



EUROPEAN COMMISSION
Employment, Social Affairs and Inclusion DG
Employment and Social Legislation, Social Dialogue
Health and Safety

Luxembourg,
EMPL B.3

**Minutes of the
Expert Group Meeting dedicated to Directive 2000/54/EC (Biological Agents)
in the context of the COVID-19 pandemic**

**27th April 2020
Luxembourg, Videoconference**

Welcome and introduction by the Commission

The meeting of the Expert Group took place with a view to discuss a possible technical update of Annex III to Directive 2000/54/EC (Biological Agents) in the context of the COVID-19 pandemic caused by the new coronavirus “SARS-CoV-2”.

The participants of the meeting were experts nominated by MSs (25 MSs were represented as HR and BE had technical issues with joining the meeting). One EFTA country, NO, also attended the meeting. Apart from the experts from the Member States, several observers attended the meeting: one from each Interest Group of the Advisory Committee on Safety and Health at Work (ACSH), as well as from DG SANTE, ECDC (European Centre for Disease Prevention and Control) and WHO (World Health Organization).

The meeting was chaired by a Commission services representative (CSR). A 'tour de table' allowed every participant to present him/herself, informing which department/service they represented.

1. Adoption of the draft agenda

The draft agenda was adopted without any amendments.

2. Information from DG EMPL

The Chair provided a summary of the current context of the meeting, and started by setting out the meeting's aim, which is to consider whether “severe acute respiratory syndrome coronavirus 2” or, in short, “SARS-CoV-2”, with the related classification and notations, should be added to Annex III to Directive 2000/54/EC. She highlighted that other biological agents would not be discussed during the meeting, and changes to the provisions of Directive 2000/54/EC would also not be addressed.

The CSR outlined the urgency and seriousness of the current pandemic and referred to guidance documents published by ECDC and WHO for laboratories, which, for example, set out the procedures to be carried out at Biosafety Level 2 or Biosafety Level 3 facilities and the

containment measures that should be put in place for certain activities. She stressed that it is important to consider these guidelines, and to ensure that the classification of the new coronavirus will not result in restrictions that would limit or put a halt on vital work done by laboratories across the EU.

Furthermore, she reminded participants that the Biological Agents Directive 2000/54 was updated last year where a number of changes were made to its Annex III in order to reflect the latest technological and scientific developments in the field. For example, a large number of biological agents were added to the annex, including the SARS-virus and the MERS-virus, which have both been classified as group 3 biological agents. Other coronaviruses that are known to be pathogenic are currently classified as group 2 biological agents. She explained that, at the time of this last update, there was no sign yet of the new coronavirus that is causing the current pandemic, and therefore Annex III of the Directive does not yet include SARS-CoV-2.

Next, the Chair explained the procedural aspects of the development of this initiative – comitology procedure - and stressed that in light of the urgency of the issue, the urgency procedure is applicable.

3. Exchange of views on first identification of main issues

The Chair initiated a 'tour de table' inviting the Member States delegations to express their views on the set of questions presented on the circulated supporting background document, which provides an inventory of the main points relevant for the update of the Directive 2000/54/EC on the context of the current COVID-19 pandemic (see in annex):

i. First round of questions:

- a) **Question 1a:** *Is there a need for a technical update to Directive 2000/54/EC by adding SARS-CoV-2 to Annex III?*
- b) **Question 1b:** *If yes, and based on the available scientific, clinical and epidemiological data, what would be the appropriate risk classification and notes to be used? In case your country has (provisionally) classified SARS-CoV-2, please state this during your intervention too.*

All 25 MS experts present unanimously agreed that there is a need for a technical update to Directive 2000/54/EC by adding SARS-CoV-2 to Annex III.

Concerning question 1b, 13 experts (AT, CY, CZ, EE, FR, HU, IT, LV, LT, PT, RO, SI, SK) indicated that, in their view, the new coronavirus should be considered a risk group 3 human pathogen, and they informed participants that at national level they have not classified SARS-CoV-2. Latvia drew the attention of participants to the national measures put in place in the context of the COVID-19 pandemic.

Norway also agreed to classify the new coronavirus as risk group 3, which is in line with the classification that they have adopted at national level. Norway has added the following note to its hazard classification: “Normally not airborne transmission”, which makes it easier to handle the virus in laboratories, hence allowing the containment level to be between 2 and 3, depending on the type of work carried out.

In addition, 10 experts (BG, DE, DK, EL, FI, IE, LU, NL, PL, SE) indicated that the new coronavirus should be classified as risk group 3, and referred to national recommendations (implemented in accordance with Directive 2000/54/EC) and/or to the (interim) guidance published by WHO on laboratory biosafety, which is closely followed by these countries. The national recommendations and WHO guidance define that non-propagative diagnostic laboratory work (e.g. sequencing, nucleic acid amplification test [NAAT]) should be conducted at a facility using procedures equivalent to Biosafety Level 2 (BSL-2), and that propagative work (e.g. virus culture, isolation or neutralization assays) should be conducted at a containment laboratory with inward directional airflow (BSL-3). Especially the Netherlands and Finland elaborated on this point.

For the Netherlands, it is of primary importance to be able to work under class II conditions for diagnostic laboratory work. Given the need for large scale testing, including point of care testing and serology as part of patient diagnostics, follow-up on policy measures, contact tracing, surveillance etc., this diagnostic practice will be seriously hampered by class III restrictions. It will not only put restrictions on the personnel, but also on laboratory capacity. For laboratory work concerning propagation of the virus, which is done in a limited number of facilities, class III is applicable.

Finland also stressed that it is very important that a recital or a preamble is added to Annex III of Directive 2000/54/EC, so that specimens of respiratory tract secretions or other specimens collected directly from patients suspected of having contracted SARS-CoV-2 can be analysed in BSL-2 laboratories – now but also in the future. Otherwise, there will not be enough laboratory capacity to analyse the high number of specimens, which is expected to further increase. Enrichment culture specimens of SARS-CoV-2 should be analysed in BSL-3 laboratories.

One expert (ES) indicated that the classification of SARS-Cov-2 in risk group 3 is appropriate as long as effective treatment or vaccine has not yet been developed. Once treatment has become available, the classification of the virus should be re-evaluated and, if relevant, the possibility of lowering the risk group classification could be considered.

Furthermore, one expert (MT) pointed that the classification of SARS-CoV-2 as a risk group 3 human pathogen would be appropriate as it is expected that a vaccine/treatment will become available.

Based on contributions provided (including in writing to the Commission services), the following countries have (provisionally) classified SARS-CoV-2 to risk group 3: Belgium, Germany, Ireland, Latvia, Malta and Sweden as well as Norway.

Croatia provided the Commission services with a written statement after the Expert Meeting, informing them that they agree with a classification of SARS-CoV-2 to risk group 3. Belgium also agrees with this risk classification, which is in line with their national temporary classification.

ii. **Second round of questions:**

- c) **Question 2a:** *Would a shorter transposition period (one - three months) than the normally laid down (12 – 24 months) be feasible?*
- d) **Question 2b:** *If yes, what should be the duration of such a shortened transposition period?*

Five of the participants (ES, FR, IT, MT, NL) did not have the mandate to make a formal statement with regards to a shorter transposition period of the technical update in question. However, most of these participants indicated that they expect that flexibility will be possible. The other 20 MS experts agreed that, considering the circumstances, a shorter transposition period would be acceptable and feasible.

Concerning question 2b, 7 MS experts (BG, DE, EL, HU, LU, SI, SE) stressed the urgency of the situation, indicating that a shortened transposition period (up to 3 months) is important and should be feasible. The other 14 MS experts agreed that the situation requires a shortened period, but considered that 3 months would be the absolute minimum and more time would be preferable, also considering procedures that require the involvement of social partners. Of these MS, 6 experts (CY, IE, PL, PT, RO, SK) as well as Norway indicated that 6 months would be a more realistic transposition period for the technical update of the annex.

Furthermore, Finland reminded participants of last year's technical update of the Biological Agents Directive of 2019 (Directive 2019/1833), and that this transposition period will expire on 20 November 2021, which is relevant to consider in the current context.

Moreover, Germany suggested that it would be helpful to establish an expert forum that would allow for a more regular updating of Annex III to Directive 2000/54/EC in the future.

Belgium provided the Commission services with a written statement after the Expert Meeting, informing them that the updating of national legislation requires the involvement of social partners and therefore considers the transposition period of three months to be too short and thus a longer period would be preferable.

Next, the Chair invited the observers to provide any further comments regarding to what was debated at the meeting.

WHO appreciated that references were made to its guidance on laboratory biosafety in the context of the COVID-19 pandemic, and explained that there is global consensus that diagnostic testing (non-propagative laboratory work) involving SARS-CoV-2 can be safely carried out in BSL-2 facilities. Propagative work should be conducted at a containment laboratory with inward directional airflow (BSL-3). This approach is not only taken in Europe, but also in countries such as Australia, Singapore, the US and Canada. It therefore looks reasonable for the EU to classify SARS-CoV-2 to risk group 3, provided non-propagative laboratory work can be performed in BSL-2. This classification would largely coincide with the WHO's present biosafety guidance for COVID-19.

A reference was made to Article 16 of Directive 2000/54/EC, where section 1(b) makes a direct association between the risk group level of the human pathogen as defined in Annex III and the containment levels and measures linked to these as described in Annexes V and VI. In

practise, this means that, in case SARS-CoV-2 would be classified as a risk group 3 biological agent, all work activities involving the virus – including those related to diagnostic testing – should be carried out in containment level 3 facilities. It is therefore crucial to find a solution that would allow diagnostic work involving SARS-CoV-2 to be continued in BSL-2 laboratories. A risk-based approach is required, linking the type of activity to the related type of risk involved, rather than connecting pathogens of certain risk groups to specific containment levels. This would be a more practical and productive way for countries to address risk classifications of biological agents.

ECDC supported the views expressed by WHO and the need for taking a risk-based approach to the classification of SARS-CoV-2 and thus to find a way to accommodate the important remarks made concerning the diagnostic work carried out in BSL-2 laboratories. The practical implementation of the Directive should accommodate real life measures and the risk management and risk mitigation measures put in place for specific activities. Different activities (e.g. diagnostic laboratory work, research and development) result in different degrees of exposure to the virus and this is important to consider when classifying the new coronavirus as well as to consider this approach for the Directive as a whole. Therefore, based on the best available scientific evidence on the biosafety protection against the risks associated with laboratory work involving biological materials containing SARS-CoV-2, and in line with guidance published by ECDC and WHO, ECDC recommends to classify the virus in risk group 3 in case of laboratory work involving viral propagation by culture or enrichment procedures, and in risk group 2 for non-propagative diagnostic laboratory work procedures.

DG SANTE also supported the position of WHO and ECDC, and vocalised the importance from a public health perspective to guarantee testing capacity. From DG SANTE's point of view, there is a need to be able to develop adequate, validated, reliable and sufficient tests for all EU MS to rely on the tests and to guarantee vaccine development. This implies that the risk category needs to strike the necessary balance between capacity development and adequate protection of workers. DG SANTE believes that risk category 3 strikes this balance; any classification higher would undermine the development of capacity and ultimately undermine public health. Moreover, very few labs in the EU could deal with a risk category 4. In conclusion, DG SANTE would currently firmly oppose a too high-risk categorisation.

ACSH, Government Interest Group (GIG): The representative stated that shortening the transposition period is very important and a matter of urgency; the implementation of the new risk classification of SARS-CoV-2 at national level should be done as soon as possible. The transposition period could be relatively 'long' (six months), but if there is a possibility to shorten it to one or even max three months this would be preferable.

ACSH, Workers Interest Group (WIG): The representative referred to Article 2 of the Directive, which provides the definitions of the different risk groups, and stressed that according to this definition, there is usually a prophylaxis or treatment available for risk group 3. As this is currently not the case for COVID-19, the WIG representative considered it more appropriate to classify SARS-CoV-2 as a risk group 4 human pathogen. For diagnostic work, the WIG can be flexible and allow these activities to be carried out in facilities that are less strict in terms of containment levels. Concerning the transposition period, this should be as short as possible but a three month period would be acceptable.

ACSH, Employers Interest Group (EIG): From the employers' side, the representative stressed that they did not have time to formulate an official position, but she believed that a risk classification of group 3 for SARS-CoV-2 could be supported as well as the note that diagnostic work can be carried out in BSL-2 facilities. Concerning the transposition period, three months may be challenging, as not only the governmental and legislative procedures should be taken into account, but also the measures that will be required for companies to be adopted.

4. Identification of technical points for possible update

The Chair concluded that all delegations present in the meeting agreed by consensus on:

- a) Adding SARS-CoV-2 to the list of viruses included in Annex III to Directive 2000/54/EC;
- b) Classifying SARS-CoV-2 as a risk group 3 virus;
- c) Including a footnote and/or recitals stating that diagnostic testing (non-propagative laboratory work) involving SARS-CoV-2 can be safely carried out in BSL-2 facilities, which is in line with article 16 (1)(c) of Directive 2000/54/EC and with the respective WHO guidelines; and
- d) Setting a shorter transposition period for this technical amendment of 3-6 months.

5. Closing of meeting and next steps

Due to the urgency of the topic, the Chair explained that the draft minutes will be circulated by the end of the same day, and that the experts will be asked to submit in writing their comments by 28 April 2020, close of business.

Next, the outcome of the discussions of the meeting will be transmitted to the relevant parties. A meeting will take place with the tripartite Advisory Committee for Safety and Health at Work to discuss the outcomes and an internal consultation among the relevant Commission departments will be organised. After this, the Technical Progress Committee meeting will take place, consisting of representatives of all EU Member States.

6. Any other business

The Chair congratulated the delegates for the outcome of the meeting and thanked them for their contribution in the procedure.

The meeting was closed without further remarks.

ANNEXES

1. Presence List
2. Supporting Document

Annex 1: Presence List

Member State experts – Participants online

#	Name	Surname	Country
1	Sabine	LEHR	Austria
2	Galin Emilov	KAMENOV	Bulgaria
3	Christos	KOKKOFITIS	Cyprus
4	Markéta	HOLUBOVÁ	Czech Republic
5	Susanne	HØYER	Denmark
6	Eneken	HIIRE	Estonia
7	Reetta	ORSILA	Finland
8	Mathieu	LASSUS	France
9	Udo	JÄCKEL	Germany
10	Ilias	TYLIGADAS	Greece
11	Ferenc	KUDÁSZ	Hungary
12	Sheena	NOTLEY	Ireland
13	Paola	TOMAO	Italy
14	Jolanta	GEDUSA	Latvia
15	Rasa	ŠIDAGYTE	Lithuania
16	Robert	GOERENS	Luxembourg
17	Catriona	FRANCICA	Malta
18	(10)(2e)	(10)(2e)	Netherlands
19	Anna	KOZAJDA	Poland
20	Emília	TELO	Portugal
21	Micaela	MARGINEANU	Romania
22	Daniela	KALLAYOVA	Slovakia
23	Petra	BECHIBANI	Slovenia
24	Belén	PEREZ AZNAR	Spain
25	Helen	KARLBERG	Sweden

Annex 1: Presence List

Member State experts – written contributions

#	Name	Surname	Country
1	Alfred	VOLCKAERTS	Belgium
2	Marija	BUBAS	Croatia

Observers

#	Name	Surname	Delegation
1	Tone	ERIKSEN	Norway
2	Rafał	L. GÓRNY	ACSH - GIG
3	Laurent	VOGEL	ACSH - WIG
4	Isabel	MAYA RUBIO	ACSH - EIG
5	Kazunobu	KOJIMA	WHO
6	Marc	STRUELENS	ECDC
7	(10)(2e)	(10)(2e) (10)(2e)	DG SANTE
8	Philippe	ROUX	DG SANTE

Commission Services

#	Name	Surname	Unit
1	Charlotte	GREVFORS ERNOULT	EMPL B/3
2	Teresa	MOITINHO DE ALMEIDA	EMPL B/3
3	Yoline	KUIPERS	EMPL B/3
4	(10)(2e)	EBELING	EMPL B/3
5	Agnieszka	JELNICKA	EMPL B/3
6	Jesus	ALVAREZ HIDALGO	EMPL B/3
7	Vera	AZEVEDO MONTEIRO	EMPL B/3
8	Sophie	CAMMARELLA	EMPL B/3

Annex 2: Supporting document

Updating the Biological Agents Directive 2000/54/EC in the context of the current COVID-19 pandemic

The EU Occupational Safety and Health (OSH) Directives set up minimum requirements at EU level for the protection of workers against risks to which they are or can be exposed to at work. The Framework Directive 89/391/EEC sets out the main principles of prevention and protection of occupational risks for all sectors of activity. These provisions are further developed by a set of individual Directives, among which, the **Biological Agents Directive 2000/54/EC** ('Directive 2000/54/EC') which lays down detailed preventive and protective measures aimed at the protection of workers against risks to their health and safety arising or likely to arise from exposure to biological agents at work.

Biological agents, which are micro-organisms that may be able to provoke any infection, allergy or toxicity, can be classified into **four risk categories**, according to their level or risk of infection (see Article 2 of Directive 2000/54/EC):

1	group 1 biological agent means one that is unlikely to cause human disease
2	group 2 biological agent means one that can cause human disease and might be a hazard to workers; it is unlikely to spread to the community; there is usually effective prophylaxis or treatment available
3	group 3 biological agent means one that can cause severe human disease and present a serious hazard to workers; it may present a risk of spreading to the community, but there is usually effective prophylaxis or treatment available
4	group 4 biological agent means one that causes severe human disease and is a serious hazard to workers; it may present a high risk of spreading to the community; there is usually no effective prophylaxis or treatment available

It is to be noted that the provisions of the Framework Directive 89/391/EEC and 2000/54/EC, as well as of other EU OSH relevant individual Directives, are fully applicable to the exposure of workers to biological agents. This means that workers exposed to COVID-19 are fully covered by the general and specific OSH obligations, in particular the obligation for employers to assess the risks and put in place the appropriate preventive and protective measures, including notifications to the competent authority of workers exposed or the provision of adequate personal protective equipment.

Annex III to Directive 2000/54/EC provides a list of biological agents known to infect humans, and sets out their classification and characteristics, which determine the type of protective measures to be put in place. In October 2019, Commission Directive 2019/1833 amended Annex III (amongst others) in order to reflect the latest technological and scientific developments in the field¹. For example, a large number of biological agents were added to the annex, including the Severe Acute Respiratory Syndrome-related coronavirus (SARS-virus) and the Middle East Respiratory Syndrome coronavirus (MERS-virus), which have both been classified as group 3 biological agents. Other coronaviruses that are known to be pathogenic are currently classified as group 2 biological agents.

¹ Commission Directive 2019/1833 was adopted in accordance with the comitology procedure provided for in Article 17 of Directive 89/391/EEC (regulatory procedure with scrutiny).

Annex 2: Supporting document

The field of infectious diseases is a constantly evolving and the identification and classification of biological agents is an ongoing activity. With the outbreak of the new coronavirus disease, **COVID-19**, early epidemiological and clinical investigations are now ongoing to identify and understand the severity of the new virus, which has been called “severe acute respiratory syndrome coronavirus 2” or, in short, “**SARS-CoV-2**”². Because of its great similarity with the SARS-virus and MERS-virus, as well as the data and knowledge currently available concerning the virus’ transmission patterns, clinical features and risk factors for infection, the current lack of a vaccine and therapy, and the large distribution possibility in the population, several EU Member States have provisionally classified SARS-CoV-2 to **risk group 3**³.

As risk classifications are thus being introduced at national level, the Commission services are organising an **expert group meeting** with Member State scientific experts to consider if a further technical update of Directive 2000/54/EC is possible and relevant, and thus to include a new entry in Annex III of SARS-CoV-2 with its respective classification and characteristics. This technical update would follow the **Comitology procedure**.

Question 1a to the Expert Group: Is there a need for a technical update to Directive 2000/54/EC by adding SARS-CoV-2 to Annex III?

Question 1b to the Expert Group: If yes, and based on the available scientific, clinical and epidemiological data, what would the appropriate risk group classification and possible notes to be used?

If the decision is taken in favour of an update of the Directive, a **shorter period of transposition** (one-three months) than the usually foreseen (12 – 24 months) could be considered in light of the urgency of the measure.

Question 2a to the Expert Group: Would a shorter transposition period (one - three months) than the normally laid down (12 – 24 months) be feasible?

Question 2b to the Expert Group: If yes, what should be the duration of such a shortened transposition period?

Depending on the risk group that a biological agent belongs to, specific obligations for workplaces and employers are triggered, as set out by the different Articles of Directive 2000/54/EC.

While the purpose of the Expert Group is not to discuss whether articles should be amended, as this falls outside the scope of the technical meeting, it could be relevant to consider these during the discussions on the above mentioned questions.

The table on the next page provides examples of such obligations triggered by the various risk groups.

² See: [https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-\(covid-2019\)-and-the-virus-that-causes-it](https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(covid-2019)-and-the-virus-that-causes-it)

³ Note:

Annex 2: Supporting document

Classification group 1	Classification group 2	Classification group 3	Classification group 4
If assessment of Article 3 shows exposure and/or potential exposure a group 1 biological agent, with no identifiable health risk to workers, Articles 5 to 17 and Article 19 shall not apply.			
		Make available, on demand, to authorities an emergency plan for protection of workers from exposure which might result from a loss of physical containment (Art. 7)	Make available, on demand, to authorities an emergency plan for protection of workers from exposure which might result from a loss of physical containment (Art. 7)
	Provide written instructions at workplace and, if appropriate, display notices on procedure in case of a serious accident or incident involving the handling of a biological agent (Art. 10)	Provide written instructions at workplace and, if appropriate, display notices on procedure in case of a serious accident or incident involving the handling of a biological agent (Art. 10)	Provide written instructions at workplace and, if appropriate, display notices on procedure in case of a serious accident or incident involving the handling of a biological agent (Art. 10)
			Provide written instructions at workplace and, if appropriate, display notices on procedure in case of handling a group 4 biological agent (Art. 10);
		Employers shall keep a list of workers exposed to Group 3 biological agents, indicating the type of work done, and whenever possible the biological agent to which they have been exposed, as well as records of exposure, accidents and incidents as appropriate. The list shall be kept for at least 10 years following the end of exposure (Art. 11)	Employers shall keep a list of workers exposed to Group 4 biological agents, indicating the type of work done, and whenever possible the biological agent to which they have been exposed, as well as records of exposure, accidents and incidents as appropriate. The list shall be kept for at least 10 years following the end of exposure (Art. 11)
	Prior notification to authorities when biological agent is used for the first time (Art. 13)	Prior notification to authorities when biological agent is used for the first time (Art. 13)	Prior notification to authorities when biological agent is used for the first time (Art. 13)

Annex 2: Supporting document

	<p>Respect⁴ of containment measures of Annex V e.g. surfaces impervious to water and easy to clean for bench and floor; specified disinfection procedures; Safe storage of a biological agent.</p>	<p>Respect⁴ of containment measures of Annex V e.g. extract air to the workplace are to be filtered using “High efficiency particulate air” (HEPA) or likewise; access is to be restricted to nominated workers only; efficient vector control, for example rodents and insects; specified disinfection procedures; safe storage of a biological agent.</p>	<p>Respect⁴ of containment measures of Annex V e.g. workplace is to be separated from any other activities in the same building; workplace is to be sealable to permit fumigation; input air and extract air to the workplace are to be filtered using “High efficiency particulate air” (HEPA) or likewise; access is to be restricted to nominated workers only and entry must be through an airlock which is a chamber isolated from the laboratory (the clean side of the airlock must be separated from the restricted side by changing or showering facilities and preferably by interlocking doors); efficient vector control, for example rodents and insects; specified disinfection procedures; safe storage of a biological agent.</p>
<p>Observe principles of good occupational safety and hygiene (Art. 4, Annex VI)</p>	<p>Respect⁵ containment measures of Annex VI, e.g. decontamination and washing facilities should be provided for personnel; personnel should wear protective work clothing;</p>	<p>Respect⁵ containment measures of Annex VI, e.g. decontamination and washing facilities should be provided for personnel; personnel should wear protective clothing; biohazard signs should be posted; access is to be restricted to nominated workers only;</p>	<p>Respect⁵ containment measures of Annex VI, e.g. decontamination and washing facilities should be provided for personnel; access is to be restricted to nominated workers only and entry must be through an airlock which is a chamber isolated from the laboratory (the clean side of the airlock must be separated from the restricted side by changing or showering facilities and preferably by interlocking doors); personnel should shower before leaving the controlled area; personnel should wear protective clothing, do a complete change; biohazard signs should be posted; effluent from sinks and showers should be collected and inactivated before release; the controlled area should be maintained at an air pressure negative to atmosphere</p>

⁴ For laboratories handling such biological agents for research, development, teaching or diagnostic purposes.

⁵ For industrial processes.