



Council of the  
European Union

Brussels, 12 July 2019  
(OR. en)

11232/19

SOC 556  
EMPL 426  
SAN 352

#### COVER NOTE

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From:	European Commission
date of receipt:	12 July 2019
To:	General Secretariat of the Council

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No. Cion doc.:	D062403/01
Subject:	COMMISSION DIRECTIVE (EU) .../... of XXX amending Annexes I, III, V and VI to Directive 2000/54/EC of the European Parliament and of the Council as regards purely technical adjustments

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Delegations will find attached document D062403/01.

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Encl.: D062403/01



Brussels, **XXX**  
D062403/01  
[...] (2019) **XXX** draft

**COMMISSION DIRECTIVE (EU) .../...**

**of **XXX****

**amending Annexes I, III, V and VI to Directive 2000/54/EC of the European Parliament  
and of the Council as regards purely technical adjustments**

# COMMISSION DIRECTIVE (EU) .../...

of **XXX**

## amending Annexes I, III, V and VI to Directive 2000/54/EC of the European Parliament and of the Council as regards purely technical adjustments

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work<sup>1</sup>, and in particular Article 19 thereof,

Whereas:

- (1) Principle 10 of the European Pillar of Social Rights<sup>2</sup>, proclaimed at Gothenburg on 17 November 2017, provides that every worker has the right to a healthy, safe and well-adapted working environment. The workers' right to a high level of protection of their health and safety at work and to a working environment that is adapted to their professional needs and that enables them to prolong their participation in the labour market includes protection from exposure to biological agents at work.
- (2) The implementation of the directives related to the health and safety of workers at work, including Directive 2000/54/EC, was the subject of an ex-post evaluation, referred to as a REFIT evaluation. The evaluation looked at the directives' relevance, at research and at new scientific knowledge in the various fields concerned. The REFIT evaluation, referred to in the Commission Staff Working Document<sup>3</sup>, concludes, among other things, that the classified list of biological agents in Annex III to Directive 2000/54/EC needs to be amended in light of scientific and technical progress and that consistency with other relevant directives should be enhanced.
- (3) In its Communication 'Safer and Healthier Work for All – Modernisation of the EU Occupational Safety and Health Legislation and Policy'<sup>4</sup>, the Commission reiterated that while the REFIT evaluation of the Union's acquis on occupational health and safety confirmed that the legislation in this field is generally effective and fit-for-purpose, there is scope for updating outdated rules and ensuring better and broader protection, compliance and enforcement on the ground. The Commission emphasises the particular need to update the list of biological agents in Annex III to Directive 2000/54/EC.

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<sup>1</sup> OJ L 262, 17.10.2000, p. 21

<sup>2</sup> European Pillar of Social Rights, November 2017, [https://ec.europa.eu/commission/priorities/deeper-and-fairer-economic-and-monetary-union/european-pillar-social-rights\\_en](https://ec.europa.eu/commission/priorities/deeper-and-fairer-economic-and-monetary-union/european-pillar-social-rights_en)

<sup>3</sup> SWD(2017) 10 final

<sup>4</sup> COM(2017) 12

- (4) Directive 2000/54/EC lays down rules to protect workers against risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to biological agents at work. Directive 2000/54/EC applies to activities in which workers are exposed, or are potentially exposed, to biological agents as a result of their work, and states the measures to be taken in the case of any activity likely to involve a risk of exposure to biological agents, to determine the nature, degree and duration of workers' exposure to biological agents.
- (5) Since the results of a risk assessment can show an unintended exposure to biological agents, there could be other work activities not included in Annex I to Directive 2000/54/EC that should also be taken into consideration. Therefore, the indicative list of activities set out in Annex I to Directive 2000/54/EC should be amended to include an introductory phrase in order to clarify the non-exhaustive nature of the list.
- (6) Annex III to Directive 2000/54/EC sets out the list of biological agents known to infect humans, classified according to their level of risk of infection. In line with introductory note 6 in that Annex, the list should be amended to take into account the latest state of knowledge as regards scientific development that have brought about significant changes since the list was last updated, particularly as regards the taxonomy, nomenclature, classification and characteristics of biological agents, and the existence of new biological agents.
- (7) Annexes V and VI to Directive 2000/54/EC lay down the containment measures and levels for laboratories, animal facilities and industry. Annexes V and VI should be amended and restructured in order to be aligned with and to take into account the containment and other protective measures included in Directive 2009/41/EC<sup>5</sup>.
- (8) In preparing the current update of Annexes I, III V and VI to Directive 2000/54/EC, consideration was given to the need to maintain the existing levels of protection for workers who are or who are potentially exposed to biological agents through their work, and to ensure that the amendments only take into account scientific developments in the area, requiring adjustments at the workplace that are merely technical in nature.
- (9) The Advisory Committee for Safety and Health at Work was consulted on the measures resulting from the adoption of the Commission's Communication 'Safer and Healthier Work for All – Modernisation of the EU Occupational Safety and Health Legislation and Policy' that are required to keep the Union's occupational health and safety legislation effective and fit-for-purpose.
- (10) In its 'Opinion on the Modernisation of Six OSH Directives to Ensure Healthier and Safer Work for All'<sup>6</sup>, adopted on 6 December 2017, the Advisory Committee for Safety and Health at Work recommends that Directive 2000/54/EC should be amended to enhance its relevance and effectiveness.
- (11) In a subsequent "Opinion on technical updates to the annexes of the Biological Agents Directive (2000/54/EC)"<sup>7</sup>, adopted on 31 May 2018, the Advisory Committee for

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<sup>5</sup> OJ L 125, 21.05.2009, p. 75

<sup>6</sup> Advisory Committee for Safety and Health at Work Doc. 1718/2017

<sup>7</sup> Advisory Committee for Safety and Health at Work Doc. 434/18

Safety and Health at Work recommends that specific updates should be made to Annex I, III, V and VI, reflecting the latest technological and scientific developments in the field.

- (12) In preparing the current update of Annexes I, III, V and VI to Directive 2000/54/EC, the Commission was assisted by experts representing Member States, who provided technical and scientific support.
- (13) In accordance with the Joint Political Declaration on explanatory documents<sup>8</sup>, adopted by the Member States and the Commission on 28 September 2011, Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments.
- (14) The measures provided for in this Directive are in accordance with the opinion of the Committee established by Article 17 of Council Directive 89/391/EEC,

HAS ADOPTED THIS DIRECTIVE:

#### *Article 1*

Annexes I, III, V and VI to Directive 2000/54/EC are replaced by the text in the Annex to this Directive.

#### *Article 2*

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [date – two years after the date of entry into force of this Directive] at the latest. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those measures, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

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<sup>8</sup> OJ C 369, 17.12.2011, p. 14

*Article 3*

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

*Article 4*

This Directive is addressed to the Member States.

Done at Brussels,

*For the Commission*  
*The President*  
*[...]*