Commission Directive (EU) 2019/1833 of 24 October 2019 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) 2019/1833

of 24 October 2019

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[(1)], and in particular Article 19 thereof,

Whereas:

(1) Principle 10 of the European Pillar of Social Rights[(2)], 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[(3)], 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'[(4)], 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confirmed that the legislation in this field is generally effective and fit-for-purpose, there is scope for updating outdated rules and ensuring better and broader protection, compliance and enforcement on the ground.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.

(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,

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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 of the European Parliament and of the Council[(5)].

(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'[(6)], 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)'[(7)], adopted on 31 May 2018, the Advisory Committee for 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[8], 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[9],

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

[[F1]1 Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 20 November 2021 at the latest. However, Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with the amendments to Annexes V and VI to Directive 2000/54/EC, insofar as they relate to the biological agent SARS-CoV-2, by 24 November 2020 at the latest.

They shall forthwith communicate to the Commission the text of the provisions referred to in the first subparagraph.

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.

Textual Amendments

F1 Substituted by Commission Directive (EU) 2020/739 of 3 June 2020 amending Annex III to Directive 2000/54/EC of the European Parliament and of the Council as regards the inclusion of SARS-CoV-2 in the list of biological agents known to infect humans and amending Commission Directive (EU) 2019/1833.

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.

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ANNEX

(1) Annex I to Directive 2000/54/EC is replaced by the following:

ANNEX I

INDICATIVE LIST OF ACTIVITIES
(Article 4(2))

Preliminary note

Where the result of the risk assessment, carried out in accordance with Article 3 and Article 4(2) of this Directive, shows an unintentional exposure to biological agents, there may be other work activities, not included in this Annex, which should be considered.

1. Work in food production plants.

2. Work in agriculture.

3. Work activities where there is contact with animals and/or products of animal origin.

4. Work in healthcare, including isolation and post-mortem units.

5. Work in clinical, veterinary and diagnostic laboratories, excluding diagnostic microbiological laboratories.

6. Work in refuse disposal plants.

7. Work in sewage purification installations.

(2) Annex III to Directive 2000/54/EC is replaced by the following:

ANNEX III

COMMUNITY CLASSIFICATIONArticle 2, second paragraph, and Article 18
INTRODUCTORY NOTES

1. In line with the scope of the Directive, only agents which are known to infect humans are to be included in the classified list.

Where appropriate, indicators are given of the toxic and allergic potential of these agents.

Animal and plant pathogens which are known not to affect man are excluded.

In drawing up this list of classified biological agents consideration has not been given to genetically modified micro-organisms.

2. The list of classified agents is based on the effect of those agents on healthy workers.

No specific account is taken of particular effects on those whose susceptibility may be affected for one or other reason such as pre-existing disease, medication, compromised immunity, pregnancy or breast feeding.

Additional risk to such workers should be considered as part of the risk assessment required by the Directive.

In certain industrial processes, certain laboratory work or certain work with animals involving actual or potential exposure to biological agents of groups 3 or 4, any technical precautions taken must comply with Article 16 of the Directive.

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3. Biological agents which have not been classified for inclusion in groups 2 to 4 of the list are not implicitly classified in group 1.

For genera where more than one species is known to be pathogenic to man, the list will include those species which are known to be the most frequently responsible for diseases, together with a more general reference to the fact that other species of the same genus may affect health.

When a whole genus is mentioned in the classified list of biological agents, it is implicit that the species and strains known to be non-pathogenic are excluded.

4. Where a strain is attenuated or has lost known virulence genes, then the containment required by the classification of its parent strain need not necessarily apply, subject to assessment appropriate for risk in the workplace.

This is the case, for example, when such a strain is to be used as a product or part of a product for prophylactic or therapeutic purposes.

5. The nomenclature of classified agents used to establish this list reflects and is in conformity with the latest international agreements of the taxonomy and nomenclature of agents at the time the list was prepared.

6. The list of classified biological agents reflects the state of knowledge at the time that it was devised.

It will be updated as soon as it no longer reflects the latest state of knowledge.

7. Member States are to ensure that all viruses which have already been isolated in humans and which have not been assessed and allocated in this Annex are classified in group 2 as a minimum, except where Member States have proof that they are unlikely to cause disease in humans.

8. Certain biological agents classified in group 3 which are indicated in the appended list by two asterisks (**), may present a limited risk of infection for workers because they are not normally infectious by the airborne route.

Member States shall assess the containment measures to be applied to such agents, taking account of the nature of specific activities in question and of the quantity of the agent involved, with a view to determining whether, in particular circumstances, some of these measures may be dispensed with.

9. The requirements as to containment consequent on the classification of parasites apply only to stages in the life cycle of the parasite in which it is liable to be infectious to humans at the workplace.

10. This list also gives a separate indication in cases where the biological agents are likely to cause allergic or toxic reactions, where an effective vaccine is available, or where it is advisable to keep a list of exposed workers for more than 10 years.

These indications are shown by the following letters:

A: Possible allergic effects

D: List of workers exposed to this biological agent to be kept for more than 10 years after the end of last known exposure

T: Toxin production

V: Effective vaccine available and registered within the EU