmethane, TCE = trichloroethylene, BBP = benzyl butyl phthalate

The most remarkable changes are observed for the number of article categories for BBP and DIBP. For DIBP no applications for authorisation have been submitted by the latest application date. Expectedly, the number of unique uses in the article categories, but also in the sector of use and product categories has decreased quite significantly after the LAD. The

Note that the steps milestone x and milestone y may be different for different substances. For example, milestone x is the first registration date for DEHP while it is the recommendation for inclusion in Annex XIV for DIBP.
remaining uses should be the ones that are not within the scope of authorisation. This, however, would require a more in-depth analysis of the registration dossiers and also probably a direct investigation through enforcement, which was not within the scope of this project. For BBP an increase in the chemical product categories and the article categories after the LAD can be observed. As BBP is also among the substances for which no application for authorisation had been submitted by the latest application date (LAD), the significant changes in AC (from 0 to 6!) and in PC (from 0 to 3) after the LAD is surprising and needs to be further examined.

For the remaining substances no or only unspectacular changes during the time period from inclusion in Annex XIV and the latest application date (LAD) have occurred in relation to the use-descriptors (unique counting).

In conclusion, looking more closely to the changes of the use-descriptors in dossier updates in the time period following the inclusion in Annex XIV until the latest application date, no or little changes occurred for most SVHCs. For some SVHCs reductions in the use-profile have been observed. This, however, should be interpreted with care, as the number of different articles on the market does not necessarily reflect the actual dimension of the potential exposure of customers to articles containing SVHCs as the number is not linked to the tonnages of SVHCs. Hence, the reduction in the number of articles may have marginal or significant effects depending on the total tonnages of SVHCs used for the production of the abandoned article category.

Where there are reduction in one of the use descriptors (e.g. AC), there are usually but not necessarily also reduction in the other descriptors (PC or SU). Significant decreases in use descriptors have been observed for two substances, the phthalate DIBP and trichloroethylene (TCE). For DIBP this result is understandable as there were no applications for authorisations, so the interest for further use of this substance in the EU is quite limited. The remaining uses should be outside of the authorisation regime. For TCE the change probably indicates that the use spectrum has been reduced in response to the authorisation process which as such can be regarded as a positive effect. It is remarkable that this effect did not occur for the other substances in Figure 12. Most surprising is a significant increase of the uses (AC, PC) for BBP after the latest application date as there were no applications for authorisation of uses for this substance.

Figure 13 and Figure 14 show the LCS-indicators describing the life-cycle stages for all selected substances over the time-line (also for the option of unique category counting).
Figure 13: Indicators describing the life-cycle stages manufacture, formulation and industrial use over the time-line (unique category counting). DEHP = bis(2-ethylhexyl)phthalate, Ditri = diarsenic trioxide, DIBP = diisobutyl phthalate, DBP = dibutyl phthalate, MDA = 4,4'-diaminodiphenylmethane, TCE = trichloroethylene, BBP = benzyl butyl phthalate, Tris = tris(2-chloroethyl) phosphate
Note: LCSs which have not been reported for a substance are not included in the figure.

Figure 14: Indicators describing the life-cycle stages professional use, consumer use and article service life use over the time-line (unique category counting). DEHP = bis(2-ethylhexyl)phthalate, DIBP = diisobutyl phthalate, DBP = dibutyl phthalate, MDA = 4,4'-diaminodiphenylmethane, TCE = trichloroethylene, BBP = benzyl butyl phthalate, Tris = tris(2-chloroethyl) phosphate
Note: LCSs which have not been reported for a substance are not included in the figure.
The LCS-indicator reflects the distribution of substance uses over the different life-cycle stages and thus can be regarded as a rough measure of the dispersity of the exposure of substances. There are more or less enhanced changes in the LCS-indicators in the time period between the inclusion in Annex XIV and the latest application date, and also after the LAD. However, most changes are difficult to interpret. A clear example is DIBP for which, similar to Figure 10 and Figure 11, the LCS-descriptors decrease sharply, indicating that there are only few uses left which should be outside of the scope of authorisation. Most cases need more sophisticated analyses which have not been possible in this project. It is noticeable that the indicator for the consumer categories (dotted lines in Figure 14) generally indicates that there is no consumer use (e.g. for diarsenic trioxide) or only relatively few consumer uses. This fact, however, cannot be quantitatively attributed to the authorisation process under REACH. It is quite obvious that the significant changes, decrease in the number of unique uses, occurred only after the latest application date (LAD). This is though not very surprising, as companies can continue using the SVHC until the sunset date has passed.

As an overall conclusion, LCS-indicators do not seem well suited to measure an effect of the authorisation process. In some obvious cases such as those SVHCs for which no application for authorisation had been submitted, the indicator should decrease, unless there are uses outside the scope of authorisation. In most cases changes in the LCS-indicators are difficult to interpret, and need additional case-by-case analysis which may be a useful tool for targeted enforcement actions.

Figure 15: Shows the indicators for the process (PROC) and the technical function (TF) for all selected substances over the time-line (applying the option of unique category counting). DEHP = bis(2-ethylhexyl)phthalate, Ditri = diarsenic trioxide, DIBP = diisobutyl phthalate, DBP = dibutyl phthalate, MDA= 4,4'-diaminodiphenylmethane, TCE = trichloroethylene, BBP = benzyl butyl phthalate, Tris = tris(2-chloroethyl)phosphate

Figure 15 depicts the changes of the indicators derived from process descriptors over the time line (applying the option of unique category counting). These changes are generally
unspectacular with the exception of DIBP, the reduction of uses relate to the reduction seen in previous figures and can be explained similarly.

Figure 16 shows the indicators based on the exposure descriptors over the time-line (applying the option of unique category counting). A similar behaviour and interpretation as for Figure 15 can be given here.

In conclusion, Figure 15 and Figure 16 also show that indicators based on either process or exposure descriptors do not seem appropriate for measuring impacts of the authorisation process for the SVHCs examined in this project. Like LCS-based indicators changes in these indicators are difficult to interpret, and need additional case-by-case analysis which may be a useful tool for targeted enforcement actions.

Figure 16: Indicators for the process category (PROC) and the environmental release category (ERC) over the time-line (unique category counting). DEHP = bis(2-ethylhexyl)phthalate, Ditri = diarsenic trioxide, DIBP = diisobutyl phthalate, DBP = dibutyl phthalate, MDA= 4,4’-diaminodiphenylmethane, TCE = trichloroethylene, BBP = benzyl butyl phthalate, Tris = tris(2-chloroethyl) phosphate

The previous data refers to the unique counting of use categories, as can be seen from the data in the Annex I the total sum of uses (including double counting of use categories) generally provide a similar picture. There are some exemptions though, in particular for the lead compounds considered in this project. The summed up uses generally show a quite significant decline of indicators (esp. for PROC and ERC) after the candidate listing (CD) while the number of unique uses tended to increase or stay unchanged. This fact may indicate that probably the number of downstream uses of the lead compounds decreased but additional types of uses have been added to the dossiers after the inclusion to the candidate list. It is noted that for other SVHCs than lead compounds candidate listing had no or little effects on the use-profile based indicators (compare Annex I).
It can be generally concluded that the simple aggregated numbers of use-profile based indicators do not exhibit a systematic and noticeable behaviour along the time line of the authorisation process and are indeed very difficult to interpret. The most significant changes of use-profile based indicators occur in the period between the inclusion of a substance in Annex XIV and the latest application date, and also thereafter. Candidate listing has not shown any measurable effect except for the lead compounds. The most sensible indicators seem to be the use category (SU), the chemical product category (PC) and the article category (AC).

It is important to note that the indicators may be flawed by a number of errors. Some registrants may not update their registrations regularly. Especially lacking updates following the sunset date may lead to misleading values of indicators. There are also remarkable findings of non-zero indicator values for those SVHCs for which no authorisation application had been submitted by the latest application date. The clarification of whether these findings are artefacts because of simple mistakes or rather uses which are outside of the scope of authorisation still needs to be examined and may merit a closer investigation.
6.1.3. Application for Authorisation - comparison with registration data

The indicators discussed above have shown quite different behaviour as a function of authorisation milestones. Even where changes occurred it seems that each substance or even each use of a substance must be considered individually.

Such a case-by-case analysis was outside of the scope of this study. However, it was decided to carry out a rough analysis of the applications for authorisation (AfAs) which had been submitted for the SVHCs of interest. The expectation was that this information may shed more light on the use-related data from registration dossiers.

All AfAs which had been submitted by mid December 2016 have been considered. For the following SVHCs ECHA has received authorisation applications by this deadline (2):

Table 11: Listing of all the SVHC’s which have an LAD before mid-December 2016. The nine substances in green are the SVHC considered in this study

<table>
<thead>
<tr>
<th>Substance</th>
<th>Number of received applications</th>
<th>LAD</th>
<th>Sunset Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bis(2-ethylhexyl) phthalate (DEHP)</td>
<td>6</td>
<td>21.08.2013</td>
<td>21.02.2015</td>
</tr>
<tr>
<td>Dibutyl phthalate (DBP)</td>
<td>3</td>
<td>21.08.2013</td>
<td>21.02.2015</td>
</tr>
<tr>
<td>Lead sulfochromate yellow (C.I. Pigment Yellow 34) and lead chromate molybdate sulphate red (C.I. Pigment Red 104)</td>
<td>1</td>
<td>21.11.2013</td>
<td>21.05.2015</td>
</tr>
<tr>
<td>Hexabromocyclododecane (HBCDD)</td>
<td>1</td>
<td>21.01.2014</td>
<td>21.07.2015</td>
</tr>
<tr>
<td>Diarsenic trioxide</td>
<td>4</td>
<td>21.09.2013</td>
<td>21.05.2015</td>
</tr>
<tr>
<td>Lead chromate</td>
<td>1</td>
<td>21.11.2013</td>
<td>21.05.2015</td>
</tr>
<tr>
<td>Chromium trioxide</td>
<td>27</td>
<td>21.03.2016</td>
<td>21.09.2017</td>
</tr>
<tr>
<td>Sodium dichromate</td>
<td>18</td>
<td>21.03.2016</td>
<td>21.09.2017</td>
</tr>
<tr>
<td>Sodium chromate</td>
<td>2</td>
<td>21.03.2016</td>
<td>21.09.2017</td>
</tr>
<tr>
<td>1,2-Dichloroethane (EDC)</td>
<td>15</td>
<td>22.05.2016</td>
<td>22.11.2017</td>
</tr>
<tr>
<td>Potassium dichromate</td>
<td>5</td>
<td>21.03.2016</td>
<td>21.09.2017</td>
</tr>
<tr>
<td>Ammonium dichromate</td>
<td>3</td>
<td>21.03.2016</td>
<td>21.09.2017</td>
</tr>
<tr>
<td>Diglyme</td>
<td>8</td>
<td>22.02.2016</td>
<td>22.08.2017</td>
</tr>
<tr>
<td>Arsenic acid</td>
<td>1</td>
<td>22.02.2016</td>
<td>22.08.2017</td>
</tr>
<tr>
<td>Chromic acid</td>
<td>1</td>
<td>21.03.2016</td>
<td>21.09.2017</td>
</tr>
<tr>
<td>Formaldehyde, oligomeric reaction products with aniline (technical MDA)</td>
<td>1</td>
<td>22.02.2016</td>
<td>22.08.2017</td>
</tr>
<tr>
<td>2,2'-dichloro-4,4'-methylenedianiline (MOCA)</td>
<td>1</td>
<td>22.05.2016</td>
<td>22.11.2017</td>
</tr>
</tbody>
</table>

Of these 18 substances nine substances are considered in the present study (see substances coloured green in Table 11). For those SVHCs the Applications for Authorisation (AfA’s) available at the ECHA website ((3), (4)) have been further investigated.
Comparison of uses applied for (AfAs) with registered uses (IUCLID)

One purpose of this exercise was intended to compare the uses applied for in the AfA’s with the registered uses in IUCLID. In an ideal world it could be expected that registrations are fully up-to-date with respect to the uses. So, use scenarios in registrations which are within the scope of authorisation should match with the uses for which an authorisation application has been submitted to ECHA. Based on this assumption a use-by-use comparison has been carried out in this project between use information from registrations and from AfAs, respectively. It should be noted, however, that the use-names in AfA’s are usually more detailed and comprehensive than the use-name descriptions in IUCLID. Hence a simple one-to-one comparison needs a highly specialised technological expertise which was not available to the author. But a comparison of the use-descriptors which are part of the AfAs with the use-descriptors in IUCLID can be carried out straightforward. Two examples are shown in Table 12 and Table 13 (for the other substances see Annex I).

The use-descriptors in red colour refer to those reported in the registrations but which are not covered by AfAs and vice-versa, the green coloured use-descriptors are those which have been applied for in AfAs but are not covered by IUCLID. In the Annex III a detailed list of the uses are provided.

Table 12: Comparison of use-descriptors in IUCLID with applied use-descriptors for Di(2-ethylhexyl)phthalate (DEHP, status May 2016)

<table>
<thead>
<tr>
<th>All uses after the Sunset Date as registered in IUCLID (Red - not applied for)</th>
<th>Uses applied for (Green - not listed in IUCLID)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SU: 0, 9, 10, 11, 12, 16, 20, 24</td>
<td>SU: 0, 10, 12, 16, 17</td>
</tr>
<tr>
<td>ERC: 1, 2, 3, 4, 5, 6a, 7, 8a, 8c, 10a, 11a, 12a</td>
<td>ERC: 2, 3, 4, 5</td>
</tr>
<tr>
<td>PROC: 1, 2, 3, 4, 5, 6, 8a, 8b, 9, 10, 13, 14, 15, 21, 26</td>
<td>PROC: 1, 2, 3, 4, 5, 6, 8a, 8b, 9, 10, 13, 14, 15, 21, 24</td>
</tr>
<tr>
<td>PC: 21, 32</td>
<td>PC: 13, 14, 32</td>
</tr>
<tr>
<td>AC: 0, 1, 5, 10, 13</td>
<td>AC: 13</td>
</tr>
</tbody>
</table>
Table 13: Comparison of use-descriptors in IUCLID with applied use-descriptors for Trichloroethylene (TCE, status May 2016) \(^{10}\)

<table>
<thead>
<tr>
<th>All uses as registered in IUCLID (Red - not applied for)</th>
<th>Uses applied for (Green - not listed in IUCLID)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SU: 0, 8, 9, 10</td>
<td>SU: 0 (manufacture, operation, maintenance, repair and overhaul of aviation products that meet the airworthiness certification requirements), 2a, 3, 5, 8, 9, 12, 17</td>
</tr>
<tr>
<td>ERC: 1, 2, 4, 6a, 7, 8d, 9a</td>
<td>ERC: 2, 4, 6b, 7, 9a</td>
</tr>
<tr>
<td>PC: 0, 19, 39</td>
<td>PC: 0, 21, 35, 40</td>
</tr>
<tr>
<td>PROC: 1, 2, 3, 4, 5, 6, 7, 8a, 9, 10, 11, 13, 14, 15</td>
<td>PROC: 0, 1, 2, 3, 4, 5, 8a, 8b, 9, 10, 13, 14, 15</td>
</tr>
<tr>
<td>AC: 5</td>
<td>Technical function: Laboratory chemicals, Solvent, Processing aid, solvents for vulcanising agent and bonding agent</td>
</tr>
</tbody>
</table>

The observed mismatch in Table 12 and Table 13 may be partially explained by the fact that some uses reported in IUCLID are outside of the scope of authorisation. Another mismatch may be due to an incomplete update of the registration dossiers. A clarification would require a case-by-case analysis of each individual use and probably lengthy discussions with the registrant which clearly was not possible in this project. However, it is important to note that there are quite significant differences in the reported uses in AfAs and in IUCLID which probably merit a closer investigation.

**Strategies of applicants in their analyses of alternatives and socio-economic analyses**

Another aspect which was analysed in this study was the strategies employed by the applicants in their analyses of alternatives and socio-economic analyses. For this purpose, Annex I, Table 39 summarises all AfAs which have been submitted by May 2016 to ECHA for the substances considered in the present study and provides the use names, the major conclusions of the applicants and the major arguments in the socio-economic analysis used by the applicants. For two selected substances, di(2-ethylhexyl) phthalate (DEHP) and trichloroethylene (TCE), the results of this analysis is summarised in Table 16 and Table 17

Table 17. A total of 11 AfAs which have been applied for for DEHP and 19 AfAs for TCE were scrutinized. Table 14E which have been applied for.

Table 14 and Table 15 respectively summarise the uses of DEHP and TCE which have been applied for.

**Table 14: Uses applied for DEHP in the applications for authorisations**

<table>
<thead>
<tr>
<th>DEHP - uses applied for</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formulation in compounds, dry-blends and plastisol formulations</td>
<td>3</td>
</tr>
<tr>
<td>Industrial production of ceramic sheets and printing pastes for production of capacitors and lambda sensor elements</td>
<td>1</td>
</tr>
</tbody>
</table>

\(^{10}\) Note that while the download of the registration data for this project was carried out by the end of 2015, the AfAs were scrutinised by mid 2016.
Industrial manufacture of solid propellants and motor charges for rockets and tactical missiles  
Processing of a stop-off formulation containing DEHP during the diffusion bonding and manufacture of aero engine fan blades.  
Industrial use in polymer processing by calendering, spread coating, extrusion, injection moulding to produce PVC articles (Uses which are not restricted under other EU regulations)  
Formulation of recycled soft PVC containing DEHP in compounds and dry-blends

<table>
<thead>
<tr>
<th>TCE - uses applied for</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extraction Solvent for Bitumen in Asphalt Analysis</td>
<td>1</td>
</tr>
<tr>
<td>Degreasing solvent in the manufacture of polyethylene separators for lead-acid batteries</td>
<td>1</td>
</tr>
<tr>
<td>Solvent for the removal and recovery of resin from dyed cloth</td>
<td>1</td>
</tr>
<tr>
<td>Extraction solvent for removal of process oil and formation of the porous structure in polyethylene based separators used in lead-acid batteries</td>
<td>1</td>
</tr>
<tr>
<td>Process solvent for the manufacturing of modules containing hollow fibre gas separation membranes</td>
<td>1</td>
</tr>
<tr>
<td>Degreasing agent in closed systems</td>
<td>1</td>
</tr>
<tr>
<td>Extraction solvent for the industrial purification of caprolactam from caprolactam oil</td>
<td>3</td>
</tr>
<tr>
<td>Solvent in the synthesis of vulcanization accelerating agents for fluoroelastomers</td>
<td>1</td>
</tr>
<tr>
<td>Industrial cleaning by Vapour Degreasing in closed Systems where specific requirements (system of use-parameters) exist</td>
<td>1</td>
</tr>
<tr>
<td>Process chemical (enclosed systems) in industrial material production</td>
<td>1</td>
</tr>
<tr>
<td>Vulcanising and bonding agent for endless connections and repair of chloroprene rubber coated conveyor belts in underground hard coal mining</td>
<td>1</td>
</tr>
<tr>
<td>Use in packaging</td>
<td>2</td>
</tr>
<tr>
<td>Use in formulation</td>
<td>2</td>
</tr>
</tbody>
</table>

Table 16 summarises the typical conclusion drawn by the applicants in their Analysis of Alternatives
Table 16: Typical conclusions in the Analyses of Alternatives for DEHP and TCE.

<table>
<thead>
<tr>
<th>Typical conclusions in the Analysis of Alternatives (AoA)</th>
<th>DEHP</th>
<th>TCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unavailability of an alternative substance</td>
<td>4</td>
<td>9</td>
</tr>
<tr>
<td>Adequate control of risks is achieved and thus no discernible benefits to workers’ health or the environment in using alternatives</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Alternatives are available but still need testing for implementation</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>R&amp;D and manufacturing program to find an alternative is in place but has not yet resulted in a feasible alternative</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Alternatives are available but are &quot;older technologies&quot; with a worse carbon footprint. This argument usually combines with the argument that these “older technologies” are economically unproductive resulting in the unprofitability of the production</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Alternative is available but would lead to unprofitability of the product</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Relocation of production outside of the EU would be the most economical alternative</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Intermediate Use, thus no authorisation required</td>
<td></td>
<td>4</td>
</tr>
</tbody>
</table>

Table 17 summarises typical arguments used in socio-economic analyses for the two substances.

Table 17: Typical arguments used by the applicants in their Socio-economic Analyses conclusions for DEHP and TCE.

<table>
<thead>
<tr>
<th>Typical arguments used by applicants in the Socio-Economic Analysis (SEA)</th>
<th>DEHP</th>
<th>TCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk management measures lead to minimal residual risks compared to the socio-economic impact in case of no-use</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Enumeration of negative effects resulting from a refusal of the authorisation</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Enumeration of positive effects if authorisation is granted</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Comparison of socio-economic impact and the human health impact</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>There are no suitable alternatives available</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>The substance is only needed for a short period when the production will be stopped</td>
<td></td>
<td>1</td>
</tr>
</tbody>
</table>

Even though this is a quite rough analysis it generally suggests that, at least for the two selected substances, there are not very substance-specific strategies in the reasoning of applicants. A similar picture is observed for other substances (compare Annex I). Admittedly, an in-depth technical and socio-economic consideration may reveal more subtle substance-specific differences but this was not possible within the scope of this project, even though the information would be available from the analysis from the SEAC committee.
6.1.4. Volume data based on IUCLID, SPIN-Database, EUROSTAT and a market study on phthalates

During the preparation of the methodological paper which forms the basis of this study (1) it became obvious that volumes or tonnages of manufacturing, formulation and uses of substances should be the most direct and vivid indicators for measuring substitution effects but the question was raised as to whether the available quality, completeness and actuality of information about these data was sufficient to draw firm conclusions. An objective of the present discussion is to gain a better understanding about the consistency and reliability of available volume or tonnages data.

Annex I contains the comprehensive information on volumes gathered for the SVHCs studied in this project. A genuine difficulty with the discussion of data on volumes is the reluctance of the industry to make these figures public for a number of reasons such as competition, confidentiality of process details or intellectual property rights. In order to account for this confidentiality aspect, it was decided to provide in this report the relative rather than the absolute volume information. Except for data from the SPIN database which are public, only relative volumes are provided in Annex I.

The information about the registered tonnages has been extracted from IUCLID and is summarised in the Annex I for each substance. It is noted that the information of the registered volume until the year 2010 is of little relevance as the registrants were not obliged to report volumes before the first registration date. The information in relation to the used tonnage is always the indicated volume for a specific year. If there was no update of information the assumption was made that the same volume stated in the specific year, remained unchanged in the following year. It is noted that REACH requires registrants to supply information on their manufactured/imported tonnage once and to update this information only if the tonnage increases and thereby change to the next tonnage band. The registrants are not required to indicate if volumes have decreased. Consequently, updates of the tonnage information in IUCLID occur only occasionally and thus have to be generally treated with much care. Information on the volumes used in different downstream sectors are very rarely reported explicitly in the chemical safety reports. Instead of using actual tonnage information registrants often carry out exposure calculations based on model assumptions.

Relative precise information on marketed volumes and number of mixtures containing SVHCs can be obtained from the SPIN data base of Nordic Countries. However, as this information covers only the four countries Denmark, Finland, Norway and Sweden, it cannot be regarded as representative for the use in Europe.

Tonnage reported Eurostat data are available only for three individual substances (1,2-dichloroethane, di(2-ethylhexyl)phthalate and trichloroethylene, compare with Table 5) while for the other substances studied in this project no information or only information which does not relate to the individual SVHCs is available.

A final source on volumes used for this project was a market study on phthalates and other plasticisers which has been purchased from a commercial provider. Due to the strict copy rights this information on marketed volumes is not provided in this report.

Figure 17, Figure 18 and Figure 19 depict a comparison of the tonnages from IUCLID and EUROSTAT for 1,2-dichloroethane, di(2-ethylhexyl)phthalate and trichloroethylene, respectively, as functions of the authorisation time-line. The volume information from the
The SPIN database could not be included as the confidentiality agreements would be breeched. The data are normalized as such that the highest reported volume in 2003 was (arbitrarily) set to a volume index of 100.

Figure 17: Available volume data of 1,2-dichloroethane (1,2-EDC) as a function of the time-line. The volume index is to the highest reported volume (Eurostat for the year 2003) which is arbitrarily set at 100. The black lines correspond to the milestones (FRD = first registration deadline, CD = candidate listing, Annex XIV = inclusion in Annex XIV, LAD = latest application date.)

Figure 18: Available volume data of Di(1-ethylhexyl)phthalate (DEHP) as a function of the time-line and the comparison of the information from IUCLID and Eurostat (sum of dibutyl and dioctyl orthophthalates which predominantly consists of DEHP). The volume index is to the highest reported volume (Eurostat for the year 2003) which is arbitrarily set at 100. The black lines correspond to the milestones (FRD = first
registration deadline, CD = candidate listing, Annex XIV = inclusion in Annex XIV, LAD = latest application date.)

Figure 19: Available volume data of trichloroethylene (TCE) as a function of the time-line and comparison of information from IUCLID and Eurostat. The volume index is to the highest reported volume (Eurostat for the year 2003) which is arbitrarily set at 100.

The black lines correspond to the milestones (FRD = first registration deadline, CD = candidate listing, Annex XIV = inclusion in Annex XIV, LAD = latest application date.)

It is firstly noted that the total volumes reported in the SPIN database are significantly lower than the tonnage based on IUCLID and Eurostat. Hence the standardised volumes reported in the SPIN database become very low. Nonetheless the SPIN data from Nordic countries show a clear and consistent decrease in the reported tonnage. In order to better visualize the volume changes Figure 20 - Figure 22 show the explicit tonnage reported in the SPIN database by Sweden for the three substances respectively as functions of the time-line. Figure 20 - Figure 22 also depict the number of mixtures reported to the SPIN data-base.
Figure 20: Volumes of 1,2-EDC and numbers of mixtures containing 1,2-EDC as reported to the SPIN data-base (sum from Sweden) as a function of the time line

Figure 21: Volumes of DEHP and numbers of mixtures containing DEHP as reported to the SPIN data-base (sum for Denmark, Finland, Norway and Sweden) as a function of the time line
Figure 22: Volumes of TCE and numbers of mixtures containing TCE as reported to the SPIN data-base (sum for Denmark, Finland, Norway and Sweden) as a function of the time line

Figure 20 – Figure 22 show that the volumes of all three substances continuously decreased in the Nordic countries to zero or near zero. A similar behaviour is seen for mixtures containing DEHP and TCE. Only mixtures containing EDC show a somewhat surprising increase since 2008.

As already mentioned in the introduction the volumes reported by the Nordic countries are not representative for the EU as a whole. Figure 17 to Figure 19 show IUCLID-based and Eurostat-based volume indices for the three investigated substances which are significantly higher than the reported SPIN data.

However, comparing IUCLID-based and Eurostat-based volume-indices a noticeable mismatch can be observed for all three substances. For TCE there is a factor of about three between Eurostat- and IUCLID-based tonnages over the full time period after 2010 (the first registration date), for the other two compounds the volumes match relatively well around the first registration date but become significantly different in the period thereafter, reaching in 2015 a difference of a factor of approx. two for EDC and a difference of about 50% for DEHP. It is difficult to explain the reasons for these differences. There is no common tendency of the mismatch. For EDC, the IUCLID-based tonnages are higher than the Eurostat-based (Figure 17), for TCE it is the other way round (Figure 18), and for DEHP the tendency changes over the time-line (Figure 19). As already mentioned in the introduction, one source of errors is a lack of updates of registration data in IUCLID. This may lead to both, over-reporting (e.g. if tonnages have decreased but no update was carried out) as well as under-reporting (e.g. if tonnages increased but did not reach the next tonnage-band and thus were not updated).

While the data from the SPIN data-base very consistently show (Figure 20 - Figure 22) decreasing volumes (and also numbers of mixtures except for EDC) of the three compounds in the Nordic countries, the European-wide data are much less clear. Eurostat-based data indicate a tendency towards a reduction in volumes for TCE and EDC but show a significant
increase of DEHP-tonnages after the latest application date (LAD). It is noted that this behaviour for DEHP is qualitatively also supported by the market analysis. On the contrary, IUCLID-based data are remarkably constant after the first registration date. It is noticeable that neither candidate listing nor the inclusion of substances in Annex XIV seems to have any visible impact on the tonnages reported in IUCLID.

Looking at substances for which the latest application dates have already passed and no applications for authorisation were submitted to ECHA (substances labelled “NAFA” in Table 4) one would expect to see a significant decrease in volumes. For two of these substances, 4,4'-diaminodiphenylmethane (MDA) and diisobutyl phthalate (DIBP) are shown in Figure 23 and Figure 24.

![Volume of MDA](image)

**Figure 23:** Volumes for MDA along the time-line on the basis of IUCLID (dotted line) and the tonnage information from the SPIN data-base (solid line). The volumes are given as different measurement units so that the confidentiality agreements are not breached.
Figure 24: Volumes for DIBP along the time-line on the basis of IUCLID (dotted line) and the tonnage information from the SPIN data-base (solid line). The volumes are given as different measurement units so that the confidentiality agreements are not breached.

While SPIN-data show the expected behaviour, IUCLID data do show some decrease (for MDA quite small) in the volumes following the first registration but after the FRD they remain at a high value. It remains to be clarified as to whether the IUCLID-based volumes actually reflect the real tonnage. The fact that these data remain relatively constant also may point to the fact that no or only marginal updates have been carried out since the first registration.

As a general conclusion of the discussion of volume/tonnage-based indicators as measures of the authorisation process, it is firstly noted that indicators based on the tonnages from the SPIN data-base provide a relative consistent picture of decreasing volumes over the last ca. 15 years. But there is no indication observed for any impact of the authorisation process. Moreover, the volume information from the SPIN-data base is neither representative for the EU as a whole nor is the decrease of tonnages over time clearly confirmed by the IUCLID or Eurostat-based indicators.

IUCLID-based tonnages show a much less clear behaviour over the time-line. For most SVHCs the volumes remain relatively constant after the first registration date. There are no indications for any effect at typical milestones in the authorisation process. For only a few SVHCs a pronounced decrease in the volumes after the FRD can be observed (e.g DEHP, DIBP). This contrast to the case of DBP and diarsenic trioxide for which the volume increased after the LAD. BBP and TRIS have stayed in the same tonnage band over the whole period. The milestone candidate listing had no visible impacts on the volumes for any SVHC except for the lead-compounds.

For those three substances for which volume data are available from Eurostat (1,2-dichloroethane, di(2-ethylhexyl)phthalate and trichloroethylene), there are significant differences (by factors up to three) in the absolute tonnages and also different trends in the evolution of volumes along the time-line. It is difficult to explain these differences and to
trace the reasons for the mismatch. The fact that the IUCLID volumes remain rather unchanged after the first registration for most SVHCs and the fact that the increase of DEHP volumes reported by Eurostat is qualitatively confirmed with the market study may suggest that the IUCLID data may be significantly flawed by the systematic errors due to an insufficient updating by registrants.

While the volume seems to be the most straightforward and best suited indicator for measuring the impacts of the authorisation process, there are obviously significant deficiencies in the data sources. In particular, the systematic errors in IUCLID-volumes because of insufficient updating seem to be significant and do not seem to make the IUCLID-volumes a good basis for indicators to measure authorisation effects. On the other hand, the volume-information from the SPIN data base is not representative for the EU and the Eurostat-tonnages are only available for very few substances.
6.2. Results related to the substance groups

6.2.1. Phthalates

The registration data of the six phthalates; benzylbutylphthalate (BBP), dibutyl phthalate (DBP), bis(2-ethylhexyl)phthalate (DEHP), diisobutyl phthalate (DIBP), 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters (BCA) and diisopentylphthalate (DIPP) are summarized in Annex I 1. Registration Data - Phthalate.

Four phthalates (BBP, DBP, DEHP, DIBP) have been included in Annex XIV and the resulting latest application date (LAD) and sunset date have already passed. BCA is on the candidate list and DIPP was recommended for inclusion in Annex XIV.

In the case of DEHP, DBP, and DIBP the number of registrations decreased after the LAD because of the inactivation of their registrations (see Figure 8). At the same milestones the spontaneous updates of registrations increased significantly (see Figure 10). These findings lead to the conclusion that only the LAD has an effect on the registrants but as the time point for the inclusion of DEHP, DBP and DIBP to the candidate list (CD) was before the FRD the impact of the CD could not be assessed. For BBP, DIPP and BCA there was only one registration for each substance which was not influenced by any of the milestones.

A similar phenomenon can be seen for the summed up use-profiles - Life Cycle Stages (LCS) and Use-Descriptor-Profile (UDP). The number of summed up identified uses for DEHP, DIBP and DBP decline after the LAD. For the other phthalates the number of summed up uses stayed the same or the uses are only added to the registrations after the LAD.

Even though the reduction of the uses is visible, it would probably be even more enhanced if the uses in IUCLID would be correctly updated. For example, there are still uses for DEHP listed which are wide dispersive outdoor and indoor uses but there are no applications for authorisation (AfAs) for these uses. If these uses would be removed from the registrations, the total summed up number of uses would decrease even stronger.

If the unique number of uses is considered (Figure 12-Figure 16), where each individual use is only counted once, the substances DEHP, DBP and DIBP show a different tendency compared to the summed up uses and are less clear to explain. For DEHP, the use categories “wide dispersive outdoor and indoor”, “Fabrics, textiles and apparel” or “Industrial spraying” have been removed from the registration dossier which could be considered as a positive impact of the authorisation process, leading effectively to a risk reduction with respect to DEHP. For DBP and BBP this effect cannot be observed, as additional uses has been added to the reported uses after the LAD.

The uses have further been scrutinised by comparing AfA’s with the registered uses (Table 12). The description of the AfA’s and the uses reported in registrations are different in their depth of information and details, so the comparison is not easy to interpret. However, it is noticeable that the information in the AfA’s and the registrations differ somewhat. Some uses are applied for in the AfA’s, but are not found in the registrations and vice versa.

The information on volumes based on the IUCLID database does not allow for making a general conclusion on the actual trend of the volume of phthalates in the EU. In the case of DEHP (Figure 21) and DIBP the used volume decreased strongly by 70% and 45% respectively compared to the volume at the FRD. This reduction also correlates with the inactivation of the registrations and the decrease of the summed up number of uses. However,
for DBP the volume increased by 30% compared to the volume at the FRD. It is noted that the number of unique uses for DBP has increased in the same period which might account for the observed increase of volume. BBP only has one registrant and the indicated tonnage band did not change over the time of this study.

As already mentioned, the SPIN-database is only representative for the Nordic countries. The trend demonstrated in relation to the tonnage data provided by SPIN is quite consistent in that a decrease in tonnage and number of mixtures for DEHP (Figure 21), DIBP and DBP is observed in all Nordic countries. This trend supports the findings for the IUCLID-based volumes for DEHP and DIBP, but not for DBP.

For DEHP there was additional information from the Eurostat database (Figure 18), which also shows a decline of the volume until 2013 as in the IUCLID database. However, after 2013 the volume strongly increased again which. If this data were correct, it would be an indication that the IUCLID-based information on uses for DEHP is significantly flawed by the fact of incomplete dossier updating.

To conclude, the findings for phthalates provide a somewhat inconsistent picture which most probably is caused by the lack of timely dossier updates in IUCLID. Given that the REACH legislation does not legally require updates unless in cases of increases of volumes to the next tonnage band, there seems to be no motivation for registrants to continuously bring their tonnage information up to date. The degree to which software errors may also contribute to data flaws cannot be substantiated in this project.
6.2.2. Glymes

For five of the six glymes considered in this study registration data are available: 2-methoxyethanol (EGME), 2-ethoxyethanol (EGEE), bis(2-methoxyethyl)ether (Diglyme), 1,2-dimethoxyethane (EGDME) and tetraethylene glycol dimethyl ether (TEGDME). The resulting indicators are summarized in Annex I 2. Registration Data - Glymes.

All substances in this group have been added to the candidate list but have not been included in Annex XIV with the exception of Diglyme. The reasons for not being included in Annex XIV are that these substances are only used in small volumes under controlled conditions, have no wide dispersive uses or, as in the case of EGDME, there were other substances with higher priority.

Regarding the IUCLID-based indicators for this group there are hardly any visible effects observed at the different milestones (see Annex I Chapter 2). This is particularly also true for Diglyme. Only for EGEE there is remarkable increase in the summed up uses for the professional and industrial life-cycle stages as well as for the indicators based on the use descriptor profile after the inclusion of this substance in the candidate list (see Annex I). It was not possible in this project to identify the specific reasons for this increase.

The SPIN database shows a decline in the volume and the number of mixtures for all substances in most Nordic countries.

There are chances that the remaining substances of the glymes group will never be included to Annex XIV and therefore it can be generally concluded that the authorisation policy has, if any, only marginal measurable impact on the use of this group of substances.
6.2.3. Lead compounds

The registration data of the four lead compounds lead monoxide (PbO), orange lead, pentalead tetraoxide sulphate (PLTS) and tetralead trioxide sulphate (TLS), are summarized in Annex I 3. Registration Data – Lead Compounds.

The four lead compounds have been finally recommended to be included in Annex XIV by ECHA in 2016, but the prioritisation for inclusion in Annex XIV was already considered by the Member State Committee in 2015, so it was decided for the purpose of this project that the lead compounds have already reached the milestone “recommendation for inclusion in Annex XIV” within the project deadline.

Based on the registration data the inclusion in the candidate list seems to have a significant influence on the number of summed up uses of the lead compound, particularly for the service life (ASL) sector (see Figure 11). However, it can be speculated that the reason of updates may have been the clarification about the status of those compounds as either being substances, mixtures or articles rather than being a direct impact of the authorisation process. If so, the authorisation process would have an indirect effect by triggering a clarification of interpretation issues.

The observed decline in number of summed up uses (see Annex I) cannot be attributed to the abandoning of a specific use but rather to the fact that a few registrants declared the stop of manufacturing. This is further confirmed by the assessment of unique uses, as the number of unique uses increases in the same time period and there is no single unique use which had been removed from the registrations (see Annex I).

The available data on IUCLID-based volumes illustrated in Figure 25 show a decrease for all four lead substances. These findings are largely supported by the data of the SPIN database (see Annex I).

[Diagram: Volume - Lead compounds]

Figure 25: Volume-data from IUCLID for the four lead substances PBO = lead monoxide, Orange lead, PLTS = pentalead tetraoxide sulphate, TLS = tetralead trioxide sulphate. The volumes are illustrated in relation to the highest volume of TLS (2013=100%) and therefore comparable with each other.
One of the most relevant sectors being potentially affected by the authorisation under REACH is the manufacturing of batteries and accumulators. Emissions from this sector into water or air are reported in the European Pollution Release and Transfer Register (E-PRTR database). Figure 26 and Figure 27 show the trend in emissions to air and water from this particular sector for the time period 2007 to 2014.

![E_PRTR emissions to surface water](image)

**Figure 26: Emissions of lead from the battery and accumulator producing sector into surface waters reported in E-PRTR**

![E_PRTR emissions to air](image)

**Figure 27: Emissions of lead from the battery and accumulator producing sector into surface waters reported in E-PRTR**

While emissions to water are difficult to interpret, the lead emissions to air show a clear decrease as from 2011. This, in principle, could be regarded as a supporting evidence for the observed decline in IUCLID-based tonnages. However, it should be noted that the E-PRTR data are based on reports from only few (four to eight) large European installations and thus probably not fully representative for the whole sector. Furthermore, reduction of lead emissions could well be the result of improvements in best available techniques and/or purification measures and thus not directly correlate with the extent of use. Within the scope of this study it was not possible to clarify this rather complicated issue.
6.2.4. Halocarbons

The registration data of the two halocarbons; 1,2-dichloroethane (EDC) and trichloroethylene (TCE) are summarized in Annex I 4. Registration Data – Halocarbons, chlorinated-brominated.

Both substances have been included in Annex XIV and thus have a defined latest application dates (LAD) and sunset dates but only for TCE the LAD has been reached before the deadline of this study.

For EDC an increase in the numbers of summed up uses as well as unique uses can be observed after its inclusion in the candidate list (see Annex I and Figure 34 and Figure 35).

For TCE a reduction in the number of summed up uses as well as unique uses in the industrial life cycle stage after the LAD can be observed (see Annex I and Figure 34 and Figure 35). Indicators based on the Use-Descriptor-Profile show some decrease in the summed up uses for the process category (PROC) and a quite remarkable decrease in the unique uses for the product category (PC) and the environmental category (ERC) (see Figure 28). The uses which have been removed from registration and which are an indication of the reduction of exposure are in the LCS-Professional – “Component of consumer products for professional use” and in the UDP category ERC – “wide dispersive uses” (see Annex I Table 25). The exclusion of these uses are, in principle, beneficial to human health and the environment, so this effect could be probably considered as an improvement triggered by the authorisation process. On the other hand, one use has been added to the registration which is the use in the product category PC 39 (cosmetics, personal care products) which seems somewhat problematic.

![TCE - UDP](image)

**Figure 28: Illustration of the number of unique uses for TCE.**

For TCE there have been some AFA’s but as the sunset date has not passed jet it does not make sense to compare the uses applied for to the uses stated in IUCLID.

The information about the volume for EDC and TCE from the IUCLID database indicates that the volume used in the EU did not significantly change after the first registration date. Hence, the authorisation process did not have any visible impact on the IUCLID-based volumes.
the other hand (Figure 22), the tonnage data from the SPIN database indicates a decrease of
the volume and the number of mixtures for TCE in the four Nordic countries. For EDC
tonnages are only reported from one Nordic country and the resulting figures are difficult to
interpret as there is no clear trend in volumes and number of mixtures and both do not seem to
correlate well (Figure 20).

For both substances data are available in the Eurostat database which indicate for EDC that
there is a reduction of the total volume used in the EU which is a striking contradiction to the
IUCLID-based volumes and suggests that IUCLID-information may be flawed, e.g. because
of lack of updating. For TCE the Eurostat volumes also decline, but compared to the data
from IUCLID the Eurostat-volume starts at a much higher level and remains significantly
above the IUCLID-based volume. This again may indicate some quite considerable flaws in
IUCLID-based tonnages.

For both halocarbons considered in this project there are additional monitoring data available
in E-PRTR database. The following figures depict the time-series of emissions of TCE and
EDC to air and water, respectively, for the European chemical industry (Figure 29 and Figure
30). While for TCE there is a clear trend of decreasing emissions to air, there is a less clear
decreasing tendency for emissions to water since 2007. For EDC the air emissions seem to
increase in this time period while the emissions to water clearly decrease by a factor of
approx. 3.

Figure 29: E-PRTR emissions of the chemical industry to air reported for TCE and
EDC between 2007 and 2014
A potentially important sector for the use of degreasing solvents like TCE is the metal manufacturing and processing sector. As Figure 31 shows, the E-PRTR emissions to air as well as water significantly decreased from the 2007 level to near zero in 2013.
It is again difficult to draw a firm conclusion on the causes which led to the quite remarkable emission reduction for TCE during the last ten years. As the reductions seem to have started well before the milestone of candidate listing (June 2010) or inclusion in Annex XIV (April 2013), the authorisation process does not seem to be a cause for these measures. The emission reduction may be the result from reduced uses of TCE but may also reflect improvements in the best available techniques and purification technologies, potentially triggered by European environment legislation such as the Water Framework Directive or the Industrial Emissions Directive.
6.2.5. Aromatic amines

The registration data of the three amines; formaldehyde oligomeric reaction products with aniline (FORM), 4,4’-diaminodiphenylmethane (MDA) and 2,2’-dichloro-4,4’-methylenedianiline (MOCA) are summarised in Annex I 5. Registration Data – Aromatic Amines.

The three substances have been included in Annex XIV and have a defined LAD and sunset date but only for MDA has the sunset date been reached before the deadline of this study.

The numbers of registrations do not provide an indication for any impact of the authorisation for MOCA and FORM until the deadline of this study. For MDA a certain increase in the number of registrations from the sunset date to the deadline of the study can be observed (see Annex I Table 26). Given that no application for authorisation has been submitted for MDA by the LAD this is another strong indication that all remaining uses of MDA fall outside of the scope of authorisation and thus logically authorisation did not have any impact on a reduction of uses of MDA.

For FORM and MDA there is no observable trend in the summed up number as well as unique uses for the life cycle stages (LCSs) until the deadline of this study (see Annex I Table 28 and Figure 51). For MOCA, one observes an unspectacular but quite consistent increase in the number of unique LCS-based indicators after the inclusion of this substance in Annex XIV, as shown in Figure 32.

![MOCA - LCS](image)

**Figure 32: The number of unique uses for MOCA over the milestones for the LCS’s**

One explanation for these changes could be clarifications and corrections of use patterns made by registrants during their preparation of an application for authorisation. If so, this would be an indirect impact form the authorisation process, resulting in a dossier improvement.

The numbers of identified uses in the Use-Descriptor-Profile (UDP) provide a slightly different picture compared to the LCS, in particular for Form (see Annex I). All the uses for the different UDP-categories exhibit first an increase in the summed up number of uses followed by a decrease to the same amount of uses as before the increase. This rather
unexpected phenomenon may be explained by some confusion of registrants about the assignment of uses to the correct categories. The unique uses for FORM do not exhibit any changes over the whole authorisation time-line. For MDA similar observations can be made for certain use categories. For MOCA one finds for the UDP-indicators a similar behaviour as for the LCS-based indicators after the inclusion in Annex XIV.

The IUCLID-based volumes of the three amines show no decline since the first registration date. This again contrasts to the volumes reported in the SPIN database (see Annex I Figure 55 – Figure 58) which indicates significant declines of both tonnages and number of mixtures for MDA and FORM to very low levels in the Nordic countries. For MOCA the data in the SPIN-database show a qualitatively similar but much less clear decline in volumes.

![Volume MDA](image)

**Figure 33: Comparison of the volumes reported for MDA in IUCLID with the sum of tonnages of MDA reported by the Nordic countries**

Given that the chemicals use in Nordic countries is certainly not representative for the whole of Europe, it is difficult to assess the reasons for the striking difference in trends between IUCLID-based and SPIN-based information. One possibility is that major uses of MDA in areas out of the scope of authorisation are not located in the Nordic countries and thus the use pattern between Nordic countries is completely different. Another possibility is, of course, that IUCLID-data are not up-to-date because of the simple fact that registrants have not reported the reduction of use volumes in their registration dossiers.

Due to the fact that the available data is rather limited and controversial no assumption can be made according to the risk of the three amines.
6.2.6. Organophosphorous compounds

The registration data for the two organophosphorous compounds; Trixylyl phosphate (Trix) and Tris(2-chloroethyl) phosphate (Tris) are summarised in Annex I – 6. Registration Data – Organophosphorus compounds.

Trix has been included into the candidate list and until the deadline of this study no changes in the number of registrations or uses have been observed (Annex I Table 31). The industry declared that “all uses apart from that intended by the manufacturer are advised against” in the industrial, professional and consumer life cycle stages (LCS) and additionally in the LCS consumer “that substance and products are not used by consumers”. These statements may allow for the conclusion that the risk from Trix seems adequately controlled. The substance has not been included into Annex XIV.

Tris has been included in Annex XIV and the sunset date has already passed. No decline in the number of registrations has been observed (see Figure 10 and Figure 11). The number of uses (unique and summed up) also did not change (see Figure 12 to Figure 16) which is somewhat surprising as there have been no applications for authorisations (AfAs). Probably all registered uses are outside the scope of authorisation, but this was not checked in this study.

The volumes based on IUCLID and the SPIN database do not allow to conclude a clear trend for Trix while for Tris the SPIN database suggests a decline of tonnages as well as the number of mixtures in most Nordic countries.
6.2.7. Arsenic compounds

The registration data for the two arsenic compounds; diarsenic trioxide (Ditri) and diarsenic pentaoxide (Dap) considered in this project are summarised in Annex I – 7. Registration Data – Arsenic Compounds.

Only Ditri has been registered and was included into Annex XIV in 2012. The LAD and sunset date have already passed and one of the two registrations has been inactivated. Dap does not seem to be used in Europe anymore; apparently its uses have been either abandoned or replaced by other substances such as Ditri. The uses for the life cycle stages and the Use-Descriptor-Profile (UDP) have remained unchanged after the LAD was reached and all but three registered uses are contained in the applications for authorisations (AfAs).

The information on the volumes of Ditri based on IUCLID show no changes after the first registration date (FRD). Volumes in SPIN are only reported in one Nordic country with a sharp decrease to zero in 2006. It seems that there is no relevant use of Ditri any more in the Nordic countries.

Additional information on the emission of arsenic compounds can be found in the E-PRTR database. Figure 34 and Figure 35 provide the emissions from two potentially relevant sectors, i.e. production of inorganic chemicals and metal manufacturing and processing, respectively, over the years 2007 to 2014. There is a clear and visible trend towards reduced air emissions, especially in the metal processing sector but for emissions to water the trend is either less clear (metal processing) or even increasing (chemical sector). This is noteworthy and remains to be further investigated.

![Production and processing of metals](image)

Figure 34: Emission of arsenic compounds from, the sector production and processing of metals into air and water from the E-PRTR database over the year’s 2007 to 2014
Figure 35: Emission of arsenic compounds from, the sector chemical industry – production of inorganic chemicals into air and water from the E-PRTR database over the years 2007 to 2014
6.2.8. ADCA

The registration data for ADCA are summarised in Annex I – 8. Registration Data – ADCA.

ADCA has been recommended for inclusion in Annex XIV in 2014, but until the deadline of the study was not been included to Annex XIV.

Since the first registration date there has been no inactivation of a registration (see Annex I Table 35).

At the milestone “final A.XIV recommendation” a quite remarkable change in the number of summed up as well as unique uses can be observed. At this milestone all the uses in the life cycle stages of professional, consumer and after service life (ASL) uses are discontinued and the registrant make an explicit advice against these uses (see Annex I Figure 78). A decrease in the number of unique uses can also be observed in the “Use-Descriptor-Profile” (UDP) for the uses in the category ERC and PROC (see Annex I Figure 80). It is noted that the uses which have been discontinued are usually wide dispersive uses, so the changes and/or clarifications regarding these uses in the registration dossiers can be taken as improvements with regard to the risk to humans and the environment.

The information on the IUCLID-based volume of ADCA shows an increase of 20% after the first registration deadline (FRD). The SPIN-based volumes exhibit a decline in two Nordic countries and an increase in the other two.
6.3. Substitution

The basic idea of the RiME Task Force paper on authorisation monitoring (1) was to retrieve – as far as possible automatically – registration data and other information from existing data bases and to calculate simple indicators which would provide an objective answer to the question how substitution works. The discussion in sections 6.1 and 6.2 has shown that the current data do not seem to allow for a clear and fully consistent answer to this question for a number of different reasons. In the drafting of the Task Force this was already anticipated by some of the involved parties and thus it was proposed in the paper that an interpretation of the indicators should be supplemented by case stories which allow a deeper insight into the benefits, problems and obstacles for substitution by industry on a case-by-case basis. Hence part of the effort in this project was dedicated to collecting case-by-case information.

The substances which are on Annex XIV, but for which no Applications for Authorisation (AfAs) have been submitted to ECHA by the latest application date (category (N)R_AXIV_LADP_NAfA in Table 4) might be good candidates for observing substitution effects. This concerned the following SVHCs considered in this project:

- benzyl butyl phthalate
- diisobutyl phthalate
- tris(2-chloroethyl)phosphate
- 4,4’-diaminodiphenylmethane
- diarsenic pentoxide

A quick search in the SUBSPORT database (5) provided that for the four substances mentioned above the two phthalates show entries on possible substitutes for certain uses, which are summarised in Table 18. The structures of these alternates are depicted in Figure 36.
| **Table 18: Information on possible alternates for selected SVHCs in the SUBSPORT database (5)** |
|---------------------------------|-----------------|-----------------|
| **Diisobutylphthalate (DIBP, CAS 84-69-5)** | 1 entry in SUBSPORT | **Electronic products** |
| Used in | Alternates | Link in SUBSPORT |
| **Benzylbutylphthalate (BBP, CAS 85-68-7)** | 5 entries in SUBSPORT | **Electronic products** |
| Used in | Alternates | Link in SUBSPORT |

| **Tris(2-chloroethyl)phosphate (Tris, CAS 115-96-8)** | no entry in SUBSPORT |
| **4,4'- Diaminodiphenylmethane (MDA, CAS 202-974-4)** | no entry in SUBSPORT |
Of these alternatives, three substances are polymers which were developed as substitutes for PVC, allowing the companies to avoid completely the use of phthalates as plasticisers. Two of the polymers are polyacrylates and polyurethanes used in child wear printing applications. The third one is a polyolefin which had been developed by the company in cooperation with their suppliers as a carpet backing component which is combined with a nylon-based face fibre. DEHA, DINCH, DOCP and TOM have certain structural similarities with alkylated phthalates. DEHA, for example, is an aliphatic di-ester with the same alcoholic component as for DEHP, DINCH a non-aromatic analogue to long-chain phthalates and DOCP is the para-substituted analogue to DEHP. These substances are mainly used as substitutes for phthalates in electronic devices and textile print applications. Lineseed oil is a naturally occurring triglyceride and tributyl-O-acetylcitrate is an ester of acetylated citric acid.

The polymers are generally privileged in REACH by not requiring a registration if the monomers which are regarded as the more problematic precursors are already registered. Of the remaining substances in Figure 36 only DEHA, TOM and tributyl-O-acetylcitrate are currently registered, no classifications being attributed by the registrants). DINCH and lineseed oil have not yet been registered, DOCP has 15 active registrations. For DINCH no self-classifications are reported in the C&L-inventory but DOCP is reported as suspected of damaging fertility or the unborn child and as may cause long lasting harmful effects to aquatic life. For Lineseed oil the following self-classifications have been reported: May cause an allergic skin reaction

Based on this information it appears that most of the proposed alternatives are less hazardous as compared to the referred phthalates, but most have not been assessed in depth (TOM, for example, is currently under substance evaluation).
For the other three substances for which no application for authorisation (AfA) have been submitted by the latest application date (tris(2-chloroethyl)phosphate, 4,4'-diaminodiphenylnmethane and diarsenic pentoxide) it seems that only 4,4'-diaminodiphenylnmethane may still be in use for applications which fall outside of authorisation (e.g. use as intermediate). Arsenic pentoxide seems to have been fully substituted by arsenic trioxide, as it reacts into the latter compound at elevated temperatures and thus has a very similar use spectrum. The registrations of tris(2-chloroethyl)phosphate have all been inactivated.

It would have been very interesting to carry out a deeper assessment of the experiences of manufacturers, traders and users who have successfully made use of the alternatives to the above mentioned phthalates but the limited resources for the project did not allow for a more extensive investigation of the market situation.

For substances in Table 4 belonging to category R_AXIV_LADP_AfA there is considerable information available on potential substitutes through the analyses of alternatives as part of applications for authorisation (AfA) as well as through the comments of third parties during the consultation (see section 4.5). This essentially concerned the following substances:

- bis (2-ethylhexyl)phthalate (DEHP)
- dibutylphthalate (DBP)
- diarsenic trioxide (Dtri)
- lead chromate (LC)
- trichloroethylene (TCE)

In most AfAs a quite comprehensive and technically detailed assessment of potential alternatives is provided. Even though SEAC has properly scrutinized the applications for authorisations it would have been very interesting in light of the project to discuss with the applicants on a case-by-case basis the experiences with potential substitutes and the specific motives why the properties of the alternatives have not been regarded as sufficient for substitution. However, this would have required a high technical expertise in very different fields which was not possible with the capacity of this project. Table 9 just provides an overview of substitution options.
6.4. Questionnaire

As already mentioned above, a survey of the experiences of registrants, applicants for authorisations and potential users of the selected SVHCs with substitution (compare section 3.4) has been made. The survey was based on a questionnaire which had been sent to a total of 224 registrants and 39 trade-associations for further distribution to companies (for details see section 3.4 and the Annex II).

As already indicated in section 4.4 the response rate to this survey was quite limited. From a total of 428 companies who reportedly received the questionnaire (including the 224 registrants whose addressees had been kindly provided by ECHA for this project), only 29 responses have been returned to the authors. These responses came from four holders of authorisations, seven applicants for authorisations and 18 other manufacturers, importers and/or users of the selected SVHCs. The resulting response rate of approx. 7% clearly cannot be claimed as providing a firm basis for drawing statistically relevant conclusions. Hence, only anecdotal reference can be made in this report. Results from the survey are given in detail in the Annex II.

Of the 29 responses, nine users indicated that the volumes have been reduced for the following substances:

- 2,2’-dichloro-4,4’-methylenedianiline (MOCA)
- trichloroethylen (TCE)
- diisobutyl phthalat (DIBP)
- dipentyl phthalat (DPP)
- bis (2-ethylhexyl)phthalat (DEHP)

A comparison with the volume-based information discussed in previous sections suggests that these may only be occasional effects rather than typical trends. This observation is based on the fact that the volume data from IUCLID was only decreasing for the substance DIBP. For MOCA it did not change after the first registration deadline and in the case of DEHP (Figure 18) and TCE (Figure 19) the available information from the different databases was inconsistent. For the last substance DPP there is no available volume data in any of the searched databases.

For the substances MDA, TCE, DEHP and DIBP indications were given in five responses that they have been at least partially replaced and only DIBP seems to have been fully replaced by another substance.

Only one former user of DEHP reported a positive overall impact of the application of the alternative substance. It was particularly noted that the performance and quality of the new product have increased and that there were positive effects for the environmental-impact, the workers and the consumer safety. The cost impact for the alternative substance in comparison to the replaced substance was in all situations considered as negative (more expensive).

One company, however, stated with respect to the substitution of DEHP that there was a: “huge impact on whole company with no benefit for the consumer or the environment. Our use is an intermediate use; however, market demands "phthalate-free" products. Big resources were taken up from R&D, Operations, Marketing, Product management, Product Stewardship for this substitution work.”

Three respondents noted that there were either no toxicological data available for the alternative substances or that they had to make considerable efforts to generate these data before they were able to use the new substance.
A remarkable finding was that seven of the nine respondents who successfully substituted a SVHC indicated that the inclusion of the substance to the candidate list was the trigger for their substitution activities. While this effect is not surprising, it is in stark contrast to the findings based on registration data discussed above. It would have been quite interesting to discuss this observation in more details.

However, only three of the authorisation holders/applicants have signalled that they would be willing to answer a more specific, individualised questionnaire, and finally only one of them actually provided a written response which is summarised in Table 19. Even though it is at best an anecdotal reference it is probably a good example for the kind of answers that could have been received in the envisaged interviews.

Table 19: Summary of the follow-up questionnaire for the authorisation holders, which was only answered by one of the three authorisation holders/applicants which agreed to do a follow up questionnaire

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>What were the biggest obstacles/problems related to the application for authorisation (AfA)?</td>
<td>Major challenges are the preparation of the Socio-Economic Assessment and especially collecting data regarding the impacts on the downstream supply chain if authorisation is not granted. It is even more difficult when the downstream supply chain (customers) uses products which are manufactured with the use of Annex XIV substances as process chemicals, i.e. if the substance is finally not present in the products used by the downstream supply chain.</td>
</tr>
<tr>
<td>If you could change something in the application procedure, what would this be?</td>
<td>Simplification for process chemicals not present in the products placed on the market</td>
</tr>
<tr>
<td>Related to the application, were there a lot of data which you were asked to provide later at request from RAC/SEAC/ECHA?</td>
<td>N/A . We did not get requests from ECHA (RAC or SEAC) since the public consultation ended in June 22nd 2016</td>
</tr>
<tr>
<td>If yes, was it clear what the missing data was?</td>
<td></td>
</tr>
<tr>
<td>How would you describe the communication between the company and the different REACH- institutions?</td>
<td>Communication has been excellent and often initiated by us</td>
</tr>
<tr>
<td>Question</td>
<td>Response</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Do you assume that an alternative substance can be found within the</td>
<td>We assume that we will be able to implement an alternative during the review period (12 years) that we have requested. But there is always a risk that the alternative does not work for all the products that are manufactured</td>
</tr>
<tr>
<td>review period of your applications or do you think it unlikely that</td>
<td></td>
</tr>
<tr>
<td>alternatives will be found on a long term basis?</td>
<td></td>
</tr>
<tr>
<td>Have there been changes related to the RMM because of the AfA?</td>
<td>Minor changes have been implemented as our company always strives at better RMM to protect health of employees and the environment. These improvements are not related to the AfA.</td>
</tr>
<tr>
<td>Have there been any other impacts which can be related to the AfA?</td>
<td>Yes, customers have shown concerns that our company will not be granted authorisation.</td>
</tr>
<tr>
<td>In your opinion is the AfA an adequate measure to protect human health</td>
<td>No, we think that other legislations/regulations could handle the risks associated with the use of SVHCs to control human health and environment. Such regulation could be related to occupational health.</td>
</tr>
<tr>
<td>and the environment?</td>
<td></td>
</tr>
</tbody>
</table>

Based on the results obtained in this project on substitution probably the following general conclusions can be made with reservations because of the lack of statistical representativeness:

- REACH and, more particularly the authorisation policy under REACH, has triggered the search for alternatives by the affected companies.
- According to the survey, already the inclusion of substances in the candidate list (identification of SVHCs) has led companies to consider the possibility of alternatives. There are a number of obstacles and barriers for implementing alternatives.
- All companies who implemented alternatives faced negative cost implications. It remained unclear if improvements as a net result of substitution would have finally outweighed the additional costs.
- An important obstacle for substitution is that most of the alternatives are toxicologically not well known and companies are hesitating to make efforts to introduce these substitutes which may, at a later stage, become also stigmatised.
- Even though authorisation seems to provide some pressure towards substitution most companies do not seem to feel that investments will actually pay and that the major implication will be a discrimination against competitors outside the EU. This is particularly the case for the use of SVHCs in articles: while EU users are bound by the authorisation the importers of articles containing SVHCs are not.
• The discussion on SVHC’s applied for in authorisation procedures seems to have triggered a scrutiny of the existing risk management measures in companies potentially resulting in improvements for worker’s health and risk reduction measures for downstream users (consumers and professionals).
• Only few companies indicated that they have ongoing relocation plans to places outside of the EU because of the costs for authorisation and/or the lack of an alternative.

Additionally it is noted that one of the respondents was a consultant service company who elaborated on the problem which the authorisation process causes for overseas suppliers. We refer here to directly their statement:
“The authorisation process is new so it confuses overseas suppliers if and when it applies. We have several clients that have SVHCs; they usually do not work on authorisations themselves, rather they might have a business relationship with an authorisation holder in the EU to handle in EU manufacturing needs. In other cases they might simply exit the market. It depends on many factors we do not know within our company”.