

# Protection of workers: exposure to biological agents (Directives 89/391/EEC, 90/679/EEC). Codification

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The Commission presented a working document accompanying the [Commission communication](#) to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions on the modernisation of the EU occupational safety and health legislation and policy.

The detailed ex-post evaluation of the EU acquis, checking their relevance as well as efficiency, effectiveness, coherence and EU added value, carried out by the Commission confirms that the framework meets its ambition to adequately protect workers.

**Main conclusions:** the evaluation concluded that the overall structure of the EU occupational safety and health acquis, consisting of a goal-oriented Framework Directive complemented by specific Directives, is generally effective and fit-for-purpose.

However, it pointed to **specific provisions of individual Directives that have become outdated or obsolete**, and highlighted the need to find effective ways to **address new risks**.

The way in which Member States have transposed the EU occupational safety and health Directives varies considerably across Member States. Compliance costs therefore vary and cannot be easily dissociated from more detailed national requirements.

**As regards SMEs:** the evaluation clearly concluded that compliance with the occupational safety and health Directives is more challenging for SMEs than large establishments, while at the same time the **major and fatal injury rates are higher for SMEs**. Specific support measures are therefore necessary to **reach SMEs** and help them increase their compliance in an efficient and effective way.

**Next steps:** the evaluation considered that occupational safety and health measures should reach the widest number of people at work, **no matter the type of working relationship they are in, and no matter the size of company they work for**. Compliance with occupational safety and health rules should be manageable for businesses of all sizes and effectively monitored on the ground.

Measures must be result-oriented, instead of paper-driven, and maximum use should be made of **new digital tools** to facilitate implementation.

**Characteristics of the evaluation:** this exercise also forms part of the Commission's Regulatory Fitness (REFIT) Programme with a special focus on SMEs. In this respect, the evaluation concentrated both on Framework Directive 89/391/EEC and on the other 23 directives related to it.

**The evaluation also concerned Directive 2000/54/EC** of the European Parliament and of the Council on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC).

The Directive aims to protect workers against risks to their health and safety arising or likely to arise from exposure to biological agents at work. It applies to all workers exposed – intentionally or unintentionally – to harmful biological agents at work. According to Article 2 biological agents mean microorganisms,

including those which have been genetically modified, cell cultures and human endoparasites, which may be able to provoke any infection, allergy or toxicity. They represent a risk because they can be infectious and toxic, but also because they can cause allergic reactions such as hypersensitivity pneumonitis, allergic rhinitis, some types of asthma and organic dust toxic syndrome (ODTS).

In order to enhance the relevance and effectiveness of the Directive, it could be considered to:

- update Annex III with the list of biological agents to ensure that it covers **comprehensively and clearly all relevant biological agents**;
- amend the Directive to ensure a procedure which allows for a more flexible approach to future updates of the list of biological agents;
- consider whether the contents of Annex V in the Directive should be taken out and instead form part of a guidance material, which elaborates more on the measures to be decided based on the classification and risk assessment;
- support further knowledge building on cause-effect relationships between exposure to various biological agents and occupational diseases; and the use of knowledge for development of better tools and techniques for measurement, criteria and protocols for assessing exposure to hazardous biological substances as well as occupational exposure limits;
- develop guidance on implementation of the Directive, especially on risk assessment and ensure that models and tools developed in some Member States are shared to the extent feasible and possible;
- support awareness raising so that sectors with unintentional use/contact with biological agents become more aware of the risks involved and can take appropriate action.

Measures are also proposed to enhance the coherence of the biological agents Directive with other Directives:

- review the risk assessment procedure under Directive 2000/54/EC to include several requirements from Directive 98/24/EC (chemical agents), such as the obligations to take into account the effect of preventive measures;
- review the worker information provisions under Directive 2000/54/EC to include the obligation to inform workers on how to detect health effects of exposure and how to report them;
- review the health record requirements under Directive 2000/54/EC to include the obligation to update these;
- review the scope of Directive 2010/32/EU to **cover all workers exposed to sharp injuries leading to infections by biological agents** and/or merge it with Biological Agents Directive.

Lastly, recommendations are proposed to ensure that the Directive is adapted to include the increasing number of situations **outside laboratories** involving a threat of biological agents and that there is a revision of the definition of an accident at work/accident in service of any case where workers are found to have been accidentally exposed to pathogenic biological agents (in order to make it unequivocal).