



Council of the
European Union

Brussels, 17 May 2016
(OR. en)

Interinstitutional File:
2016/0130 (COD)

8962/16
ADD 3

SOC 255
EMPL 158
SAN 187
IA 23
CODEC 666

COVER NOTE

From: Secretary-General of the European Commission,
signed by Mr Jordi AYET PUIGARNAU, Director

date of receipt: 13 May 2016

To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of
the European Union

No. Cion doc.: SWD(2016) 153 final

Subject: COMMISSION STAFF WORKING DOCUMENT EXECUTIVE SUMMARY
OF THE IMPACT ASSESSMENT Accompanying the document Proposal
for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE
COUNCIL amending Directive 2004/37/EC on the protection of workers
from the risks related to exposure to carcinogens or mutagens at work

Delegations will find attached document SWD(2016) 153 final.

Encl.: SWD(2016) 153 final



Brussels, 13.5.2016
SWD(2016) 153 final

COMMISSION STAFF WORKING DOCUMENT
EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT

Accompanying the document

**Proposal for a
DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

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

{COM(2016) 248 final}
{SWD(2016) 152 final}

Executive Summary Sheet

Impact assessment on Proposal for a Directive amending the Carcinogens and Mutagens Directive to identify new 'process generated substances' and establish/revise binding Occupational Exposure Limit Values

A. Need for action

Why? What is the problem being addressed?

Exposure to some chemical agents in the workplace can cause cancer, which is the first cause of work-related deaths in the EU. To protect workers against such risks, the EU has adopted the Carcinogens and Mutagens Directive (CMD), which sets out steps to be taken to eliminate or limit exposure to carcinogenic chemical agents and includes Occupational Exposure Limit (OEL) values. However, the CMD is out of date as it does not take into account the available scientific evidence. The Commission has conducted a scientific and economic assessment of 25 priority chemical agents to which around 20 million workers are exposed in the EU. Out of those 13 agents, for which data sets are ready, are covered in the impact assessment. Member States have introduced OELs for some of them but they are highly divergent and sometimes set too high to protect workers.

Occupational cancer impacts the economy at large, reducing labour supply (either temporarily or permanently), decreasing labour productivity and increasing the burden on public finances through avoidable public expenditure on health care, disability benefits, pensions for early retirement, and other benefits. For the workers and their families, cancer results not only in substantial quality of life losses, but also in direct health care costs and indirect loss of present and future earnings. For business, occupational cancer implies staff replacement costs, productivity losses and the need to pay higher wages to compensate for the higher occupational risk, what affects their competitiveness.

What is this initiative expected to achieve?

The initiative pursues three objectives:

- To reduce EU workers occupational exposure to carcinogenic chemical agents
- To increase the effectiveness of the EU framework
- To ensure more clarity and a better level playing field for economic operators

What is the value added of action at the EU level?

The current differences in Member States regarding national OELs for the identified carcinogens do not provide a minimum basis of protection for all EU workers against the risks arising from occupational exposure. The current situation also creates an unlevelled playing field for firms as those operating in Member States with less protective OELs have a competitive advantage. Action taken by Member States alone cannot address these concerns, and consequently EU level action to achieve this objective appears necessary and in line with TEU Article 5(3).

B. Solutions

What legislative and non-legislative policy options have been considered? Is there a preferred choice or not? Why?

Following discussions by scientists, employers, workers and Member States representatives suggestions for OELs have been developed for the 13 chemical agents. For most of them more stringent and less stringent options were also considered. For some agents (e.g. chromium (VI) compounds, hardwood dust and respirable crystalline silica (RCS)) more significant impacts were identified. For others (e.g. 2 nitropropane and acrylamide), the estimated costs/benefits of the baseline (no action) and of setting an EU OEL are closely matched.

Banning the carcinogens from the workplace was considered but discarded as disproportionate. While REACH and CMD are complementary, workplace exposure to chemical carcinogens can be most efficiently regulated by the CMD. Setting sector, industry or use-specific OELs had to be discarded as the current legal framework does not provide a legal basis for such provisions. Non-legislative policy options, such as developing guidance and other implementation support for CMD or reliance on self-regulation have also been considered. It has been decided however that those measures alone would not be able to substantially contribute to the solving of the identified problems. Legal certainty for stakeholders is best achieved through clear listing of chemical agents under the CMD together with OELs allowing management of the risk of occupational exposure to chemical carcinogens.

Who supports which option?

Social Partners and Member States, represented in the Advisory Committee on Safety and Health at work, support including RCS into the CMD list of process generated substances and adopting OELs at values they recommend. In general, where positions differed, workers pushed for lower (more 'protective') and employers for higher (less costly to implement) OEL values. The inclusion of RCS as a process-generated occupational carcinogen has caused concern for some sectors of industry both regarding the standard of risk management this may entail and also regarding stigmatisation of the bulk commodity equivalent (i.e. sand and other silica

products) as 'cancer-causing'. These factors are discussed in the analysis.

C. Impacts of the preferred option

What are the benefits of the preferred option (if any, otherwise main ones)?

The benefits of the retained policy options will consist in a substantial reduction of work-related cancer cases and deaths. A conservative estimate concludes that around 100,000 lives could be saved as a result of the initiative. Workers and their families will experience less quality of life losses caused by work-related cancer. There will also be direct and indirect individual healthcare cost savings in relation to cancer. Social security systems will benefit from a reduction of cancer treatment costs, together with reduced expenditure on associated inactivity/early retirement and compensation for occupational diseases. Employers are likely to benefit from reduced productivity losses, arising from loss of workers due to work-related ill-health and their replacement costs. A study undertaken on behalf of Commission services, shows the main benefits are expected from the introduction of the OEL at 0.1 mg/m³ for RCS and at 0.025 mg/m³ for chromium (VI) compounds. As regards RCS it is expected that, over the period 2010-69, around 99,000 cancer cases will be avoided, corresponding to a monetary value between € 34 billion and 89 billion. Regarding chromium (VI), the preferred option will lead to around 1,800 avoided cases over the same period (€591 million-1,7 billion). The main monetary benefits in relation to the introduction of an OEL under the option retained for the other agents are: Hardwood Dust (€12-54 million); Vinyl chloride (€1-4 million); o-Toluidine (€1.3-10.1 million); Hydrazine (€0.01-0.05 million); Refractory ceramic fibres (€1.1-3.4 million).

What are the costs of the preferred option (if any, otherwise main ones)?

For some carcinogens, the retained option will affect operating costs for enterprises which will have to put in place additional protective and preventive measures. This will be in particular the case for Chromium (VI) compounds and RCS. As regards RCS, the costs to industry of anticipating investment to comply with an exposure level of 0.1 mg/m³ are estimated to be at €3.5 billion until 2069. For the remaining carcinogens, the impact on operating costs for business (including small and medium enterprises) will be minimal as only small adjustments will be needed to ensure full compliance. The package of retained options will not impose any additional information obligations or lead to an increase in administrative burdens on enterprises and is not likely to generate any significant environmental costs.

How will businesses, SMEs and micro-enterprises be affected?

Businesses would profit from a greater clarity and a more levelled playing-field. For many of the agents covered in this impact assessment, OELs (some at different values between Member States) exist already at national level. Establishing the OELs foreseen in this initiative should have no impact on those businesses situated in those EU Member States where the national OELs are either equal or lower (more strict) than the proposed values. No lighter regimes were foreseen for SMEs, which are not exonerated from the CMD obligations as this would lead to an unequal protection of workers depending on the company size. The main impact in situations where higher exposures are expected to occur will be for SMEs where workers are exposed to RCS and Chromium (VI).

Will there be significant impacts on national budgets and administrations?

While the current situation imposes substantial economic costs on workers due to their exposure to hazardous substances, the retained option also mitigates 'knock on' financial losses for Member States' social security systems. Administrative and enforcement costs for public administrations will differ according to present status of each chemical agent in each MS, but are not expected to be significant. In addition, setting EU OELs will limit the need to conduct scientific analysis separately by Member States.

Will there be other significant impacts?

Implementing the retained option would have a positive impact on competition within the internal market. EU-wide OELs for the agents concerned by this initiative will reduce competitive distortion between firms located in Member States with different national OELs. In addition, as the proposed OELs are similar to those prevailing in most EU trade partners, there should not be a significant impact on the external competitiveness of EU firms. The impact on fundamental rights is positive - in particular with regard to article 2 (Right to life) and article 31 (Right to fair and just working conditions which respect his/her health, safety and dignity).

D. Follow up

When will the policy be reviewed?

The effectiveness of the proposed CMD revision would be measured in the framework of the next evaluation of the EU Occupational Health and Safety (OSH) framework as foreseen in the Article 17a of the Directive 89/391/EEC. It should be noted that monitoring and evaluation mechanisms might be modified in the meantime as a result of the ongoing ex-post evaluation of the OSH acquis (covering the period 2007-2012).