Inclusion of Reprotoxic Substances within the scope of the Carcinogens and Mutagens Directive

The aim of this Brief is to stress the importance of including reprotoxic substances in the fourth revision of Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (CMD).

Reptotoxic substances, a definition

Reprotoxic substances are chemical substances that, if inhaled, ingested, or if they penetrate the skin, they can adversely affect the ability of men and women to reproduce (and pose a threat to fertility) they cam also alter child development during gestation and after birth (and pose a threat to development). Exposure to reprotoxic substances causes effects on libido, the formation of sperm or eggs, the fertilisation and implantation of the embryo, but also miscarriage, stillbirth, reduced birth weight, congenital disabilities and alterations in mental and physical development, up to and including pubertal development.

Examples of Reptotoxic substances

Substances such as **Glycol ethers** used as solvents or even certain **phthalates** used as plasticizers can, for example, reduce the quality or number of sperm. These effects can occur either in adulthood or following prenatal exposure. They can be reversible or irreversible depending on the substance. Another example is **warfarin**, that is used as a biocide, and anticoagulant is teratogenic for humans. Following exposure during pregnancy, it causes cardiac defects, facial hypoplasia and mental disabilities. In this case, the effects are not reversible. Other known reprotoxic substances that are frequently found in the workplace are **lead and its compounds** used in the manufacturing of alloys, batteries, glass, etc. Lead has harmful effects on fertility, foetuses and babies fed with breastmilk.

Finally, many of the **endocrine disruptors** (EDC) affect reproductive functions (and therefore are classified as reprotoxins such as **Bisphenol A** and some phthalates), whilst others may influence other functions, such as the thyroid. Numerous endocrine disruptors used in workplaces have already been identified as being reprotoxic. EDC are thought to be the leading cause in hormone-sensitive cancers such as breast, prostate or thyroid cancer (Kabir *et al.*, 2015).

Reprotoxins and its effects of the workforce

Although it is difficult to estimate how many individuals in the EU are affected by the exposure to reprotoxins whilst on the workplace, studies have shown that victims are found especially in certain occupational sectors namely agriculture, care services, cleaning and maintenance, metallurgy and petrochemicals, hairdressing and cosmetology (Graham *et al.*, 1993; Havet *et al.*, 2017; Kim *et al.*, 2016; Musu, 2018).

According to the ETUI's conservative estimates (based on the survey conducted by the French Ministry of Labour - SUMER, 2010), a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. This represents more than 2 million workers in the EU-28. The distribution of exposed workers in each EU country is given in the table below (estimation based on the Eurostat data 2017 for the EU workforce)

Country	Estimate of the number of workers exposed to reprotoxins
Belgium	45.872
Bulgaria	30.734
Czech Republic	50.939
Denmark	27.340
Germany	404.816
Estonia	6.256
Ireland	21.249
Greece	36.827
Spain	186.485
France	265.118
Croatia	16.030
Italy	224.436
Cyprus	3.690
Latvia	8.619
Lithuania	13.056
Luxembourg	2.699
Hungary	43.734
Malta	1.952
Netherlands	83.764

Austria	41.853
Poland	160.788
Portugal	45.154
Romania	83.632
Slovenia	9.435
Slovakia	25.021
Finland	24.026
Sweden	48.339
United Kingdom	307.831
EU-28 total	**2.219.695**

A patchy EU legislation for workers exposed to reprotoxic substances

The current EU OSH legislation that protects workers in the European Union from the exposure to reprotoxic substances is made up of two Directives: the Chemical Agents Directive (CAD 98/24/EC) and the Pregnant Workers Directive (92/85/EEC). Both Directives present serious loopholes.

The 1992 Directive on the protection of pregnant workers and workers who have recently given birth or are breastfeeding is 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 reprotoxins during the early weeks of gestation can result in miscarriage or a higher risk of congenital disabilities. 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 CAD also lacks adequate protection for workers. The Directive 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 to binding limit values to date under this Directive, which is lead and its compounds. The inhalation and biological OELs for lead and its compounds, determined in the early 1980s, has not been updated yet. As a result of union lobbying, scientific work to revise these OELs has finally begun recently.

As regards indicative OELs under the CAD, these currently cover 150 substances, of which only 11 are toxic for reproduction. An ETUI study found that around 60 extra reprotoxics should be subject to limit values for workers' exposure (Wriedt, 2016). However, it will still take several years before the CAD is revised and the updated binding OELs for lead and its compounds or these 60+ indicative OELs are included in the legal text.

Why is the CMD the best framework?

The CMD provides a solid basis for harmonized EU wide minimum requirements for the protection of workers from exposure to reprotoxic substances. Such a Directive could strengthen the current system, bring legal coherence and better alignment of chemical legislation at the EU level. The rationale of the CMD's more stringent preventative measures is based on two criteria: potential severe harm due to exposure (that can result in death, severe diseases or impairment) and the long latency period between the exposure and the harm which resulted in a low visibility of the risk. Moreover, 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 CMD is, therefore, more demanding than the CAD in terms of reducing exposure levels in the workplace.

In addition, including substances that are toxic for reproduction 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 all these legislations.

Finally, seven European Member States representing 46% of the EU workforce (Austria, Belgium, Czech Republic, Finland, France, Germany and Sweden) have already extended the scope of the Carcinogens Directive to substances toxic for reproduction when transposing it into national legislation. The inclusion of reprotoxic substances within the CMD would thus allow for an improved legal coherence and alignment among Member States.

The legislative paralysis of the CMD: a short history

An EU Directive on the protection of workers to the exposure to carcinogens has existed since 1990. In 1999, its scope was expanded to include mutagens. The CMD of 2004 was a consolidation of the 1990 Directive with amendments adopted in 1997 and 1999. In 2007 the EC announced to be in favour of extending the scope of the CMD and including reprotoxins. This announcement, however, was short lived, the CMD remained unmuted for the 10 years of the Barroso Commission, that disregarded the numerous requests of both the EU Parliament and Trade Unions to extend the CMD and to include reprotoxins as harmful substances for workers.

When the EC finally started the first revision process in 2016, it performed abrupt U-turn on reprotoxins. In May 2016, Marianne Thyssen, former EU Commissioner for Employment and Social Affairs, stated that the impact study requested by the Commission "did not sufficiently clarify the costs and potential benefits" of extending the CMD to include reprotoxins. The EC de facto utilized a cost-benefit impact study to justify a political decision.

During the first revision process of the CMD in 2017, the EP passed an amendment demanded for the expansion of the scope of the CMD to include reprotoxins. However, the final approved text that resulted from a compromise between the EP and the Council was less clear cut. It required the Commission to reach a decision on the possible inclusion of reprotoxins by no later than 31 March 2019. Between 2017 and 2019, the Commission's position hardened, in part as a result of internal disagreements. The DGs responsible for regulating chemical risks (DG GROW and DG ENV) considered it logical to ensure that workers benefit from the EU legislation, which applies the same regulation to carcinogens as to reprotoxins. The expansion to reprotoxins, however, was opposed by DG EMPL.

The EC, therefore, decided to sidestep the firm deadline defined by the EP and Council and instead of expanding CMD to reprotoxins, it simply published a second (heavily biased) impact study to justify its inaction (Vogel, 2020). This position is all the more puzzling because there has not been any lobbying from industry against the inclusion of reprotoxins. Far from it in fact. The chemical industry is in favour of it, as long as there are derogations for substances for which a health-based OEL has been made compulsory at the European level (Joint ETUC-IndustriAll Europe-Cefic-ECEG press release, 2018). For other issues that would come under the revision to the Directive, such as emissions from diesel engines and crystalline silica, there has been intense industry lobbying, but not over reprotoxins.

Action required on behalf of the European Parliament – the inclusion of reprotoxins 1a and 1b in the scope of the CMD

Every day, Workers in all 27 Member States are handling substances that we know, from the several independent academic studies reported above, pose a serious threat to their health. While the EC is unwilling to make a step forward in including reprotoxic substances in CMD4, as shown several Member states have already added reprotoxins to their national legislation on workplace carcinogens.

For the reasons laid out in this brief we therefore request the EP to demand for the inclusion of reprotoxic substances within the scope of the Directive.

Further readings & references

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