

Chapter 17

Why should the scope of the Carcinogens and Mutagens Directive be extended to reprotoxic substances?

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1. Risks for reproduction: largely ignored by EU legislation on protecting workers' health and safety

Reprotoxic (or toxic for reproduction) substances can adversely affect the ability of men and women to reproduce (threat to fertility) and alter child development during gestation and after birth (threat to development). These effects concern libido, the formation of sperm or eggs, fertilisation and implantation of the embryo, but also miscarriage, stillbirth, reduced birth weight, congenital defects and alterations in mental and physical development, up to and including pubertal development.

In France alone, over 234,000 workers were exposed to at least one reprotoxic substance in 2010 (Cavet *et al.* 2015). Some glycol ethers used as solvents or even certain phthalates used as plasticisers can, for example, reduce the quality or number of sperm. These effects can occur either in adulthood or following pre-natal exposure. They may be reversible or irreversible depending on the substance. Other known reprotoxic substances frequently found in the workplace are lead and its compounds, used in the manufacture of alloys, batteries, glass, etc. Lead has effects not only on fertility but also on the neuronal development of children following exposure before or after birth. It is responsible for mental disabilities and losses of IQ. There is no threshold for the neurotoxic effects of lead and all exposures pose a risk. Warfarin used as a biocide and anticoagulant is teratogenic for humans. Following exposure during pregnancy, it causes cardiac defects, facial hypoplasia and mental retardation. In this case, the effects are not reversible.

Although difficult to put a figure on, many of these threats to reproductive health are due to occupational exposures¹, with victims being concentrated in certain sectors such as agriculture, care services, cleaning and maintenance, metallurgy and petrochemicals (Mengeot and Vogel 2008) and hairdressing and cosmetology (Kim *et al.* 2016). These occupational exposures are entirely preventable, with effective prevention therefore essential.

European legislation on the prevention of reproductive risks in the workplace is very patchy. There is no specific text and existing provisions are not only unsatisfactory but also scattered among various pieces of legislation. The 1992 Directive on the protection of pregnant workers and workers who have recently given birth or are breastfeeding

1. In addition to the chemical substances, there are other occupational risk factors for reproductive health: biological agents, ionising radiation, load carrying, prolonged and static work in a standing position, noise, stress, and irregular or night working. These will not be covered here.

(Directive 92/85/EEC) is, for example, inconsistent in terms of prevention. Measures to avoid exposure do not have to be taken until the worker informs her employer that she is pregnant, which occurs around the 10th week of pregnancy. However, exposure to a reprotoxic substance during the early weeks of gestation can result in miscarriage or a higher risk of congenital defects. The options of changing job or possibly taking leave from work, as recommended in the Directive, therefore come too late to prevent these risks.

The 1998 Directive on the protection of workers from chemical risks (Directive 98/24/EC) is also unsatisfactory. It covers all chemical substances produced or used in the workplace without laying down any specific provisions on reprotoxic substances. It requires employers to eliminate or reduce risks to a minimum and provides for binding or indicative occupational exposure limit values (OELs) to be set.

However, just one substance has been attributed binding limit values to date under this Directive: lead and its compounds (Table 1). The inhalation and biological OEL for lead and its compounds, determined in the early 1980s, have never been updated. In its 2002 Recommendation, the Scientific Committee on Occupational Exposure Limits (SCOEL) suggested lowering the biological limit value from 70 µg to 30 µg per 100 ml of blood, while acknowledging that this will not fully protect the offspring of working women (SCOEL 2002). An opinion of the European Chemicals Agency confirms that lead is toxic for child development and that a no-effect level does not exist for pre- or post-natal exposure. The Agency proposes classifying lead in the category of proven reproductive toxicants for humans (category 1A) with harmful effects on fertility, fetuses and breast-fed babies (ECHA 2013).

Table 1 Reprotoxic substance with Binding OEL under Dir 98/24/EC

Name	CAS	Inhalation OEL (8h TWA)		Inhalation OEL (short term)		Notation	Biological OEL	Classification
		mg/ml	ppm	mg/ml	ppm			
Lead and its compounds		0.15				-	70 µg Pb /100 ml blood	R1A

As regards indicative OELs under the Chemical Agents Directive, these currently cover only 150 substances, of which 11 are toxic for reproduction categories R1A or R1B (Table 2). These values are based on health. This means that the available scientific data has identified an exposure threshold below which exposure to the substance does not cause any harmful effect. However, while it is generally accepted that such a threshold can be defined for most reprotoxic effects, this is not always the case, as shown by the example of lead. Moreover, this threshold is unknown for many reprotoxic substances.

This is one of the major failings of the Chemical Agents Directive with regard to preventing risks for reproductive health. If a reprotoxic substance has a threshold, but no OEL has been set, employers do not have any guidance on the exposure level not to be exceeded, and there is no minimisation obligation in the Directive ensuring that the exposure level is reduced, particularly below the threshold of effect.

Table 2 Reprotoxic substances with Indicative OEL under Dir 98/24/EC

Name	CAS	IOEL (8h TWA)		IOEL (short term)		Notation	Specific Directive	Classification
		mg/ml	ppm	mg/ml	ppm			
N,N-Dimethylacetamide	127-19-5	36	10	72	20	skin	2000/39/EC	R1B
Nitrobenzene	98-95-3	1	0.2	-	-	skin	2006/15/EC	R1B, C2
N,N Dimethylformamide	68-12-2	15	5	30	10	skin	2009/161/EU	R1B
2-Methoxyethanol	109-86-4	-	1	-	-	skin	2009/161/EU	R1B
2-Methoxyethyl acetate	110-49-6	-	1	-	-	skin	2009/161/EU	R1B
2-Ethoxy ethanol	110-80-5	8	2	-	-	skin	2009/161/EU	R1B
2-Ethoxyethyl acetate	111-15-9	11	2	-	-	skin	2009/161/EU	R1B
N-Methyl-2-pyrrolidone	872-50-4	40	10	80	20	skin	2009/161/EU	R1B
Mercury and divalent inorganic mercury compounds		0.02	-	-	-	-	2009/161/EU	R1B
Bisphenol A	201-245-8	2	-	-	-	-	2017/164/EU	R1B
Carbon Monoxide	630-08-0	23	20	117	100	-	2017/164/EU	R1A

2. Benefits of the Carcinogens and Mutagens Directive

The nature, severity and potential irreversibility of the health effects resulting from exposure to reprotoxic substances are particularly worrying for exposed workers. Levels of protection at work should therefore be improved by applying the more stringent provisions of the Carcinogens and Mutagens Directive to reprotoxic substances.

This Directive, which was codified in 2004 (Directive 2004/37/EC), specifically covers all substances that are proven or suspected to be carcinogenic and mutagenic for humans (categories 1A and 1B). It requires employers to replace carcinogens and mutagens with safer alternatives where technically possible. If such precautions cannot be taken, employers must ensure that work is carried out in a closed system and they must reduce exposure to a minimum. The OELs adopted under this Directive are always binding and, even if the exposure level for workers is below the OEL, the obligation remains to reduce this level as far as possible. The Carcinogens and Mutagens Directive is therefore more demanding than the Chemical Agents Directive in terms of reducing workplace exposure levels.

The Carcinogens and Mutagens Directive has been under revision since 2004. Under consideration are the extension of its scope to reprotoxic substances and the adoption of binding OELs for new substances. This revision has unfortunately been held up by the European Commission for over 10 years (see chapter 18). However, there are good reasons to include these improvements in a revised directive.

Many reprotoxic substances are currently produced and marketed in the European Union. According to the health, socioeconomic and environmental impact study ordered by the European Commission as part of the revision procedures, in 2012 there were

105 reprotoxic substances in categories 1A and 1B out of the scope of the Carcinogens and Mutagens Directive (Milieu and RPA 2013). In 2017, they were 134 according to an update prepared by ETUI. These are substances with a harmonised classification as reprotoxic agents, but that are not also classified as carcinogens or mutagens under the CLP Regulation. These substances are therefore currently covered by the unsatisfactory provisions of the Chemical Agents Directive. However, in order to have a comprehensive view of the number of reprotoxic substances currently present on the European market and to which workers are potentially exposed, we should also take into account those substances that have been self-classified as R1A or R1B by companies under the CLP Regulation. A search of the Classification & Labelling Inventory available on the ECHA website shows that there are around 1,800 of these substances.

Including reprotoxic substances within the scope of the Carcinogens and Mutagens Directive would be consistent with the REACH Regulation and all other EU legislations on chemicals (Pesticides, Biocides, Cosmetic regulations, etc). Under REACH, those chemicals identified as substances of very high concern include not only category 1A and 1B carcinogens (C) and mutagens (M), but also reprotoxic substances (R) in the same categories. This alignment with REACH and the other EU legislations on chemicals where C, M and R are treated the same could be seen as a regulatory simplification. It would also improve the synergies between these legislations.

Many reprotoxic substances like Bisphenol A or some phthalates have also been identified as endocrine disruptors (see the Ristox database on the ETUI website). As it is impossible to determine a no-effect exposure level for endocrine disruptors (Kortenkamp *et al.* 2011), health-based OELs for threshold reprotoxic substances would be useless for protecting workers from the adverse effects of endocrine disruptors. Including reprotoxic substances within the scope of Directive 2004/37/EC would automatically ensure that the more stringent provisions of the Carcinogens and Mutagens Directive are applied to numerous endocrine disruptors.

Six European countries (Austria, Belgium, the Czech Republic, Finland, France and Germany) have already extended the scope of the Carcinogens and Mutagens Directive to reprotoxic substances when transposing it into their national law. The findings of the impact study ordered by the European Commission are that, in two of these countries (France and Germany – the only ones studied within the group of six), this extension has clearly led to benefits in terms of reducing the exposure of workers to reprotoxic substances (Milieu and RPA 2013).

Finally, it is worth mentioning that according to the revised version of the Carcinogens and Mutagens Directive adopted by the European Parliament and the Council in September 2017, the EU Commission will have to assess the possibility of including reprotoxic substances in the scope of the Directive by the first quarter of 2019 at the latest².

2. Directive (EU) 2017/2398.

References

- Cavet M., Memmi S. and Léonard M. (2015) Les expositions aux cancérrogènes, mutagènes et reprotoxiques : un zoom sur huit produits chimiques, Dares Analyses 74, Paris, Direction de l'animation de la recherche, des études et des statistiques. <http://dares.travail-emploi.gouv.fr/IMG/pdf/2015-074.pdf>
- ECHA (2013) Opinion proposing harmonized classification and labelling at EU level of lead. <http://echa.europa.eu/documents/10162/57ceb1ac-aafc-4852-9aa5-db81bcb04da3>
- Kim D *et al.* (2016) Reproductive disorders among cosmetologists and hairdressers: a meta-analysis, *International Archives of Occupational and Environmental Health*, 89 (5), 739-753.
- Kortenkamp A. *et al.* (2011) State of the art assessment of endocrine disrupters: final report. http://ec.europa.eu/environment/chemicals/endocrine/pdf/sota_edc_final_report.pdf
- Mengeot M.A. and Vogel L. (2008) Production and reproduction: stealing the health of future generations, Brussels, ETUI. <https://www.etui.org/Publications2/Guides/Production-and-reproduction>
- Milieu and RPA (2013) Final report for the analysis at EU-level of health, socioeconomic and environmental impacts in connection with possible amendment to Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens and mutagens at work to extend the scope to include category 1A and 1B reprotoxic substances. Contract number: VC/2010/0400.
- SCOEL (2002) Recommendation from the Scientific Committee on Occupational Exposure Limits for lead and its inorganic compounds, SCOEL/SUM/83. <http://ec.europa.eu/social/BlobServlet?docId=6506&langId=en>

All links were checked on 24.07.2018.