PAPER | September 2021

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SOCIAL AND ECONOMIC COUNCIL

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SOCIAL-ECONOMIC COUNCIL

The Social and Economic Council of the Netherlands

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Inhoudsopgave

Paper

What is the purpose of this paper?

The Netherlands is an advocate of the adoption of a harmonized risk-based approach for deriving OELs at EU level for carcinogens without a threshold. This attitude is in the first place motivated by the positive experience with this type of approach in the Netherlands and the confidence that harmonization will increase the level playing field for both employers and employees and also will enable easy cooperation between scientific bodies leading to a better use of available resources and expertise in Europe. The latter is expected to have a positive effect on the capacity of the EU to develop and regularly update OELs.

This paper has two main purposes. The first is to provide a concise overview of the state of the discussion. The second purpose is to act as a reference document from which arguments can be drawn for the European debate on this.

1 OELs for non-threshold carcinogens – two main approaches

Occupational cancer is a major societal problem in the EU. An estimated 120,000 new occupational cancer cases and some 100,000 fatal work-related deaths occur each year in the EU as a result of occupational exposure to carcinogens[1]. A recommended approach is to replace carcinogens with other (less "dangerous") substances with the same functionality. However, where substitution of carcinogens is not or not yet possible or desirable and/or exposure is unavoidable, the employer's duty of care is aimed primarily at reducing the exposure to as low a level as is technically possible[2].

Setting occupational exposure limits (OELs) is one of the legal instruments to ensure exposure is reduced. However, for carcinogens which directly damage DNA and for genotoxic carcinogens for which the existence of a threshold cannot be

1 *https://roadmaponcarcinogens.eu/about/the-facts/* AND recent presentation (March 2021) by Jukka Tamala.
2 From the text of the Carinogens and Mutagens Directive; see: *https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32004L0037&from=EN*

sufficiently supported at present (the "non-threshold carcinogens") it is not possible to derive a safe OEL.

At present there are basically two approaches for setting OEL for such non-threshold carcinogens:

- defining OEL based on the best available techniques, e.g. based only on feasibility considerations;
- defining risk-based OEL, according to an approach built around the scientific derivation of exposure-risk relationships (ERR). In some cases, the term "risk-based OELs" *also* refers to a notion of risk acceptability.

The first approach is based merely on practical considerations. The flipside to this is the disregard of the risk when setting such OELs and, consequently, there is no clear perspective on the risk they represent. There is a certain risk, but it is unclear whether it is a high or low risk. In the risk-based approach the risk corresponding to the OEL is known.

According to Pronk (RIVM, 2014)[3] the EU, Germany, the Netherlands, France and Poland have some methodology in place for setting OELs for non-threshold carcinogens that could be described as risk-based. Refer to the appendix for a short description of those systems.

Most other countries (including Austria, Belgium, Denmark, Finland, Norway, Slovakia and Spain) do not set OELs for non-threshold carcinogens themselves, but adopt OELs for these substances as derived by other agencies/committees (like SCOEL, the American Conference of Governmental Industrial Hygienists (ACGIH), etc.).

3 Pronk, M.E.J. (2014) Overview of methodologies for the derivation of Occupational Exposure Limits for non-threshold carcinogens in the EU, RIVM Letter report 2014-0153

2 Risk-based approach building blocks

There are different ways of implementing a risk-based approach. The key building blocks are:

- science and data, deriving the relationship between levels of exposure and the risk (ERR) of cancer development associated with these levels;
- societal consensus on the level of accepted risk associated with developing cancer at work;
- feasibility assessment of risk-based OEL in occupational practice.

All the OELs referred to as "risk-based" depart from the scientific derivation of exposure-risk relationships (ERR). However, not all involve a consensus on the level of accepted risk or an explicit feasibility assessment.

Science

The scientific methodology for deriving exposure-risk relationships (ERR) is well developed and enjoys a broad consensus in the scientific community. When looking at the various methods used in the EU for deriving OELs for non-threshold carcinogens at the workplace, all are based on similar toxicological principles and all apply similar general criteria for quality and adequacy of the epidemiological and experimental data (Pronk RIVM, 2014)[2]. Additionally the use of human data, when available, for risk assessment is preferred but will often not be a sufficient basis on their own.

A critical factor in deriving exposure-risk relationships (ERR) is the adequacy of data and especially the extrapolation of available data to low dose levels. An assessment of the quality of the data set is part of the procedure. The general viewpoint here is that a risk-based approach may therefore not be suitable for carcinogens with a poor data-set. However, in general, it is expected that for highly relevant carcinogens in the workplace enough data is available. These are often the subject of strong scientific interest and the OSH regulation puts specific obligations on employers concerning the monitoring of such chemicals. In other words, the scientific fundamentals for the risk-based approach are often in order. The discussions pertaining to the scientific methodology and the reason why different scientific committees may derive different ERRs are more related to details regarding the study used as starting point for the analysis, the uncertainty factors applied for extrapolation and differences in exposure conditions.

A great step forward towards a harmonized EU methodology for risk-based OELs would be a consolidated methodology applied by the different scientific committees deriving exposure-risk relationships. But, transparency on the methodologies of the different committees could be a good start to allow mutual evaluation and comparison of the outcomes.

Risk-acceptance

The acceptance of a certain cancer risk, e.g. due to occupational exposure, and the use of specific predefined risk-levels is not a generally accepted and applied approach. Currently, this is the case only in the Dutch and German system. Both systems derive OELs that correspond to an exposure at a predefined, substance-independent upper risk level of developing cancer due to exposure at work. Above this upper risk level the exposure is deemed "intolerable", "unacceptable" or "prohibitive". Both systems also derive OELs that correspond to an exposure at a predefined, substance-independent low risk level of developing cancer. Below this lower risk level exposure is deemed "acceptable"; sometimes, this may be referred to as an "action" level. In both the Dutch and German systems the upper risk level corresponds to a probability of developing cancer due to work exposure equal to $4x10^{-3}$. The lower risk level in the Dutch system is equal to $4x10^{-5}$. In the German system the lower risk level is currently $4x10^{-4}$ but the aim is to further lower this level to $4x10^{-5}$.

Defining risk-acceptance is, however, not the domain of natural science experts. It needs a wide consensus among stakeholders and requires political decision-making. The non-technical nature of the concept of risk acceptance is often met with scepticism or even mistrust by individuals and societies, *but even a number of EU Member States as well*, depending on their ethical, psychological, sociological and cultural perspectives and risk perception.

The use of predefined risk acceptance levels offers a number of advantages:
Policy consistency and predictability;
Level playing field among different industries;
The upper risk level acts as a backstop and definite legal demarcation;
Prevents employees and employers
from falsely perceiving OELs carrying very different levels of risk as being equally safe.

Due to the absence of an upper risk limit in the current EU process, the residual risk associated with BOELs[4] can vary from what is generally perceived as high risk

associated with a considerable burden of disease to what is generally perceived as low risk.

A well-developed risk based approach and the use of risk-acceptance levels also increases the incentive for:

- Minimizing exposure;
- Innovation in use of chemicals and substitution;
- Greater awareness;
- Continuously improving
- and innovating in risk management requirements and measures.

On the flipside, this mechanism may increase the demands (cost, resources) on the industry and may also distract companies from the general principle of reducing the exposure to a level as low as technically possible[2] when binding limits are set at levels that still represent some level of risk.

Last but not least, communication regarding risk-acceptance levels may prove challenging. Many experts and stakeholders agree that good communication is a key factor for a well-functioning risk-based system involving predefined risk levels.

Feasibility assessment

A feasibility assessment refers to the analysis and monitoring of exposure in practice and the cost, resources and technical potential to reduce exposure. This assesses the 'viability' of a risk-based OEL and may involve technical and socio-economic considerations.

Not all risk-based approaches currently in place involve a distinct feasibility assessment. In the Dutch system the feasibility assessment of risk-based OELs for carcinogens looks only at technical and practical feasibility. A socio-economic analysis is not included in the Dutch process, because the Carcinogens and Mutagens Directive is interpreted as not allowing for economic arguments to play a role in the mitigation of risks associated with carcinogens. At the EU level, however, an impact assessment (IA) is done as part of setting binding OELs, and socio-economic and technical feasibility studies are one of the inputs of such an IA. It is important to note here that the IA is a requirement of the EU decision-making process for the adoption of BOELs, a process that needs to follow the common legislative procedure and needs to be elaborated according to the European

4 EU-OELs for carcinogens are typically referred as BOEL because they are binding.

Commission's Better Regulation guidelines. Under these guidelines evidence has to be provided about the impacts of proposed legislation.

There are 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 available for all of them;
- That stakeholders in the costs and the benefits are different (one stakeholder bears the cost and another one
- reaps 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 is very difficult to correctly quantify cumulative impacts where the costs associated with the risk measures are part of many pressures that the company faces. Another issue is how to quantify a level playing field. A further problem is how to capture all uncertainty in a sensitivity analysis. Finally, it iss very difficult to be forward-looking in that assessment, because it's very difficult to predict what might be feasible in the future.

The general view is that whatever the approach, it is still important to consider feasibility. The question that needs to be answered is which kind of a methodology fits the purpose with the appropriate level of detail. Ideally such a methodology would reflect a balance between understanding the impacts of OELs and having them actually officially adopted. The feasibility step creates a firm basis for discussion and acceptance.

One of the issues that may be considered when setting an OEL is the ability to monitor the exposure levels. This requires suitable and reliable sampling and analytical methods. The analytical LOD (limit of detection) influences the feasibility of a standard. Instrumental sampling and analytics always have limitations and there should (always) be an incentive for innovation and development, potentially CEN-driven or, as in Germany, to let the derivation of a risk-based OEL actually *trigger* the development of appropriate analytical methods by obligation.

Annex

Methodologies for the derivation of risk-based OELs in EU

EU

The current EU process for setting OELs for non-threshold carcinogens can be partially considered a risk-based approach, as it departs from the scientific calculation of the exposure-risk relationship (ERR) by the European Chemicals Agency's Committee for Risk Assessment (RAC). The RAC derives a series of exposure levels associated with estimated risks; however, it does not offer a position on the acceptability of such risks, as that is not within its remit[1].

The EU-OELs for non-threshold carcinogens (BOELs) are subsequently adopted following the common legislative procedure for adoption by the Council and the European Parliament[2]. The common legislative procedure requires the performance of an impact assessment[3] and, as a consequence, the BOELs are not purely health-based, but also reflect socio-economic and technical feasibility factors.

However, as the EU process does not apply the concept of risk acceptance, the level of protection of BOELs may broadly vary.

The Netherlands

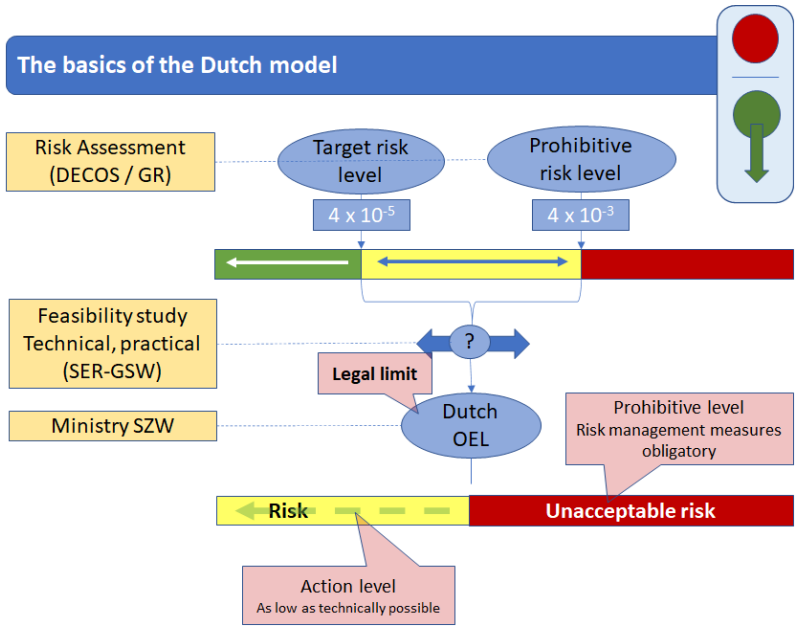
In the Netherlands, OELs for non-threshold carcinogens are set using a three-step procedure. At the request of the Minister of Social Affairs and Employment, the Dutch Expert Committee on Occupational Safety (DECOS), a committee of the Health Council of the Netherlands, needs to first understand whether the weight of evidence shows the carcinogen to have a threshold or non-threshold mode of action. If non-threshold applies, DECOS – based on the exposure-risk relationship (ERR) – derives health-based calculated occupational cancer risk values (HBC-OCRVs). These are exposure levels corresponding to an extra risk of cancer that is predefined and supported by the government and social partners. Two general reference risk levels have been defined in the Netherlands: a target risk level of 4×10^{-5} (4 additional cases per 100,000) and a prohibitive risk level of 4×10^{-3} (4 additional cases per 1,000) calculated for 40 years of occupational exposure.

In a subsequent step the feasibility of risk-based OEL is evaluated by the OEL Subcommittee of the Social and Economic Council (SER-GSW), a committee which

1 Previously, this scientific analysis was done the SCOEL.
2 *https://echa.europa.eu/oel-process*
3 *https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/impact-assessments_en*

consists of the major employer and employee organizations in the Netherlands and independent experts. The SER-GSW evaluates the technical feasibility of using the HBC-OCRVs as regulatory occupational exposure limits and advises the Ministry of Social Affairs and Employment accordingly. The evaluation of the feasibility is based on information from companies, branch organizations and sector groups. The principle applied here is that the OEL is preferably set at the level of target risk but not higher than the prohibitive risk. Deviation from this principle is theoretically possible but only in very exceptional cases[4]. If the target risk level is not feasible, social partners in the Netherlands will discuss what is the lowest possible exposure (between target and prohibitive risk). This is purely based on the possible technical measures; it does not include an assessment on application of organizational measures or PPE. Dutch OELs are set for 8 hr TWA exposure.

Finally, the Ministry of Social Affairs adopts the legal binding OEL, based on the advice of SER-GSW. In practice, the established OELs vary between the target risk level and the prohibitive risk level.

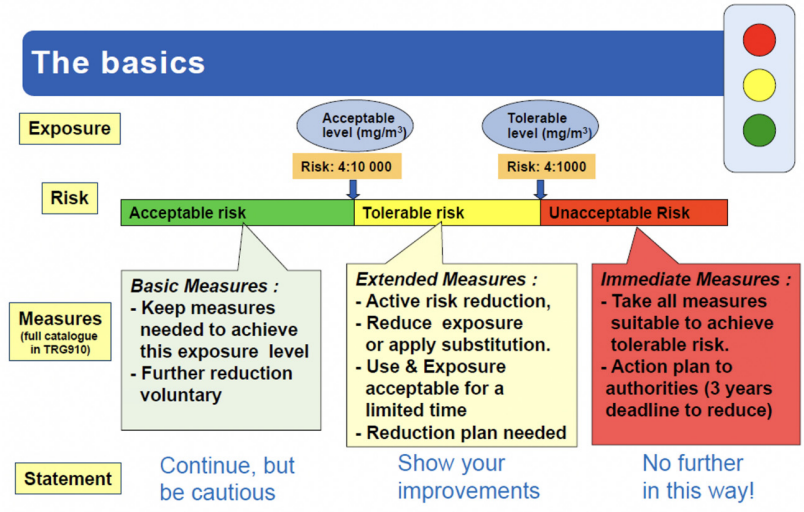


4 This only happened once in the more than 20 years of experience, and only recently, in the case of diesel exhaust emissions where the background concentrations are higher than the prohibitive risk level.

Germany

It is the Committee on Hazardous Substances (AGS) which advises the Federal Ministry of Labour and Social Affairs on OELs in the workplace. For carcinogenic hazardous substances, a risk-related approach is in place that is laid down in Technical Rule 910 (AGS, 2014), also known as the traffic light model. In this model, three risk areas are defined based on two socio-politically established risk levels. The upper risk level is the tolerable risk, which is $4x10^{-3}$, and the lower risk level is the acceptable risk, which is currently $4x10^{-4}$ but is intended[5] to be lowered to $4x10^{-5}$. Below a schematic representation of the traffic light model[6] is shown.

For workplace exposures in the green/low risk area (area below the acceptable risk), the risk is considered acceptable and the need to carry out additional measures is low, but general protective measures like basic hygiene procedures have to be fulfilled anyway. For exposures in the yellow/medium risk area (area between the acceptable and tolerable risk), the risk involved is assessed as undesirable, and only tolerable if accompanied by further measures for risk reduction and control. The need for additional measures increases considerably as the exposure approaches the tolerable risk level. For exposures in the red/high risk area (area above the tolerable risk), the risk is not acceptable (intolerable) and there is a direct necessity for additional measures in order to return at least to the medium risk area.



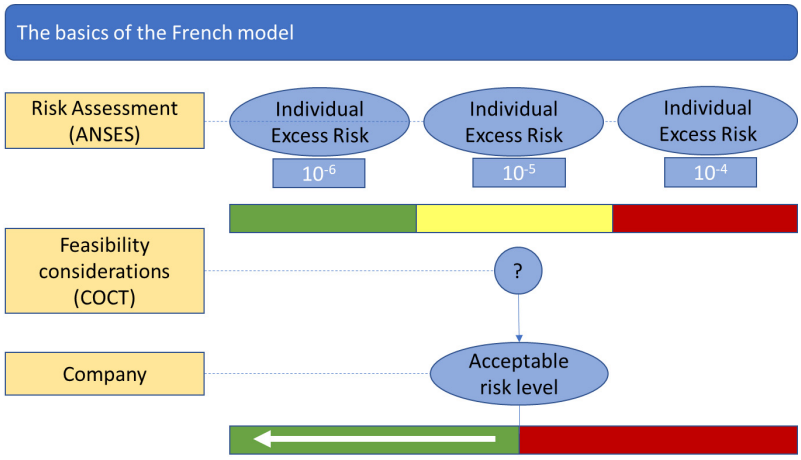
5 The initial intention was to lower the acceptable risk to $4x10^{-5}$ by 2018.
6 Rouw A. (2016) The German approach – Traffic light model, Brussels November 22, 2016.

France

The French system for establishing OELs involves three clearly distinct phases[7]:

- Independent scientific analysis conducted by ANSES (the French OEL Committee CES VLEP);
- Proposal by the Ministry of Labour of a draft OEL;
- Stakeholder consultation (including consultation of employers and employees organizations) in the French Steering Committee on Working Conditions (COCT). The aim of this phase is to discuss the effectiveness of the limit values and if necessary to determine a possible implementation timetable, depending on technical and economic feasibility considerations.

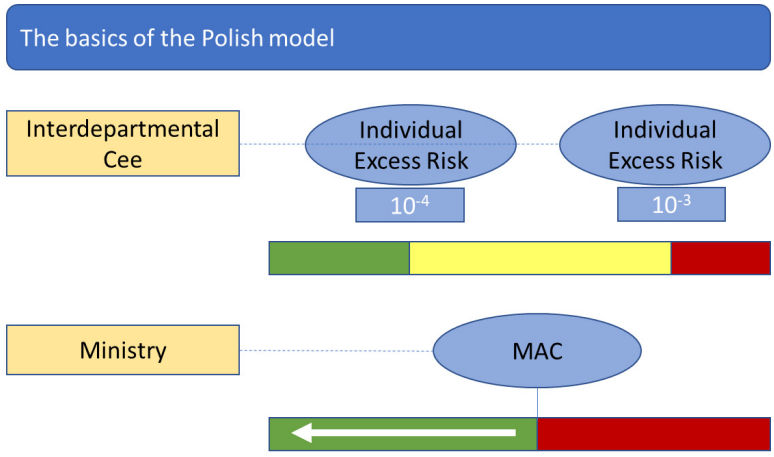
For substances considered to act through a non-threshold mechanism, the French OEL Committee studies the different quantifications of risk published in scientific literature and decides on the most coherent and reliable model to adopt for quantitative risk assessment. Data permitting, and when no published risk assessment is deemed satisfactory, the OEL Committee can decide to carry out its own risk assessment following its methodology. The output of this scientific exercise is the calculation of individual excess risk (IER) at three different risk levels, i.e. 10^{-4}, 10^{-5} and 10^{-6}. Determining an acceptable risk level is then the responsibility of risk managers at company level.



7 ANSES (2014). Expert appraisal on recommending occupational exposure limits for chemical agents – Reference Document for the derivation and the measurement of exposure limit values for chemical agents in the workplace (OELs). Collective expert appraisal. Request n°2009-SA-0339. Report of October 10, 2013, as modified on January 8, 2014. Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail, Maisons-Alfort Cedex.

Poland

In Poland, it is the Interdepartmental Commission for Maximum Allowable Concentrations and Intensities for Harmful to Health Agents in the Working Environment that proposes MACs (Maximum Admissible Concentrations) for occupational exposure to chemical compounds to the Minister of Labour and Social Policy. For carcinogenic agents, the Commission calculates extra cancer risk per unit of air concentration at two socially accepted risk levels of 10^{-3} to 10^{-4}. The risk connected with the presence of a carcinogenic agent in workplace air is assessed as high, even if the exposure is lower than the MAC.



Colophon

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Text
SER Social and Economic Council of the Netherlands
Sub-commission on Occupational Exposure Limits

Photo
Cover: Shutterstock

Graphic design
2D3D, The Hague (basic design);
SER, communications department, Design

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