



*Brussels, 3.11.2016
C(2016) 6569 final*

*Mr Pietro GRASSO
President of the
Senato della Repubblica
Piazza Madama, 1
I-00186 Roma*

Dear President,

The Commission would like to thank the Senato della Repubblica for its Opinion on the 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}.

This proposal is among the priority actions identified in the Commission Work Programme for 2016. It fits with the Commission's priority to establish a fair and truly pan-European labour market that provides workers with decent protection and sustainable jobs, as well as with the strategic goal set out in the EU Strategic Framework on Health and Safety at Work 2014 – 2020¹ of ensuring a safe and healthy work environment for workers in the EU.

An initiative to address cancer caused by occupational exposure has been a priority for the Dutch Presidency as well as the Commission. A new 'Roadmap to Vienna' covenant was agreed at the end of May by Dutch and Austrian ministries, the Commission, the EU Occupational Safety and Health Agency, and social partners. This Roadmap presents a commitment to support in practice efforts to limit exposure to carcinogens.

The proposed Directive aims to prevent cancer caused by occupational exposure - the largest cause of worker deaths in the EU – to increase the effectiveness of the EU legislation in this area and to provide more clarity and a better level playing field for economic operators. To that effect, it identifies certain cancer-causing chemicals and sets 13 specific occupational exposure limit values.

The Commission is pleased that the Senato della Repubblica shares the view that the expected effects of the proposal are positive for workers, for employers and for Member States and that it considers that it is compatible with the principles of proportionality and subsidiarity.

¹ COM(2014) 332 final,
<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52014DC0332&from=EN>

The Commission notes the recommendation expressed by the Senato della Repubblica for further work for the effective implementation of the obligation set forth in Article 15 of Directive 2004/37/EC to keep medical records referred to in Article 14 (4) for at least 40 years following the end of exposure.

The action against cancer caused by occupational exposure is a common concern for the Commission and the Member States, in particular for Italy where, based on the available data for the period 2009-2010, cancers are the third largest group of occupational diseases (7%). In this context, the Commission welcomes the adoption in Italy in 2012 of the Guidance setting criteria and tools for assessing and managing chemical risk in working environments with a view to assist SMEs in understanding the interfaces in the Union legal acts concerning carcinogens or mutagens as they are implemented at national level.

Discussions concerning the proposal between the Commission and the co-legislators – the European Parliament and the Council, in which the Italian government is represented – are now underway and the Commission remains hopeful that an agreement can be reached in the near future.

In response to the more technical comments in the Opinion, the Commission would like to refer to the attached annex.

The Commission hopes that the clarifications provided in this reply address the issues raised by the Senato della Repubblica and looks forward to continuing the political dialogue in the future.

Yours faithfully,

*Frans Timmermans
First Vice-President*

*Marianne Thyssen
Member of the Commission*

ANNEX

The Commission has carefully considered the recommendations made and the issues raised by the Senato della Repubblica in its Opinion and would like to offer the following observations:

As regards the recommendation for the effective implementation of the obligation set forth in Article 15 (1) of Directive 2004/37/EC, this fits with the Commission's key strategic objectives and related actions set forth in the EU Strategic Framework on Health and Safety at Work 2014 – 2020 of facilitating compliance with occupational safety and health legislation, particularly by micro and small enterprises, and of better enforcement of occupational health and safety Directives by Member States.

As regards the incorporation in the Directive 2004/37/EC of a prohibition of the use of carcinogens and mutagens in the workplace by a given deadline, the Commission would like to point out that Directive 2004/37/EC lays down minimum requirements in the social policy area on the basis of Article 153 (2) (b) in conjunction with Article 153 (1) (a) of the Treaty on the Functioning of the European Union ('TFEU').

In order to reduce the occupational exposure to these substances or mixtures, Directive 2004/37/EC provides for a hierarchy of preventive and protective measures, amongst which the obligation of the employer to substitute these chemicals by less or non-hazardous substances, mixtures or processes as far as technically possible has the highest priority. If substitution is not technically possible, other measures to prevent exposure like working in a closed system or to reduce the number of workers potentially exposed have to be put in place by the employer.

Amongst these other measures, employers have the obligation to ensure that occupational exposure limits set out in Annex III to the Directive shall not be exceeded.

This Directive applies without prejudice to existing or future national and EU provisions which are more favourable to protection of the safety and health of workers.

As regards the establishment of occupational exposure limits for specific sectors, industries or uses by means of a regulatory framework providing the necessary legal basis, the Commission would like to point out that occupational exposure limits set forth in EU Directives adopted in the social policy area on the basis of Article 153 (2) (b) in conjunction with Article 153(1) (a) TFEU, are adopted further to the consultation of the Advisory Committee on Health and Safety at Work ('ACSH') and that the impact of such values in respect of specific sectors, industries and uses is discussed in that framework. The Directive as such does not provide for the possibility to establish such values for individual industrial sectors.