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# Proposal to amend Directive 98/24/EC and Directive 2004/37/EC on the protection of workers from the risks related to chemical agents (lead and diisocyanates)

Opinion from German Social Insurance issued 25 May 2023

## I. Preliminary remark

On 13 February 2023, the European Commission published a proposal for a Directive amending Directive 98/24/EC of the European Council and Directive 2004/37/EC of the European Parliament and of the Council as regards the limit values for lead and its inorganic compounds and diisocyanates. For the first time, the proposal aims at revising the current limit values for lead and introducing limits for diisocyanates.

The German Social Insurance (DSV) shares the European Commission's goal of continually improving safety and health at work. The European Commission's initiative to protect workers from exposure to lead and diisocyanates is another important step here. Effective occupational health and safety and appropriate preventive measures are essential to maintain the health of workers. They also help to reduce the financial burden on social insurance systems caused by illness or disability and to stabilise the systems.

## II. Opinion

### 1 \_ Reducing limit values of lead and inorganic lead compounds: Amendment of Directive 2004/37/EC, Annex III and IIIa

Lead and its inorganic compounds are reproductive toxins that can have adverse effects on sexual function, fertility and foetal development, as well as other adverse health effects.

#### 1.1 \_ Occupational exposure limit

The DSV supports, in principle, a lowering of the occupational exposure limit value proposed with the amendment of Directive 2004/37/EC, which limits the content of lead and inorganic lead compounds in ambient air. This is also intended to adapt the corresponding entry in Annex I of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

However, the DSV points out that even compliance with a lower maximum allowable concentration for lead and inorganic lead compounds of 0.03 mg/m<sup>3</sup> <sup>1</sup>, as proposed by the European Commission, as a weighted average value for a reference period of

<sup>1</sup> Mg/m<sup>3</sup> = milligrams per cubic metre of air at 20 degrees Celsius and 101.3 kPA (760mm mercury column)

eight hours cannot be safely classified as harmless to health. The derivation of the maximum allowable concentration proposed by the European Commission is based on a monocausal relationship between an increase in the concentration of lead in the air at the workplace and the increase in lead levels in the blood. In the view of the DSV, the scientific data and mathematical modelling used for this purpose from the Biological Agents Tolerance Value<sup>2</sup> are not sufficient to scientifically prove this connection, especially in the low concentration range.

## 1.2 \_ Biological limit value

In addition, inhalation exposure is not the only decisive factor for exposure during work with hazardous substances containing lead. Therefore, the biological limit value is the more important instrument to protect workers against the toxic effects of lead and inorganic lead compounds and to monitor accumulation in the body. The biological limit value is based on the internal exposure of those affected, which depends not only on inhalation exposure during work with hazardous substances containing lead, but also on oral and thus, very individual lead intake and remobilisation<sup>3</sup> of lead in the body. Oral intake exists due to poor hygiene in the workplace. Dust containing lead can enter the body through dirty hands, e.g. when ingesting food (eating and drinking) or through smoking. Since the personal behaviour of workers with regard to hygiene is decisive for the absorption of lead into the body and thus, for blood lead levels, personal hygiene measures must be ensured in addition to technical and organisational protective measures.

The DSV therefore supports in particular the proposal of the European Commission to set the biological limit value for lead and its compounds at 15 µg Pb/100 ml blood. Compliance with the biological limit value has priority from the DSV's point of view, as this protects workers most effectively from oral as well as inhalation hazards.

## 1.3 \_ Women of childbearing age

Women of childbearing age require an increased level of protection against exposures to lead and its inorganic compounds due to their reproductive toxicity. For female workers of childbearing age, the European Commission considers that blood lead levels should not be higher than the reference levels for the general population in the Member State concerned who are not occupationally exposed to lead. In the absence of national reference values, a guideline value of 4.5 µg Pb/100 ml blood is recommended by the European Commission for women of childbearing age. The

<sup>2</sup> The biological agent tolerance value (BAT value) is a limit value for the concentration of an agent, its metabolites or an exposure indicator in biological material, e.g. the blood of an employee

<sup>3</sup> The BGW is based on measurements of lead concentrations in the blood / urine of the worker. When lead is ingested, it spreads to various organs, especially bones. Remobilisation means that lead stored in the bone is released and enters the bloodstream.

DSV points out that this guideline value is a population-based mean that cannot be scientifically justified. However, the aim should always be to keep the value as low as possible. Therefore, care must be taken to minimise exposure to risk. Gender equality aspects must be taken into account.

#### 1.4 \_ Medical surveillance

Medical surveillance of workers is recommended by the European Commission at concentrations above 0.015 mg/m<sup>3</sup> lead in air. This is calculated as a time-weighted average based on 40 hours per week. Alternatively, an individual worker blood lead level of more than 9 µg Pb/100 ml blood triggers medical surveillance. The current values in Germany are still 0.075 mg/m<sup>3</sup> lead in the air or 40 µg Pb/100 ml blood. However, a reduction has already been decided. Against this background, the DSV supports the European Commission's proposal in this regard.

However, the DSV points out that, in addition to lowering the limits, consistent implementation of supplementary technical and organisational protective measures as well as personal hygiene measures<sup>4</sup> are imperative for safe protection against exposure to lead.

#### 2 \_ Inclusion of occupational exposure limit values for diisocyanates: Amendment of Directive 98/24/EC, Annex I

Diisocyanates have a sensitising effect on the respiratory tract and can cause allergy, asthma-like symptoms or breathing difficulties. Skin contact can also cause allergic skin reactions and trigger asthma<sup>5</sup>. The adverse health effects are due to the NCO group, a component found in all diisocyanates.

The DSV welcomes the aim of promoting occupational safety and health by introducing binding limit values for diisocyanates. A group-based approach is being considered by the European Commission, which should make it possible to set a common occupational exposure limit value and a short-term value for all diisocyanates. Specifically, a common occupational exposure limit value (BOEL)<sup>6</sup> of 6 µg NCO/m<sup>3</sup> and a common short-term exposure limit value (STEL)<sup>7</sup> of 12 µg 5/6

<sup>4</sup> Further information can be found in TRGS 505 "Lead". Under section 4 "Protective measures", "Measures for personal hygiene" (4.7) are named (general hygiene rules; work clothing; food, drink, tobacco).

<sup>5</sup> Institute for Prevention and Occupational Medicine (IPA) in cooperation with the Federal Institute for Occupational Safety and Health (BAuA) and the European trade association for producers of aromatic diisocyanates and polyols ISOPA & ALIPA: "Occupational safety and health protection during activities with diisocyanate-containing materials" study

<sup>6</sup> BOEL: Binding Occupational Exposure Limit Values (European occupational exposure limit value, related to a period of 8 hours).

<sup>7</sup> STEL: Short Time Exposure Limit Values (limit value for short time exposure, related to a period of 15 minutes).

NCO/m<sup>3</sup> are proposed. This is viewed critically by the DSV.

## 2.1 \_ Occupational exposure limit

The European Commission provides for the determination of diisocyanate concentrations by means of classical analysis of monomeric diisocyanates and subsequent conversion into NCO concentrations. However, the occupational exposure limit proposed in Annex I of the draft Directive cannot be applied equally for all diisocyanate groups (monomers, dimers, (pre-)polymers), but only for monomeric diisocyanates. As the calculation of the occupational exposure limit value is based on measurements of individual monomeric diisocyanate concentrations, no direct conversion into an NCO concentration can be made for dimeric isocyanates as well as (pre-)polymers. Here, an actual measurement of NCO groups (including calibration) has to be carried out and an additional, specific limit value for these diisocyanates has to be established.

The introduction of a limit value that is aimed at the assessment of all NCO groups and not at individual diisocyanates has the advantage that diisocyanates that are not covered by their own limit values (e.g. new diisocyanates) can also be better assessed. On the contrary, toxicological studies show that monomeric diisocyanates have a higher toxic potential than oligomeric and polymeric isocyanates. With a uniform NCO limit value, it is no longer possible to distinguish the toxicity of isocyanates.

## 2.2 \_ Regulation in Germany

In Germany, a system has been established which provides limit values or equivalents for all diisocyanate groups. This is based on occupational exposure limits for individual monomeric diisocyanates and the exposure guideline value (ELV), which is derived from the occupational exposure limits for monomeric diisocyanates. The exposure guideline value corresponds to the sum of all reactive NCO groups of monomers and polymers in the air at the workplace and is applied to all diisocyanates for which no occupational exposure limit value is set or can be set (dimers, polymers and new diisocyanates). Exceeding the exposure guideline value may provide initial indications of harmful exposure to a complex isocyanate mixture at the workplace<sup>8</sup>.

<sup>8</sup> TRGS 430 "Isocyanates risk assessment and protective measures" and TRGS 900 "Occupational exposure limits"

## 2.3 \_ Short-term exposure and measurement methods

Monitoring of short-term elevated exposures at critical sites or during critical operations for occupational safety and health is relevant. More severe hazards occur e.g. in spraying processes and hot applications, where aerosol formation may occur, and are further dependent on the toxicological and chemical properties of the individual diisocyanates (e.g. differences in toxicity or vapour pressures). However, the verification of short-term exposures causes difficulties due to measurement uncertainties, especially in the low concentration range and at exposure peaks. Thus, collecting sampling methods are subject to a large measurement uncertainty for short-term measurements. There are also no known directly indicating measuring instruments that could provide reliable measured values in the low concentration range (limit value range) for all diisocyanates.

Scientifically, it is also not currently possible to set limit values below which exposure to diisocyanates has no harmful effects on health. Particularly in sensitised persons, impacts can trigger respiratory diseases even below the proposed limit values. Occupational medicine evidence also suggests that the allergy risk depends more on intensity than concentration.

## 2.4 \_ Transition period

Due to the aforementioned difficulties and uncertainties, it remains important to reduce the risk of exposure. Primarily, the sources of short-term exposures must be identified and, if possible, eliminated. Existing protective measures should be checked for their effectiveness and employees should be trained accordingly.

In addition, the measuring instruments and methods must be further developed with the aim of achieving greater sensitivity in order to be able to check and comply with the planned EU limit values (BOEL and STEL). Furthermore, metrological monitoring of exposure peaks must be ensured. The proposed transition period until December 2028 is a prerequisite for this as well as for the implementation of protective measures at the workplace.

## About us

The German Federal Pension Insurance (DRV Bund), the German Social Accident Insurance (DGUV), the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband), the national associations for statutory health and longterm care insurance funds at the federal level and the Social Insurance for Agriculture, Forestry and Horticulture (SVLFG) have joined forces to form the "German Social Insurance - Working Group Europe" (Deutsche Sozialversicherung Arbeitsgemeinschaft Europa e. V.) with a view to their common European policy interests. The association represents the interests of its members vis-à-vis the bodies of the European Union (EU) as well as other European institutions and advises the relevant stakeholders in the context of current legislative projects and initiatives. As part of the statutory insurance system in Germany, health and longterm care insurance, pension insurance and accident insurance offer effective protection against the consequences of major risks to life.