

Carcinogenic Substances: Risks and Prevention  
Web-Symposium 15 June 2021

# Occupational Exposure Limits under the Carcinogens and Mutagens Directive

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# Outline

- Carcinogens & Mutagens Directive (CMD) & Occupational Exposure Limits (BOEL)
- Revisions of the CMD & BOEL
- Regulatory implementation in Austria (examples)
- CMD & reprotoxic substances

# Carcinogens & Mutagens Directive (CMD)

- Directive 2004/37/EC on the **protection of workers** from the risks related to exposure to **carcinogens or mutagens** at work (6<sup>th</sup> individual Directive of Council Directive 89/391/EEC)
- Objective: protection of workers against risks of carcinogens or mutagens
- Minimum requirements for the health and safety e.g.:
  - Determination & assessment of risks
  - Reduction, replacement, prevention of exposure
  - Information and training of workers
  - Health surveillance
  - **Including limit values** (Annex III)
- At national level more restrictive regulations possible
- Since 2004 – 3 amendments concerning limit values

## CMD: Limit values

- CMD: **B**inding **O**ccupational **E**xposure **L**imits (BOEL)
- Minimum requirements
- Member States can set more stringent OEL
- **Annex III** of the CMD
  - Substance name, EC No, CAS No
  - 8 hours time weighted average (TWA)
  - Short-term exposure limit (STEL)
  - Notation: skin, sensitisation
- Currently 25 carcinogen & mutagene agents with limit values (BOEL)

# Binding Occupational Exposure Limits (BOEL)

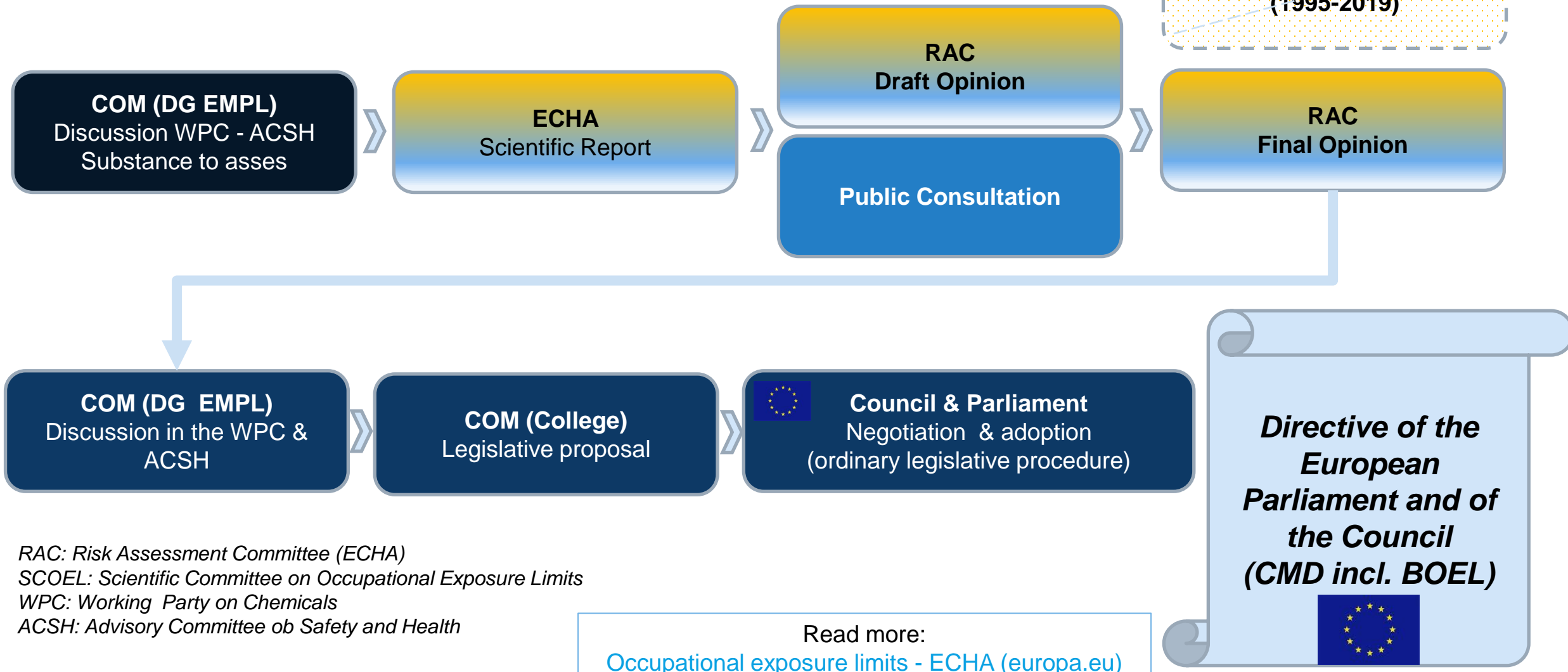
- BOEL established on the basis of:
  - available information including scientific & technical data
  - economic feasibility
  - socioeconomic impact
  - availability of
  - exposure measurement protocols & techniques at the workplace

- Most carcinogens & mutagens: **non-threshold**

*“...it is not scientifically possible to identify levels below which exposure would not lead to adverse effects.”*

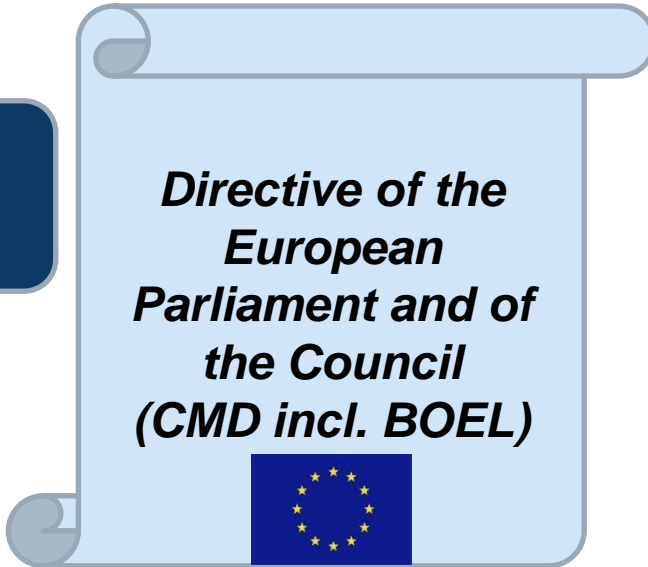
- Residual cancer-risks remain (partly they are high)
- Evaluation & revision

# Short overview: BOEL-process



RAC: Risk Assessment Committee (ECHA)  
SCOEL: Scientific Committee on Occupational Exposure Limits  
WPC: Working Party on Chemicals  
ACSH: Advisory Committee of Safety and Health

Read more:  
[Occupational exposure limits - ECHA \(europa.eu\)](http://Occupational%20exposure%20limits%20-%20ECHA%20(europa.eu))

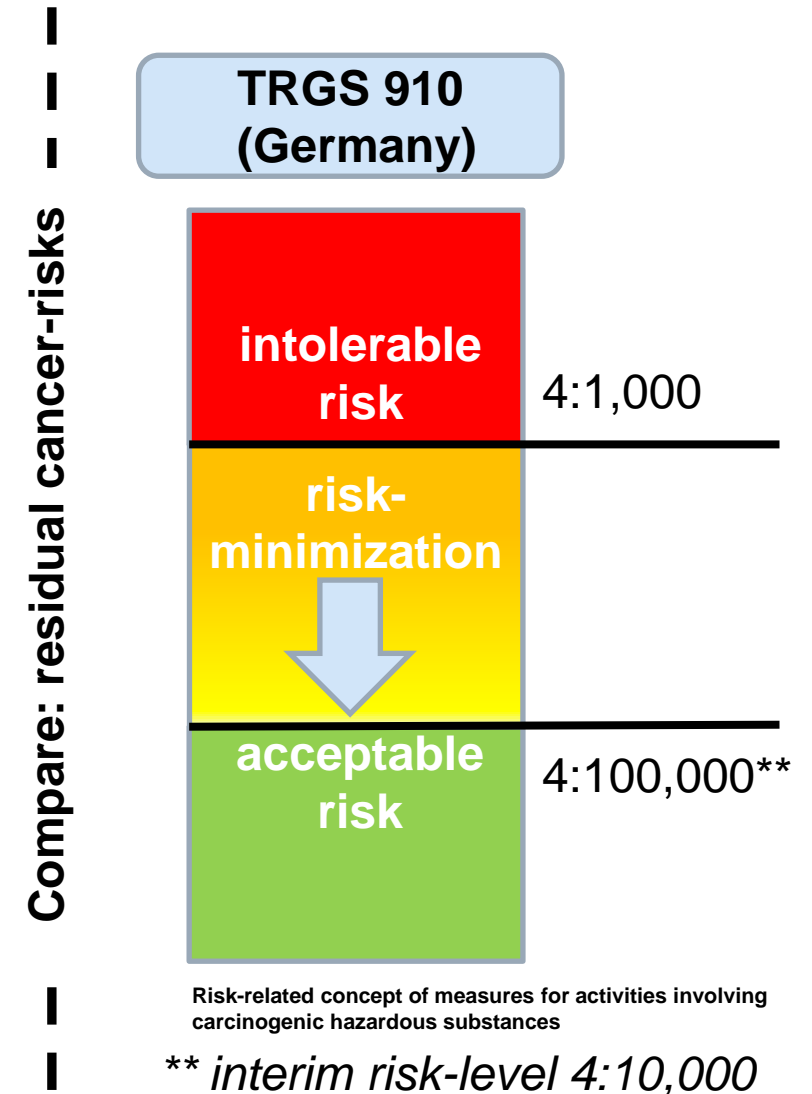


# Residual cancer-risks (examples)

Substance	CAS No	TWA [mg/m <sup>3</sup> ] CMD	<i>residual cancer-risk</i> [lifetime working-risk*]
2-Nitropropane	79-46-9	18	4,045:100,000
Acrylamide	79-06-1	0,1	57:100,000
Arsenic acide, salts, inorganic compounds		0,01	480:100,000
Benzene	71-43-2	3,25	685:100,000
Cadmium and its inorganic compounds from 12.07.2027		0,001	250:100,000
Cadmium and its inorganic compounds until 11.07.2027		0,004	1,000:100,000
Chromium VI compounds		0,005	2,000:100,000
Chromium VI compounds until 17.01.2025		0,01	4,000:100,000
Chromium VI compounds until 17.01.2025 for welding or plasma cutting processes or similar work processes that generate fume		0,025	10,000:100,000
Ethylene dichloride	107-06-2	8,2	490:100,000
Ethylene oxide	75-21-8	1,8	305:100,000
Hydrazine	302-01-2	0,013	235:100,000
Trichlororthylene	79-01-06	54,7	320:100,000

Source: A-Expert, 06/2020, J. Püringer

\* working lifetime of 40 years and exposure for 8 h every working day.



## Revisions of the CMD – BOEL

- Directive (EU) 2017/2398 of 12 December 2017
  - National implementation latest by 17.01.2020
- Directive (EU) 2019/130 of 16 January 2019
  - National implementation latest by 20.02.2021
- Directive (EU) 983 of 16 June 2019
  - National implementation latest by 11.07.2021
- Proposal (COM 2020/571)
  - Acrylonitrile: 1 mg/m<sup>3</sup> (8-hours TWA)
  - Benzene: 0,66 mg/m<sup>3</sup> (8-hours TWA)
  - Nickel compounds: 0,01Ni mg/m<sup>3</sup> (TWA, respirable fraction); 0,05 Ni mg/m<sup>3</sup> (TWA, inhalable fraction)
  - National implementation 2 years after the date of its entry into force

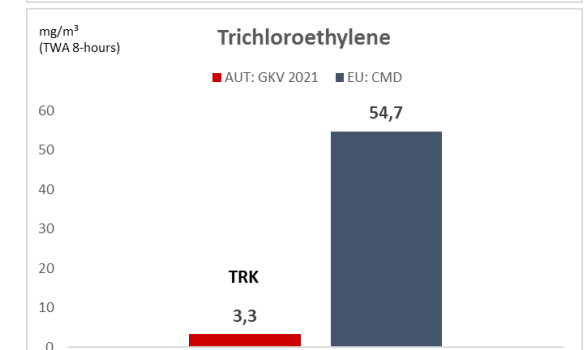
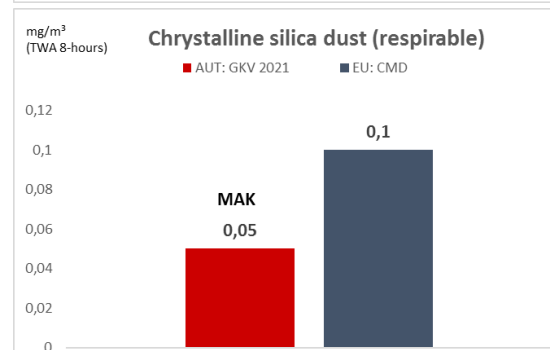
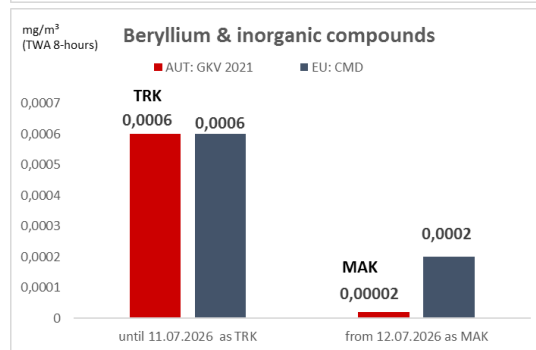
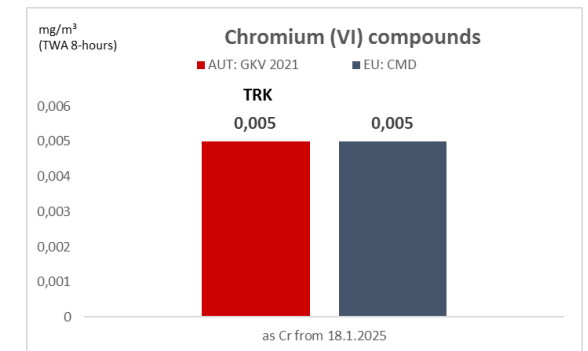
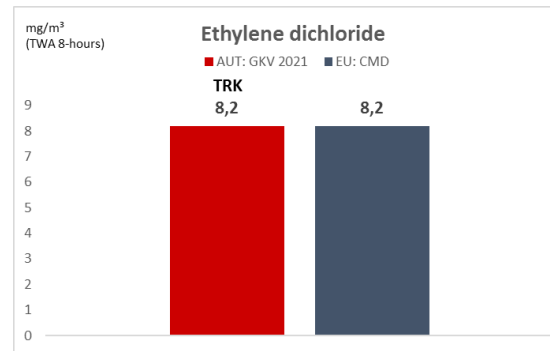
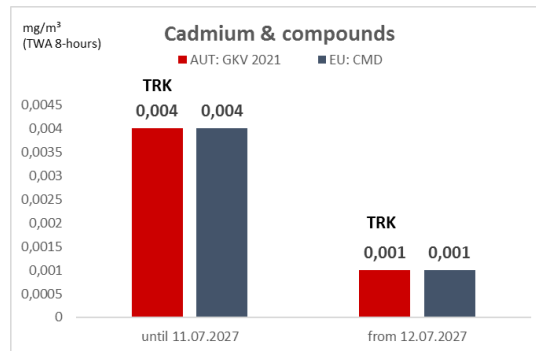
Member States  
can set  
more stringent OEL!



# CMD: Implementation in Austria

- Austrian-Regulation: „Grenzwerteverordnung 2021 – GKV“
  - TRK: technical reference concentration (without a threshold; „Technische Richtkonzentration“)
  - MAK: maximum concentration at the workplace (threshold; „Maximale Arbeitsplatz-Konzentration“)
- Mostly EU-minimum-level (TWA 8-h): 21 of 25 substances
- Residual cancer-risks published: [website Labour Inspectorate](https://www.la-nr.at/)

Some examples:



■ AUT: GKV 2021  
■ EU: CMD

# CMD & reprotoxic substances

- Adverse effects on reproductive systems:
  - sexual function and fertility
  - development of the offspring
  - lactation
- European Parliament (amendment) - enlarge the scope of CMD to reprotoxic substances
- Reprotoxic substances are of high concern
- Legal coherence to REACH
- Same workplace prevention as to carcinogens and mutagens
- Replacement by less dangerous substance/mixture/process to the health or safety of workers
- Austria: same workplace prevention for reprotoxic substances as for carcinogens & mutagens

# OSH provisions: limit values

- CMD: [Directive 2004/37/EC of 29 April 2004](#) (current consolidated version)
- CMD - amendment: [Directive \(EU\) 2019/2398 of 12 December 2017](#)
- CMD – amendment: [Directive \(EU\) 2019/130 of 16 January 2019](#)
- CMD – amendment: [Directive \(EU\) 2019/983 of 5 June 2019](#)
- Chemical Agents Directive (CAD): [information on the OSHA-website](#)
- Health & Safety at Work Act (Austria): [ArbeitnehmerInnenschutzgesetz \(ASchG\)](#)
- Regulation for limit values & C(M)R substances (Austria): [Grenzwerteverordnung 2021 - GKV](#)
- Limit Values (Austria): [Anhang I/2021 Stoffliste mit MAK-Werte und TRK-Werte](#)
- Website Labour Inspectorate (Austria) > [Limit Values](#)



# THANK YOU !

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