Regulatory application of science and stakeholder engagement - setting EU Occupational Exposure Limits

Particles and Health Conference
Critical issues in Science and Regulation

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European Commission

Summary

- EU Pillar of Social Rights Action Plan
- EU Occupational Safety and Health strategic framework
- Key steps in setting Occupational Exposure Limits & Biological Limit Values
- Practical benefits of EU OELs & BLVs
- Social partners participation in regulatory decision making
- ACSH adopts new list of priorities for future limit values – May 2021
- Ongoing OSH initiatives – Asbestos, Lead & Diisocyanates
- Carcinogens and Mutagens Directive - some recently adopted OELs

#SocialRights

« The European Pillar of Social Rights has been our reference point for building a strong social Europe. Now we breathe new life into it, turning its principles into actions. »

Nicolas Schmit, European Commissioner for Jobs and Social Rights

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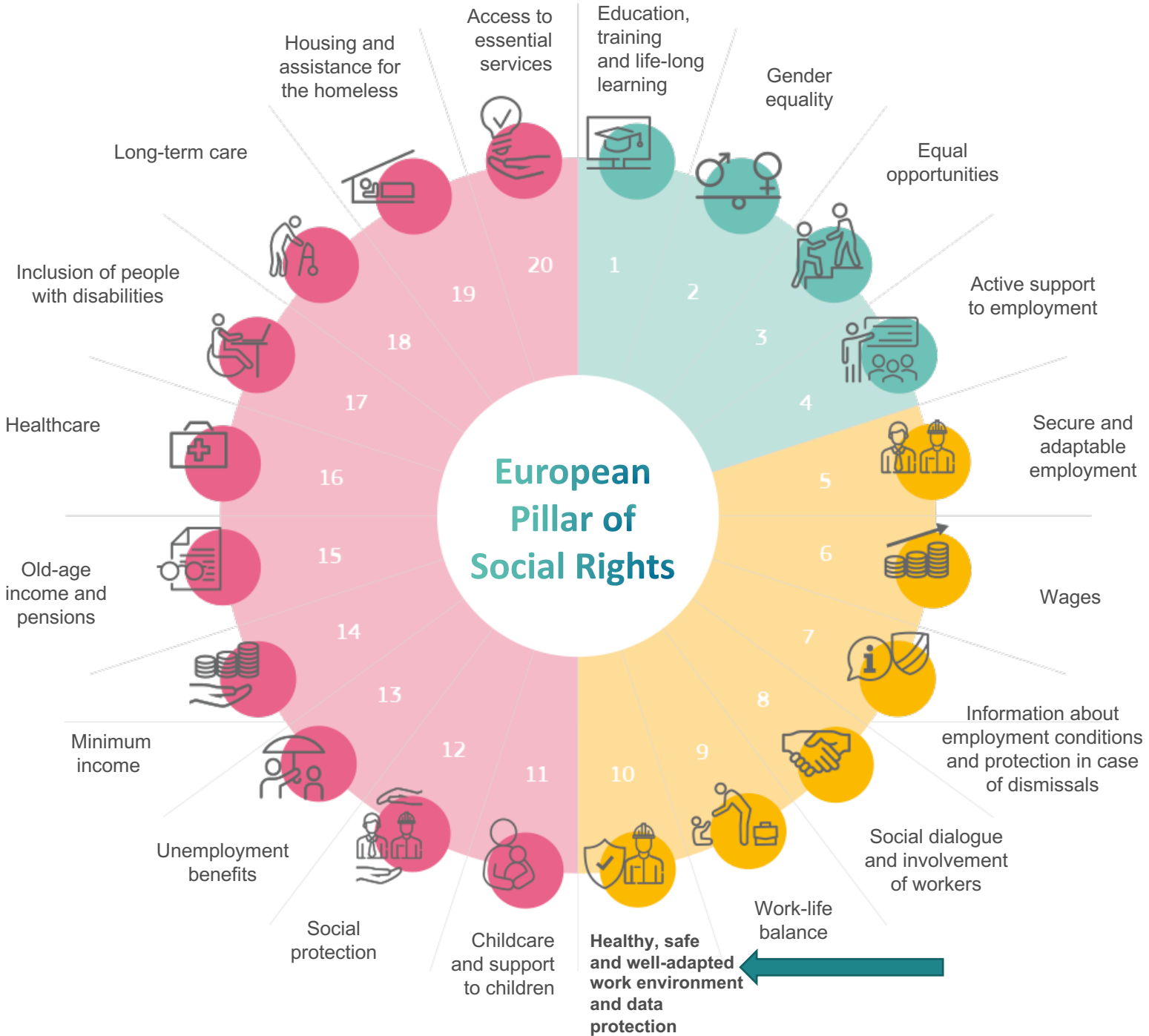

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EU Pillar of Social Rights Action Plan

- The EPSR Action Plan was adopted on March 2021

- Action Plan outlines concrete actions to further implement the principles of the EPSR including **adoption of a new strategic framework on occupational safety and health**

- Joint effort by MSs and the EU, with the active involvement of social partners and civil society

- Porto Social Summit in May 2021

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EU Occupational Safety and Health strategic framework

Occupational safety and health in a changing world of work 2021 – 2027 *(28.6.2021 COM(2021) 323 final)*.
https://ec.europa.eu/social/main.jsp?catId=151

EU OSH policy – tripartite approach to policy making – Member States, employers' and workers' representative organisations supported by the scientific community.

Three key objectives:

- **anticipating and managing change** in the new world of work brought about by the green, digital and demographic transitions;
- **improving prevention** of workplace accidents and illnesses;
- **increasing preparedness** for any potential future health crises.

- Recognises that hazardous substances can be found in nearly all workplaces, and millions of workers in the EU are exposed to these substances every day.
- Plan to adopt new and updated OELs/BLVs to update Asbestos at Work Directive, Chemical Agents Directive, Carcinogens and Mutagens Directive - including asbestos, lead, diisocyanates, cobalt etc..

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Key steps in setting Occupational Exposure Limits & Biological Limit Values

For binding limit values need also to consult social partners in two stages in accordance with social policy requirements of Article 154 TFEU

1

Selection of chemicals for Scientific Evaluation

DG EMPL establishes lists of priorities for scientific evaluation based on inputs from various sources and application of priority criteria.

2

Scientific Opinion

DG EMPL mandates ECHA for RAC the scientific committee to deliver an Opinion. This includes the dose response relationship or exposure-risk-relationships (ERR) for non-threshold carcinogens, or a practical threshold when possible. ECHA scientific reports are subject to external consultation.

3

WPC - ACSH

The Working Party on Chemicals (WPC) discusses the scientific Opinion 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 IA containing policy options and associated impacts. IA is discussed within an Interservice Steering Group and submitted to the Regulatory Scrutiny Board (RSB). A positive reply is required.

5

Draft legislative proposal

DG EMPL prepares the draft legislative proposal and submits it to inter-service consultation. 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.

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Practical benefits of EU Occupational Exposure Limits & Biological Limit Values

- Protects workers' health.
- Defines effective control of exposure.
- Indicates level of exposure considered to be safe (health based) or appropriate (where feasibility factors are also taken into consideration).
- Provides a "level playing field" for all users – promotes consistency.
- Provides a benchmark for new users and designers of process plant.
- Defines a common objective for employers, workers and enforcement agencies.
- Contributes to more effective health surveillance.

Social partners participation in regulatory decision making

- Two stage social partners consultation at EU level in accordance with TFEU Article 154.
- Selecting priority chemicals for scientific evaluation (WPC).
- Respond to public consultations on the draft scientific reports of ECHA that support RAC.
- Participate in meetings of RAC as WPC experts.
- Represented in the Working Party on Chemicals (together with Member State experts) where they prepare the draft Opinions for the Advisory Committee on Safety and Health.
- Adoption of Opinions by the plenary of the ACSH.
- External study to support the Impact Assessments makes use of data provided by external stakeholders. Social partners representatives are members of the steering group for the study (WPC).
- Bilateral discussions with DG EMPL.

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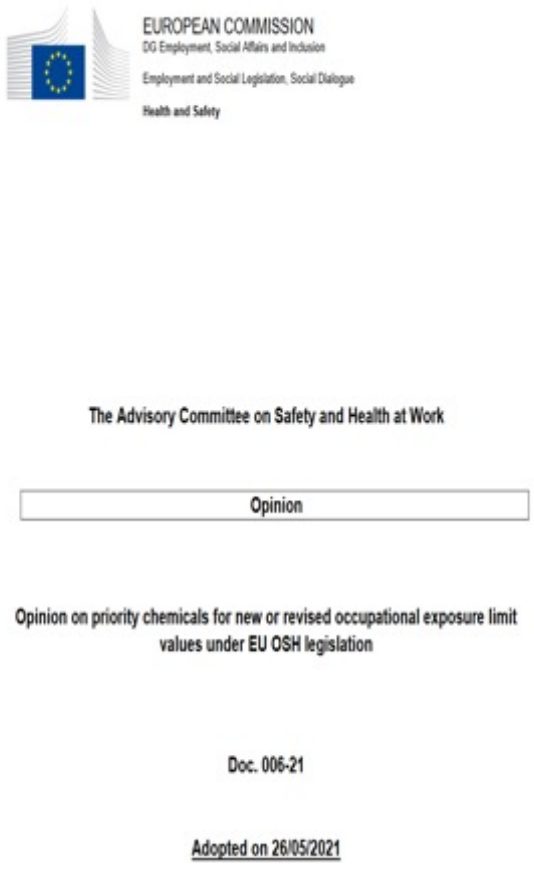
ACSH adopts new list of priorities for future limit values – May 2021



EUROPEAN COMMISSION
DG Employment, Social Affairs and Inclusion
Employment and Social Legislation, Social Dialogue
Health and Safety

The Advisory Committee on Safety and Health at Work

Opinion

Opinion on priority chemicals for new or revised occupational exposure limit values under EU OSH legislation

Doc. 006-21

Adopted on 26/05/2021

- Adopted by the Advisory Committee on Safety and Health – May 2021.
- This lists priority chemicals for future scientific evaluation by ECHA RAC and subsequent development of Commission proposals for limit values.
- For each priority chemical (or group of chemicals) it lists the name, CAS number, whether there is an existing scientific evaluation together with a justification and summary of any relevant background information.
- Includes: asbestos, welding fume, PSLTs, MMMFs/MMVFs…
- The Commission (in practice DG Employment, Social Affairs and Inclusion) mandates ECHA to carry out the scientific evaluation – normally 5 priority chemicals per year.
- For more info on ACSH
  https://ec.europa.eu/social/main.jsp?catId=148&intPageId=683&langId=en

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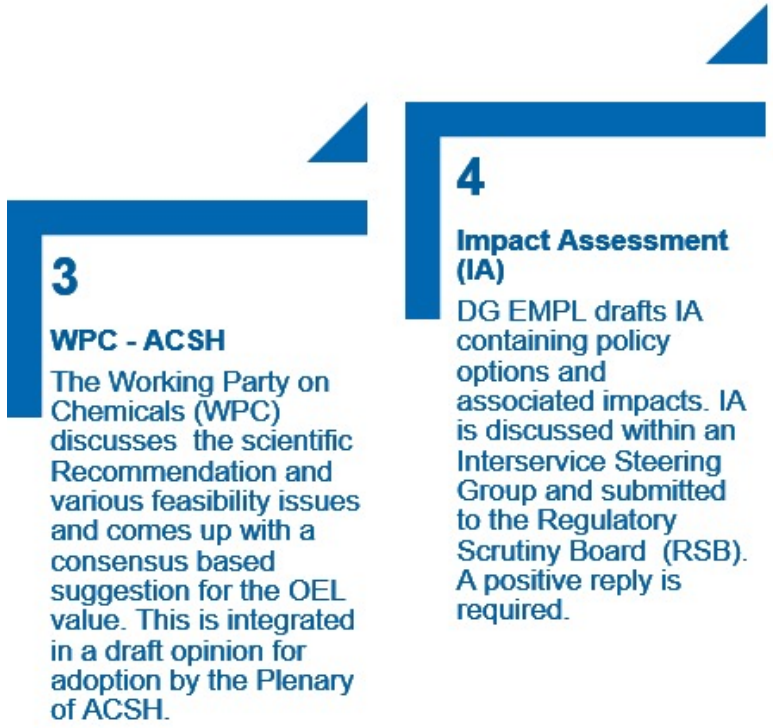
Ongoing OSH initiatives – Asbestos, Lead* & Diisocyanates

- **RAC Opinions** adopted in June 2020 (Pb//DII) and June 2021 (asbestos)
- **External study to assess health, socio-economic & environmental impacts.** Final Report received end of August 2021 - supports WPC in preparing draft Opinion & EMPL to prepare impact assessment. **WPC** members in study steering group
- **Social Partners Consultation** first stage launched in December 2020, second stage launched June 2021
- Discussions initiated within the **WPC** to prepare draft Opinion by October/November 2021
- **Opinion of ACSH** planned adoption by end of 2021
- **Impact Assessment** and **Commission proposals** expected by summer 2022



***Lead and its compounds = major reprotoxic substance**

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Carcinogens and Mutagens Directive - some recently adopted OELs

DIRECTIVE (EU) 2017/2398 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 12 December 2017

amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work

A. LIMIT VALUES FOR OCCUPATIONAL EXPOSURE

Name of agent	EC No (1)	CAS No (2)	Limit values (3)			Notation	Transitional measures
			mg/m³ (4)	ppm (5)	f/ml (6)		
Hardwood dusts	—	—	2 (7)	—	—	—	Limit value 3 mg/m³ until 17 January 2023
Chromium (VI) compounds which are carcinogens within the meaning of point (i) of Article 2(a) (as chromium)	—	—	0,005	—	—	—	Limit value 0,010 mg/m³ until 17 January 2025 Limit value: 0,025 mg/m³ for welding or plasma cutting processes or similar work processes that generate fume until 17 January 2025
Refractory ceramic fibres which are carcinogens within the meaning of point (i) of Article 2(a)	—	—	—	—	0,3	—	
Respirable crystalline silica dust	—	—	0,1 (8)	—	—	—	
Benzene	200-753-7	71-43-2	3,25	1	—	skin (9)	
Vinyl chloride monomer	200-831-0	75-01-4	2,6	1	—	—	
Ethylene oxide	200-849-9	75-21-8	1,8	1	—	skin (9)	
1,2-Epoxypropane	200-879-2	75-56-9	2,4	1	—	—	
Acrylamide	201-173-7	79-06-1	0,1	—	—	skin (9)	
2-Nitropropane	201-209-1	79-46-9	18	5	—	—	
o-Toluidine	202-429-0	95-53-4	0,5	0,1	—	skin (9)	
1,3-Butadiene	203-450-8	106-99-0	2,2	1	—	—	
Hydrazine	206-114-9	302-01-2	0,013	0,01	—	skin (9)	
Bromoethylene	209-800-6	593-60-2	4,4	1	—	—	

B. OTHER DIRECTLY RELATED PROVISIONS

In conclusion

- Science has a key role in supporting EU regulatory policy development
- Science underpins the effective protection of workers health by helping to set priorities and by evaluating the relationship between exposure and health effects
- Good outcomes rely on collaborative working between all stakeholders – Commission, Member States, Employers, Workers and Scientists
- The story does not end here …policy must be implemented at the level of actual workplaces
    - Support mechanisms are in place – EU-OSHA, WPC, Roadmap on Carcinogens, Sectoral Social Dialogue etc.

Thank you

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