
# Service contract to create a database and develop a model to estimate the occupational exposure for a list of hazardous chemicals in the Member States of the European Union and in the EFTA/EEA countries
# No VT/2013/079

Final report

Kooperationsstelle Hamburg IFE GmbH

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# List of abbreviations and acronyms

| | |
|---|---|
| AC | Article category: it describes the type of article into which the substance has eventually been processed. It is one of five descriptor-lists to standardise the description of the use of substances under REACH |
| APPE | Association of Petrochemicals Producers in Europe |
| AWES | Australian Work Exposures Study |
| BAT | Best available technique |
| BOELV | Binding occupational exposure limit value |
| BREFs | Reference documents on Best Available Techniques |
| CARE | CARE - Controlled and Reduced Exposure: an industrial hygiene assistance programme initiated by ECIFA " |
| CAREX | International Information System on Occupational Exposure to Carcinogens |
| CAS number | A unique numerical identifier assigned by Chemical Abstracts Service (CAS) to every chemical substance described in the open scientific literature. |
| CEFIC | The European Chemical Industry Council |
| CLP regulation | Regulation on classification, labelling and packaging of substances and mix-tures, EC No 1272/2008 |
| CMD | Carcinogens and Mutagens Directive |
| CMR | Carcinogenic, mutagenic, reprotoxic substances |
| COLCHIC | French database for occupational exposure to chemical agents |
| CSR | Chemical Safety Report |
| DEE | Diesel Engine Exhaust |
| DESTATIS | Federal Statistical Office of Germany (Statistisches Bundesamt) |
| DG EMPL | Directorate-General for Employment, Social Affairs and Inclusion |

| | |
|---|---|
| ECDC | European Centre of Disease Prevention and Control |
| ECHA | European Chemicals Agency |
| ECFIA | ECFIA represents the European High Temperature Insulation Wool industry in matters relating to health and safety. |
| EEA | European Environmental Agency |
| EINECS | European Inventory of Existing Commercial Chemical Substances |
| EIONET | European environment information and observation network |
| ESCO | European skills/competences, qualifications and occupations |
| ESIS | European chemical Substances Information System |
| EUROSTAT | Eurostat is the statistical office of the EU |
| FIOH | Finnish Institute of Occupational Safety and Health |
| GDP | Gross domestic product |
| GENESIS | Gemeinsames Neues Statistisches Informations-System - new information databases of official statistics set up by the Federal Statistical Office and the statistical offices of the Länder in Germany. |
| GESTIS | GESTIS is an information system on hazardous substances of the German Social Accident Insurance. It contains information for the safe handling of hazardous substances and other chemical substances at work. |
| HPV-LPV | High production volume – low production volume |
| HSE | Health and Safety Executive |
| HSL | Health and Safety Laboratory |
| IAB | Institute for Employment Research in Germany (Institut für Arbeitsmarkt und Berufsforschung) |
| ICD 10 | 10th revision of the International Statistical Classification of Diseases and Related Health Problems |
| IED | Industrial Emissions Directive 2010/75/EU |
| IFA | Institute for Occupational Safety and Health of the German Social Accident Insurance (Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung) |
| ILO | International Labour organization |
| IOELV | Indicative occupational exposure limit value |
| IPCheM | The Information Platform for Chemical Monitoring. It is a single access point for discovering chemical monitoring data collections managed and available to European Commission bodies, Member States, international and national organisations and researchers. |
| IPPC | Integrated Pollution Prevention and Control |
| ISCO 08 | International Standard Classification of Occupations, endorsed by the Governing Body of the ILO March 2008. |
| IUCLID | International Uniform Chemical Information Database |
| JEM | Job exposure matrixes |
| JRC | Joint Research Centre |
| KEMI | Swedish Chemicals Agency |
| LFS | Labour force survey |

| | |
|---|---|
| LVOC | Large Volume Organic Chemical Industry |
| MEASE | A tool for the estimation and assessment of substance exposure scenarios specific to handling of metals. |
| MEGA | A German exposure database "Measurement data relating to workplace exposure to hazardous substances" (Messdaten zur Exposition gegenüber Gefahrstoffen am Arbeitsplatz") |
| MonCom | Monitoring Committee |
| NACE | Nomenclature statistique des activités économiques dans la Communauté européenne - NACE is the European standard classification of productive economic activities. |
| NKG | Nordic Chemical Group |
| OccIDEAS | Occupational Integrated Database Exposure Assessment System, a web-based application which is used to assess occupational exposure in epidemiological studies. |
| OECD | Organisation for Economic Co-operation and Development |
| OEL | Occupational exposure limit |
| OSH | Occupational safety and health |
| PAH | Poly-Aromatic Hydrocarbons |
| PC | product category: it describes in which types of chemical the substance is finally contained when it is supplied to end-uses (by industrial, professional or consumer users) – one of five descriptor-lists to standardise the description of the use of substances under REACH. |
| PPE | Personal protective equipment, |
| PROC | Process categories: Application techniques or process types defined from the occupational perspective. It is one of five descriptor-lists to standardise the description of the use of substances under REACH. |
| PRODCOM | PRODCOM is the classification of goods used for statistics on industrial production in the EU. |
| RCS | Respirable Crystalline Silica |
| REACH | A regulation of the European Union, adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry. |
| REACH-IT | The central IT system that supports Industry, Member State competent authorities and the European Chemicals Agency to securely submit, process and manage data and dossiers. |
| SCOEL | Scientific Committee on Occupational Exposure Limits |
| SLIC | Senior Labour Inspectors Committee |
| SPIN | Database on the use of Substances in Products in the Nordic Countries. The database is based on data from the Product Registries of Norway, Sweden, Denmark and Finland. |
| UC | Use category |
| WOODex | International Information System on Occupational Exposure to wood dust |
| WP | Work package |
| | |
| | |

# 1 Introduction

Despite long-existing EU legislation for workers' protection and sometimes even longer national traditions, aggregated data on workplace risks from chemical exposure only exists at national level in a selected number of Member States. There has not been a collection of such data in a harmonised way at EU-level. Although employers are obliged to report on use of and exposure to carcinogens and mutagens (Directive 2004/37/EC), they only have to do this when asked by authorities; the same with the number of employees exposed to these substances. There is no specific legal requirement to provide information on the exposed working population.

Such information should be readily available for political decision-makers, trade associations, workers and unions. The implementation of political measures and strategies for targeted workplace risk assessment and risk management requires knowledge on which substances are used at which workplaces (sectors, occupations) and via which technologies.

The HazChem@Work project was initiated by DG EMPL to support implementation of EU OSH requirements on chemicals.

The overall aim of the HazChem@Work database was to make available valuable information on the exposure of groups of workers to chemical agents in the EU Member States and the EFTA to allow interested stakeholders to access and use this exposure data for risk management measures at enterprise level and for improving occupational health, for example by setting priorities for prevention, regulatory risk management, as well as occupational disease recognition at national and European level, for example for:

- Policymakers developing risk assessment and management programs for workplaces
- Employers and safety and health practitioners assessing workplace risks and improving conditions
- The EU Commission and its Directorates that target further policies and worker protection programmes
- Substance manufacturers and importers conducting chemical safety assessments in the context of registrations under REACH etc.

The HazChem@Work addresses the following key questions:

1. Which hazardous substances are being used in EU workplaces?
2. What are the industries / employment sectors involved?
3. What type of companies (e.g. micro enterprises, SMEs and their proportion) are involved?
4. What are the use categories (e.g. sector of use, process categories as used in the REACH registration database)?
5. How many workers are exposed (e.g. per sector / per industry / per country)?
6. What is the type, level and duration of exposure to these workers?
7. What type of risk management measures (RMM) are in use and indication?

The HazChem@Work project started in September 2014 and ended in October 2106. The consortium consisted of three partners (KOOP, INCDPM, BAuA (until January 2016)) and one subcontractor (Claudia Berg – design & development). The project was supported by a Monitoring Committee (MonCom) comprising members of the tri-partite Working Party on Chemicals -WPC (MS authorities, employer and worker representatives).

The essential outcomes of the project are

- Collection of data from national databases and data sources in a harmonised way

- Methodological criteria for a list of substances, including the list itself
- Description of main challenges for the generation of exposure data on a collective level
- A database containing the data in an easily accessible way including instructions, update and maintenance plans and technical documentation
- An analysis of models for estimating exposure levels with recommendations for future use of models in the database.
- Recommendations for improvement and continuation of the HazChem@Work database.

# 2 Work package 1: Search and analysis of data sources

## 2.1 Aim of the work package

The main aim of work package 1 was to create an overview of available data sources and up-to-date data on occupational exposures to chemicals in the EU and the EFTA/EEA states. In addition, a format for data on occupational exposures to chemicals should be developed to facilitate future information collection from various stakeholders and/or information sources. A third aim of this work package was to identify reasons why occupational exposure information is not available, in particular data which should be reported according to Article 6 of the Carcinogens and Mutagens Directive (CMD).[1]

## 2.2 Survey among data source providers, national authorities and relevant stakeholders

To get an overview of available data sources, a survey questionnaire was developed and agreed with the DG Employment (see https://de.surveymonkey.com/s/HazChem@Work and Annex 1). The aim was to get a more detailed description of the available data and the organisational, technical and legal preconditions for a second use in a European database.

For the survey, a letter from the consortium members was sent to about 130 potential data owners and providers. For the survey, a support letter from DG Employment (see Annex 2) was used to motivate the data providers to get involved in the project (see Annex 3). Overall 40 replies from data providers were received. After the initial contact stage, some of the larger data providers were contacted directly.

After the stakeholder workshop in Luxemburg in June 2015 (see WP 6), a second round of letters was sent to the members of the enforcement working group of the Senior Labour Inspectors Committee SLIC, with a request for a national contact responsible for the enforcement of the CMD directive. In total 15 replies containing a contact address were received. An overview of the identified contacts can be found in Annex 16.

The identified authorities (excluding those which were already contacted during the first round) were then contacted in July 2015 with a request for filling in the original questionnaire. From the 15 contacted authorities 5 replies were received. Four replies contained additional data sources. A summary of these identified data sources can be found in Annex 7. For four authorities sufficient information was received to create fact sheets. These fact sheets can be found in Annex 8.

[1] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:229:0023:0034:EN:PDF

## 2.3 Overview of available information sources

A template has been developed to be used for short descriptions of data sources in the reports and has already been used for the first interim report.

The template includes the following sections:

1. Name/title of the data source
2. Originator/owner of the data source
3. Time period of data collection and frequency of updates
4. Language(s) covered in the data source
5. Geographical area(s) covered in the data source
6. Publication form and reference
7. Legal background and/or reason for data collection
8. Content of the data source
9. Constraints for using the data source

Annex 5 contains an updated overview table of those data sources that have sent back a completed questionnaire and the one created by the contractor. Annex 7 descriptions of these 40 data sources following the template are presented.

## 2.4 Overview of information sources to be considered in future work

As a rather broad variety of data sources was addressed (e.g. exposure databases, chemicals registers, cancer registers) the questionnaire is organised in different sets of questions, where not all might be relevant for each data source. In the introduction to the questionnaire it was mentioned that unanswered questions will be interpreted as not relevant for the data source / authority / organisation the respondent is representing. Therefore, questions were not obligatory to be answered with the exception of contact details and data source names and owners.

During the survey 29 exposure data sources (72.5%), 6 production and use data sources (15%) and 5 disease data sources (12.5%) have been identified. The summary information and overview figures of the first interim report have been updated and can be found in Annex 6.

## 2.5 Criteria for the quality of data/information sources

The project team proposes the following list of criteria to assess the quality of data for a European exposure database:

1. Availability and completeness of occupational hygiene information (e.g. documentation of working tasks and working operations including risk management measures in use, exposure patterns, analytical methods)
2. Variability and precision issues (e.g. sample size, similarity of averaging times)
3. Internal validity of the data (presence of biases due to e.g. systematic measurement errors or sample design)
4. External validity of the data (possibility for generalization of measurement data).

These criteria were proposed by Tielemans[2] and were already successfully applied during the ETEAM-project.[3] For the pilot study the mentioned criteria were not applied, due to a very poor

[2] Tielemans, E., *A Proposal for Evaluation of Exposure Data.* Annals of Occupational Hygiene, 2002. **46**(3): p. 287-297.

[3] The project reports can be found at the following website : http://www.baua.de/en/Publications/Expert-Papers/F2303-D26-D28.html

respond of database providers. It was necessary to include as many data as possible to be able to develop the pilot database. The quality criteria have been discussed in 2015 in a workshop with the stakeholders, as presented further in chapter 7.

## 2.6 Project website

The contractor prepared a project website presenting the project's background, activities and contact details at www.HazChem@Work.eu. In 2015 the website included a link to the online version of the survey's questionnaire. Currently, it provides a link to the survey results and analysis (http://www.HazChemAtWork.eu/survey/), a link to the minutes of the stakeholder workshop organised in June 2015, as well as a call to support the project. A screenshot of the project website is presented in Annex 14.

## 2.7 Summary and findings

The aim of WP 1 was to provide an overview of available data sources and actual data on occupational exposure to chemicals and to identify reasons why occupational exposure information is not available. To get an overview of available data sources and their exposure information the consortium carried out a desk research and made use of its network and experience as well as a survey. 130 database sources were identified and contacted for the survey. 40 database owners participated in the survey, of which 29 exposure data sources, 6 production and use data sources and 5 disease data sources.

The main challenge of this WP was to convince database owners to participate in the survey.

The survey addressed among others questions concerning the content of the database (substances, substance groups, mixtures), questions concerning data on production, use of chemicals, disease data and adverse effects as well as questions concerning reasons for data collection and obstacles to generate/collect exposure data and constraints to use the data.

The main reasons for data collection were: regular compliance monitoring (40%), post compliant and accident check (18%), notification of exposure due to legal requirements (42%), disease notifications (21%), others (47%).

The following obstacles to generate exposure data and constraints for using data were mentioned:

- Reported data concerning enterprises is partly treated as confidential
- Reported data concerning enterprises is often incomplete
- Small enterprises cannot afford to perform studies to produce exposure data
- In many Member States no legal obligation to make employers to submit data
- Lack of funding for quantitative exposure measurements and the lack of exposure measurements conducted for representative samples
- Exposure data collected over time might not have been classified and stored using a (common) format for easy access and analysis
- Lack of data due to insufficient enforcement of the obligation to perform exposure measurements
- Lack of knowledge, poor risk assessment, limited ability to set risk management measures based on measured data

# 3 Work package 2: Building up the list of chemicals to be included in the scope of the study

## 3.1 Aim of the work package

The aim of work package 2 was to establish a list of substances which has been included in the further work of the study. The selected substances should be relevant for workplaces in Europe, form a sound and representative information basis to be included in the database and allow modelling of exposure levels. Therefore, a combination of criteria has been defined, addressing the need for selecting relevant substances for occupational safety and health as well as representativeness and availability.

## 3.2 Criteria for deciding on the relevance of substances for occupational exposures

In the tender documents some criteria regarding the selection of substances were already given. Similar criteria were also documented in the bid. These include:

- Substances with a high exposure potential due to typical working tasks
- Substances known to be linked to occupational diseases
- Substances with CMR (carcinogenic, mutagenic, reprotoxic) properties according to Annex VI of regulation EC No 1272/2008 (CLP regulation)
- Substances considered to be of an equivalent level of concern to human health according to Article 57f of REACH regulation
- Dermal and respiratory sensitizers
- Substances produced or used in very large amounts
- Substances with a large number of different uses

The data sources used for the initial set of chemicals included REACH registered substances (available on ECHA site) and data from projects like CAREX (International Information System on Occupational Exposure to Carcinogens)[4]. As presented below several steps of selection based on scoring were used to reduce this initial set of chemicals.

**Applying these broad criteria** the expected number of substances to be identified was in the range of five to six thousand. Given the scope of the project and the expected number of data per substance in national data sources this preliminary list clearly needed to be reduced to a more manageable number for the final database.

**A further filtering in three steps was proposed**. The first two steps both use a scoring system to rank the substances. Both scoring systems use the following broad categories:

- Exposure potential
- Nature of the hazard to human health
- Assumed consumption

[4] International Information System on Occupational Exposure to Carcinogens
http://www.ttl.fi/en/chemical_safety/carex/pages/default.aspx

The difference between the first and second step was the level of detail of the scoring criteria.

The third selection step used as criterion the availability of exposure data for the remaining substances. Thus, it is ensured that the database will contain a substantial amount of exposure data and not too many "exotic substances" with very little exposure information.

The categories were chosen for maximising the likelihood of being relevant with regard to occupational safety and health and the availability of measurement data:

- A high potential for exposure to a substance leads to higher ranking in terms of relevance to occupational safety and health.
- Similarly, a substance which is classified more hazardous will also be more relevant for OSH in terms of the level of concern.
- Substances which are produced or used in very large amounts might be used by a large number of workers if the use patterns are other than mere industrial uses/uses as intermediates. Therefore it is more likely that measurement data exist for such substances even if the risks linked to such usages might be relatively low. Another category is the existence of occupational exposure limits (OEL) for the substance. A substance for which such an OEL exists has previously been targeted by some kind of OSH regulation, thus increasing its relevance. In the course of the first scoring step, Binding Occupational Exposure Limit Values (BOELV) or Indicative Occupational Exposure Limit Values (IOELV) can be considered as well to ensure not to miss such agents.

The score from each category is combined to obtain the final score for each substance.

**Table 1: Proposed categories for the coarse scoring system**

| **Coarse Scoring** | **Exposure potential** | **Assumed Consumption** | **Nature of hazard to human health** | Existing OEL |
|---|---|---|---|---|
| **Tier 1** | Wide dispersive use<br><br>Professional use | Produced in the EU and EFTA more than 10,000-100,000 tonnes per annum (tpa) (total tonnage band) | Cat. 1A/1B carcinogens<br>Cat. 1A/1B mutagens<br>Cat 1A/1B toxic to reproduction<br>Sensitizers (dermal, respiratory)<br>Linked to known occupational diseases | - OEL in the European Union |
| **Tier 2** | PROC[5] other than 1, 2, 3 | Produced in the EU and EFTA more than 1,000 tpa but less than 10,000-100,000 tpa (total tonnage band) | - Cat. 2 carcinogens<br>- Cat. 2 mutagens<br>- Cat 2 toxic to reproduction | |

[5] The process category (PROC) describes the tasks, application techniques or process types defined from the occupational perspective, including use and processing of articles by workers. There are 27 PROCs; PROC 1, 2, 3 refer to closed systems with unlikely or limited exposure. The definition of each PROC can be looked up in the Guidance on Information Requirements and Chemical Safety Assessment. Chapter R.12: Use description. Available at:
https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf

Table 1 summarises the scoring categories for the coarse scoring system. Substances with a high likelihood of existing exposure data (e.g. due to being part of CAREX/WOODEX or similar projects) have been favoured when selecting substances in the first step of reduction. This ensures that no obvious candidate will be omitted in this early step.

The scoring was used because it has some advantages:

- A score can be assigned fully automated.
- A scoring system is transparent. For each substance the reasons for its score can be easily comprehended.
- Expert judgement can be used to ensure the relevance of the selected substances, as substances are only ranked but not filtered.

Table 2 lists the number of substances after each step of the scoring system. In the first step, only coarse information was used to reduce the number of substances to 500.

For these substances more detailed information could be collected (e.g. detailed REACH registration information from ECHA or regulatory information from the EU Member States). This information was then used for a more fine/refined scoring system from which about 100 substances were selected.

**Table 2: Number of substances at each step of selection**

| Step of selection | Number of remaining substances |
|---|---|
| Step 0: Initial | 5000 – 6000 |
| Step 1: Coarse Scoring System | 500 – |
| Step 2: Fine Scoring System | 100 |
| Step 3: Data availability | 50 – 100 |

Expert judgement has been involved to finalise the selection and to ensure that the list of selected substances contains a reasonable cross section of substances used in Europe. The general approach proposed by the project team was accepted by the experts of the stakeholder workshop and the MonCom. Suggestions for improvement were implemented to the coarse and fine scoring system.

## 3.3 Feedback from the Workshop in Luxemburg

At the Workshop, the general proposal was received well. However, it was highlighted by several participants that the scoring system must not give too much emphasis to substances that are registered in the framework of REACH. Additionally it was proposed that process generated and legacy substances should be added at a later stage as the scoring system cannot assess them very well. Also, a grouping approach may be considered, as many substance groups have similar properties (e.g. various chromates). These substances often share similar classifications or OELs which could be used as a base for such a grouping. It was agreed that consideration of the availability of data at an early stage would entail a disproportionately great effort. Additional comments concerned the exact assignment of scores to the various categories (e.g. whether sensitsers should be assigned the same score as CMR properties).

Based on this feedback it was decided that substance generated and legacy substances will, based on this input, added to the selection at the stage where data availability of such substances can be better estimated. At the same time, a grouping (e.g. similar to groupings in OELs) approach will be considered. Prominent examples of candidates for this list are: quartz dust, welding fumes, diesel exhaust, lead, asbestos, wood dust, organic dust, inorganic dust (sanding of metals), metal working fluids, combustion products, including combustion from plastics, other heavy metals.

## 3.4 Feedback from the Monitoring Committee

Comments regarding the list of 500 chemicals were received from one member of the MonCom. It was noted that substances referring to petroleum and coal stream substances could be deleted as they are usually of variable composition and instead to focus on their specific carcinogenic components such as benzene, butadiene, or PAHs[6]. It was also proposed to combine chromium compounds, cobalt compounds, cadmium compounds, nickel compounds. The comments were implemented in the list of 500 substances in Annex 9.

## 3.5 Implementation of the coarse scoring system – Step 1

The coarse scoring system uses mainly data available from ECHA. The assigned scores are summarised in Table 3.

For the scores regarding hazards types, CMR properties were assigned a score of 10 or 5, depending on whether it is a CMR Cat 1 respectively a Cat 2 substance. Sensitisers (respiratory /skin) were assigned a score of 8 based on the feedback from the workshop. Both of these scores (for CMR and for sensitising properties) are applied separately in this rationale and cumulated accordingly if the substance had both types of hazards.

**Scores for the assumed consumption** are either 10, if the tonnage band of all REACH registrations is larger than 100 kT, 5 for a tonnage band larger than 1 kT, or 0 if lower. The score was chosen to give, on average, lower results than the previous two categories to not let high-producing substances with little concern for occupational safety and health dominate the selection.

Consequently, the **scores for occupational exposure potential** were chosen to be slightly higher than the ones for assumed consumption: wide dispersive use has a score of 5, respectively 10 if no consumer uses were registered. In the latter case it is more likely that the wide dispersive use stems from occupational use, thus being more relevant for this study.

Finally the existence of an IOELV/BOELV value was considered. If such a value exists a score of 5 is assigned.

[6] Poly-Aromatic Hydrocarbons

**Table 3: Assigned scores for various properties/categories used for the coarse scoring system**

| Property | Score |
|---|---|
| CMR Cat 1 | 10 |
| CMR Cat 2 | 5 |
| Sensitiser (dermal/inhalative) | 8 |
| REACH Tonnage Band > 100 kT | 10 |
| REACH Tonnage Band > 1 kT | 5 |
| Wide Dispersive Use | 5 |
| Wide Dispersive Use without consumer Use | 10 |
| PROC other than 1,2,3 | 5 |
| Existing IOELV/BOELV | 5 |

The first list of 500 resulting substances was refined according to the comments from the Monitoring Committee. Annex 9 contains the full list of the 500 resulting substances. They can be roughly grouped in the following categories:

- Substances with high scores (>10 points) in all categories
- Substances with medium scores (5 to 10 points) in all categories
- Substances with high scores for human health concern but lower score (0 to 5 points) in the other categories
- Substances with low score for human health concern but high scores in the other categories

This selection of substances appears reasonable. The remaining 500 substances contain a reasonable mix. Substances with higher concern for human health but lower use and occupational exposure potential are present as well as widely used substances with lower concern for human health.

The ten highest scoring substances and their resulting scores using this system are shown in table 4. As expected, the highest scoring substances score high in all categories, except for the existence of OELs. This is explained by the fact that only few IOELV/BOELVs exist.

Some of the substances in the group of 10 with the highest scoring were included in a priority list used to collect data from the providers for the pilot database.

**Table 4: Substances and scores for the ten highest scoring substances in the coarse scoring system – step 1**

| Substance Information | | | | Score | | | | |
|---|---|---|---|---|---|---|---|---|
| CAS Nr. | EC Nr. | Name | Main adverse health outcome (CMR and sentisisers classification according to CLP regulation) | Human Health concerns | Assumed Production or Consumption | Exposure Potential | Existing OEL | Total |
| 302-01-2 | 206-114-9 | hydrazine | Carc. 1B, Skin Sens. 1 | 18 | 10 | 15 | 0 | 43 |
| 1333-82-0 | 215-607-8 | chromium trioxide | Carc. 1A, Muta. 1B | 18 | 10 | 15 | 0 | 43 |
| 513-79-1 | 208-169-4 | cobalt carbonate | Carc. 1B, Muta. 2, Repr. 1B, Skin Sens. 1 | 18 | 10 | 15 | 0 | 43 |
| 71-43-2 | 200-753-7 | benzene | Carc. 1A, Muta. 1B | 10 | 10 | 15 | 5 | 40 |
| 106-89-8 | 203-439-8 | 1-chloro-2,3-epoxypropane | Carc. 1B, Skin Sens. 1 | 18 | 10 | 10 | 0 | 38 |
| 107-13-1 | 203-466-5 | acrylonitrile | Carc. 1B, Skin Sens. 1 | 18 | 10 | 10 | 0 | 38 |
| 50-00-0 | 200-001-8 | formaldehyde | Carc 1B, Muta. 2, Skin Sens. 1, | 18 | 10 | 10 | 0 | 38 |
| 71-48-7 | 200-755-8 | cobalt di(acetate) | Carc. 1B, Muta. 2, Repr. 1B, Skin Sens. 1 | 18 | 5 | 15 | 0 | 38 |
| 10588-01-9 | 234-190-3 | sodium dichromate | Carc. 1B, Muta. 1B, Repr. 1B, Skin Sens. 1 | 18 | 5 | 15 | 0 | 38 |
| 584-84-9 | 209-544-5 | 4-methyl-m-phenylene diisocyanate | Carc. 2, Skin Sens. 1 | 13 | 10 | 15 | 0 | 38 |

## 3.6 Implementation of the fine scoring system – Step 2

**Step 2: Fine scoring system**

For the fine scoring system the following refinements were made:

In addition to the ECHA data resources data from SPIN[7] and the GESTIS[8] international OEL database were included[9]. In the second step dangerous substances relevant at work places were considered that are not covered by the REACH data compilations (particularly asbestos, wood dust, diesel engine emissions or respirable crystalline silica) or are only partly covered like lead.

The concerns for human health were refined by amendment of the category 'Other serious occupational diseases'. This is necessary to be able to include diseases like silicosis that were – in the first coarse step - not covered due to restriction to the carcinogenic and sensitising properties

The existence of OEL was refined for multiple countries. The used data source for this information was the GESTIS international limit values database.

Concerning occupational exposure potential, each use of a substance has got an individual score assigned. This allows uses with lower concern (especially the ones containing closed systems, as present already in the coarse scoring system) to score less than uses with a higher concern (e.g. open spraying). This refinement is based on the information from ECHA and from the SPIN database[10] .

For the assumed consumption, the registered tonnages were broken further down, into three categories; REACH Tonnage Band > 1kT; REACH Tonnage Band > 100 kT and REACH Tonnage Band > 1 mT.

The revised categories and scores are presented in table 5, with the new additions marked in grey.

[7] SPIN is a database on the use of Substances in Products in the Nordic Countries. The database is based on data from the Product Registries of Norway, Sweden, Denmark and Finland . The database contains volumes in use for each substance in the four countries divided by industrial branch and product type. Available at: http://www.spin2000.net

[8] GESTIS is an information system on hazardous substances of the German Social Accident Insurance. It contains information for the safe handling of hazardous substances and other chemical substances at work. Available at: http://www.dguv.de/ifa/gestis/gestis-stoffdatenbank/index-2.jsp

[9] http://limitvalue.ifa.dguv.de/

[10] www.spin2000.net

**Table 5: Assigned scores for various properties – Step 2**

| Property | Score | Categories |
|---|---|---|
| CMR Cat 1 | 10 | Human Health |
| CMR Cat 2 | 5 | |
| Sensitiser (dermal/inhalative) | 8 | |
| Other serious occupational diseases | 8 | |
| Reach Tonnage Band > 1 mT less than 10 mT | 15 | Assumed production or consumption |
| Reach Tonnage Band > 100 kT | 10 | |
| Reach Tonnage Band > 1 kT | 5 | |
| SPIN USEs : Very narrow range of appl. 1 star | 1 | Applications and use: occupational exposure potential |
| SPIN USEs : Narrow range of appl., 2 stars | 2 | |
| SPIN USEs : Intermediate range of appl., 3 stars | 3 | |
| SPIN USEs : Wide range of appl. 4 stars | 7 | |
| SPIN USEs : Very wide range of appl. 5 stars | 15 | |
| REACH: Wide Dispersive Use | 5 | |
| REACH: Wide Dispersive Use without consumer Use | 10 | |
| REACH: PROC other than 1, 2, 3[11] | 5 | |
| SPIN Occupational Exposure 1 star | 1 | Occupational exposure estimate |
| SPIN Occupational Exposure 2 stars | 2 | |
| SPIN Occupational Exposure 3 stars | 3 | |
| SPIN Occupational Exposure 4 stars | 4 | |
| SPIN Occupational Exposure 5 stars | 5 | |
| Existing IOELV/BOELV (EU) | 5 | Existing OEL |
| Between 3 and 10 countries (GESTIS) | 1 | |
| More than 10 countries (GESTIS) | 3 | |
| OEL in more than 20 countries (GESTIS) | 5 | |

The application of this list plus the tentative inclusion of three process generated substances (RCS[12], Wood dust and DEE[13]) and two legacy substances asbestos (fully) and lead (partly) gave a more realistic picture of relevant exposures at work places than the ECHA-data, as seen in the table 6.

[11] The process category (PROC) describes the tasks, application techniques or process types defined from the occupational perspective, including use and processing of articles by workers. There are 27 PROCs; PROC 1, 2, 3 refer to closed systems with unlikely or limited exposure. The definition of each PROC can be looked up in the Guidance on Information Requirements and Chemical Safety Assessment. Chapter R.12: Use description. Available at:
https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf

[12] Respirable Crystalline Silica

[13] Diesel Engine Exhaust

**Table 6: Substances and scores for the ten high scoring substances in the refined scoring system – Step 2**

| Fine scoring | CAS-Nr | EC-Nr | Substance name | Human Health | Production ReACH | Wide Range of appl. SPIN | Worker Expo REACH | Worker Expo SPIN | OEL EU | OEL Nat | Total | Obs. |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 71-43-2 | 200-753-7 | Benzene | 18 | 15 | 7 | 15 | 5 | 5 | 5 | 70 | |
| 2 | 50-00-0 | 200-001-8 | Formaldehyde | 18 | 15 | 15 | 10 | 5 | 0 | 5 | 68 | |
| 2 | 14808-60-7 | | Quartz (RCS=Respirable Crystalline silica) | 18 | 10 | 15 | 15 | 5 | 0 | 5 | 68 | Assumption: More than 1mT of RCS (Quartz dust) produced during work per annum in Europe. Assumption: CMR Cat1, |
| 4 | 7439-92-1 | 231-100-4 | Lead | 18 | 15 | 7 | 10 | 5 | 5 | 5 | 65 | |
| 5 | 67-66-3 | 200-663-8 | chloroform | 5 | 18 | 7 | 15 | 5 | 5 | 5 | 60 | Acute intoxication risk |
| 5 | 107-13-1 | 203-466-5 | Acrylonitrile | 18 | 15 | 7 | 10 | 5 | 0 | 5 | 60 | |
| 5 | 108-88-3 | 203-625-9 | Toluene | 10 | 10 | 15 | 10 | 5 | 5 | 5 | 60 | |
| 5 | 872-50-4 | 212-828-1 | 1-methyl-2-pyrrolidone | 10 | 10 | 15 | 10 | 5 | 5 | 5 | 60 | |
| 9 | | | wood dust | 10 | 15 | 5 | 15 | 5 | 5 | 3 | 58 | Assumption: More than 1mT of wood dust produced during work per annum in Europe. Assumption: CMR-cat1, Worker exposure for REACH and SPIN estimated |
| 10 | 101-68-8 | 202-966-0 | 4,4'-methylenediphenyl diisocyanate | 13 | 10 | 15 | 10 | 5 | 0 | 3 | 56 | |
| 10 | | | Diesel engine Emissions (DEE) | 10 | 15 | 15 | 10 | 5 | 0 | 1 | 56 | Assumption: More than 1mT of DEE produced during work per annum in Europe Assumption: CMR Cat 1, Worker exposure estimated |

As in the coarse system the substances with high data availability score highest. To reduce this effect we did an estimation of data (see the figures in Italics) if they were missing. The estimate was based on literature related to the concerned substances / materials (quartz, asbestos, wood dust and diesel engine emissions). We estimated which scores they would achieve, if registered under REACH or if included in SPIN (e.g. which uses in which sectors would asbestos or quartz dust get if they were covered).

**Step 3: Data availability**

In a third step the availability of data on exposure was evaluated for the substances selected in step 2, in order to avoid 'exotic" chemicals being selected without the possibility to gather corresponding data on them. Based on the experience of the members of the project team it was considered that the substances selected in step 2 were among those for which it is possible to find data on exposure. It would be necessary to compile available studies on production, use and exposures per substance, if the list will be further extended in time. The main focus of the HazChem@Work study was on a methodological approach and tentative application based on existing data sets.

## 3.7 Summary and findings

The aim of WP 2 was to to establish a list of substances which are relevant for the occupational setting and form a relevant, sound and representative data basis for HazChem@Work. The WP consisted of three work steps. For the initial set of chemicals (step 0) substances were included with a high exposure potential due to typical working tasks, substances known to be linked to occupational diseases, substances with CMR properties, dermal and respiratory sentisisers, substances produced in very large amounts, substances with a large number of different uses as well as substances considered to be of an equivalent level of concern to human health which resulted in a list of 5,000 substances. The step 1 and 2 used a coarse scoring system and a fine scoring system to filter the list. Both systems used the following broad categories:

- Exposure potential
- Nature of the hazard
- Assumed consumption

For step 1 (coarse scoring system) public ECHA data were used (human health toxicity, production and worker exposure assessment). This resulted in a list of 500 substances. The coarse scoring system did not cover some relevant dangerous substances at work (e.g. asbestos, diesel engine emissions, wood dust), which lead to the conclusion that several sources have to be considered to perform a ranking of relevant dangerous substances. The concerns for human health of workers were better taken into account by four amendments:

- Inclusion of occupational diseases beyond carcinogens and sensitisers
- The 'Range of use' in the large Nordic database SPIN was one additional criterion
- The assessment of workers exposure - again from SPIN - was the third additional criterion
- The number of countries that introduced an OEL was taken into account (GESTIS international limit values database).

Step 2 resulted in a list of 100 substances.
An additional step (step 3) evaluated substances according to the availability of data; it was deemed that it is possible to find exposure data for all substances in step 2.

# 4 Work package 3: Collection of exposure data at national level

## 4.1 Aim of the work package

The aim of this work package (WP) was to collect exposure information for the database of substances, as pre-selected in work package 2. The data collection was supported by IT-applications for data mining and extraction from existing databases.

**Data structure**

The collection of data was built on the template developed in WP 1 (see Annex 10), as well as the experience gathered from establishing the relevance criteria and the considerations of the functionalities and purposes of the model and the database (see WP4 and WP5).

## 4.2 Data structure for information collection and storage in the database

The template for collecting data is presented in Annex 10. The template was amended and adapted several times to the requirements of database providers. It contains a large number of parameters, to be able to include/integrate as many data providers as possible. The following six sections are included in the template:

- Chemical substances
- Exposure and contextual data
- Production and use of chemicals at national and European level
- Disease data and adverse effects
- Sector and occupation data
- General information

For each of the section and sub-section support information on how to register it in the database has been elaborated and is made available for the users on the HazChem@Work database website, in a separate document as presented below (partly) and in Annex 11 in full. In the same time indication is presented in windows that will open when clicking on each sub-section title in the data template.

1. Chemical substances* THIS WHOLE FIELD IS MANDATORY
   - **Name**- the chemical name will be the English e.g. CAS name, IUPAC, or other names commonly used for the chemical (e.g. the name used in the Annex of CLP Regulation or in the C&L Inventory published by ECHA which can be found on ECHA's website).
   - **ID number** (e.g. CAS, EC, Index)

2. Exposure and contextual data
   - **Kind of exposure (inhalation/dermal)** : Put Yes for the type of exposure that has been measured. THIS FIELD IS MANDATORY
   - **Measurement method** : THIS FIELD IS MANDATORY
     - Name: specify the abbreviated name of the method when standardised e.g. ISO 15202-1:2012; NIOSH Mercury 6009 is.2; the same for national standards.
     - Standardised: put Yes if it is a national or international standard and No if is not.
   - **Exposure measurement** (e.g. different values such as average, peak, minimum, percentiles, kind of exposure) THIS FIELD IS MANDATORY
     - **Measurand** (measured quantity or object) if different from the substance in section 1 ( e.g. for metabolites in biological samples)

- **Measurement conditions**: specify type of measurement – personal sampling, static sampling, skin wipe sampling, fluorescence stain skin sample, other
- **Matrix** – if the substance is measured in a special matrix (e.g. in blood) specify it in English.
- **Peak value** : put the highest short-term/instantaneous measured value per shift
- **Average value:** put the corresponding 15 minutes or 8 hours values, arithmetic mean, other
- **Value**: use point to separate the decimals
- **Unit** : specify the unit in a standardized way ( e.g. mg/m$^3$) ; use the same units as those specified by legislation in case of (B)OELs

- **Work process, kind of workplace, task, technology**: specify briefly, in English
- **Number of exposed workers** (e.g. per substance/ task/ sector/ occupation/ country): put the number of workers if known at country level for all sectors, occupations etc, or at national level for a sector, or occupation or task. Information referring only to an individual workplace or company should not be registered.
- **Duration and frequency of exposure**: provide the total duration in minutes per shift and the frequency as number of occurrences per shift (N.B. the total duration may result from performing the operation several times per shift, each time having a different duration).
- **Risk management measures** (e.g. PPE, exposure monitoring, substitution) put Yes or No, for individual cases not for bigger groups (e.g. sector, country).

3. Production and use of chemicals at national and European level

- **Production:** put the value in tonnes per year and specify the year in section 6
- **Consumption:** put the value in tonnes per year and specify the year in section 6. If it refers to a sector add the sector code in section 6.
- Uses: specify Process category (PROC), product category (PC) or article category (AC) as in REACH.

4. Disease data and adverse effects

- **Type of diseases** (e.g. occupational diseases, cancer, adverse effects) : recommendation to use the ICD 10 codes -International Classification of Diseases elaborated by WHO
- **Contextual data** (e.g. work history, workplace conditions, exposure to chemicals) -
- **Sector, occupation**: put corresponding data in section 5 (see below).
- **Type of workers**:

- for individual cases put age, gender (M or F), qualification, new workers (Yes/No) , maintenance workers (Yes/No), pregnant or breastfeeding workers(Yes/No), young workers (16-18 years, Yes/No)

- for group statistics- put related figures, or percentages whenever available.

5. Sector and occupation data

- **Categorisation for sector:** use NACE codes (at least two digit level e.g. C10.1) THIS FIELD IS MANDATORY FOR SECTION 2, 3 and 4.
- **Company size:** choose one of the following: micro for less than 10 employees, small for less than 50, medium for less than 250, large for more than 250 employees
- **Categorisation for occupation***: use ESCO, ISCO 08 code THIS FILED IS MANDATORY FOR SECTION 2

6. General information * THIS WHOLE FIELD IS MANDATORY

- **Procedure of data collection:** for measurements specify if it is – a compliance check, a post accident/incident inspection, preventive monitoring, national campaign
- **Name of database** : provide the name of the database in English and its abbreviation in the original language
- **Owner of the data source:** provide the full name of the owner
- **Year of collection:** provide the year when the data was generated
- **Country** : provide the name of the country in English

## 4.3 Data collection

The collection sheet developed in WP 1 was sent to database providers to be filled in with substance data for the testing phase. The test with real data was a crucial step in the development of the HazChem@Work database. It enabled the project consortium to further improve the format. In addition, the database structure benefits from the experience gathered from the data source providers. During the test phase we started with a list of 72 parameters and ended with a list of 86 maximum requested information details (see Annex 10). However, the database providers were asked to fill in only the columns for which they possess data.

In the test phase the consortium focused on the following substances/substance groups/ process generated substances presented in table 7, if a selection could be made by the data providers. That selection did not exclude other substances.

**Table 7: Proposed substances/ substance groups/ process generated substances for the testing phase**

| Substance Name | Reason for inclusion |
|---|---|
| Respiratory Crystalline Silica (RSC) | Very wide exposure population |
| Asbestos | Legacy substance |
| Formaldehyde | Use restricted to some well-defined sectors |
| Wood dust | Wide exposure population |
| Benzene | Broad use, dermal contact |
| Chromium and compounds | Broad use in industry |
| Cadmium and compounds | Specific use |
| Nickel and compounds | Specific use in industry, wide use in welding |
| Cobalt and compounds | Specific use |
| HTIW - high temperature insulation wool[14] | Very specific exposure |
| Isocyanates | Highly sensitising, broad open and manual use |
| Acrylamide | Highly sensitising, broad open and manual use |

Data were provided for about 204 substances (the list of substances for which data have been provided is attached in Annex 17).

## 4.4 Contacting owners of exposure data

The preliminary test phase started with dummy data provided by BAuA. This was an ideally situation as the dummy data contained all parameters needed in contrast to the "real" testing.

Following, the second test phase was carried out with "real" data from three databases to gain experiences with the collection form and the procedure of inserting data to the database.

The following three databases were selected for the test phase 1:

- Central Register of Data on Exposure to Carcinogenic or Mutagenic Substances, Mixtures, Agents or Technological Processes (Database provider NOFER). The database contains exposure measurements at enterprise level from more than 450 substances (on their own or in mixtures) including coal and petroleum derivatives as well as some sector data.
- Unit 4.4 "Measurement of Hazardous Substances" of BAuA maintains a database of measurements performed by the unit containing exposure measurements for about 80 substances. Most measurements substances did measure dust (inhalable and respirable fractions).

[14] The contractor expected data for HTIW from ECFIA, but in the end the discussions took too long and no data were provided, until now.

- The register on exposure measurements in the workplace (INCDPM) contains mostly time weighted averages (8 hours and/or 15 minutes), and some pick values for chemicals and particulate matter. The measurements were made for companies that regularly check their compliance with the compulsory OELs. Beside the values of resulting averages the register contains information on the measurement method, the ambient conditions (temperature, pressure), existence/state of the ventilation, operations carried out by the exposed workers during sampling.

The owners of the databases were contacted by mail and in addition by phone. The requests were supported by an official letter of the European Commission (see Annex 2).

The test phase ended successfully. The project consortium and the IT developers gained practical experiences and further improved the database and collection format according to available data and comments from database providers.

In the next step additional database owners were contacted (test phase 2). A cover letter was drafted and sent to all database providers who expressed interest in the first survey as well as at the stakeholder workshop. The contact list can be found in Annex 4. A cooperation agreement was prepared in case some database providers require a cooperation agreement before sharing their data. The cover letter and cooperation agreement is attached to this report (Annexes 12 and 13).

The database providers who sent answers or provided data for the test phase are listed in table 8.

**Table 8**: List of database provider who answered to the request in January/February 2016**:**

| **Organisation** | **Database** | **Answer** |
|---|---|---|
| Working Environmental Authority (Denmark) | Danish Product Register (Produktregistret) | No data on exposure levels, offers the possibility to extract data manually from SPIN |
| Finnish Institute of Occupational Health (FIOH) (Finland) | Several databases | Data provision only possible if there is a budget (if they will be paid for the work) |
| Laboratory of Hygiene and Occupational Diseases of Institute of Occupational Safety and Environmental Health of Riga Stradins Universikty (Latvia) | | Email was forwarded to the responsible person – no respond |
| State Sanitary Inspection (Poland) | Reporting form MZ-50 (Annual report of the State Sanitary Inspection) | No data on exposure levels. The State Sanitary Inspection explained that they have not such data required for the HazChem@Work database. |
| Norwegian Environment Agency (Norway) | Product Register | Information is available about substances in dangerous chemicals placed on the marked in Norway, but no data on production of substances. They offer the possibility to extract data manually from spin2000. In addition they forwarded the request to the |

| | | |
|---|---|---|
| | | Norwegian National Institute of Occupational Health – no response |
| Central Institute for Labour Protection - National Research Institute (Poland) | Chempyl | Word document with Polish data, extracted manually, translation necessary |
| BG Bau, Reinhold Rühl (Germany) | Reports | Data extracted from reports |
| INRS (France) | COLCHIC | No authorisation to use the data |
| IFA (Germany) | MEGA | No contribution due to data ownership reasons |
| ECHA (Europe) | Registration dossiers | No contribution due to data ownership reasons, but is still discussing a cooperation with HazChem@Work |
| Cosanta (The Netherlands) | Stoffenmanager | Interested in a cooperation for including exposure models to HazChem@Work |
| Netherlands Working Conditions Survey | Netherlands Working Conditions Survey | Willing to provide data, but data were not suitable for HazChem@Work, the data are based on self-assessments of workers. |
| HSL/HSE | Different databases | A cooperation could not be agreed in the period of the project |
| ECFIA | Exposure data | A cooperation could not be agreed in the period of the project |
| Croatia | Registry of workers exposed to carcinogens and mutagens | Data provided in excel format |
| Slovakia | Automatic System of Sorting of Risks (ASTR) | Data provided in excel format |
| OMFI (Hungary) | Disease data | Data provided in excel format. Disease data encoded. |

Due to the poor amount of provided data, the contractor decided to include date from public available reports. All data were extracted manually, included in an excel table and inserted to HazChem@Work with help of an automated procedure. Exposure data from following reports were transferred to HazChem@Work:

- Wehde, J., Nitschke,L., Zimmermann, R., Lahrz, T., Wolf, M., Exposition von Beschäftigten gegenüber Lösemitteln bei der industriellen Metallreinigung - Projektbericht. Regierungspräsidium Kassel, 2011, pp. 1-48. Available at: https://www.lgl.bayern.de/arbeitsschutz/stofflicher_arbeitsschutz/projekte_a_z/ir_loesemittel.htm
- DGUV Information 213-715, Verwendung von reaktiven PUR-Schmelzklebstoffen bei der Verarbeitung von Holz, Papier und Leder Empfehlungen Gefährdungsermittlung der Unfallversicherungsträger (EGU) nach der Gefahrstoffverordnung, 2012. Available at: http://publikationen.dguv.de/dguv/pdf/10002/i-790-015.pdf

- BGIA report 8/2006, Quarzexpositionen am Arbeitsplatz, Hauptverband der gewerblichen Berufsgenossenschaften (HVBG). Available at: http://www.dguv.de/ifa/Publikationen/Reports-Download/BGIA-Reports-2005-bis-2006/BGIA-Report-8-2006/index.jsp

### 4.4.1 Results

**Test phase 1:**

- **Polish Central Register of Data on Exposure to Carcinogenic or Mutagenic Substances, Mixtures, Agents or Technological Processes** (database provider NOFER): First contacts started in June 2015 by phone. NOFER expressed its interest and was officially addressed at October 5, 2015. The request was positive and end of October NOFER sent in total 500 data for Benzene, Chromium trioxide, Acrylamide, Nickel sulphate. Transferring the data to the test database worked without problems. Some information is still in Polish. How to deal with different languages has to be further discussed.
- **BAuA measurements:** After an initial test where information was converted to the HazChem@Work data format manually an automated conversion was performed. The database format is Microsoft Access which allowed an easy conversion to the data collection format after the data were exported. Manual work was still needed for translations (e.g. substance name or type of measurement) and identifying correct workplace descriptions. Also, the measurement procedure is not documented explicitly in the database. After discussion with the maintainers the procedure, which is always the same (EN 481) was added to the data collection output. In total, 3069 data were converted.
- **INCDPM** established a register of exposure measurements carried out by the Laboratory for Chemical and Biological Risks. Except for the use of data in the HazChem@Work pilot study, the register is for internal use only. The exposure measurements are made almost exclusively as part of contracts with companies in different sectors that periodically check legal compliance to OELS. Some of the data in the register is confidential. Information in the register is collected in Romanian in a structured way that fits the needs of its owner, and it has never been transformed into a database. On the occasion of the pilot testing the information has been translated and codes were used for sectors and operations.

**Test phase 2:**

Table 8 lists the database providers that sent answers. A reply was received from **IFA** (Institute for Occupational Safety and Health of the German Social Accident Insurance, the operating institute of the MEGA database[15]). In the reply it was stated that IFA could not contribute to the database for data ownership reasons. However, several publications of MEGA data do exist which could be used in the scope of this study. But it has to be noted that all of the exposure data used for the publications are aggregated data. The publications can be accesses at http://www.dguv.de/ifa/gestis/expositionsdatenbank-mega/expositionsdaten-aus-mega-in-publikationen/index-2.jsp. Many of them are available free of charge. Some of them are published in English.

[15] MEGA is an exposure database in Germany: "Measurement data relating to workplace exposure to hazardous substances" (**M**essdaten zur **E**xposition gegenüber **G**efahrstoffen am **A**rbeitsplatz" in German)

The publications are listed on the IFA website by subject:

- General MEGA publications
- Branch-specific MEGA publications
- Data on exposures by substances
- Substance specific MEGA publications on Biological agents

A summary has been written for the MEGA database and can be found in Annex 7.

From **INRS** a reply has been received in September containing publications about COLCHIC from which a summary could be created. However, the contactors got no authorisation to use the data for the scope of the study.

Regarding access to data from **ECHA** it was originally planned to contact ECHA through a joint request from the DGs EMPL, ENVIRONMENT and GROW. After some discussion with DG EMPL it was decided to contact ECHA directly using the original supporting letter. A letter was sent on the 15th of September 2015 and a reply from ECHA was received on the 2nd of October 2015, stating that ECHA was internally discussing the request.

On 21 October 2015 BAuA received a further reply from ECHA with a letter from 16 October 2015 signed by the director Geert Dancet, confirming that it is ECHA's intent to support the project. A teleconference between ECHA, KOOP and BAuA took place on 11 December 2015. It was decided to send data via REACH-IT to BAuA, so that BAuA could check if the data could be used for HazChem@Work. A final decision on ECHA's participation would depend on the specifics of data need and resources available. However, due to the exit of BAuA it was not possible for the contractor to access the ECHA data. The consortium of KOOP and INCDPM does not include anymore a competent authority which would do confidentiality and intellectual property rights assessment for third party publication.

A second teleconference with ECHA took place on 22 June 2016. As a possible way to get access to some of the REACH registration data, ECHA proposed that we could make use of the limited data set that is planned to be disseminated to the public in a separate database in 2017. This data would need to be used according to the terms and conditions and e.g. restricts commercial use by third-parties.

FIOH (Finland) internally discussed intensively the possibility to co-operate and tried to get any national funding to be able to co-operate on HazChem@Work project. They informed us that they didn't manage to get national funding and that it would only be possible to provide data for HazChem@Work if they would be paid for their work.

Discussions with **HSE and HSL** (UK) are still ongoing. The institutes are still considering how best to share information with HazChem@Work. However, following provisions have to be fulfilled before they would be able to provide data:

- Data cannot be disclosed to any person other than employees who need access to undertake work on the database – the 'Purpose' and such employees should be informed of the confidential nature of the Data.
- Reasonable steps should be taken to ensure the reliability of all persons who have access to the Data.
- The Data are not retained for any longer than is necessary for the 'Purpose'.
- Only make copies of the Data to the extent reasonably necessary for the 'Purpose'.
- Do not extract, re-utilise, use, exploit, redistribute, re-disseminate, copy or store the Data other than for the 'Purpose'.

A user management was implemented to comply with the requirements of HSE and HSL. Users have to register before entering the HazChem@Work database. During the test phase the contractor checked the registration data and sent log-in-data only to authorised persons.

An intensive discussion took place with **ECFIA**. A meeting was organised in December 2015, followed by several emails. ECFIA signalised that they are interested in supporting HazChem@Work with CARE[16] data. However, a final decision has not been taken, until now. ECFIA will discuss internally a possible co-operation end of 2016. The discussion so far indicates that a co-operation will not be done free of charge.

Answers were received from the Danish Product Register, State Sanitary Inspection (Poland), The Netherlands Working Condition Survey and the Laboratory of Hygiene and Occupational Diseases of Institute of Occupational Safety and Environmental Health of Riga Stradins Universikty (Latvia). Unfortunately, the data did not fit to the HazChem@Work database.

Cosanta the provider of Stoffenmanager, was interested in a co-operation regarding the development of an exposure model for HazChem@Work. Costs for IT- work as well as platform running costs will arise.

Until now, data were delivered by the following data providers:

- ASTR (Slovakia)
- BAuA-DB (Germany)
- BG Bau – Walzasphalt (Germany)
- Chempyl (Poland)
- Expossm (Romania)
- HU RODEE (Hungary)
- HZZZSR (Croatia)
- NOFER (Poland)

A description of the databases can be found in Annex 19.

It should be noted that the database providers were willing to send data for the testing phase free of charge. This may change for further updates and additional data provision in case the database will go online.

## 4.5 Summary and findings

The aim of WP 3 was to collect exposure information for the database of substances. A template was developed for the collection of data. The template was adjusted several times to meet the requirements of the data providers. It consists of 86 fields grouped in 6 sections:

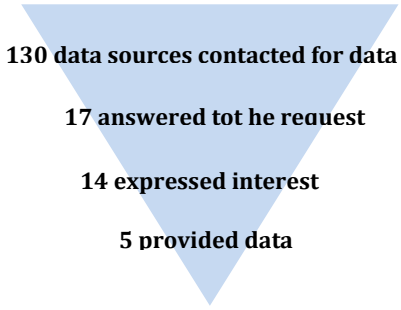
- Data on the chemical substance
- Exposure and contextual data
- Production and use of chemicals (national and EU level)
- Disease data and adverse effects
- Sector and occupation data
- General information

[16] http://www.ecfia.eu/has_care.htm

A preliminary test with three database provider was successfully carried out, the collection template was adopted, the automatic transfer of data worked well.

130 database owners were contacted for the actual test, 17 of which answered. In the end five database owners provided data (Figure 1).

**Figure 1: Pyramid of contribution with data to the test phase of the data base**




Due to the poor number of provided data, exposure data from published reports were included manually to the HazChem@Work database. Currently the database consists of 1397 data from 204 substances as well as of 32 dummy data which were included to be able to show additional functionalities of the database, such as visualistaion of data series.

Following observations were made during the test phase:

- Database owners are very cautious to provide data. Legal constraints based on ownership rights are the main hindrance.
- There is a high variety of data collection in EU Member States: differences exist in the type of data and in the way they are presented.
- Not all data were suitable for HazChem@Work, e.g. the data of the Netherlands Working Conditions Survey are based on self-assessments of workers and not on measurements.
- It is easier to get aggregated data than single data.
- Few of the priority substances were monitored by the participants; providers seem to have more data on other substances.

# 5 Work package 4: Development of a model for estimating prevalence and level of occupational exposures

## 5.1 Aim of the work package

The aim of the work package was to analyse and recommend exposure estimation models and to provide guidance for the database user (refinements):

This task was split into different modules/steps, which include modules for estimating:

- Module 1: Assessment of the total production, export and import (MS and/or EU)
- Module 2: Assessment of the use in sectors (MS and/or EU)
- Module 3: Assessment of the use in chemical products (MS and/or EU)
- Module 4: Assessment of the exposure in certain applications / work places / enterprises /sectors / (MS and/or EU)

- Module 5: Estimation of the number of workers exposed (MS and/or EU)

A modular approach has the advantage that each of the modules can be used independent of each other. In situations where some of the information is available (e.g. on the number of exposed workers) but other is not (e.g. the level of exposure) only that part of the model needs to be used to obtain the missing information.

From ten substances (see table 7) three were selected to demonstrate the strengths and weaknesses of the proposed model.

*Formaldehyde*
A single substance with widespread applications but the major exposures derive from two applications, glue in wood panel and furniture production and disinfectant in the health sector.

*Respiratory Crystalline Silica (RCS, quartz dust)*
Substances process generated, widespread in different industries like foundries and glass production, and particularly in the construction sector.

*Isocyanates*
Widespread open and professional use as reactive component, mainly in specialised crafts but also in industry.

*Wood dust*
Process generated but restricted to forestry and the wood and furniture sector. Already in the nineties a very well known approach was made to calculate exposure populations for wood dust (WOODEX)

*Asbestos*
A group of hazardous minerals, banned in the EU. However, due to increasing renovation work in buildings from periods of high asbestos use probably an emerging risk.

## 5.2 Estimation of the number of workers exposed to specific substances or process generated work place contaminants

The estimation of the number of workers exposed is necessary, since most statistical sources on production and market volumes of chemical substances in the EU (e.g. PRODCOM and national equivalents), and also exposure measurement data sources (see the data sources from the HazChem@Work-survey) do not contain information on the number of employees on a sectoral, national or EU-level. Information on use patterns in means of volume of chemicals is rare. This is one of the most relevant data gaps hampering the estimation of the number of exposed workers.

However, it is plausible to assume some correlation between market volume of substances used in industry and the professional sector and the number of exposed workers. It is also plausible to assume some correlation between the number of welders and the exposure to welding fumes.

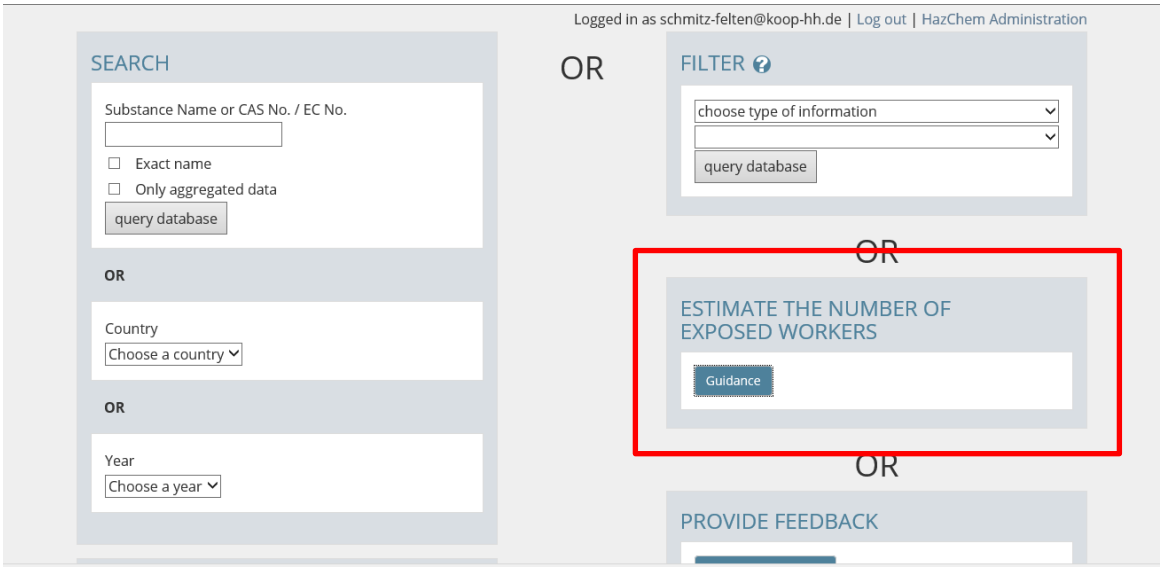
To estimate the number of affected workers it is necessary to assign the use or generation of such substances to specific sectors or occupations. National or EU wide employment statistics can give a first figure of the number of workers in a sector which has then to be refined.

Substance based databases (like the Scandinavian product registers SPIN, KEMI or the Danish Product Registry) can provide figures of exposed workers for several substances. Such national figures can serve as a basis for extrapolation.

REACH registrations from ECHA, particularly those on 'Manufacture, Use and Exposure' [17] might also serve as a basis for estimating the number of exposed workers by analysing the sectors in which uses of a substance are registered. Similarly to the number of exposed workers the use in sectors or chemical products can be extrapolated by proxies like the GDP.

Following the **HazChem@Work methodology** is described in detail. The methodology was formulated as guidance for the database users of HazChem@Work. Figure 2shows a screenshot of the entry page.

**Figure 2**: Screenshot of the entry page to the guidance




The extrapolation methodology consists of five steps, called modules:

- Module 1: Assessment of the total production, export and import (MS and/or EU)
- Module 2: Assessment of the use in sectors (MS and/or EU)
- Module 3: Assessment of the use in chemical products (MS and/or EU)
- Module 4: Assessment of the exposure in certain applications / work places / enterprises /sectors / (MS and/or EU)
- Module 5: Estimation of the number of workers exposed (MS and/or EU)

The final objective of all these five steps is to have the best possible estimate of the number of exposed workers in the EU.

In the overall description of the methodology sometimes formaldehyde is used as example, or to illustrate certain steps. Later, when the modules will be applied to the three selected substances including formaldehyde, some of the observations are repeated.

### 5.2.1 Module 1: Assessment of the total production, export and import (MS and/or EU) and the sector use

The first proxy of interest is the amount of a chemical substance which is produced in the EU or a country (production plus import minus export). This amount is the first clue to an estimate of the uses and 'Exposed worker population'. To identify the total volume produced in the EU,

[17] https://echa.europa.eu/information-on-chemicals/registered-substances/information

HazChem@Work recommends using the following statistical sources and (additionally as further possible sources) specific studies plus international sources.

The EU Database PRODCOM[18] and national equivalents

- The EU Database PRODCOM[19] and national equivalents
- The ECHA registered substance database[20]
- The Nordic Product Register (SPIN)[21]
- Reference documents under the IPPC Directive and the IED (BREFs) [22]
- Data from industry associations
- Market studies (if available)
- Data from international sources as reference ( e.g. from CAREX Canada[23] )

The **PRODCOM** database[24] is provided by EUROSTAT and contains EU-production data of approx. 3,800 products. It includes 200 major chemicals (substances or substance groups) and over 500 typical chemical products (from 'varnish' to 'polishing powder') and a number of products related to chemical production (e.g. plastic doors, cables, electronic parts). However, PRODCOM only provides figures about high volume chemicals or products.. PRODCOM displays per product quantity, weight and value (RU and Member States), import and export.,

The focus on production and manufacturing involves that process generated substances (wood dust, silica) and banned substances without production or import and export activities (asbestos) are not covered by PRODCOM, but substances like formaldehyde and isocyanates.

**National production statistics**

National data can provide additional information and can help confirm and validate European based figures; they can also paint a different picture. An extrapolation from national figures to the European level is only acceptable if there is reason to assume that the production and use patterns are similar throughout Europe. This can be checked by comparing statistics on industrial structure and production output.

Statistical problems to be considered:

a) Even if the quantitative figures are similar (e.g. on the size of the car industry), the chemicals used might vary from country to country.
b) It is clear that one cannot extrapolate specific regional production and consumption figures, e.g. chemicals used to treat Mediterranean fruit or chemicals used in Northern forestry to accelerate the growth of pine trees.

PRODCOM is based on national equivalents that apply the same methodology and submit the national data to EUROSTAT. For example, for Germany these data are provided through the GENESIS database that is run by the National Statistical Office 'destatis' (https://www-genesis.destatis.de/genesis/online/logon). for some thousand products and substances (like in PRODCOM). These are listed in a searchable directory, and are also available as an online tool.

[18] http://epp.eurostat.ec.europa.eu/portal/page/portal/prodcom/data/tables_excel
[19] http://epp.eurostat.ec.europa.eu/portal/page/portal/prodcom/data/tables_excel
[20] **http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances**
[21] http://www.spin2000.info
[22] http://eippcb.jrc.ec.europa.eu/reference/
[23] http://www.carexcanada.ca/en/about/
[24] http://ec.europa.eu/eurostat/web/prodcom/overview
"PRODCOM is a community scheme, based on Regulation of 1991, for producing detailed product output information at the EU level. …"

The **ECHA database** on registered substances provides ranges of production in the EU. The total tonnage by substances (joint registration) is provided in the disseminated information as a tonnage band. The tonnage bands cover a range between the basic value and end value that is in general a factor 10 of the basic value. Such a large range poses also a challenge for a model on exposure population. Like PRODCOM it also does not cover process generated substances. No volume has to be registered for the use of a substance as intermediate.

More detailed information about the volume of chemicals and products containing certain chemicals can be derived from the four **Nordic Product Registers** of Denmark, Finland, Norway and Sweden that are combined in a common database, called **SPIN**[25]. Authorities in these countries use the obligation to register chemicals to provide particular statistics or special evaluations. SPIN covers also –at least partly - silica and asbestos uses.

The **SPIN database** contains information on 27,320 chemicals or substance groups (2016). It provides information on production volume but also quantitative information on major use sectors.[26] The database compiles data from 1999 onwards, and allows an insight into the development of the different uses and their volumes.

**Data from BREF's**

The European IPPC Bureau publishes Best Available Techniques (BAT) reference documents so-called BREFS. This exchange of information between Member States and the industries concerned on Best Available Techniques (BAT) is required by Article 13(1) of the Industrial Emissions Directive (IED, 2010/75/EU). The IED regulates around 50,000 installations in the EU dealing with a wide range of industrial and agricultural activities.

BREF documents are comprehensive descriptions describing currently applied techniques, present emissions and consumption levels. In 2016 in total 31 BREF documents were available, ranging from the cement industry to the production of wooden panels. [27]

**Statistics and data from business associations**

More statistical data can be found on the website of business and industry associations, e.g. on the homepage of the European association of the chemical industry CEFIC.
CEFIC www.cefic.eu: "About CEFIC", members' links to sector specific business associations and "Facts and Figures" links to data.

For many sectors and areas of the chemical industry particular associations exist like the
Association of Petrochemical Producers in Europe APPE
http://www.petrochemistry.net/production-statistics-ethylene-propylene-butadiene.html

European producers of refractory materials
http://www.pre-europe.eu/en/statistics

**Market studies and consultancy**

Specialised consultancies compiled specific studies for most of the markets, be it for single substances or substance groups or chemical products. Many are not free of charge, and the price may even exceed 1,000 €. Here are two examples:
http://www.reportlinker.com/report/search/keywords/toluene
http://www.businessmonitor.com/

[25] www.spin2000.info
[26] SPIN is currently developing a tool for a rough assessment of potential occupational exposure
[27] http://eippcb.jrc.ec.europa.eu/reference/

A typical study is "Europe Toluene Industry Outlook to 2015 – Market Size, Company Share, Price Trends, Capacity Forecasts of All Active and Planned Plants".

**Extrapolations for EU-wide volumes with SPIN as basis**

The easiest way to identify the total production volume is the use of the PRODCOM database. However this approach is limited to a small number of high volume chemicals (200).

For an estimate of the total production volume of many other chemicals it might be the most promising approach to extrapolate SPIN data. One of the major advantages of SPIN is that it contains data on much more chemical substances than PRODCOM. Moreover, it gives sector based volumes of use. In many cases, it is reasonable to estimate the total use volume by extrapolating the SPIN-data to the EU-level.

This requires an extrapolation from the data of three EU Member states to the whole EU. Furthermore, in advance it requires an assessment whether the use patterns in the Nordic countries are similar to Europe

It is possible to apply two options. One can use the contribution of the Nordic countries to the **EU Gross Domestic Production (GDP)**. If we assume that production patterns are different, but consumption patterns very similar in the Nordic countries to Europe, one can use the **share of the population** of the three EU Member States Denmark, Finland and Sweden at the EU population. As a general rule the highly industrialised sectors like car production can be regarded as similar due to international standards and collaboration between countries, whilst other sectors like construction vary significantly depending on the region.

The GDP mirrors the economic strength of a country. The share of the Nordic countries is roughly 8.6 % of the EU Member States Denmark, Finland and Sweden around 6.3 % (see table 9).

**Table 9: GDP 2015 of the Nordic countries (SE, DK, FI) in relation to the EU[28]**

| GDP EU 2015 billion € | SE, DK, FI, NO | SE, DK, FI (EU-MS) | SE | DK | FI | NO |
|---|---|---|---|---|---|---|
| 14702 | 1270 | 922 | 447 | 266 | 209 | 348 |
| 100% | 8.64% | 6.27% | 3.04% | 1.81% | 1.42% | 2.37% |

To estimate the total consumption by extrapolation of the SPIN-data with the GDP-factor would mean to multiply the amount of the total volume of a substance from the SPIN database roughly with the factor 16 (15.9). In the case of formaldehyde this would result in an estimated total production for EU of 707,000 tons. Compared with the PRODCOM figure ((stat PRODCOM EU = 2,865,828 t) this is an underestimation of 75%. The main reason is a low production capacity of formaldehyde in these countries.

[28] GDP Domestic product at market prices
http://ec.europa.eu/eurostat/tgm/refreshTableAction.do?tab=table&plugin=1&pcode=tec00001&language=en

Another method would be to use the number of citizens[29] and to assume that the consumption patterns are similar in the Nordic countries and the EU. As an example: assuming that only one of the Nordic countries produces formaldehyde, but all countries use it in a similar way e.g. for disinfection in hospitals. In this case the number of workers in hospitals is a more appropriate indicator than the production figures.

**Table 10**: **Population of the Nordic countries (SE, DK, FI, NO) in relation to the population in the EU in Mio (EU Member States 2015)** [30]

| POPUL EU 2015 | SE, DK, FI, NO | SE, DK, FI (EU-MS) | SE | DK | FI | NO |
|---|---|---|---|---|---|---|
| 508.3 | 26.1 | 20.9 | 9.7 | 5.7 | 5.5 | 5.2 |
| 100% | 5.13% | 4.11% | 1.91% | 1.12% | 1.08% | 1.02% |

The share of the population of the three EU Member States Denmark, Finland and Sweden is 4.1% (table 10). This would mean that an extrapolation to the EU would require a multiplication with 24.4.

The similarity of consumption patterns is a very vague and doubtful assumption, and a test of this extrapolation with formaldehyde leads to a total estimate of 1,166.000 Mio tons. This is a smaller underestimation than by extrapolation based on the GDP but still not much more than 40% of the use figures from PRODCOM of 2,872,253 t. The reason for this deviation might be huge divergences between the Member States, e.g. some countries export high volumes of formaldehyde (Germany or the Netherlands) to countries outside the four Nordic countries.

### 5.2.2 Module 2: Assessment of the use in sectors and special products

Some production statistics and data bases also provide detailed data on sectors. There are different statistics available. Most useful are:

- The Nordic Product Register (SPIN) and its data on sectoral uses, in particular its report section[31]
- The ECHA list of identified uses
- The KEMI Flow charts
- Data from European industry associations and consultancy studies
- Data from European or national studies or databases
- Data from international sources as additional option to check the reliability. Useful are up-to-date CAREX applications like CAREX Canada, and other studies like the Australian AWES (Australian Work Exposures Study). In some cases other national regulators provided extensive background documents, e.g. US OSHA for Respiratory Crystalline Silica)

### 5.2.3 Module 3: Assessment of the use in chemical products

### 5.2.4 Module 3: Assessment of the use in chemical products

Some substances are mainly used in products, e.g. isocyanates. To assess the amounts of use in principal the same sources as for Module 1 and 2 can be consulted:

[29] Eurostat Yearbook 2011, p126
[30] Eurostat
http://ec.europa.eu/eurostat/tgm/table.do?tab=table&init=1&language=en&pcode=tps00001&plugin=1
[31] See CAS-Reports in the SPIN-database, www.spin2000.info

- SPIN, ECHA, KEMI and PRODCOM data on chemical products.
- Specific Studies and Technology Reports.
- National and sector-specific statistics.

### 5.2.5 Module 4: Assessment of the exposure in certain applications/ work places/ enterprises/ sectors/ (MS and/or EU)

There are different analyses – tools surveys, data compilations and evaluations - available that can be used for the objective of Module 4. In principal there are two assessment models necessary, one to assess the number of exposed workers, and one to assess the level exposure from measurements or proxies.

In 2011 the General Directorate Employment of the EU Commission contracted IOM (Institute of Occupational Medicine) to provide studies on 25 carcinogens using a harmonised methodology. The common title of all studies is "Health, socio-economic and environmental aspects of possible amendments to the EU Directive on the protection of workers from the risks related to exposure to carcinogens and mutagens at work", in short SHEcan studies (table 11). [32] One of the objectives of these studies was to estimate the number of exposed workers.[33] The studies use data from CAREX 99 and combine them with newer sector workforce data (EUROSTAT) and other newer studies and articles. The data are not adapted to the current NACE 2 coding but use the older 1.1. .These studies can be used to triangulate the findings with data from other sources.

**Table 11: Available SHEcan studies**

| Substance | CAS-No. |
|---|---|
| 1,2-dichloroethane | 107-06-2 |
| 1,2-dibromoethane | 106-93-4 |
| 1,2-epoxypropane | 75-56-9 |
| 1-chloro-2,3-epoxypropane | 106-89-8 |
| 2-nitropropoane | 79-46-9 |
| 4,4, methylene bis 2-chloroaniline | 101-14-4 |
| 4,4' methylenedianiline | 101-77-9 |
| Benzo-a-pyrene | 50-32-8 |
| Beryllium and compounds | 7440-41-7 (beryllium only) |
| Bromoethylene | 593-60-2 |
| Ethylene oxide | 75-21-8 |
| Hexachlorobenzene | 118-74-1 |
| Hydrazine | 302-01-2 |
| o-toluidine | 95-53-4 |
| Refractory ceramic fibres | - |
| Trichloroethylene | 79-01-6 |

[32] Health, socio-economic and environmental aspects of possible amendments to the EU Directive on the protection of workers from the risks related to exposure to carcinogens and mutagens at work", Executive summary Report, Cherrie et al, Dec 2011

[33] All studies are available under: *ec.europa.eu/social/*

| | |
|---|---|
| Acrylamide | 79-06-1 |
| Chromium VI | - |
| 1,3-butadiene | 106-99-0 |
| Vinyl chloride | 75-01-4 |
| Diesel exhaust emissions | - |
| Respirable crystalline silica | - |
| Rubber process dust and fume | - |
| Mineral oils - as used engine oil | - |
| Hardwood dust | - |

**International sources: CAREX Canada and Australian Work Exposures Study**

**CAREX Canada** is a national surveillance project that estimates the number of Canadians exposed to substances associated with cancer in workplace and the environment. CAREX Canada builds on the CAREX project developed by the Finnish Institute of Occupational health in the early nineties. [34]

To date, CAREX Canada provides data and estimates on the following topics:

- *Identify what carcinogens people are exposed*
- *Locate where people are exposed*
- *Calculate how many people are exposed*
- *Estimate how much of a carcinogen people are exposed to (where data exist to calculate levels)*

Compared to the EU CAREX (last data from 2007, most data from before 2000) the Canadian version is up-to-date and run as a permanent project.

In 2011-2012, the **Australian Work Exposures Study (AWES)** developed a web-based approach to collecting data on exposure to carcinogens among Australian workers. The AWES is a cross-sectional computer-assisted telephone survey investigating the prevalence of occupational exposure to 38 known or probable carcinogens among Australian workers. In an attempt to overcome limitations of current approaches, e.g. self-reporting in large-scale worker surveys or 'job exposure matrices', a special workers' survey incorporating expert assessment has been developed. A specific strength is the standardised expert assessment achieved through an automated assessment method (OccIDEAS). [35]

[34] http://www.ttl.fi/en/chemical_safety/carex/countries/pages/default.aspx

[35] Carey RN, Driscoll TR, Peters S, Glass DC, Reid A, Benke G, Fritschi L. Estimated prevalence of exposure to occupational carcinogens in Australia (2011-2012), *Occup Environ Med*. 2014;71:55-62. Available at http://oem.bmj.com/content/71/1/55.full

Carey RN, Glass DC, Peters S, Reid A, Benke G, Driscoll TR, Fritschi L. Occupational exposure to solar radiation in Australia: who is exposed and what protection do they use? *Aust N Z J Public Health*. 2014;38:54-9.

Driscoll TR, Carey RN, Peters S, Glass DC, Benke G, Reid A, Fritschi L. The Australian Work Exposures Study: Prevalence of Occupational Exposure to Formaldehyde, *Ann. Occup. Hyg.* 2016, Vol. 60, No. 1, 132–138.

SafeWork Australia, The Australian Work Exposures Study (AWES): Carcinogen exposures in the construction industry. 2016. Report. Available at:
http://www.safeworkaustralia.gov.au/sites/SWA/about/Publications/Documents/964/AWES%20-%20Carcinogen%20exposures%20in%20the%20construction%20industry.pdf

#### 5.2.5.1 Selection of a suitable model for estimating exposure

Estimating levels of exposure by modelling is very complex. Mechanistic-mathematical models require both, information of substance specific properties and detailed specifics information on the workplace situation which is usually not available or not given in such detail to allow mathematical modelling. Another approach which is used by some models is a categorisation approach. A model using this approach is created by grouping available data into categories with similar exposure conditions.

Several models exist which facilitate estimates of exposure levels with more or less generic input parameters. Examples include the ECETOC TRA[36] model or the Stoffenmanager[37] which can be used to fill existing data gaps in the database. Thus, where a data gap exists and cannot be filled with analogous data, one or more of these existing models will be used for estimation of exposure levels of these exposure situations.

In the first interim report the requirements for an exposure estimation model were discussed. The main points for consideration were:

1. Most of the existing exposure models that are deemed suitable for the purpose of filling gaps in the database are intended to be Tier 1 exposure models. This means that one of the goals in their development is to give conservative estimates, i.e. their estimates tend to err on the side of caution/overestimation. As the final database should reflect the actual situation in European workplaces the selected model should not overestimate the exposure too much.
2. When coding the parameter values for the database not all parameters for all exposure situations will be known exactly, especially for very detailed parameters. This must be reflected as an uncertainty of the estimate. For that uncertainty to be as small as possible, robustness against parameter variations should be preferred.
3. As mentioned in the previous point, too many unknown parameters will lessen the accuracy of the estimate within HazChem@Work. Thus, a model should not have too many specific parameters which rely on an in-depth knowledge of the workplace at hand.
4. If possible, the model should output an exposure range (or, if possible, a distribution of the exposure). This would allow to present information as minimum/average/maximum exposure instead of a single value.

At the workshop discussion it was recommended to aim for a realistic worst case instead of realistic case. This should ease the use of the database for prioritization of substances. In general, such an approach will facilitate the use of existing exposure models for HazChem@Work as they aim to be conservative.

An additional requirement is the applicability of the exposure assessment model. The larger the scope of the model, the more scenarios it can be used for in the context of HazChem@Work.

**Description of candidate exposure assessment models**

The following three exposure models are considered as suitable candidates with respect to the above-mentioned criteria: ECETOC TRA v3 (worker exposure module), EMKG-Expo-Tool and the Stoffenmanager.

[36] http://www.ecetoc.org/tra

[37] https://stoffenmanager.nl/

The reason for selecting these models is that each of them aims at a general scope of exposure scenarios (unlike e.g. MEASE[38], which limits its scope to handling exposure scenarios specific to handling of metals). Also, each of them are considered Tier 1 exposure models reducing the number of detail needed to be known for coding exposure scenarios.

Additionally, the three models have been recently evaluated by the ETEAM[39] project. One step of the evaluation was a comparison with measurement data yielding information about the degree of conservatism of the respective model: If the exposure estimation of the model for a measurement exceeds (overestimates) the measurement result the model is deemed conservative for that situation. For a large number of measurements this allows general statements about the degree of conservatism a model employs. Also, the correlation coefficient between the model estimate and measurement data was calculated in the ETEAM project. For this project, this information can be combined to evaluate whether a model delivers a realistic worst case: A suitable model for HazChem@Work should rather over- than underestimate the exposure (worst case) and also have a high correlation coefficient with actual data (realistic).

For each of these models a short description and an evaluation on their suitability for the HazChem@Work study are given.

**ECETOC TRA v3**

ECETOC TRA (targeted risk assessment) v3 is an integrated set of tier 1 models developed for the REACH registration process. Besides a tool for estimating worker exposure also tools for consumer and environmental exposure exist but are not relevant for this study.

A key feature of ECETOC TRA v3 is that the implemented input parameters correspond to the REACH use descriptor system such as the process categories (PROCs) as an input variable for determining the tasks linked to an exposure situation. ECETOC TRA v3 is applicable for volatile liquids and solids but some other exposure types are out of the scope of ECETOC TRA v3. For example, it is not intended to be used for estimation of exposure to liquid aerosols, fibres or process generated substances like fumes. It is also stated, that caution should be exercised when applying ECETOC TRA v3 to substances with CMR properties.

The TRA exposure estimates are based on a categorization approach. Each set of PROCs is categorized according to a fugacity class (high, medium or low). An initial exposure estimate is assigned to each of these sets which is originally based on the EASE model (which itself is based on actual workplace exposure measurements (historical data from UK)). Other input parameters include physical/chemical properties (like fugacity/dustiness and aggregate state of the substance), the concentration of the substance if used in mixtures, duration of task and optional risk management measures applied. The output value is intended to reflect the 75$^{th}$ percentile of the eight hour exposure value.[40]

**EMKG-Expo-Tool**

The aim of the EMKG-Expo-Tool is to be an easy-to-use tool for estimating occupational exposure especially for small and medium sized companies. The EMKG-Expo-Tool – as ECETOC TRA – categorizes its input parameters to assess the inhalation exposure at the workplace. Most input parameters are not specified directly but rather assigned to a range, called “band”. Input param-

[38] http://www.ebrc.de/industrial-chemicals-reach/projects-and-references/mease.php
[39] Evaluation of Tier 1 Exposure Assessment Models under REACH

[40] ECETOC, T., version 3: Background and Rationale for the Improvements. 2012, Technical Report

eters are the amount of the substance used, the fugacity or dustiness of the substance and the level of control (based on detailed control guidance sheets). Two additional parameters, which are only used in very specific cases, are the surface area for application of liquids on surfaces and the duration of exposure, if it is very short.

The level of control is, depending on the exposure situation at hand, specified by control guidance sheets which exist for general task and control measures (e.g. general ventilation) but also more specific tasks like surface coating or dust workplaces.

The tool is applicable to solid and liquid substances. Out of scope are gases, abrasive techniques, open spraying, wood dust, pesticides and fumes. It is also not applicable to substance with CMR properties. The output of the tool is an exposure range scoping an order of magnitude of possible exposures (e.g. 0.01 – 0.1 ppm or 5 – 50 mg/m$^3$).

**Stoffenmanager**

Stoffenmanager has similar aims to the EMKG-Expo-Tool in providing small and medium sized companies an easy to use tool for exposure estimation. It is available for free on the Stoffenmanager website (www.stoffenmanager.nl).

Other than the other two models described so far, Stoffenmanager is based on a mechanistic model for estimating exposure. The exposure score for an exposure situation is based on the emission potential for a substance (determined by e.g. the volatility), type and frequency of handling the substance and the level of control. Each input parameter has an assigned score on a logarithmic scale, depending on the exposure situation. These scores are multiplied to obtain a final score for that task. These scores were correlated against actual exposure data thus obtaining a calibration function which allows computing a range for the exposure estimates for each score. Additional parameters include the possibility of further exposure by far-field sources (e.g. more workers carrying out the same task in the room) or background sources of emission.

Stoffenmanager can be used to assess workplace exposures to liquid and solid substances. It is not applicable for fibres, gases and hot working techniques. It is notable that the Stoffenmanager is the only considered tool applicable to liquid aerosols.

The output of Stoffenmanager is a whole exposure distribution which allows the selection of each percentile.[41]

**Evaluation**

All three tools have a comparable scope of applicability. A notable exception is the exclusion of CMR substances and spraying techniques from the EMKG-Expo-Tool. As the scoring system (mentioned in chapter 3) assigns high scores to CMR substances this limits the usability of the EMKG-Expo-Tool for this study. Similarly the fact that caution needs to be applied for ECETOC TRA v3 when applying it to CMR substances needs to be considered, however this is not deemed as severe as the situation for the EMKG-Expo-Tool as ECETOC TRA v3 is still applicable for these kinds of scenarios.

For the project it is also very important that the input parameters of the model can be provided by the HazChem@Work project. This is easily applicable for substance-based parameters like the volatility or the dustiness but more complicated for parameters which depend on the actual task performed of the worker or the level of control. To integrate a model to HazChem@Work

[41] https://stoffenmanager.nl/

database these parameters will need to be connected with the database task description, work place categorisations and control levels (see Annex 10) in order to find corresponding values.

**Table 12: Overview of the parameters of the EMKG-Expo-Tool and their database integration prospects.**

| Parameter | Type | Database integration |
|---|---|---|
| Physical state | Property of substance | Direct |
| Volatility/Dustiness | Property of substance | Direct |
| Scale of use | Depending on Task/Workplace | Via database correspondences* |
| Control Approach | Depending on Task/Workplace | Via database correspondences |
| Application on large surfaces | Depending on Task/Workplace | Via database correspondences |
| Short-term exposure | Depending on Task/Workplace | Via database correspondences |

**Table 13: Overview of the parameters of ECETOC TRA v3 and their database integration prospects**

| Parameter | Type | Database integration |
|---|---|---|
| Physical state | Property of substance | Direct |
| Volatility/Dustiness | Property of substance | Direct |
| Process category | Depending on Task/Workplace | Via database correspondences |
| Type of setting (industrial/professional) | Depending on Task/Workplace | Via database correspondences |
| Content in preparation | Depending on Task/Workplace | Via database correspondences* |
| Use of ventilation | Depending on Task/Workplace | Via database correspondences |
| Respiratory protective equipment | Depending on Task/Workplace | Via database correspondences |
| Duration of the activity | Depending on Task/Workplace | Via database correspondences |

**Table 14: Overview of the parameters of the Stoffenmanager and their database integration prospects**

| Parameter | Type | Database integration |
|---|---|---|
| Physical state | Property of substance | Direct |
| Volatility/Dustiness | Property of substance | Direct |
| Content in preparation | Depending on Task/Workplace | Via database correspondences* |
| Task description | Depending on | Via database correspondences |

| | | |
|---|---|---|
| | Task/Workplace | |
| Available control measures | Depending on Task/Workplace | Via database correspondences |
| Distance of worker from source | Depending on Task/Workplace | Via database correspondences* |
| Is the task followed by period of evaporation, drying or curing? | Depending on Task/Workplace | Via database correspondences* |
| Is there more than one worker carrying out the same task simultaneously? | Depending on Task/Workplace | Via database correspondences |
| Room size | Depending on Task/Workplace | Via database correspondences* |
| General ventilation | Depending on Task/Workplace | Via database correspondences |
| Is there daily cleaning of machines and equipment? | Depending on Task/Workplace | Via database correspondences* |
| Is there regular inspections and maintenance of machines and equipment? | Depending on Task/Workplace | Via database correspondences* |
| Respiratory protective equipment | Depending on Task/Workplace | Via database correspondences |
| Duration of the task | Depending on Task/Workplace | Via database correspondences* |

Table 12 to table 14 show the parameters for each of the three models and an assessment of their database integration prospects. Parameters marked with a * do not have an existing field in the current database format, and additional input may be needed to find suitable values for them. The EMKG-Expo-Tool has with six parameters the fewest input parameters among the considered exposure assessment tools. ECETOC TRA v3 employs eight and the Stoffenmanager 14 parameters. All three models have two parameters which can be fed into the database directly as they are substance inherent properties. For the EMKG-Expo-Tool the least and for the Stoffenmanager the most information about the workplace is needed.

For filling data gaps and easy integration into the database, an output value similar to an exposure measurement (e.g. output of a level of exposure contrary to a large band) is preferable. This is fulfilled by the ECETOC TRA v3 tool as described above. Contrary, the control bands of the EMKG-Expo-Tool only allow a coarse estimation of exposure. Depending on the final level of detail of the database that estimation may prove to be too broad. Stoffenmanager's output of a whole exposure distribution allows to easily calculating more than a single value (e.g. presenting minimum/maximum values and/or average values). Thus – even though outputting a larger area of possible exposure – Stoffenmanager allows a presentation of results similar to one of multiple measurements combined which is deemed suitable for this project.

Based on the ETEAM study[42], Stoffenmanager shows the highest correlation between the tool estimates and measurement results, independent on the type of the substance evaluated (vola-

[42] Lamb, J., et al., Evaluation of Tier 1 Exposure Assessment Models under REACH (eteam) Project: Substudy Report on External Validation Exercise. 2015

tile liquids, non-volatile liquids, metal abrasion, metal processing and powder handling. Not all tools were applicable for all scenarios). In general, all three tools show decent correlations for powder handling (69-83 %) while the EMKG-Expo-Tool (28 %) and ECETOC TRA v3 (34 %) show a much lower correlation in case of volatile liquids than Stoffenmanager (55 %)[43].

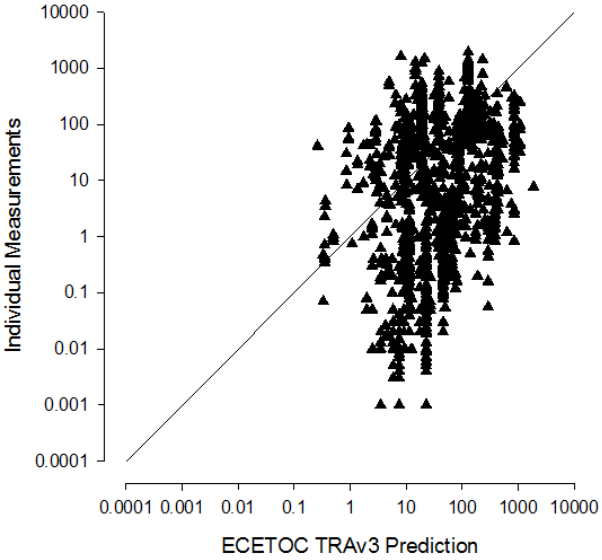



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**Figure 3: Comparison of the volatile liquids measurement data and the tool predictions for ECETOC TRA v3 based from the ETEAM study.**

The degree of conservatism of the models yields the following results: For volatile liquids, the EMKG-Expo-Tool shows the highest degree of conservatism with only 5 % of the measurements exceeding the model estimate. For ECETOC TRA v3 the value is 32 % while for Stoffenmanager (depending on the percentile) it is 19 % (75$^{th}$) respectively 11 % (90$^{th}$) of the measurements. Figure 3 to figure 5 display the measurement data and tool predictions found in the ETEAM project for volatile liquids.

[43] Only the results of individual measurement points are presented here. In the same study, also aggregated data were evaluated. The overall picture stays the same, but the correlation coefficients are, in general, lower for the aggregated data.

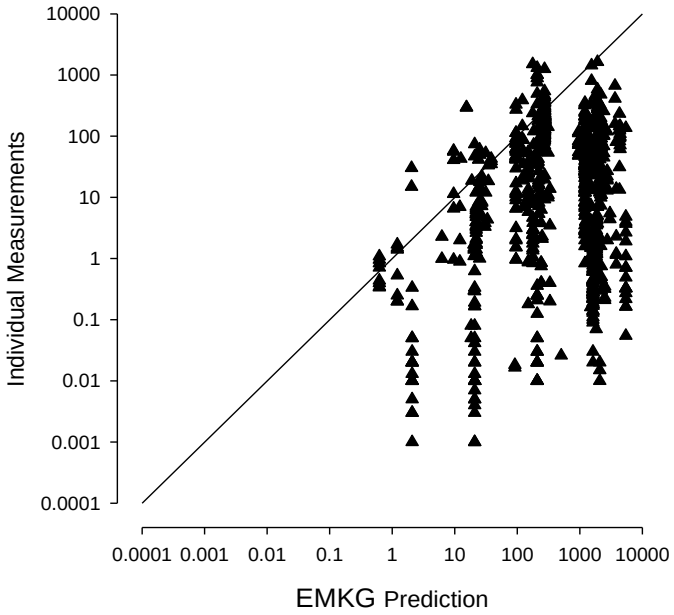



**Figure 4: Comparison of the volatile liquids measurement data and the tool predictions for the EMKG-Expo-Tool based from the ETEAM study.**

When evaluating powder handling, Stoffenmanager shows the highest degree of conservatism. 8 % (75th percentile) respectively 3 % (90th percentile) of the model estimates are not sufficiently conservative. EMKG-Expo-Tool underestimates 17 % of the measurement while ECETOC TRA v3 does so for 21 % of them.

Stoffenmanager and the EMKG-Expo-Tool both show decent values regarding the degree of conservatism, with ECETOC TRA v3 performing slightly worse for powder handling scenarios and moderately worse for handling of volatile liquids scenarios.

Being the best model in correlation coefficients and also being sufficiently conservative for more than 80% of scenarios (75th percentile) scenarios, Stoffenmanager seems to fulfil the requirement of a realistic worst case the best.

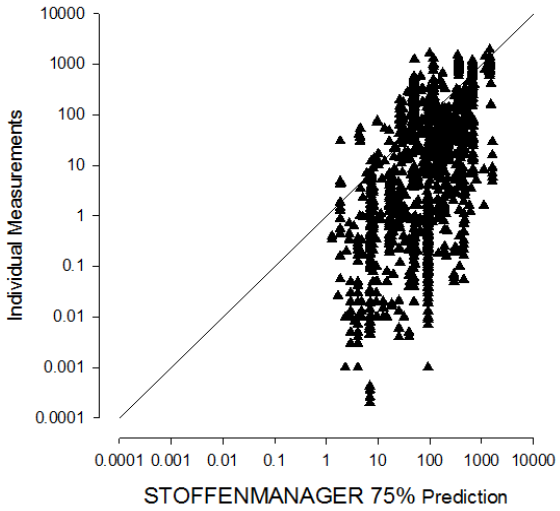



**Figure 5: Comparison of the volatile liquids measurement data and the tool predictions the Stoffenmanager based from the ETEAM study.**

Based on this evaluation described above, Stoffenmanager fulfils most of the requirements of HazChem@Work the most but ECETOC TRA v3 could also be used, while EMKG model is less suited.

### 5.2.6 Module 5: Estimation of the number of workers exposed (MS and/or EU)

Basically this module includes four objectives. It is necessary to assess / define

- the sectors with exposures,
- the number of workers in these sectors
- the percentage of exposed workers in these sectors
- the exposure levels for these workers

This requires to use expert knowledge on sectors, to analyse the available substance specific literature and statistics on exposures, also from international sources.

The available literature and statistics are highly substance specific. For some substances the use and exposure is clear and limited, for others very broad uses make this estimate a difficult exercise. For some substances extensive measurement and exposure reports are available, for others only a few such reports can be found.

We recommend to compare the estimated numbers for Europe with international source, particularly CAREX Canada and AWES Australia.

This is the most difficult MODULE, because statistics on labour force and employment issues are designed with different purposes in mind. A European statistic on work place exposures does not exist, only some survey data are available. These surveys may contain general questions on chemical exposure (EWCS[44], BIBB/BAuA[45]), but they never go beyond or in detail, e.g. asking about specific substances.

[44] http://www.eurofound.europa.eu/surveys/european-working-conditions-surveys
[45] http://www.baua.de/de/Informationen-fuer-die-Praxis/Statistiken/Arbeitsbedingungen/Erwerbstaetigenbefragung-2011-2012.html

**Module 5.1: Database or studies**

There are only a few studies which calculate the number of exposed workers, based on measurements and further calculations. Examples of such databases or studies are limited, and most of them are related to carcinogens or asbestos.

CMR inventory in France, 2005
http://www.inrs.fr/accueil/produits/mediatheque/doc/publications.html?refINRS=PR%2026

Asbestos Survey 21975-2005, UK, 2009
http://www.hse.gov.uk/research/rrpdf/rr730.pdf

Permanente surveillance of asbestos exposed persons, DE, since 1987
http://www.odin-info.de/ ODIN

**Module 5.2: Make use of proxies**

Use a number of proxies, especially the statistics based on NACE-codes for industry, ISCO-codes for occupations and LFS Data for employed workers.

**Module 5.2 a: NACE – sector specific employment** (NACE = Nomenclature statistique des activités économiques dans la Communauté européenne)

Eurostat offers an overview of the number of employees in NACE classes (Four digit level). If a substance is mainly used in clearly defined NACE classes, the calculation of employees in these NACE classes is perhaps the most precise approach. NACE counts all employees, but it does not differentiate between blue-collar and white-collar workers.

**Module 5.2 b: ISCO – International Standard Classification of Occupations**

The ILO ISCO-database contains information on occupations. The current 2008 version contains over 600 categories with approx. 500 different occupations.

ISCO is the most precise and most reliable proxy when a job is closely related to substance exposure. However, some occupations (e.g. fitters) are spread over so many sectors that a specific exposure to a substance cannot be attributed. Other occupations indicate high probability exposure to certain substances, e.g. carpenters and wood dust exposure. The choice of ISCO as proxy depends on the substance in question.

**Module 5.2 c: Apply for detailed data at the Labour Force Statistics Database of Eurostat (LFS)**

If the data on employment in a sector is not sufficiently detailed, apply for a micro study at LFS (see the application form in Annex 1 of this guidance). The template and application form can be downloaded here: http://epp.eurostat.ec.europa.eu/portal/page/portal/microdata/lfs

**Module 5.3: Use national labour statistics**

Some national statistics provide more detailed insights, e.g. the German IAB-statistics (‚Berufe im Spiegel der Statistik', Institut für Arbeitsmarkt und Berufsforschung). (http://bisds.infosys.iab.de/bisds/faces/Start.jsp?mainForm:tProfessionTree:AB0:AB0_link_submittedLink=mainForm:tProfessionTree:AB0:AB0_link) These statistics provide the number of qualified employees for an occupation, the number of unemployed, the development in the last decade, the sector and other demographic data (age, sex, nationality, etc).

To extrapolate the data from to Europe, it must be remembered that, in most cases, industrial sectors in Germany have a higher share of the national economy than in most European Member

States. However, this also differs from sector to sector, e.g. the pulp and paper industry has a larger share in Nordic economies than in Germany.

**Module 5.4: Use company information**

Another option is to check enterprise data and reports to find information about the numbers working in areas of production, etc. The annual reports of large enterprises sometimes provide such data.

## 5.3 Summary and findings

The aim of WP 4 was to analyse and recommend exposure assessment tools and to prepare a model to guide the user through the estimation of the number of exposed workers.

A generic guidance to quantify the workers exposed to hazardous substances in Europe was developed and integrated in the HazChem@Work database. The guidance is based on five modules:

Module 1: Assessment of the total production, export and import

Module 2: Assessment of the use in sectors

Module 3: Assessment of the use in chemical products

Module 4: Assessment of the exposure in certain applications/ workplaces/sectors

Module 5: Estimation of the number of workers exposed

Several exposure assessment tools (Stoffenmanager, EMKG, ECETOc TRA v3) were analysed in view of usefulness for HazChem@Work. A useful tool for HazChem@Work should

- reflect the actual situation at workplaces and not overestimate the exposure too much
- be robust against parameter variations
- not need too many specific parameters which rely on in-depth knowledge of the workplace
- present the results as an exposure range
- aim for a realistic worst case instead of a realistic case.

All three assessment tools have a comparable scope of applicability, except for CMR substances and spraying techniques from the EMKG tool. Stoffenmanager fulfils most of the requirements of a useful tool for HazChem@Work. However, for Stoffenmanager the most information about the workplace is needed.

As there is no standard approach possible an estimation should be made cases by case. It is not possible to apply one extrapolation method to different substances. Therefore three examples (formaldehyde, respiratory crystalline silica, acrylamides) are provided to support users who are tasked with quantifying worker populations exposed to hazardous substances in Europe.

## 5.4 Example: Formaldehyde

### 5.4.1 Module 1: Total Production, Export and Import

Based on a synopsis of different data sources (PRODCOM, SPIN, ECHA, BREF, FORMACARE) an estimate of the EU-wide total production of a little less than 3 mio tons of formaldehyde is very realistic and reasonable. When taking ex- and imports into account this figure does not change significantly.

**Table 15: Formaldehyde volume from different sources, including SPIN Data from Nordic countries**

| Source | Formaldehyde | SE, DK, FI (EU-Member States) | SE | DK | FI | NO |
|---|---|---|---|---|---|---|
| | t | t | t | t | t | t |
| **PRODCOM (2014)** | **2,865,828** | | Confid. | Estimated | 40,786 | Confid |
| **SPIN (2013)** | | 53,260 | 6,285 | 13,665 | 33,310 | 32,799 |
| **ECHA** | **>1,000,000 < 10,000,000** | | | | | |
| **BREF** | **No data in draft on LVOC 2016**[46] | | | | | |
| **FORMACARE (2009)** | **3,600,000 t capacity**[47] | | | | | |

### 5.4.2 Module 2: Use in Sectors - Formaldehyde

The most detailed usage data can be derived from SPIN. Using the NACE code, SPIN provides the following sector-related data (table 16):

**Table 16: Use of formaldehyde –Report SPIN 2011**

| Use data divided on industrial code (2011) | SE, DK, FI, NO | SE | DK | FI | NO |
|---|---|---|---|---|---|
| **NACE** | tonnes | tonnes | tonnes | tonnes | Tonnes |
| C20 Manufacture of chem. and chem. prod. | 100,210 | 3,355 | 25,382 | 33,100 | 38,373 |
| C16 Man of wood and prod. of wood | 76,467 | 3,871 | 14,249 | 28,541 | 29,806 |
| C23 Man of other non-metallic mineral products | 2,167 | 401 | 0 | 1.714 | 52 |
| A01 Crop and animal prod. | 930 | 224 | 8 | 0 | 698 |
| B06 Extraction of crude petrol and natural gas | 302 | 0 | 0 | 0 | 302 |
| **Top 5 total** | **180,076** | **7,851** | **39,639** | **63,355** | **69,231** |

[46] Best Available Techniques (BAT) Reference Document in the Large Volume Organic Chemical Industry Industrial Emissions Directive 2010/75/EU (Integrated Pollution Prevention and Control) JOINT RESEARCH CENTRE Institute for Prospective Technological Studies Sustainable Production and Consumption

[47] Formacare: http://www.formacare.org/about-formaldehyde/eu-market/

The total usage in the top five sectors amounts to 180,000 tonnes, whilst the total volume is reported to be 76,500 tonnes. The explanation is that the amount of formaldehyde is counted more than once; first during production in the chemical sector, and then in manufacturing sectors.

This demonstrates a relevant advantage of use statistics when the objective is to estimate the number of exposed workers. A double or triple use in the supply chain, from manufacturer via formulator to user and finally perhaps recycler can lead to four times more exposures than the production figures indicate.

For the assessment of the number of exposed workers, it is clearly more useful to count the sector production volume by using the SPIN database.

**ECHA list of uses**

ECHA provides a huge amount of identified uses - for formaldehyde there are over 40.[48] The main drawback of the ECHA data is that no volume is given for a specific use. If the volumes per use could be specified, this would be a huge step towards better assessment of exposure patterns.

Moreover, ECHA provides a brief profile with general information about uses:

*This substance is used in the following areas: formulation of mixtures and/or re-packaging and building & construction work. This substance is used for the manufacture of: chemicals, plastic products, textile, leather or fur, pulp, paper and paper products, mineral products (e.g. plasters, cement) and rubber products.* https://echa.europa.eu/registration-dossier/-/registered-dossier/

**The KEMI-flow charts**

The KEMI-flow charts present Nordic register data in a different way (as flow charts) but only for Sweden. They provide an overview of approx. 1000 chemicals used in Sweden. These descriptions provide easily accessible information regarding the uses of the substances.

*KEMI FLOW CHART – DESCRIPTION FORMALDEHYDE*[49]
*Formaldehyde in its pure form is used as a preservative and disinfectant. Substances capable of emitting formaldehyde (hexamethylentetramine, for example) are also used as preservatives. Formaldehyde has a corrosion-inhibiting effect and is therefore used in metal industry. In photography it is used as a hardener in the emulsion layer of film and also as a stabiliser in stabilising baths for pigment etc in the photosensitive emulsion layer.*
*Large quantities of formaldehyde are used as raw material for synthesis. The largest quantities go on production of polymers together with urea or melamine. Urea-formaldehyde polymers are mainly used as binders in the production of chipboard and suchlike products, while melamine-formaldehyde polymers are mainly used as binders in the production of laminates, varnishes, etc. Phenol-formaldehyde polymers are used for similar purposes and for moulding compounds. Urea-formaldehyde resins are also used for crease-resistant finishing of textiles. Low concentrations of formaldehyde can be retained by the products as residual monomers.*
*Plastics of urea-formaldehyde polymer or melamine-formaldehyde are included among the amino-plastics, which are widely used in many fields. Phenol-formaldehyde plastic, for example, is used when the plastic material needs to be heat-resistant. The acetal plastic oxymethylene plastic is also made from formaldehyde. This plastic is used as a material for various structural and machine parts.*
*Formaldehyde is used for synthesising polyols such as pentaerythritol and trimethylolpropane, which are used in the manufacture of polyurethane plastic and alkydes.*

[48] http://apps.echa.europa.eu/registered/data/dossiers/DISS-9daa7594-c409-0ed0-e044-00144f67d249/AGGR-ca2e6917-1e53-49b2-8b28-535ec5333a8d_DISS-9daa7594-c409-0ed0-e044-00144f67d249.html#section_3_5
[49] http://www.kemi.se/en/Content/Statistics/Flow-analyses-of-chemical-substances/

*The complex ones EDTA and NTA are synthesised from hydroxyacetonitrile (formaldehyde cyanohydrine) and ethenediamine and ammonia respectively. Hydroxyacetonitrile is produced from formaldehyde and hydrogen cyanide (prussic acid).*
*Within the EU about 3,000,000 tonnes of formaldehyde was produced in 2007. World production was about 21,000,000 tonnes in 2006.*

Sweden has exceptionally low consumption of formaldehyde, compared to the three other Nordic countries. This makes the KEMI Flow charts in this case of formaldehyde useless. However, in many other cases the flow charts provide relevant information on volumes used in sectors.

### 5.4.3 Module 3: Use in chemical products - Formaldehyde

According to CEFIC:

- A huge variety of resins from the reaction of formaldehyde with phenol, urea, melamine, furfuryl alcohol or resorcinol. Resin products are used as adhesives, bonding agents, glues, paints, coatings, insulators and sealants.
- Formaldehyde is one of the feedstocks in the production of MDI (methyl diisocyanate) used to produce polyurethanes (for foams, synthetic leather, and engineering plastics).
- Polyoxymethylene is a 100 % formaldehyde polymer used as an engineering plastic (e.g. for ski bindings, toothed wheels, kitchen articles).
- Water-soluble paints and coatings use formaldehyde polyols.
- Hydraulic fluids and lubricants based on polyol-esters are used in the aircraft industry.
- Pharmaceuticals, food and feed use formaldehyde intermediates (e.g. provitamin B3).
- Chelating agents that are used in agricultural products, detergents, soaps, cleaners, food industry, mining industry, metal plating, pulp and paper, and textiles

**Industry associations**

Industry associations and consultancies also provide aggregated data and analyses on chemicals and their uses. There exists extensive literature, e.g. for formaldehyde the data from Formacare[50] and the 'Global insight' report.[51]

Figure 6 is provided by the business association Formacare It is a different way to approach the quantity of used formaldehyde in different products.

[50] http://www.formacare.org/applications/
[51] Global Insight (2007): Socio-Economic Benefits of Formaldehyde to the European Union (EU 25) and Norway, Lexington

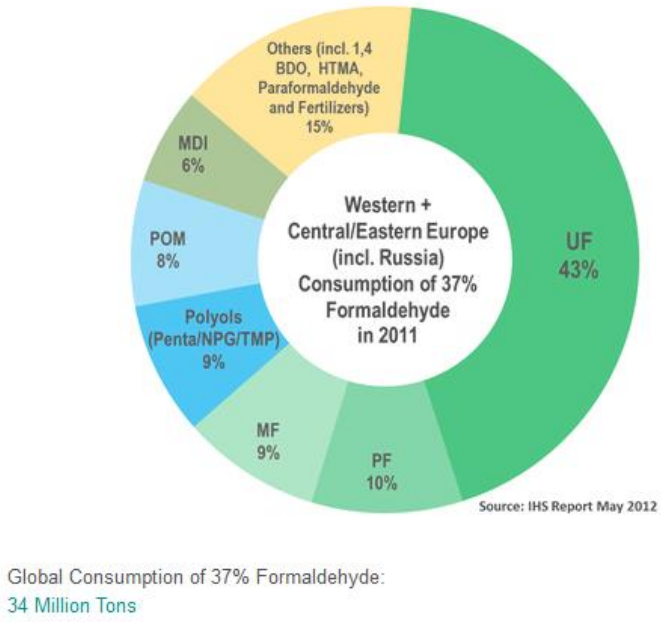



**Figure 6: Formacare data on demand and uses of formaldehyde (Screenshot)**

The SPIN database also provides figures on usage in products. This might be useful if chemical products are a source of exposure, e.g. volatile or dusty products.

The usage of formaldehyde differs quite significantly in the four Nordic countries.[52] The reasons are unclear and would require a request to the provider of SPIN.

**Table 17: Use of formaldehyde – CAS Report SPIN - Nace codes**

| **Use data divided on Product category** | **SE, DK, FI, NO** | **SE** | **DK** | **FI** | **NO** |
|---|---|---|---|---|---|
| | tonnes | tonnes | tonnes | tonnes | tonnes |
| 39 Non agricultural pesticides and preservatives | 66,855 | 256 | 485 | 66,114 | 0 |
| 33 Intermediates | 59,172 | 0 | 25,868 | 0 | 33,304 |
| 02 Adhesives | 27,829 | 485 | 91 | 27,148 | 105 |
| 43 Process regulators | 5,330 | 5 | 0 | 0 | 5,325 |
| 55 Others | 3,349 | 3,340 | 0 | 9 | 0 |
| **Top 5 total** | **162,535** | **4,086** | **26,444** | **93,271** | **38,734** |

This data is confirmed by a publication on dangerous substances by the Danish National Labour Inspectorate,[53] which stated that approx. 25,000 tonnes of formaldehyde are used in 194 chemical products.

[52] There seem to be some statistical data collection divergences. E.g., it is unreasonable that only Finland uses more than 66,000 tonnes of formaldehyde in agricultural pesticides and preservatives, but the other three countries less than 500 tonnes (or even 0 tonnes as in Norway). The same large divergence can be seen for adhesives and intermediates.

### 5.4.4 Module 4 : Exposure in certain applications and exposure levels - Formaldehyde

The best way to assess the exposure is to have comprehensive information from a significant amount of measurement data. Technological differences might occur between enterprises and Member States.

The Institute for Occupational Safety and Health of the German Social Accident Insurance (IFA) published a report on exposure measurements to formaldehyde in and France (N= 8,211) and Germany (N=7,238) for the period from 2002 to 2011. Overall, 220 sectors and 535 different working areas were evaluated and the report gives a comprehensive and detailed picture of the occupational exposure to formaldehyde in France and Germany which might also serve as a basis for extrapolation.[54] Table 17 shows that 24 % of all measurement exceeded the proposed limit value that SCOEL proposed in 2008 (0.25 mg/m$^3$). SCOEL changed its recommendation later to 0,369 mg/m[55].

**Table 18: Overview of filtered measurements, i.e. sampling duration ≥ 30 minutes and ≤ 240 minutes; GM = geometric mean**

| | All | | Area | | Personal | |
|---|---|---|---|---|---|---|
| | COLCHIC | MEGA | COLCHIC | MEGA | COLCHIC | MEGA |
| N | 6,784 | 6,469 | 4,041 | 3,663 | 2,743 | 2,796 |
| GM in mg/m$^3$ | 0.07 | 0.04 | 0.07 | 0.03 | 0.09 | 0.06 |
| Median in mg/m$^3$ | 0.07 | 0.04 | 0.06 | 0.02 | 0.09 | 0.06 |
| 75$^{th}$ percentile in mg/m$^3$ | 0.24 | 0.13 | 0.21 | 0.09 | 0.26 | 0.19 |
| 90$^{th}$ percentile in mg/m$^3$ | 0.59 | 0.42 | 0.62 | 0.3 | 0.55 | 0.52 |
| 95$^{th}$ percentile in mg/m$^3$ | 1.11 | 0.7 | 1.2 | 0.58 | 0.9 | 0.8 |
| % ≥ SCOEL limit value (0.25 mg/m$^3$) | 24 | 16 | 23 | 12 | 26 | 21 |

**Table 19: Formaldehyde in the human health activities sector**

| | All | | Area | | Personal | |
|---|---|---|---|---|---|---|
| | COLCHIC | MEGA | COLCHIC | MEGA | COLCHIC | MEGA |
| N | 1,157 | 482 | 574 | 228 | 583 | 254 |
| GM in mg/m$^3$ | 0.11 | 0.15 | 0.07 | 0.09 | 0.16 | 0.23 |
| Median in mg/m$^3$ | 0.11 | 0.20 | 0.08 | 0.12 | 0.18 | 0.30 |
| 75$^{th}$ percentile in mg/m$^3$ | 0.30 | 0.47 | 0.20 | 0.29 | 0.41 | 0.56 |
| 90$^{th}$ percentile in mg/m$^3$ | 0.75 | 0.89 | 0.48 | 0.73 | 1.07 | 0.94 |
| 95$^{th}$ percentile in mg/m$^3$ | 1.40 | 1.40 | 0.87 | 1.20 | 1.74 | 1.60 |
| % ≥ SCOEL limit value (0.25 mg/m$^3$) | 29 | 44 | 20 | 29 | 39 | 58 |

[53] Arbejdstilsynet 2010: Farlige kemikalier i Danmark - Opgørelse af anvendelsen i 2008 (Dangerous chemicals in Denmark - Report about their applications) AT-rapport 1 – 2010, Arbejdstilsynet, March 2010, p 14

[54] Clerc, F. et al.: : Comparison of formaldehyde exposure measurements stored in French and German databases, in Gefahrstoffe - Reinhaltung der Luft, 75 (2015) Nr. 4 - April http://www.dguv.de/medien/ifa/de/pub/grl/pdf/2015_066.pdf

[55] COEL/REC/125 Formaldehyde Recommendation from the Scientific Committee on Occupational Exposure Limits Draft document for public consultation 2015-11-17

**Table 20: Formaldehyde in the manufacture of wood and furniture sector**

| | All | | Area | | Personal | |
|---|---|---|---|---|---|---|
| | COLCHIC | MEGA | COLCHIC | MEGA | COLCHIC | MEGA |
| N | 1,076 | 1,308 | 610 | 245 | 466 | 1,063 |
| GM in mg/m³ | 0.12 | 0.08 | 0.13 | 0.13 | 0.12 | 0.07 |
| Median in mg/m³ | 0.12 | 0.07 | 0.12 | 0.11 | 0.13 | 0.07 |
| 75th percentile in mg/m³ | 0.30 | 0.2 | 0.35 | 0.44 | 0.24 | 0.17 |
| 90th percentile in mg/m³ | 0.52 | 0.56 | 0.63 | 1.22 | 0.41 | 0.47 |
| 95th percentile in mg/m³ | 0.75 | 0.89 | 0.98 | 1.78 | 0.50 | 0.7 |
| % ≥ SCOEL limit value (0.25 mg/m³) | 30 | 23 | 34 | 37 | 25 | 19 |

The authors conclude (table 19 and 20):

*"Human health activities and the manufacture of wood and furniture are industrial sectors in which a large proportion of the formaldehyde concentrations observed are above the SCOEL TWA (33% and 26% for each industrial sector, COLCHIC and MEGA combined). Moreover, the high number of measurements available for computing the values permits asserting that these values are reliable. Consequently, specific prevention measures to reduce exposure to formaldehyde should be taken by enterprises and workers in these industrial sectors. However, it does not appear easy to put this into practice."*

**International data - Canada and Australia**

**CAREX Canada**

CAREX Canada estimates for the top five sectors different percentages of exposed workforce. It varies between 5% and 21%. According to Carex Canada *"approximately 152,000 Canadians are occupationally exposed to formaldehyde; 66% of these workers are male. Wood product manufacturing workers are the largest industrial group exposed, where exposure occurs from the use of formaldehyde-containing resins and glues. More women than men are exposed to formaldehyde in hospitals, schools, and clothing manufacturing, while exposure for men is much more common in furniture manufacturing and related industries."*[56]

In the Australian AWES study the authors estimate that 2.3 % of the workforce is exposed to formaldehyde.[57] According to the study following are the most relevant areas of exposure:

*"The main tasks associated with probable exposures to formaldehyde were,*

*"In decreasing order: working with particle board, fire-fighting, fire overhaul and clean-up, sanding prior to painting, sterilising medical equipment, manicuring and working in a pathology laboratory. The majority of tasks (approximately 96%), with the exception of sterilising medical equipment, were assessed as resulting in medium or low exposures."*

[56] Carex Canada, Formaldehyde. http://images.google.de/imgres?imgurl=http%3A%2F%2Fwww.carexcanada.ca%2Fcdn%2FO_FORM_IND.jpg&imgrefurl=http%3A%2F%2Fwww.carexcanada.ca%2Fen%2Fformaldehyde%2Foccupational_estimate%2F&h=347&w=486&tbnid=_wAQEmtFihMPRM%3A&vet=1&docid=CJCtU7zs05PLvM&ei=Djs0WPOzIsOlsAGaubqwBQ&tbm=isch&iact=rc&uact=3&dur=239&page=0&start=0&ndsp=22&ved=0ahUKEwjz8ovRr7zQAhXDEiwKHZqcDlYQMwghKAQwBA&bih=826&biw=1173

[57] The Australian Work Exposures Study (AWES): Formaldehyde, November 2014, p viii http://www.safeworkaustralia.gov.au/sites/SWA/about/Publications/Documents/890/Research-Report-AWES-Formaldehyde.pdf

### 5.4.5 Module 5: Number of workers performing tasks involving exposure to formaldehyde

EUROSTAT offers figures of employed people in the two most relevant detailed NACE classes (16 and 31, which cover most of the formaldehyde usage in the NACE classes on manufacturing. However, it would require a statement from technical and statistical experts on the extent that these NACE classes really covers most of the formaldehyde use, and which other sectors might use significant amounts of formaldehyde glues.

According to EUROSTAT, there were 823,000 active employees in NACE class 16: Manufacture of products of wood, cork, straw and plaiting material' in Europe in 2015 and just 1,000,000 employed persons in NACE Class 31 'Manufacture of furniture'.

Finally, we used the Canadian estimates, and concluded that around 18% of the workers in NACE Class 16 and 31 are exposed (table 21).

The second largest group of exposed workers are the employees in hospitals. Eurostat provides less complete and detailed statistics than the OECD: According to OECD there are around 11,000,000 employees in the EU working in hospitals. The Canadian CAREX estimates that less than 5 % of the workforce in hospitals is exposed to formaldehyde[58], the number for the EU was estimated at 500,000.

According to CAREX 99 these two sectors cover around 44% of the exposed worker population, 56% work in 43 other sectors like 'Agriculture and hunting' or 'Personal and household services'. CAREX counts 971,000 exposed workers, 44% of the total exposed number of workers work in the production of wood and furniture (Industry 331 and 332) and in the medical, dental, other health and veterinary services (Industry 933).[59] Because no detailed data or expert assessments for other sectors are available, the CAREX calculation from 1999 was used and 56% for workers exposed in other sectors added (table 21).

[58] http://www.carexcanada.ca/en/formaldehyde/occupational_estimate/
[59] http://www.ttl.fi/en/chemical_safety/carex/Documents/5_exposures_by_agent_and_industry.pdf

**Table 21:– Formaldehyde exposed workers population in the EU**

| Sector | European Union 28 | % of exposed | Exposed worker population | Remark |
|---|---|---|---|---|
| *Sector or subsector* | *European figures* | | | |
| NACE class 16: Manufacture of products of wood, cork, straw and plaiting material | 823,000 [60] | 18% [61] | 148,000 | |
| NACE class 31: Manufacture of furniture | 1,000,000[62] | 18% [63] | 180,000 | |
| Labour force in hospitals | 11,000,000 | < 5% | 500, 000 | |
| According to CAREX 1999 56% of the totally exposed workers work in other sectors than NACE 16 and 31 and hospitals | | | 1,072,000 | Calculation (148,000 + 180,000 + 500,000) = 44%<br>Rest of 56 % =1,072,000 |
| **Total[64]** | **215,000,000** | **0,88%** | **1,900,000** | |

**Table 22: Percentage of Formaldehyde exposed workers population in the EU, Canada and Australia**

| Country/ Region | Source | Exposed workers[65] | Total workforce* | |
|---|---|---|---|---|
| HazChem@Work Calculations[66] | Diverse | 1,900,000 | 215,000,000 | **0,88%** |
| Canada | Carex Canada | 152,000 | 19,800,000 | **0,77%** |
| Australia[67] | AWES | 235,000 | 10,200,000 | **2.3 %** |

The Canadian figures are very similar to the HazChem@Work calculation (table 22). The Australian figures are nearly three times higher. The authors of the Australian study explain this difference with their methodology.

[60] Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E) [sbs_na_ind_r2]: Filter selection: Number of persons employed, Last update: 04-11-2016
[61] Based on Canada
[62] Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E) [sbs_na_ind_r2]: Filter selection: Number of persons employed, Last update: 04-11-2016
[63] Based on Canada
[64] Employed persons in the EU 28:
http://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=lfsi_emp_a&lang=de
Sector employment
http://ec.europa.eu/eurostat/tgm/table.do?tab=table&init=1&plugin=1&pcode=tec00109&language=en
215 000 Beschäftigte (211 mio in 2013) (238 mio Erwerbsbevölkerung) (237 in 2013) 15 bis 64
[65] Labor force statistics, productivity and unit labor costs, consumer prices http://www.bls.gov/fls/#data
[66] Beschäftigte und Erwerbspersonen nach
[67] http://annhyg.oxfordjournals.org/content/60/1/132.abstract and The Australian Work Exposures Study (AWES): Formaldehyde, November 2014, p**13**
http://www.safeworkaustralia.gov.au/sites/SWA/about/Publications/Documents/890/Research-Report-AWES-Formaldehyde.pdf

"*This estimate is much higher than that found in major overseas studies, the differences probably due primarily to differences in study methodologies in terms of the type of data collected and the approach used to estimate exposure*

### 5.4.6 Conclusion

Finally, based on estimations from CAREX 99 and CAREX Canada it can be concluded that around 1.9 m or 0.88 % employed persons in the EU 28 are exposed to formaldehyde. By extrapolation of the Canadian estimates to the EU this figure would be at 1.7 m. By application of the Australian AWES figures to the EU of this figure would be higher for the factor 2.6 and add up to 4.9 m. The Canadian figures are very similar to the HazChem@Work calculation, the Australian figures are nearly three times higher.
The reports from measurement databases show that approximately 25% of the measurements exceed the proposed limit value of 0,25 mg/m$^3$ that SCOEL proposed in 2008 , i.e. around 475,000 workers were working under conditions that do not match these recommendations. SCOEL changed its recommendation later to 0,369 mg/m [68], consequently the percentage of over exposed workers will be lower. An exact figure would require a new data evaluation from Colchic and MEGA-Data.

## 5.5 Example: Respiratory Crystalline Silica (RCS)

### 5.5.1 Introduction

In the case of Respiratory Crystalline silica (RCS) the total and sectoral production figures have practically no significance for the exposure. The silica tonnage that is reported in production statistics is mainly used as sand in different manufacturing industries or construction, e.g. for the preparation of subgrades. These volumes report silica or silicon dioxide that are used without RCS producing operations. Of interest is the volume of RCS at work places where workers treat silica containing material in a way the RCS is formed, e.g. by drilling, blasting, cutting, and similar work operations.

There is practically no clear relation between the use of silica and the generation of RCS without assessing the technologies that are applied. Without knowing exactly the work operations in these industries it is impossible to conclude from tons to exposures. Consequently, PRODCOM, ECHA and SPIN do not register data of the volume of such process generated substances.

The most important source are sector based measurement data. However, most of these reports (e.g. the quartz dust measurement reports of BIA, 2006[69][70]) aims not at calculating the number of exposed persons. For decades now there is a large number of publications on the exposure quartz dust at work places, most of them deal with the health impact or present measurement data. The reason for such measurements was the health impairing impact of quartz dust, leading to silicosis. Silicosis is one of the most recognised and oldest occupational diseases.

[68] COEL/REC/125 Formaldehyde Recommendation from the Scientific Committee on Occupational Exposure Limits Draft document for public consultation 2015-11-17
[69] BGIA: Exposure to quartz at the workplace (BGIA-Report 8/2006e), see: http://www.dguv.de/ifa/publikationen/reports-download/bgia-reports-2005-bis-2006/bgia-report-8-2006/index-2.jsp
[70] S. Gabriel, S. et al: Comparison of the determination and evaluation of quartz exposure and exposure levels at workplaces across Europe, Gefahrstoffe - Reinhaltung der Luft 74 (2014) Nr. 9 - September

Many data have been collected or compiled by regulators like the US OSHA[71]. In a few of these studies - compilations or surveys like CAREX 99[72], the SHEcan-Study[73] on RCS, CAREX Canada[74], and AWES[75] - the authors make an attempt to estimate the numbers of exposed workers.

The voluntary agreement of the 'European Network on Silica' (NEPSI) covers major quartz using industries like glass or ceramics, in total 15 industry sectors with 2 m employees.. It does not include the construction industry employing most exposed workers. [76]

### 5.5.2 Number of exposed workers – sectors and total

In all estimates the number of exposed workers one **of** the most crucial step is to determine the sectors with a relevant RCS exposure and consequently the total number of exposed workers. Many newer studies are still based on the CAREX figures from the FIOH-led consortium, although like the SHEcan study they were refined based on the data from a large HSE Study from 2003[77], the NEPSI data and other sources.

The CAREX 99 data are often used due to its high level of detail. However, until now no adaptation to the new NACE system has been made since then. Structural economic and also technological developments might have led to larger changes in RCS exposure

**Table 23: Sectors with a relevant level of RCS Exposure according to CAREX 99**

| Industry | NACECODE | Estimate Exposed Workers |
|---|---|---|
| Agriculture and hunting | 11 | 31,600 |
| Coal mining | 21 | 100 |
| Crude Petroleum and Natural Gas Production | 22 | 4,002 |
| Metal Ore Mining | 23 | 54,956 |
| Other Mining | 29 | 132,042 |
| Food manufacturing | 311-2 | 2,525 |
| Beverage industries | 313 | 110 |
| Tobacco manufacture | 314 | 7 |
| Manufacture of textiles | 321 | 1,971 |
| Manufacture of wearing apparel, except footwear | 322 | 2,155 |
| Manufacture of leather and products of leather or of its | 323 | 1,623 |

[71] Department of Labor ,Occupational Safety and Health Administration, 29 CFR Parts 1910, 1915, and 1926
Occupational Exposure to Respirable Crystalline Silica; Final Rule, March 25, 2016, https://www.osha.gov/silica/

[72] http://www.ttl.fi/en/chemical_safety/carex/Documents/5_exposures_by_agent_and_industry.pdf, see: Silica, crystalline

[73] IOM, Cherrie, JW et al.: Health, socio-economic and environmental aspects of possible amendments to the EU Directive on the protection of workers from the risks related to exposure to carcinogens and mutagens at work, Respirable crystalline silica, May 2011

[74] http://www.carexcanada.ca/en/silica_(crystalline)/occupational_estimate/

[75] The Australian Work Exposures Study: Prevalence of Occupational Exposure to Respirable Crystalline Silica, https://www.ncbi.nlm.nih.gov/pubmed/26888888

[76] NEPSI Consortium: Application of the European Multi-Sectoral Social Dialogue Agreement on Workers' Health Protection through the Good Handling and Use of Crystalline Silica and Products Containing It. The NEPSI consortium consists 15 industry sector associations of see: http://www.nepsi.eu/home
Executive Summary, September 2016, see:
http://www.nepsi.eu/sites/nepsi.eu/files/content/document/file/nepsi_2016_executive_summary_final.pdf

[77] Health and Safety Executive (HSE). (2003). A Regulatory Impact Assessment (RIA) on proposals to reduce the UK occupational exposure limit for respirable crystalline silica (RCS)
http://products.ihs.com/Ohsis-SEO/856909.html

| | | |
|---|---|---|
| Manufacture of footwear | 324 | 1,153 |
| Manufacture of wood and wood and cork products, except | 331 | 300 |
| Manufacture of furniture and fixtures, except primary of | 332 | 1,804 |
| Manufacture of paper and paper products | 341 | 600 |
| Printing, publishing and allied industries | 342 | 3,147 |
| Manufacture of industrial chemicals | 351 | 5,651 |
| Manufacture of other chemical products | 352 | 30,909 |
| Petroleum refineries | 353 | 800 |
| Manufacture of miscellaneous products of petroleum | 354 | 4,869 |
| Manufacture of rubber products | 355 | 3,245 |
| Manufacture of plastic products not elsewhere classified | 356 | 9,096 |
| Manufacture of pottery, china and earthenware | 361 | 96,097 |
| Manufacture of glass and glass products | 362 | 43,281 |
| Manufacture of other non-metallic mineral products | 369 | 191,243 |
| Iron and steel basic industries | 371 | 68,475 |
| Non-ferrous metal basic industries | 372 | 9,114 |
| Manufacture of fabricated metal products, except | 381 | 68,348 |
| Manufacture of machinery except electrical | 382 | 77,548 |
| Manufacture of electrical machinery, apparatus, appliances | 383 | 6,758 |
| Manufacture of transport equipment | 384 | 38,721 |
| Manufacture of instruments, photographic and optical | 385 | 15,848 |
| Other manufacturing industries | 39 | 8,482 |
| Electricity, gas and steam | 41 | 19,276 |
| Water works and supply | 42 | 250 |
| Construction | 5 | 2,080,435 |
| Wholesale and retail trade and restaurants and hotels | 6 | 4,000 |
| Land transport | 711 | 31,201 |
| Water transport | 712 | 5,165 |
| Air transport | 713 | 2,819 |
| Services allied to transport | 719 | 3,972 |
| Financing, insurance, real estate and business services | 8 | 200 |
| Sanitary and similar services | 92 | 14,127 |
| Education services | 931 | 3,129 |
| Research and scientific institutes | 932 | 4,300 |
| Medical, dental, other health and veterinary services | 933 | 2,600 |
| Personal and household services | 95 | 1,000 |
| **Total** | | **3,089,054** |

CAREX 99 concludes that there were more than 3 m workers exposed to RCS in the EU. However, these figures relate to the EU 15 with workforce of around 155,000,000 workers. Extrapolated to the EU 28 with around 215,000,000 employees[78] this figure would be 38% higher or at 4,290,000.

The US OSHA concludes that more than 11 m worker or 6.9% of the work force is exposed. [79] They also present a detailed list of sectors with RCS exposed workers, even determining different levels of exposures called 'silica exposure ranges'[80]. US OSHA states:

[78] A clear definition of ‚workforce' or 'workers' is often missing in these studies. It sometime includes only employees, sometimes in addition self-employed and sometimes also employers. In the case of RCS, e.g. in the construction industry, particularly in micro and small enterprises, employers and self-employed might be exposed in the same way as workers. In larger industry dominated sectors the exposure of employers will be an exceptional case.

[79] Department of Labor, Occupational Safety and Health Administration, 29 CFR Parts 1910, 1915, and 1926

*"There are over 30 major industries and operations where exposures to crystalline silica can occur. They include such diverse workplaces as foundries, dental laboratories, concrete products and paint and coating manufacture, as well as construction activities including masonry cutting, drilling, grinding and tuckpointing, and use of heavy equipment during demolition activities involving silica- containing materials."*[81]

**Table 24: Number of workers exposed to silica (by affected industry and exposure level) (Screen shot from the US OSHA Final rule p 16432)**

| | | | | Number of Employees Exposed to Silica | | | | |
|---|---|---|---|---|---|---|---|---|
| NAICS | Industry | Number of Establishments | Number of Employees | >=0 | >=25 | >=50 | >=100 | >=250 |
| 423840 | Industrial Supplies Merchant Wholesalers | 7,614 | 82,871 | 1,773 | 1,182 | 591 | 591 | 591 |
| 444110 | Home Centers | 6,569 | 609,186 | 107 | 55 | 41 | 29 | 13 |
| 482110 | Rail transportation | Not Applicable | Not Applicable | 16,895 | 10,668 | 5,340 | 2,948 | 1,233 |
| 561730 | Landscaping Services | 92,976 | 548,662 | 43,033 | 24,747 | 12,612 | 497 | 156 |
| 621210 | Offices of Dentists | 133,107 | 873,172 | 8,525 | 1,421 | 237 | 0 | 0 |
| | **Subtotals – General Industry and Maritime** | **351,998** | **5,335,502** | **294,844** | **152,263** | **100,375** | **58,779** | **29,718** |
| | | | | | | | | |
| | **Totals – All Industries** | **1,015,301** | **11,106,148** | **2,312,261** | **1,249,249** | **948,090** | **577,969** | **258,221** |

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis, based on Table VII-4 and the technological feasibility analysis presented in Chapter IV of the FEA.

CAREX Canada estimates 380,000 RCS exposed workers or roughly 1.9% of the total workforce[82].

The Australian Work Exposures Study finds a percentages of RCS exposed workers in the range of the US figures. According to this survey 6.4% of the workforce or 806,000 workers in Australia are exposed to RCS. [83]

### 5.5.3 Conclusions and recommendations

The following table is based on CAREX 99, the SHEcan study on RCS, the extensive background documentation for the RCS Rule from US OHSA, CAREX Canada and the AWES Australian study.

Occupational Exposure to Respirable Crystalline Silica; Final Rule, p 16432, https://www.osha.gov/silica/
[80] ibid. P 16420 - 16432
[81] ibid. P 16299
[82] http://www.carexcanada.ca/en/silica_(crystalline)/occupational_estimate/
[83] The Australian Work Exposures Study: Prevalence of Occupational Exposure to Respirable Crystalline Silica, https://www.ncbi.nlm.nih.gov/pubmed/26888888

**Table 25: Number and percentage of RCS exposed workers**

| Country/ Region | Source | Exposed workers[84] | Total work-force [85] | Percentage |
|---|---|---|---|---|
| EU 28 | IOM SHEcan Study | 5,300,000 | 215,000,000[86] | 2.5% |
| EU 15<br>CAREX 99 (93 figures) | FIOH, Carex consortium | 3,090,000 | 155,000,000[87] | 2,0% |
| EU 28<br>CAREX figures extrapolated to EU 28 | | 4,290,000 | 215,000,000[88] | 2,0% |
| Canada | CAREX Canada | 380,000 | 19,800,000 | 1.9% |
| US | US OSHA | 11,100,000 | 162,000,000 | 6.9% |
| Australia[89] | AWES | 806,000 | 12,600,000 | 6,4% |

Estimates from other countries have a certain value, particularly if technologies are globally standardised. In the main sector with high RCS exposure, i.e. the construction industry, a huge variety of the used materials and standards exists (e.g. wood versus stone as construction material). Accordingly the international data on RCS have a lower value than for other substances.

SHEcan concludes that 5,300,000 m workers are exposed to RCS. This estimate is based on CAREX 99, the HSE study on RCS from 2003 [90] and combined with newer sector workforce data from EUROSTAT. The CAREX 99 figures extrapolated to the extended EU 28 results in an estimate of 4.290,000 exposed workers. CARAX Canada obtains very similar data. Both the US OSHA study and the AWES Survey in Australia find three times higher percentages. (6.9% for US and 6.4% for Australia).

[84] **Labour force statistics, productivity and unit labour costs, consumer prices,** http://www.bls.gov/fls/#data

[85] Sometimes workforce covers employers, sometimes only employees. In small enterprises, e.g. of the craft sector, employers might be exposed like the workers. As in most country the share of employers is around 10% it would be better to eliminate this factor but this correction will not change the whole picture.

[86] EUROSTAT: http://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=lfsi_emp_a&lang=de
Sector employment:
http://ec.europa.eu/eurostat/tgm/table.do?tab=table&init=1&plugin=1&pcode=tec00109&language=en
215 m employees (211 m in 2013), 238 mio employees plus self-employed (237 in 2013) age 15 to 64

[87] Data for EU 15, Eurostat Yearbook 2004, Data 1992-2002

[88] Ibid.

[89] The Australian Work Exposures Study: Prevalence of Occupational Exposure to Respirable Crystalline Silica, https://www.ncbi.nlm.nih.gov/pubmed/26888888

[90] Health and Safety Executive (HSE). (2003). A Regulatory Impact Assessment (RIA) on proposals to reduce the UK occupational exposure limit for respirable crystalline silica (RCS)
http://products.ihs.com/Ohsis-SEO/856909.html

Finally, based on estimations from the different sources it can be concluded that between 2.0% and 6.9 % of the workers in the EU 28 are exposed to RCS. In numbers these are between 4.29 m and 14.83 m workers (application of the US percentage). By extrapolation of the Canadian estimates to the EU this figure would be slightly lower (4.085 m). By application of the Australian AWES this figure would be higher for more than the factor 3 and add up to 12.6 m exposed workers.

An explanation might be that particularly the construction industry is very much based on regional materials (wood vs. stone) and regional construction practices and standards. Also the relative share of industries with a high importance plays a large role.

A new detailed estimate would require to triangulate the sector findings from CAREX, SHEcan, HSE, US OSHA, AWES and CAREX Canada and to adapt it to the NACE 2 systematic. In addition expert knowledge about technological and economic developments in these sectors and particularly related to RCS generating operations is needed.

**The example of acrylamide can be found in Annex 22**.

# 6 Work package 5: IT Project

## 6.1 Aim of the work package

The aim of work package 5 was to develop a database that can be published on the internet and provide the collected and modelled information in a flexible and user-friendly way, which respects data protection rules. The work on the database was subcontracted to Claudia Berg - design & development, an IT-provider with long-standing experience on similar databases.

The aims of the database were to:

- Provide policy makers and policy actors with overview information on exposure levels and related risks from the use of hazardous substances in workplaces, in order to monitor policy success and develop new risk management measures, if necessary.
- Provide companies – employers and/or employees – with information on workplace exposures, to check whether or not the conditions in their workplaces could be improved (or comply with current EU practice).
- Provide scientific institutions with a guideline to estimate exposures to target the development of more efficient protection measures at workplaces, to conduct epidemiologic studies, or to analyse trends in occupational diseases.
- Provide registrants under REACH with information on the operational conditions of use and risk management measures at workplaces, to support their chemical safety assessment.

Following the database is described in detail.

### 6.1.1 Database access

The test database is available at: http://otterl.han-solo.net/hazchematwork.

**Log-in/registration**

To keep test data safe, a user management was implemented. The user has to log-in before entering the database. Experts and data providers have to register to get the log-in data. A registration form is provided where the user has to enter the name, the company and the email address. The registration data is reviewed by the contractor before sending log-in-data to the user.

### 6.1.2 IT-functionalities of the test version/technical background

The current version of the database contains all tables and fields listed in WP3.

It is set up as MySQL. MySQL is an open-source relational database management system. Its source code is available under the terms of the GNU General Public License.

The Data are organised in various tables, which contain different information (e.g. substance data, exposure data, disease data) and are linked to each other by unique keys to identify data for each set of data.

A front-end and protected backend for maintaining and using the database was designed, programmed, and implemented using the programming language PHP, a script language for dynamic websites and web-based applications. The database was designed to facilitate the exchange (import and export) of data in various formats (SQL, XML, CSV).

The web GUI (graphical user interface) of the database allows users to execute targeted searches and filter data according to a range of parameters (e.g. chronological order, countries, substanc-

es, work processes, work tasks). The search, filter and overview results are available to users for exporting data to various file formats (XML, CSV).

In order to meet the requirements of the various users, the database is designed to fulfil the following properties:

- The database is designed in a user friendly way with an intuitive graphic user interface.
- Most parts of it (except diagrams) are using a responsive web design.
- The database is designed in order to allow easy update.
- A "data collection tool" is established to enable database provider to deliver information in the correct format for the database (CSV, XML, SQL format are accepted). See also chapter 8 – recommendations (data format).
- The database IT-format and data structure are based on international standards and comply with the requirements of the different data providers.
- The database has a user-friendly interface, allowing data mining by selecting specific combinations of input data, and requesting different types of processing and results. Results can be currently differentiated at geographical level, year, work process and work task. The small selection is due to the limited data provided for the test phase. However, a differentiation according to e.g. industry sectors, company sizes, uses, and groups of exposed workers can easily be incorporated depending on available data.

### 6.1.3 Illustration of the design and functionality of the database

**General information and feedback possibilities**

**Informative text**

After the user has logged-in, an informative text opens in order to explain the purpose and status of the pilot database. This overlay has to be marked with "I have read this information" to access the database.

**Overview of data provided for HazChem@Work**

The test database gives a brief overview of data provided for HazChem@Work. On the bottom right side of the database's home screen, users can receive information about substances provided, database providers and measurement methods used by clicking on the respective hyperlink.

The overview of provided substances gives additional detailed information about the data provider (title and owner of the data source, country, legal background and further information provided).

The overview of data providers shows detailed information about the provider (as explained above) and gives additional information of substances provided by this data provider.

An overview of measurement methods is added with additional information and background about each measurement method if provided by the database owner. The measurement methods are also linked to substances.

**Feedback form/Methodology for providing data**

Users can easily access the feedback form. The user's name and organisation are automatically pre-filled, in order to make the feedback as easy as possible.

It is also possible for users or data providers to access the methodology for providing data.

**Search and filter functionalities**

**Search**

The database is searchable through search options for substances CAS or EC numbers, years or countries (figure 7).

The auto-complete functionality (JSON) facilitates the search function: with two letters or digits the program predicts a list of possible substances/words as suggestion.

Additional options enable to display substances matching the exact name or to display only aggregated data.

The methodology for use of data can be accessed from the entry page, too.

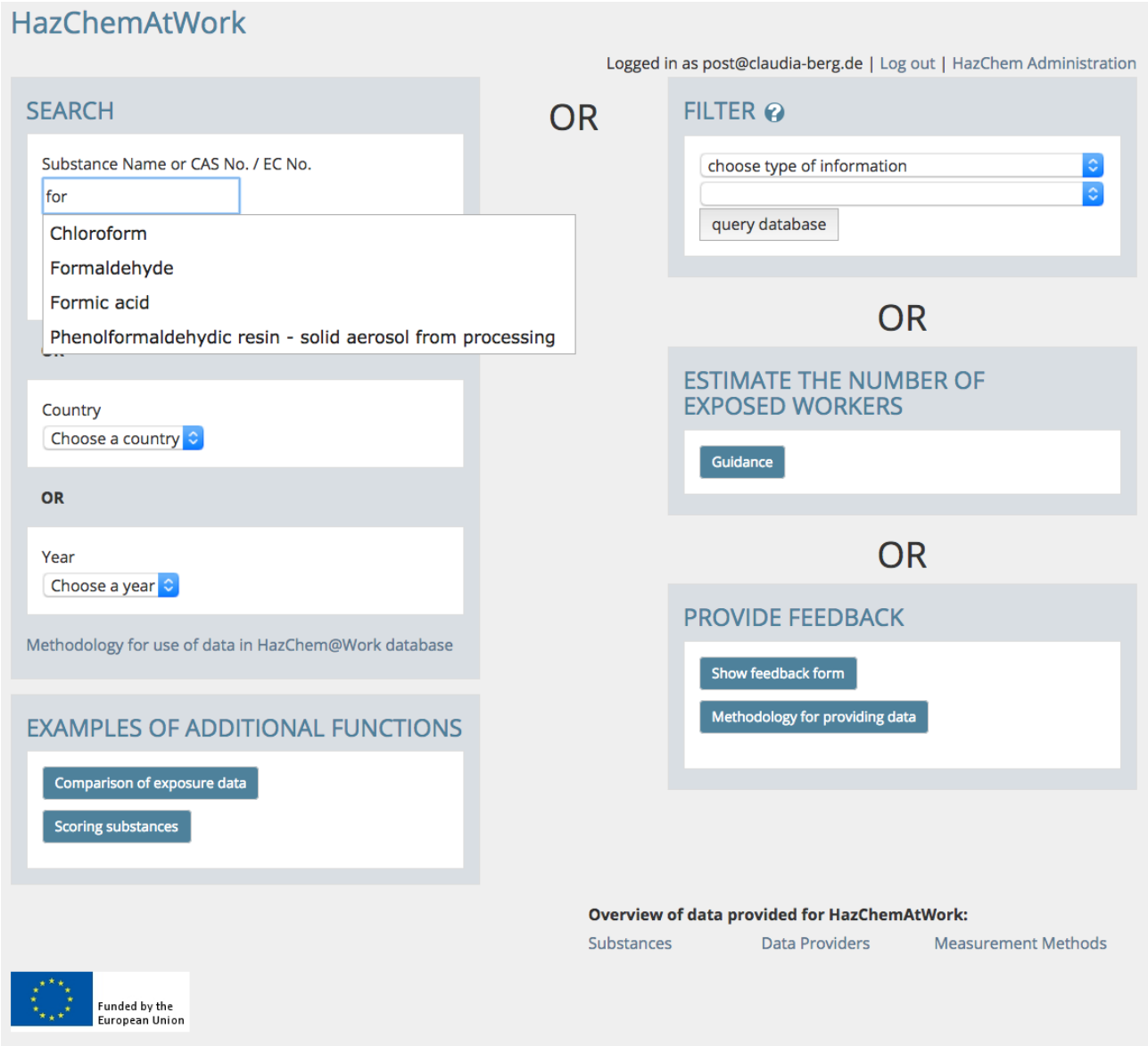



**Figure 7: Interface with search options for substances, CAS or EC numbers (showing example of auto-complete function (letters/digits)), year or country, additional options, link to methodology, filter functionalities, guidance and feedback form.**

**Filter**

Additional filter options allow a search by type of information. Currently, it is only available for work process and work task due to the limited data received. However, the filter options can easily be extended. After choosing one of these types of information from the first drop down menu, a second dropdown menu displays all available options (figure 8, upper right corner).

Filter results are displayed in the same way as the search results.

**Example: Running a search for Benzene**

After running a search for a substance, an overview is displayed showing the substance name, CAS and EC number (and index number if available), countries that provided data, years and type of data in a general section (figure 8). Country, year and data type are clickable for additional filter functions. A click on the cross resets the filter.

The list can easily be sorted by choosing the sort column in the dropdown menu (by substance name (if searched for country or year), country, year, type of data (e.g. exposure, disease) and database).

A link to ECHA's Classification and Labelling Inventory is provided.

A new search is easily possible by clicking on "new search".

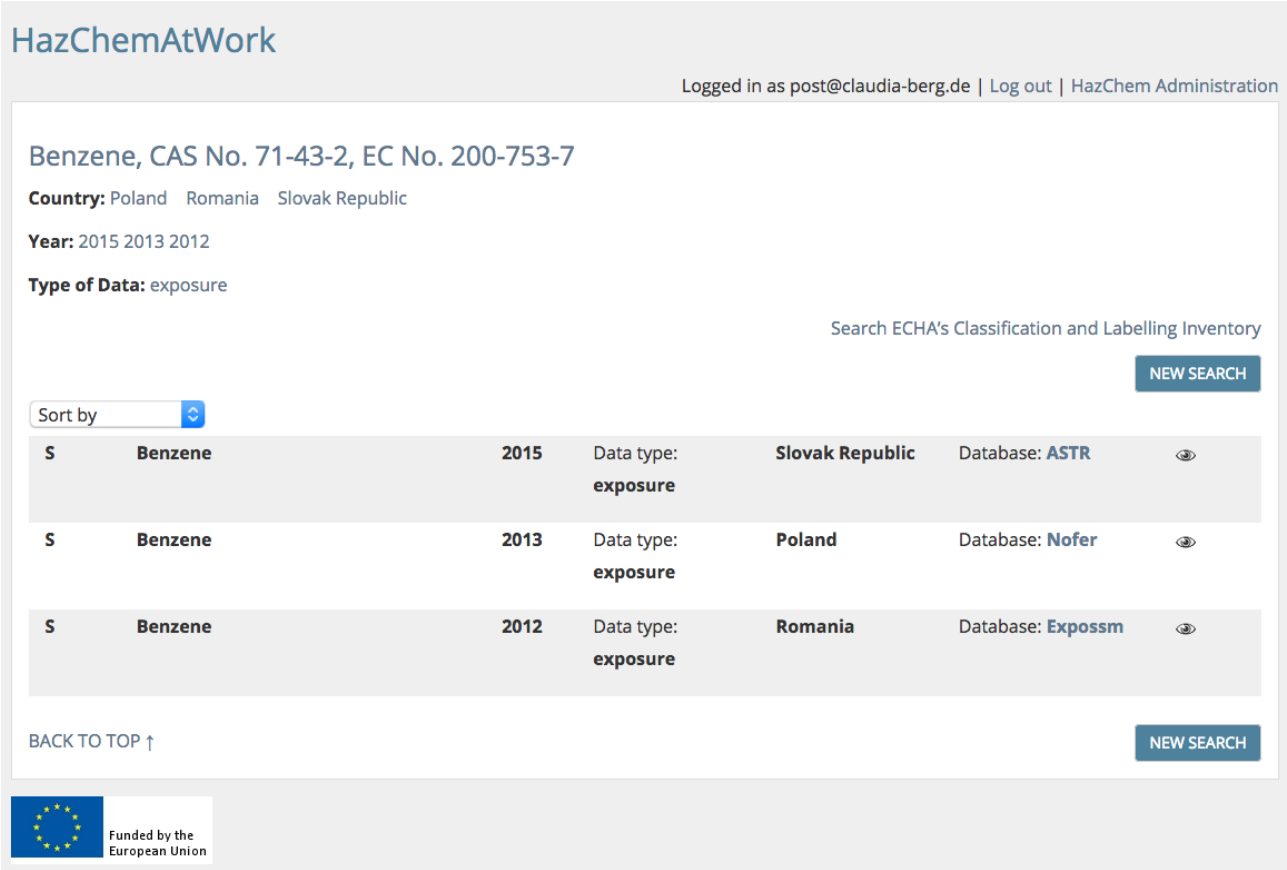


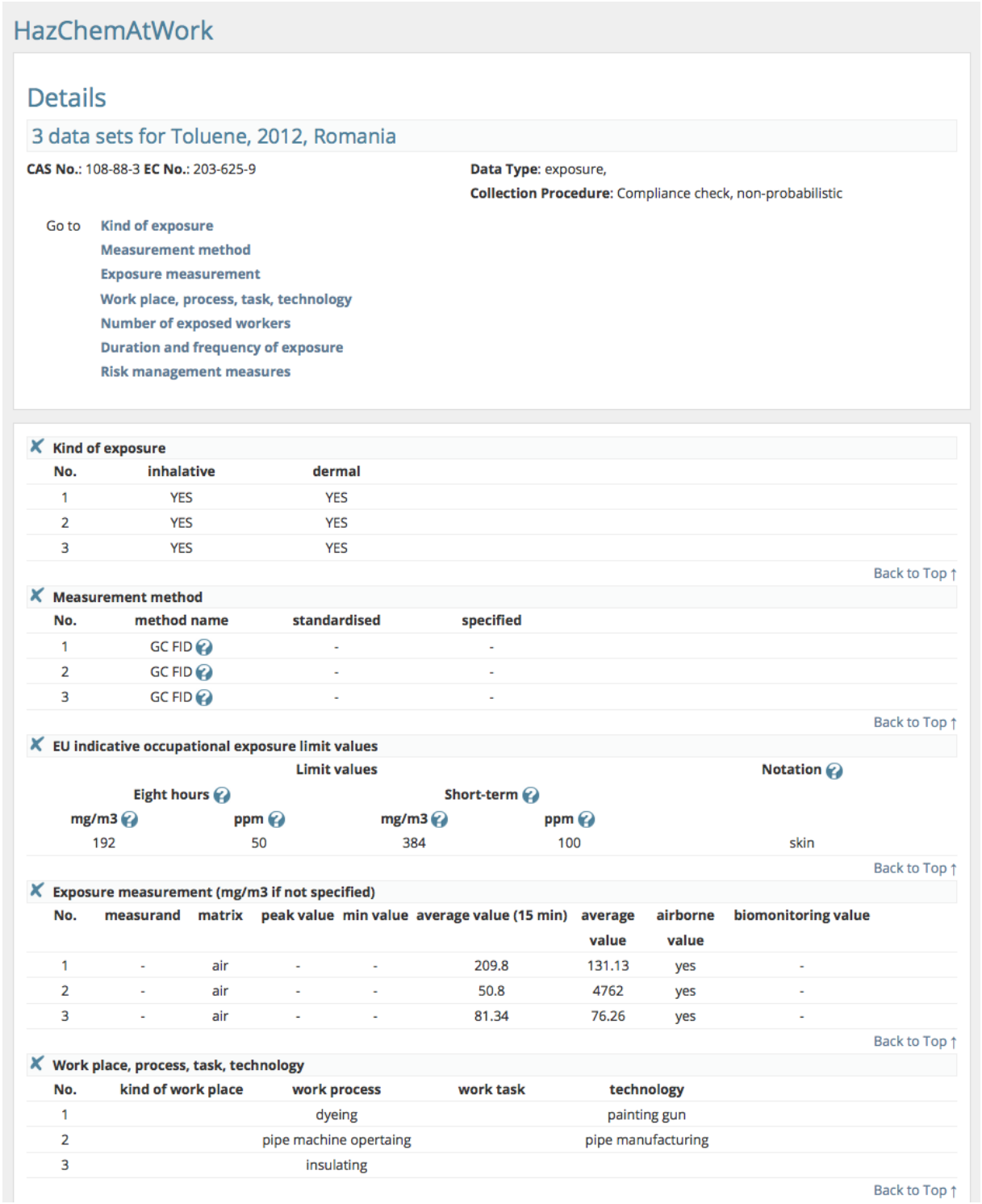

**Figure 8: Screen after running a search for Benzene and clicking on 'Show Data'**

A detailed overview opens in a new window after clicking on the 'Eye' (see figure 8).

The overview shows among others details on the kind of exposure, measurement methods, and exposure measurements. The green point indicates that data are available.  Red means “no data”.

A printable detail view can be obtained by clicking on “View all details”

This printable overview shows all details including European OEL information if available (figure 9).



HazChemAtWork

Details

3 data sets for Toluene, 2012, Romania

**CAS No.**: 108-88-3 **EC No.**: 203-625-9

**Data Type**: exposure,

**Collection Procedure**: Compliance check, non-probabilistic

Go to
- Kind of exposure
- Measurement method
- Exposure measurement
- Work place, process, task, technology
- Number of exposed workers
- Duration and frequency of exposure
- Risk management measures

**Kind of exposure**

| No. | inhalative | dermal |
|---|---|---|
| 1 | YES | YES |
| 2 | YES | YES |
| 3 | YES | YES |

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**Measurement method**

| No. | method name | standardised | specified |
|---|---|---|---|
| 1 | GC FID | - | - |
| 2 | GC FID | - | - |
| 3 | GC FID | - | - |

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**EU indicative occupational exposure limit values**

| Limit values | | | | Notation |
|---|---|---|---|---|
| Eight hours | | Short-term | | |
| mg/m3 | ppm | mg/m3 | ppm | |
| 192 | 50 | 384 | 100 | skin |

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**Exposure measurement (mg/m3 if not specified)**

| No. | measurand | matrix | peak value | min value | average value (15 min) | average value | airborne value | biomonitoring value |
|---|---|---|---|---|---|---|---|---|
| 1 | - | air | - | - | 209.8 | 131.13 | yes | - |
| 2 | - | air | - | - | 50.8 | 4762 | yes | - |
| 3 | - | air | - | - | 81.34 | 76.26 | yes | - |

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**Work place, process, task, technology**

| No. | kind of work place | work process | work task | technology |
|---|---|---|---|---|
| 1 | | dyeing | | painting gun |
| 2 | | pipe machine opertaing | | pipe manufacturing |
| 3 | | insulating | | |

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**Figure 9: Printable detail view**

**Displaying disease data details**

The detail view after a search for disease data looks slightly different: The parameters displayed depend on those provided and differ from the exposure data. It is possible to visualise the results with e.g. a pie chart.

**Guidance to estimate the number of exposed workers**

A guidance on how to estimate the number of exposed workers is provided in a web friendly format. It is divided in modules, showing an analysis and examples. Users are guided from one module to the next one, but each module is also accessible from the overview.

**Examples of useful additional functions**

**Comparison of exposure data**

The test database offers the possibility to compare exposure data and to show the development of exposure. **Please note, that this part of the database application uses dummy data**, since not enough "real" data have been provided until the end of the test phase. The dummy data are used to demonstrate the useful functionalities that could be included to the database.

Currently, substance data can be compared by country, year, and value representation.

The result of the comparison can be displayed as column chart or curve chart (figure 10). Depending on the needs of the users the functionality can be extended, provided that the data is available.

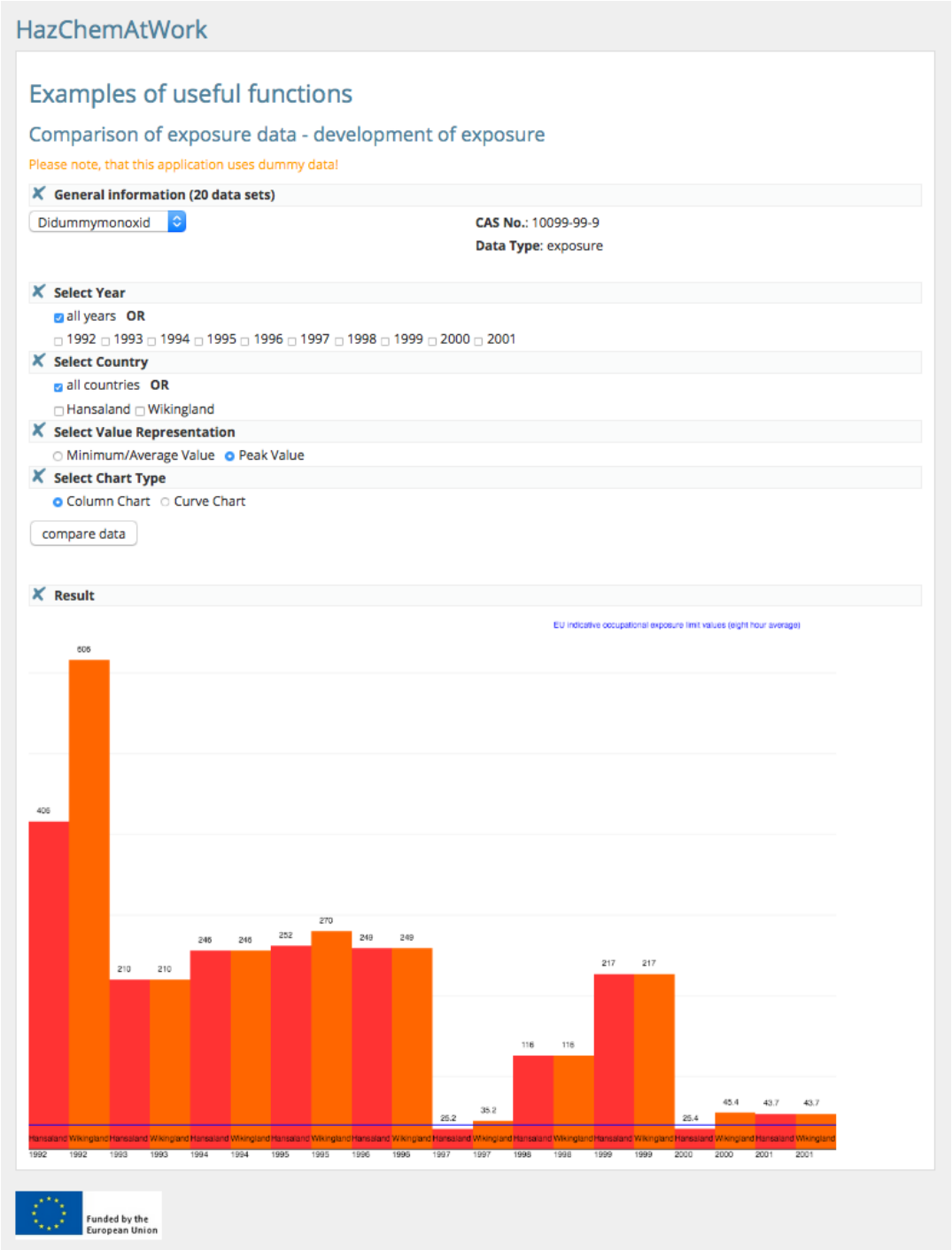


**Figure 10: Example of peak value comparison (two countries, all years) as column chart**

### Scoring substances (List of relevant substances)

The test database provides list of substances relevant for workplaces to be included in the database. It is based on a scoring system that triangulates data from REACH, SPIN and GESTIS. Substances with a European OEL are highlighted in orange. The OEL is displayed when clicking on the question mark.

More general information about the scoring methodology can be obtained by clicking on the question mark in the upper right corner.

**Protected backend**

For administrators the protected backend provides the possibility to edit substance data, data source data, and exposure data. It also provides the possibility to import and export data.

Data can be imported automatically, if one of the specified formats is used (see Annex 21: Technical documentation_IT)

## 6.2 Summary and findings

- The implementation and functioning of the pilot database was the focus of WP 5.
- The pilot database itself has been opened to experts and data providers end of May 2016.
- Although the number of provided data was limited, many options were programmed and are open for further development.
- The link to access the pilot database was sent to 80 persons, of which 39 have registered:

Safety experts: 7
Members of the European Commission: 5
Members of ECHA: 2
Members of EU OSHA: 5
Database owners: 5
National authorities: 3
Working Party Chemicals: 4
Research institutes: 3
Participants of the workshop: 5

**Findings**

See 7.5 for a list of encountered problems regarding the comparability of data.

Based on comments we got, the database itself was refined in the following points:

**Usability**

- Auto-complete functionality, better web site navigation, responsive design for mobile devices, ways to get in touch with the contractor (feedback form).

**Functionality**

- Additional functionalities (comparison of exposure data, development of exposure, different type of charts, different detail view for disease data).

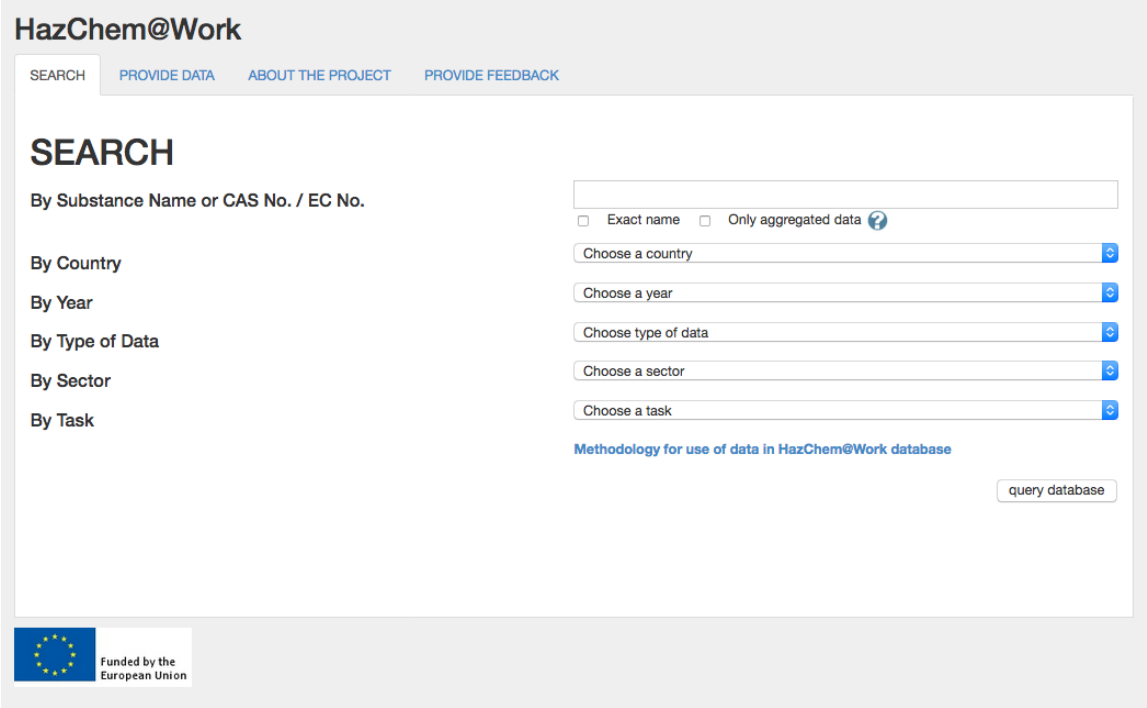


**Figure 11: Example of optimised search (dummy)**

### Outlook/Recommendations for future developments

For further refinement, we recommend to:

- change the structure to optimise functionality for searching and providing data (see figure 11)
- make search results more easy accessible (customizable „interactive overview“, figure 12)
- expand use and functionality (CMR substances)

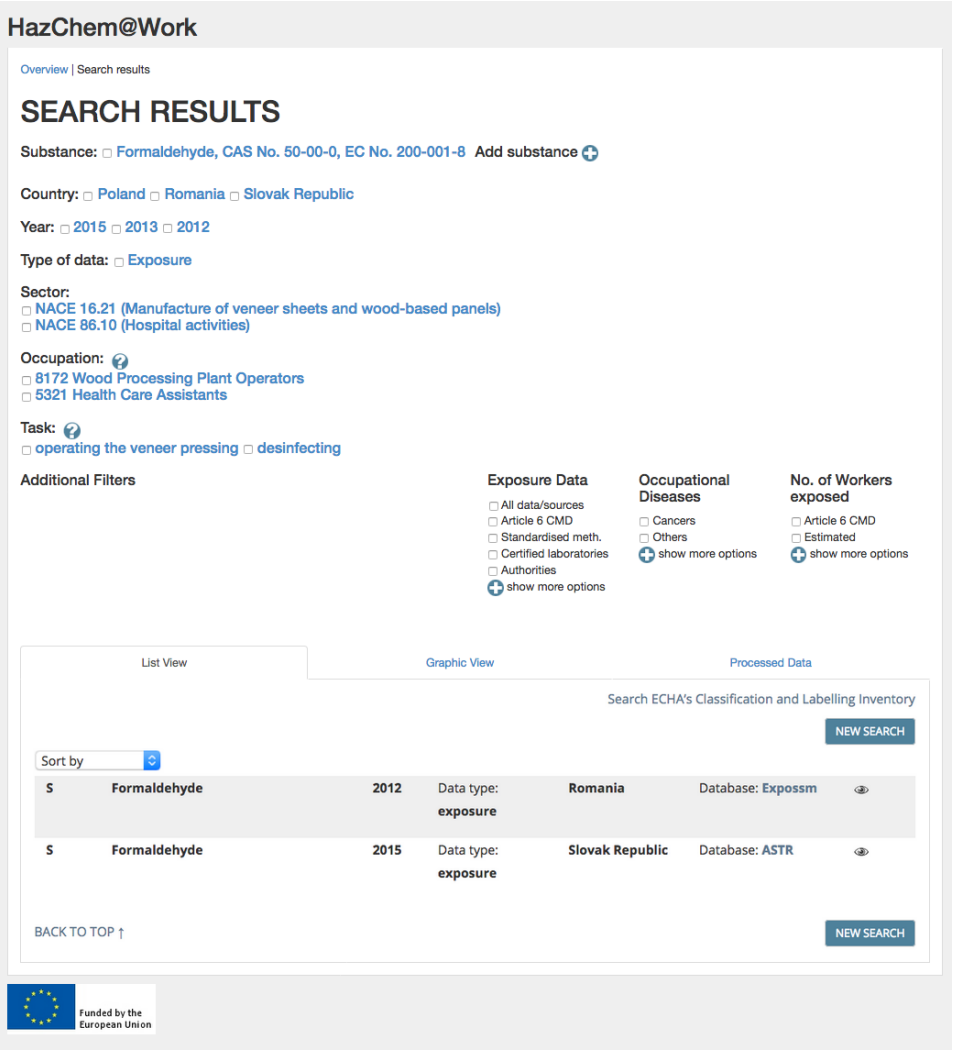


**Figure 12: Example of "interactive overview" (dummy)**

# 7 Work package 6: Organisation of a stakeholder workshop in Luxembourg

## 7.1 Aim of the work package

The aim of the stakeholder workshop was to receive feedback on the interim results of the project from a wider audience of interested stakeholders. The workshop was conducted by the contractor, in close cooperation with the DG Employment.

After an introduction, the workshop was split into several working groups, each having two sessions. Between the sessions, the participants could change working groups. Following the sessions a plenary session was held with short reports from the working groups and a final discussion.

A summarised description of the workshop is attached in Annex 19. A full report of the workshop has been provided by the consortium and submitted to DG EMPL.

## 7.2 Planning and realisation of the workshop

The workshop took place in Luxembourg on 9 June 2015. The administrative and content aspects were conducted by the contractor, in close cooperation with the DG Employment.

On 9 January 2015 a list of the consortium's proposals for workshop participants was sent to DG Employment. A first 'save the date' e-mail was sent to 85 possible workshop participants. An official invitation was sent in the middle of April.

In total 42 representatives of the European Commission, national governments, employers' and workers' associations, data source providers, exposure measurement experts and exposure model experts participated in the workshop (see Annex 15). Four working groups were organised for the workshop covering following issues:

1. Accessibility and quality of data

Legal issues like ownership, language issues, data transfer issues, preparation of data for transfer to EU and additional workload for data providers, minimum quality level of data for inclusion in the database, marking or highlighting of such levels, comparability of different monitoring methods.

2. Relevant substances for occupational exposure

Criteria for deciding on the relevance of substances for occupational exposure and a list of substances proposed for selection.

3. Model Development

Application of models in the case of missing data, calculation of the exposure levels, calculation of the number of exposed workers, preparation of a calculator.

4. Features of a future database

Size and major content, number and characteristics of included substances or process generated hazardous substances, exposure models.

Each working group was chaired by a consortium member or an invited expert. One consortium member per working group was responsible for taking notes. The agenda for the workshop is attached in Annex 20.

## 7.3 Brief summary of the workshop

The workshop demonstrated the high interest of many stakeholders in the development of such European Exposure database. It is currently not possible to make use of national data on a European level due to restrictions starting from access difficulties to language issues. The approach was welcomed to exploit in a suitable way the data from national data sources.

However the participants see it as a huge task and had many doubts whether this demanding approach can be successful. The major doubts concern the quality of data, the comparability, and the access and confidentiality problems. As a doable option it was recommended to prepare an interface - or access portal - for a limited number of substances, working together with a few data providers selecting data of a similar quality and finally achieving a pilot version of a European database.

Report of each working group to the plenum was held by working group chairs.

**Summary Working Group 1: Accessibility and quality of data**

The quality criteria for the data depend on the foreseen uses of the database. It is important to be transparent and clear about the criteria and the methodologies used.

Databases often publish processed/ aggregated data and access to raw data may be more difficult.

Availability of data will also be influenced by the foreseen use of the databases. Data providers may be reluctant to give data if the use is not clear or if they fear it would show their company/country in a bad light. Who runs the database is important, since data providers might be more willing to collaborate with institutions they trust or they regard as representative ( e.g. authorities).

The pilot database of HazChem@Work will help because after being published, it will provide a clear picture on how data is used.

**Summary Working Group 2: Relevant substances for occupational exposure**

The presented scoring system was discussed in detail and comments were received for adjustment. In addition, helpful remarks were made to implement the "finer scoring system". The substance list should not only be based on "substances placed on the market" but should also consider substances generated in processes like dust, diesel engine emissions and "legacy" substances (e.g. asbestos). In this context, there was a general agreement on the importance of expert judgement.

Beside the scoring system, it might be a possibility to set up a list of pilot substances, which are the most prominent representatives from different areas (i.e. placed on the market, generated in processes, legacy) and for which it is known that good data is available.

**Summary Working Group 3:** Model Development

The use of a modular approach (splitting the estimation of e.g. exposure heights or number of exposed workers into independent modules) was received well by the participants. However, the link between these modules should be considered at an early stage in the development. When estimating the level of exposure a reasonable worst case estimate should be aimed for. For taking differences between the regions in Europe into account an approach of grouping regions with similar exposure patterns into zones (similar to the approach in the pesticide regulation) should be investigated.

An extrapolation of the Finnish JEM has been tried by various countries and was deemed to be too simplistic.

**Summary Working Group 4: Features of a future database**

The participants recommended considering the target groups of the databases. Will it be only qualified experts or should also groups with limited expertise be considered as addressees? Such a decision sets the background for the presentation and the level of detail in explanations of the presented data. This question is closely connected to the overall objective, a clear definition of the purpose was also strongly recommended.

A part of the discussion was related to the access issue: How will the European database get access to data, will it function as an interface or portal to national data sources, or will it have data of its own?

Harmonisation of data quality and data presentation between the different sources is also seen as a prerequisite for an effective and user friendly database. That of course depends on the selec-

tion of presented data. Which data will be presented, only measurement data, information on the context, measuring technologies, risk management measures, etc..

The consortium and EU DG EMPL should also consider long term prospects of the database and interests of the national data owners. What can be their interest to submit data to a European level – short term and long term?

A description of the workshop is attached in Annex 19.

## 7.4 Summary and findings

The aim of the stakeholder workshop was to receive feedback on the interim results of the project from a wider audience of interested stakeholders. The workshop took place on June 2015. 42 representatives European Commission, national governments, employers' and workers' associations, data source providers, exposure measurement experts and exposure model experts participated in the workshop. The workshop demonstrated the high interest of many stakeholders in the development of such European Exposure database.

The participants were informed in four working groups about the project and asked for their expert opinion. The topics of the working groups covered important issues for the database development:

- Accessibility and quality of data
- Relevant substances for occupational exposure
- Models for the estimation of the number of exposed workers and for the level of exposure
- Features of a future

Intensive discussions took place in the working groups and the project team got many useful feedback and recommendations.

The main doubts concerned the quality of data, the comparability, and the access and confidentiality problems. Transparency, a clear picture of the intended use and a sound decision about the future host of the database were seen as crucial for a European exposure database.

Concerning workplace relevant substances for the exposure database, the participants recommended that they should not only be based on "substances placed on the market" but should also consider substances generated in processes like dust, diesel engine emissions and "legacy" substances (e.g. asbestos) The participants recommended considering the target group of the database and the interest of national database owner to submit data for long term to a European Exposure database. A clear definition of the purpose of such a database was also strongly recommended.

The workshop provided many useful ideas and information and was very helpful for the development of the pilot database.

# 8 Work package 7: Practical implementation of the database - conclusions and recommendations

## 8.1 Aim of the work package

The aim of this work package was to illustrate how the database functions, to identify practical constraints and to identify subsequent actions for the future.

## 8.2 List of chemicals relevant for workplaces

The relative ranking of substances has been performed and described in Work package 2. The approach follows a stepwise scoring system. According to the methodology the selected substances were narrowed from over 5000 to 100. A particular problem is the alignment between REACH data and other data sources on occupational exposure. The proposal for a ranking methodology aims at an integration of the best available data. Expert judgement can be used to ensure the relevance of the selected substances. One major conclusion surely is that only one data source is not sufficient to perform such a ranking. Public ECHA data can be used for a first selection, but some relevant dangerous substances are not covered by REACH (asbestos, wood dust, diesel engine emissions, welding fumes, respirable crystalline silica).

However, data provider did not necessarily stick to the proposed list. Other substances were accepted in order to have more data for the HazChem@Work test phase.

## 8.3 Availability of data

There is an enormous variety of data collection approaches between the European Member States. The variety has its background in diverse national infrastructures, resources for such data collection and overall political frameworks.

- Data are recorded by enterprises and submitted to public institutions or social insurances on a voluntary or mandatory base. Such data can be measurements, use of certain substances or exposure to certain substances including process generated substances.
- The measurements are performed by public institutions either in the frame of inspections or focused inspection projects or on request by the companies.

According to the HazChem@Work survey national data providers collect their databased on diverse political mostly legal obligations (figure 13). The legal basis for data collection is mainly national or European legislation; in the UK also some voluntary initiatives can be found.

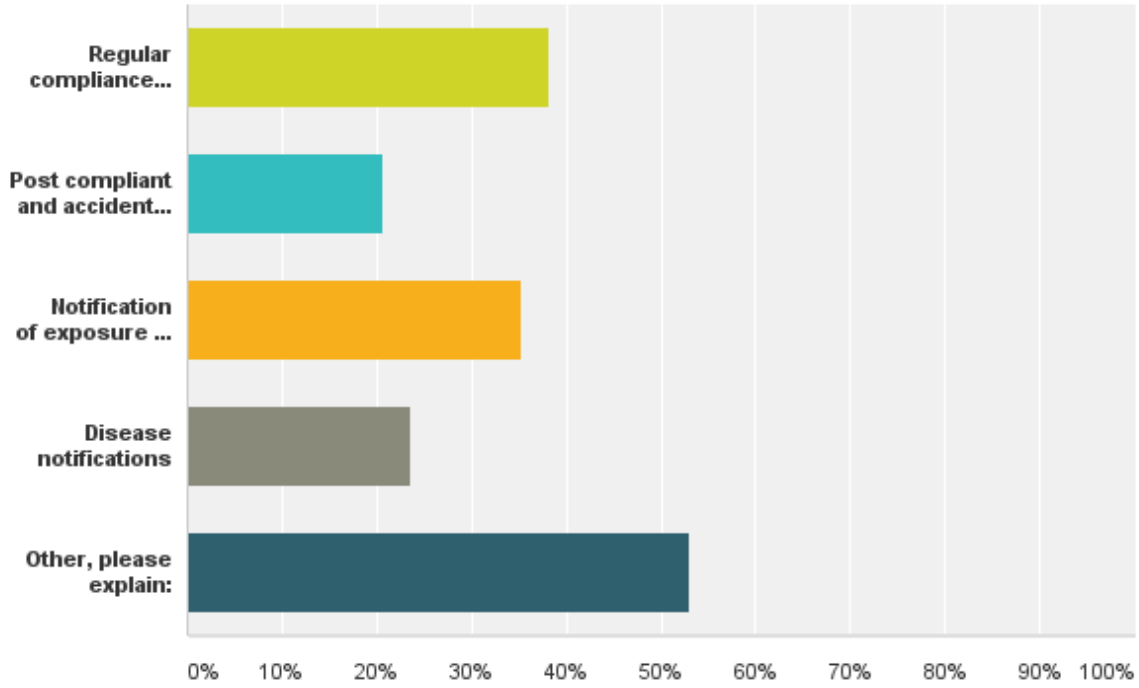


**Figure 13: Graph illustrating the relative distribution of answers related to the reason of data collection.**

Notification of exposure due to legal requirements and the regular compliance monitoring are the main reasons for collecting data (Figure 13). Other reasons include disease notification and post compliant and accident check. Other reasons mentioned in the HazChem@Work survey were among others:

- *Research and surveillance*
- *Supervision and control regarding the chemical substances and preparations to prevent accidents*
- *Generating/compiling statistics for the authorities*
- *Planning and exercising inspections of importers, manufacturers and sellers of chemical products*
- *Monitor incidence and trends in incidence of work-related ill-health*

Within the scope of the survey about 145 identified contacts of institutions were addressed and asked to fill in the questionnaire. 40 institutions/database providers participated in the survey (WP1). 25 exposure data sources (69%), 6 production and use data sources (17%) and 5 disease data sources (14%) have been identified during the survey.

Finally eight data providers supported the development of the test database by submitting 1397 data sets from 204 substances. Three database providers are still discussing a possible contribution to the HazChem@Work database. In total the consortium estimates that between 80 and 100 institutions in Europe have relevant sets of data. Moreover larger enterprises obtain such data sets but these are not made public. Several telephone conferences took place to discuss with ECHA a possible cooperation and use of data provided through the registration dossiers. Unfortunately, it was not possible for the project team to get the possibility to check the registra-

tion dossiers and to extract data for the HazChem@Work database. The main reason were confidentiality and intellectual property rights of the data provided in the dossiers. An automatically distinction between confidential data and other data in the registration dossiers was not possible (see also chapter 8.3.1 Constraints of data provision).

The existence of data depends very much on legal requirements for that type of data, the Community and local policy in the field and on other factors such as economic development, or general cultural aspects.

The project revealed that even when there is a legal indication that some type of data should be generated and collected, like in the case of the provisions of article 6 of the CMD, this does not always happen, for various reasons. For example:

- the companies have not been requested by authorities to do it;
- the data format is not clear,
- authorities have not decided how to centralise it and use it further

It appears that if the EU or national legislation is not clear in making a type of data compulsory there will be a shortage off such information.

The survey and the data received for the database show that even when companies do make measurements, substances for which hazards are more severe, like carcinogens, are not very numerous, as it would be expected considering their risks. It could be they are reluctant to revealing high exposures that would need measures, or they are not willing to pay more for these analyses which may be more expensive, or they are not fully aware of the risks. If authorities do not specifically ask for such data or if they do not have their own monitoring programmes, such data may remain scarce. When it exists it may not be made available for third part users.

**Recommendations to enhance the availability of data:**

A long term common development and negotiation with data provider will be necessary.

- Start negotiation with currant provider
- Use the EU-OSHA campaign 2017 to motivate data provider
- Expand the database and create a possibility for companies to submit information required by CMD Art 6

### 8.3.1 Constrains of data provision

The main reasons for restrictions and reservations towards a submission of data to a European database can be allocated to four major categories:

- Legal constraints
- Concerns about adequate treatment and processing of data
- The need for manual adaptation of own data to a common format
- Language differences

**Legal constraints**

A first and major hindrance to submit data from national sources to a European database are data protection rules.

There are legal constraints based on ownership rights. These rights are often shared between the enterprise and the institutions performing the measurement, collecting and storing the data. Enterprises and data providers have to agree on the publication and confidentiality regulations

in detail. The more exposure measurements would be carried out due to inspection demands, the less ownership rights would remain with the enterprises.

However, the purpose of the HazChem@Work test database is not to have a background for inspections but for a better European overview on exposure levels to dangerous substances. This does not require access to the names of companies. Testing the HazChem@Work database the consortium partners never asked for names of companies. It was always communicated that HazChem@Work is not a database to support the inspection of enterprises, but to receive an overview about exposure situations at work places.

Personal data protection – names of the workers who were involved in the working tasks during the measurements – again play no role for the development of HazChem@Work. To our knowledge even the internal data files for the recording of the measurement don't contain names of workers.

A further legal constraint can be the obligation in the founding rules to keep all data well protected including strict binding data protection rules.

**Concerns about adequate treatment and processing of data**

A second reason was clearly related to the cautiousness of the data providers to let their data be used by other institutions and be presented in a different way and context. The preparation of publication is out of their reach. They fear that if the information will be displayed in another context, important information might get lost, explanations will be missing and consequently their data can easily be misinterpreted. Moreover the test character of the database might have been a further reason not to submit data. To overcome such a restricted collaboration a long-term common development with data providers seems to be the only adequate way.

The consortium took part in the opening of the IPChem database in October 2015 in Brussels (see: https://ec.europa.eu/jrc/en/event/conference/ipchem). The aim of IPChem is the provision of European data on chemicals in the environment based on national data (https://ipchem.jrc.ec.europa.eu/RDSIdiscovery/ipchem/index.html). Many similar concerns were expressed by the data providers or staff from the JRC or DG Environment who were involved into these negotiations. Often only the detailed negotiations about the contract – after principal agreements on collaboration - lasted two years, the whole development five years.

The European Environment Agency has also established a permanent network of national data suppliers, called EIONET, the European environment information and observation network (see: http://www.eea.europa.eu/about-us/countries-and-eionet, and: http://www.eionet.europa.eu/partners )

(an example of data visualisation: http://www.eea.europa.eu/data-and-maps/indicators/hazardous-substances-in-marine-organisms/hazardous-substances-in-marine-organisms-1)

**The need for manual adaptation of the own data to a common format**

Data provided in an Excel or similar format can easily be transferred to the HazChem@Work database. The consortium developed an Excel Sheet of six chapters and overall more than 86 columns (See Annex 10). This large size was necessary to cover the diversity of the measurements and data in the national data sets.

It may require a significant amount of manual work for data providers to adapt their data according to the Excel table. Personal or financial resources to adapt data for a European Exposure database will be unavoidable.

Manual adaptation has been done by the consortium members for their own data or for the data of some of the providers.

**Recommendations:**

Take into consideration to compensate database owner for their work.

**Language differences**

Many databases have a long tradition and fulfil their purpose on national level. An English version however, was not foreseen and therefore is not available. This is a particular problem for columns with free text input (e.g. risk management measures, contextual data such as work history, workplace conditions).

**Recommendations**

This problem could be solved, if database provider would use inter-national coding like NACE, ISCO, ICD10 or others used for REACH registration. An additional advantage of coding would be that HazChem@Work could be easily translated in the EU Member State languages.

### 8.3.2 Constraints of using data from REACH registration

After several teleconferences and the exchange of messages between the consortium and ECHA representatives over the possibilities to use REACH registered data in the project and later in the future the following have been communicated by ECHA.

When the data is an information requirement under REACH, it usually has a dedicated data field in the registration dossier if it is relevant for that tonnage band. For data extraction, it is easier to perform searches on the fields in the dossier itself, than in attachments, which consist of free text format. Free field text can be extracted, but needs to be analysed individually. If the data is not required but optional under REACH, then it might not be present for all substances.

**Exposure and contextual data**

According to REACH Art 14 registrants have, under certain conditions, to perform a chemical safety assessment, which includes human health hazard assessment. A part of the risk assessment is related to occupational health for professional use and use at industrial sites. It needs to be noted that REACH only requires registrants of substances to submit measured exposure data if they have been used for the exposure assessment to demonstrate safe use. The exposure assessment is often based on estimates derived from modelling tools, and therefore not relevant for this project.

With regard to conditions of use e.g. duration, frequency, PPE, ventilation, etc., these are also reported as part of the Chemical Safety Report CSR. The latest IUCLID version 6 has improved the structured fields in IUCLID for this information but as mentioned before, it is not mandatory to provide these data.

It is foreseen that available information on exposure, like measured data, exposure estimates and related conditions of use, will be disseminated on the ECHA website in the course of next year. This information will only be disseminated where registrants have provided it voluntarily in a structured way in IUCLID.

**Production and use of chemicals**

ECHA has information where the production site(s) is located and how much is produced, but this information is considered confidential and therefore it is never published. The total tonnage by substances (joint registration) is provided in the disseminated information as a tonnage band. Data on tonnages per uses is not mandatory, and is provided if the registrant considers it useful for the registration.

**Medical or adverse effect data and adverse effects**

Medical or adverse effect data is not collected under REACH in the way indicated in the specifications. For instance what kind of a worker (in a sociological or ethnical aspect) is exposed to the chemical or how often accidents have taken place, is not recorded in the registration.

**Outcome of ECHA investigation**

Based on the data requested for the project and data submitted under the REACH legislation, it was concluded that the REACH registration is not the vehicle that systematically collects this kind of data, as it is for the most part not a requirement under REACH. Some of the requested data can be submitted voluntarily in a structured or unstructured manner, but it has not been submitted for the majority of dossiers and individual analysis is required for each of the e.g. free text fields. ECHA publishes most of the database with information on chemicals, excluding the limited confidential data.

Additional information which may be of interest to the project as conditions of use, or the presence of measured data, as well as exposure estimates is planned to be published in future updates of the disseminated information.

## 8.4 Quality, representativity and comparability of data

There is an enormous variety of data collection approaches between the European Member States. The variety has its background in diverse national infrastructures, resources for such data collection and overall political frameworks.

- Data are recorded by enterprises and submitted to public institutions or social insurances on a voluntary or mandatory base. Such data can be measurements, use of certain substances or exposure to certain substances including process generated substances.
- The measurements are performed by public institutions either in the frame of inspections or focused inspection projects or on request by the companies.

This variability is also reflected in the quality, representativity and comparability of the data in the Hazchem@Work database.

**Quality of data**

Generating data like those in HazChem@Work involves complex processes in which technical, procedural, legal and expertise related aspects have significant impact on the results.

Technical infrastructure, the methods used, the sampling strategies, the transportation and processing of samples, the processing of raw data into final results or the human error are well known factors that influence all measurements. There is also contextual information that needs to be considered.

For statistical data there are also factors that influence significantly the results: the definitions and categorisations used for various types of data, collecting information, (under)reporting are just some examples.

Quality control of such data is hard to manage for all the input providers that work independently, according to their own procedures.

Improving data quality is possible but the effort to do it may not always pay off, moreover this may eliminate a considerable amount of existing data, which is not necessarily of low quality, but for which quality cannot be assigned to a certain level based on available information..

Since HazChem@Work is, at least at this stage, an instrument that is not replacing the ones already existing at international and especially at national level, high non- homogeneity of data collected from such sources is inevitable and the users have to be made aware of it.

HazChem@Work database specifies the methods used and the type of provider of information; the user may have a very broad idea on the quality the data may have based on these elements, but not more. Users could be able to select only data from authorities or accredited bodies or only standardised methods; how much will this influence the level of quality cannot be estimated.

**Representativity**

The limited number of available data and the various strategies of sampling affect the representativity of data collected compared to the larger groups that data is part of: workplace, task, sector, and country. Any interpretation of data should consider this aspect and extrapolating /generalising results should be avoided.

**Comparability of data**

The comparability of the data is highly affected by numerous factors that are practically impossible to control in case of various data providers collaborating voluntarily and informally, as is the case with the current HazChem@Work database.

The quality control, as presented above, is a major factor that impacts comparability. Processing the values and aggregating them in different ways can highly impact the comparability of data.

There is also contextual information that may interfere, like the situation at the sampling point and the objective of the measurement, as some studies show. Measurements made for legal compliance, during campaigns or for preventive reasons led to differences in results.

Policy factors have their influence, some countries being more (pro)active than others in establishing systems that generate and compile data regarding the use of chemicals and the exposure to them.

The fact that in various years data may be generated in different conditions (like when enterprises/workplaces surveyed for the same country and sector, were not the same in different years) impede comparability in time. Beside this there is inherent variability between sectors, countries and even regions that need to be taken into consideration when comparing data.

For each substance, the user of HazChem@Work database will be able to indicatively compare data by country, sector or year. The interpretation of such data should carefully consider the limitations described above.

During the test of the database the consortium has encountered numerous punctual problems:

- Names of the substances, were different, wrong, not corresponding to CAS/EC numbers or not translated
- Names of process generated substances were different; different definitions and types of dust or of complex hydrocarbon mixtures were used.

- Different duration and frequency of the exposure (short-term, task- and shift related exposure measurements)
- Measuring methods, were not unitary or vaguely indicated
- Differences in the type of measurements: personal inhalation, area sampler, dermal sampler
- Different sampling methods (duration of sampling, carrier etc.)Results of measurements are in ppm, mg/m3, mg/l and so forth
- Different measurement results/units of central tendency (peak, minimum, or average value, percentiles (10, 50, 90, 95)
- Context information had probably the highest variety
- National sector descriptions were inconsistent
- Information of production and use and information on diseases is never combined in one source database etc.

As a result of the test phase some of the problems mentioned were already solved manually.

Sectors may also have different coding or national descriptions. A standardised coding (NACE) would be beneficial.

Some database providers have aggregated data, others single measurements. The HazChem@Work database differentiates between aggregated data and single measurements. The user can filter accordingly.

For the pilot database the project team asked for the measurement method and provided a short explanation that can be obtained by clicking on the question mark.

**Preliminary solutions in the test database and recommendations**

As mentioned a lot of the problems encountered when inspecting data provided, were manually solved by the consortium.

A methodology was elaborated and is published for the users in the database as well as at the website, to inform them on how to fill in the data, the meaning of each field and its relations to other sections, when applicable. The users will be made aware of the possibilities and limitations of the database (Annex 11).

To improve the comparability of data the project team defined mandatory fields for data provision. Filters were introduced to improve comparability, e.g. filter for raw data and aggregated data. The team recommends to use mainly standardised coding and drop down lists.

To improve the quality of data, quality criteria could be used to filter data for example to select only measurements according to standardised methods, or performed by accredited bodies/authorities.

After testing a large variety of fields the database could give up some of them that have not proved useful during the tests (e.g. individual data like age) and detail further some others, like the type of average in which results are presented.

## 8.5 Estimating prevalence and level of occupational exposure

The IT-extrapolation tools related to the estimation of the product volumes and the number of exposed workers will very probably only function if specific calculation algorithms and confounding factors according to the specifics of a substance and its use and exposure patterns are applied.

It will not be possible to apply one extrapolation method to different substances. Even for very similar substances regional and national differences can be strong, e.g. for different types of wood dust. It might be that only a few substances with similar use and exposure pattern can be grouped.

The development of a HAZCHEM@WORK JEM included in the HazChem@Work IT-Tool for the assessment at EU-Level could consist of the following IT-based and partly automatised steps:

1. Establish a list of substances for which exposure will be assessed.
2. Establish the sector and occupational classifications and codes (NACE digit codes could be used for sector and ISCO for occupations.)
3. Comparison to the systems used by other JEMs could allow cross-checking and further competition of data.
4. Screen the use of the substances in 1 according to information from REACH registration (Sector of Use SU), other JEMS and databases - SPIN, COLCHIC, CARE, etc.
5. Obtain statistical data at EU level from EUROSTAT, LFS, for the level of sector/ occupation description established at 2 and for the sectors/occupation where substances in 1 are used. Stratify for gender, age etc.
6. Include expert judgment on exposure. Prevalence of exposed could be assessed based on forms collecting and structuring data, using quantitative or Yes/no scoring etc.
7. Adjust EU results to national using statistical data on population, and occupation product registries.

The HazChem@Work database provides a modular guideline to support users who are tasked with quantifying worker populations exposed to hazardous substances in Europe. Three examples support the user by showing the way to use the guideline.

**Exposure assessment models**

Stoffenmanager and the EMKG-Expo-Tool both show decent values regarding the degree of conservatism, with ECETOC TRA v3 performing slightly worse for powder handling scenarios and moderately worse for handling of volatile liquids scenarios.

Being the best model in correlation coefficients and also being sufficiently conservative for more than 80% of scenarios (75$^{th}$ percentile) scenarios, Stoffenmanager seems to fulfil the requirement of a realistic worst case the best.

The only point for consideration is the larger number of parameters needed for coding. ECETOC TRA v3 also shows a good coverage of the requirements and could also be considered, while the limited scope and the output of an exposure band limit the suitability of the EMKG-Expo-Tool for the project.

Another point is the technical integration of the exposure model into the final database. ECETOC TRA v3 is used as a Microsoft Excel document which uses macros to calculate the exposure score. This may complicate the inclusion into the HazChem@Work database structure. Contrarily, Stoffenmanager is used via a web interface. In principle, this interface could be combined

with the HazChem@Work web interface directly. This would provide a simple way of running the data gap model directly from the HazChem@Work final database. However, due to our experiences (data provided) it will be unlikely that HazChem@Work will get the required parameters needed.

**Recommendations**

After further developing the database the need for estimated exposure data should be re-evaluated. If needed an agreement to integrate the estimation model (e.g. Stoffenmanager) and the HazChem@Work database should be made.

## 8.6 Overall recommendations

A European database on hazardous substances at work places is most useful if the majority of national data providers participate in a contractually fixed and organised way. The preparation of such a database requires organisational efforts, individual negotiations and individual technical and organisational solutions with a total of at least 50 providers, i.e. a little more than half of the existing data providers.

Based on the experience with HazChem@Work we expect a period of five years for the development of a well-functioning permanent database on a European level. The essential challenges of such a development phase can now be better specified after testing the feasibility of HazChem@Work.

The political and organisational background of every data source is different. Most of the databases were introduced and developed before the idea of a European occupational safety and health policy and legislation became political and legal reality. For example, one specific feature of the data sets is that - different from many newer environmental and or scientific data sets - only national language versions exist, English versions seem to be a development of the last years.

We see mainly five areas of action:

- Designation of a host
- Negotiation of specific contracts between data providers and the host
- Specific technical and organisational solutions
- Resources to keep the database running
- Collaboration to harmonise terms and definitions

### 8.6.1 Designation of a responsible host

The responsible host for such as database should be an EU-Organisation, be it a General Directorate, an Agency or the Joint Research Centre. The development, permanent update and maintenance of such a database would be an additional task that probably requires organisational and budget changes at the host side and the data providers' side. This would be a highly technical and complex task requiring appropriately skilled and experienced personnel. The findings of the study showed that the designation of a suitable and competent host is an essential pre-condition for any further development of the HazChem@Work database.

Beyond contractual regulations, the development of such a database requires a common understanding of the objectives between the organisation that acts as a central host and the contributors, particularly during the development phase.

### 8.6.2 Negotiation of specific contracts between data providers and the host: tasks, rights and obligations

The providers need individual contractual solutions. The following issues need to be specified:

- Ownership rights and ownership obligations
- Confidentiality
- Technical provision of data
- Quality assurance of data
- Maintenance and update
- Share of responsibilities for quality and maintenance
- Costs for the host/costs for the data provider (contributors)
- Design and functionalities
- Decision making committees or advisory boards

JRC (Joint Research Centre) has developed together with national environmental and scientific organisations and larger projects the database IPChem.[91] These contracts might be used as examples or models.

Negotiations with the currant provider of data for the test phase should be started.

### 8.6.3 Technical and organisational tasks

The automatisation of data transfer is a crucial issue. It might require essential changes on the side of the submitting national organisations. The alternative is a manual input by the host based on the data formats that are delivered. The manual input is an option as long as the number of data is relatively small.

The automatisation of data transfer should also cover translations, at least of the technical terms. For a permanent communication it would be a big ease if main terms can be translated automatically.

In addition to the pure data a number of functions need to be developed that enhance comparability and visualisation. Some proposals can be found in Chapter 5 of this report.

### 8.6.4 Resources to keep the database running

Both the host organisation and the data providers need to restructure or amend their resources to develop such a database and keep it running. The submission of existing data sets to a harmonised and different database structure simply requires adaptations. The coordination and organisation of structured communication requires again personal and financial resources at the host organisation.

The following tasks require resources:

- Specific contracts with every provider: tasks rights and obligations,
- Meetings with data providers, more frequently in the development phase
- Resources for programming of automatisation of submission
- Resources for automatic and manual translation from national languages
- Resources for technical and manual adaptation
- Resources for certain functionalities enhancing comparability and visualisation

[91] https://ec.europa.eu/jrc/sites/jrcsh/files/IPCHEM%20Flyer_13.10.2015.pdf ; Website available at: https://ipchem.jrc.ec.europa.eu/RDSIdiscovery/ipchem/index.html

- Collaboration with Eurostat / ILO / ECHA etc. to implement common terminology for context description (sectors, occupations, processes etc.)
- Resources for coordination and organisation

### 8.6.5 Collaboration to harmonise terms and definitions

A realistic understanding of the work place exposures requires also a harmonised interpretation of the context information. The databases use different terms and definitions for sectors, processes, uses and applications and working tasks. The harmonisation of such terms has partly been done by organisations like Eurostat (for sectors) or ILO (for occupations) by ECHA (for processes and uses) and by SPIN (for applications). Still there is a lot of work to do, e.g., the description work processes that generate dangerous substances.

## 8.7 Outlook

A database like HazChem@Work can be the sound base for political decision making, both for evaluating the effectiveness of existing policy requirements and for assessing the likely impacts of possible new initiatives. Only a structured compilation of the rich data at national level can facilitate such an evidence based decision making. The theoretical option of a broad European measurement programme is not viable.

The long history and complete national framework of the existing databases is the biggest technical, organisational and political challenge for the development of a European database. HazChem@Work has shown the difficulties but also the opportunities if such a European database would become reality, for example: a quick access to measurement data, much better priority setting, a broad base for decisions on actions.

The following table 23 present rough approximations of possible costs associated with further developing the ideas presented in this study report. It is presented to provide an estimation of the order of magnitude of the likely financial impacts of taking this project to the next level.

**Table 26: Financial considerations**

| **Tasks** | **Rough estimate of budget for five years** |
|---|---|
| Specific contracts with every provider: tasks rights and obligations, 20 contracts x 10,000 | Personal / legal advisers: 200,000 € |
| One responsible host at the end (e.g. DG EMPL, EU OSHA, JRC) | |
| Meetings with DB providers, more often in the development phase, later less | 12 meetings x 25,000 €: 300,000 € |
| Resources for programming of automatisation of submission | 20 x 20,000: 400,000 € |
| Resources for translation from national languages | 18 x 5,000: 100,000 € (later automatised) |
| Resources for technical and manual adaptation | 20 x 5,000: 100,000 € (later automatised) |
| Visualisation of European DBM: Exchange and | 250,000 € |

| | |
|---|---|
| development with EEA, ECDC and IPCHEM | |
| Involvement of Eurostat / ILO to implement common terminology for Sectors and Occupations | 50,000 € |
| Resources for coordination and organisation | 5 x 70,000 € x 2 staff: 700,000 € |
| Total | 2,1 m € |

# 9 Project Management

## 9.1 Aim of the project management

The aim of the project management was quality assurance and timely delivery of all project results. A further objective was to ensure that the work process is transparent for the contractor and other involved parties, and to prepare a comprehensive final report.

## 9.2 Project management within the consortium

Communication and collaboration with the member organisations of the consortium was thoroughly organised. A common 'Master-To-Do-List' was prepared by KOOP as coordinator, which compiled the major activities and deliverables for all work packages, along with deadlines and information on the progress of each activity. This list was used for the overall time planning and controlling of the project's progress. More detailed To-Do-Lists are prepared for short term planning, certain activities or after meetings or telephone conferences.

The major way of communication was realised by e-mail exchange. To organise the communication via e-mail, a contact list compiling contact details for each person within the consortium was prepared. E-mail communication was also used to comment on working papers and to agree on final deliverables. The project partners used telephone or video conferences and personal meetings for more strategic and long term discussions.

The first telephone conference was held on the 3rd of June 2014 and focused mainly on administrative issues and preliminary work steps. The first meeting was followed by seven other meetings (face to face meetings as well as teleconferences) during the project to discuss the project's progress. Regular contacts by phone were held between the partners.

During the running time of the project some personnel changes took place at KOOP. End of January 2016 one partner (BAuA) terminated the contract (Nr. VC/2015/0584) and left the consortium. A teleconference between KOOP and BAuA to clarify the status of the tasks performed by BAuA took place end of January. The remaining tasks were taken over by KOOP. The changes did not affect the progress of the project and its results.

The project could be continued and finalised without major problems.

## 9.3 Communication with the DG Employment and reporting

A monitoring committee (MonCom) was installed to support the project comprising members of the tri-partite WPC (Governments' Interest Group, Workers' Interest Group, Employers' Interest Group). Communication with the MonCom was realised through DG EMPL.

In total six meetings were held with the DG Employment in Luxembourg.

On 18 September 2014 the project's kick-off meeting took place in Luxembourg. The documentation of the meeting was included in the Inception Report. A To-Do-List after the kick-off meeting was prepared to document where input from DG EMPL was necessary for the project.

The draft Inception Report was submitted on 18 October 2014, the final version was agreed on 17 December 2014.

The second meeting with DG EMPL and the MonCom took place at 13 May 2015 in Luxembourg at the premises of DG EMPL. Main topic was the discussion of the draft 1st Interim Report and the Workshop (WP 6). The final 1st Interim Report took account of the comments during the meeting and was submitted on June 30, 2015.

A third meeting was held in connection to the workshop, to discuss the organisation of the workshop.

A fourth meeting with DG EMPL took place on 16 December. The meeting was stated to be a provisional meeting between DG EMPL and the contractors, because the MonCom members as well as the responsible DG EMPL project officer could not attend the meeting.

The official meeting on the 2nd Interim Report was scheduled to February 18th. The main topic was the draft 2nd Interim Report and comments on the 2nd Interim Report provided by the MonCom and the continuation of the project after the exit of the consortium partner BAuA.

A teleconference between DG EMPL, KOOP and the subcontractor was carried out 13 June 2016. The contractor informed DG EMPL about the progress and continuation of the project. Deadlines for the final reporting were defined.

In October 5, the contractor presented the project findings to the members of the Working Party on Chemicals, followed by a meeting with DG EMPL.

On 21 October 2016 a teleconference took place with DG EMPL to discuss comments on the draft final report and to define the final steps of the project.

On 1st May KOOP as coordinator applied for an extension of three months until October 22, 2016. The main reason of the application for an extension was that the project's progress depended on the responses and willingness of data providers. It was not expected that the decision process of the database provider would take a very long time. The project team had to wait for internal decisions of the data providers and could not influence the speed of this decision.

An extension of the project of three month was granted by DG EMPL

The mile stones of the project are presented in table 24.

**Table 27: Mile stones of the project**

| Mile stones | Date |
|---|---|
| Kick-off meeting | 18 Sep 2014 |
| Meetings with DG EMPL , incl. two with the Monitoring Committee | 13 May 2015<br>09 June 2015<br>16 Dec 2015<br>18 Feb 2016<br>5 Oct 2016 |
| Website | Dez 2014 |
| Survey | Feb to July 2015 |
| Workshop | 9 June 2015 |
| Opening of the pilot database | 31 Mai 2016 |

## 9.4 Communication with the Subcontractor

The IT-work on the database was subcontracted to Claudia Berg - design & development, an IT-provider with long-standing experience on similar databases. The task of the subcontractor was to develop a database that can be published on the internet and provide the collected and modelled information in a flexible and user-friendly way, which respects data protection rules. Communication and collaboration with the subcontractor were done mainly face to face. The subcontractor presented the progress of the database at the premises of KOOP regularly. In case of questions, the subcontractor was contacted via phone or email. Since December 2015, the subcontractor is located at the premises of KOOP. This ensured a close cooperation and effective communication at all times.

## 9.5 Organisational challenges

Workshop

A workshop to receive feedback on the interim results of the project from a wider audience of interested stakeholders took place in Luxembourg on 9 June 2015.

The administrative and content aspects were conducted by the contractor, in close cooperation with the DG EMPL.

On 9 January 2015 a list with the consortium's proposals for workshop participants has been sent to DG Employment. A first 'save the date' e-mail was sent to 85 possible workshop participants. An official invitation was sent in the middle of April. In total 41 representatives of the European Commission, national governments, employers' and workers' associations, data source providers, exposure measurement experts and exposure model experts participated in the workshop. The contractor organised the workshop and working groups, prepared materials and presentations. Four workshops were organised following issues:

1. Accessibility and quality of data
2. Relevant substances for occupational expo-sure
3. Exposure models
4. Features of a future database

Each working group was chaired by a consortium member or an invited expert. One consortium member per working group was responsible for taking notes.

Survey and data collection

To get an overview of available data sources, a survey questionnaire has been developed and agreed with the DG Employment. The contractor identified relevant data providers and National Authorities and contacted them via email. Only a small amount of the contacted data provider participated in the survey. Some larger data providers (e.g. Matgene, MEGA, Colchic, ASA etc.) did not react and did not complete the questionnaire until the first deadline - middle of February 2015. A reminder was sent to these non-respondents (as well as to others) in the first days of March 2015 with a deadline, middle of March. Still, even after that deadline, some well-known and large providers did not react.

The contractor faced the same problem when asking for data to populate the pilot database. In January 2016, database providers were asked to provide exposure measurement data for the testing phase of HazChem@Work.

Only a few database providers responded. In total 17 database providers answered:

5 database provider sent exposure data

5 database providers had no data requested for HazChem@Work

4 database providers could not provide data because of data ownership reasons

3 database providers still in the decision process.

The expectation to motivate database provider to provide data were clearly higher than data received. To be able to show the functionality of the database the contractor and subcontractor included a demo version with dummy data.

# Annexes

## Annex 1: Questionnaire for survey (separate doc)

This annex can be found in a separate document named 'Annex 1_Questionnaire'.

## Annex 2: Support letter from European Commission for survey (separate doc)

This annex can be found in a separate document named 'Annex 2_Supporting letter European Commission '.

## Annex 3: Letter to database providers for survey (separate doc)

This annex can be found in a separate document named 'Annex 3_Letter to database providers for survey'.

## Annex 4: Contact list for survey and collecting data (separate doc)

This annex can be found in a separate document named 'Annex 4_Contact list for survey_data collection'.

## Annex 5: Overview of data sources

This is a short overview of the data sources for which we received an answer. A more detailed description of these data sources can be found in Annex 7 (separate document).

| Name / title of the data source | Originator / owner of the data source | Time period of data collection and frequency of updates | Language(s) covered in the data source | Geographical area(s) covered in the data source |
|---|---|---|---|---|
| Exposure to carcinogens and work-related cancer: a review of assessment methods | EU-OSHA | Various | English | EU Member States<br>Canada<br>Australia |
| Database of using carcinogens and mutagens chemicals | The labour inspectorate of Estonia | When performing a risk assessment | Estonian | Estonia |
| Organisationsdienst für nachgehende Untersuchungen (ODIN) | ODIN | 1987 until today<br>No regular updates | German | Germany |
| BAuA measurement reports | BAuA | 1996-2007 | German | Germany |
| Messdaten zur Exposition gegenüber Gefahrstoffen am Arbeitsplatz (MEGA) | Institut für Arbeitschtuz der Deutschen Gesetzlichen Unfallversicherung | 1972 until today | German | Germany |
| Colchic | INRS | 1987 until today | French | France |

| Name / title of the data source | Originator / owner of the data source | Time period of data collection and frequency of updates | Language(s) covered in the data source | Geographical area(s) covered in the data source |
|---|---|---|---|---|
| MatEmEsp | University of Valencia<br>University Pompeu Fabra<br>ISTAS | 1995-2006 | Spanish | Spain |
| The Health and Occupation Research (THOR) network | University of Manchester | Either monthly reports or yearly reports<br>The start date of data collection for each scheme was as follows:<br>SWORD 1989<br>EPIDERM 1993<br>OPRA 1996<br>THOR-GP June 2005<br>SIDAW 1996<br>ROI-EPIDERM 2005<br>ROI-SWORD 2005<br>ROI-OPRA 2007<br>THOR-GP in the ROI 2015 | English | United Kingdom<br>Ireland |
| Annual reports of "external services for prevention and protection at work" (ESPP) in Belgium. | The respective ESPP | Yearly updates. | French<br>Dutch | Belgium |
| The database of environmental permits | The Environmental Board of Estonia | Yearly updates | Estonian | Estonia |
| Netherlands Working Conditions Survey | TNO and Statistics Netherlands in collaboration with the Dutch Ministry of Social Affairs and Employment | 2005 until today<br>Yearly updates | Dutch | The Netherlands |

| Name / title of the data source | Originator / owner of the data source | Time period of data collection and frequency of updates | Language(s) covered in the data source | Geographical area(s) covered in the data source |
|---|---|---|---|---|
| ART Database | International consortium of: TNO, IOM, HSL, IRAS, NRCWE, BAuA<br><br>Data owned by institute which collected the data | 1996-2010 | English | Netherlands, UK, Ireland, Germany |
| IMA-Europe Dust Monitoring Database | IMA-Europe, Industrial Minerals Association - Europe | 2001-2014 (ongoing)<br>Updates twice per year (summer and winter) | English | Europe<br>Ukraine<br>Russia<br>Turkey |
| Industrial Injuries Disablement Benefit (IIDB) scheme | Department for Work and Pensions | 1992 until today<br>Yearly updates | English | Great Britain |
| Exposure to lead in Great Britain - Medical Surveillance of blood lead levels in British workers | Health and Safety Executive | Early 1980s until today<br>Yearly Updates | English | Great Britain |
| Asbestos Worker Survey | Health and Safety Executive / Health and Safety Laboratory | 1971 until today | English | Great Britain |
| Biological Monitoring DataBase (BMDB) | Health and Safety Laboratory | 1996 until today<br>Daily updates | English | United Kingdom<br>Small fraction of data covering outside of the UK |
| National Exposure Database (NEDB) | Health and Safety Executive | 1986 until today<br>Very few updates after 1993<br>Specific group of Asbestos measurements from the 1970s and 1980s | English | Great Britain |

| Name / title of the data source | Originator / owner of the data source | Time period of data collection and frequency of updates | Language(s) covered in the data source | Geographical area(s) covered in the data source |
|---|---|---|---|---|
| Prospective Investigation of Pesticide Applicators Health Study (PIPAH) | Health and Safety Executive / Health and Safety Laboratory | 2013 until today Different update frequencies for different parts (baseline data: 5 years, self-reported pesticide use: 1 year) | English | Great Britain |
| Pesticide Users Health Study | Health and Safety Executive / Health and Safety Laboratory | 1998 until 2006 | English | Great Britain |
| The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR) | Health and Safety Executive | 2001 until today | English | Great Britain |
| Annual report on employment and working conditions from private employers | Originator: Authority for Working Conditions (ACT) and Directorate-General of Health (DGS) of Portugal<br>Owner of the data are the private employers surveyed | 2014, yearly updates | Portuguese | Portugal |
| Cyprus Chemicals Registry | Department of Labour Inspection, Ministry of Labour, Welfare and Social Insurance | Data has been collected since 2012 | Greek and English | The Republic of Cyprus |
| Product Register, Denmark | National Working Environment Authority and Environmental Protection Agency | Data collected since 1983. Daily update. Volume mandatory update every second year. | Danish and English | Denmark |

| Name / title of the data source | Originator / owner of the data source | Time period of data collection and frequency of updates | Language(s) covered in the data source | Geographical area(s) covered in the data source |
|---|---|---|---|---|
| Finnish Product Register (KETU) | Tukes/Chemicals department | Starting 1996, 6 000 new notification/year and 6 000 updates to old notifications | Finnish (Swedish) | Finland |
| Latvian Chemicals Database | Republic of Latvia; Holder of Chemicals Database: „Latvian Environment, Geology and Meteorology Centre" State Ltd. (LEGMC) | This database has been established in 2002. Chemicals Database is updated yearly. Every entity producing or introducing (both import and from EU) to the Latvian market any chemical whether as substance or in mixture, have to make an annual Report to Latvian Chemicals Database. | Latvian | Republic of Latvia |
| Work environment measurements database of Workplaces in Latvia | Laboratory of Hygiene and Occupational Diseases (LHOD) of Institute of Occupational Safety and Environmental Health (IOSEH) of Riga Stradins University (RSU) | Since 1996 according to demand of companies – no regular and planned measurements are included in the database if they are not requested by the companies. However there are few companies were measurements are being collected over many years. | Latvian | Republic of Latvia |

| Name / title of the data source | Originator / owner of the data source | Time period of data collection and frequency of updates | Language(s) covered in the data source | Geographical area(s) covered in the data source |
|---|---|---|---|---|
| EXPO | National Institute of Occupational Health (STAMI), Oslo | 1984-2015, Continuously updated | Norwegian | Norway |
| Product Register | Norwegian Environment Agency | 1) Annual report of quantity information.<br>2) Significant changes must be report as soon as such changes arise, independent of the annual report. | Norwegian, some information as chemical name, use-code and industrial code can be given in English | Norway |
| Reporting form MZ-50 | The Chief Sanitary Inspectorate | once a year; in respect to the group of chemical substances; in addition, - detailed report including number of the employees exposed on particular chemical substance is drawn up every three years | Polish | Poland |
| Central Register of Data on Exposure to Carcinogenic or Mutagenic Substances, Mixtures, Agents or Technological Processes | Nofer Institute of Occupational Medicine, Lodz, Poland | Data collected annually from 1999. From 2005 our list of carcinogenic or mutagenic chemical substances is in accordance with EU classification of chemicals (DSD/DPD and CLP). | Polish | Poland |

| Name / title of the data source | Originator / owner of the data source | Time period of data collection and frequency of updates | Language(s) covered in the data source | Geographical area(s) covered in the data source |
|---|---|---|---|---|
| Registry of workers exposed to carcinogens and mutagens | Croatian Institute for Health Protection and Safety at Work/ same as data source owner | Since 2010, updates every month. | Croatian | Republic of Croatia |
| Registry of Safety Data Sheets (SDSs) | Croatian Institute for Toxicology and Anti-doping (CITA) collect data sent by enterprise | Time period - since 2006.Frequency of updates - once a year. | Croatian | Republic of Croatia |
| Register of measured exposure to chemicals in the workplace | The National Institute for R&D on Safety and Health at Work- Alexandru Darabont, Bucharest- INCDPM | data has been collected since 2008 | Romanian | Romania |
| SIGAM | Labour inspection | from 2005, quarterly | Romanian | Romania |
| Incidence of occupational diseases | Ministry of Health | once a year | Romanian | Romania |
| Automatic System of Sorting of Risks (ASTR) | Public Health Authority of the Slovak Republic | Data about occupational exposure are collected till 1995 and the database is updated once in a year. | Slovak | Slovak Republic |

| Name / title of the data source | Originator / owner of the data source | Time period of data collection and frequency of updates | Language(s) covered in the data source | Geographical area(s) covered in the data source |
|---|---|---|---|---|
| Annual report on employment and working conditions from private employers | Originator: Authority for Working Conditions (ACT) and Directorate-General of Health (DGS) of Portugal<br>Owner of the data are the private employers surveyed | Year of compilation is 2014<br>Update frequency is/will be once a year | Portuguese | Portugal<br>Results from Madeira and Azores (Islands) can also be obtained, although they are treated by other Services: Azores: Observatorio do Emprego e Formação Profissional // Madeira: Direção Regional de Estatística da Madeira.3 |
| Foglalkozási betegségek és fokozott expozíciók nyilvántartása/ Registry of occupational diseases and excessive exposures | Office of the Chief Medical Officer (Department of Occupational Health). Usually the case (original data) is reported to the regional labour inspectorate by the physician suspecting the occupational origin of a disease. Data on registered cases is collated at the Office of the Chief Medical Officer. | data is collected continuously and compiled annually. | Hungarian | Hungary |

| Name / title of the data source | Originator / owner of the data source | Time period of data collection and frequency of updates | Language(s) covered in the data source | Geographical area(s) covered in the data source |
|---|---|---|---|---|
| Veszélyes anyagokkal, illetve veszélyes keverékekkel végzett tevékenység bejelentése/ Report on activities with hazardous substances and mixtures | The regional public health body/Employers send the data to the regional public health body. | Reporting is only once and is updated in case the substance/mixture changes. | Hungarian | Hungary |
| Beszámolójelentés a foglalkozás-egészségügyi alapszolgálatok munkájáról (OSAP-1485)/Report on the activities of occupational health services | Office of the Chief Medical Officer (Department of Occupational Health). Original data is sent by occupational health services. Data compiled on national level is sent to the Hungarian Central Statistical Office (KSH). | data is collected annually | Hungarian | Hungary |
| Rákkeltő anyaggal végzett tevékenységek nyilvántartása/Registry of activities with carcinogen substances | The government body responsible for occupational health: Office of the Chief Medical Officer - Department of Occupational Health/The original data on individuals, company and prevention measures are supplied by the employer to the regional inspectorate. Data is collated on national level. | data is updated annually | Hungarian | Hungary |

| Name / title of the data source | Originator / owner of the data source | Time period of data collection and frequency of updates | Language(s) covered in the data source | Geographical area(s) covered in the data source |
|---|---|---|---|---|
| Registry of Persons Occupationally Exposed to Carcinogens (abbreviated as REGEX) | National Institute of Public Health at Prague | 1997 until today; since 2015 mandatory participation of all Regional Public Health Authorities on data collection | Czech | The Czech Republic |

# Annex 6: Descriptive overview of answers to the HazChem@Work questionnaire

For the descriptive overview answers were summarised where appropriate. When original answers are cited the text is presented in italics.

For most multiple choice questions diagrams illustrating the relative distribution of answers are presented along with the available answer options if these are not completely visible as part of the diagrams. The response rate was calculated as the number of respondents who answered the question divided by the number of all respondents (40).

Additionally, Q18, Q19, Q20, Q22 and Q26 illustrate a separation of data sources into three types. Three types or categories of data providers can be differentiated as follow:

- **Exposure data sources** (measurement data, description of context at the work place level, rarely disease or production / consumption data on the level of sectors or states)
- **Production and use data source** (sectoral and national production and use data, no exposure data)
- **Disease data sources** (diseases, occupational diseases, occupations and sectors, rarely exposure data).

## Questionnaire section 2: General information

**Table 1: Overview of answers to Q 2 and Q 3 Original answers are presented. In square brackets additions were made by the contractor for clarification.**

| Q 2. What is the name / title of the data source? | Q 3. Who is the originator / owner of the data source (institution / authority etc.)? |
|---|---|
| Central Register of Data on Exposure to Carcinogenic or Mutagenic Substances, Mixtures, Agents or Technological Processes | Nofer Institute of Occupational Medicine, Lodz, Poland |
| Product Register, Denmark | National Working Environment Authority and Environmental Protection Agency, Denmark |
| Cyprus Chemicals Registry | Department of Labour Inspection, Ministry of Labour, Welfare and Social Insurance |
| Latvian Chemicals Database | Owner of Chemicals Database: Republic of Latvia; Holder of Chemicals Database: „Latvian Environment, Geology and Meteorology Centre" State Ltd. (LEGMC) |
| EXPO | National Institute of Occupational Health (STAMI), Oslo [Norway] |
| The Product Register | Norwegian Environment Agency |
| Reporting form MZ-50 | The Chief Sanitary Inspectorate [Poland] |

| Q 2. What is the name / title of the data source? | Q 3. Who is the originator / owner of the data source (institution / authority etc.)? |
|---|---|
| Automatic System of Sorting of Risks (ASTR) | Public Health Authority of the Slovak Republic |
| Only Registry of workers exposed to carcinogens and mutagens. | Croatian Institute for Health Protection and Safety at Work |
| 1. Database on work accidents at national level 2. Database on occupational diseases at national level | 1. Labour Inspectorate 2."National Center for Monitoring of Community Environmental Risks" from "National Institute for Public Health" [Romania] |
| MatEmESp (Spanish Job-Exposure Matrix) | It was originally developed from University of Valencia, University Pompeu Fabra (Centre for Research in Occupational Health) and ISTAS (Trade Union Institute for Work, Environment and Health), all Spanish institutions. |
| The Health and Occupation Research (THOR) network | University of Manchester [UK] |
| 1. The database of environmental permits; 2. Database of using carcinogenes and mutagenes chemicals (from enterprises) | The Environmental Board; 2. Labour Inspectorate of Estonia |
| 1. Surveillance of Work-related and Occupational Respiratory Disease (SWORD) 2. The Occupational Skin Disease Surveillance (EPIDERM) | The University of Manchester / the Health and Safety Executive [UK] |
| The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR) | The Health and Safety Executive (on behalf of the UK government) |
| Pesticide Users Health Study | Health and Safety Executive [UK] |
| Prospective Investigation of Pesticide Applicators Health Study | Health and Safety Executive [UK] |
| National Exposure Database (NEDB) | The UK Government (Health and Safety Executive) |
| IMA-Europe Dust Monitoring Database | IMA-Europe, Industrial Minerals Association – Europe |
| Industrial Injuries Disablement Benefit (IIDB) scheme | Department for Work and Pensions [UK] |
| Exposure to carcinogens and work-related cancer: a review of assessment methods. Report and summary | EU-OSHA |
| Biological Monitoring DataBase (BMDB) | Health and Safety Laboratory [UK] |

| Q 2. What is the name / title of the data source? | Q 3. Who is the originator / owner of the data source (institution / authority etc.)? |
|---|---|
| Exposure to lead in Great Britain – Medical Surveillance of blood lead levels in British workers | Health and Safety Executive [UK] |
| Asbestos Workers Survey | Health and Safety Executive [UK] |
| ODIN Organisationsdienst für nachgehende Untersuchungen | *ODIN* [Germany] |
| Registry of Safety Data Sheets (SDSs) Registry of manufactured and imported/entered chemicals on Croatian market | Croatian Institute for Toxicology and Anti-doping (CITA) collect data sent by enterprises |
| Netherlands Working Conditions Survey | TNO and Statistics Netherlands, in collaboration with the Ministry of Social Affairs and Employment |
| We do not have a real database, but annual reports of prevention services: Data concerning exposure at the workplace are mostly registered by the "external services for prevention and protection at work" (ESPPs): In order to assure the health and safety of his workers, a Belgian employer can apply to an ESPP (if the employer's "internal service for prevention and protection at work" cannot fulfil all the legally required tasks, which is most often the case). These ESPPs consist of two departments: a department "risk management" and a department "medical surveillance". They generally have several thousands to tens of thousands of companies as clients. By law, these ESPPs have to send yearly an annual report to the Federal Public Service Employment, Labour and Social Dialogue. In this annual report, they have to provide a.o. data about the number of workers exposed to certain individual substances (benzene, asbestos, …), but mostly to categories of substances (e.g. "chromium and its organic compounds"). | The data originate from the external services for prevention and protection at work, and are sent to the Federal Public Service Employment, Labour and Social Dialogue [Belgium]. |
| Finnish Product Register (KETU) | Tukes/Chemicals department |
| Beszámolójelentés a foglalkozás-egészségügyi alapszolgálatok munkájáról (OSAP-1485) Report on the activities of oc- | Országos Tisztifőorvosi Hivatal (Munkahigié-nés és Foglalkozás-egészségügyi Főosztály) Office of the Chief Medical Officer (Depart- |

| Q 2. What is the name / title of the data source? | Q 3. Who is the originator / owner of the data source (institution / authority etc.)? |
|---|---|
| cupational health services [HU] | ment of Occupational Health) |
| Foglalkozási betegségek és fokozott expozíciók nyilvántartása Registry of occupational diseases and excessive exposures [HU] | Országos Tisztifőorvosi Hivatal (Munkahigiénés és Foglalkozás-egészségügyi Főosztály) Office of the Chief Medical Officer (Department of Occupational Health) |
| Veszélyes anyagokkal, illetve veszélyes keverékekkel végzett tevékenység bejelentése Report on activities with hazardous substances and mixtures [HU] | The regional public health body |
| Rákkeltő anyaggal végzett tevékenységek nyilvántartása Registry of activities with carcinogen substances [HU] | Munkahigiénés és foglalkozás-egészségügyi szerv: Országos Tisztifőorvosi Hivatal – Munkahigiénés és Foglalkozás-egészségügyi Főosztály The government body responsible for occupational health: Office of the Chief Medical Officer – Department of Occupational Health |
| The single report, is an anual report with the employment, and working conditions information from private employers. This report has an annex D on health and safety services activity including health and safety information. All the private employers have to submitt this annual report between 16th march and 15th april (informatin regarding the year before) according to Ordinance n.º 55/2010, 21st january. [PT] | Authority for Working Conditions (ACT) and Directorate-General of Health (DGS) The Department of Studies and Strategy of the Ministry of Economy manages the statistical information system in order to simplify the statistical data gathering and processing. |
| SIGAM | Inspectia Muncii |
| Registry of Persons Occupationally Exposed to Carcinogens (abbreviated as REGEX) | National Institute of Public Health at Prague |
| Work environment measurements database of Workplaces in Latvia | Laboratory of Hygiene and Occupational Diseases (LHOD) of Institute of Occupational Safety and Environmental Health (IOSEH) of Riga Stradins University (RSU) |
| ART Database | International consortium of: TNO, IOM, HSL, IRAS, NRCWE, BAuA |
| Register of occupational carcinogens [HU] | Regional labour safety inspectorates and Ministry for National Economy Department of Labour Inspection (OSH), |

Q 4. Who is the owner of the data in the data source?

(Response rate 92.5%)

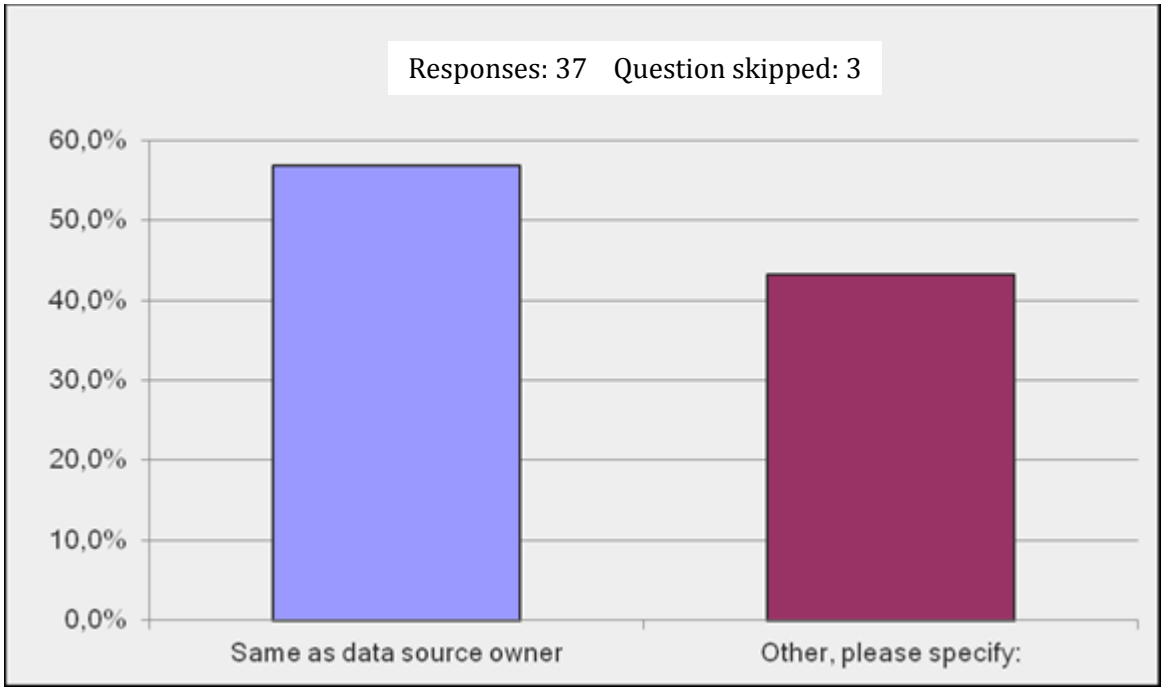


**Figure 1: Graph illustrating the relative distribution of answers to Q 4**

In figure 1 one can find the owners of the data in the data sources compared to the owners of the data sources (and data source names) for those cases where these two owners - owners of the data and owners of the data source - were not identical. In the right column, the data owners are presented as entered in question 4 under 'other, please specify'. In the left and middle columns the corresponding names and originators/owners of the data sources are listed (questions 2 and 3).

**Table 2: Comparison of data owners (Q 4) with names and owners of the data sources (Q 2 and Q 3) Original answers are presented. In square brackets additions were made by the contractor for clarification.**

| Q 2. What is the name / title of the data source? | Q 3. Who is the originator / owner of the data source? | Q 4. Who is the owner of the data in the data source?<br>Other, please specify: |
|---|---|---|
| Central Register of Data on Exposure to Carcinogenic or Mutagenic Substances, Mixtures, Agents or Technological Processes | Nofer Institute of Occupational Medicine, Lodz, Poland | Sanitary Inspection |
| Latvian Chemicals Database | Owner of Chemicals Database: Republic of Latvia; Holder of Chemicals Database: „Latvian Environment, Geology and Meteorology Centre" State Ltd. | Owner of Chemicals Database: Republic of Latvia |

| Q 2. What is the name / title of the data source? | Q 3. Who is the originator / owner of the data source? | Q 4. Who is the owner of the data in the data source?<br>Other, please specify: |
|---|---|---|
| | (LEGMC) | |
| The Product Register | Norwegian Environment Agency | The following directorates and institutes are among the users of data from the Product Register: Norwegian Poison Information Centre, Norwegian Labour Inspection Authority, Norwegian Institute of Public Health. Petroleum Safety Authority Norway, National Institute of Occupational Health, Norwegian Environment Agency, Directorate for Civil Protection and Emergency Planning, Statistics Norway, Norwegian Directorate of Customs and Excise |
| MatEmESp (Spanish Job-Exposure Matrix) | It was originally developed from University of Valencia, University Pompeu Fabra (Centre for Research in Occupational Health) and ISTAS (Trade Union Institute for Work, Environment and Health), all Spanish institutions. | MatEmESp is open access, provided the origin of the data (a project developed by University of Valencia, University Pompeu Fabra (Centre for Research in Occupational Health) and ISTAS (Trade Union Institute for Work, Environment and Health) is recognised in any use/publication. |
| 1. Surveillance of Work-related and Occupational Respiratory Disease (SWORD) 2. The Occupational Skin Disease Surveillance (EPIDERM) | The University of Manchester / the Health and Safety Executive [UK] | The Health and Safety Executive has funded the data collection in SWORD and EPIDERM. SWORD was initiated at the National Heart and Lung Institute in London and has been collective cases reports from consultant chest physicians since 1989. EPIDERM was initiated at the Centre for Occupational and Environmental Health (COEH), the University of Manchester, |

| Q 2. What is the name / title of the data source? | Q 3. Who is the originator / owner of the data source? | Q 4. Who is the owner of the data in the data source?<br>Other, please specify: |
|---|---|---|
| | | and has been collecting case reports from dermatologists since 1993. Both SWORD and EPIDERM are constituent schemes of The Health and Occupational Research network (THOR) currently run from COEH, the University of Manchester. |
| Pesticide Users Health Study | Health and Safety Executive [UK] | Health and Safety Laboratory |
| Prospective Investigation of Pesticide Applicators Health Study | Health and Safety Executive [UK] | Health and Safety Laboratory |
| Exposure to carcinogens and work-related cancer: a review of assessment methods. Report and summary | EU-OSHA | The report provides an overview of data sources that monitor or estimate exposures to carcinogens and non-chemical cancer risk factors |
| Asbestos Workers Survey | Health and Safety Executive [UK] | Health and Safety Laboratory |
| Beszámolójelentés a foglalkozás-egészségügyi alapszolgálatok munkájáról (OSAP-1485)<br>Report on the activities of occupational health services | Országos Tisztifőorvosi Hivatal (Munkahigiénés és Foglalkozás-egészségügyi Főosztály)<br>Office of the Chief Medical Officer (Department of Occupational Health) | Original data is sent by occupational health services. |
| Foglalkozási betegségek és fokozott expozíciók nyilvántartása Registry of occupational diseases and excessive exposures [HU] | Országos Tisztifőorvosi Hivatal (Munkahigiénés és Foglalkozás-egészségügyi Főosztály)<br>Office of the Chief Medical Officer (Department of Occupational Health) | Usually the case (original data) is reported to the regional labour inspectorate by the physician suspecting the occupational origin of a disease. Data on registered cases is collated at the Office of the Chief Medical Officer. |
| Veszélyes anyagokkal, illetve veszélyes keverékekkel végzett tevékenység bejelentése Report on activities with hazardous substances and | The regional public health body | Employers send the data to the regional public health body. |

| Q 2. What is the name / title of the data source? | Q 3. Who is the originator / owner of the data source? | Q 4. Who is the owner of the data in the data source?<br>Other, please specify: |
|---|---|---|
| mixtures [HU] | | |
| Rákkeltő anyaggal végzett tevékenységek nyilvántartása Registry of activities with carcinogen substances [HU] | Munkahigiénés és foglalkozás-egészségügyi szerv: Országos Tisztifőorvosi Hivatal - Munkahigiénés és Foglalkozás-egészségügyi Főosztály<br>The government body responsible for occupational health: Office of the Chief Medical Officer - Department of Occupational Health | The original data on individuals, company and prevention measures are supplied by the employer to the regional inspectorate. Data is collated on national level. |
| The single report is an annual report with the employment, and working conditions information from private employers. This report has an annex D on health and safety services activity including health and safety information. All the private employers have to submit this annual report between 16th march and 15th April (information regarding the year before) according to Ordinance n.º 55/2010, 21st January. [PT] | Authority for Working Conditions (ACT) and Directorate-General of Health (DGS) The Department of Studies and Strategy of the Ministry of Economy manages the statistical information system in order to simplify the statistical data gathering and processing. | Private employers |
| Registry of Persons Occupationally Exposed to Carcinogens (abbreviated as REGEX) | National Institute of Public Health at Prague<br><br>Contact: National Institute of Public Health at Prague<br>Prague 10, Srobarova 48<br>michael.vit@szu.cz | National Institute of Public Health at Prague<br>Prague 10, Srobarova 48<br>michael.vit@szu.cz |
| Work environment measurements database of Workplaces in Latvia | Laboratory of Hygiene and Occupational Diseases (LHOD) of Institute of Occupational Safety and Environmental | Data are owned by the institutes that collected the data. |

| Q 2. What is the name / title of the data source? | Q 3. Who is the originator / owner of the data source? | Q 4. Who is the owner of the data in the data source?<br>Other, please specify: |
|---|---|---|
| | Health (IOSEH) of Riga Stradins University (RSU) | |

**Q 5. What is the legal background of the data collection? Please enter the name of the regulation / legislation.**

The legal basis for data collection is mainly national or European legislation; in the UK also some voluntary initiatives can be found.

**Q 6. For what reason is the data collected? (Response rate: 95%)**

- Regular compliance monitoring
- Post compliant and accident check
- Notification of exposure due to legal requirements
- Disease notifications
- Other, please explain:

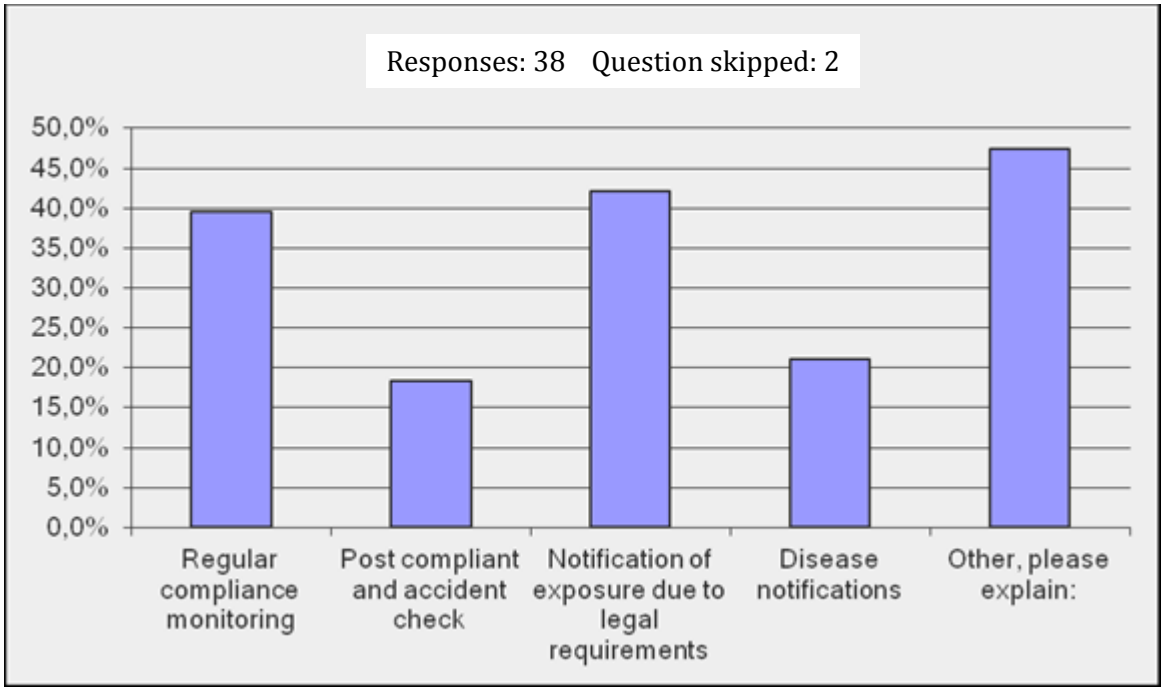


**Figure 2: Graph illustrating the relative distribution of answers to Q 6**

The complete answer options can be found above.

Under 'other' the following explanations were entered:

- The Chemicals Database shall include the information necessary for the elimination of accidents, implementation of supervision and control regarding the chemical substances and preparations used in Latvia.
- Data from the Product Register is used for purposes that include:
  • The authorities' supervision of hazard labelling and chemicals documentation
  • Risk analyses of chemical substances and different areas of use
  • Generating/compiling statistics for the authorities
  • Advice and guidance in connection with acute poisoning
  • Planning and exercising inspections of importers, manufacturers and sellers of chemical products
  • Legislative work
  • International work
- Research and surveillance
- THOR is a surveillance scheme, enabling physicians to voluntarily report cases of work-related illness (WRI) seen during their usual clinical practice. The primary aim is to monitor incidence and trends in incidence of work-related ill-health in the UK and the ROI.THOR comprises a number of different schemes set up to enable different physicians to report. Current schemes are SWORD (chest physicians to report respiratory disease), EPIDERM (dermatologists to report skin disease), OPRA (occupational physicians to report any type of WRI), THOR-GP (general practitioners with the diploma in occupational medicine to report any type of WRI) and SIDAW (consultants in communicable disease control to report infectious disease). THOR is partially funded by the UK HSE and one of the (many) uses of THOR data is to help inform the HSE's annual statistical release on WRI. For those schemes having analogous schemes in the ROI (ROI-SWORD, ROI-EPIDERM, ROI-OPRA and THOR-GP in the ROI), data collection is funded by the ROI Health and Safety Authority.
- The reason of the data collection is to estimate the incidence and incidence rate of work-related respiratory and skin conditions and the associated causal agents in the UK and to monitor their trends over time. [tick box not activated]
- Cohort study to monitor the long-term health of professional/licensed pesticide users
- Cohort study to monitor the health of professional/licensed pesticide users
- Data are collected: i) as part of research work, ii) to inform specific investigations and iii) to inform routine inspections. The intended purpose was: (i) to provide detailed and comprehensive exposure data for setting new occupational exposure limits; (ii) to provide a major source of exposure data for use in epidemiological studies; and (iii) to facilitate dissemination of information on occupational exposures.
- The IMA-Europe exposure database allows to evaluate time trends in exposure to respirable dust and its crystalline silica content and would be useful when studying health effects due to exposure to respirable dust among these workers.
- To summarise how many new cases of occupational disease are occurring for those disease included in the scheme
- The data sources described shortly in the report are used for different purposes incl. prospective exposure and disease burden estimation

- Research into trends, impacts of interventions etc.
- To reduce the incidence of ill health due to occupation exposure to lead
- Cohort study to monitor the health of licensed asbestos workers
- Information on hazardous chemicals in emergency situations and poisoning
- Collecting data in accordance with article 45 of Regulation (EC) No. 1272/2008
- to produce statistics and conduct research
- National chemical statistic

**Q 7. Time period of data collection: Please indicate the year(s) of data compilation and the frequency of updates.**

Data sources cover the time period from 1971-today, frequencies of updates vary from daily to no regular updates.

**Q 8. Which language(s) are covered in the data source?**

**Table 3: Overview of languages covered in the data sources (Q 8)**

| Language(s) | Number of data sources |
|---|---|
| English | 12 |
| Polish | 2 |
| Croatian | 2 |
| Norwegian | 2 (for one some information as chemical name, usecode and industrial code can be given in English) |
| Danish and English | 1 |
| Greek and English | 1 |
| Finnish (Swedish) | 1 |
| French and Dutch | 1 |
| Dutch | 1 |
| Estonian | 1 |
| Latvian | 2 |
| Slovak | 1 |
| Spanish | 1 |
| German | 1 |
| Hungarian | 5 |
| Portuguese | 1 |

| | |
|---|---|
| Romanian | 2 |
| Czech | 1 |

**Q 9. Which geographical area(s) are covered in the data source?**

Below you can find the answers to this question. Multiple identical answers are only mentioned once.

- Belgium
- Denmark
- Europe + Ukraine, Russia and Turkey
- Examples were from selected EU Member States, Canada, Australia
- Finland
- Germany
- Great Britain
- Great Britain and NUTS3
- Majority UK, limited Europe and elsewhere
- Norway
- Poland (the whole country, 16 voivodeships)
- Republic of Croatia
- Republic of Latvia
- Slovak republic
- Spain
- The Netherlands
- The Republic of Cyprus
- UK and the Government Office Regions (GOR)
- United Kingdom and the Republic of Ireland
- whole Estonia
- Hungary
- The data source is National. Results from Madeira and Azores (Islands) can also be obtained, although they are treated by other Services: Azores: Observatorio do Emprego e Formação Profissional // Madeira: Direção Regional de Estatística da Madeira
- Romania
- The Czech Republic
- Netherlands, UK, Ireland, Germany.

**Q 10. Are other statistical sources used as data source (e.g. disease statistics)?**

Answers received for this question were:

- For many data source not.
- NACE
- chemical or occupational disease registers
- deaths, cancers, Hospital Episode Statistics
- Certified occupational diseases (from de Protection Department against professional risks, Social Security Institute)// communications for prohibited substances// notifications of asbestos removal works.

**Q 12. Are there any fees for using the data source?**

Most data sources can be used free of charge, more complex requests may involve some costs.

**Q 13. Are there constraints (others than user fees) for using the data source? (Response rate: 87.5%)**

- No constraints
- There are constraints for using certain parts of the data (e.g. due to confidentiality). Please specify in the text field below.
- Only accessible for specific user groups (e.g. authorities etc.). Please specify in the text field below.
- Other constraints. Please specify in the text field below.
- Please specify your answer, if necessary:

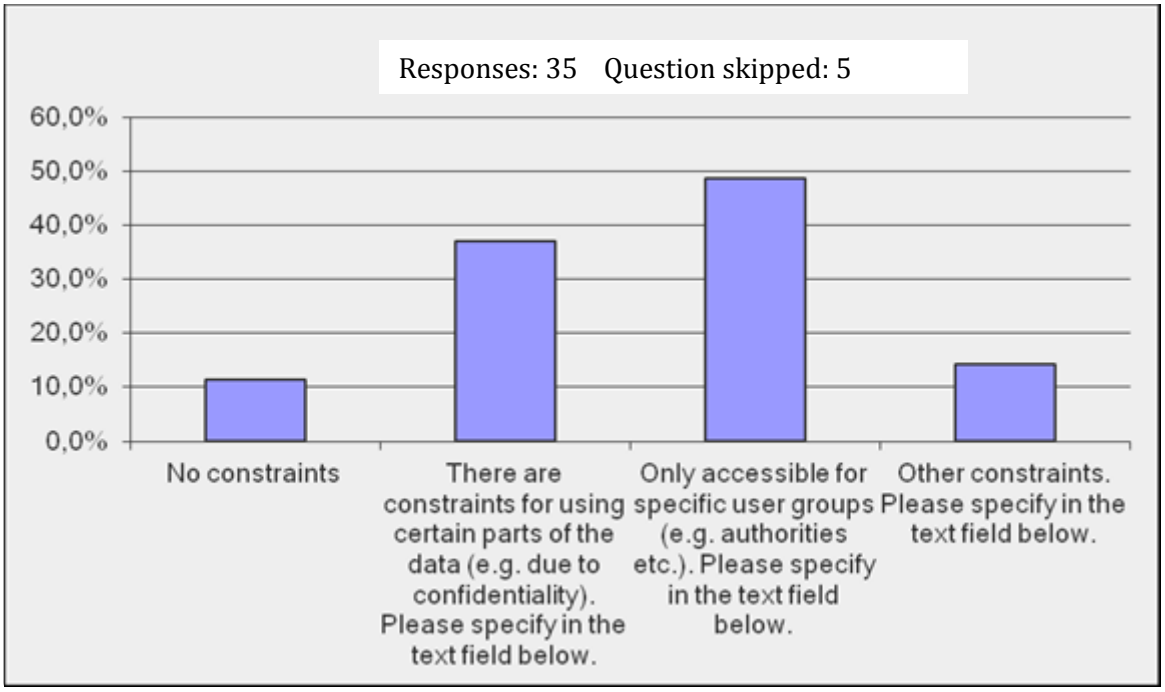


**Figure 3: Graph illustrating the relative distribution of answers to Q 13**

The complete answer options can be found above.

For several data sources access is limited to certain authorities or the data owners. For some data sources only the raw data are not publically accessible. However, anonymised data and non-confidential parts are available for several data sources or yearly data analysis reports are published.

## Questionnaire section 3: Substances / substance groups / mixtures covered in the data source

**Q 14. How many single chemical substances / substance groups / mixtures are covered in the data source?**

Answers varied from one to app. 140,000 substances or substance groups.

**Q 15. Which substance identifiers are used?**

Most providers use the CAS-numbers, 21% also the EC- and 14% the Index-Number. Many other specifications are common, e.g. due to a thematic focus or based on a national classification system. According to one Romanian source search criteria can also be: *Stare lichidã - scurgere, înnoroire, curgere, împroscare, stropire Stare gazoasã - vaporizare, aerosoli, formatiuni gazoase Material pulverizant - fum, praf/particule în suspensie/emisii sau Contact cu substante nocive – pe cale nazalã sau bucalã, prin inhalare Contact cu substante nocive - pe/prin piele sau ochi Contact cu substante nocive – pe cale digestivã prin înghitire sau 67- Contact sau manipulare substanţe toxice 68- Contact sau manipulare substanţe caustice 69- Contact sau manipulare substanţe inflamabile 70- Contact sau manipulare substanţe explozive s.a* [liquid - drain, mud, flowing, splashes, splash gaseous - vapor, aerosols, spray Material gaseous formations - smoke, dust / particulates / or contact with harmful substances emissions - by nasal or buccal inhalation contact with harmful substances - on / through skin or eye contact with harmful substances - about digestive swallowed or 67- contact or manipulation or handling toxic caustic 68- Contact 69- 70- Contact or handling flammable substances - Contact or handling explosives].

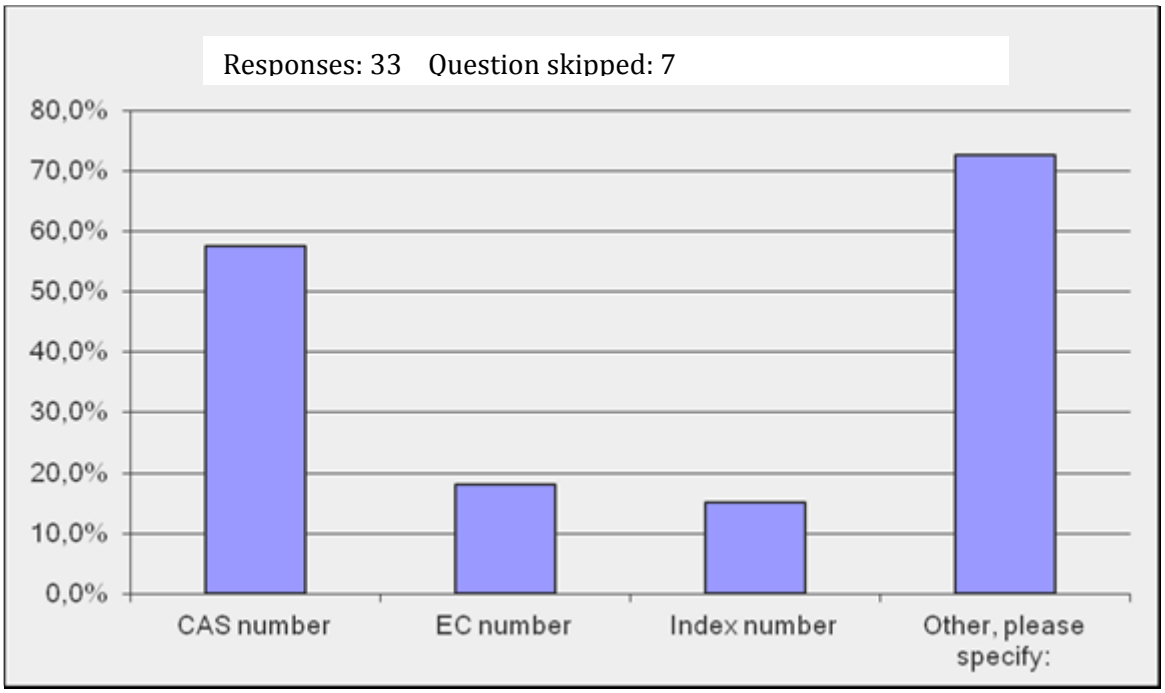


**Figure 4: Graph illustrating the relative distribution of answers to Q 15**

The complete answer options can be found above.

**Q 16. Please specify what type of substances / substance groups / mixtures is covered in the data source?**

Chemical registers often include any kind of substances or mixtures classified as hazardous (according to the CLP Regulation). Some data sources are focused on substance groups like pesticides and biocides, asbestos or minerals (general) dust, quartz, cristobalite and tridymite. More cancer-related data sources mainly include carcinogenic and mutagenic substances (as defined by the CLP Regulation) or more general 'known (but not specific) sensitisers', 'biological agents' and any 'hazard' that may cause occupational cancer. Data sources on occupational exposures cover air concentrations of solvents, inorganic elements, dust, welding fumes, diesel exhaust, silica, oil mist, PAH, inorganic gases, microorganisms, isocyanates, aldehydes, VOC and more as well as biological monitoring of lead in blood and mercury in urine or organic and inorganic substances that are suitable for monitoring using biological monitoring. One data source focuses on substances for which maximum admissible concentrations in the work environment are determined. One data source focuses on gases, vapors, dusts, smoke,aerosol, fibers - air contaminants in inhaled air. One data source focuses on inhalable dust Pyridoxine hydrochloride, Fluticasone propionate, Lactose, Amoxicillin, Cuprous oxide, Copper, Copper(II)oxide, Glyphosate, Chlorpyrifos (cy),Permethrin, Lindane, Cis-delthamethrin, Cyfluthrin, Cocoalkyl dimethylbenzylammonium chloride, Methomyl, Bitertanol, Captan, Glutaraldehyde, NMP, NCO groups, Total hydrocarbons, Arsenic, Benzene, Chromium, Xylene, Methylethylketon, Dichlofluanide, Styrene, Ethanol, Boron, Dimethylketon, Methylethylketon. One data source focuses on petroleum compounds, nickel, chromium compounds, and hardwood.

**Q 17. If applicable please specify the (legal) criteria used for substance inclusion in the data source. (Response rate: 70%)**

- Carcinogens classified according to Regulation (EC) 1272/2008 (CLP Regulation)
- Mutagens classified according to Regulation (EC) 1272/2008
- Substances toxic to reproduction classified according to Regulation (EC) 1272/2008
- Process generated substances (e.g. welding fumes, diesel exhaust emissions etc.)
- Other, please explain:

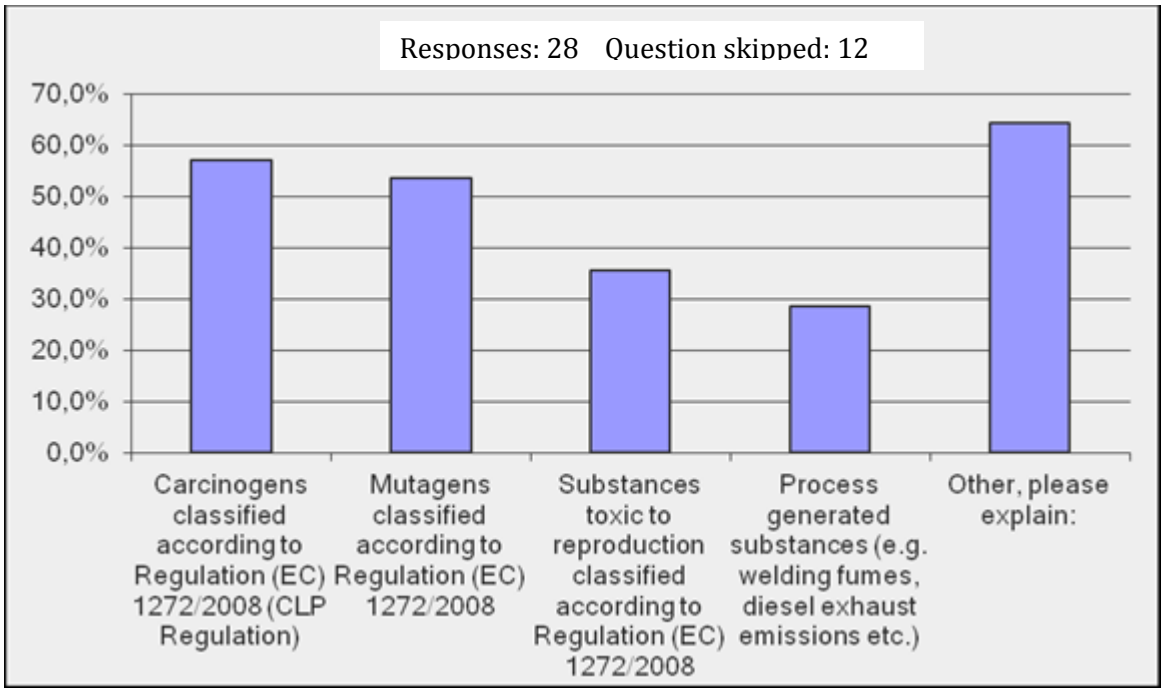


**Figure 5: Graph illustrating the relative distribution of answers to Q 17**

The complete answer options can be found above.

Other legal criteria mentioned were chemical products (substances and mixtures) classified according to the CLP Regulation or art. 31 of the REACH Regulation as well as Directive 2008/50/EC on ambient air quality and cleaner air for Europe, Directive 2010/75/EU on industrial emissions (integrated pollution prevention and control) and Directive 2004/42/EC on the limitation of emissions of volatile organic compounds due to the use of organic solvents in decorative paints and varnishes and vehicle refinishing products.

One data source included substances that in specialist physicians' judgements have caused or aggravated the work-related respiratory conditions (reported in SWORD) and the work-related skin conditions (reported in EPIDERM). More general criteria were chemical agents that pose a risk to workers or customer requests for biological monitoring. One data source included hardwood (oak, beech).

## Questionnaire section 4: Exposure measurement and contextual data at enterprise level

**Q 18. Please specify the type of exposure measurement details and results that can be found in the data source. (Response rate: 72.5%)**

- Measurement method
- Measurand (measured quantity or object)
- Matrix
- Peak values
- Average values

- Airborne measurements
- Bio-monitoring
- Other, please explain:

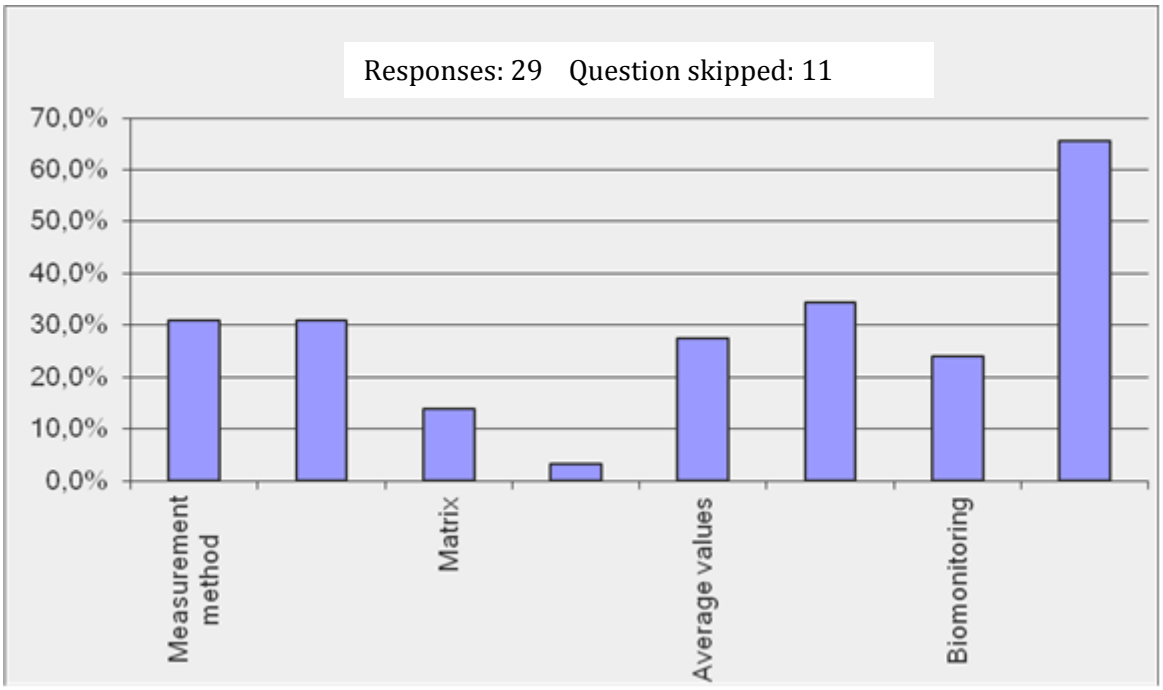


**Figure 6: Graph illustrating the relative distribution of answers to Q 18**

The complete answer options can be found above.

Under 'other' the following explanations were entered:

- ASTR database provides only information about the number of workers in risky professions (i.e. if their occupational exposure limit value has been exceeded). No other information about measurement method, values etc. are included.
- Data from employer: 1) employer's name and address; 2) list of carcinogenic and mutagenic substances, what are used in the enterprise 3) work processes or technologies (description of purpose) 4) quantity of these chemicals 5) number of employees, who work with these chemicals, type of exposure end exposing time; 6) safety measurements, PPE
- Self-reported pesticide use
- Self-reported use of pesticide; frequency and duration of use in previous year.
- Self-reported job (within the asbestos industry)
- The employee indicates whether he or she is exposed never/sometimes/often/Always.
- dermal exposure assessment, if applicable
- Measurement reports annexed, if available.

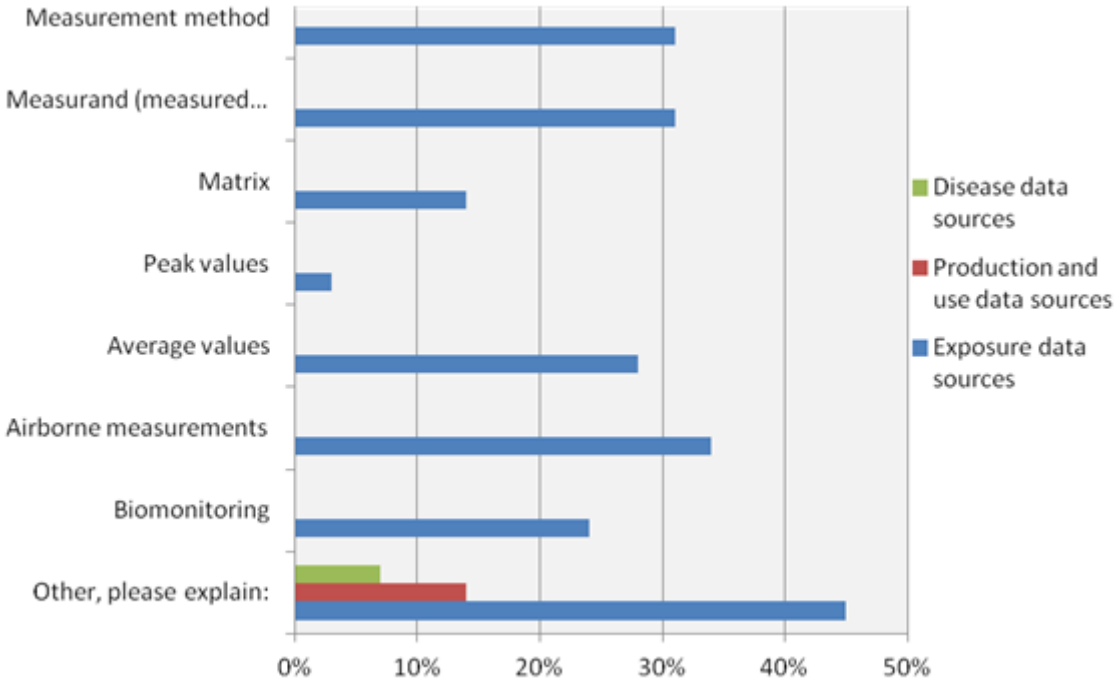


**Figure 7: Graph illustrating the relative distribution of answers to Q 18 with a separation of data sources into three types (Exposure data sources, Production and use data sources, Disease data sources)**

Exposure measurement details and results can be mainly found in the exposure data sources.

**Q19. Which additional information about the work and the work place is provided?** (Response rate: 72.5%)

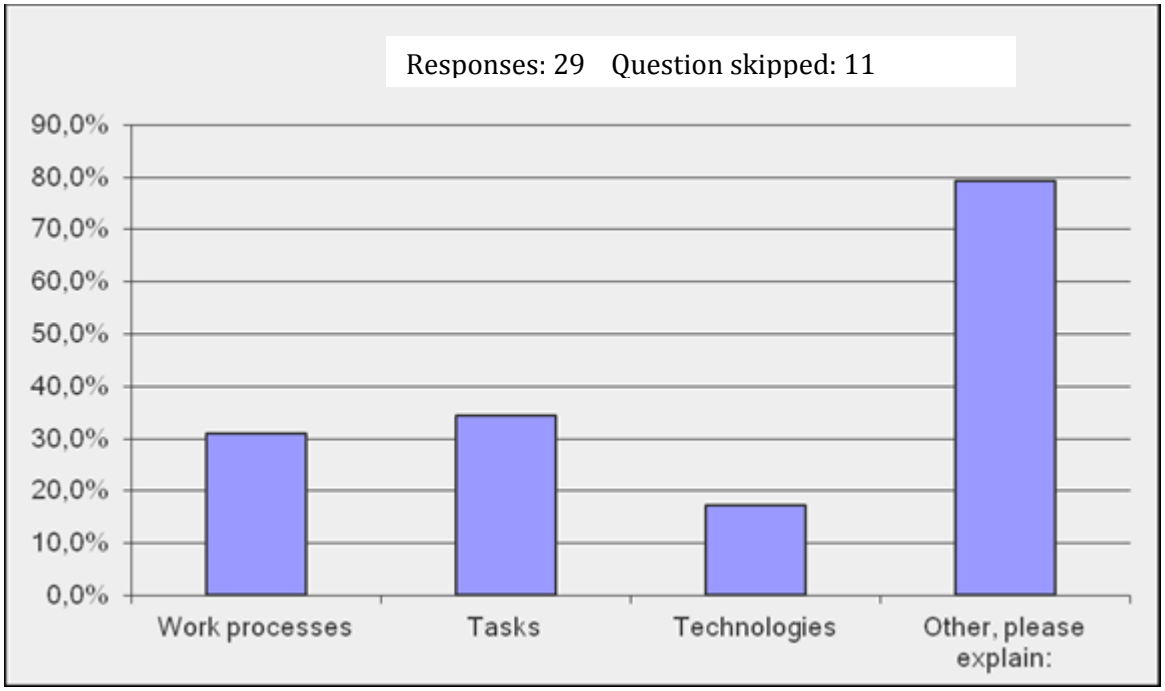


**Figure 8: Graph illustrating the relative distribution of answers to Q 19**

Other information provided includes type of work place, number of workers, route of exposure, average time of exposure, quantity of substance per year/enterprise, profession, enterprise, economic activity, the number of employees, department, working conditions during sampling, risk management measures, method of application and use of personal protective equipment. For one data source information about the types of workplaces, where the maximum admissible concentrations levels of the chemical agents were exceeded, are specified along with information about the administrative order to stop the activity of the particular workplace, section or the whole plant.

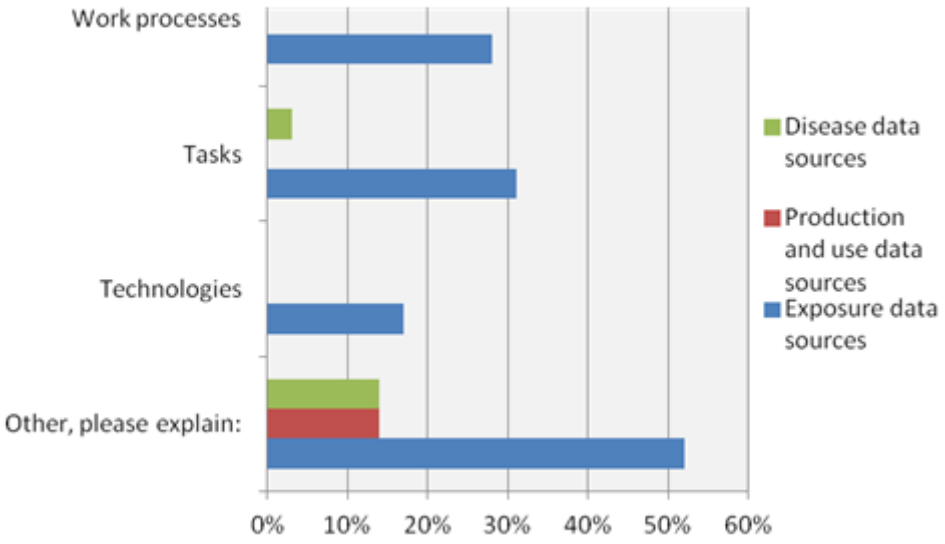


**Figure 9: Graph illustrating the relative distribution of answers to Q 19 with a separation of data sources into three types (Exposure data sources, Production and use data sources, Disease data sources)**

**Q20. Is the number of exposed workers provided? If yes, please specify how this data is processed and / or how it can be retrieved?** (Response rate: 85%)

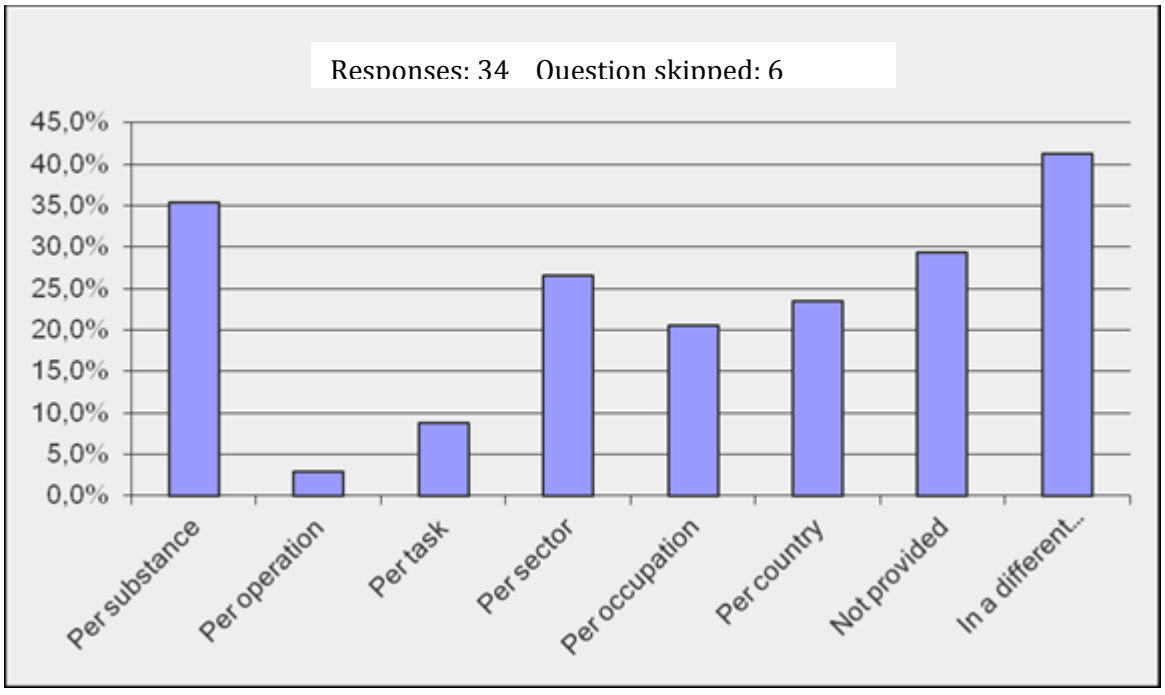


**Figure 10: Graph illustrating the relative distribution of answers to Q 20**

Different ways how the number of workers is provided include numbers per area (eg. voivodship, target organ, region), per participating company site, per prevention measures adopted and per disease. In one data source the number of workers exposed to exceeded limits of the

maximum admissible concentrations of chemicals in the work environment - according to the Polish Classification of Activities - is provided. For another data source the number of exposed workers is estimated based on the number of employed in the country by industry (sector) and occupation which is available from the Office for National Statistics Annual Population Survey (APS). In one data source samples are assigned to individual workers so that the number of workers sampled is known.

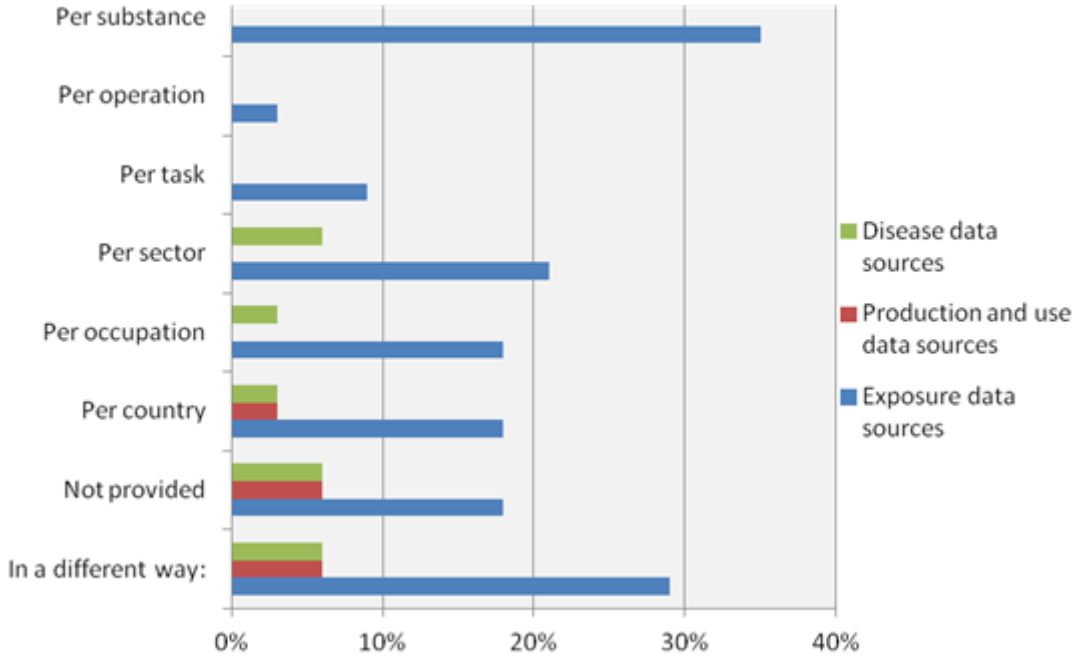


**Figure 11: Graph illustrating the relative distribution of answers to Q 20 with a separation of data sources into three types (Exposure data sources, Production and use data sources, Disease data sources)**

Only some information regarding the number of exposed workers is provided by disease data sources and production and use data sources.

**Q21. Is information on duration and frequency of exposure provided?** (Response rate: 87.5%)

Only for about 23% of the data sources this question was answered with yes, for 40% the answer no was chosen. In 37% of the cases the answer was partly along with the following comments: Mean level of exposure (quantitative, long-term, 1-year average, concentration of exposure to the agent among the exposed workers, according to the usual tasks performed and the working environment for their occupational category) and prevalence of exposure (% of workers in the job code exposed) are the estimations. Very general information on past use of pesticides for the whole cohort and more detailed information on use for a sub-set of the cohort is provided for one data source. One report contains a free-text narrative, which may or may not contain additional details of exposure episodes; there is no legal requirement to provide. For two data sources the questionnaire requests information on frequency and duration covering the previous year and the employee indicates whether he or she is exposed nev-

er/sometimes/often/always. For one data source the time spent in the suspected occupation is reported.

**Q 22. Is information on risk management measures applied / performed provided?** (Response rate: 87.5%)

- Personal protective equipment (PPE)
- Exposure monitoring
- Health surveillance
- Substitution
- Technical measures (e.g. ventilation)
- Organisational measures (e.g. employee training, written working instructions, changes of working procedures)
- No
- Partly, please explain:

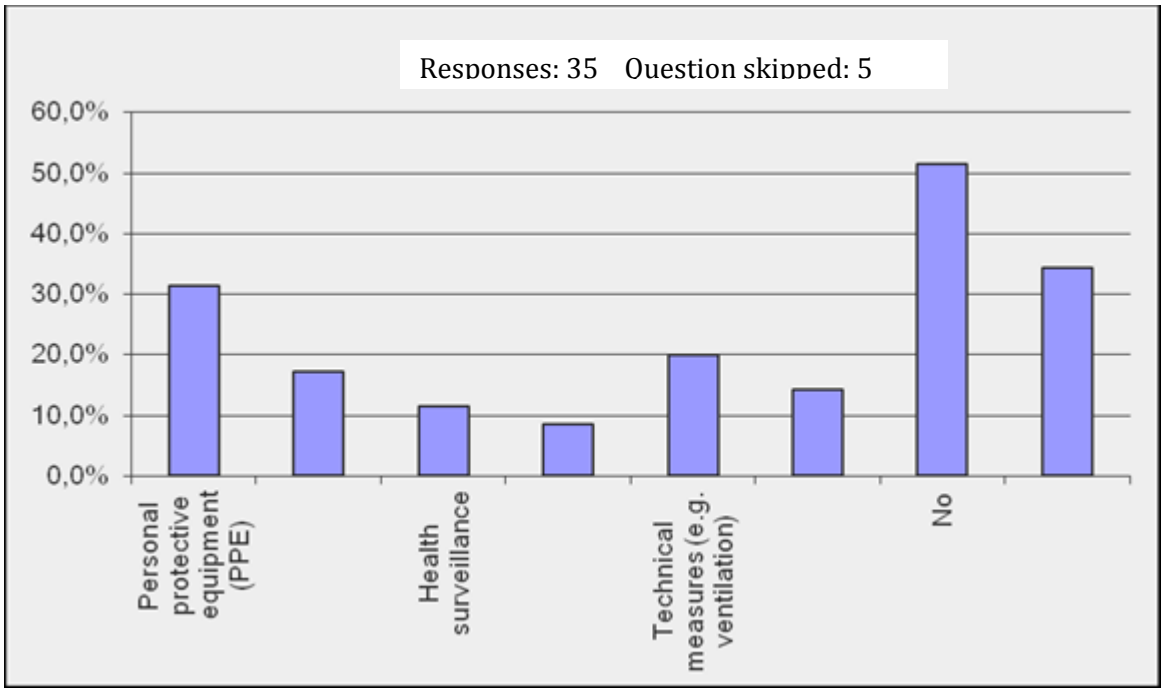


**Figure 12: Graph illustrating the relative distribution of answers to Q 22**

The complete answer options can be found above.

Under 'partly' the following explanations were entered:

- Substitution information is available in some cases.
- Information on risk management measures, arising from the use of the chemical substances is provided.
- Impact to ambient environment.

- Some of the reports made by employers are investigated by labour inspectors (only a minority of reports are actually investigated). An investigation may or may not record risk management procedures.
- Information available for a subset of the cohort.
- If RPE or local exhaust ventilation are provided then this is listed.
- Some research data has PPE and task details recorded but minor component of database.
- The questionnaire asks whether the employee thinks that measures should be taken concerning hazardous substances or concerning viruses/bacteria/mould. The answer categories are: not necessary because it does not apply/not necessary because sufficient measures are already taken / necessary because taken measures are not sufficient/necessary because no measures have been taken yet.
- Besides the risk management measures listed above, others are considered and the Code "oo" exists and stands for no risk management measures applied.

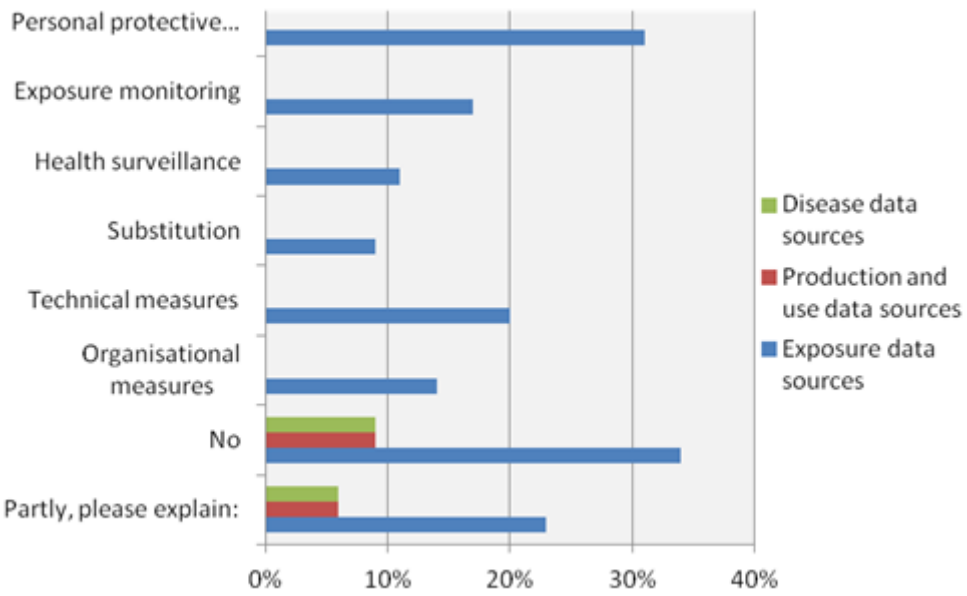


**Figure 13: Graph illustrating the relative distribution of answers to Q 22 with a separation of data sources into three types (Exposure data sources, Production and use data sources, Disease data sources)**

Information on risk management measures can be mainly found in the exposure data sources.

## Questionnaire section 5: Production and use of chemicals at national or EU, EFTA / EEA level

**Q 23. Is the total production provided?** (Response rate: 75%)

For about 17% of the data sources the information is provided at national level (but not at European level), for 80% it is not provided.

**Q 24. Is the consumption provided along with data on export and import?** (Response rate: 72.5%)

For about 10% of the data sources the information is provided at national level (but not at European level), for about 90% it is not provided.

**Q 25. Is information on uses provided? (Response rate: 77.5%)**

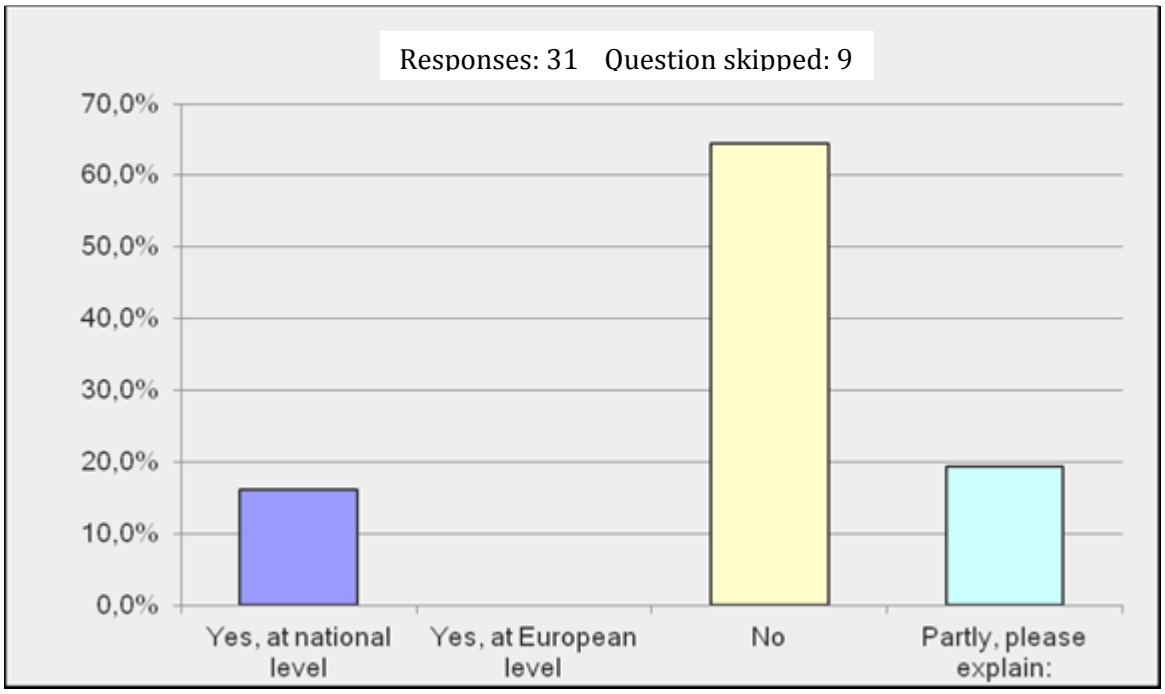


**Figure 14: Graph illustrating the relative distribution of answers to Q 25**

The following explanations were added:

- Each use should be justified by employer.
- Information on uses is provided in the Safety Data Sheets.
- The descriptive report provides an information on the use of substances e.g. in the detergents, or in biocides.
- For some data sources, such information is provided.
- Via the number of people under medical surveillance in specific industrial sectors.

## Questionnaire section 6: Disease data and adverse effects

**Q 26. Which types of diseases are covered in the data source?** (Response rate: 65%)

- List of occupational diseases related to chemicals
- Adverse effects
- Cancer
- All diseases
- Other diseases, please specify:

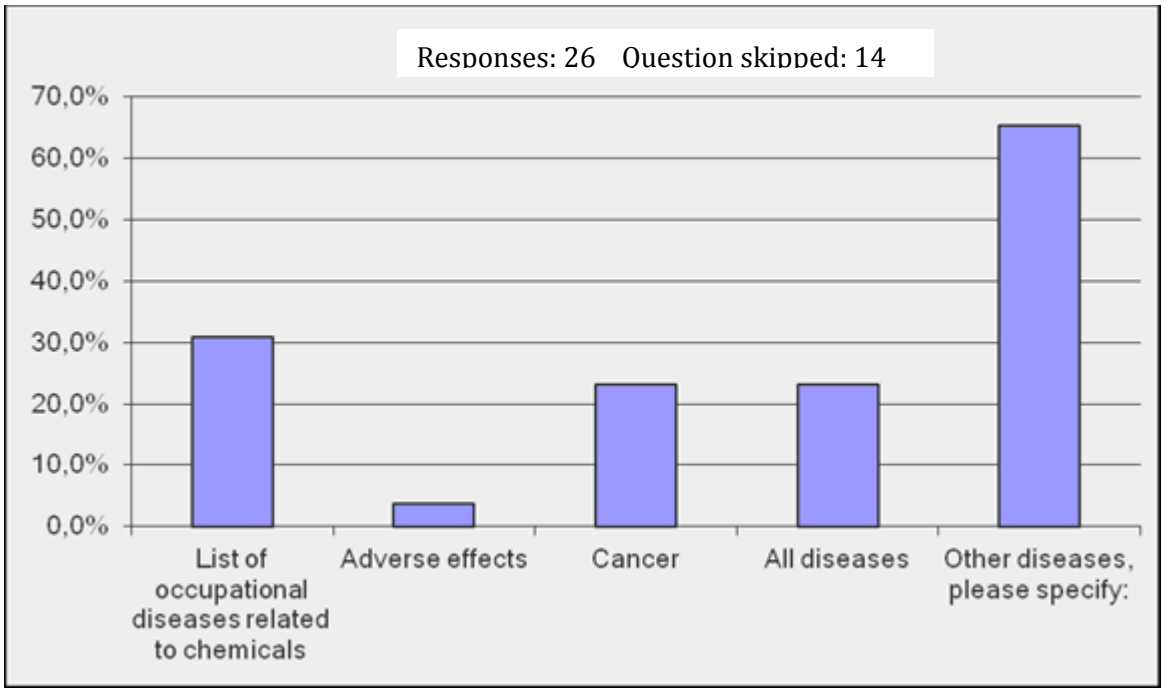


**Figure 15: Graph illustrating the relative distribution of answers to Q 26**

The complete answer options can be found above.

Under 'other diseases' the following specifications were made:

- All occupational diseases which are listed in the Annex to the regulation of the Council of Ministers of 30 June 2009 on occupational diseases (Official Journal 2013, item 1379).
- All occupational and work-related diseases (criteria for reporting is if the physician believes, on the balance of probabilities, that the condition has been caused or aggravated by work).
- The main categories of work-related respiratory conditions reported in SWORD include: Allergic alveolitis, asthma, bronchitis/emphysema, infectious diseases, inhalation accidents, benign pleural disease, malignant mesothelioma, lung cancer, pneumoconiosis and other respiratory illness. The main categories of work-related skin conditions reported in EPIDERM include: contact dermatitis, contact urticaria, folliculitis/acne, infective skin disease, mechanical skin disease, nail conditions, skin neoplasia and other dermatoses.
- In relation to chemical exposure, these are restricted by legislation to occupational (a) asthma (b) dermatitis (c) cancer and (d) all diseases and any acute illness needing medical treatment when it is attributable to a work-related exposure to a biological agent.
- All diseases where there is epidemiological evidence of a link to workplace exposures and a pragmatic means of attributing cases to certain occupational circumstances (either via clinical features or doubling of risk).
- List of occupational diseases not necessarily related to chemicals asked in 2014 questionnaire, list of chronic conditions asked in previous years, list of reasons for most recent sickness absence asked every year.

- Note that occupational diseases identified in this database are not strictly related to chemical agents.
- List of occupational diseases related to chemicals in Latvia are registered in Latvian State Register of Occupational Disease Patients and People Exposed to Ionising Radiation due to Chernobyl NPP Accident. This database doesn't cover any medical data or conditions.
- Only the data on exposure is collected. It can be linked to other health registries. Routinely it has been done in case of the National Oncologic Registry.

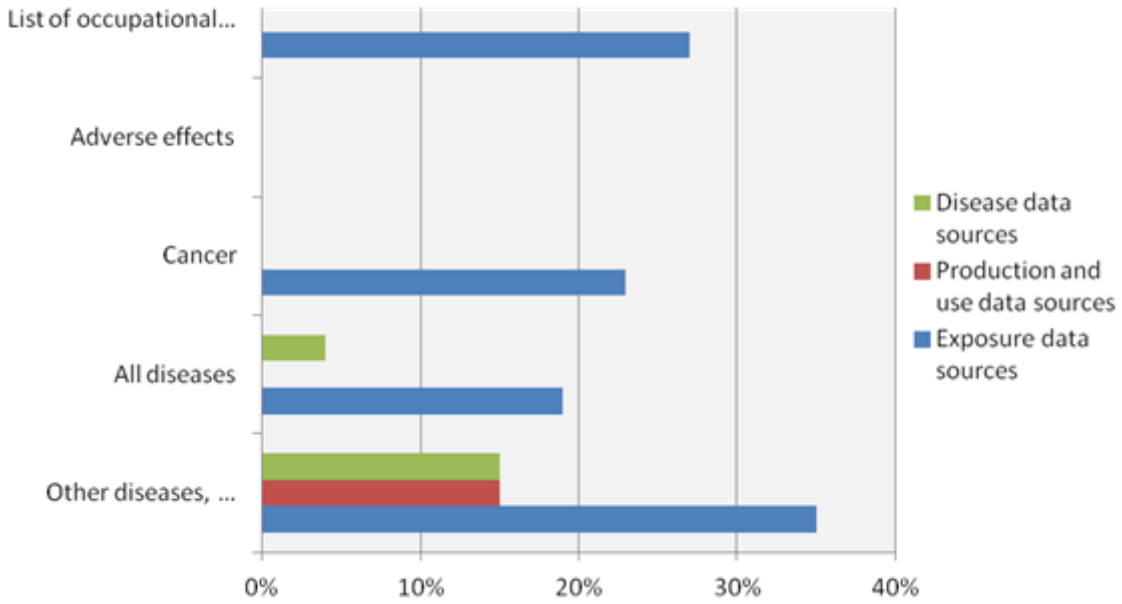


**Figure 16: Graph illustrating the relative distribution of answers to Q 26 with a separation of data sources into three types (Exposure data sources, Production and use data sources, Disease data sources)**

**Q 27. Which type of data collection is used?** (Response rate: 65%)

- Specific register
- Collection of data from medical examinations
- Other, please explain:

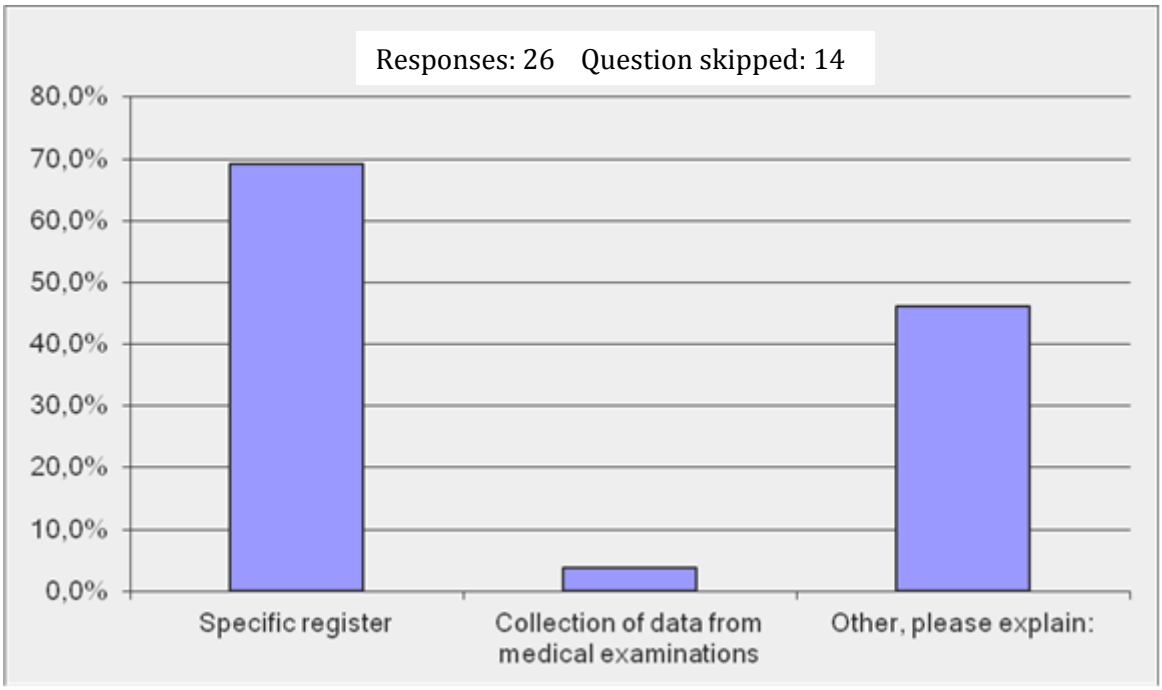


**Figure 17: Graph illustrating the relative distribution of answers to Q 27**

The complete answer options can be found above.

Other types of data collection were case reports from consultant chest physicians and dermatologists in the UK, legal employer reporting, national registers and self-report, national registers for deaths and cancers as well as a survey among employees, national decree in HU.

**Q 28. Which type of contextual information is provided?** (Response rate: 55%)

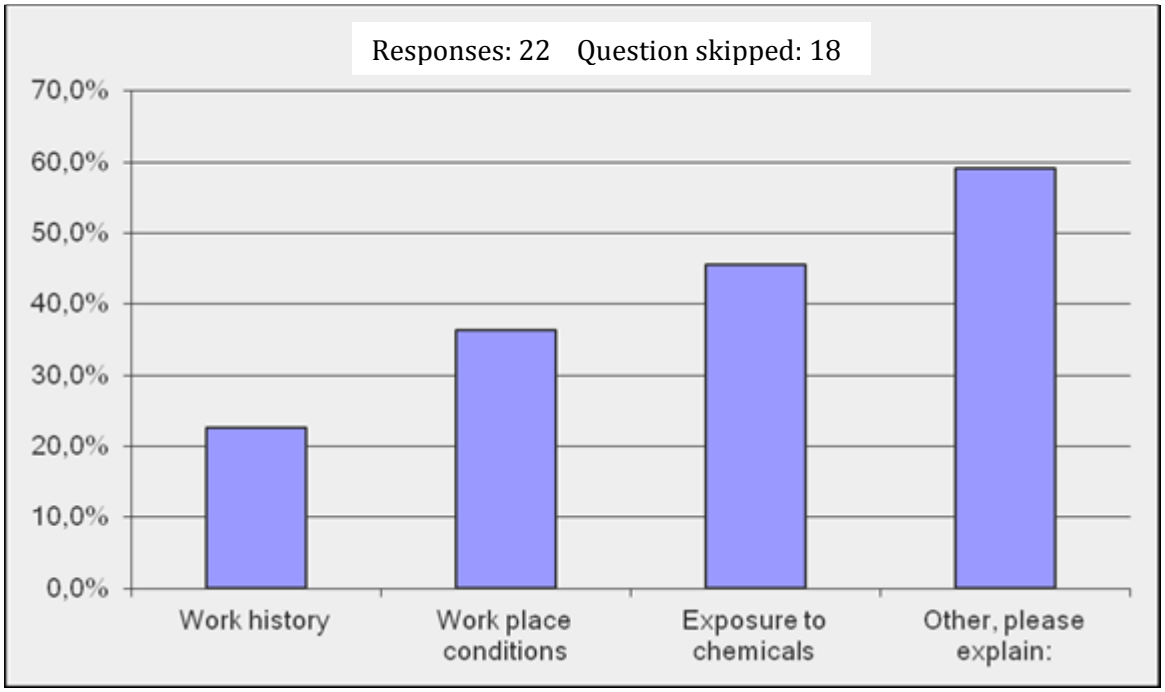


**Figure 18: Graph illustrating the relative distribution of answers to Q 28**

For one data source physicians are only asked to provide a diagnosis, gender, age, first half of postcode, industry, job, suspected agent(s) and date of onset of symptoms. GPs (reporting to THOR-GP) are asked to provide additional information on whether (and to whom) the case was referred and whether there was any sickness absence certified.

Other information includes industry, occupation where exposure to suspected causal agents occurs, very general information on exposure to chemicals and duration of exposure, calendar period, smoking. For one data source a questionnaire is used on working conditions, so various topics including sickness absence and accidents at work, are asked.

**Q 29. Is related information on sector and occupation provided?** (Response rate 77.5%)

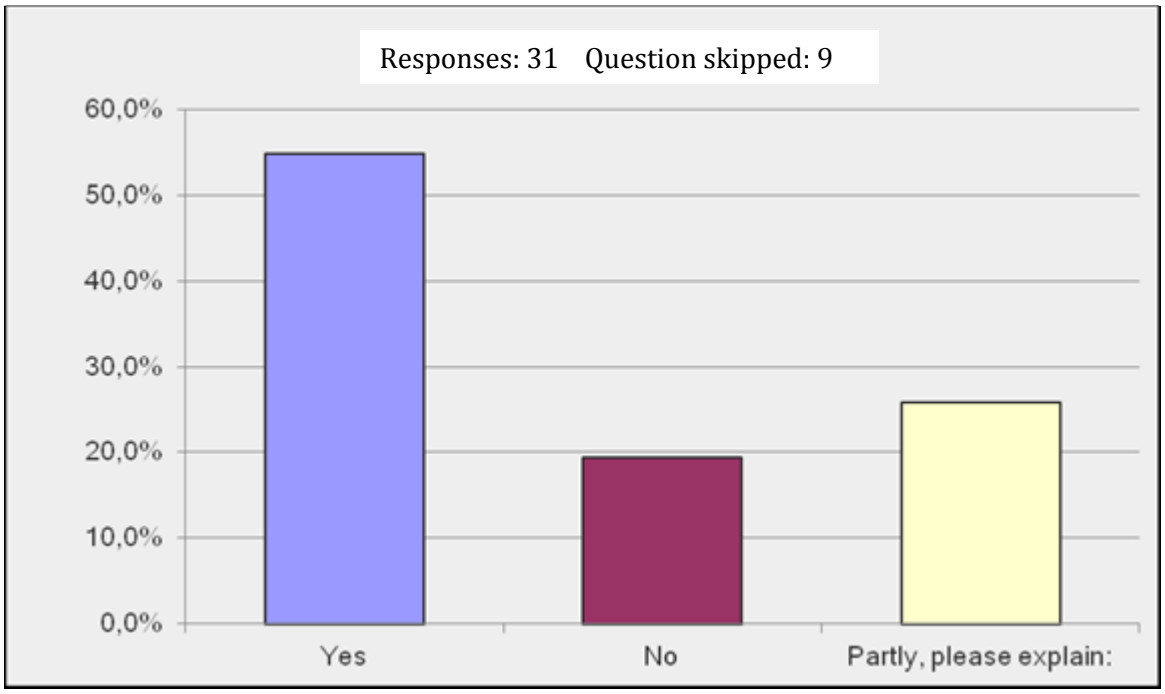


**Figure 19: Graph illustrating the relative distribution of answers to Q 29**

**Under 'partly' the following explanations were entered:**

- Suppliers provide their contact information as well as information related to their distributors at the national market.
- **The notifying companies must state which sectors the chemical is marketed for.**
- NACE Rev 2 (Industry); ISCO 08 (Occupation).
- The database contains basic information on industrial sectors (according to NACE) and in most cases also the information on occupation.

**Q 30. Is information provided on the type of workers/specific groups?** (Response rate 85%)

- Gender
- Age
- Qualification
- Migrant workers
- Young people
- Workers with medical conditions
- New workers
- Maintenance workers
- Pregnant or breastfeeding workers

- No
- Partly, please explain:

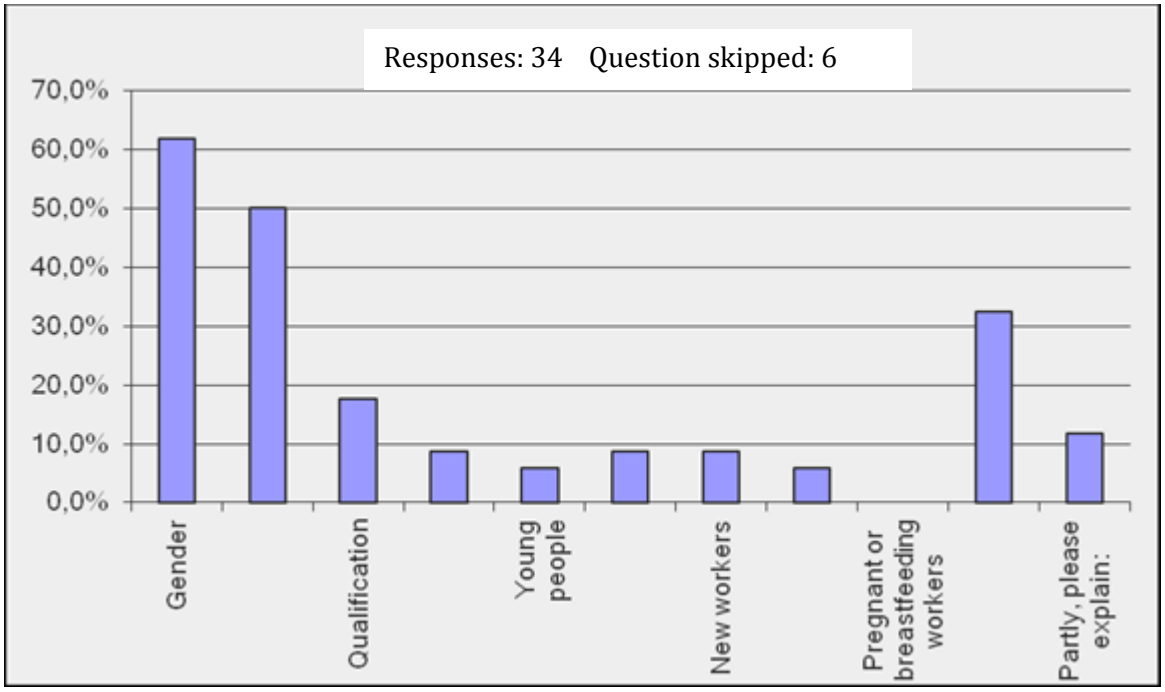


**Figure 20: Graph illustrating the relative distribution of answers to Q 30**

The complete answer options can be found above.

It was mentioned that apart from the information specified, there is no formal requirement to provide any of these. However, each report contains a free-text narrative, which may or may not contain additional information. For one data source data on age and gender and type of work (e.g. temporary, maintenance, etc.) is often missing, but is considered very relevant for exposure length and exposure level.

## Questionnaire section 7: Sector and occupation data

### Q 31. Which categorisation (and which levels e.g. of the NACE codes) is used for sector information?

Twelve data sources use NACE codes (2- or 4-digit). Two Polish data sources use the Polish Classification of Activities (PKD) codes[92], which are based on the NACE system. Five data sources from the UK use the UK Standard Industrial Classification (UK SIC 2007)[93]. Data source from Portugal is used the Maximum disaggregated level (5 digits)[94]. The Romanian data source uses the coduri CAEN.

[92] Polish Classification of Activities (PKD) see http://stat.gov.pl/en/metainformations/classifications/#Polish%20Classification%20of%20Activities%20%28PKD%29

[93] UK Standard Industrial Classification of Economic Activities 2007 (UK SIC 2007) see http://www.ons.gov.uk/ons/guide-method/classifications/current-standard-classifications/standard-industrial-classification/index.html

[94] More information was sent as an annex.

**Q 32. Is the size of the enterprise provided?** (Response rate 85%)

For about 82% of the data sources the size of the enterprise is not provided, for about 12% it is provided according to EU categorisation (micro <10, small < 50, medium-sized < 250) and for about 15% other categorisations were used (1-4, 5-9, 10-19, 20-49, 50-99, 100-249 (from 2014 onward), 250-499, 500-999, 1000+, number of workers on site, number of employees per participating enterprise, total employers at the Local Units).

**Q 33. Which categorisation (and which levels e.g. of the ESCO, ISCO codes) is used for occupation information?**

Eight data sources use ISCO codes up to four levels. A Spanish data source uses the Spanish Classification of Occupations (CNO94)[95], a national system based on ISCO88. Three data source from the UK use the Standard occupational classification 2010 (SOC10)[96] or the previous version (SOC2000)[97]. A Portuguese data source uses the number of employers for a local unit of the same enterprise.

## Questionnaire section 8: Reporting of data according to the Carcinogens and Mutagens Directive

**Q 34. Does the competent authority of your Member State request from employers to report data on the exposure to carcinogens or mutagens at work, according to article 6 of Directive 2004/37/EC (Carcinogens and Mutagens Directive)?** (Response rate 60%)

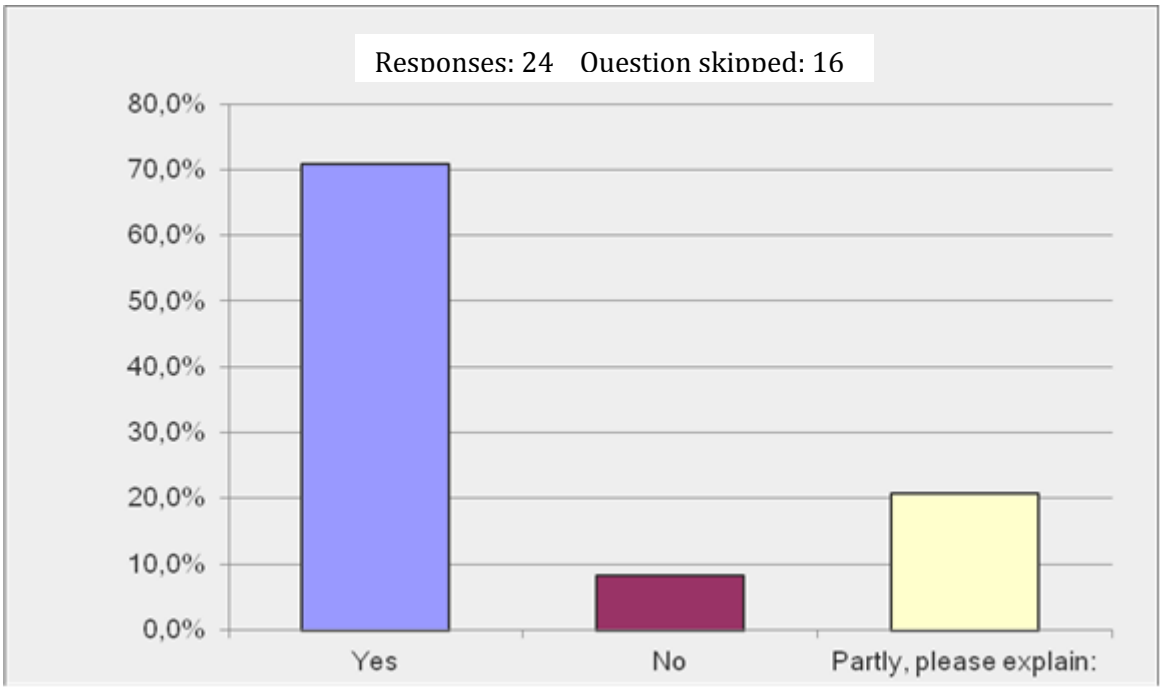


**Figure 21: Graph illustrating the relative distribution of answers to Q 34**

[95] Spanish Classification of Occupations (CNO94) see http://www.ine.es/jaxi/menu.do?type=pcaxis&path=%2Ft40%2Fcno94%2F&file=inebase&L=1

[96] Standard occupational classification 2010 (SOC10) see http://www.ons.gov.uk/ons/guide-method/classifications/current-standard-classifications/soc2010/index.html

[97] Standard occupational classification 2000 (SOC2000) see http://www.ons.gov.uk/ons/guide-method/classifications/archived-standard-classifications/standard-occupational-classification-2000/index.html

Under 'partly' the following explanations were entered:

- According to the Cyprus Legislation the employer is required to perform risk assessment. In the case of any activity likely to involve a risk of exposure to carcinogens or mutagens, the nature, degree and duration of workers' exposure shall be determined in order to make it possible to assess any risk to the workers' health or safety and to lay down the measures to be taken. The employers according to the Cyprus Legislation shall, if requested, make available to the Department of Labour Inspection (the competent authority) the above mentioned data.
- The Belgian law states that employers have to provide the data when the labour inspector asks it.

**Q 35. Is the information reported by the employers made publically available?** (Response rate 52.5%)

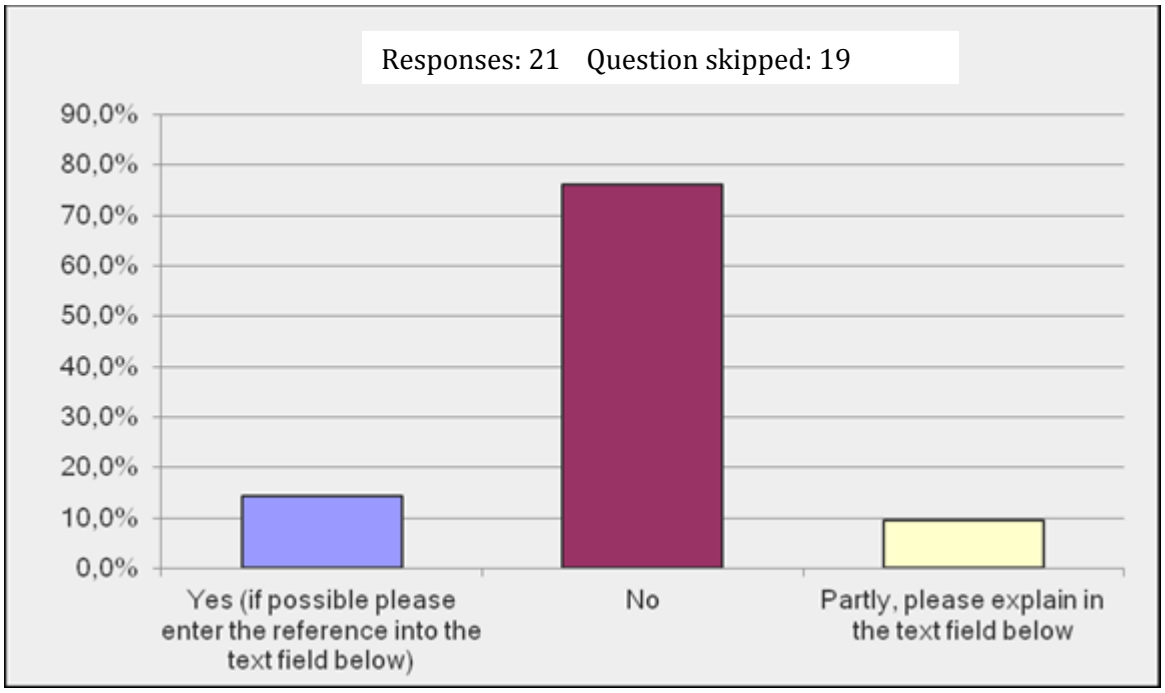


**Figure 22: Graph illustrating the relative distribution of answers to Q 35**

Under 'partly' the following explanation were entered:

- Completed register from every voivodeship is submited by competent sanitary inspector to the Central Register of Data on Exposure to Chemical Substances, Mixtures, Factors or Technological Processes with Carcinogenic or Mutagenic Potency - which is maintained by Nofer Institute for Occupational Medicine in Lodz.
- In annual report of activities of Regional Public Health Authorities of the Slovak Republic for example: http://www.uvzsr.sk/docs/vs/vyrocna_sprava_SR_2013.pdf
- http://www.hse.gov.uk/Statistics/tables/index.htm#cancer
- Every employer sees only his/her data, not others.

- This data is not made available publicly for confidentiality reasons, and because it is highly un-representative of the scale of the problem. Actual reports represent only a tiny fraction of each condition reported.
- In most of the referenced sources, it is not.

**Q 36. If this information is not collected, can you specify the reasons and obstacles?** (Response rate 25%)

Ten answers were received for this question:

- Article 6 of Directive 2004/37/EC requires information on exposure to carcinogens and mutagens to be required when requested by the regulator (Competent authority). The UK regulator does not routinely request this information, when such information is requested it is recorded separately and is not linked to NEDB.
- Policy decision.
- Some information is provided in the report (e.g. confidentiality, company-related data, changes in accuracy of measurements over time, changes in exposure profiles over time).
- Not relevant.
- n.a.
- There is a duty to register after directive 2004/37/EC but there is no report of this to our register.
- This Regulation of the Cabinet of Ministers of 29 June 2010 No. 575 do not submit this type of information.
- The quantity and the nature of chemicals change daily in the industry therefore the administrative burden of keeping such a database is very high.
- see above
- Information collected.

## Questionnaire section 9: Obstacles to generate exposure data and constraints for using data

**Q 37. What do you think are the main obstacles to generate exposure data at enterprise level and to make this data available to all stakeholders like employers, employees, health and safety experts, researchers or national and European authorities?**

The following answers were received for this question:

- Part of the reported data concerning enterprises is treated as confidential. There is possibility to prepare general analysis for groups of enterprises (e.g. by substance, by NACE, by area). We have data about number of exposed workers (men, women, and women under 45) in each enterprise, but the data on level of often incomplete (lack of measurements, lack of exposures exceeding OEL values).
- I think it is difficult for the producers to know exactly with their product at the down stream user.

- Cyprus companies are small in size and they cannot afford to perform studies to produce exposure data. However they take all the necessary measures to reduce exposure to as low as technically possible.
- There are not main obstacles to generate data on the exposure of workers exposed to harmful substances and make available to the legal stakeholders.
- There is no legal obligation to oblige the employers to submit data.
- The employers will fear this information being publicly available, I guess. Sanctions, workers' complaints and compensations will be likely the effect.
- Lack of knowledge, poor risk assessment.
- The main obstacles include the lack of funding for quantitative exposure measurements and the lack of exposure measurements conducted among representative samples. Exposure data collected over time might not have been classified and stored using a common format for easy access and analysis. Furthermore, people may still worry about the confidentiality issues when making their data available. They may be afraid that the exposure data at enterprise level would disclose the ineffectiveness of exposure control in individual companies.
- i) Lack of awareness of the need to measure exposure ii) The cost of measurements iii) The resources required. iv) The wish for confidentiality v) competition vi) employers don't see any benefits.
- The only limitations are related to the confidentiality of the data. The availability of the data is decided by IMA-Europe on a case-by-case basis.
- Confidentiality is handled in very different ways across the EU. For data owners and stakeholders: Access to data from owners is very limited; lacking links between data sources for use, production, distribution and exposures, as well as diseases. At enterprise level: For many enterprises, knowledge about exposure assessment is low. Dangerous substances management is seen as an expert topic and risk assessment is often done by external experts or confined to the OSH experts at enterprise level. Worker representation and worker involvement in these issues may be low.
- Data ownership / Security / Compatibility of different sources - collation of data in different ways, different classifications/definitions.
- Personal opinion: lack of data due to insufficient enforcement of the obligation to perform exposure measurements.
- The confidentiality of the data.
- 1) Missing obligatory system of a unified notification to the substances of interest. There is a legal duty for employers to collect data on individual's exposures to carcinogens in the Czech Republic; however, there is no obligation to report the data in unified way to the Public Health Authorities. Therefore, the data is collected in the framework of the inspection activities of the Regional Public Health Authorities (PHA). The capacity of the PHA to cover this activity, however, is limited by the lack of financial and personal resources. 2) Unwillingness of employers to provide the exposure data under the pretext of data confidentiality. 3) A lack of knowledge about the issue in small and medium sized enterprises. 4) A low interest of Regional PHA and other institutions to use this sort of data, inability to analyse it and apply it to enforce better working conditions.

- In the frames of the new approach to occupational health and safety issues (measures should be related to risks and their prevention instead of fighting the consequences) promotion of preventive culture in the field of occupational health and safety at national scale is essential. Therefore the real work condition database, that correspond to all risks at workplace and information on health and safety measures should be available to all stakeholders. In Latvia main obstacles are: - no regular monitoring is provided (no funding available) so only selected companies are included; - there are 5-10 laboratories working in the field of OSH in Latvia to some extent and their data is not available at all even upon request. So this database is the largest in Latvia (~50 000 measurement data on different workplaces) but not inclusive or systematically created. - Practical difficulties in classification of companies (e.g. to choose primary NACE code), occupations (current registry of occupational is terribly complicated and far from the real life) and also the classification of work equipment is difficult.
- Hungarian Institute of Occupational Health is the owner of the data in the data source. The Institute carries out the following as ancillary activities, within the scope of its basic activities register of occupational carcinogens and those exposed to occupational carcinogens. (Carries out data collection, data storage, data processing and analysis activities related to its scope of activities (e.g. register of occupational carcinogens and those exposed to occupational carcinogens, as well as maintaining the database of occupational diseases, cases of increased exposure) This data available to all stakeholders like employers, employees, health and safety experts, researchers or national and European authorities.

**Q 38. How could possible obstacles be overcome, in your opinion?**

Respondents proposed the following activities:

- Technical support from EU e.g. guidance.
- Continuous monitoring should be applied.
- MatEmESp was also intended to be a first step towards a national-level registry centralising occupational exposure data , as we realised that in Spain there is a lot of information, but hardly available, nor public, nor centralised, neither homogeneous. We liked the Finish system, the Finish Institute for Occupational Health (FIOH) centralises data on occupational measurements at enterprise level, this is the base for FINJEM and many other useful databases, this centralised registry allows surveillance, prioritising and evaluation of occupational health and safety policies in the country, and it's also a very valuable resource for research. However, in Spain we don't have a strong institution like FIOH supporting this development. To my view, this initiative for a European centralised database also opens new and very interesting potentials.
- Better distributing of information and knowledge.
- In my view, it will be cost-effective to use, in the initial stage, as many as possible the readily available exposure data sources. Furthermore, it will also be helpful to develop and implement a harmonised standard for exposure data collection and storage and to develop a national exposure database with clear data governance policy.
- Improving/raising awareness ii) Providing financial or other means of support iii) Promoting good business practice iv) Promoting the benefits to employers.

- The goals of the call for data should be explained to enable IMA-Europe to decide its willingness to share them and how.
- Some recommendations are given in the report: - Awareness raising and simple tools for assessment - An inventory of substances, products and mixtures used and generated at work - Information exchange on exposure data at national level, some approaches of multi-country data gathering are provided in the report - Information exchange on the challenges posed by specific exposure situations between OSH and REACH stakeholders - Information throughout the supply chain - Data analysis linking job-exposure matrix data with outcome data and data on employment - Sentinel systems as those used in the US for specific exposures.
- Designing a central database with well defined compartments/definitions so that data can be reliably populated from multiple sources.
- Personal opinion: - more enforcement of the obligation to perform exposure measurements; - obligation to keep data in a format that allows rapid transfer when the authority asks the data and that allows the authority to process the data efficiently.
- 1) Establishment of obligatory system of reporting of the data on exposures to substances of interest to the Regional Public Health Authorities. (Employers are legally obliged to carry out the measurements, and collect and store this data.) 2) Covering of the costs associated with this activity, particularly in case of the Regional Public Health Authorities. 3) Improvement of knowledge on the importance of occupational carcinogens at all levels. 4) Coordination of the organization of obligatory exposure registries at EU level.
- Data collection on working environment could be delegated to IOSEH (Institute of Occupational Safety and Environmental Health, Agency of Riga Stradins University on the basis of existing work environment measurements data of accredited Laboratory of Hygiene and Occupational Diseases of mentioned Institute). Considering functions of this institute, which include establishment of a united information and research centre, this would ensure most effective use of available information. To develop real connection with existing hazardous chemicals flow in Latvia according to Cabinet Regulation Nr. 575/2010 on registration of the chemical substances and mixtures and database could be foreseen spread of the information from enterprises on toxic substances to IOSEH in this Regulation.

**Q 39. What are the reasons for constraints using the data source you are representing?**

The following explanations were entered:

- Data confidentiality and limited founding
- Risk of identification of individuals, workplaces, participating physicians etc. Although data collected by THOR are pseudonymised, and comprise only a limited number of personal identifiers, this risk is still a possibility. However, as described under question 13, access to (raw) THOR data is possible under certain circumstances and access to summary data is possible via the data enquiry service
- The data sources presented here include individual level data on work-related respiratory and skin conditions and the suspected causal agents. There is no constraint when using the published statistics from the data sources. However, if an access is required for individual level micro data, the data steward should be contacted. Only a broad category of data that are deemed to be non-identifiable can be used with Research Ethics Committee's approval.

- It is highly unrepresentative of the problem due to very significant non-reporting. (2) It also concentrates on specific conditions and outcomes, rather than exposure per se. (3) The data provided is also very un-structured, making analysis difficult and time consuming. (4) Each report also requires confirmation by a medical practitioner on the condition, and connection to work activity. (5) Also, the requirement to report only applies if the condition develops (or made noticeably worse) whilst with the current employer. Exposure in previous jobs removes the requirement to report. (6) Data confidentiality, especially for rarely-reported conditions and circumstances.
- The main constraints are imposed by Research Ethics considerations and Data Protection requirements.
- The main constraints are imposed by Research Ethics considerations and Data Protection requirements.
- i) data protection ii) some of the data is very old ii) the resource required to search the database, anonymise results and supply the information to an external enquirer.
- The guarantee of the confidentiality of the data is a pre-condition to participate in the exposure data collection and it is why the project is successful. Only aggregated and anonymised data can be released.
- Designed primarily as a customer reporting tool so limited contextual data as customers retain that information separately.
- Confidentiality.
- 1) There are no restrictions to use aggregated data. On the other hand, the usage of data at individual's level is prohibited by the Act No 101/2000 Coll., on data confidentiality. So, for example to carry out a linkage studies based conditional on agreement of participating institution and the Office on Personal Data Protection. 2) Incompleteness of available data, which restrict the possible ways of interpretations. 3) Restricted capacity of the National Institute of Public Health to analyse the data and report results.
- The database operation is not included in official tasks for IOSEH according to occupational safety and health program (financing and staff) in Latvia, as well as there are lack of technical support from IT specialists for operating database.

## Questionnaire section 10: Your proposals for improvement

**Q 40. Which data is not collected, but should be collected in your country or Europewide?**

Respondents entered the following proposals:

- Data on poisoning (Europe wide)
- Nanomaterials...probably would be interesting information about the produced and imported quantities of nanomaterials at both levels: national and EU level.
- All substances and mixtures which are utilized in each enterprise or undertaking, in Romania, and what purpose for;
- Gender inequities in occupational exposures are increasingly worrying me.

- We are trying to improve the contextual information collected with the exposure measurement - the protective equipment used, controls systems in place, tasks carried out etc. It is important to set the measurement into context and it would be helpful to include this sort of information alongside any Europe-wide data.
- Data from compulsory reporting as is laid down in the carcinogens Directive Disease data, for example from cancer registries, by occupation products registries could help provide data on uses and amounts data on process-generated substances is very limited it should be possible to link data through data warehouse approaches, as many are owned by public bodies (exposure databases, results from health monitoring, but anonymised, job-exposure matrices, employment histories, disease compensation data, company registries, etc.)
- Besides of well established risks, such as well known carcinogens, the exposure registries should focus and collect data on exposures, to knew emerging risk, where the link between health and occupational exposure is not clear, for example select engineered nanomaterials. (Of course, on condition that it is feasible and sensible.)
- There should be organized unified collection and sharing of data of LVGMC and IOSEH on CMD substances in enterprises and measurements of occupational exposure of chemical pollution in Latvia with a view to make available information on health risks and safety measures for all stakeholders. So first all the data should be collected and made available.

**Q 41. Which ideal data format (data structure) for information collection would you propose?**

Below you can find the proposals received:

- A European Online submission tool accessible to all the Member State Competent Authorities.
- You are asking for a whole project... To my view, the most important: public availability of information, and a clear reference to the methods and sources for data collection
- HSE is developing a form for completion - the current draft is sent separately.
- The data structure is reviewed regularly and can be updated if necessary.
- 1) ID, which makes it possible to carry out record linking studies. 2) Substance/mixture (CAS, trade mark, 3) Length, frequency of exposure. 4) Level of exposure (it can differ according to substances and route of exposure). 5) Use of personal protective equipment 6) Potential confounders - age, gender, smoking. 7) Concomitant occupational exposures 8) Categorization of work
- We are satisfied with our data format, but we could broaden the information on substance with CAS number, measurement data with min and max results as well as to improve the classifications of companies and occupations.

## Questionnaire section 11: Additional information and comments

**Q 42. Do you have any comments or information about the data source that is considered relevant and not yet covered by the above questions?**

These comments were entered:

- According to Polish legislation employer should register all works in contact with carcinogens and mutagens and workers exposed to these agents. But the clear definitions of "con-

tact" and "exposure" are lacking in the regulation concerning occupational carcinogens and mutagens. These terms are defined only in NIOM guidelines made available to employers and sanitary and labour inspections.

- This is still a very new cohort, and it will be a few years before prospective information on health becomes available.
- NEDB is old and unlikely to be compatible with modern systems (exposure values can be exported into an Excel spreadsheet but summaries and reports cannot - and need to be anonymised) ii) In the last few years there has been a decline in the addition of new data to NEDB iii) The data collected are not representative of exposures across GB.
- Any submission of data would be data on aggregated level and on averages and will depend on the research question. Individual data will never be provided.
- Concerning the quality of the data: random sample surveys have shown that the information supplied by the external services is not always accurate.
- The identification of nanomaterials is not considered in this data source.
- Questions on awareness of risk group regarding provisions of the Labour Protection Law and regulations on occupational risk assessment, as well as other related issues could be interesting for preventive measure planning; more attention should be paid to rising awareness of young persons because, on one hand, number of young people employed during summers and probably exposed to occupational risks is increasing, and, on the other hand, number of employees working for less than a year and affected by workplace accidents in Latvia is high. Also the information of worker demography should be added.
- description of the ART database is provided in: Schinkel J, Ritchie P, Goede H, Fransman W, van Tongeren M, Cherrie JW, Tielemans E, Kromhout H, Warren N. (2013) The Advanced REACH Tool (ART): Incorporation of an Exposure Measurement Database. Ann Occup Hyg 57: 717-727.

## Annex 7. Description of data sources (separate doc)

A description of data sources according to the template presented in chapter 2.3 can be found in a separate document named 'Annex 7_Description of data sources'.

## Annex 8. Description of competent authorities (separate doc)

A description of data sources according to the template presented in chapter 2.3 can be found in a separate document named 'Annex 8_Description of competent authorities'.

## Annex 9: List of substances selected by the scoring system – TOP 500 and TOP 100 (separate doc)

This annex can be found in a separate document named 'Annex 9 _Scoring_Top500_100'.

## Annex 10: Data collection format (separate doc)

This annex can be found in a separate document named 'Annex 10_data_collection_format'.

## Annex 11: Methodology for data provider and database user (separate doc)

This annex can be found in a separate document named 'Annex 11_methodology_database'.

## Annex 12: Draft letter to potential data providers (separate doc)

This annex can be found in a separate document named 'Annex 12_Draft letter to potential data providers HazChem@Work.

## Annex 13: Memorandum of understanding (separate doc)

This annex can be found in a separate document named 'Annex 13_MemorandumofUnderstanding-HazChemAtWork_KOOP'.

## Annex 14: Screenshot of the www.HazChemAtWork.eu Website

## Annex 15: Workshop participants (separate doc)

This annex can be found in a separate document named 'Annex 15_workshop participants'.

## Annex 16: Identified contact persons for implementation and enforcement of the CMD directive

**Identified contact persons for implementation and enforcement of the CMD directive**

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| | |
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| United Kingdom | Gill Smith<br>Redgrave Court<br>Merton Road, Merseyside L20 7HS, UK<br>Tel: 0151 951 4919<br>Email: Gill.FOD.Smith@hse.gsi.gov.uk |

## Annex 17: List of Substances provided for the database (separate doc)

This annex can be found in a separate document named 'Annex 17_list of substances_database'.

## Annex 18: Description of data provider (separate doc)

This annex can be found in a separate document named 'Annex 18_Description of data provider'.

## Annex 19: Summary of the workshop (separate doc)

This annex can be found in a separate document named 'Annex 19_summary of the workshop'.

## Annex 20: Agenda of the workshop (separate doc)

This annex can be found in a separate document named 'Annex 20_agenda of the workshop'

## Annex 21: Technical documentation_IT (separate doc)

This annex can be found in a separate document named 'Annex 21_ Technical documentation_IT

## Annex 22: Estimation of exposed workers - Example: Acrylamide

This annex can be found in a separate document named Annex 22_number of exposed workers_example_acrylamide

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