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FIEC and EBC joint position paper on the proposed amendment of the Carcinogens Directive (2004/37/EC) [COM(2016)248]

A) Key messages

- 1. The figures used in the impact assessment undertaken by the European Commission do not reflect the reality of the construction industry and therefore they do not constitute a reliable basis for supporting the proposal submitted.
- 2. Including "Respirable Crystalline Silica" dust generated by a work process (hereafter: RCS) in the scope of the "Carcinogens" Directive would introduce requirements on construction companies which are disproportionate in respect to the objectives to be achieved, in particular for medium and small-sized enterprises. The Chemical Agents directive (98/24/EC) would be a more appropriate framework providing an adequate level of protection to workers, whilst at the same time avoiding disproportionate burdens for employers.
- 3. In order to be effectively implemented a limit exposure level must be proportionate to the concerned occupational risk and be technically measurable. It should therefore not go below the proposed level of 0.1 mg/m³.
- 4. Further improvements in the protection of workers can more efficiently be achieved by means of preventive actions through dissemination and exchange of best practices.

B) Background

On 13/5/2016 the European Commission presented a proposal for amending the existing "Carcinogens" Directive (2004/37/EC) with the aim of improving workers' health protection by reducing occupational exposure to carcinogenic chemical agents.

The Commission proposes to revise or to introduce exposure limit values for 13 chemical agents, including "exposure to respirable crystalline silica dust generated by a work process" with a corresponding limit value, defined in Annex III, of 0.1 mg/m³.

The Directive sets a number of general minimum requirements to eliminate or reduce exposure for all carcinogens and mutagens falling under its scope. Employers must identify and assess risks to workers associated with exposure to specific carcinogens (and mutagens), and must prevent exposure where risks occur. Substitution to a non or less-hazardous process or chemical agent is required where this is technically possible. Where substitution is not technically possible chemical carcinogens must, as far as it is technically possible, be manufactured and used in a closed system to prevent exposure. Where this is not technically possible, worker exposure must be reduced to as low a level as is technically possible (minimisation obligation under Article 5(2) and Article 5 (3) of the Directive).

C) Explanation of the key messages

1. The data provided in the impact assessment study (IOM SHE Can report) do not reflect the reality of exposure to RCS in the construction industry

When the impact assessment study on which the proposal of the European Commission is based was published, FIEC and EBC questioned the validity of such study, which was presenting figures on exposure to RCS which, according to official data available at national level, did not correspond at all to the reality of facts.

Looking closer at Austria, Italy, Slovenia, Spain and Belgium, as examples, the official data available present a picture of the reality in these countries which is completely different than the one highlighted in the impact assessment:

- According to the impact assessment study, it was estimated that in 2010 there would be 101 deaths from lung cancer and 119 lung cancer cases that could be attributed to past exposure to RCS. In reality, the Austrian Accidents-Insurance fund reported only 2 cases of silicosis, not lung cancers, in 2010 in the construction industry.
- In Italy, INAIL (the Italian Institute for Insurance against Accidents at Work, which represents the
 official source of data for accidents at work), reported in 2010 only 11 cases of silicosis in the
 Italian construction industry eligible for compensation: figures that are hardly comparable with the
 409 lung cancer cases that could be attributed to past exposure to RCS estimated for Italy by the
 impact assessment.
- In Slovenia, in 2015 the National Institute of Public Health reported only 1 case of silicosis (out of a total of 51.612 workers) in the construction sector and 7 cases of lung cancer per year, on average, between 2010 and 2015, whilst the impact assessment study forecasted 944 cases of lung cancers only for 2010.
- In Spain, the impact assessment study estimated that in 2010 there would have been 963 deaths from lung cancer and 1.010 lung cancer cases that could be attributed to past exposure to RCS. However, according to the official statistics from the Ministry of Labour and Social Security, in 2010 in the construction industry only 9 cases of medical leaves due to silica dust inhalation were reported in the whole country. According to the official data from the "Instituto Nacional de Silicosis" only 5 new cases of silicosis were reported in 2010 in the construction industry.
- In Belgium, the national public body "Fonds des maladies professionnelles" registered 69 cases
 of silicosis accepted as "permanent disability" in the whole private sector in 2010, far thus from
 the 217 registrations attributed to past exposure to RCS only in the construction industry
 according to the IOM impact assessment study.

Furthermore, silicosis is a disease which has a long latency period and which may develop only after decades of repeated exposure to high concentrations of RCS. Therefore, the cases reported in statistics for recent years refer to possible exposure to RCS which occurred in times when current H&S legislation was not yet in force and when processes, materials and protective equipment where not at the levels of nowadays standards.

In addition it should not be forgotten that it is silicosis that may generate lung cancer and not directly exposure to RCS dust. As recognised by scientific experts and regulatory committees (including the SCOEL¹ and the IARC²), RCS carcinogenicity, if it occurs, is expressed through a secondary

¹ Recommendation from the Scientific Committee on Occupational Exposure Limits for Silica, Crystalline (respirable dust), SCOEL/SUM/94-final, June 2002.

mechanism. This means that lung cancer risk due to RCS exposure is restricted to workers who previously contracted silicosis and therefore, by preventing silicosis, RCS-related lung cancer is also prevented. This is also illustrated in a study entitled "Crystalline silica and lung cancer: A critical review of the occupational epidemiology literature of exposure-response studies testing this hypothesis" (Gamble J. F. USA) which comes to the conclusion that the weight of evidence from occupational epidemiology does not support a causal association of lung cancer and silica exposure, which is not on the same line as the IARC conclusion using essentially the same data. In a nutshell, there is no consensus on the question whether silica dust is a direct carcinogen or only acts in a secondary stage on pre-existing silicosis lesions.

FIEC and EBC therefore share the opinion that the prevention of and protection against the silicosis risk would be adequately ensured by the provisions of the Chemical Agents Directive, which provides a complete risk assessment and management procedure.

2. The proposal of the European Commission would introduce requirements on construction companies which are disproportionate in respect to the objectives to be achieved, especially for SMEs

The data mentioned under item C1 here above is an evidence of the fact that the basis on which the proposal of the Commission is based overestimates by far the reality. As a consequence the proposal contains provisions which would put disproportionate organisational and financial burdens on construction companies in comparison to the wrongly estimated potential benefits in terms of workers' protection. The foreseen additional costs related to measuring limit values, risk assessment and replacement/reduction costs will specially be unbearable for smaller companies, the majority of the construction industry enterprises, and their clients.

The minimisation obligation foreseen under Article 5(2) and Article 5(3) of the Directive implies the obligation of substitution to a non or less-hazardous process or chemical agent where this is technically possible. Where substitution is not technically possible chemical carcinogens must, as far as it is technically possible, be manufactured and used in a closed system to prevent exposure. Where this is not technically possible, worker exposure must be reduced to as low a level as is technically possible. Including "Silica dust generated by a work process" in the "Carcinogens" Directive would therefore bear significant changes that employers will have to put in place:

- Technical changes :
 - o extraction system for some equipment (road millers, handheld machines, special civil engineering machines, grinders, etc.)
 - o moistening systems, etc.
- Organisational changes:
 - o provision of spatial partitions,
 - o working hours, etc.
- Personal changes :
 - o minimising the exposure of the workers,
 - o cleaning of work clothing,
 - o use of personal protective equipment (respirators, disposable suits), etc.

Agency for Research on Cancer, Lyon.

² IARC Monograph Volume 100C (2011) A Review of Human Carcinogens: Arsenic, Metals, Fibres, and Dusts, International Agency for Research on Cancer, Lyon.

IARC Monograph Volume 68 (1997) Silica, Some Silicates, Coal Dust and para-Aramid Fibrils, International

The whole built environment is based on products containing crystalline silica and it involves also the entire value chain from raw materials production, continuing with preparation and processing of the products, up to demolition and disposal of the structures.

This means that these technical and organisational changes would need to be applied to every construction process and to every worker, regardless of their effective exposure to RCS dust. Furthermore, some technical requirements such as working in closed systems or encapsulation of construction works are either unfeasible or possible only at economically unjustifiable costs. As 91.9% of the European construction enterprises have less than 10 employees, the risk of non-compliance will be high if compliance costs are not reduced to a minimum.

It should not be forgotten that the construction sector is characterised by a wide variety of activities with a temporary nature, which imply significant variations of the possible levels and types of exposure of workers to RCS: for example, during the same day the same worker could undertake the same task in a closed environment and then in open air. Construction may even end paralyzed as lowered limit values will impede basic construction tasks, for example involving sand.

Including RCS into the "Carcinogens" Directive, would therefore impose inappropriate, unnecessary and unfair constraints in construction activities/processes where the hazard does not exist or in which workers are exposed to low concentrations. Exposure to RCS is a complex issue and each profession has its specificities, risk assessment procedures and risk management measures should take these sectoral differences into account.

Therefore, FIEC and EBC consider that the Chemical Agents Directive (98/24/EC), which is based on risk assessment and risk minimisation, provides the right legislative framework for an adequate workers protection to RCS exposure, whereas the Carcinogens Directive (2004/37/EC) would impose unnecessary and impracticable obligations.

3. In order to be effectively implemented a limit exposure level must be proportionate to the concerned occupational risk and be technically measurable. It should therefore not go below the proposed level of 0.1 mg/m³.

Silicosis, as disease, has a long latency period, therefore the small number of cases of silicosis that are detected now, have been originated mostly when the preventive and protective measures currently applied were not yet used.

Furthermore, if on the one hand there are studies that state that above the level of 0.1 mg/m³ the risk of silicosis increases significantly, on the other hand there are no studies demonstrating that a lower OEL would reduce the risk of silicosis more effectively than the proposed value of 0.1 mg/m³.

Silica dust is a natural raw material, essential for numerous and diversified activities; going below the proposed limit exposure level of 0.1 mg/m³ would not only bear unjustified compliance cost, it could also lead to a unjustified stigmatisation.

4. Prevention through dissemination and exchange of best practices

Over the years the protection of workers in the construction industry, in particular as regards exposure to RCS dust, has increased significantly thanks to technological progress, as well as to changes in work processes and methods.

Some examples of improved work techniques that have led to lower work exposure are:

- extraction for handheld drills, grinders, cutters, milling machines
- wet drilling processes instead of dry drilling
- application of sprayed concrete in a wet process instead of in a dry process
- housings, e.g. for conveyor belts and crushing plants
- closed driver's cabs with filtering devices for off-road equipment
- etc.

The official data mentioned in item C1 here above reporting the few cases of silicosis registered in the construction industry confirm such improvements.

FIEC, EBC and their national member organisations will continue to work on prevention against exposure to RCS dust in construction activities, amongst others by means of dissemination and exchanges of best practices.

EBC - European Builders Confederation

Established in 1990, the European Builders Confederation - EBC - is a European professional organisation representing national associations of micro, small and medium-sized enterprises working in the construction sector. EBC is a member of UEAPME (the European association ofmicro-enterprises and SMEs), on behalf of which it chairs the UEAPME Construction Forum.

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FIEC - European Construction Industry Federation

Established in 1905, represents via its 29 National Member Federations in 26 countries (23 EU & EFTA and Turkey) construction enterprises of all sizes, i.e. small and medium-sized enterprises as well as "global players", carrying out all forms of building and civil engineering activities. FIEC is the Social Partner representing employers in the European Social Dialogue of the construction industry.

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