



*Methodology establishing risk-based limit values for
non-threshold carcinogens, for the purposes of
Article 1 (18a) of Directive 2004/37/EC*

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1. Context

The aim of this document is to describe methodology for setting risk-based limit values at EU level for non-threshold carcinogens¹.

The Carcinogens, Mutagens and Reprotoxic Substances Directive 2004/37/EC (CMRD) is the main EU legislative tool to ensure workers' protection against risks arising from the exposure to carcinogens, mutagens and reprotoxic substances at the place of work. In 2016, the Commission initiated a continuous revision process of the CMRD to continue improving worker protection. The main objective of this continuous revision process is to set new or revised occupational exposure limit values (OELs) for priority substances.

The European Parliament, the Council and relevant stakeholders support the Commission's commitment to continuously update the CMRD and they also suggest further optimisation of the OELs setting process. As part of its fourth amendment, the Commission was invited to *"Where appropriate, after receipt of an opinion from the ACSH [Advisory Committee on Safety and Health at Work], the Commission shall, taking into account the existing methodology for setting limit values for carcinogens in some Member States and the opinion of the ACSH, establish upper and lower risk levels. No later than 12 months after receipt of the ACSH opinion, the Commission shall, after appropriate consultation of relevant stakeholders, prepare Union guidelines on the methodology establishing risk-based limit values. Those guidelines shall be published on the EU-OSHA website and disseminated in all Member States by the relevant competent authorities"*.

2. Description of the OELs setting process at EU level

The revision of the CMRD is based on a sound, comprehensive and evidence-based process, during which the consultation of the relevant stakeholders is key. This process ensures that the limit values set at EU level take account of scientific evidence (including information on residual risk), technical feasibility and socio-economic considerations.

The figure below summarizes in a simplified and non-binding manner this 5-step process starting with the prioritisation of the substances to be addressed and ending with the adoption of the legal proposal by the Commission. This 5-steps process takes on average 3 years depending on the complexity of the substances to be evaluated. Following the adoption of the legal proposal by the co-legislators, the transposition into national law then usually takes another two years.

Figure 1: simple representation of typical EU OEL setting procedure



¹ Carcinogens for which no safe exposure level is identifiable

Step 1: Consultation of the social partners and priority setting

The selection of the substances to address at EU level is based on a consultative approach, including Member States and social partners within the ACSH (ACSH opinions), and the outcome of the formal two-stage consultation of the social partners at EU level in line with Article 154 of the Treaty on the Functioning of the European Union, as well as taking into account a Commission Staff Working Document (SWD(2022)/438) listing priority substances for scientific assessment.

Furthermore, general considerations are also taken into consideration such as the estimated number of workers exposed, the route of exposure, the degree of evidence for adverse effects or the potential to cause adverse health effects resulting from occupational exposure.

Step 2: Scientific evaluation

Sound scientific basis is essential to underpin any occupational safety and health action, particularly in relation to setting occupational exposure limits to carcinogenic hazardous chemicals. The Commission is basing its proposals on scientific assessments from the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA). The Commission may use, if assessments from this committee are not available, other independent scientific assessment sources, as long as the data is adequately robust and is in the public domain.

The RAC procedure for the adoption of an opinion includes an external consultation of relevant stakeholders. This ensures scrutiny of the scientific evidence and methodological approach used by RAC and ensures transparency of the process.

More information on the ECHA methodology used by RAC can be found on the ECHA website: <https://echa.europa.eu/en/about-us/who-we-are/committee-for-risk-assessment>.

Step 3: Tripartite consultation of Member States and social partners

The Commission proposals for OELs, and where appropriate, biological limit values (BLVs) and notations, also take into account scientific-technical feasibility of monitoring exposure, including the availability of suitable measurement and analytical techniques and socio-economic feasibility aspects. In order to support the assessment of impacts the European Commission commissions a study for detailed analysis of scientific and technical data and the socio-economic information which is carried out by external consultants. This study is a key source of objective information on the uses and consequences of different policy options. Socio-economic and further technical feasibility factors identified through this study are discussed within the Working Party "Chemicals at the Workplace" (WPC) of the ACSH in view of agreeing on draft opinions. Representatives of the WPC together with representatives of relevant Commission services and EU agencies participate in a Steering Committee overseeing external studies.

The ACSH discusses WPC draft opinions (and/or other appropriate scientific evidence) and adopts a formal opinion. The adopted ACSH opinions may include, if necessary, specific comments from the interest groups (governments, employers and workers)

which broadly reflect the principal points maintained by each interest group in the discussions of the WPC.

Step 4: Impact assessment

The impact assessment (IA) accompanying the legislative proposal takes into consideration social, economic and environmental impacts. The findings of the IA are summarised in an impact assessment report, which is presented to the Regulatory Scrutiny Board in accordance with the Better Regulation policy of the Commission.

Steps 5: Legislative proposal

After completion of the previous steps, the Commission prepares the legislative proposal which will be negotiated between co-legislators following the ordinary legislative procedure.

3. Methodology for establishing risk-based limit values at EU level for non-threshold carcinogens

Based on the current knowledge, for the majority of carcinogenic substances it is not possible to identify a safe level of exposure (so-called “threshold”) below which no additional cancer risk would appear. Setting binding OELs for such non-threshold carcinogens results in limit values which are still associated with residual risk for workers. Often it is possible to establish a so-called exposure-risk relationship (ERR)², which allows for levels of the residual risks to be identified. The current EU process for setting OELs for non-threshold carcinogens starts with the derivation of the ERR by the RAC. It 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.

As requested by the co-legislators in the fourth amendment of the CMRD, the Commission services tasked the tripartite WPC of the ACSH with exploring the possibility to adopt a risk-based methodology on the basis of available information, including scientific and technical data, and Member States practices (see annex 1). This methodology should include an upper and a lower risk level between which EU OELs should be set.

The ACSH, based on the input from the WPC, adopted its opinion on limit values setting for non-threshold carcinogens, a Risk-Based Approach (Doc. 005-22)³ on 30 November 2022. It identifies the main principles, and the upper and lower risk levels to be considered when developing future OELs under the CMRD for non-threshold carcinogens. The ACSH opinion presents an approach that provides a systematic way to address the risks from non-threshold carcinogens and promotes adoption of an OEL whilst identifying the associated risk. The OEL shall be as protective as possible whilst considering feasibility aspects. It provides a structured and coherent system that ensures transparency and consistency for the decision-making process.

² The ERR of a carcinogenic hazardous substance refers to the relationship between the substance concentration (inhalation) and the statistical probability of developing cancer (additional risk beyond the background incidence)

³<https://circabc.europa.eu/ui/group/cb9293be-4563-4f19-89cf-4c4588bd6541/library/78479925-4a39-46fd-b2dc-085a244db2d6/details>

The methodology presented in this document is duly based on the above opinion supported by all interest groups (governments, workers and employers) in the ACSH. This methodology will be used in the future by the WPC / ACSH for issuing opinions for non-threshold carcinogens underpinning the Commission proposals.

Key elements of the risk-based approach setting limit values for non-threshold carcinogens as set out in the ACSH opinion

- Limit values for non-threshold substances will be set in between the predetermined “upper risk level” and the “lower risk level”. It is agreed that the upper risk level is 4:1 000 (corresponding to 4 predicted cancer cases in 1 000 employees) and the lower risk level is 4:100 000. This assumes exposure occurs over 8 hours per day, 5 days a week and 40 years of working life.
- The opinions of the ACSH will aim to recommend limit values that will be set on a consensus manner and on a case-by-case evaluation taking into account the scientific data as well as technical and socio-economic feasibility aspects.
- Only one EU OEL for each substance, or group of substances, should apply at a time.
- The OEL cannot be set above the risk level of 4:1 000. In exceptional cases, longer entry into force periods may be used if necessary due to technical and/or socio-economic feasibility aspects that require sufficient time to adapt the risk management measures to the requirements of the OEL. Such exceptional cases should be identified as cases of high concern and mentioned as such in the opinions of ACSH which are accessible to all ACSH members and publicly available.
- The proximity of the OEL to the upper or lower risk level will be a key factor in deciding when the OEL will need to be reviewed. It is agreed that if the risk is between 4:1 000 and 4:10 000 priority action is needed, whereas if the risk is in the range between 4:10 000 and 4:100 000 there is less need for a review action.
- When the initial OEL value is set at a risk level above 4:10 000 the aim should be to replace it by a more protective OEL that will apply after a transition period. The transition period and the targeted more protective OEL is to be determined on a case-by-case basis and shall be included in the ACSH opinion. When it is not yet possible to agree on a more protective OEL and a transition period, an updating/revising period shall be introduced. The intention is to revise the value (usually downwards) as necessary on the basis of new, or developing, science and/or socioeconomic and technical feasibility information. If WPC concludes that the intended further lowering is at that moment not possible, the reasons why, need to be documented and communicated via an ACSH opinion.
- If the OEL can be set below the risk level of 4:10 000 one value is sufficient. The value will be reviewed on a non-priority basis unless new, or developing, science and/or socioeconomic and technical feasibility information become available.

This risk-based approach is without prejudice to the minimisation requirement (of CMRD article 5⁴) which will continue to apply. It is, however, agreed by the three interest groups of the ACSH that there may be limited benefits applying minimisation requirement below the lower risk level, i.e. 4:100 000. This aspect needs further consideration in the WPC. This discussion should take into account supporting employers to comply with the OELs and the minimisation principle.

The three interest groups agree that the residual risk associated with the OEL needs to be communicated transparently, and that further work is necessary as regards how best to communicate this information. The WPC is willing to provide support to the Commission services to update the guidelines, if necessary.

Annex 1: Existing methodologies in Member States for setting limit values for non-threshold carcinogens⁵

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 (HBCOCRVs). 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 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 cases⁴. 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.

⁴ The employer shall ensure that the level of exposure of workers to the carcinogen, mutagen or non-threshold reprotoxic substance is reduced to as low a level as is technically possible.

⁵ Source: Towards a harmonized risk-based approach for OELs in the EU for carcinogens without a threshold (ser.nl) <https://www.ser.nl/-/media/ser/downloads/engels/2021/oels-eu-carcinogens-without-threshold.pdf>

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.

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 currently 4×10^{-4} but is intended⁶ to be lowered to 4×10^{-5} .

France

The French system for establishing OELs involves three clearly distinct phases⁷:

- Independent scientific analysis conducted by ANSES (the French Agency for Food, Environmental and Occupational Health & Safety, OEL Committee);
- 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 ANSES 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} . It is then the responsibility of the French government to decide with the help of the social partner the level of the OEL and the associated risk level that will be integrated in the legislation.

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

⁶ The initial intention was to lower the acceptable risk to 4×10^{-5} by 2018.

⁷ ANSES (2014). Expert appraisal on recommending OELs 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.

connected with the presence of a carcinogenic agent in workplace air is assessed as high, even if the exposure is lower than the MAC.