MIDAS includes the descriptions of models in use by the Commission in support to the policy cycle. MIDAS is developed and managed by the **Competence Centre on Modelling** of the European Commission.

Find out more at https://ec.europa.eu/knowledge4policy/modelling_en
Contact: EU-MIDAS@ec.europa.eu

Factsheet

SWD/2020/183 final

IMPACT ASSESSMENT Accompanying the document Proposal for a Directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work

Supporting model(s)

CMD IV Model

Impact assessment
SWD/2020/183 final

Fact sheet on model contributions

Source: Commission modelling inventory and knowledge management system (MIDAS)

Date of Report Generation: 12/04/2021

Dissemination: Public

Overview

Title
IMPACT ASSESSMENT Accompanying the document Proposal for a Directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work

Document ID
SWD/2020/183 final

Year of publication
2020

Led by
EMPL

Model(s) used
CMD IV Model

Additional information

The analysis in support of the impact assessment was run by COWI together with RPA Risk and Policy Analysts and FoBiG Forschungs- und Beratungsinstitut Gefahrstoffe GmbH.

CMD IV Model

Full title
Fourth revision of the Carcinogens and Mutagens Directive Model

Run for this impact assessment by
COWI

Contributed to
Evaluation of existing policy

CMD IV Model

Full title
Fourth revision of the Carcinogens and Mutagens Directive Model

Run for this impact assessment by
COWI

Contributed to
Problem definition

CMD IV Model

Full title
Fourth revision of the Carcinogens and Mutagens Directive Model

Run for this impact assessment by
COWI

Contributed to
Baseline and assessment of policy options

Helped to assess the following impacts

Impact area	*Impact category*	*Impact subcategory*
Economic impacts	Operating costs and conduct of business	Adjustment, compliance or transaction costs
Economic impacts	Operating costs and conduct of business	Business access to finance
Economic impacts	Operating costs and conduct of business	Opening/closing down of business
Economic impacts	Trade and investment flows	EU Exports & imports
Economic impacts	Competitiveness (sectoral) of business	Cost of doing business
Economic impacts	Competitiveness (sectoral) of business	Business' capacity to innovate
Economic impacts	Competitiveness (sectoral) of business	Market share & advantages in international context
Economic impacts	Position of SMEs	Operation and competitiveness of SMEs and micro SMEs
Economic impacts	Public authorities	Budgetary consequences for public authorities
Economic impacts	Public authorities	Governmental administrative burden
Economic impacts	Consumers and households	Prices, quality, availability or choice of consumer goods and services
Economic impacts	Specific regions or sectors	Significant effects on sectors
Social	Employment	Impact on jobs
Social	Employment	Impact on jobs in specific sectors, professions, regions or countries
Social	Employment	Factors preventing or enhancing the potential to create jobs or prevent job losses
Social	Working Conditions	Occupational health and safety

Social	Public health and safety and health systems	Health and safety of individuals/populations
Environmental	Air quality	Emissions of acidifying, eutrophying, photochemical or harmful air pollutants

CMD IV Model

Fourth revision of the Carcinogens and Mutagens Directive Model

Fact sheet

Source: Commission modelling inventory and knowledge management system (MIDAS)

Date of Report Generation: 12/04/2021

Dissemination: Public

Overview

Acronym CMD IV Model
Full title Fourth revision of the Carcinogens and Mutagens Directive Model

Main purpose
The model was developed to assess the costs and benefits related to different policy options for addressing three carcinogenic substances in the frame of the fourth amendment of the Carcinogens and Mutagens Directive 2004/37/EC. These costs and benefits were assessed for a broad range of stakeholders, including employers, workers and public sector.

Summary
The model was designed by the consulting group COWI in co-operation with RPA Risk and Policy Analysts and FoBiG to simulate the costs and benefits related to different policy options aiming to improve the protection of workers at EU level from the occupational exposure to three carcinogens, namely acrylonitrile, nickel compounds and benzene. Based on these costs and benefits, the Commission carried out the impact assessment accompanying its legislative proposal amending the Carcinogens and Mutagens Directive 2004/37/EC.

The model was designed to simulate both the costs and benefits related to different scenarios.

Benefit model: The introduction of an occupational exposure limit (OEL) is expected to result in a reduction in the occupational exposure to the carcinogen concerned. The extent of such reduction depends on the current levels of exposure, as well as on the projected future levels of exposure in the absence of the proposed measure, i.e. the 'baseline scenario'. For a given reduction in exposure levels, it is then necessary to estimate the expected decrease in the incidence of cancer cases and other non cancer health effects over a given timeframe to the substance in question.The health benefits of implementing new or revised OELs are then calculated in terms of the costs of ill health avoided.

Cost model: The introduction of an OEL is expected to result in compliance and monitoring costs for companies. With regard to compliance costs, the estimates are based on the risk management measures (RMMs) needed to comply with an OEL, the costs of the RMMs, the life span of the RMMs and the number of companies and/or workstations. The costs of monitoring air concentrations (sampling and analysis) are estimated separately to the core model on the basis of data for several Member States.

The model could be used the carry out impact assessments when preparing legislative proposals amending the Carcinogens and Mutagens Directive 2004/37/EC.

Keywords
Occupational safety and health , workers' protection , fight against cancer

Model category (thematic)
Health

Model home page
No information provided

Ownership & license

Ownership
Sole ownership [European Union]

Ownership details
No information provided

Licence type
Non-Free Software licence. The license has one or more of the following restrictions: it prohibits creation of derivative works; it prohibits commercial use; it obliges to share the licensed or derivative works on the same conditions.

Details

Model structure and approach

This model, which consists in a benefit model and a cost model, was developed to assess the costs and benefits related to different occupational exposure limit scenarios for three carcinogenic substances.

The benefit model enables to estimate the current and future cases of ill health for both cancer and non-cancer endpoints. The key inputs used are described below. The inputs are those parameters whose variation changes the results and for which the model is run multiple times to derive a benefits curve.

In addition to the inputs, the model is underpinned by a range of default assumptions regarding the onset of the disease and its effects. These assumptions differ by substance but do not change depending on the variations in the input data. Some of these assumptions are a simplification of complex real life scenarios or best estimates (where authoritative evidence could not be identified from readily available literature).

The benefit model provides a good approximation of the order of magnitude of the expected impacts and the core calculations are supported by sensitivity analysis. The outputs of the model include:

- The number of new cases for each health endpoint assigned to a specific year in the 60 year assessment period;
- The Present Value (PV) of the direct, indirect, and intangible costs of each case.

The health benefits of implementing new or revised OELs are then calculated in terms of the costs of ill health avoided.

The cost model enables to assess the compliance costs for companies. These costs are estimated on the basis of the inputs described below and are calculated in a worksheet model.

For some sectors, where non-specific data are available, a likelihood model is applied. The likelihood model calculates the costs for a group of similar companies incurred in reducing air exposure to a target OEL based on an assumed sequence of Risk Management Measures implementation which is determined by suitability, effectiveness, and cost. The model is run several times to construct a continuous cost curve.

For other sectors, where the Risk Management Measures to be applied are more well-described, a more simple model is applied, but the same unit costs and life span parameters are used as in the more complex model.

Input and parametrization

The key inputs used for the benefit model are:

- Rx – Estimate of the risk or fraction of workers affected: this information is based on the Exposure-Risk Relationship (ERR) or Dose-Response Relationship (DRR):
    - ERR: excess risk of developing cancer due to lifetime occupational exposure to a substance (taken here to mean 40 years); and
    - DRR: the proportion of workers that will develop an endpoint when exposed to a certain level.
- ExW – Exposed workforce: number of workers exposed at different points in time.
- Cx: Exposure concentration: 8-hr time-weighted average (TWA) that the workers are exposed to (real concentration, i.e. if personal protection equipment (PPE) is currently worn, the measured concentrations are adjusted to take into account PPE where possible)

The key assumptions are:

- MinEx – the minimum exposure duration required to develop the endpoint
- MaxEx – the time needed to reach the maximum risk (I.e. after the MaxEx has been reached, the risk of effects do not increase)
- ModEx – the modelled exposure duration (the ERRs and DRRs are for a 40 year period)
- Lat – the latency with which the effect is demonstrated
- The distribution of cases over the period between MinEx and 60 years
- Mortality – Mortality rate as a result of the relevant condition
- Value of a DALY – Monetary value of a case taking into account the direct, indirect, and tangible costs
- Turnover percentage of staff per year;
- Value of a Statistical Life (VSL);
- Willingness to pay (WTP) to avoid for morbidity;
- Disability weights;
- Discount rates.

The compliance costs are estimated on the basis of:

- Exposure concentration: 8-hr time-weighted average (TWA) that the workers are exposed to (real concentration, i.e. if personal protection equipment (PPE) is currently worn, the measured concentrations are adjusted to take into account PPE where possible);
- Risk Management Measures (RMMs) needed for reducing the air exposure levels from the actual levels to the target level;
- The costs of the RMMs (one-off and recurrent) for each company and/or workstation;
- The % reduction in exposure of the RMMs;
- The life span of the RMMs;
- The number of companies by size (small, medium and large)
- The number of workstations by size (small, medium and large company)
- The discount rate

Main output

The key outputs produced by the benefit model include:

- The number of new cases for each health endpoint assigned to a specific year in the 60 year assessment period;
- The Present value of the direct, indirect and intangible costs of each case.

The health benefits of implementing new or revised OELs are then calculated in terms of the costs of ill health avoided.

The key outputs produced by the cost model are the compliance and monitoring costs for companies for each policy option over the next 60 years.

Spatial - temporal extent

The output has the following spatial-temporal resolution and extent:

Parameter	Description
Spatial Extent / Country Coverage	EU Member states 27 and UK
(Spatial) resolution	World-regions (supranational)
Temporal extent	Long-term (more than 15 years)
Temporal resolution	Multiple years

Quality & transparency

Quality

Question	Answer	Details
Models are by definition affected by uncertainties (in input data, input parameters, scenario definitions, etc.). Have the model uncertainties been quantified? Are uncertainties accounted for in your simulations?	yes	This cost-benefit analysis posed several challenges, including additional endpoints, number of workers exposed, the future trends, the available epidemiologic evidence, the discount rate. Despite these challenges, some of these parameters have been quantified.
Sensitivity analysis helps identifying the uncertain inputs mostly responsible for the uncertainty in the model responses. Has the model undergone sensitivity analysis?	yes	Sensitivity analysis has been performed for one substance by taking into consideration lower and higher costs than the main estimate.
Has the model undergone external peer review by a panel of experts, or have results been published in peer-reviewed journals?	no	
Has model validation been done? Have model predictions been confronted with observed data (ex-post)?	yes	For benzene, a comparison between the estimation of past exposure with actual reported cases was performed. The model results were then discussed against the reported cases.

References related to external peer-review and publication in scientific journals:

- No references provided in MIDAS

Transparency

Question	Answer	Details
Is the model underlying database (i.e. the database the model runs are based on) publicly available?	yes	The databases used have been mentioned in the different reports of the study commissioned by the Commission to support the fourth revision of the Carcinogens and Mutagens Directive 2004/37/EC
Can model outputs be made publicly available?	yes	The costs and benefits related to the policy options identified by the Commission are available in the impact assessment report accompanying the legislative proposal aiming to amend for the fourth time the Carcinogens and Mutagens Directive 2004/37/EC
Is the model transparently documented (including underlying data, assumptions and equations, architecture, results) and are these documents available to the general public?	yes	Yes, all the information is available in the different reports of the study
Is the model source code publicly accessible or open for inspection?	no	

References related to documentation:

- No references provided in MIDAS

The model's policy relevance and intended role in the policy cycle

The model is designed to contribute to the following policy areas

- Employment and social affairs

The model is designed to contribute to the following phases of the policy cycle

- Formulation

The model's potential

The model was developed to support the impact assessment accompanying the legislative proposal aiming to revise the Carcinogens and Mutagens Directive 2004/37/EC. It enabled to estimate the costs and benefits related to different policy options envisaged in the impact assessment.

Previous use of the model in ex-ante impact assessments of the European Commission

Use of the model in ex-ante impact assessments since July 2017.

In the Year	Unknown contributed to the Impact assessment called	Led by	By providing input to the	The model was run by	Details of the contribution
2020	SWD(2020) 183 final – IA accompanying the document Proposal for a Directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to the exposure to carcinogens or mutagens at work.	DG EMPL	evaluation of existing policy	COWI	The model was used for evaluation of the existing policy.
2020	SWD(2020) 183 final – IA accompanying the document Proposal for a Directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to the exposure to carcinogens or mutagens at work.	DG EMPL	problem definition	COWI	The model was used for problem definition.
2020	SWD(2020) 183 final – IA accompanying the document Proposal for a Directive of the European Parliament and of the Council amending Directive 2004/37/EC on the	DG EMPL	baseline and assessment of policy options	COWI	The model helped to assess the following impacts: • Adjustment, compliance or transaction costs • Business access to finance • Opening/closing down of business • EU Exports & imports • Cost of doing business • Business' capacity to innovate

	protection of workers from the risks related to the exposure to carcinogens or mutagens at work.		• Market share & advantages in international context • Operation and competitiveness of SMEs and micro SMEs • Budgetary consequences for public authorities • Governmental administrative burden • Prices, quality, availability or choice of consumer goods and services • Significant effects on sectors • Impact on jobs • Impact on jobs in specific sectors, professions, regions or countries • Factors preventing or enhancing the potential to create jobs or prevent job losses • Occupational health and safety • Health and safety of individuals/populations • Emissions of acidifying, eutrophying, photochemical or harmful air pollutants

Bibliographic references

- *No references provided in MIDAS*