ANNEX 19

Summary of the

HazChem@Work Workshop - Luxembourg 09.06.2015

1.1 Introduction and status of the project

Mrs Maria-Teresa Moitinho De Almeida, Head of Unit at DG EMPL gave an introduction to the workshop. She highlighted the following topics:

- Background information to the project
- Main reasons for the Commission to start the project
    - The Commission is aware about exposure to chemicals and workers suffering from work related diseases (silicosis, asbestosis, skin diseases)
    - The evaluation of the previous strategy showed that there is a need to tackle work related diseases
    - Prevention of work related diseases by tackling new work related risks
    - Better data on occupational exposure will help identifying needs for action
    - There exists a huge data gap regarding the exposure to certain chemicals
    - With HazChem@Work the Commission hopes to target the problems better
- HazChem@Work will develop a pilot model on exposure data for those chemicals where data are available, data gaps can be filled in later.

Mr Lothar Lissner from the contractor consortium presented the status of the study work.

1.2 Expectations of participants on a European database (plenary)

Mr Lothar Lissner from Consortium led the discussion with workshop participants.

Introduction:
Participants were asked about their expectation and opinion regarding the planned European exposure database.

Discussion:
- Feeding the database will be the key issue
- Cooperation with database providers is crucial – is there already willingness for cooperation?
- Confidentiality issues will be a problem to get access to data
- Structure will be crucial, a basic level has to be defined otherwise, the database makes no sense
- Make the model operational
- HazChem@Work should not replace existing databases. What can this database do more?
- Member state databases are very different – it will be difficult to compare data
- It is one task of the contractors to evaluate if a database will be feasible and make sense

- It will be difficult to transfer data to the database, exposure models should be the latest step
- Quality of the data is very important
- The database will help to understand data. Steps: understand the meaning of data, develop standards, concentrate on few data
- A new database should not be developed, but something interfacing, bringing data together. REACH has already many data, also workplace relevant ones
- Concentrating only on very few data may help to overcome confidentiality problems

1.3 Introduction of the working groups

Mrs Karola Grodzki from DG EMPL gave an introduction to the four working groups.

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 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?

1.4 Working group phase 1 and 2

1.4.1 Working Group 1: Accessibility and quality of data

Mrs Raluca Stepa form the contractor consortium made a short introduction and proposed the structure for discussions.

Introduction:
General data quality criteria, like completeness, timeliness, bias/variability etc., have to match the specific needs of the database, in a way that is feasible and appropriate for the users. HazChem@Work methodology/s should be transparent on what is (or is not) behind the data and how this is related to the quality. Users like SMEs should be able of having an idea on the (levels of) quality of the data, even if they ignore the details.

Discussion:
1. Quality criteria

The quality criteria depend on the foreseen use of the database, so it is important to establish clearly who is going to use it and how.
As the database is going to be used by authorities, but also by others (e.g. OSH professionals, enterprises) a rather broad range of uses should be considered for now: e.g. filling gaps in existing databases, help enterprises get information on possible exposures to chemicals in various sectors or activities, as well as on the range of exposure levels.
Data quality of the database will mainly refer to the exposure level and the number of exposed workers. Data will also cover the level of production/import & export, number of occupational diseases.

1.1. Exposure level

1.1.1. Analysis

- there are many criteria for the analysis phase (e.g. the method is standardized, reference materials are used, equipment complies with legal metrology provisions and is calibrated, the detection limit is suited, uncertainty is calculated, etc.);
- some users may be confused by terms (too many, too technical);
- quality criteria set at a higher level (i.e. covering several *detailed* criteria) could be used: e.g. the laboratory is certified (ISO 17025) by a national/international body/ has successfully completed inter laboratory comparisons, works according to standardized/validated methods;
- if we chose a quality level that is too high, we may end up with no or scarce data;
- criteria should not be used to eliminate data, at this stage, but to assess available, existing data;
- some users might want to filter data according to the quality level, this should be possible (e.g. certified lab/ not certified but using standardized method/ method not specified) etc.

1.1.2. Sampling

Quality criteria may address:

- sampling method – according to a standardized/ validated method (generally included in the analytical method);
- sampling strategy – specified type of approach: e.g. probabilistic (random, stratified etc.) or non-probabilistic (authoritative);
- it might be possible to define levels of quality for sampling data (to be further investigated).

1.1.3. Contextual data

- a large variety of information is needed to describe the context: e.g. purpose of measurements (compliance monitoring, research, post-accident investigation), frequency, duration, relevant details about the method, sector, process, operation, collective & individual protective measures, type of result (raw/processed), number of exposed persons and gender, exposure frequency, etc.
- data providers may not be willing to provide such/so much data;
- minimum requirements could be established (depending on the foreseen use);
- defining quality levels might not be possible for contextual data.

1.2. Number of persons exposed

- does refer to the EU/national/ regional number, not to the number included in 1.1.3;
- quality criteria would depend on the type of approach: questionnaire, job exposure matrix , use of existing reports.

1.3. The level of production/import& export

(not discussed)

1.4. Number of occupational diseases

- data on diseases could provide complementary information to the one on exposure;

- cancer registers do not always provide sufficient information regarding the occupational nature of the disease;
- beside the problems regarding the quality of medical investigation there is often high underreporting.

2. Availability of data
- who uses the data and how, should be clearly stated because it will have a decisive influence on the willingness/conditions to make data available;
- publishing the HazChem@Work pilot will help, since potential data providers will be able to see how their data will be used, in case they decide to provide it;

3. Other observations
- efforts should be made to ensure real comparability of data;
- many of the aspects discussed are similar to those in other databases and they could be harmonized, while maintaining specificity;
- the HazChem@Work questionnaire was not meant to provide a deep investigation of the quality criteria used by the respondents, this will be done for a limited number of sources.
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1.4.2 Working Group 2: Relevant substances for occupational exposure

Introduction:

The selected substances should be relevant for occupational settings, form a sound and representative information basis to be included in the database and allow modelling exposure levels (if measured data is not complete).

To create such a list a multiple-stage scoring system is proposed, starting from substances that are placed on the market. This scoring system uses four different groups of information:
- exposure potential (e.g. tasks, activities),
- production/consumption of a substance,
- existing regulations (e.g. limit values),
- concerns for human health (e.g. hazards, occupational diseases)

At all stages expert judgement will be used for selection and to ensure, that the selected substances are a reasonable cross section of substances used in Europe.

The scoring system reduces the amount of substances from about 6000 to approx. 600 substances and a first estimation of the "top 10 substances" was presented.

The information used for the scoring system is
- the existence of an IOELV/BOELV
  - CMR and sensitizing properties of the substance
  - Registration tonnage (to include also substances with are not of high concern caused by the hazard but widespread and therefore a high number of workers is affected at many workplaces in many situations)
  - Reach registration PROCs (uses which are not enclosed)

The 600 substances filtered out by the scoring system need to be further reduced to a number of 100-200, for these substances the availability of measurement data will be checked. To limit the effort, the availability of measurement data should not already be considered at the first step. It

is expected that at the end 50-100 substances with "plenty" exposure data & occupational weight will remain, these will be used for the database.

Substances, which are generated during processes (welding fumes, dust, soot, diesel emissions) are not included in the 6000 *placed-on-the-market*-substances to start with. These substances need to be included manually at an appropriate step.

The following list includes some of the potential categories for the "fine scoring":

- Order of magnitude of production (e.g. registered tonnage)
- Consumption figures
- Number of EU/EEA countries with professional uses
- Scores for each individual PROC
- Wide dispersive use (without consumer use/environmental release)
- Existence of OELs besides BOELVs/IOELVs in member states or countries outside EU/EFTA
- Entries in other databases

Discussion:

1. Is the general proposal acceptable?

- Yes, if substances which are generated during processes and legacy substances are added later on, the approach is acceptable
- The selection should focus more on the occupational situation than on registration data.
- A grouping-approach should be considered. Many substances have a similar classification (petroleum-based chemicals) or substance-groups have the same OEL (often for metal containing substances where the OEL is triggered by the metal cation but not the anion).
- Fundamental comments concerning the selection of scores:
    - If the presented scoring system is only a "first version", why is it already presented? How it is possible to show the "top 10 substances" if the scoring factors are not finalized yet.
    - Scores for hazard:
        - Same score for sensitization and CMR-properties:
          Contra: CMR-Properties should have a higher score than sensitization properties.
          Pro: The severity of the final disease is obvious not comparable, but the impact to the work place situation for sensitization is very high. Therefore, a high score for this endpoint appears appropriate.
    - Scores for tonnage:
        - Tonnage should not be considered since some of the most critical substances have only a low tonnage. In a project for carcinogens, a similar list was prepared and the tonnage was not taken into account. Note: 10 different top-scorer were identified in this project.
        - Tonnage should be considered, since the scores are not multiplied but summed up. Therefore, a low score at the tonnage level will not un-prioritize a substances. However, substances that have only low hazardous properties by their intrinsic properties might be available at many different work places and might therefore be of importance for a high number of employees. Due to the lower hazard of these substances, they are often handled without the appropriate precaution.
    - Score for endocrine disrupting properties:
        - The criteria to classify a substance as endocrine disrupting are not generally accepted so far. How can it already be used as a score in this system?
          Response: ED-properties have been included for reasons of completeness. For the substances considered so far, none got a score for ED-properties.
    - Score for PROCs:

        - Cleaning & Maintenance should not be considered. Obviously, these tasks are directly connected with high level of exposures. But they do not represent the common use of the substance and are always accompanied with peak exposures and the use of PPE.
        - Intermediates should not be included.
    - Wide dispersive use has a higher score than the potential of the substance this should be rethought.

- Different approach should be considered:
  Instead of a scoring system, some substances should be selected as pilots (10-15 substances). They should be the most prominent representatives from different areas. Substances for which it is known that good data is available.

  For example:
  Legacy: asbestos
  Generated during processes: diesel motor emissions
  Substances placed on the market: petrol based substance, chromates

2. Should the availability of data be considered at an earlier stage?

Agreement, that a consideration at an earlier state entails a disproportionately great effort.

3. Which information could be used (except the ones listed in the interim report) for the finer scoring system?

- The relevance of substances for SME should be considered
- Additional information sources should be considered. Many countries, here GB, has own lists of substances of concern. They can be compared with the results from the scoring.
- Extension to other use descriptors than PROCs should be considered (e.g. SU, PC, …)
- Extension to other reference values (e.g. biological limit values, OEL other than EU values)
- Availability of analytical methods should be considered for a substance to be selected

4. How and in which step should substances generated at work places be included?

- What was measured? The vapour as a whole or the individual substances in the vapour? Welding fumes or the carcinogens in it? This needs to be considered to clarify which data is actually available.
- Legacy substances, for example asbestos, have good data and need to be included in the list.
- The main problem is dust, which is complicated to include in the scoring system (e.g. flour dust)

<u>Comments to the Database:</u>

- Not only has the quality of data needed to be considered but also the representativeness. For example, many data from one country mixed with little data from another country will not create a representative picture for both of the countries and even less for the whole European Union. Branches? Data regional or national?
  Response: the source of data will be mentioned and qualified in the database
- Chromium trioxide is a substance for authorization in REACH (Annex XIV), therefore the tonnage will decrease. Is it possible to delete a substance from the database?
  Response: Yes, at each time substances can be included in the database or deleted from the database. However, the aim of the database is not to identify the worst chemicals but serious substances with good exposure data.
- The database might give the opportunity to get a better feeling about the data in the rest of Europe. However, the extrapolation to all states of Europe is difficult.

- One should distinguish between substances of concern and substances with good data. Substances in the database should fulfil both criteria. Only small data gaps should be filled with model estimations.
- Dermal exposure is for many substances the exposure route of major concern. This cannot be covered by the exposure data as the vast majority is for inhalation exposure only. Suggestion: Implementation of an extra field in the database. This field is ticked if the dermal exposure has great influence and it is not if the inhalation exposure is the main exposure route.
- Many working situations and chemicals can only be measured by experts, like for example metals. For the first test run of the database these substances should not be included.
- Outcome might help to set future OELs.

1.4.3 Working Group 3: Model Development

Mr Dag Rother from the contractor consortium made a short introduction and proposed the structure for discussions.

Introduction:

By 'exposures' both aspects of the issue are meant to be covered: the levels of exposure on the one hand and the number of workers exposed on the other. To address this topic a modular approach is suggested by applying two separate models, one for estimating exposure levels and one for estimating the number of workers exposed. The advantage of such an approach is that there are several established models (with different degree on detail) for estimating levels of exposure one could choose from. The question of how to estimate the number of workers exposed at a national and an EU wide level then can be addressed according to use of a substance in certain sectors or particular products.

Discussion:

1. General Comments

- Modular approach (separate consideration of level of exposure and number of exposed workers into different sub-models) was received well.
- Link between the different modules is very important. Need to take this into account at an early stage.
- It might be worthwhile first to finalise the list of considered substances before fleshing out the model too much.

2. Level of exposure

- Long discussion about the goals of the overall project as this can drive the requirements of the model, especially in terms of how conservative the estimates should be.
- Criteria for choosing a particular model as most appropriate for an exposure situation should defined.
- General opinion was to strive for a realistic worst case estimate in order to support prioritization efforts by users of the final database.
- Process generated substances may be very challenging when using REACH tier 1 exposure models; need to check whether dedicated models are available and more appropriate.
- Adapt "Zone" model as in pesticides for finding relevant default values in different areas across Europe. Possible interesting factors may include climatic and educational differences or different structured workforces.
- Job Exposure Matrices (JEMs) should be favoured over REACH type of Exposure Scenarios (ES) since the frequency of tasks is not well covered under REACH ES.

3. Exposure collectives

- Similar efforts by various groups have been very challenging, especially if level of detail is very high.
- The NOCCA data might be very helpful.
- Simple extrapolation of workforce statistics from given databases (like union data, the Nordic Countries product registers, especially the Finnish database from NOCCA) has been tried by various countries, but national data have to be interpreted with caution to fit other countries.
- Need to take into account differences between the various member states in order to perform such an extrapolation (for both, climatic as well as different behavioural (educational) contexts might lead to significant impacts).
- In the UK there exist well documented exposure collective data about lead. These might be very helpful for model validation.

4. Other Comments

- Data on production exists. Use might be difficult though, as there are a lot of uncertainties down the market chain.

1.4.4 Working group 4: Features of a future database

Mr Lothar Lissner made a short introduction and proposed the structure for discussions.

Introduction:

Participants were asked 1) how they would approach the development of such a database, 2) about their experience with databases (exposure databases, cancer databases, bio-monitoring data, REACH…)

Discussion:

- The database has to be constructed so that it can be evolved for future developments
- Industry databases could be helpful – send requests to database owners
- Maybe the database should have more a portal structure who looks down to other databases (e.g. new industry database)
- The database should be flexible
- Transfer of data will be important: How will it be done: manual, electronically?
- Propose a structure of the database and ask database owners - simplify data transfer
- Define the kind of use of the database
- Classify exposure in classes/exposure categories
- Use "expert" opinions for estimations. Measures are mainly done in exceptional situations and may not reflect the real exposure
- Combine different expertise – databases on exposures and also others.
- Exposure data: how many people are exposed, level and number of exposures, controlled and uncontrolled exposure
- Develop a kind of interface, not asking for direct data but develop a kind of interface, because:
    - legislation is not the same in the member states
    - quality of data is different
    - legal obligation of collecting data
    - confidentiality
    - responsibility

- Many industries have collected information about their employees. In Finland they share the information. Very precise estimation of exposure (individuals)
- In UK it is not so easy to get information about industry exposure data
- It would be necessary to control access to the database – who will have access? The demand for data can become huge. Industry wants to keep control of their data. Define data for special purposes; what goes behind cannot be used.
- It would be necessary to offer some benefits for database owners and to prevent burden.
- Data protection – discuss with industry what will be possible. Some data are destroyed because of data protection.
- Anonymise data, reduce facilities
- The feature of the database depends on the purpose of the database. What is the purpose, who will be the user?
    - Working Party chemicals need those exposure data about for socio economic considerations.
    - Pilot project, for a better overview about national data
    - Many data exist, but only in the national languages. They cannot be used by others
    - Possible users: Public institutes, insurances, associations, ...Could maybe be given on request)
- Database has to be simple and easy accessible
- Create a sustainable database, get the database owners/providers to give input to the database and to take over also the update (they know their data best). How can database provider be engaged?
- A quality control process has to be implemented. We need the data – member sates have to support the database.
- We will build up a portal to simplify and standardise data and prepare data in a convenient way. We won't reinvent the wheel.
- What will be the interest of database owner to prepare and provide data for HazChem@Work? Incentives? Access and confidentiality
- Concentrate on few substances, (about 30 to 50 substances) and define categories. Take a choice and leave the more complicated issues.
- Choose substances where you can get information
- Transparency will be important: be clear on what is not possible and on what can be achieved.
- A validation step is needed

1.5 Report / short presentations of each working group to the plenum and detailed discussion of actions

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 haw 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 (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 data bases. 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 data base 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 data base. That of course depends on the

selection 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?

1.6 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 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.