Conference report: Working together on the future of the limit values for carcinogens in Europe

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Foreword

The Dutch Social and Economic Council (SER) would like to present the following report of a European Conference on Occupational Exposure Limit (OELs) values for carcinogens, which took place in the city of The Hague, the Netherlands, on 10 and 11 of February 2020.

OELs are a quantitative benchmark for occupational exposure and are considered as an important regulatory instrument for controlling the risks from chemicals in general, including carcinogens, at work. OELs increase the awareness of employers and employees regarding risks present at their workplace and are instrumental in specifying and evaluating effective prevention measures. Employers can use OELs as an indicator for the need to apply control measures, prioritization of substances that need to be addressed for their risk and for the evaluation of the exposure. Additionally, OELs are seen as clear-cut references that allow for straightforward enforcement. Finally, OELs established in EU provide a level playing-field for business and workers who are in this way assured a similar high level of health protection across the EU.

With the overall theme 'Working together on the future of the limit values in Europe', the aim of the conference was to contribute to the discussion taking place in the tri-partite Advisory Committee on Safety and Health in its Working Party on Chemicals on the principles used when setting EU OELs for carcinogens and mutagens under the Carcinogens and Mutagens Directive (CMD). The specific focus of the conference was the identification of harmonization principles that would enable better cooperation in Europe and more efficient use of people and resources.

Managing social issues through dialogue and cooperation among all relevant stakeholders is our motto in the SER. This applies also to the setting of EU OELs. It was therefore heartening to see that the audience came from a variety of backgrounds: the European Commission, national ministries, governmental organizations, industry, employers' and employees' organizations and experts.

The conference program was designed to promote the exchange of ideas. The presentations and round table discussions were therefore exploratory in nature and not designed to derive conclusions or set a firm course for the future. Nonetheless, there seemed to be fairly strong support for the notion that a harmonized process would speed up the developing limit values at European level for all relevant carcinogens by allowing the cooperation of different European institutions.

I hope you enjoy reading this report, which aims to capture the main impressions and outputs of the conference. By compiling this overview we hope to provide inspiration for all stakeholders and most notably for the Working Party on Chemicals about how to move forward with setting limit values for carcinogens.

Mariëtte Hamer

Overview of the conference

Over the course of the two-day conference, from 10 to 11 February 2020, 80 participants from 12 different countries discussed about the prioritization of relevant carcinogens, the notion of acceptable level of risk for non-threshold carcinogens and the scientific methodology employed and the socio-economic considerations when setting limit values for carcinogens in Europe.

The conference was organized by the Dutch Social and Economic Council (SER) in close consultation with the Dutch Ministry of Social Affairs and Employment and the main European stakeholders in the field of Occupational Safety and Health, including the European Commission and members of the Working Party on Chemicals (WPC).

The chairman of the conference was Mr. Ruben Maes. The audience included representatives from Belgium, Brazil, Denmark, Finland, France, Germany, Luxemburg, Netherlands, Portugal, Slovenia, Sweden, United Kingdom. Organizations represented included governmental organizations (e.g. DG EMPL, DG GROW, ECHA, EU-OSHA, BAuA, ANSES, RIVM), industry/ employers' organization (e.g. Business Europe, Cefic), employees' organization (e.g. ETUI) and experts (e.g. Institute of Occupational Medicine, Karlsruhe Institute of Technology, TNO, Risk & Policy Analysts).

A major part of the conference was organised in group sessions, but there were also presentations and plenary discussions. The program and presentations are now available to view at *https://www.ser.nl/nl/actueel/Kalender/limit-values-system-carcinogens*

Day 1

The chairman, **Mr. Ruben Maes**, welcomed the participants and invited them to reflect on their expectations of this conference. Besides learning from each other, a number of participants expressed the hope that the conference will contribute to a harmonized and standardized European approach for developing OELs. The argument made here was that such an approach will accelerate the process and help remove confusing differences in OELs among organizations/governments.

Mrs. Tamara van Ark, the Dutch State Secretary for Social Affairs and Employment officially opened the conference. Then, Mrs. Charlotte Grevfors-Ernoult Head of Unit Health and Safety DG Employment, Social Affairs and Inclusion took the floor followed by Dr. Martin Wieske from the Employers Interest Group in the WPC and Mr. Tony Musu of the Workers Interest Group in the WPC. The subjects for roundtable discussions were introduced by Mr. Kris van Eyck, ACV and Member of the WPC and Mr. Patrick Levy, Health Senior Advisor CEFIC Occupational / Medical Advisor of France Chimie and Member of the Employers Interest Group of the WPC.

The day was concluded by a plenary discussion led by Mr. Ruben Maas.

Mrs. Tamara van Ark stressed the importance of jointly supported solutions by all stakeholders when it comes to societal issues. She called occupational cancer an urgent problem that both employers and employees have a shared interest in tackling it. She went on to explain how the long Dutch tradition of consensus-based economic and social policy (the "poldermodel") also works well in the case of setting limit values for carcinogens in the workplace. Its strength lies in the ability to deliver well-substantiated and well-accepted limit values which is a guarantee for good implementation. In this respect she pointed to a recent agreement among Dutch employers and employees for a binding limit value for diesel exhaust emissions.

To place the subject in its broader context, Mrs. Van Ark referred to some figures which illustrate the gravity of occupational diseases. According to the International Labour Organisation, 374 million people worldwide are injured or become sick at work each year. Every day 6,500 people die because of work-related diseases. In the Netherlands alone, 3,000 people a year die from diseases that are associated with occupational exposure to hazardous substances. In 80% of the cases, an employee doesn't become ill until after retirement due to the relatively long latency period between exposure and the onset of identifiable adverse health effects. She also mentioned the economic losses that go with that. A loss of 4% of global GDP, 3% for Europe. But most importantly, it's the suffering and the grief of people and the effects to the society at large, that count. Each and every case is one too many, she said.

Carcinogens pose special challenges, stated Mrs. Van Ark. They can have far reaching effects for the health of employees but these effects stay invisible for many years. For carcinogens for which banning isn't an option (as they may be needed or are unavoidable), society needs to talk about risks and how to reduce them. Limit values play a key role here.

She then continued with explaining the Dutch model of limit values. In the Netherlands, for most hazardous substances, companies themselves set limit values. For some substances - notably for carcinogens - the limits are set by the government, in consultation with scientists and social partners based on careful and transparent balancing of health risks on one side and feasibility issues on the other. In this process the various responsibilities are clearly divided. The Health Council of the Netherlands focuses on science and the estimation of health risks. The Social and Economic Council focuses on feasibility. At the end the Government decides on the binding limits based on the advices from the Health Council and the Social and Economic Council.

But setting a limit value isn't enough, Mrs. Van Ark stated. The Dutch approach also leans heavily on the EU STOP strategy (Substitution, Technical measures, Organizational measures and Personal protection, and in this order). Another key condition, is an open culture in companies where people can freely talk about managing risks, both internally and with external actors and learn from each other. Finally, the importance education shouldn't be forgotten.

A European approach, that maximizes the level playing field for employers and employees from all member states, is needed, according to Mrs. Van Ark. She expressed the hope that the conference will contribute to this goal in line with the Roadmap on Carcinogens, an EU initiative, launched during the Dutch presidency in 2016. The setting of the EU wide exposure limit values for 25 carcinogens is "a good start", she said but not

enough. The next EU target is 50 limit values. But as far as Mrs. Van Ark is concerned, that could be a lot more. Perhaps this conference can pave the way for even more ambitious goals.

To a question of the chairman about the right attitude when balancing health and feasibility issues, Mrs. Van Ark argued that employers and employees have a common interest in ensuring a healthy and safe working environment and stressed the importance of entrepreneurial mindset and innovation. Indeed, some people may lose their business if their chemical is substituted. Those who are entrepreneurial, will reinvent their business and stay on the market.

Mrs. Charlotte Grevfors-Ernoult gave clear overview of the current status and developments in the field of setting occupational exposure limit values for carcinogens at EU level. After a short introduction to the history of the Chemical Agents Directive (CAD) and the Carcinogens and Mutagens Directive (CMD), Mrs. Grevfors-Ernoult pointed at the urgency of tackling occupational cancer and the strong desire among stakeholders to establish occupational exposure limit values (OEL's). This is in line with principle 10 of the European pillar of social rights which makes a very clear reference to a healthy, safe and well-adapted work environment.

The broader theme of fighting cancer is also one of the priorities of the President of the European Commission Ursula von der Leyen. Mrs. Grevfors-Ernoult also touched upon the 'Europe's Beating cancer Plan' presented by Mrs. Von der Leyen to the EU parliament is put on the 4th of February 2020. The plan is currently open for public consultation and it is expected to be agreed and formally adopted by the Commission by the end of the year. The cancer plan will be the main agenda for this topic in the coming years. Everyone is invited to put forward suggestion.

Mrs. Grevfors-Ernoult also recalled the progress that has been made the last years in the field of OEL's, resulting in new OEL's for 26 substance or group of substances. The development of OEL's for 3 more substances (acrylonitrile, benzene and nickel compounds), is still ongoing and

adoption of the Commission proposals is expected for the second half of 2020. Then it will follow the ordinary legislative procedure for adoption by the Council and the European Parliament. For the future, an update of the OEL of asbestos is proposed as this carcinogen potentially affects millions of workers.

The core of Mrs. Grevfors-Ernoult presentation revolved around the different steps of setting up OEL's at EU level under the CMD:

1. Selection of chemicals for Scientific Evaluation: DG EMPL establishes lists to prioritize the scientific evaluation, based on inputs from various sources and application of priority criteria. An important source is the Working Party on Chemicals (WPC), which is a tripartite advisory committee. At this point there also very close discussions with other services of the Commission that are dealing with chemicals (such as the REACH regulation) in order to avoid duplication of work.
2. Scientific recommendations: DG EMPL issues mandates to the scientific committee, who will deliver as a rule the exposure-risk relationship (ERR) for non-threshold carcinogens, or a practical threshold when possible. Scientific Recommendations are subject to external consultation before adoption. Since a few years, the Commission works with ECHA and RAC to establish a sound scientific ground and to know from a scientific point of view what should be recommended for a specific chemical. Once RAC has finalized the assessment, the outcome goes to the WPC.
3. WPC (Working Party on Chemicals), the working group of the ACSH (Advisory Committee on Safety and Health) discusses the scientific recommendation and various feasibility issues and comes up with a consensus-based suggestion for the OEL value. This is integrated in a draft opinion for adoption by the Plenary of ACSH.
4. Impact Assessment (IA): DG EMPL drafts an IA containing policy options and associated impacts. In the IA, different values are analysed (the value that the WPC has put forward, but also values that are a bit higher or lower) to be sure about the costs and benefits of what will be proposed. The IA is discussed within an Interservice steering Group and submitted to the Regulatory Scrutiny Board (RSB). A positive reply of the RSB is required to continue with the legislative process.
5. Draft legislative proposal: DG EMPL prepares the draft legislative proposal and submits it to inter-service consultation within the Commission services. Thereafter a final draft legislative proposal is prepared.
6. College of Commissioners: the College of Commissioners adopts the proposal and sends it to Council and Parliament for negotiation and subsequent adoption as a directive.
7. Adopted directive published in EU Official Journal: MSs will transpose the legal text into national legislation by the date set in the directive.

These are many steps but once they are taken and the result is adopted, the OEL has quite a solid value. It's still challenging and it needs to be enforced and checked by labour inspections. But with the science, the tripartite approach and the impact assessment, the procedure is thorough. However, legislation in the form of OEL's is not enough. Enforcement and implementation at the workplaces, in particular in small and micro companies, constantly has to be improved.

At this point, Mrs. Grevfors-Ernoult elaborated a bit more on the involvement of social partners in the process. Working in a tripartite setting for workplace issues, is crucial, she said. Going forward in the area of occupational issues, isn't possible without a strong tripartite ground to stand on. The tripartite approach means that experts from the member states are consulted, as well as employer and worker representative organisations and the scientific community. When proposals are

put forward under the ordinary legislative procedure (which is the case for the CMD), there is a two-stage social partner consultation in addition to the above mentioned seven steps. When the WPC does the selection of priority chemicals for scientific evaluation and also during a public consultation for the draft scientific evaluations (done by RAC). The WPC prepares the draft opinion, which is adopted by the ACSH. The IA is supported by an external study. Social partners are involved in the steering group for this study. Furthermore, there are discussions within the services of the Commission.

One of the participants asked if and where occupational cancer is mentioned in the plan of Mrs. Von der Leyen. Mrs. Grevfors Ernoult referred to the part about prevention. Occupational cancer is about prevention, she said.

Mr. Van Veelen (FNV) asked whether there should be more emphasis on legislation and enforcement as, according to an EU-OSHA study, legislation is proven to be more effective in the case of SME's and 90% of the workforce is working in SMEs'. Mrs. Grevfors Ernoult replied that OSH hasn't taken the approach to introduce specific legislation for SME's. One of

the strengths of the CMD, is that it should cover all the enterprises. The Commission is, however, very well aware that it's challenging for SME's to comply with OSH regulation, and looks at all the possible ways to help them. The Bilbao agency has specific tools, like risk assessment tools, for SME's. And there is more legislation coming. Legislation alone, however, is not going to solve the problem. It's also about the enforcement. Here the SLIC (Senior Labour Inspectors Committee) has done important work. A holistic approach is necessary, Mrs. Grevfors Ernoult concluded.

Mr. Martin Wieske provided a further glimpse into the work of the Working Party Chemicals and noted that the conference in The Hague covers different areas of the work within the WPC.

He explained how chair, vice-chair and rapporteur positions in the WPC are shared by the interest groups and rotate every two years. The WPC has three or four two-day meetings a year and works with sub-groups to monitor specific studies initiated by the Commission. Sometimes there are lively discussions, he said, but usually the members agree on draft opinions going to ACSH for formal adoption.
Not all member states are represented in the WPC. Still, the WPC tries to consider all views from member states – and even from other counties outside the EU – collected during the broader consultations carried out by the Commission.

Mr. Wieske went on and threw some more light on the tasks of the WPC:

- Actively engages with and supports the activities related to the scientific opinions on which it has to judge coming from SCOEL or more recently RAC. It doesn't matter where these scientific opinions come from, Mr. Wieske said, as long as they are sound and based on a common accepted methodology.
- Develops activities within the framework of the CAD and the CMD, et cetera. The WPC doesn't only discuss how to set up OEL's for specific chemicals now, but also how to do it in the future in a more harmonized way and referred in this respect to the current discussion within the WPC on criteria and principles to be considered when developing OELs for carcinogens under the CMD.
- Advises the Commission on significant developments regarding approaches to chemical risk assessment and risk management at the workplace.
- Deals with occupational health and safety issues arising from the inter-relationship between EU OSH requirements and other EU legislation and initiatives including REACH and CLP.

Concerning the setting up of OEL's Mr. Wieske explained that the WPC is involved in all steps of the process:

- Setting up a priority list of chemicals
- Discussing the scientific recommendations for OEL's
- Discussing the feasibility and benefits of proposed OEL's
- Discussing a draft opinion.

With regard to the subject of the conference he offered a couple of thoughts for further discussion. Concerning the prioritization of relevant chemicals, Mr. Wieske stressed the importance of social partners involvement at an early stage.

He acknowledged it may not always be easy to identify the relevant substances, sometimes because these are impurities hidden in another substance. For a carcinogen to be prioritized it must fulfil the criteria for classification as carcinogen. Good prioritizing requires knowledge on the epidemiology and toxicology involved and information on exposure,

production volumes and existence of an OEL at national level. Also important is the overlap or the interaction with REACH.

Concerning the integration of reprotoxic substances in the CMD, Mr. Wieske said that in the opinion of the Employers Interest Group there doesn't seem to be a strong call to do so at the moment as these substances are already addressed under the CAD. The WPC is, however, very supportive of more substances under the CMD. He would like that this conference would keep the speed going and even to speed up the process. Still the number alone, is not the only objective, he said. It's important to ensure that the work is done in the proper way.

Concerning the risk-based approach for non-threshold carcinogens Mr. Wieske made reference to the current work of WPC on this topic (WPC is currently preparing an opinion on this topic).

An advantage of the risk-based approach, he said, is that it allows for a fair comparison of the risks posed by different chemicals. The risk-based approach brings with it the discussion over how much risk is to be considered as acceptable which should be linked to the discussion of minimization.

Regarding the scientific analysis involved in the development of limit values system, Mr. Wieske referred to the so-called R.8 ECHA guidance as a relevant guidance document [Guidance on information requirements and chemical safety assessment (ECHA,2019)] and said that also non-carcinogenic effects needed to be reflected upon when developing OELs for carcinogens. He also called for further strengthening the OSH expertise within the Committee for Risk Assessment (RAC) of the ECHA.

Concerning the socio-economic and technical feasibility analysis he stressed that it needs to be available at an early stage in order to be available for the WPC to take it into account when developing their consensus-based suggestion for an OEL. A lot of factors need to be taken into account for this analysis, for example:

- affected sectors exposed workforces,
- exposure data,
- existing OELs and national specifics,
- data on ill-health cases and trends,
- benefits and costs,
- measurability,
- risk management measures already in place,
- et cetera.

A complicated factor, he said, is that very often exposure data aren't available at the low levels of exposure corresponding to the anticipated OEL.

Mr. Wieske concluded with the statement that the common goal is to put up balanced OEL's which should be measurable, achievable enforceable and protective. Not only the number of implemented OEL's is key. Quality is a key aspect as well. In any case, the WPC would like to be engaged in the process as early as possible, even at the level of scientific analysis. In this respect he welcomed the invitation to the WPC to participate in RAC as an observer.

Mr. Tony Musu made clear that cancer is the first cause of death at work and that's why limit values are needed. The aim of the ETUI campaign Stop Cancer at Work, is to come to binding limit values for at least 50 priority carcinogens (single as well as group substances). He emphasized that the hierarchy of prevention and control measures should be

respected and that the limit values are only a secondary tool to be used when closed system isn't possible and there is a residual exposure that has to be reduced.

Mr. Musu made reference to two publications on priority carcinogens, from RIVM[1] and from ETUI[2] . Both research institutes came to the same conclusion, he noted. Selection criteria considered as relevant include:

- Elimination/substitution and closed system not feasible
- Number of workers exposed
- Extent of exposure (level, duration, frequency)/ production volume
- Potency (exposure-risk relationship)
- Inhalation is a recognised route of exposure
- CLP carcinogens (harmonised and self-classification as 1A/1B)
- Process generated Substances
- IARC carcinogens
- Existence of a national OEL
- Existing EU OEL outdated
- REACH management option analysis (RMOA) indicates the development of an OEL as an appropriate regulatory

Mr. Musu then raised some issues surrounding the current methodology to set OELs under the CMD and more specifically the external study

on which the Commission Impact Study will later be based. Such a study is carried out after the scientific committee has given its opinion and should be explicitly mentioned as an important element of step 3 in the description of the current methodology made by Mrs. Grevfors-Ernoult (see text hereabove). It is prepared by an external party commissioned by DG Employment and results in the cost-benefit analysis of different options for OELs pre-selected by DG Employment. Currently this is done case by case, without necessarily spelling out major principles for the choice of these options (i.e different possible numerical values

1 Puts C. and ter Burg W. (2015) Identifying prevalent carcinogens at the workplace in Europe, Bilthoven, National Institute for Public Health and the Environment
2 Henning Wriedt (2016) Carcinogens that should be subject to binding limits on workers' exposure, European Trade Union Institute

for a specific OEL). At the end, this leads to big differences in the residual cancer risks associated to the limit values adopted under the CMD and therefore different levels of protection from one carcinogen to another which is problematic.

Moreover, Mr. Musu also pointed to the need, if ever we change the current system, to keep an incentive to further minimize the exposure beyond the limit value. Indeed, according to the CMD minimization principle, it is not enough to comply with the limit value and the exposure should be reduced further down when technically possible. This is particularly important for non-threshold carcinogens.
Regarding the current system he, however, positively highlighted the tripartite discussion with employers, workers and governments.
Mr. Musu went on and made an argument for a possible future risk-based approach and the following suggestions:

- Make a distinction between threshold and non-threshold carcinogens.
- For threshold carcinogens the limit value should be set at the threshold. In that case, it can be described as a health-based limit value that also must provide protection against other potentially harmful effects besides cancer. For transparency reasons, the legal texts should make clear whether a limit value is health-based or not.
- For non-threshold carcinogens (when every level of exposure is associated with a risk of adverse effects) a key piece of information to be provided by science is the exposure risk relationship, that is the relation between the substance concentration in the air (inhalation) and the statistical probability of developing cancer.
- For the non-threshold carcinogens, everybody needs to agree on the risk boundaries of the system, meaning the number of excess cancer risks that can tolerated. Determining risk boundaries is not a scientific discussion after all, he said, but a subject for careful societal and political deliberation. That can be, for instance, four death on 10,000 workers, after 40 years of occupational exposure (exposed eight hours a day, five days a week). Or it can be four death over 1,000 workers in that same period. That's a political discussion.
- If this approach is adopted at an EU-level, the legal text should make clear what risks are associated to the limit value so that they are transparent for everybody.

Mr. Musu summarized the advantages of the risk-based approach: more transparency and a coherent methodology; the same range of excess cancer risk for all carcinogens, a dynamic system that provides incentives to minimize the exposure and risk boundaries that can also be used in the REACH framework.

Concerning the scientific analysis and the work of RAC Mr. Musu, like Mr. Wieske, made a point of the importance of strengthening the OSH independent expertise in the RAC. He also mentioned that it was a good thing for the transparency that WPC could be present in RAC-meetings as observers. He further elaborated on what RAC should deliver in order for the WPC to make balanced decisions:

- a good description of the substances and groups of substances under consideration,
- whether the substance is threshold or non-threshold for carcinogenic and non-carcinogenic endpoints,
- a dose-response relationship and/or an exposure risk relationship.

If possible, the RAC also has to recommend the OELs and (if relevant) the biological limit value or biological guidance value, Mr. Musu said. And RAC has to give information on available measurement techniques and their status within REACH. However, Mr. Musu expressed the opinion that

a decision on the limit value should not hang on the ready availability of measurement methods as these can be developed after the limit is set.

Next, Mr. Musu voiced some critical remarks about the EU impact assessment that is required when setting limit values for carcinogens in EU. EU impact assessment is an ex ante evaluation of the costs and benefits of legislative proposals and as such an integral part of the process of setting limit values in EU.

Impact assessment, he said, puts a tag on the health and life of workers by comparing the costs for employers to the health benefits for workers. From an ethical point of view, this can be questioned. Besides, cost-benefit analyses have many methodological flaws and involve assumptions and uncertainties which often lead to endless discussions regarding interpretation of the findings and sometimes to a bad decision. Another question is whether a new OSH initiative should only be accepted if the benefits exceed the costs. That's should not be the case, according Mr. Musu. Feasibility is important, but such analyses can only serve the discussions about the transitional period that's necessary to give employers enough time to comply to a new limit value.]

Mr. Musu also mentioned a joined declaration from 2018 signed by the trade unions and the chemical industry. In this declaration they called for a) inclusion of reptrotoxic substances in the CMD scope and b) a derogation to the exposure minimization for the threshold substances under the CMD.

Concerning the interface between REACH and OSH, Mr. Musu thinks that these two frameworks can act synergetic to protect worker's health. In the example of Chromium VI, they complement each other as some exposure to Chromium VI was not in the scope of REACH authorisation (i.e. The BOEL under the CMD covers all exposure including welding fumes).

At the end of his presentation, Mr. Musu summarized his points as follows. The objective is to have limit values for 50 carcinogens or groups of carcinogens that have already been identified. A difference must be made between threshold and non-threshold carcinogens. The limit value for the threshold carcinogens should be health-based. For the non-threshold carcinogens, progress can be made by using the risk-based approach. Furthermore, the scope of the CMD has to be extended with the reprotoxics. And REACH and OSH have to be complementary to improve worker protection.

Prioritization of relevant chemicals

Mr. Kris Van Eyck gave an introduction on the topic "Prioritization of relevant chemicals". He started by highlighting the process followed by DG EMPL to select chemical agents for which to request a scientific evaluation to develop proposals for OEL's.

It's a two-step approach:

Step 1: the development of lists with priority chemicals, including process chemicals, based on the potential of chemicals to cause cancer; evidence of cancer after exposure and emerging specific issues (like reported specific problems with a chemical, technical difficulty for controlling exposures or reported cases of occupational diseases).

Step 2: selection of candidate chemical agents. For this, criteria are used like the degree of evidence for adverse effects, considering toxicological and epidemiological data; characteristics of the adverse effects (severity, potency, reversibility, specificity); estimated number of workers exposed; identified exposure patterns that pose difficulties for the control of exposures; policy considerations (problematic disparity between relevant threshold values established elsewhere, degree of stakeholders' interest in having an EU OELV, or other institutional priorities).

For this work, different sources of information are used: DG EMPL stakeholders (WPC, trade union reports governments' reports, industry reports); scientific literature or study reports; operation or other EU regulatory regimes for chemicals, in particular REACH (e.g. chemicals identified in the so-called risk management options analysis, RMOA); and other commission services.

The encountered problems when trying to set the right priorities, Mr. Van Eyck said, are most often related to the lack of data. Other issues are related to the measurability of a limit value.

Risk-based approach

Mr. Patrick Levy provided the plenary introduction on the topic "Risk-based approach". He explained first some key elements for the risk-based approach starting with the distinction between carcinogens with a threshold and non-threshold mode of action (MoA); called respectively threshold and non-threshold carcinogens.

For threshold carcinogens a health-based OEL can be derived by the scientific body in charge. For substances that don't have a threshold, some residual risk remains at all levels of exposure. This means that the risk of cancer is directly linked to the level of exposure. In that case, an exposure risk relationship (ERR) is the basis for deriving OEL's.

At the level of member states, there are two major approaches when deriving OEL's for non-threshold carcinogens. Those who derive OEL's based on the efficiency of best available technics, that is based on feasibility considerations, and those who follow the so-called risk based approach like Germany and the Netherlands.

Starting point in the risk-based approach is the derivation of the exposure-risk relationship by a scientific body based on experimental and/or epidemiological data. The approach is based on a societal consensus regarding maximum accepted additional cancer risk in a working life of 4 extra cancer cases per 1,000 workers. The most importance difference between the German and the Dutch approach, concerns the feasibility. In the Dutch approach, the feasibility is taken into account in a separate step.

Mr. Patrick Levy mentioned two relevant documents available at EU-level that can be used when deriving limit values for carcinogens:

- ECHA R.8 guidance for preparing a scientific report for health-based exposure limits at the workplace
- WPC paper in progress on criteria and approaches for setting EU OELs for carcinogens and mutagens under CMD:

He concluded by calling (also on behalf of CEFIC) for the adoption of key principles for EU harmonised process for setting OEL's for carcinogens based on the risk-based approach. He also raised the question if a maximum risk level for non-threshold carcinogens is compatible with the prerequisite of impact assessment at EU level. He concluded by emphasizing the importance of involving social partners in the final decision. The ACSH, especially the WPC, is the right place for reaching a consensual value at an EU-level before going through the regulatory process, Mr. Patrick Levy concluded.

Highlights and take away messages roundtable discussion day 1

Prioritization of relevant chemicals - general remarks

- There are 40.000 substances on the market, possibly 1.000 are relevant but you cannot make an OEL for all of them.
- Do we really need OELs to protect workers? According to the so-called minimization obligation under Article 5 of the CMD worker exposure must be reduced to as low a level as is technically possible. Yes, as OELs provide clarification on how this minimization obligation can be met.
- Well-known carcinogens (50-70) are already identified. But for relative new substances the information on the carcinogenicity is lacking behind as studies providing evidence for carcinogenicity are not (or almost not) required under REACH.
- There are already several lists with prioritized chemicals. So it is better to start with those lists than to spend more time collecting data to refine the prioritization. Considering the limited capacity of RAC/ ECHA, it will still take a long time to develop the envisaged OELs.

Criteria for prioritization

- There was a broad agreement on the selection criteria. Chemicals to be prioritized should have an impact. Proxy to be used concerning the risk:
  a. Number of workers exposed (that's a need to know! However small worker populations with high risk require also high priority)
  b. Tonnage (proxy for exposure)
  c. Level of exposure (nice to know)
  d. Evidence for burden of risk (cancer incidences, is the agent a carcinogen for humans/animals?)
  e. Other significant effects than carcinogenicity
  f. Exposure can occur via multiple exposure routes

Policy/process considerations:

a. If substance is included in candidate list or restriction, it is a reason also to derive an OEL to create synergy
b. Substances not regulated under REACH (like process generated substances)
c. Existing national OELs (EU "harmonization" or by way of mutual recognition)

Criteria for de-prioritization:

a. Chemicals which can be easily substituted, substitution should be the first action
b. Chemicals for which adequate control can be realized by applying readily available protecting measures (protecting workers should be effectuated in such cases by enforcing the existing control measures)
c. Chemicals which are legitimate for authorization under REACH.

Necessary data – broad agreement on which data are necessary but also that there is a lack of data in many areas

- Necessary data include: epidemiological and toxicological data, population exposed, ways of application (uses and processes), sectoral and geographical distribution, information on the supply chain.
- But consolidated data are currently not available or they are not easy to use because of lack of harmonization.

Advices and remarks

- Resources should be allocated to use the list of the already identified carcinogens rather than developing prioritization criteria (once again).
- Real data are needed representing the situation in the real workplace.
- There is already a lot of information in databases that can be used to develop OELs, but nobody has a good way of using it and some of this information isn't publicly available but is only available within companies. A system is needed to make it possible to better use the information already available including unpublished information from companies.
- To improve the availability of data for the purpose of OEL derivation one should inform and involve the industry at an early stage as for the industry to start generating the necessary data.
- Ideally one should be able to combine cancer data with data on occupational exposure throughout a working life. For example it would be helpful if every worker has his "working life passport"; how many years which job, with certain activities.
- It's necessary to see what's already in place and to address the information gaps by financing research. This is a task for member states and the European Commission but also for the industry.
- Also important is to develop a format with minimum data requirements (which data and what are the quality requirements) that industry sectors can utilize to generate/gather the data from individual companies at an early stage in the process.
- One should start with substances for which sufficient data exist to develop an OEL. However, lack of data does not exclude chemicals from putting them on a priority list. This depends on the type of data. Options to overcome data gaps are: modeling, read across (similarity analysis, etc.), grouping of chemicals, use of REACH or company data (ask for data, exposure data, etc.) or perform specific studies. However, REACH as a source of data doesn't fulfil all data needs as it does not provide information on the process generated chemicals.
- Connect the OEL development to the regulatory management option analysis (RMOA) under REACH[3] . This is an important step and should be formalized. In general, it's necessary to integrate REACH and OSH.
- One consideration is that substances with missing data be coupled with very stringent OELs.
- One consideration could be to develop OELs for all the IARC classified carcinogens but CMD is relying on CLP classification or equivalent information.
- Asbestos is important, the size and shape of the fibres plays a role. When a substance has an asbestos like shape it could be prioritized.
- Consider developing a decision tree type of approach to prioritize carcinogens for the purpose of developing an OEL.
- In the context of national cancer registration, information about occupational history of the patients should be gathered.
- Prioritize also substances which are likely to be hazardous, for which scientific data do not permit a complete evaluation of the risk but which pose a significant risk for workers (apply the precautionary principle).
- In setting priorities the Working Party on Chemicals should be leading.
- When setting priorities at EU level one should consider the priorities set by other institutions/experts/member states.
- The participants of this conference should push their governments to put more pressure on the European Commission, in order to increase the political will for expanding resources for prevention.

3 https://echa.europa.eu/nl/understandng-rmoa

- To keep progressing, an ambitious timetable should be set for the list. Communication about this is also important to create urgency in the field. EU-OSHA could take a more prominent role in the communication.
- More resources needed for RAC/ECHA. Alternatively, priorities one should a accept/utilize the expertise that can be delivered by others (institutions/member states). The cooperation among member states and the European Commission needs to be enhanced.
- Expanding the CMD list to 50 substances will cover approximately 80% of workers' exposure. So let's get going!
- We don't have an issue with prioritizing chemicals. We rather have a capacity problem!

Risk-based approach

Is there support for a risk-based approach? Advantages and disadvantages.

- Overall there was support for a harmonized approach and the concept of a risk-based approach was well received.
- The scientific approach for developing exposure-risk relationships for non-threshold carcinogens is well established in the scientific community and already followed by RAC (and previously also by SCOEL) and also by national scientific committees but a framework is not yet in place at the European level.
- The acceptable risk level (although perhaps not set in stone but as a guideline) is an important element of such a framework.
- The decision on the acceptable risk level is a political one.
- In the context of the conference, the risk based approach was discussed as an alternative to OELs based only on feasibility considerations (on the efficiency of best available technics). In the risk-based approach the OEL is derived from an exposure-risk relationship (based on experimental and epidemiological data) taken into account a predefined maximum level of risk that is set at a generic level that is considered acceptable and which applies to all carcinogens (high risk level). Depending on the system the OEL also allows for feasibility considerations, as it is the case in the Netherlands, and it is set as a rule at a level lower than the maximum level of risk. Systems based on the risk-based approach also employ the notion of a lower risk, a target risk level, at which the OELs should be preferably set.
- Advantages of the risk based approach: a pragmatic approach when carcinogens cannot be eliminated and exposure is still an issue. The risk-based approach facilitates the decision making process because it is based on consensus/agreement on (acceptable) risk levels instead of case-by-case decisions and makes it more predictable and transparent; it brings coherency with other legislation; creates level playing field; allows communicating what the residual risk is; making explicit what the residual risk is, increase the incentive for minimizing exposure leading to a lowering of the risks for workers. Also, the lower/target risk stimulates innovation.
- Disadvantages: you accept certain level of risk, for chemicals for which exposure should be prevented completely (however, as long as these chemicals cannot be completely banned and exposure is still an issue, there is always a risk taken; also, the minimization principle also applies); the experimental and epidemiological data necessary to derive an exposure-risk relationship may not always be available; difficult to communicate to the work floor; occasionally very low OELs that are not feasible in practice (for example not measurable).

Prerequisites for establishing a RB approach

- The necessary data should be available to derive the exposure-risk relationship.

- Consensus at political/societal level on what is an acceptable level of risk (high risk level) to set as maximum risk level and what should be the target risk level (low risk level)

Need to define a maximum acceptable level of risk at EU level when deriving OELs for carcinogens?

- In general there was support for an agreement at EU level on a maximum acceptable level of risks for carcinogens.
- Participants tend to believe that an agreed acceptable risk level (high risk level) should be more of a guideline rather than a binding upper limit set in stone. A guideline for an acceptable risk level is moreover expected to be beneficial for the tripartite discussions in the WPC.
- There was also a discussion on how a lower limit (a target limit) should apply and whether it should be binding or a guideline. Some suggested to apply the target limit (lower risk level) as a hard limit, one that companies should reach at a certain point of time and use different transition periods for sectors if necessary based on feasibility considerations.

Advice and remarks

- The European Commission should take this discussion further by including this topic in the upcoming Europe's beating cancer plan.
- Think of ways (who?) in order to agree on a maximum acceptable level of risk without setting it in stone.
- Communication is key! Not everyone shares the shame clear understanding of the different elements comprising a risk-based approach. Develop a language to make RB approach understandable for all, policy makers and the work place. For example by publishing an article on the topic.
- Clarity is needed about the minimization principle: does this stop at the target (lower) limit, or should exposure be lowered even further?
- Only two of the EU member states have a methodology (the risk-based approach) in place which is enforced. It's possible to develop the scientific part for the EU level. But from a regulatory point of view, one also has to consider the different systems at a national level. It's important to start the discussions at the level of the member states.

Day 2

Mr. Marko Bos, acting secretary of the Social and Economic Council of the Netherlands (SER) made opening statements followed by Mr. Joost Korte, Director-General Employment, Social Affairs and Inclusion for the European Commission, who gave a keynote speech. The introductions to the roundtable discussions were given by Mrs. Andrea Hartwig, professor at the Karlsruhe Institute of Technology (KIT) and Mr. Daniel Vencovsky, consultant at Risk & Policy Analysts an external consultancy agency that has been involved in the socio-economic studies for certain limit values.

Mr. Marko Bos welcomed the participants and conveyed the greetings and best wishes for a fruitful conference from Mrs. Hamer, president of the Social and Economic Council of the Netherlands (SER).
He highlighted the role of the SER in creating social consensus on socio-economic issues. SER was established by law in 1950 and consists of independent Crown-appointed experts and employers and union representatives. It is as a major advisory and consultative body of the Dutch Government and Parliament. Its activities are guided by three common goals of social and economic policy:

- To promote balanced and sustainable economic growth;
- To promote full employment;
- To promote a fair income distribution.

SER serves these goals by organizing dialogue with all relevant stakeholders from different backgrounds and by formulating opinions following the motto 'Denkwerk, voor Draagvlak door Dialoog' (Creating common ground through Dialogue).

The labor market, social security and safe working conditions are at the core of the SER's work, Mr. Bos said. And so are socio-economic issues at European level.

He situated the conference within the broader work of the SER concerning conditions for a fair Europe. In a recent report "Priorities for a fair Europe" the importance of cohesion and upward convergence within the European Union is stressed. The report stated that Europe should reinforce existing mechanisms and, if necessary, develop new ones to see that low performers are encouraged to higher

standards (and not the other way around). Such mechanisms are necessary for maintaining and strengthening the social support for European integration and to increase the level of prosperity. This also applies to safe working conditions and limit values for carcinogens at work, he continued. All the more because limit values for carcinogens cannot be constructed based on solely scientific considerations. They unavoidably involve socio-economic reflections which brings us to the discussion of societal acceptability of risks, for both the health of workers and for business.

In the Netherlands stakeholders have been able to operate a solid system for establishing such limits. When social partners, supported by solid science and evidence from the field, agree on a limit, the limit is easily adopted by the government and there are less implementation issues.

Consensus on the common principles and methodology is a prerequisite for the much-needed European cooperation in this field, Mr. Bos, stressed. More cooperation means more efficient deployment of European resources and that leads to well-founded limit values for more relevant substances, and in less time.
Mr. Bos invited the participants to continue

their work at the dialogue tables and to ensure that Europe is made a better place to live and to work.

Mr. Joost Korte, welcomed the audience and expressed his pleasure to stand in the heart of tripartism, the Social and Economic Council of the Netherlands. He started by calling attention to the Commission's launch of a public consultation to help shape Europe's Beating Cancer Plan and invited all participants to submit their expert input.
He continued by stressing the importance of preventing cancer in the European Union where every year 3.5 million persons are diagnosed with cancer. 40% of cancer are preventable, he said, including those that originate at the workplace.

He stressed that today still too many workers are exposed to carcinogens in the workplace. For example more than 1 million workers in the EU are still exposed to benzene from activities such as petroleum refinery processes, or the manufacturing of some types of, dyes, detergents, among many other products.
And worse still there remains an unacceptably high burden of preventable disease. With over

100,000 deaths each year, occupational cancer is the first cause of work-related deaths. More than half [53%] of all deaths caused by work-related illnesses. Cancer also causes the highest share (25%) of life years lost or years lived with disability due to work-related illnesses or accidents.

Investment in OSH rules and limit values in particular, therefore makes a lot of sense, he said. Every euro invested brings more and two euro in returns for companies, thus boosting EU economies and competitiveness.

Mr. Korte went on and spoke about the past and future actions of the Commission in the field of limit values, why they are important and how they are established.

He talked about the 26 new limit values introduced the last years under the Carcinogens and Mutagens Directive (CMD) and the 41 new or revised ones under the Chemical Agents Directive (CAD).

Limit values make part of the Commission's effort to implement the tenth principle of the European Pillar of Social rights (healthy, safe and well-adapted work environment). The amendments to the CMD alone will lead to real

improvements by better protecting more than 40 million of people and helping to save the lives of more than 100,000 of workers over the next 50 years.

Concerning the importance of limit values he underlined the following:

I. Limit values are a practical tool for employers and occupational health and safety professionals to objectively assess compliance with the requirements of legislation and to monitor the workplace.
II. Limit values provide a level playing-field ensuring that all workers are assured a similar high level of health protection across the EU. The EU sets minimum requirements below which no Member State can go. You can be stricter, but not less strict.

He stated that when setting limit values for carcinogens it is important to take account of not just the science but also the implementation aspects, including a detailed analysis of socio-economic factors. Here lies an important task for the tri-partite Advisory Committee and its Working Party on Chemicals in achieving consensus on what represents an effective and achievable level of protection for workers. In this respect he very much welcomed the recent initiative of the Working Party on

Chemicals to document its recent experiences in developing Opinions to support the Commission's proposals for limit values under the Carcinogens and Mutagens Directive. He expects that this document will make this part of the process more transparent and consistent.

Mr. Korte concluded his presentation with a look ahead to the future work of the Commission. He mentioned first the review of the occupational safety and health strategy after the current framework expires at the end of the year as announced on 14 January in the communication on "A strong social Europe for just transitions". The contribution received by the Advisory Committee on Safety and Health and other relevant stakeholders will be taken into account, including the call to action from the Council. It is too early to go into details, he said, but the new framework will certainly continue to place great attention on exposure to dangerous substances, alongside risk of accidents at work and a renewed focus on new and emerging risks.

Concerning specific substances he also mentioned the 4th amendment to the Carcinogens and Mutagens Directive to include binding limit values for acrylonitrile, benzene and nickel compounds.

He also referred to the recent requests from the Commission to the European Chemicals Agency (ECHA) to carry out a scientific assessment of lead, and asthma causing diisocyanates. Based on the outcome of this work and future discussions with experts the Commission will decide whether to bring forward legislative proposals for occupational exposure limits under the Chemical Agents Directive.
Finally, the Commission is also working on asbestos. This substance is important not only because of the large number of workers' potentially exposed, but also in the context of the broader topic of energy efficiency through building renovation, contributing to the objective of a European Green Deal.
The Commission will assess the need for a possible revision of the existing limit value for asbestos based on the scientific evaluation of the European Chemicals Agency (ECHA) and discussion with stakeholders in the Advisory Committee.
Mr. Korte concluded by thanking the Dutch initiative and calling on all participants to contribute to discussions on better protection of workers against dangerous substances.

Scientific analysis

Mrs. Andrea Hartwig, professor at the Karlsruhe Institute of Technology (KIT), gave a thorough introduction to the science behind the development of limit values depending on the mode of action.

The first step is always to answer the question whether it's feasible to put up a health-based limit value for carcinogens. When the underlying mechanisms by which the carcinogen exerts its carcinogenic effect does not allow the defining of a threshold a risk-based approach can be followed.

She then explained that the German and Dutch risk based approach are well comparable. Finally she called attention to the European approach of setting Binding Occupational Exposure Limits (BOEL) for carcinogens. She explained that due to the absence of an upper risk boundary for the system, some of the current BOELs correspond to a much too high residual risk.

Analysis of the socio-economic and technical feasibility

Mr. Daniel Vencovsky, explained that external studies on socio-economic and technical feasibility aren't the same as the Commission impact assessments (IA). IA is prepared by the European Commission and needs to accompany a proposal for a limit value for carcinogens.

Socio-economic and technical feasibility studies are one of the inputs of such an IA. His presentation focused on two topics: the role of socio-economic and technical feasibility assessments in the process of OEL's and how to reach conclusions about the most appropriate OEL's.

Mr. Vencovsky elaborated a bit more on where the need for a socio-economic and technical feasibility study stems from. This is due to the fact that limit values for carcinogens under the Carcinogens and Mutagens Directive (CMD) are adopted at EU level according to the ordinary legislative procedure. An impact assessment is necessary for decision making within this process and needs to be elaborated according to the Better Regulation guidelines of the European Commission. According to these guidelines evidence has to be provided about the impacts of proposed legislation.

Mr. Vencovsky noted that the Better Regulation guidelines are developed for all legislation and not specifically for OEL's. As such they don't give a lot of guidelines for answers that are specific to the process of impact assessing OEL's.

The second issue that was addressed by Mr. Vencovsky, is how to reach a conclusion on the right OEL value based. In this respect he mentioned several issues encountered when carrying out the cost-benefit approach: ethical objections against putting a price tag to human lives; the fact that many of these substances have a number of effects and there might not be assessments for all of them; that stakeholders for the costs and the benefits are different (one stakeholder bears the cost and another one the benefits); timeframes for costs and benefits are also different (costs are paid immediately, whereas benefits arise in the future). On the cost side, it's very difficult to correctly quantify cumulative impacts where the costs associated with the risk measures are part of many pressures that the company faces and could tip the company over the edge. Another issue is how to quantify level playing field. A problem is also how to capture all uncertainty in a sensitivity analysis. Finally, it's very difficult to be forward-looking in that assessment, because it's very difficult to figure out what might be feasible in the future.

Mr. Vencovsky concluded with the remark that whatever the approach, also in a risk-based approach, it's still important to consider feasibility. Feasibility includes aspects as measurability, technical feasibility, economic feasibility, and other considerations.

Highlights roundtable and take away messages day 2

Scientific analysis

General remarks

- Expertise is needed from very different scientists for a good scientific analysis; not only toxicologists, but also epidemiologists, occupational health experts, and experts in exposure assessments.

Closer cooperation between scientific institutions in EU feasible and desirable?

- Yes! A lot of support among the participants for cooperation. The differences of the scientific derivation of limit values are of minor importance and can be overcome. Working together is desirable and it might be worthwhile to consider OELs of member states to be the basis of a OEL to share workload.
- Consider the possibility of allowing other stakeholders like Member States to make and submit an OEL proposal to the European Commission/ECHA (like the procedure in place for CLH dossiers[4]). Additionally, sharing the workload between MS prevents that activities on OELs between MS overlap.
- When cooperating and sharing information among different institutes, independancy must be guaranteed. A harmonized template/ methodology also supports this. A common protocol is needed.
- Science and politics should be separated: the prioritization of substances should be done by DG Employment, while the derivation of OELs should be done by science (RAC, national institutes).
- Organize regular meetings between the heads of the national scientific bodies to foster cooperation.
- Investigate ways of cooperation among European institutions in a pilot.
- RAC and DG EMPL need more resources in order to do more than one or two substances per year. There might be a role for the member states to help ECHA and RAC. By streamlining the cooperation, the whole process can be speed up.

Socio-economic and technical feasibility

What should be the role of an IA in the process of setting of OELs? On what basis should conclusions about the OEL value be reached?

- The socio-economic and feasibility considerations and IA should not play a disproportionate role in establishing limit values for carcinogens.
- The risk-based approach is a way to confine their importance within to the notion of a societal acceptable risk.

4 https://echa.europa.eu/nl/regulations/clp/harmonised-classification-and-labelling

Advice and remarks

- Feasibility considerations in the IA have to be transparently documented. When and how these consideration are taken into account (for example only when defining transitional periods) did not find a common understanding.
- It is desirable to develop tailor made guideline for IA in the case of OELs.
- The IA should take into consideration the conclusions of the risk-based approach. The IA should make clear what is science and what are the feasibility considerations.

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