Consulta Interassociativa
Italiana per la Prevenzione

Milan, January 21st 2021

To Whom It May Concern,

CIIP (Consulta Interassociativa Italiana per la Prevenzione, www.ciip-consulta.it) was founded in 1990 and collaborates with 14 technical-scientific associations, representing different areas of prevention professions, in both the private and public sectors.

For some time now, a special CIIP Working Group, coordinated by dr. Carlo Sala, has organized a discussion on Chemical and Carcinogenic Risk and would like to make some observations on the European Commission's proposal (COM (2020) 571 final). The comments concern the fourth amendment of Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (on which the European Parliament is called upon to rule).

Below are some of the observations articulated in the attached document that would contribute to improving such a proposal:

1. The proposal includes in Annex III the limit values for two new substances or classes of such substances (Acrylonitrile and Nickel compounds) and reduces the limit value for Benzene.

2. However, it does not sufficiently consider the latest developments in European scientific knowledge and regulations (e.g., REACH and CLP Regulations).

3. In particular, the number of substances or groups of substances considered (less than 30) is very low. It does not even contemplate some of the substances already included in the Candidate List according to the REACH Regulation.

4. Sometimes, proposed limits do not represent the lowest applicable values, already existing in some Member States or suggested by international Agencies. Moreover, it often takes a long period of time to fully implement such limits, possibly leading to further unacceptable cases of neoplastic disease in exposed workers.

5. Despite the explicit statements in Directives 2019/130 and 2019/983, reprotoxic substances and certain hazardous drugs recognized as potential carcinogens or mutagens have not been taken into consideration, as would have been desirable, by introducing them, respectively, in Annex III or Annex I of Directive 2004/37 / EC.

6. The proposal does not consider the need to review the methodology for setting limit values so that they finally comply with the provisions of Article 168 of the Treaties. It is worthwhile to define two types of limit values, Health-Based (NOAEL, LOAEL, DNEL) or Risk-Based, depending on whether there is clear evidence of threshold values for a given substance. If there is no evidence of threshold values, the limit could be determined in such a way as to reduce the risk as much as possible by defining a range of predefined probabilities of effect, regardless of the substance.

We are pleased to remain at your disposal should you have any further inquiries or requests.

Respectfully,

President
Susanna Cantoni

References

Carlo Sala salacarlo.sala@alice.it
Giulio Andrea Tozzi gnd.tzz@gmail.com