Monitoring of the authorisation process under the REACH Regulation

Test of a proposed methodology

Final Report, May 2017

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LEGAL NOTICE

This project “Monitoring of the Authorisation under REACH” has been carried out on behalf of the Austrian Federal Ministry of Agriculture, Forestry, Environment and Water Management (BMLFUW) as the competent authority for REACH in Austria.
The author: Dipl.-Agr.Biol. Diana Backes MSc. executed this work in the context of an administration internship in the Department V/5 (“Chemicals policy and Biocides”) under the head of the unit, Dr. Thomas Jakl, and under supervision of Dr. Martin Wimmer.

Disclaimer: The content of this report reflects the opinion of the author. The responsibility for the use and interpretation of the data is only with the author. It is noted that ECHA has not carefully reviewed and endorsed the report.
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<th>Description</th>
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</thead>
<tbody>
<tr>
<td>A.XIV</td>
<td>Annex XIV</td>
</tr>
<tr>
<td>A&amp;V</td>
<td>Animal&amp;vegetable products from the food &amp; beverage sector</td>
</tr>
<tr>
<td>AC</td>
<td>Article category</td>
</tr>
<tr>
<td>ADCA</td>
<td>Azodicarbonamide</td>
</tr>
<tr>
<td>AfA</td>
<td>Application for Authorisation</td>
</tr>
<tr>
<td>AoA</td>
<td>Analysis of Alternatives</td>
</tr>
<tr>
<td>ASL</td>
<td>Article Service Life</td>
</tr>
<tr>
<td>BBP</td>
<td>Benzyl butyl phthalate</td>
</tr>
<tr>
<td>BCA</td>
<td>1,2-Benzenedi-Carboxylic Acid, di-C6-10-alkyl esters (EC#271-094-0)</td>
</tr>
<tr>
<td>BCA 1</td>
<td>1,2-Benzenedicarboxylic acid (EC#284-032-2)</td>
</tr>
<tr>
<td>BCA 2</td>
<td>1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear (EC# 271-093-5)</td>
</tr>
<tr>
<td>CD</td>
<td>Candidate List</td>
</tr>
<tr>
<td>CLH</td>
<td>Harmonised classification and labelling</td>
</tr>
<tr>
<td>CMR</td>
<td>Cancerogenic, Mutagenic and Reprotoxic</td>
</tr>
<tr>
<td>COM</td>
<td>European Commission</td>
</tr>
<tr>
<td>CS</td>
<td>Chemical Industry</td>
</tr>
<tr>
<td>CSR</td>
<td>Chemical Safety Report</td>
</tr>
<tr>
<td>DBP</td>
<td>Dibutyl phthalate</td>
</tr>
<tr>
<td>DC</td>
<td>Data collection</td>
</tr>
<tr>
<td>DEHP</td>
<td>Bis(2-ethylhexyl) phthalate</td>
</tr>
<tr>
<td>DHNUP</td>
<td>5.1.14. 1,2-Benzenedicarboxylic acid (EC# 68515-42-4)</td>
</tr>
<tr>
<td>DIBP</td>
<td>Diisobutyl phthalate</td>
</tr>
<tr>
<td>Diglyme</td>
<td>Bis(2-methoxyethyl) ether</td>
</tr>
<tr>
<td>DIHP</td>
<td>1,2-Benzenedicarboxylic acid (EC# 276-158-1)</td>
</tr>
<tr>
<td>DIPP</td>
<td>Diisopentyl phthalate</td>
</tr>
<tr>
<td>DMEP</td>
<td>Bis(2-methoxymethyl) phthalate</td>
</tr>
<tr>
<td>DnHP</td>
<td>Dihexyl phthalate</td>
</tr>
<tr>
<td>EDC</td>
<td>1,2 Dichloroethane</td>
</tr>
<tr>
<td>EGDME</td>
<td>1,2-Dimethoxyethane</td>
</tr>
<tr>
<td>EGEE</td>
<td>2-Ethoxyethanol</td>
</tr>
<tr>
<td>EGME</td>
<td>2-Methoxyethanol</td>
</tr>
<tr>
<td>E-PRTR</td>
<td>European Pollutant Release and Transfer Register</td>
</tr>
<tr>
<td>EQ</td>
<td>Economic Questions</td>
</tr>
<tr>
<td>ERC</td>
<td>Environmental release category</td>
</tr>
<tr>
<td>ES</td>
<td>Energy Sector</td>
</tr>
<tr>
<td>F.A.XIV R.</td>
<td>Final Annex XIV recommendation</td>
</tr>
<tr>
<td>Form</td>
<td>Formaldehyde</td>
</tr>
<tr>
<td>FRD</td>
<td>First registration deadline</td>
</tr>
<tr>
<td>GE</td>
<td>Glycole ethers</td>
</tr>
<tr>
<td>IIUD</td>
<td>Identified industrial uses</td>
</tr>
<tr>
<td>IUCLID</td>
<td>International Uniform Chemical Information Database</td>
</tr>
<tr>
<td>--------</td>
<td>----------------------------------------------------</td>
</tr>
<tr>
<td>LAD</td>
<td>Latest Application Date</td>
</tr>
<tr>
<td>LCS</td>
<td>Life cycle stages</td>
</tr>
<tr>
<td>MAA</td>
<td>Methoxyacetic acid</td>
</tr>
<tr>
<td>MDA</td>
<td>4,4’.Diaminodiphenylmethane</td>
</tr>
<tr>
<td>MEIA</td>
<td>Monitoring and evaluation of the impacts of the authorisation process</td>
</tr>
<tr>
<td>MI</td>
<td>Mineral Industry</td>
</tr>
<tr>
<td>MOCA</td>
<td>2,2’-Dichloro-4,4’-Methylenedianiline</td>
</tr>
<tr>
<td>NACE</td>
<td>The Statistical Classification of Economic Activities in the European Community</td>
</tr>
<tr>
<td>OSII</td>
<td>On sight isolated intermediate</td>
</tr>
<tr>
<td>P&amp;W</td>
<td>Paper &amp; wood production processing</td>
</tr>
<tr>
<td>PbO</td>
<td>Lead monoxide</td>
</tr>
<tr>
<td>PBT</td>
<td>Persistent, Bioaccumulative, Toxic</td>
</tr>
<tr>
<td>PC</td>
<td>Product category</td>
</tr>
<tr>
<td>PLTS</td>
<td>Pentalead tetraoxide sulphate</td>
</tr>
<tr>
<td>PpM</td>
<td>Production &amp; processing of metals</td>
</tr>
<tr>
<td>PROC</td>
<td>Process category</td>
</tr>
<tr>
<td>RAC</td>
<td>Risk Assessment Comitee</td>
</tr>
<tr>
<td>REACH</td>
<td>Registration, evaluation, authorisation of chemicals</td>
</tr>
<tr>
<td>RIME</td>
<td>Risk Management Expert Meeting</td>
</tr>
<tr>
<td>RMM</td>
<td>Risk reduction measures</td>
</tr>
<tr>
<td>ROI</td>
<td>Registration of intention</td>
</tr>
<tr>
<td>SD</td>
<td>Sunset Date</td>
</tr>
<tr>
<td>SEAC</td>
<td>Committee for Socio-Economic Analysis</td>
</tr>
<tr>
<td>SPIN</td>
<td>Substances in Preparations in Nordic Countries</td>
</tr>
<tr>
<td>SU</td>
<td>Sector of end use</td>
</tr>
<tr>
<td>SVHC</td>
<td>Substances of very high concern</td>
</tr>
<tr>
<td>TCE</td>
<td>Trichloroethylene</td>
</tr>
<tr>
<td>TEGDME</td>
<td>Tetraethylene glycol dimethyl ether</td>
</tr>
<tr>
<td>TF</td>
<td>Technical Function</td>
</tr>
<tr>
<td>TLS</td>
<td>Tetralead trioxide sulphate</td>
</tr>
<tr>
<td>Tris</td>
<td>Tris(2-chloroethyl)Phosphate</td>
</tr>
<tr>
<td>Trix</td>
<td>Trixylyl phosphate</td>
</tr>
<tr>
<td>UAA</td>
<td>Uses advised against</td>
</tr>
<tr>
<td>UDP</td>
<td>Use-Descriptor-Profile</td>
</tr>
<tr>
<td>VOC</td>
<td>Volatile organic compounds</td>
</tr>
<tr>
<td>vPvB</td>
<td>Very persistent, very bioaccumulative</td>
</tr>
<tr>
<td>WWM</td>
<td>Waste and waste water management</td>
</tr>
</tbody>
</table>
Executive Summary

The motivation for carrying out this project named MEIA (Monitoring and Evaluation of the Impacts of the Authorisation) was to test a methodology proposed by the Monitoring Task Force of RiME (1) to measure if and how the objectives of the authorisation under REACH have been achieved.

The Monitoring Task Force has been initiated in RiME with the intention to shed more light on the rather controversial discussion about the impacts of authorisation policy under REACH. While some parties consider this new element of the REACH legislation as a new and efficient instrument to motivate substitution measures by industry others reckon that authorisation is an additional burden for companies which causes high costs and competitive disadvantages in the world market but no significant positive effects in terms of risk reduction and safety.

The monitoring methodology proposed by the Monitoring Task Force of RiME is based on the idea of deriving a number of relative simple, quantitative indicators based on information from REACH registration data and other information sources, supplemented with additional, more qualitative and case-by-case background information, which in combination should allow to monitor the progress made by the authorisation policy in relation to its major objectives.

More specifically, the indicators together with the other information were considered to support answering the main policy questions concerning the achievement of the goals of authorisation under REACH such as:

1. Has the objective of substitution worked?
2. Are there less articles containing substances of very high concern (SVHCs) on the market or has production and uses of SVHCs just been shifted outside Europe?
3. What are the major substitutes for SVHCs and are these alternates safer?
4. Have authorisation decisions led to better control of risks?
5. Is the authorisation as such or parts thereof a cost-effective policy for protecting man and environment?
6. Does authorisation work better for certain types of substances than for others and would this help to make more appropriate choices on SVHC candidates?

For the purpose of this project for a number of totally 34 selected SVHCs the proposed indicators based on registration information reported in the International Uniform Chemical Information Database (IUCLID) such as the numbers of registrations, annual tonnages, use descriptors, supplemented by other types of information have been collected and assessed in this project. The supplementing information included the following elements:

- Information of uses from applications for authorisations and public consultations at the ECHA website on the authorisation process
- Tonnage information from the “Substances in Preparations in Nordic Countries database” (SPIN)
- Tonnage information from EUROSTAT (provided by the European Commission)
- Aggregation of ambient monitoring data based on European initiatives such as the Water Framework Directive, the Rhine and Danube conventions, the European Pollutant Release and Transfer Register (E-PRTR)
- A survey of experiences of companies with the authorisation process.
• Market analysis of regional and worldwide uses of phthalates in the period 2007 – 2015 from Ceresana

Of the 34 selected substances, 24 were registered and 10 were not registered. The information for the substances was collected, summarised, aggregated and converted into the indicators proposed in (1) for each of the selected substances as a function of the time-line.

The selected SVHCs are advanced at different levels in the authorisation process as illustrated in the following table.

<table>
<thead>
<tr>
<th>Status in the process level at the project deadline</th>
<th>No. of selected SVHCs</th>
</tr>
</thead>
<tbody>
<tr>
<td>SVHCs registered and not included in Annex XIV</td>
<td>12</td>
</tr>
<tr>
<td>SVHCs not registered and not included in Annex XIV</td>
<td>8</td>
</tr>
<tr>
<td>SVHCs registered, included in Annex XIV, but latest date of application (LAD) not yet passed</td>
<td>4</td>
</tr>
<tr>
<td>SVHCs not registered, included in Annex XIV, but latest date of application (LAD) not yet passed</td>
<td>0</td>
</tr>
<tr>
<td>SVHCs registered, included in Annex XIV, latest date of application (LAD) has been passed and there are applications for authorisation (AfA)</td>
<td>4</td>
</tr>
<tr>
<td>SVHCs not registered, included in Annex XIV, latest date of application (LAD) has been passed and there are applications for authorisation (AfA)</td>
<td>1</td>
</tr>
<tr>
<td>SVHCs registered, included in Annex XIV, latest date of application (LAD) has been passed and there are no applications for authorisation (AfA)</td>
<td>4</td>
</tr>
<tr>
<td>SVHCs not registered, included in Annex XIV, latest date of application (LAD) has been passed and there are no applications for authorisation (AfA)</td>
<td>1</td>
</tr>
</tbody>
</table>

It is important to note that the proposed approach by the Monitoring Task Force of RiME was largely based on the assumption that relative simple indicators, mainly derived from registration information, would provide quantitative figures which allow for a more or less informed answer to the policy questions cited above.

As an overall result from the discussion in section 6 it must be concluded that the proposed indicators together with the level of detail of other information gathered in this project were clearly insufficient to provide an informed answer to the policy questions cited above.

A shortcoming for most of the proposed indicators is that the relevant registration data available electronically in ECHA’s data-base are flawed for a number of possible reasons such as:
- incomplete updates by registrants (e.g. of tonnages)
- misinterpretations of certain requirements under REACH by registrants
- lack of understanding of the required information, e.g. use descriptors, by registrants
- limitations of the detail of information in the electronically stored data, e.g. on the uses
- possible errors in data connected with IUCLID migration issues
Recommendation 1: Even if joined efforts may lead to a significant increase of the quality of registration information in ECHA’s database, the indicators studied in this project may, in principle, be too simple to provide a sufficiently detailed measure for the achievement of authorisation objectives. It will thus be necessary to consider alternative approaches.

One option would be the establishing of a set of more detailed and complex indicators/parameters which would allow for a more precise mapping of the existing information in registration dossiers to the policy questions quoted above. For example: An in-depth case-by-case analysis of the use-profiles and categories for each individual substance may be carried out, leading to a new set of quantitative measurable indicators which provide a more detailed information with respect to the policy questions.

Another option would be to move the focus of the assessment from the registration information and the authorisation procedures to success stories of substitution. Companies who have successfully achieved the substitution of a SVHC should be generally expected to be interested in sharing their experiences. Studying the reasons, the detailed steps and the efforts needed for implementing alternatives would provide, inter alia, concrete information about the barriers for substitution. Such an approach may also provide a new set of indicators which may allow for a quantitative or semi-quantitative description of degree to which substitution has been achieved.

It is recommended that ECHA could play a key role in the assessment of substitution and in the development of reliable indicators describing the progress of substitution, and the barriers to it.

Information box I illustrates for two selected SVHCs which are already very advanced in the REACH process a typical difficulty of interpretation observed for use-category based indicators and registered volumes. Even though no applications for authorisations have been submitted for both substances until the latest application date, the indicators suggest that there are still active uses which may be artefacts due to insufficient updates by registrants.
Recommendation 2: For SVHCs which have already reached the sunset date, the analysis of the indicators based on registered tonnages and use descriptors over the time line should be used for a consistency check. If there are indications of continuing uses following the sunset date, it should be examined as to whether these uses are legal (i.e. either outside of the scope of authorisation or already authorised), artefacts due to lack of dossier updates or illegal activities which need enforcement actions. For this purpose, ECHA could send letters to the registrants for uses that are no longer allowed. This information could at the same time be transmitted to the Forum to be used for the design of future enforcement programmes on authorisation.

TCE is another SVHC rather far advanced in the authorisation process which has been widely used in the past but was continuously substituted by other solvents because of its health and environmental impacts. Information box II illustrates the well reported successes in substitution, e.g. in Scandinavian countries, but also the difficulty in interpreting volume as well as emission information as potential indicators of use.
The discrepancies between registration-based and Eurostat-based data could not be explained in this project. It is important to note that there is currently no obligation by registrants to continuously update their volume information. Updates of tonnages are only legally required if the tonnages increase up to the next tonnage band (REACH Article 22 (1c). If tonnages do not reach the next tonnage band or even decrease, registrants are not required to update the information. In this report strong indications were found that registrants do not regularly update their volume information in IUCLID. While this is not necessarily a breach of REACH, this obviously causes systematic errors in IUCLID volumes because of lack of updating. Information box III reflects some further results with respect to updating activities by registrants.
Information box III: Updated or not updated – this is the question?

Regular updates of registration dossiers are not formally required by REACH, but are a necessary pre-condition for using registration data for the derivation of quantitative indicators on substitution progress. In this project it became obvious that even for SVHCs at milestones which can be expected to require intensified updating, the average number of updates per dossier is rather low. This is exemplified by the following table

<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>
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</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>
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<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>
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<tr>
<td>MDA</td>
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</tbody>
</table>

What one can see in the table is the number of spontaneous updates n of the registration dossiers and the number of active dossiers M at the latest application date (LAD) for those SVHCs which have reached the LAD before the deadline of this study. Even though the LAD was the milestone with the relative highest updating frequency the average number of updates per dossier is for most substances less or equal 0.5. This means that only every second dossier was updated on average. Given the key role of registration data in an exercise as the one carried out in this project, it is obvious that such a low updating frequency will inevitably lead to data of low actuality and thus to data of little use.

⇒ Recommendation 3: The project has found strong indications that volume information is not regularly updated by registrants. While this is not necessarily a breach of REACH, it creates systematic errors in the IUCLID volume information which would otherwise be a very valuable indicator for measuring e.g. substitution progresses. Given that REACH does not require regular (annual) updates (REACH Article 22 (1c)), it is recommended that ECHA and Member States authorities continue to make strong efforts in motivating industry to carry out regular dossier updates on a voluntary basis. If this turns out to be finally not successful, the Commission needs to consider an adequate change of the existing legislation under REACH.

For substances for which applications for authorisations have been submitted to ECHA, there is a bulk of information available about the applied uses. A comparison of these uses with the uses descriptions reported in IUCLID provides noticeable mismatches even for quite well documented substances such as DEHP. The observed discrepancies may be partially explained by the fact that some uses reported in IUCLID are outside of the scope of authorisation. Another reason for the differences may be due to an incomplete update of the registration dossiers. A clarification of these questions was not possible in this project.
Recommendation 4: For SVHCs for which ECHA has received an application for authorisation (AfA) it is recommended that a systematic comparison between the applied (category of) uses with the uses reported in IUCLID should be carried out during the authorisation procedure. Applicants should be inquired to explain differences where they exist. If inconsistencies are substantiated the responsible registrants should be requested by ECHA to properly update the registration dossier. Where a breach of REACH Article 22 is identified, enforcement actions must be considered.

Information on the volumes of substances and mixtures in Nordic countries in the SPIN database show for a number of SVHCs a significant decrease over the last years. As information box IV illustrates, volume information over time provides an excellent indicator for substitution progresses for the three selected SVHCs. The situation in Scandinavian countries is, however, not representative for the whole of Europe. Also, the most significant substitution effects in the Nordic region can be observed long before REACH came into force, so in those cases REACH policy has clearly not been the trigger for substitution.

Information box IV: Nordic substitution success stories – but not triggered by REACH

Another remarkable result found in this project is the fact that for the selected SVHCs the milestone “inclusion of a substance in the candidate list” has had no visible impact on any of the indicators (the only exceptions are the four lead compounds). This result challenges the frequent criticism raised by industry that candidate listing would have a significant negative impact on companies because of the so called “black listing effect”. On the basis of the indicators considered in this report no “black listing effect” has been observed.
The project did show for some selected SVHCs that the authorisation process does contribute to the improvement of dossier quality as it gives a strong incentive for industry to reconsider their database and bring more consistency to their registration data. For example, clarifications made in the registered use descriptors and in exposure scenarios certainly contribute to the quality of information in registration dossiers. Given that this information is passed down the supply chain this means that authorisation indirectly contributes to risk management improvements. However, it should be noted that improving quality of registrations is not the main aim of the authorisation process and the same objective may be reached by other less costly measures such as enforcement actions.

For the incorporation of SVHCs into articles within the EU the most direct use-related indicator is the article category of use. Ideally, the number of article categories of use should be an indicator for the intensity of use of the substance in article manufacturing. Information box V illustrates the results for the respective substances studied in this project.
Information box V: Less article categories for only two phthalates!

The indicator “article category” displays the total number of different article categories reported by registrants. The figure shows the change of this indicator over the time line for the eight substances considered in this project for which the latest application date has already passed. It is remarkable that only for two phthalates, DEHP and DIBP, there are significant decreases in the number of different article categories reported, which is an indication that the manufacturing of articles containing DEHP and/or DIBP has probably been reduced after the latest application date. It is noteworthy to still find one article category for DIBP (manufacturing of vehicles) even though there were no applications for use of DIBP. Potentially this may address the use of DIBP for spare articles for which extended deadlines in Annex XIV are currently discussed. For the other six substances no changes in article categories can be observed so that authorisation does not seem to have a measurable effect on the use of these substances in the production of articles.

The register of notification of SVHCs in articles pursuant to REACH article 7 (2) contains currently 20 entries covering a number of article containing DIBP. These uses are depicted in the following figure. As by the sunset date for DIBP (February 2015) there is no legal use of DIBP in the EU (expect those uses which are exempted from authorisation), the notifications should only concern imported articles (there may be notification). It is not possible at this time to say with confidence if the total amount if DIBP originating from the import of articles to Europe may compensate or even over-compensate for the reduced uses of DIBP for article production in Europe.
This shows that the article categories in its simple form are not well interpretable indicators for article uses. A reduction in the number of articles does not necessarily reflect a decrease of the potential exposure of customers to articles containing SVHCs as it is not linked to the tonnages of SVHCs. Furthermore, a reduction of the indicator based on article categories over time may not even be a desired substitution effect. If in response to the public consultations in the authorisation process further information about downstream uses is becoming evident, this may result in an increase of the number of article categories in the registration dossier but this could be considered as a positive effect of improving dossier quality. Only under the assumption that registrants would report adequate article categories a decrease in the number of article categories after the latest application date may be interpreted as an indication for a reduction of the diversity of articles containing the SVHC.

 Recommendation 5: The proposed indicator based on the number of article categories is not appropriate to answer the question if the manufacturing of the number of articles containing a SVHC has decreased over time. And there is also no simple indicator or information source available on the volume of SVHCs imported into the European market via articles.

 The major source for the occurrence and amount of SVHCs in articles in the EU are product monitoring reports carried out by Member States. In order to derive meaningful, representative information on SHVCs in articles from such reports, the monitoring approaches applied by Member States would need to be coordinated so that statistically robust information could be produced. It is recommended that Member States authorities, the Commission and ECHA should discuss whether a coordinated monitoring approach would be agreeable on an informal basis. For the purpose of a concerted monitoring action, the notifications of articles to ECHA under REACH Article 7(2) may be a useful starting point. These notifications, though incomplete, relate to a range of article categories which reportedly contain SVHCs and thus could serve as monitoring targets in a coordinated monitoring programme.

The subject of chemical’s alternative assessment which is key to substitution has only been marginally touched in this project as it would have required significant additional resources and expertise on chemical alternatives and comparative hazard and risk assessment. From the survey of industry there are only very anecdotal hints evidencing the fact that the lack of information on existing alternatives, including (eco)toxicological information is a significant barrier to successful substitution.

 Recommendation 6: The answer to the question on suitable alternatives is key to authorisation. It requires substance-specific expertise in a broad area of fields including comparative hazard and risk assessment. There are numerous such assessment tools available\(^1\). Also ECHA has already taken up this issue and provides a specific Website attributed to substitution\(^2\).

 It is recommended that the European Commission, ECHA and the Member States discuss further steps and options to integrate the search for alternatives and the

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application of alternative assessment tools into the existing European chemicals policy framework, especially in the already existing tools for substitution under REACH. One option would be the establishment of a kind of competence centre or focal point on substitution and alternatives assessment. The European Commission, ECHA and the Member States authorities are invited to discuss the possibility for the installation of such a focal point and the specific tasks as well as the needs of personnel and financial resources.

Next to substitution the adequate control of risks when handling SVHCs is another important objective of the authorisation. Like for the alternatives assessment this question requires a substance specific consideration which is provided for some groups of selected SVHCs to a certain (but due to the limited resources only rather limited) extent in this report. One interesting example may be the four lead compounds considered in this study. ECHA has only very recently made the recommendation for inclusion in Annex XIV. The Commission has not yet made a regulatory proposal for inclusion in Annex XIV.

It is noteworthy that a certain reduction in IUCLID volumes can be observed for these compounds. These findings are largely supported by the information from the SPIN database. Insofar as a reduction in volumes will usually lead to decreased exposure (either in exposure levels or in the number of exposure events) this change may be interpreted as as risk reduction. An important sector for the selected lead compounds is the manufacturing of rechargeable batteries and accumulators. The lead emissions of this sector into water or air reported in the E-PRTR are difficult to interpret for the water compartment but show a clear decrease until 2011 for the air compartment. This, in principle, could also be regarded as a supporting evidence for the observed decline in IUCLID-based tonnages, and thus for the reduction in terms of risks. 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 equally well be the result of improvements in best available techniques and/or purification measures and thus do not directly correlate with the extent of use. Within the scope of this study it was not possible to clarify this rather complicated issue.

⇒ Recommendation 7: The European Pollution Release and Transfer Register (E-PRTR) appears to be a useful source for a quite limited number of SVHCs. The download tool (http://prtr.ec.europa.eu/#/pollutantreleases) allows for an extraction of information about emissions into the air and into the water compartment in relation to specific sectors of activities. This selective information enables a linkage between the total emissions of lead and a specific activity. If the use of the concerned substance in this activity is well known, the total emissions to air and water may be a good parameter for measuring the use intensity. As an example in this project the use of the four lead compounds in the manufacturing of rechargeable batteries and accumulators has been discussed. In order to interpret the observed changes in emissions in terms of use intensity it is, however, important to know about the local circumstances. It is, therefore, recommended to use emissions based on the E-PRTR always in combination with a direct dialogue with the particular company that has reported to the E-PRTR (an analysis which has not been possible in this project). This would enable the assessor to clarify whether the changes in emissions were caused by changes in the use intensity or by other risk reduction measures such as waste water treatment or purification of exhaust gases.
In order to better understand the reasons of companies for making the decision to continue the use of a SVHC on the basis of an authorised use or to make efforts to replace the substance by a less problematic alternative (alternative substance and/or techniques) it was envisaged for the present project to survey a broad spectrum of potential users of SVHCs on their experiences about the incentives for and the obstacles against substitution in order to obtain robust statistical information. The low response rate of 7% (or 29 respondents in absolute figures) does not allow for drawing a statistically relevant conclusion. Only one authorisation holder agreed to provide more detailed information on his experiences. Due to statistically irrelevant information obtained from the industry survey it is not possible to draw a well-informed conclusion. The following conclusions are rather anecdotal responses but are reproduced here as they may be considered useful for further discussions on different, possibly more successful, approaches:

i. REACH and, more particularly, the authorisation policy under REACH has triggered the search for alternatives by the affected companies.

ii. 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.

iii. 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.

iv. 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.

v. 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 disadvantage 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.

vi. The discussion on SVHCs 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).

vii. 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.

The MEIA project was a first attempt to test a methodology proposed by the Monitoring Task Force of RiME (1) to measure if and how the objectives of the authorisation under REACH have been achieved. The monitoring methodology proposed by the Monitoring Task Force of RiME is based on the idea of deriving a number of relative simple, quantitative indicators derived mainly from REACH registration data in combination with additional, more qualitative background information.

For a number of reasons the project failed to prove the proposed methodology as adequate to monitor the progress made through authorisation under REACH. One reason certainly lies in the rather limited quality of data, in particular of the data retrieved from REACH registrations. However, even if these flaws could be eliminated with much effort by all parties
involved, there remain doubts that the proposed methodology as such is actually adequate. Probably a set of more complex and sophisticated indicators based on available REACH registration data (and other sources) could be developed as an alternative. Another option could be the establishing of a different set of key questions focusing more on an analysis of substitution success stories. It is hoped that the results provided in this report are useful for the further discussion on possible measures of the authorisation instrument under REACH.
1. **Introduction**

Authorisation is a new instrument of chemicals policy introduced by REACH and there are quite different views on the relevance and effectiveness of this tool amongst policy makers, industry and other stakeholders. In the Risk Management Expert Meetings (RiME-meetings) which have been installed by the European Chemicals Agency and the European Commission to provide a discussion forum for national experts on risk management measures under REACH, a Task Force has been established with the aim of developing a methodology for measuring and evaluating the effects of the authorisation process as a whole. The Task Force has elaborated a concept for the monitoring of the impacts of authorisation under REACH which was presented at the RiME meeting 2015 in Brussels (1). The proposed methodology introduced a number of indicators and other information which could be potentially applied for the evaluation of the effects and impacts caused by the authorisation process. As substitution is the most relevant aim of authorisation policy with respect to environment and health protection, the focus of the methodology was on measuring the substitution effect. The RiME document (1) proposes that by measuring the proposed quantitative indicators and other more qualitative information over the time-line of the substitution process, from inclusion of a substance in the candidate list to the individual authorisation procedure for Annex XIV substances, it could be possible to identify and quantify the progress of substitution for selected substances. This should establish a firm basis on which key questions related to the effectiveness of the authorisation process under REACH could be discussed in a mostly objective manner, such as (1):

- 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 present project named MEIA (Monitoring and Evaluation of the Impacts of the Authorisation process) has been developed with the aim to test the proposed approach in practice on a selection of substances which are more or less evolved in the authorisation process.

For this purpose, in the MEIA project a total of 34 substances of very high concern (SVHC’s) which are at different stages in the authorisation process have been selected. For these substances information was retrieved from a number of data sources, i.e.

- Registration information from the International Uniform Chemical Information Database (IUCLID)\(^3\) database (provided by ECHA)
- Information of uses from applications for authorisations and public consultations at the ECHA website on the authorisation process

\(^3\) IUCLID is a software application to record, store, maintain and exchange data on intrinsic and hazard properties of chemical substances
• Tonnage information from the “Substances in Preparations in Nordic Countries database” (SPIN)
• Tonnage information from EUROSTAT (provided by the European Commission)
• Aggregation of ambient monitoring data based on European initiatives such as the Water Framework Directive, the Rhine and Danube conventions, the European Pollutant Release and Transfer Register (E-PRTR)
• A survey of experiences of companies with the authorisation process.
• Market analysis of regional and worldwide uses of phthalates in the period 2007 – 2015 from Ceresana

This information was collected, summarised, aggregated and converted into the indicators proposed in (1) for each of the selected substances as a function of the time-line.

An analysis of the quality of the indicators and of the change of indicator values in response to key milestones within the authorisation process was carried out.

The discussion and conclusion of the MEIA project focuses on the question to what extent these indicators may be useful measures of the effects and impacts of the authorisation process with particular emphasis on the substitution effect, and also provides recommendations for future work.

The sections of this report are organised as follows.

Section 2 provides a brief introduction to the relevant terminology.

Section 3 describes the method for the selection of the substances analysed in this project.

Section 4 gives an overview of key properties and uses of the individual substances selected for MEIA analysis, structured in substance groups.

Section 5 provides a summary of the information sources and data used and assessed in this project.

Section 6 contains a discussion of the results of the project for each of the substances which was analysed.

Section 7 provides conclusions and recommendations on the basis of the experiences made in the MEIA project.
2. **Terminology**

The REACH regulation is one of the most comprehensive and complex pieces of European law and through its implementation a specific terminology and numerous abbreviations have been introduced to facilitate the discussion. This chapter introduced the most important terms and abbreviations used in the context of the present study. For more comprehensive information on REACH terminology the reader may consult ECHA-term (2).

**Registration**

The key obligation under REACH is the registration by manufacturers and importers of a substance if the annual tonnage is above one ton. The registrants must provide comprehensive information on the substance electronically in IUCLID format to ECHA. If the annual tonnage exceeds 10 t/a the registration must also include a comprehensive risk assessment compiled in a document which is called chemical safety report.

First registration Deadline

All substances which are manufactured or imported in the EU and meet the following specifications, are illegal to be used after the 1. December 2010 if they have not been registered.

- ≥ 1 000 tonnes per annum (tpa)
- ≥ 1 tpa carcinogens, mutagens, reprotoxins (CMRs)
- ≥100 tpa dangerous to the environment R50/53

**Substances of very high concern (SVHC)**

SVHCs are chemical substances which have been identified as candidates for becoming subject to authorisation under the REACH regulation. Substances may become SVHCs if they have one of the following properties:

- The substance fulfil the criteria for being carcinogenic, mutagenic or toxic for reproduction of categories 1A or 1B under the CLP regulation (CMR)
- The substance is persistent, bioaccumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) in accordance with Annex XIII of the REACH regulation
- The substance is endocrine or persistent, bioaccumulative and toxic or very persistent and very bioaccumulative, but does not fulfil the criteria of Annex XIII of REACH and there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those which fulfil the abovementioned criteria.

It is noted that a substance meeting one or more of the above-mentioned criteria does not necessarily become a SVHC. Only if a Member State authority or the ECHA on behalf of the Commission submits an Annex XV dossier proposing the identification of a selected substance as SVHC on the basis of its properties and the Member State Committee of ECHA, after public consultation, comes to the decision that the selected substance indeed fulfils the criteria mentioned above, the substance is formally identified as SVHC and included in the public candidate list(3).
Substances subject to authorisation under REACH

Substances which are listed on the candidate list are further assessed by the Member State Committee of ECHA whether they also fulfil the priority criteria established under REACH. Priority shall normally be given to a substances if

- it is PBT or vPvB OR
- it is used in a wide dispersive manner OR
- it is used in high volumes

If the Member State Committee, after a second public consultation, comes to the conclusion that a SVHC fulfils these criteria, ECHA recommends to the European Commission the substance for inclusion in Annex XIV.

A final decision about the inclusion of a substance in Annex XIV is made, on the basis of a Commission’s proposal, by comitology procedure.

After a certain date (“sunset date”), which is specified in Annex XIV, any use of a substance included in Annex XIV requires a prior authorisation by the European Commission, unless the use is specifically exempted under REACH.

The following uses are exempted from authorisation under REACH:

- Uses which are explicitly exempted in REACH Annex XIV
- On-site isolated intermediates and transported isolated intermediates
- Uses in scientific research and development (Art. 56(3)) (Annex XIV shall specify if the authorisation requirement applies to product and process research and development)
- Uses in biocidal products within the scope of Directive 98/8/EC
- Uses as motor fuels covered by Directive 98/70/EEC
- Uses as fuel in mobile or fixed combustion plants of mineral oil products and use of fuels in closed systems
- Uses in cosmetic products within the scope of Council Directive 76/768/EEC (this exemption applies to substances listed on Annex XIV on the basis of their hazard to human health only)
- Uses in food contact materials within the scope of Regulation (EC) No 1935/2004 (this exemption applies to substances listed on Annex XIV on the basis of their hazard to human health only)
- Uses of substances when present in mixtures below a concentration limit of 0.1% by weight. This applies only to substances listed in Annex XIV on the basis of being persistent, bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB) or listed in Annex XIV on the basis that there is scientific evidence of probable serious effects to human health or the environment which give an equivalent level of
concern to substances with PBT or vPvB properties, or an equivalent level of concern to substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR) category 1 and 2

- Uses of substances when present in mixtures below the lowest concentration limits specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 which results in the classification of the mixture as dangerous. This applies only to substance listed in Annex

**Authorisation procedure**

If a substance is included in Annex XIV, users of that substance, manufacturer, importers or downstream users of the substance must apply for an authorisation before a certain date (“application date”) specified in Annex XIV which is typically set at 1.5 years before the sunset date.

The following terms are frequently used in authorisation procedures:

- ECHA’s Risk Assessment Committee (RAC)
- Committee for Socio-Economic Analysis (SEAC)
- Chemical Safety Report (CSR)
- Socio-Economic Analysis (SEA)
- Analysis of Alternatives (AoA)

**Risk management option analysis**

According to REACH the initiative for proposing additional risk management reduction measures lies either with the European Commission (via ECHA) or the national competent authorities (MSCAs = Members State Competent Authorities). In order to make the process transparent to industry and stakeholders the involved parties have agreed to prepare prior to the formal proposal of a risk management measure a so called risk management option analysis (RMOA) which explains the motivation of the initiating institution for considering a certain regulative measure as the best risk management option. Conclusions of RMOAs are published on ECHA’s website (4)

If the initiating institution concludes that a certain regulatory measure under REACH (e.g. restriction, identification of SVHC, substance evaluation) or CLP (e.g. new classification or update of the current classification) would be the most appropriate measure it will prepare that measure in accordance with REACH.

**The Registry of Intentions (RoI)**

Prior to the submission of a dossier initiating a certain risk management measure under REACH or CLP, MSCAs and ECHA have agreed voluntarily to make the intended measure public at the Registry of Intentions (RoI) so that interested parties become aware of the intended action and can timely prepare their comments for the subsequent consultations later in the respective procedure.
Description of uses and exposure scenarios

A key element of the assessment of chemical under the REACH regulation is the assessment of risks to the human health and/or to the environment. For this purpose, ECHA has developed a comprehensive inventory of guidance (5), an essential part of which deals with the prediction of exposure levels under certain use conditions (6).

Use-Descriptor-System (Number; Name; Description)

For the purpose of the present study the characterisation, classification and categorisation of uses as applied in guidance of ECHA for exposure assessments. The following provides a summary of the terminology applied by ECHA (7). The corresponding tables summarising the different use categories can be found in Annex III.

- Sector of use categories (SU):
  The sector of use (SU) describes in which sector of the economy the substance is used. This includes manufacture in the chemical industry, mixing of substances at formulator’s level as well as industrial, professional and consumer end-use.
  If the manufacturer/importer or the downstream user is unable to identify a suitable sector of use category from the list, the category “SU0 - other” can be selected and the type of sector should be specified. If possible, a code (and the corresponding phrasing) from the NACE system should be selected to describe such a sector.

- Chemical product category (PC):
  The aim of the PC is to characterise the type of mixture in which the substance in contained and has two functions:

  o They describe the sectors formulating mixtures by mixture types (information relevant at formulation life-cycle stage). The categories listed help to further structure the uses of the substance along the supply chain based on the product types;
  o They describe the product types used by the end-users (industrial, professional or consumer end-users). The product type implicitly includes some information on the potential for exposure/release of the substance.

- Process categories (PROC)
  The process category (PROC) describes the technical process, defined tasks and/or process types or applications in which the substance is used from the occupational perspective. In this category the exposure potential for workers during respective tasks or process type are considered and there are different categories for the individual release potentials. The descriptor can also be assigned to workers activities contributing to a specific use.

- Environmental release category (ERC)
  The environmental release category (ERC) describes the broad conditions of use from the environmental perspective. It describes the life cycle stage at which a use takes place by associating a specific type of emission/release to the use. The ERC also considers the technical fate of the substance resulting from a use, this gives an indication for the destination of the substance e.g. become part of an article, is consumed on use, is expected to be released to soil, water, air or waste.
Additionally the indoor or outdoor use is taken into account and indicated whether direct release to non-industrial soil or surface water may be relevant. Articles are also indicated for release-promoting conditions or if a release of the substance is intended. E.g. weathering conditions, abrasion from tyres, or processing techniques like sanding.

- Article category (AC)
  The article category (AC) describes the type of article into which the substance has eventually been processed and is relevant for the service life stages describing the activities of workers and consumers. The category outlines essentially the type of material (matrix) and the type of the articles in which the substance is embedded in.
3. **Selection of the substances for the MEIA project**

A major goal of the MEIA project was to test the proposed set of indicators and other elements of information on a number of SVHCs. For this purpose a number of substances were selected from the candidate list. The following selection criteria have been applied:

- In order to assess the effects of the different stages of a substance within the authorisation process the substance should be in a more progressed stage
- For reasons of comparison all SVHCs belonging to a substance group were selected, irrespective of the different progress stages in which these substances were
- The selected substances should cover different endpoints for which they were identified as SVHCs
- The selected substances should vary as much as possible with respect to the use patterns and exposure characteristics
- In view of the limited capacity the number of selected substances was limited to about 30-40 SVHCs

Before this background the candidate list of SVHCs was screened with respect to the stages of each substance within the authorisation process. Five characteristic milestones during the REACH authorisation process were selected as significant stages in the authorisation process, as illustrated in Figure 1:

- **First point in time:** submission date of the Annex XV dossier for identification of the substances as SVHC.
- **Second point in time:** Inclusion of the substance in the candidate list
- **Third point in time:** Recommendation of the substance for the inclusion in Annex XIV.
- **Fourth point in time:** Inclusion in Annex XIV.
- **Fifth point in time:** the LAD was passed until the end of 2015.

![Figure 1: The process of REACH authorisation for SVHCs and the five milestones chosen as characteristic points in time for the assessment of impacts of authorisation](image)

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*It is noted that the time frame for the data collection in MEIA was until end of 2015. Hence, the attribution of the selected SVHCs to the following milestones reflects the situation at that time. Any changes during 2016 are normally not reflected in this document unless it is specifically mentioned.*
Table 1 summarises the key milestones in the authorisation process considered in the assessment of indicators in the MEIA project.

**Table 1: summarises the key milestones defined in figure 1**

<table>
<thead>
<tr>
<th>Milestone</th>
<th>Abbreviation</th>
<th>Common date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Register of intentions for substances of very high concern</td>
<td>ROI SVHC</td>
<td>No common date</td>
</tr>
<tr>
<td>Candidate List</td>
<td>CD</td>
<td>No common date</td>
</tr>
<tr>
<td>Final AXIV recommendation</td>
<td>F.A.XIV R.</td>
<td>No common date</td>
</tr>
<tr>
<td>First registration deadline</td>
<td>FRD</td>
<td>30.11.2010</td>
</tr>
<tr>
<td>Annex XIV</td>
<td>A.XIV</td>
<td>No common date</td>
</tr>
<tr>
<td>Latest Application Date</td>
<td>LAD</td>
<td>No common date</td>
</tr>
<tr>
<td>Sunset Date</td>
<td>SD</td>
<td>No common date</td>
</tr>
<tr>
<td>Data Collection</td>
<td>DC</td>
<td>23.10.2015</td>
</tr>
</tbody>
</table>

For each substance the latest milestone which it has successfully passed has been identified, with December 2015 as the final date of assessment[^4]. This means that all the time points which have been reached by a substance after the “deadline” are not considered and were therefore not reliable for this study.

Based on the attribution of SVHCs to these milestones and on the other selection criteria mentioned above finally 34 substances have been selected for the MEIA project.

It is important to note that the selected list of SVHCs included both, registered as well as non-registered substances. Non-registered substances were included in the MEIA project by intention. Even though there is no information for these substances from registration dossiers, some of those substances have progressed far in the authorisation process and so information from public consultations and authorisation procedures were available for some of them which could be made use of in this project. It is, however, fair to say that for some of these substances the information, e.g. on uses, exposure, risks and/or alternatives is very limited as will be seen in the results.

Table 2 lists the selected substances which have been registered by end of 2015. The substances are listed with respect to the substance groups to which they can be attributed.
<table>
<thead>
<tr>
<th>Name</th>
<th>EC Number</th>
<th>CAS Number</th>
<th>Substance Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Methoxyethanol</td>
<td>203-713-7</td>
<td>109-86-4</td>
<td>acyclic alcohols</td>
</tr>
<tr>
<td>2-Ethoxyethanol</td>
<td>203-804-1</td>
<td>110-80-5</td>
<td>acyclic alcohols</td>
</tr>
<tr>
<td>1,2-dichloroethane</td>
<td>203-458-1</td>
<td>107-06-2</td>
<td>aliphates, chlorinated/brominated</td>
</tr>
<tr>
<td>Trichloroethylene</td>
<td>201-167-4</td>
<td>79-01-6</td>
<td>aliphates, chlorinated/brominated</td>
</tr>
<tr>
<td>2,2'-dichloro-4,4'-methylenedianiline</td>
<td>202-918-9</td>
<td>101-14-4</td>
<td>aromatic amines</td>
</tr>
<tr>
<td>Formaldehyde, oligomeric reaction products with aniline</td>
<td>500-036-1</td>
<td>25214-70-4</td>
<td>aromatic amines</td>
</tr>
<tr>
<td>4,4'-Diaminodiphenylmethane (MDA)</td>
<td>202-974-4</td>
<td>101-77-9</td>
<td>aromatic amines</td>
</tr>
<tr>
<td>Diarsenic trioxide</td>
<td>215-481-4</td>
<td>1327-53-3</td>
<td>arsenic compounds</td>
</tr>
<tr>
<td>Diazene-1,2-dicarboxamide (C,C'-azodi(formamide)) (ADCA)</td>
<td>204-650-8</td>
<td>123-77-3</td>
<td>azo dyes</td>
</tr>
<tr>
<td>1,2-Dimethoxyethane; ethylene glycol dimethyl ether (EGDME)</td>
<td>203-794-9</td>
<td>110-71-4</td>
<td>ethers</td>
</tr>
<tr>
<td>1,2-bis(2-methoxyethoxy)ethane (TEGDME; triglyme)</td>
<td>203-977-3</td>
<td>112-49-2</td>
<td>ethers</td>
</tr>
<tr>
<td>Bis(2-methoxyethyl) ether</td>
<td>203-924-4</td>
<td>111-96-6</td>
<td>ethers</td>
</tr>
<tr>
<td>Pentalead tetraoxide sulphate</td>
<td>235-067-7</td>
<td>12065-90-6</td>
<td>lead compounds</td>
</tr>
<tr>
<td>Tetralead trioxide sulphate</td>
<td>235-380-9</td>
<td>12202-17-4</td>
<td>lead compounds</td>
</tr>
<tr>
<td>Orange lead (lead tetroxide)</td>
<td>215-235-6</td>
<td>1314-41-6</td>
<td>lead compounds</td>
</tr>
<tr>
<td>Lead monoxide (lead oxide)</td>
<td>215-267-0</td>
<td>1317-36-8</td>
<td>lead compounds</td>
</tr>
<tr>
<td>Trixylyl phosphate</td>
<td>246-677-8</td>
<td>25155-23-1</td>
<td>organophosphorus compounds</td>
</tr>
<tr>
<td>Tris(2-chloroethyl)phosphate</td>
<td>204-118-5</td>
<td>115-96-8</td>
<td>organophosphorus compounds</td>
</tr>
<tr>
<td>Diisopentylphthalate</td>
<td>210-088-4</td>
<td>605-50-5</td>
<td>phthalates</td>
</tr>
<tr>
<td>1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (EC No. 201-559-5)</td>
<td>271-094-0, 272-013-1</td>
<td>68515-51-5, 68648-93-1</td>
<td>phthalates</td>
</tr>
<tr>
<td>Bis (2-ethylhexyl)phthalate (DEHP)</td>
<td>204-211-0</td>
<td>117-81-7</td>
<td>phthalates</td>
</tr>
<tr>
<td>Diisobutyl phthalate</td>
<td>201-553-2</td>
<td>84-69-5</td>
<td>phthalates</td>
</tr>
<tr>
<td>Dibutyl phthalate (DBP)</td>
<td>201-557-4</td>
<td>84-74-2</td>
<td>phthalates</td>
</tr>
<tr>
<td>Benzyl butyl phthalate (BBP)</td>
<td>201-622-7</td>
<td>85-68-7</td>
<td>phthalates</td>
</tr>
</tbody>
</table>
Table 3 lists the selected substances which have not been registered (and probably will never be registered under REACH).

Table 3: Non-registered substance selected for the MEIA project: name, EC number, CAS number and allocation to substance group

<table>
<thead>
<tr>
<th>Name</th>
<th>EC Number</th>
<th>CAS Number</th>
<th>Substance Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diarsenic pentaoxide</td>
<td>215-116-9</td>
<td>1303-28-2</td>
<td>arsenic compounds</td>
</tr>
<tr>
<td>1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters</td>
<td>271-084-6</td>
<td>68515-42-4</td>
<td>esters of phthalic acid</td>
</tr>
<tr>
<td>1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich</td>
<td>276-158-1</td>
<td>71888-89-6</td>
<td>esters of phthalic acid</td>
</tr>
<tr>
<td>1,2-Benzenedicarboxylic acid, dipentylester, branched and linear</td>
<td>284-032-2</td>
<td>84777-06-0</td>
<td>esters of phthalic acid</td>
</tr>
<tr>
<td>1,2-Diethoxyethane</td>
<td>211-076-1</td>
<td>629-14-1</td>
<td>Ethers</td>
</tr>
<tr>
<td>1,2-Benzenedicarboxylic acid, dihexylester, branched and linear</td>
<td>271-093-5</td>
<td>68515-50-4</td>
<td>phthalates</td>
</tr>
<tr>
<td>Dihexyl phthalate</td>
<td>201-559-5</td>
<td>84-75-3</td>
<td>phthalates</td>
</tr>
<tr>
<td>Bis(2-methoxyethyl) phthalate</td>
<td>204-212-6</td>
<td>117-82-8</td>
<td>phthalates</td>
</tr>
<tr>
<td>Dipentyl phthalate (DPP)</td>
<td>205-017-9</td>
<td>131-18-0</td>
<td>phthalates</td>
</tr>
<tr>
<td>Lead chromate</td>
<td>231-846-0</td>
<td>7758-97-6</td>
<td>substances containing chromium, lead</td>
</tr>
</tbody>
</table>

For the purpose of this project it was essential that the selected SVHCs represent possibly all different milestone stages within the authorisation process. Therefore, the 34 selected SVHCs have been grouped into the different stages in the authorisation process as illustrated in Figure 2.
As one can see from Figure 2 there are a total of 8 different groups of SVHC’s which differ with respect to the key milestones of authorisation (status end of 2015):

R_NAXIV: SVHCs registered and not included in Annex XIV
NR_NAXIV: SVHCs not registered and not included in Annex XIV
R_AXIV_LADNP: SVHCs registered, included in Annex XIV, but latest date of application (LAD) not yet passed
NR_AXIV_LADNP: SVHCs not registered, included in Annex XIV, but latest date of application (LAD) not yet passed
R_AXIV_LADP_AfA: SVHCs registered, included in Annex XIV, latest date of application (LAD) has been passed and there are applications for authorisation (AfA)
NR_AXIV_LADP_AfA: SVHCs not registered, included in Annex XIV, latest date of application (LAD) has been passed and there are applications for authorisation (AfA)
Table 4 allocates the selected SVHCs to these groups.

**Table 4: List of selected SVHCs with respect to the groups defined in Figure 2**

<table>
<thead>
<tr>
<th>Name</th>
<th>CAS</th>
<th>Abbreviation</th>
<th>Categories</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Methoxyethanol</td>
<td>109-86-4</td>
<td>EGME</td>
<td>R_NAXIV</td>
</tr>
<tr>
<td>1,2-Dimethoxyethane</td>
<td>110-71-4</td>
<td>EGDM</td>
<td>R_NAXIV</td>
</tr>
<tr>
<td>2-Ethoxyethanol</td>
<td>110-80-5</td>
<td>EGEE</td>
<td>R_NAXIV</td>
</tr>
<tr>
<td>1,2-Bis(2-methoxyethoxy)ethane</td>
<td>112-49-2</td>
<td>TEGDME</td>
<td>R_NAXIV</td>
</tr>
<tr>
<td>Diazene-1,2-dicarboxamide</td>
<td>123-77-3</td>
<td>ADCA</td>
<td>R_NAXIV</td>
</tr>
<tr>
<td>Diisopentylphthalate</td>
<td>605-50-5</td>
<td>DIPP</td>
<td>R_NAXIV</td>
</tr>
<tr>
<td>Orange lead</td>
<td>1314-41-6</td>
<td>OL</td>
<td>R_NAXIV</td>
</tr>
<tr>
<td>Lead monoxide</td>
<td>1317-36-8</td>
<td>PbO</td>
<td>R_NAXIV</td>
</tr>
<tr>
<td>Pentalead tetraoxide sulphate</td>
<td>12065-90-6</td>
<td>PLTS</td>
<td>R_NAXIV</td>
</tr>
<tr>
<td>Tetralead trioxide sulphate</td>
<td>12202-17-4</td>
<td>TLS</td>
<td>R_NAXIV</td>
</tr>
<tr>
<td>Trixylyl phosphate</td>
<td>25155-23-1</td>
<td>Trix</td>
<td>R_NAXIV</td>
</tr>
<tr>
<td>1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters;</td>
<td>68515-51-5</td>
<td>BCA</td>
<td>R_NAXIV</td>
</tr>
<tr>
<td></td>
<td>68648-93-1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diisobutyl phthalate</td>
<td>84-69-5</td>
<td>DIBP</td>
<td>R_AXIV_LADP_NAfA</td>
</tr>
<tr>
<td>Benzyl butyl phthalate</td>
<td>85-68-7</td>
<td>BBP</td>
<td>R_AXIV_LADP_NAfA</td>
</tr>
<tr>
<td>Tris(2-chloroethyl)phosphate</td>
<td>115-96-8</td>
<td>Tris</td>
<td>R_AXIV_LADP_NAfA</td>
</tr>
<tr>
<td>4,4-Diaminodiphenylmethane</td>
<td>101-77-9</td>
<td>MDA</td>
<td>R_AXIV_LADP_NAfA</td>
</tr>
<tr>
<td>Trichloroethylene</td>
<td>79-01-6</td>
<td>TCE</td>
<td>R_AXIV_LADP_AfA</td>
</tr>
<tr>
<td>Dibutyl phthalate</td>
<td>84-74-2</td>
<td>DBP</td>
<td>R_AXIV_LADP_AfA</td>
</tr>
<tr>
<td>Bis (2-ethylhexyl)phthalate</td>
<td>117-81-7</td>
<td>DEHP</td>
<td>R_AXIV_LADP_AfA</td>
</tr>
<tr>
<td>Diarsenic trioxide</td>
<td>1327-53-3</td>
<td>Ditri</td>
<td>R_AXIV_LADP_AfA</td>
</tr>
<tr>
<td>2,2'-Dichloro-4'-methylenedianiline</td>
<td>101-14-4</td>
<td>MOCA</td>
<td>R_AXIV_LADNP</td>
</tr>
<tr>
<td>1,2 Dichloroethane</td>
<td>107-06-2</td>
<td>EDC</td>
<td>R_AXIV_LADNP</td>
</tr>
<tr>
<td>Bis(2-methoxyethyl)ether</td>
<td>111-96-6</td>
<td>Diglyme</td>
<td>R_AXIV_LADNP</td>
</tr>
<tr>
<td>Formaldehyde, oligomeric reaction products with aniline</td>
<td>25214-70-4</td>
<td>Form</td>
<td>R_AXIV_LADNP</td>
</tr>
<tr>
<td>Dihexylphthalate</td>
<td>84-75-3</td>
<td>DnHP</td>
<td>NR_NAXIV</td>
</tr>
<tr>
<td>Bis(2-methoxyethyl)phthalate</td>
<td>117-82-8</td>
<td>DMEP</td>
<td>NR_NAXIV</td>
</tr>
<tr>
<td>Dipentylphthalate</td>
<td>131-18-0</td>
<td>DPP</td>
<td>NR_NAXIV</td>
</tr>
<tr>
<td>1,2-Diethoxyethane</td>
<td>629-14-1</td>
<td>DE</td>
<td>NR_NAXIV</td>
</tr>
<tr>
<td>1,2-Benzenedicarboxylic acid, diC7-11-branched and linear alkyl ester</td>
<td>68515-42-4</td>
<td>DHNUP</td>
<td>NR_NAXIV</td>
</tr>
<tr>
<td>1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear</td>
<td>68515-50-4</td>
<td>BCA2</td>
<td>NR_NAXIV</td>
</tr>
<tr>
<td>1,2-Benzenedicarboxylic acid, di-C6-8-branched and linear alkyl ester</td>
<td>71888-89-6</td>
<td>DIHP</td>
<td>NR_NAXIV</td>
</tr>
<tr>
<td>1,2-Benzenedicarboxylic acid, dipentylester, branched and linear</td>
<td>84777-06-0</td>
<td>BCA1</td>
<td>NR_NAXIV</td>
</tr>
<tr>
<td>Lead chromate</td>
<td>7758-97-6</td>
<td>LC</td>
<td>NR_AXIV_LADP_AfA</td>
</tr>
<tr>
<td>Diarsenic Pentoxide</td>
<td>117-82-8</td>
<td>DAP</td>
<td>NR_AXIV_LADP_NAfA</td>
</tr>
</tbody>
</table>
Table 4 illustrates that of the eight possible groups six groups are represented by at least one selected SVHC. For the registered substances (see green boxes in Figure 2) all possible groups are represented:

R_NAXIV by 12 SVHCs
R_AXIV_LADNP by four substances
R_AXIV_LADP_AfA by four substances
R_AXIV_LADP_NAfA by four substances

Only for the non-registered substances one group (NR_AXIV_LADNP) are not represented in the selection of SVHCs chosen for this project. Taking into account that information from non-registered SVHCs is significantly lower than for registered SVHCs, the selection seems to provide a fairly good representation with respect to the different milestone stages.

Table 5 lists the relevant endpoints for which the selected substances have been identified as SVHCs (compare to ECHA’s candidate list(3)). The Table 5 shows that most selected SVHCs have been identified on the basis of reproductive toxicity (27 cases), eight SVHCs have been identified because of their carcinogenicity and two because of a similar concern in the sense of REACH article 57f (one as respiratory sensitising agent and one as endocrine disruptor for the environment). Thus, R and C substances are relatively well represented (the majority of reproductive toxicity is partially due to the fact that the group of phthalate which is relatively big has been fully included in this study). Also the two main cases for identification of SVHC based on article 57f are represented. A clear weakness of the selection is that no substances have been identified with concern for PBT or vPvB behaviour as there are presently about 30 SVHCs in the candidate list with this concern. One reason for the under-representation of this concern is the fact that those PBT/vPvB identifications which have been made early in the process are polyaromatic hydrocarbons, the discussion of which is closely related to the group of petroleum substances for which discussion in the screening process have not yet resulted in a clear strategy. On the other, a number of PBT/vPvB-based identifications of SVHCs came quite late on the candidate list so that they are not yet far advanced in the authorisation process. Nevertheless it must be admitted that it would have been very appropriate also to include PBT/vPvB-based SVHCs in the present study.

Table 5 also lists the restrictions for the selected SVHCs under Annex XVII of REACH. The following relevant entries apply to the substances considered in this project:

- Entry 19: Arsenic compounds
  1. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use to prevent the fouling by micro-organisms, plants or animals of:
     - the hulls of boats,
     - cages, floats, nets and any other appliances or equipment used for fish or shellfish farming,
     - any totally or partly submerged appliances or equipment.
  2. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use in the treatment of industrial waters, irrespective of their use.
  3. Shall not be used in the preservation of wood. Furthermore, wood so treated shall not be placed on the market.
  4. By way of derogation from paragraph 3:
(a) Relating to the substances and mixtures for the preservation of wood: these may only be used in industrial installations using vacuum or pressure to impregnate wood if they are solutions of inorganic compounds of the copper, chromium, arsenic (CCA) type C and if they are authorised in accordance with Article 5(1) of Directive 98/8/EC. Wood so treated shall not be placed on the market before fixation of the preservative is completed.

(b) Wood treated with CCA solution in accordance with point (a) may be placed on the market for professional and industrial use provided that the structural integrity of the wood is required for human or livestock safety and skin contact by the general public during its service life is unlikely:

- as structural timber in public and agricultural buildings, office buildings, and industrial premises,
- in bridges and bridgework,
- as constructional timber in freshwater areas and brackish waters, for example jetties and bridges,
- as noise barriers,
- in avalanche control,
- in highway safety fencing and barriers,
- as debarked round conifer livestock fence posts,
- in earth retaining structures,
- as electric power transmission and telecommunications poles,
- as underground railway sleepers.

(c) Without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that all treated wood placed on the market is individually labelled ‘For professional and industrial installation and use only, contains arsenic’. In addition, all wood placed on the market in packs shall also bear a label stating ‘Wear gloves when handling this wood. Wear a dust mask and eye protection when cutting or otherwise crafting this wood. Waste from this wood shall be treated as hazardous by an authorised undertaking’.

(d) Treated wood referred to under point (a) shall not be used:

- in residential or domestic constructions, whatever the purpose,
- in any application where there is a risk of repeated skin contact,
- in marine waters,
- for agricultural purposes other than for livestock fence posts and structural uses in accordance with point (b),
- in any application where the treated wood may come into contact with intermediate or finished products intended for human and/or animal consumption.

5. Wood treated with arsenic compounds that was in use in the Community before 30 September 2007, or that was placed on the market in accordance with paragraph 4 may remain in place and continue to be used until it reaches the end of its service life.

6. Wood treated with CCA type C that was in use in the Community before 30 September 2007, or that was placed on the market in accordance with paragraph 4:

- may be used or reused subject to the conditions pertaining to its use listed under points 4(b), (c) and (d),
- may be placed on the market subject to the conditions pertaining to its use listed under points 4(b), (c) and (d).

7. Member States may allow wood treated with other types of CCA solutions that was in use in the Community before 30 September 2007:

- to be used or reused subject to the conditions pertaining to its use listed under points 4 (b), (c) and (d),
to be placed on the market subject to the conditions pertaining to its use listed under points 4(b), (c) and (d).

- Entry 28 concerning substances which appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 classified as carcinogen category 1A or 1B (Table 3.1):

1. Shall not be placed on the market, or used,
   — as substances,
   — as constituents of other substances, or,
   — in mixtures,
   for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than:
   — either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or,

Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows:
‘Restricted to professional users’.

2. By way of derogation, paragraph 1 shall not apply to:
(a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC;
(b) cosmetic products as defined by Directive 76/768/EEC;
(c) the following fuels and oil products:
   — motor fuels which are covered by Directive 98/70/EC,
   — mineral oil products intended for use as fuel in mobile or fixed combustion plants,
   — fuels sold in closed systems (e.g. liquid gas bottles);
(d) artists' paints covered by Regulation (EC) No 1272/2008;
(e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date.

1) Entry 30 concerning substances which appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 classified as toxic to reproduction category 1A or 1B (Table 3.1):

1. Shall not be placed on the market, or used,
   — as substances,
   — as constituents of other substances, or,
   — in mixtures,
   for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than:
   — either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or,

Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure
before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows:
‘Restricted to professional users’.

2. By way of derogation, paragraph 1 shall not apply to:
(a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC;
(b) cosmetic products as defined by Directive 76/768/EEC;
(c) the following fuels and oil products:
— motor fuels which are covered by Directive 98/70/EC,
— mineral oil products intended for use as fuel in mobile or fixed combustion plants,
— fuels sold in closed systems (e.g. liquid gas bottles);
(d) artists’ paints covered by Regulation (EC) No 1272/2008;
(e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date.

2) Entry 43 on azo dyes:
1. Azo dyes which, by reductive cleavage of one or more azo groups, may release one or more of the aromatic amines listed in Appendix 8, in detectable concentrations, i.e. above 30 ppm in the finished articles or in the dyed parts thereof, according to the testing methods listed in Appendix 10, shall not be used in textile and leather articles which may come into direct and prolonged contact with the human skin or oral cavity, such as:
– clothing, bedding, towels, hairpieces, wigs, hats, nappies and other sanitary items, sleeping bags,
– footwear, gloves, wristwatch straps, handbags, purses/wallets, briefcases, chair covers, purses worn round the neck, – textile or leather toys and toys which include textile or leather garments, – yarn and fabrics intended for use by the final consumer.
2. Furthermore, the textile and leather articles referred to in paragraph 1 above shall not be placed on the market unless they conform to the requirements set out in that paragraph. 30.12.2006 EN Official Journal of the European Union L 396/433
3. Azo dyes, which are contained in Appendix 9, "List of azo dyes", shall not be placed on the market or used for colouring textile and leather articles as a substance or constituent of preparations in concentrations higher than 0,1 % by mass.
4. The Commission shall, in the light of new scientific knowledge, review the provisions on azo colourants.

- Entry 47 on chromium(VI) compounds:
  1. Cement and cement-containing preparations shall not be used or placed on the market, if they contain, when hydrated, more than 0,0002 % soluble chromium VI of the total dry weight of the cement.
  2. If reducing agents are used, then without prejudice to the application of other Community provisions on the classification, packaging and labelling of dangerous substances and preparations, the packaging of cement or cement containing preparations shall be legibly and indelibly marked with information on the packing date, as well as on
the storage conditions and the storage period appropriate to maintaining the activity of the reducing agent and to keeping the content of soluble chromium VI below the limit indicated in paragraph 1.

3. By way of derogation, paragraphs 1 and 2 shall not apply to the placing on the market for, and use in, controlled closed and totally automated processes in which cement and cement-containing preparations are handled solely by machines and in which there is no possibility of contact with the skin.

5. Leather articles coming into contact with the skin shall not be placed on the market where they contain chromium VI in concentrations equal to or greater than 3 mg/kg (0,0003 % by weight) of the total dry weight of the leather.

6. Articles containing leather parts coming into contact with the skin shall not be placed on the market where any of those leather parts contains chromium VI in concentrations equal to or greater than 3 mg/kg (0,0003 % by weight) of the total dry weight of that leather part.

7. Paragraphs 5 and 6 shall not apply to the placing on the market of second-hand articles which were in end-use in the Union before 1 May 2015.

- Entry 51 on DEHP, DBP and BBP:
  1. Shall not be used as substances or in mixtures, in concentrations greater than 0,1 % by weight of the plasticised material, in toys and childcare articles.
  2. Toys and childcare articles containing these phthalates in a concentration greater than 0,1 % by weight of the plasticised material shall not be placed on the market.
  (3. Regulation (EU) No 326/2015: paragraph 3 is deleted.)
  4. For the purpose of this entry ‘childcare article’ shall mean any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children.

- Entry 63 on lead and its compounds:
  1. Shall not be placed on the market or used in any individual part of jewellery articles if the concentration of lead (expressed as metal) in such a part is equal to or greater than 0,05 % by weight.
  2. For the purposes of paragraph 1:
     (i) "jewellery articles" shall include jewellery and imitation jewellery articles and hair accessories, including;
         o (a) bracelets, necklaces and rings;
         o (b) piercing jewellery;
         o (c) wrist watches and wrist-wear;
         o (d) brooches and cufflinks;
     (ii) "any individual part" shall include the materials from which the jewellery is made, as well as the individual components of the jewellery articles.
  3. Paragraph 1 shall also apply to individual parts when placed on the market or used for jewellery-making.
  4. By way of derogation, paragraph 1 shall not apply to:
     o (a) crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Council Directive 69/493/EEC(*);
     o (b) internal components of watch timepieces inaccessible to consumers;
     o (c) non synthetic or reconstructed precious and semiprecious stones (CN code 7103, as established by Regulation (EEC) No 2658/87), unless they have been treated with lead or its compounds or mixtures containing these substances;
     (d) enamels, defined as vitrifiable mixtures resulting from the fusion, vitrification or sintering of minerals melted at a temperature of at least 500 °C.
5. By way of derogation, paragraph 1 shall not apply to jewellery articles placed on the market for the first time before 9th of October 2013 and jewellery articles produced before 10 December 1961.

6. By 9th October 2017 the Commission shall re-evaluate this entry in the light of new scientific information, including the availability of alternatives and the migration of lead from the articles referred to in paragraph 1 and, if appropriate, modify this entry accordingly.


Table 5: Relevant endpoints for the identification of the selected SVHCs (the symbols in column 3 have the following meaning: C = concerns of carcinogenicity, R = concern of reproduction toxicity, Endo = concern of adverse endocrine effects, Sens = concern for respiratory sensitising properties) and restrictions under REACH Annex XVII

<table>
<thead>
<tr>
<th>Substance name</th>
<th>CAS Number</th>
<th>Properties of concern</th>
<th>Entry in Annex XVII</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,2-Dichloroethane</td>
<td>107-06-2</td>
<td>C</td>
<td>28</td>
</tr>
<tr>
<td>2,2’-Dichloro-4,4’-methyleneedianiline</td>
<td>101-14-4</td>
<td>C</td>
<td>28, 43</td>
</tr>
<tr>
<td>Formaldehyde, oligomeric reaction products with aniline</td>
<td>25214-70-4</td>
<td>C</td>
<td>major constituent MDA covered by 28, 43</td>
</tr>
<tr>
<td>4,4’- Diaminodiphenylmethane (MDA)</td>
<td>101-77-9</td>
<td>C</td>
<td>28, 43</td>
</tr>
<tr>
<td>Diarsenic pentaoxide</td>
<td>1303-28-2</td>
<td>C</td>
<td>19, 30</td>
</tr>
<tr>
<td>Diarsenic trioxide</td>
<td>1327-53-3</td>
<td>C</td>
<td>19, 28</td>
</tr>
<tr>
<td>Trichloroethylene</td>
<td>79-01-6</td>
<td>C</td>
<td>28</td>
</tr>
<tr>
<td>Lead chromate</td>
<td>7758-97-6</td>
<td>C, R</td>
<td>28, 30, 63</td>
</tr>
<tr>
<td>Bis (2-ethylhexyl)phthalate (DEHP)</td>
<td>117-81-7</td>
<td>R, Endo (Art 57f)</td>
<td>30, 51</td>
</tr>
<tr>
<td>Diazene-1,2-dicarboxamide (ADCA)</td>
<td>123-77-3</td>
<td>Sens (Art 57f)</td>
<td>~</td>
</tr>
<tr>
<td>1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (EC No. 201-559-5)</td>
<td>68515-51-5, 68648-93-1</td>
<td>R</td>
<td>Impurity DnHP covered by 30</td>
</tr>
<tr>
<td>1,2-Benzenedicarboxylic acid, dihexylester, branched and linear</td>
<td>68515-50-4</td>
<td>R</td>
<td>~</td>
</tr>
<tr>
<td>1,2-Bis(2-methoxyethoxy)ethane (TEGDME; triglyme)</td>
<td>112-49-2</td>
<td>R</td>
<td>30</td>
</tr>
<tr>
<td>1,2-Diethoxyethane</td>
<td>629-14-1</td>
<td>R</td>
<td>30</td>
</tr>
<tr>
<td>1,2-Dimethoxyethane; ethylene glycol dimethyl ether (EGDME)</td>
<td>110-71-4</td>
<td>R</td>
<td>30</td>
</tr>
<tr>
<td>2-Ethoxyethanol</td>
<td>110-80-5</td>
<td>R</td>
<td>30</td>
</tr>
<tr>
<td>2-Methoxyethanol</td>
<td>109-86-4</td>
<td>R</td>
<td>30</td>
</tr>
<tr>
<td>Dihexyl phthalate</td>
<td>84-75-3</td>
<td>R</td>
<td>30</td>
</tr>
<tr>
<td>Lead monoxide (lead oxide)</td>
<td>1317-36-8</td>
<td>R</td>
<td>30 (covered by entry Index No 082-001-00-6), 63</td>
</tr>
<tr>
<td>Orange lead (lead tetroxide)</td>
<td>1314-41-6</td>
<td>R</td>
<td></td>
</tr>
<tr>
<td>Pentalead tetroxide sulphate</td>
<td>12065-90-6</td>
<td>R</td>
<td></td>
</tr>
<tr>
<td>Tetralead trioxide sulphate</td>
<td>12202-17-4</td>
<td>R</td>
<td></td>
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<tr>
<td>Substance name</td>
<td>CAS Number</td>
<td>Properties of concern</td>
<td>Entry in Annex XVII</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------------</td>
<td>------------------</td>
<td>------------------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>Trixylyl phosphate</td>
<td>25155-23-1</td>
<td>R</td>
<td>30</td>
</tr>
<tr>
<td>1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich</td>
<td>71888-89-6</td>
<td>R</td>
<td>30</td>
</tr>
<tr>
<td>1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters</td>
<td>68515-42-4</td>
<td>R</td>
<td>30</td>
</tr>
<tr>
<td>1,2-Benzenedicarboxylic acid, dipentylester, branched and linear</td>
<td>84777-06-0</td>
<td>R</td>
<td>30</td>
</tr>
<tr>
<td>Bis(2-methoxyethyl) phthalate</td>
<td>117-82-8</td>
<td>R</td>
<td>30</td>
</tr>
<tr>
<td>Diisopentylphthalate</td>
<td>605-50-5</td>
<td>R</td>
<td>30</td>
</tr>
<tr>
<td>Dipentyl phthalate (DPP)</td>
<td>131-18-0</td>
<td>R</td>
<td>30</td>
</tr>
<tr>
<td>Bis(2-methoxyethyl) ether</td>
<td>111-96-6</td>
<td>R</td>
<td>30</td>
</tr>
<tr>
<td>Benzyl butyl phthalate (BBP)</td>
<td>85-68-7</td>
<td>R</td>
<td>30, 51</td>
</tr>
<tr>
<td>Dibutyl phthalate (DBP)</td>
<td>84-74-2</td>
<td>R</td>
<td>30, 51</td>
</tr>
<tr>
<td>Diisobutyl phthalate</td>
<td>84-69-5</td>
<td>R</td>
<td>30</td>
</tr>
<tr>
<td>Tris(2-chloroethyl)phosphate</td>
<td>115-96-8</td>
<td>R</td>
<td>30</td>
</tr>
</tbody>
</table>
4. Introduction to the Substance groups

The following chapters provide a brief overview of the substances considered in this project. The focus lies on the uses and classification of the substances. The discussion is divided into substance groups.

4.1. Phthalates

Phthalates are a family of compounds consisting of an ester or salt of phthalic acid. They are widely used in the manufacture of plastics, as synthetic additives in perfumes and cosmetics and as softeners because of their strong performance, durability and stability to increase the flexibility of plastics. Phthalates are the most common used plasticizers in the world and are categorized as either high or low, depending on their molecular weight.

- High phthalates are those with a carbon backbone from 7-13, which increases their durability and performance. They are particularly used for PVC products such as wire, cable, flooring, synthetic leather, self-adhesive films, wall covering, self-adhesive films, coated fabrics and automobile applications.

- Low phthalates have a carbon backbone with 3-6 carbon atoms. They are commonly used in medical devices, adhesives, inks and general purpose PVC. The most common types of low phthalates which are also included in our study are di(2-ethylhexyl) phthalate (DEHP) and dibutyl phthalate (DBP).

The phthalates which are in the highest demand are colourless, odourless and their optimal characteristics include: flexibility, durability, weather and high temperature resistance.

The problem in the use of phthalates as plasticizers, e.g. for PVC, is that there is no chemical bond between the softener and the polymer causing migration or leaching of phthalates into the environment or food (in case of use in packaging materials). This can lead to the uptake into the body through ingestion, inhalation and/or dermal uptake. The different phthalates are known to have various effects on human health like influencing the endocrine balance, reproductive capacity, disruption of the immune and nervous system, but also a number of negative effects on the environment, mainly due to their adverse endocrine action.

Phthalates are characterised by a combination of specific technical properties which makes it difficult to replace them in a number of applications.

4.1.1. Bis(2-ethylhexyl) phthalates

Bis(2-ethylhexyl) phthalate (DEHP), is a colourless viscous liquid that is not water soluble and it is one of the most common used plasticizer in the class of phthalates. It has a Kow of about 7.5 and therefore is expected to be strongly adsorbed to organic hydrophobic matter. The release to the environment is expected during production mainly via wastewater and exhaust gases for processing when this involves heating. The release relating to the
service life of DEHP containing articles mainly occurs during washing and cleaning of the article.

According to the harmonised classification DEHP is classified as:
H360FD: May damage fertility. May damage the unborn child.

Additionally DEHP is notified according to the C&L inventory of ECHA:
H400: Very toxic to aquatic life
H412: Harmful to aquatic life with long lasting effects
H362: May cause harm to breast-fed children.

4.1.2. Dibutyl phthalate

Dibutyl phthalate (DBP) is used in the industry as a plasticiser in resins and polymers but also as a softener in adhesives, lacquers, varnishes and printing inks. Before the authorisation policy was implemented DBP was also used as lubricant for aerosol valves; as a suspension agent for solids in aerosols and as plasticiser in nail polish and fingernail elongations. Humans are exposed to DBP mainly by the absorption through the skin. DBP can cause endocrine disruptions and may particularly cause harm to the unborn child or impair fertility.

According to the harmonised classification DBP is classified as:
H360DF: May damage the unborn child. Suspected of damaging fertility.
H400: Very toxic to aquatic life.

Additionally DBP is notified according to the C&L inventory of ECHA
H411: Toxic to aquatic life with long lasting effects

4.1.3. Diisobutyl phthalate

Diisobutyl phthalate (DIBP) is an odourless plasticizer, with excellent heat and light stability. It is used as a plasticizer in synthetic materials and is found in products like coatings, putties, fillers, plasters, modelling clay, polymers, adhesives and sealants. It generally can be found in products were the material is based on: plastics, metal, rubber, leather and wood. The substance is also used as an intermediate to produce another substance. There is a potential for DIBP of being released to the environment during production and manufacture and during the usage of DIBP containing mixtures and articles indoors and outdoors (e.g. as a binding agent in paints, coatings or adhesives) (European Chemicals Agency, 2007).

According to the harmonised classification DIBP is classified as:
H360DF: May damage the unborn child. Suspected of damaging fertility

Additionally DIBP is notified according to the C&L inventory of ECHA:
H412: Harmful to aquatic life with long lasting effects
H410: Very toxic to aquatic life with long lasting effects
H400: Very toxic to aquatic life
H311: Toxic in contact with skin
H331: Toxic if inhaled
H302: Harmful if swallowed

4.1.4. Diisopentyl phthalate

Diisopentyl phthalate (DIPP) is a clear, slightly yellow, liquid with excellent heat and light stability; it has similar structure and physical-chemical properties as DBP and DIBP. It is used by producers of ammunition as a propellant due to its property to regulate the rate of burn. It has also a potential for being used as a plasticiser for plastics.

According to the harmonised classification DIPB is labelled as:
H360Df: May damage the unborn child. Suspected of damaging fertility
H400: Very toxic to aquatic life

Additionally DIPP is notified according to the C&L inventory of ECHA:
H317: May cause an allergic skin reaction

4.1.5. Benzyl butyl phthalate

Benzyl butyl phthalate (BBP) is a colourless and odourless, oily liquid which is mostly used as an adhesive, sealant and coating of articles. Such as fabrics, textiles, rubber and plastics.

According to the harmonised classification BBP is classified as:
H360Df: May damage the unborn child. Suspected of damaging fertility.
H410: Very toxic to aquatic life with long lasting effects
H400: Very toxic to aquatic life

Additionally BBP is notified according to the C&L inventory of ECHA:
H331: Toxic if inhaled

4.1.6. Bis(2-methoxyethyl) phthalate

Bis(2-methoxyethyl) phthalate (DMEP) is a colourless liquid which is mainly used as plasticizer. It has structural similarities to DBP and DEHP and therefore can be potentially used in the same types of applications. As it is a substance which has not been registered, it is assumed that it has already been replaced by on other substance.

According to the harmonised classification DMEP is classified as:
H360Df: May damage the unborn child. Suspected of damaging fertility.
4.1.7. Dihexyl phthalate

Dihexyl phthalate (DnHP) is included in the candidate list but has not been registered. It may function as a plasticizer for cellulose and vinyl plastics, in the manufacture of automobile parts and dip-moulded products. Articles in which DnHP could be contained include shoes, conveyor belts, food packaging, canvas tarps and notebook covers.

According to the harmonised classification DnHP is classified as:
H360Df: May damage the unborn child. Suspected of damaging fertility

4.1.8. Dipentyl phthalate

Dipentyl phthalate is included in the candidate list but has also not been registered. It has structural similarities to DBP and DEHP and, therefore, could be potentially used in the same types of applications.

According to the harmonised classification dipentyl phthalate is classified as:
H360Df: May damage the unborn child. Suspected of damaging fertility

4.1.9. 1,2-Benzenedi-Carboxylic Acid, di-C6-10-alkyl esters (CAS# 68515-51-5)

1,2-Benzenedi-Carboxylic Acid, di-C6-10-alkyl esters (BCA) It is registered once in IUCLID.

BCA is used in the production of polymers, coating products, fillers, putties, plasters, modelling clay, inks and toners, lubricants and greases and finger paints. There is potential exposure to the substance from mixtures and articles, both to consumers, professional workers and workers at industrial settings.

There is no harmonised classification and also no notification according to the C&L inventory of ECHA.

4.1.10. 1,2-Benzenedicarboxylic acid (CAS# 84777-06-0)

1,2-Benzenedicarboxylic acid (BCA1) is a substance of very high concern (SVHC) and was included in the candidate list. It is not registered in IUCLID and assumed not to be manufactured or placed on the marked in quantities bigger than 1 tonne per year.
The only known use is as a laboratory chemical for analytical purposes.

According to the harmonised classification 1,2-benzenedicarboxylic acid is classified as:
H400: Very toxic to aquatic life
H360FD: May damage fertility. May damage the unborn child

4.1.11. 1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear (CAS# 68515-50-4)

1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear (BCA2) is included in the candidate list but has not been registered in IUCLID.

The only known use of the substance is in sealant/jointing agents and as a component in engine oil stabilizer on the US market and as automotive gear lubricant on the German market.

There is no harmonised classification but it is notified according to the C&L inventory of ECHA:
H361: Suspected of damaging fertility or the unborn child

4.1.12. 1,2-Benzenedicarboxylic acid (CAS# 71888-89-6)

1,2-Benzenedicarboxylic acid (DIHP) is included in the candidate list but has not been registered in IUCLID.

On the basis of available information from ECHA it can be assumed that there are no manufacturing sites in the EU. The main use in 2005 was as a plasticiser in PVC sealants and printing inks in the EU.

According to the harmonised classification 1,2-benzenedicarboxylic acid is classified as:
H360DF: May damage the unborn child

Additionally 1,2-benzenedicarboxylic acid is notified according to the C&L inventory of ECHA:
H373: May cause damage to organs

4.1.13. 1,2-Benzenedicarboxylic acid (CAS# 68515-42-4)

1,2-Benzenedicarboxylic acid (DHNUP) is included in the candidate list but has not been registered in IUCLID.

On the basis of available information from ECHA it is believed that there are zero manufacturing sites in the EU.

According to the harmonised classification 1,2-benzenedicarboxylic acid is classified as:
Glymes or glycol ethers (GEs) are a group of solvents which have a number of similar physical and chemical properties, including a good solubility in water, in most organic solvents and oils. These properties make the GEs very useful for industry as “bridging” compounds, helping to mix two substances which without the GE would be insoluble. GE provides the following technical advantages:

- Improves the wetting properties of water-based products
- Gives good long-term stability and shelf-life of products
- Works at low concentrations
- Has little odour

There are two kinds of glymes:

- E-series glycol ethers which are made from ethylene oxide and alcohols and can be found in pharmaceuticals, sunscreens, cosmetics, dyes, inks and water based paints
- P-series glycol ethers which are made from propylene oxide and alcohols and are use in degreasers, aerosol paints, cleaners and adhesives. In general one can say that the p-series has a lower toxicity than the e-series.

The GE family consists of more than 30 different solvents. They have similar physical properties but they have different technical characteristics and different toxicity profiles. Toxic effects from short-term exposure of human’s to high concentrations of certain GEs may result in narcosis, severe liver and kidney damage and pulmonary edema. Long-term exposure may lead to neurological and blood effects, including fatigue, nausea, tremor and anemia. The general public can be exposed to GEs through the use of consumer products and occupational exposure may occur in the chemical industry.

The substances selected from the GE-group comprise 2-methoxyethanol, 2-ethoxyethanol, bis(2-methoxyethyl)-ether, 1,2-dimethoxyethane, tetraethylene glycol dimethyl ether and methoxyacetic acid.

### 4.2.1. 2-Methoxyethanol

2-Methoxyethanol (EGME) is a clear, colourless liquid with an ether-like odour and is mainly used as a solvent for varnishes, resins and dyes. Even though EGME exhibits significant hazardous properties the substance was not prioritised for inclusion in REACH Annex XIV as it´s releases and exposures are considered as well controlled.

According to the harmonised classification EGME is classified as:

- **H360FD: May damage fertility. May damage the unborn child**
- **H226: Flammable liquid and vapour**
- **H312: Harmful in contact with skin**
- **H302: Harmful if swallowed**
- **H332: Harmful if inhaled**
Additionally EGME is notified according to the C&L inventory of ECHA:
H331: Toxic if inhaled
H370: Causes damage to organs
H373: May cause damage to organs through prolonged or repeated exposure
H319: causes serious eye irritation

4.2.2. 2-Ethoxyethanol

2-Ethoxyethanol (EGEE) is a clear, colorless, nearly odorless liquid that is miscible with water, ethanol, diethyl ether, acetona and ethyl acetate. It is widely used in commercial and industrial applications. EGEE is used in low volume and only in industrial settings, leading to the conclusion that the potential risks are low. Therefore, the substance was not prioritised for inclusion in Annex XIV.

According to the harmonised classification EGEE is classified as:
H360DF: May damage fertility. May damage the unborn child
H226: Flammable liquid and vapour
H302: Harmful if swallowed
H331: Toxic if inhaled

Additionally EGEE is notified according to the C&L inventory of ECHA:
H312: Harmful in contact with skin
H332: Harmful if inhaled
H319: Causes serious eye irritation

4.2.3. Bis(2-methoxyethyl) ether

Bis(2-methoxyethyl) (diglyme) is the only representative of glymes considered in this project which has been registered. Diglyme is a clear, colourless solvent with a ether-like odour and a high boiling point. It is miscible with water, alcohols, diethyl ether and hydrocarbon solvents. It is most often used in organic reactions were it has the ability to chelate small cations, leaving anions more active. In reactions like the Grignard reaction or metal hydride reduction rates can be significantly enhanced.

According to the harmonised classification diglyme is classified as:
H360DF: May damage fertility. May damage the unborn child
H226: Flammable liquid and vapour

Additionally diglyme is notified according to the C&L inventory of ECHA:
H319: Causes serious eye irritation
H351: Suspected of causing cancer
H335: May cause respiratory irritation
4.2.4. 1,2-Dimethoxyethane

1,2-Dimethoxyethane is also known as glyme, monoglyme and EGDME. It is a clear, aprotic, colourless and liquid ether that is also used as a solvent especially in batteries and it is miscible with water. EGDME forms chelate complexes with cations and acts as a ligand; it is often used in organometallic chemistry like hydride reductions, Grignard reactions and palladium-catalysed reactions like Suzuki reactions and Stille couplings. Furthermore, it is a good solvent for oligo- and polysaccharides. Even though the priority score for EGDME is relatively high, ECHA has not recommended its inclusion in Annex XIV because of the limited personnel capacity of the Agency.

According to the harmonised classification EGDME is classified as:
H360FD: May damage fertility. May damage the unborn child
H225: Highly flammable liquid and vapour
H332: Harmful if inhaled

Additionally EGDME is notified according to the C&L inventory of ECHA:
H315: Causes skin irritation
H351: Suspected of causing cancer
H302: Harmful if swallowed
H341: suspected of causing genetic defects

4.2.5. Tetraethylene glycol dimethyl ether

Tetraethylene glycol dimethyl ether, also called tetraglyme or TEGDME, is a polar aprotic solvent with an ethereal odour with excellent thermal and chemical stability. This makes it an ideal candidate for separation processes and high temperature reactions. Furthermore it is used in lithium-ion batteries and in combination with trifluoroethanol as working pair for organic absorption heat pumps. Due to the fact that TEGDME is used in relatively low volume and the releases are likely to be controlled TEGDME has not been recommended for the inclusion in Annex XIV.

According to the harmonised classification TEGDME is classified as:
H360DF: May damage the unborn child. Suspected of damaging fertility

Additionally TEGDME is notified according to the C&L inventory of ECHA:
H319: Causes serious eye irritation
4.2.6.1,2-Diethoxyethane

1,2-Diethoxyethane is included in the candidate list but has not been registered in IUCLID. The available information on uses of the substance is quite limited. There are only assumptions to its worldwide use according to the substance group.

According to the harmonised classification 1,2-Diethoxyethane is classified as:
H360Df: May damage the unborn child. Suspected of damaging fertility
H225: Highly flammable liquid and vapour
H319: Causes serious eye irritation