EVALUATION OF THE PRACTICAL IMPLEMENTATION OF THE EU OCCUPATIONAL SAFETY AND HEALTH (OSH) DIRECTIVES IN EU MEMBER STATES

REPORT BY DIRECTIVE: DIRECTIVE 2000/54/EC ON THE PROTECTION OF WORKERS FROM RISKS RELATED TO EXPOSURE TO BIOLOGICAL AGENTS AT WORK
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<td>ACSH (WP)</td>
<td>Advisory Committee on safety and health at work (Working party)</td>
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<td>Art</td>
<td>Article</td>
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<td>CISID</td>
<td>Centralised Information System for Infectious Diseases</td>
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<td>CPM</td>
<td>Common Processes and Mechanisms</td>
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<td>CSR</td>
<td>Country Summary Report</td>
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<td>DWEA</td>
<td>Danish Working Environment Authority</td>
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<td>ECDC</td>
<td>European Centre for Disease Control and Prevention</td>
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<td>EQR</td>
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<td>EODS</td>
<td>European Occupational Diseases Statistics</td>
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<td>ESAW</td>
<td>European Statistics on Accidents at Work</td>
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<td>ESENER</td>
<td>European Survey on New and Emerging Risks</td>
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<td>EU</td>
<td>European Union</td>
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<td>EU-OSHA</td>
<td>European Agency for Safety and Health at Work</td>
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<td>EWCS</td>
<td>European Working Conditions Survey</td>
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<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<td>HSE</td>
<td>Health and Safety Executive</td>
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<td>ILO</td>
<td>International Labour Organisation</td>
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<td>KR</td>
<td>Key requirement</td>
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<td>MS</td>
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<td>N/a</td>
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<tr>
<td>NACE</td>
<td>Nomenclature statistique des Activités économiques dans la Communauté Européenne</td>
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<tr>
<td>NIR</td>
<td>National Implementation Report</td>
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<tr>
<td>ODTS</td>
<td>Organic Dust Toxic Syndrome</td>
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<td>OSH</td>
<td>Occupational Safety and Health</td>
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<td>PPE</td>
<td>Personal Protective Equipment</td>
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<tr>
<td>SARS</td>
<td>Severe Acute Respiratory Syndrome</td>
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<td>SBS</td>
<td>Structural Business Statistics</td>
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<td>Acronym</td>
<td>Definition</td>
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<td>SLIC</td>
<td>Senior Labour Inspectors Committee</td>
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<td>SME</td>
<td>Small and Medium Sized Enterprise</td>
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<td>TFEU</td>
<td>Treaty on the Functioning of the European Union</td>
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<td>WHO</td>
<td>World Health Organisation</td>
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Executive summary

The present report is a Directive-specific report, which forms part of the overall reporting of the evaluation of the 24 Directives on occupational Safety and Health (OSH) commissioned by the European Commission. The aim of the evaluation is to evaluate the practical implementation of EU OSH Directives in Member States (MS) with a view to assessing their relevance, effectiveness and coherence, and identifying possible improvements to the regulatory framework. This report presents the evaluation of Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work, which we refer to as the ‘Biological Agents Directive’.

The evaluation covers 24 Directives consisting of a Framework Directive (89/391), which describes the overall responsibilities of workers and employers and forms the basis of the specific 23 OSH Directives, including the Biological Agents Directive.

The Main Report provides a comprehensive overview of cross-cutting findings, conclusions and recommendations from the evaluation. The report includes the 24 Directive-specific reports (enclosed in Appendix A in the Main Report) and 27 Country Summary Reports (CSRs) on implementation of the Directives in the Member States (enclosed in Appendix B in the Main Report). Furthermore, the Main Report is complemented by a synthesis report providing a summarised version of the key findings, conclusions and recommendations.

Methodology

The evaluation is based on the analysis of transposition and implementation of OSH legislation in each Member State, official statistics at national and EU-level, National Implementation Reports (NIRs) submitted to the Commission by Member States in 2013, scientific literature, existing studies and interviews with national and EU stakeholders. However, statistical data on the compliance in enterprises and the health and safety impact is limited. Thus, we had to rely on other sources of information. The analyses of the effectiveness is therefore also based on data from the available scientific literature and qualitative information.

The Biological Agents Directive

The Directive applies to all workers exposed – intentionally or unintentionally – to harmful biological agents at work.
Biological agents are living organisms or products of living organisms. They include viruses, bacteria and fungi and their metabolites, as well as parasitic worms and plants. Many are present in the natural environment, but they also include micro-organisms which have been genetically modified as well as cell cultures. Biological agents 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 addition, some agents may have a carcinogenic effect after a chronic infection.

Objective

The Biological Agents Directive lays down minimum requirements for the protection of workers from risks related to exposure to biological agents at work. The objective of the Directive is thus to protect workers against risks to their health and safety and the prevention of such risks arising or likely to arise from exposure to biological agents at work.

Implementation

The analysis of the implementation of the Biological Agents Directive at Member State level shows that the Directive has been transposed in all Member States, and that the majority of Member States have transposed more detailed or stringent requirements than stipulated by the EU. Most of these additional requirements are related to health surveillance and the content and form of information to workers. The data also shows that the number of discrepancies between national provisions and the EU Directive is very limited.

Compliance

The evidence on level of compliance with the Directive is weak and fragmented. The data indicates that compliance is generally at a medium to high level with 50 – 90% of establishments being in compliance. Based on the data, it seems that the level of compliance relies to an extent on sectors rather than on size of establishment, with the sectors comprising intentional users or handlers of biological agents (laboratories, health care facilities, etc.) being most aware and thus most in compliance.

Based on the data, we have very limited information about how performance in work places has developed over time and thus it is also difficult to establish whether the medium-high levels of compliance are caused by the Directive or whether the same would have been the case without the Directive. Stakeholders who assess the importance of the Directive generally recognise that the Directive has played a role, but some NIRS also consider that national measures were in place before the adoption of the Directive.

Relevance

Exposure to biological agents can occur whenever people are in contact at work with natural or organic materials such as: soil, clay, plant materials (hay, straw, cotton, etc.), substances of animal origin (wool, hair, etc.), food, organic dust (e.g. flour, paper dust, animal dander), waste, wastewater, blood and other body fluids. They are therefore potentially encountered in a wide variety of occupational groups represented in all Member States and so the Directive remains relevant in all Member States.

Despite the shortcomings of the data, the cumulative evidence from ill-health associated with infection from biological agents, as demonstrated by the contents of this report, is that biological agents remain a significant potential cause of work-
related ill-health. However, it is apparent that the classified list of biological agents is out of date and should be updated to improve the relevance of the Directive. There is also evidence to suggest that the prescriptive approach to identifying correct measures in Annex V is not suitable and a more flexible approach scoping the measures in accordance with the results of the risk assessment would be more appropriate.

Effectiveness

The data does not allow for firm conclusions about the effect of the Biological Agents Directive on occupational safety and health. Workplace impacts are assessed as medium-high and there is good reason to believe that the Biological Agents Directive has also led to positive safety and health impacts. However, based on the available data it is not possible to quantify this impact.

The data indicates that implementation is strongest where biological agents are intentionally used, which points to a high degree of objective achievement in the sectors and work places, which handle biological agents as part of the work processes, e.g. health care sector, test laboratories, etc.

The Directive (art. 15 and 16 and associated annexes) provides specific measures for containment in respect to these types of work places (health and veterinary facilities, industrial processes, laboratories and animal rooms), whereas for other sectors, the Directive is much less specific about the measures to be applied. This in itself could potentially be part of the explanation why awareness and compliance is considered to be higher in these sectors. However, it is also likely that awareness and compliance in these sectors are higher precisely because these sectors comprise intentional users of biological agents or professionals (e.g. doctors, nurses, laboratory workers) who through their occupation and training are aware of the risks.

However, the Directive does not encompass all biological agents, and as such, it does not provide for an all-encompassing protection against risks associated with biological agents. The Directive makes provision for possible technical adjustment to the Annex containing the list of biological agents, however, no such adjustment has taken place since the Directive was adopted.

In addition, the Directive does not include limit values for exposure to various biological agents (and neither does it include methods for measuring biological agents), which gives rise to uncertainty about whether workers are sufficiently protected. This situation reflects that knowledge about biological agents and their effects on human health is still limited (when it comes to biological agents which are not infectious diseases).

Coherence with other OSH Directives

The analysis of coherence with other OSH Directives found some examples of requirements under other Directives in respect to risk assessment, information of workers and health records, which could also be relevant to include in the Biological Agents Directives. Similarly to all directives that regulate worker risks from specific agents, Directive 2000/54/EC (biological agents) contains a detailed risk assessment procedure. Despite the differences between chemical agents and biological agents (properties and hazards) and the differences on the risk control measures for these two distinct agents several requirements under Directive
98/24/EC (chemical agents) could also apply to the risk assessment of biological agents as they are not specifically tailored for chemical agents.

Several physical agent Directives contain an employer obligation to inform on how to detect health effects of exposure and how to report them. Since there are adverse health effects of exposure to biological agents, such information obligation could also apply for biological agents.

Among the Directives that set health record requirements, Directive 2000/54/EC (biological agents) does not explicitly require to keep them up to date as is the case under the chemical agents Directives. Neither does it specify that the health records must contain the summary of the results of health surveillance like other Directives. However, it mentions that health records must contain the medical and occupational history, which is considered quite similar and does not lead to inconsistencies.

The definition of biological agents under Directive 2000/54/EC includes microorganisms that have been genetically modified. However according to Article 1 of Directive 2000/54/EC (biological agents) must apply without prejudice to Directive 90/219/EEC on contained use of genetically modified micro-organisms. These Directives both set containment measures to avoid the dispersion of these biological agents in the environment. These measures are not entirely similar in their approach, content and scope. Overlaps and double regulation should however be avoided by the application of the without prejudice clause under Directive 2000/54/EC (biological agent).

There are overlaps between the Biological Agents Directive and Directive 2010/32/EU (sharps injuries) concerning obligations to offer vaccines to workers, however, these do not lead to double regulation in practise. Despite the close links with Directive 2000/54/EC (biological agents), the scope of Directive 2010/32/EU (sharps injuries) does not cover all the categories of workers that might be exposed to infection through sharp injuries (e.g. workers dealing with special/contaminated waste management treatments, cleaners, police or researchers in laboratories). The broadening of the scope to all workers exposed to sharp injuries could have a positive impact on limiting worker exposure to biological agents.

Recommendations

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 to the Directive should be taken out and instead form part of a guidance material, which elaborates more on the

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1 This Directive was repealed by Directive 2009/41/EC on the contained use of genetically modified micro-organisms.
measures to be decided based on the classification and risk assessment. This could entail a strengthening in the Directive’s provisions of the principle that the risk assessment should be used to establish the most appropriate measures safeguarding workers against the risks of exposure and that such measures should be appropriate in handling the risks.

› 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.

To enhance the coherence of the Biological Agents Directive with other Directives, it could be considered to:

› 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, to obtain additional information from suppliers, to take into account conclusions to be drawn from health surveillance, to include activities with foreseeable exposures in the risk assessment and include a justification by the employer that the nature and extent of the risks make a further detailed assessment unnecessary.

› 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.
1 Introduction

This report is a Directive-specific report, which forms part of the reporting of an overall evaluation of 24 Directives on Occupational Safety and Health (OSH) commissioned by DG Employment. The report concerns Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work, from now on referred to as the 'Biological Agents Directive'.

The evaluation of 24 OSH Directives was initiated in 2013 and finalised in June 2015. The evaluation produced cross-cutting findings on the implementation of the 24 Directives, which have been documented in the Main Report. Annexed to the Main Report are Directive-specific reports – such as this one – for each of the 24 Directives (Annex A) and reports on the implementation of the 24 Directives in the Member States (Annex B comprising 27 reports).

The objective was to evaluate the practical implementation of EU OSH Directives in EU Member States with a view to assessing their impact and identifying their strengths and weaknesses in order to suggest possible improvement to the regulatory framework. Two sets of questions, and subsequent evaluation criteria, were formulated to address and clarify the various impact of directives within the Member States.

The first set dealt with the implementation of the Directives within the Member States:

\[ \text{Implementation: MQ1-MQ7 are mapping questions which, apart from addressing the overall implementation of the Directives, look at specific implementation issues, such as derogations, transitional periods, compliance and enforcement:} \]

MQ1: Across the Member States, how are the different Common Processes and Mechanisms foreseen by the Directives put in place, and how do they operate and interact with each other?

MQ2: What derogations and transitional periods are applied or have been used under national law under several of the Directives concerned?

MQ3: What are the differences in approach to and degree of fulfilment of the
requirements of the EU OSH Directives in private undertakings and public-sector bodies, across different sectors of economic activity and across different sizes of companies, especially for SMEs, microenterprises and self-employed?

MQ4: What accompanying actions to OSH legislation have been undertaken by different actors (the Commission, the national authorities, social partners, EU-OSHA, Eurofound, etc.) to improve the level of protection of safety and health at work, and to what extent are they actually used by companies and establishments to pursue the objective of protecting safety and health of workers? Are there any information needs that are not met?

MQ5: What are the enforcement (including sanctions) and other related activities of the competent authorities at national level and how are the priorities set among the subjects covered by the Directives?

MQ6: What are the differences of approach across Member States and across establishments with regard to potentially vulnerable groups of workers depending on gender, age, disability, employment status, migration status, etc., and to what extent are their specificities resulting in particular from their greater unfamiliarity, lack of experience, absence of awareness of existing or potential dangers or their immaturity, addressed by the arrangements under question?

MQ7: What measures have been undertaken by the Member States to support SMEs and microenterprises (e.g. lighter regimes, exemptions, incentives, guidance, etc.)?

The second set addressed the three main evaluation criteria which were relevance, effectiveness and coherence (a total of 11 evaluation questions):

› **Relevance:** EQR1-EQR2 relates to the extent to which Directive provisions are relevant for current and future risks as well as the composition of industrial sectors:

- **EQR1:** To what extent do the Directives adequately address current occupational risk factors and protect the safety and health of workers?
- **EQR2:** Based on known trends (e.g. new and emerging risks and changes in the labour force and sectoral composition), how might the relevance of the Directives evolve in the future, and stay adapted to the workplaces of the future in light of the horizon of 2020? Does the need for EU level action persist?

› **Effectiveness:** EQE1-EQE7 explore whether or not the introduction of a Directive has led to changes to enterprise behaviour and the occupational safety and health of workers:

- **EQE1:** To what extent has the Directive influenced workers' safety and health, the activities of workers' representatives, and the behaviour of establishments?
- **EQE2:** What are the effects on the protection of workers' safety and health of the various derogations and transitional periods foreseen in several of the Directives concerned?
- **EQE3:** How and to what extent do the different Common Processes and Mechanisms that were mapped contribute to the effectiveness of the Directives?
- **EQE4:** To what extent do sanctions and other related enforcement activities contribute to the effectiveness of the Directives?
- **EQE5:** What benefits and costs arise for society and employers as a result of fulfilling the requirements of the Directives?
- **EQE6:** To what extent do the Directives generate broader impacts (including side
effects) in society and the economy?

**EQE7**: To what extent are the objectives achieving their aims and, if they are not, what cause could play a role? What factors have particularly contributed to the achievement of the objectives?

› **Coherence**: EQC1-EQC2 address the extent to which objectives and actions from a given OSH Directive interact, or overlap, with other OSH Directives and/or with other EU policies:

**EQC1**: What, if any, inconsistencies, overlaps, or synergies can be identified across and between the Directives (for example, any positive interactions improving health and safety outcomes, or negative impact on the burdens of regulation)?

**EQC2**: How is the interrelation of the Directives with other measures and/or policies at European level also covering aspects related to health and safety at work, such as EU legislation in other policy areas (e.g. legislation: REACH, Cosmetics Directive, Machinery Directive, policy: Road Transport Safety, Public Health, Environment Protection), European Social Partners Agreements or ILO Conventions?

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**Methodology and sources of information**

The overall methodology used for the evaluation, and thus also for the analysis presented in this report, is described in detail in Chapter 2 of the Main Report. The Directive-specific report findings are based on the analysis of the OSH legislation in each of the Member States, official statistics at national and EU level, National Implementation Reports (NIRs) submitted to the Commission by each of the Member States before the end of 2013 (in accordance with Article 17a of Directive 89/291/EEC), as well as selected scientific articles, studies and interviews with both national and EU stakeholders.

**Report structure**

The report is structured according to the themes and issues listed above.

› Chapter 2 presents the overall understanding of the Directive, i.e. its rationale, provisions and intervention logic. It also describes issues relating to measuring impacts resulting from the Directive.

› Chapter 3 provides the relevant findings with regard to the implementation of the Directive in the Member States (addressing questions MQ1-MQ7).

› Chapter 4 provides the relevant findings with regard to the relevance of the Directive (addressing questions EQR1-EQR2).

› Chapter 5 provides the relevant findings with regard to the effectiveness of the Directive (addressing questions EQE1-EQE7).

› Chapter 6 provides the relevant findings with regard to the coherence of the Directive (addressing questions EQC1-EQC2).

› Chapter 7 describes the main conclusions emanating from the findings presented in Chapters 3-6.
2 The Directive

This chapter describes the background of the Directive and outlines its rationale; including the risks that the Directive aims to address, the expected effects, and the intervention logic for the Directive.

2.1 Background and objective

The Biological Agents Directive was adopted on 18 September 2000 as the Seventh individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC (Framework Directive). The Directive has not been amended since then.

EU action in the area of safety and health of workers and protection from risks associated with biological agents was initiated already in the 1970s. The first action programme of the European Communities on Safety and Health at Work (1978) provided for the harmonisation of provisions and measures regarding the protection of workers with respect to chemical, physical and biological agents. This was followed by the adoption, in 1980, of the Directive on the protection of workers from the risks associated with exposure to chemical, physical and biological agents at work. The rationale behind this Directive was that certain differences in measures taken by various Member States had been found and it was considered relevant to approximate and improve the measures in order to ensure the functioning of the common market. The 1980 Directive made provision for the Council to lay down limit values and other specific requirements for certain agents in individual (additional) Directives.

The Council resolution on the second action programme of the European Communities on Safety and Health at Work (1984) provided for the development of protective measures for workers exposed to dangerous agents. On this basis, and taking into account the Framework Directive (89/391/EEC) adopted in 1989, the

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2 OJ No C 165, 11.7.1978, p.1
3 COUNCIL DIRECTIVE of 27 November 1980 on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work (80/1107/EEC)
4 Directive 80/1107 was adopted on the basis of the common market provisions (harmonisation) before the introduction of the Social Policy title in the Treaty establishing the European Community by the Single European Act (1986). Directive 89/391/EEC was adopted on the basis of the Social Policy.
first version of the Biological Agents Directive (90/679/EEC) was adopted in 1990 as the seventh individual Directive within the meaning of Article 16(1) of the Framework Directive. This was followed by successive amendments (93/88/EEC, 95/30/EC, 97/59/EC, 97/65/EC), which largely focused on specifying the classification and list of biological agents contained in Annex III to the Directive.

In 2000, it was found relevant to codify the Directive for the sake of clarity and rationality. This was done with the adoption of the present Directive, which thus repealed and replaced the previous Directives.

### Objective

The Directive lays down minimum requirements for the protection of workers from risks related to exposure to biological agents at work. The objective of the Directive is thus to protect workers against risks to their health and safety and the prevention of such risks arising or likely to arise from exposure to biological agents at work. Apart from the obvious intention to protect workers from the adverse effects resulting from exposure to biological agents, the Directive also focuses on keeping records of cases of exposure and resulting cases of diseases or deaths, and in this way obtaining more precise knowledge of the risks involved.

### 2.2 Risks

Biological agents are living organisms or products of living organisms. They include viruses, bacteria and fungi and their metabolites, as well as parasitic worms and plants. Many are present in the natural environment, but they also include microorganisms which have been genetically modified as well as cell cultures. They vary in their level of harmfulness at exposure. Some biological agents are harmless or even beneficial while others may be dangerous at encounter. Biological agents may be used deliberately but most of the time workers are exposed to them unintentionally. Risks of exposure to biological agents are prevalent where workers are in contact with:

- Natural or organic materials like soil, clay, plant materials (hay, straw, cotton, etc.);
- Substances of animal origin (wool, hair, etc.);
- Food;
- Organic dust (e.g. flour, paper dust, animal dander);
- Waste, wastewater;
- Blood and other body fluids.

Hence, a sizeable portion of the working population faces the risk of exposure to biological agents. However, risk assessment for biological agents is challenging due to several factors:

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5 Preamble, recital 4
6 Sources used in this section: EU-OSHA E-Facts 53, EU-OSHA Facts 41.
7 The biological agents defined in the Directive are not harmless. The Directive focuses on the agents which ‘may be able to provoke any infection, allergy or toxicity’ (art. 2).
Biological agents are usually invisible, and it is therefore often difficult to comprehend the risks they present.

There is great diversity between the different agents. Exposure limits have not been set. Even if no agents are detected, micro-organisms may provoke toxic or allergic effects via their metabolites (mycotoxins or their component endotoxins).

In addition, biological agents have the ability to reproduce rapidly, require minimal resources to survive and can infect at very small doses. Moreover, some can be passed from one person to another.

Biological agents 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 addition, some agents may have a carcinogenic effect after a chronic infection.

### Table 2-1  Health and safety risks in relation to biological agents

<table>
<thead>
<tr>
<th>Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acute risks</strong></td>
</tr>
<tr>
<td>Infection or contact causing an allergic or toxic reaction or infectious disease due to:</td>
</tr>
<tr>
<td>‣ Inhalation – e.g. breathing in aerosols or vapour containing dangerous biological substances</td>
</tr>
<tr>
<td>‣ Ingestion – e.g. through poor hygiene or eating/drinking in a work area containing dangerous biological substances</td>
</tr>
<tr>
<td>‣ Skin penetration – e.g. due to an injury by a contaminated sharp object or entry via an uncovered wound.</td>
</tr>
<tr>
<td><strong>Long term risks</strong></td>
</tr>
<tr>
<td>‣ Longer term effects of having suffered or continued suffering from an infectious disease</td>
</tr>
<tr>
<td>‣ Chronic illness, e.g. asthma, arthritis</td>
</tr>
<tr>
<td>‣ Cancer</td>
</tr>
</tbody>
</table>

### 2.3 Key provisions

Table 2-2 lists the Key Requirements (KR) of the Biological Agents Directive, which firstly emphasises that it applies to:

"… activities in which workers are or are potentially exposed to biological agents as a result of their work."  

Article 3 of the Directive thus provides that the Biological Agents Directive is applicable to any activity that exposes or potentially exposes workers to biological agents as a result of their work. The Directive applies both when workers are exposed to biological agents deliberately and when they are exposed unintentionally.

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8 2000/54/EC, Article 3(1)
Hence, the Directive applies to all sectors where workers are exposed, however, specific measures for health and veterinary care facilities and industries involving industrial processes, laboratories and animal rooms are given specific mention.9

Article 2 of the Directive defines biological agents as:

“micro-organisms, including those which have been genetically modified, cell cultures and human endoparasites, which may be able to provoke any infection, allergy or toxicity.”

The Directive classifies biological agents into four infection risk groups on the basis of the following criteria:

**Group 1** biological agent means one that is unlikely to cause human disease.

**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.

**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.

**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.

A list of biological agents belonging to groups 2-4 is included in Annex III to the Directive. The Directive provides for technical adjustments to the Annex in the light of technical progress, changes in international regulations or specifications and new findings in the field of biological agents following the procedure laid down in the Framework Directive (art. 17). Such adjustment has not taken place since the adoption of the Directive and the list thus reflects the state of knowledge at the time the Directive was drawn up.

Table 2-2 lists the provisions of the Biological Agents Directive that have been identified as the ones that in particular need to be addressed when assessing the impacts of the Directive. The assessment focuses on the so-called Common Processes and Mechanisms (CPMs)10 and Other Key Requirements (KRs)11.

Table 2-2 shows that the Biological Agents Directive puts emphasis on all six CPMs that were introduced by and specified within the Framework Directive:

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9 Articles 15 and 16 of the Directive.

10 These processes and mechanisms are selected because they derive from the Framework Directive 89/391/EEC and are included in all or several individual directives.

11 The provisions in this category are selected on the basis of the Directive's background and rationale. Hence, they include Directive-specific provisions, which can be seen as fundamental to the intended outcome of that Directive.
Conducting a risk assessment: The Directive (art. 3 (2)) specifies that the risk assessment related to any activity likely to involve a risk of exposure to biological agents shall determine the nature, degree and duration of workers’ exposure and assess any risk to workers’ health and safety. It is also emphasised that in case activities involve several groups of biological agents, the combined risks of the presence of these agents shall be assessed. Following art. 3 (3) the risk assessment shall be conducted on the basis of all available information including the classification of biological agents as referred in Article 18.

Preventive and protective services: The Directive (art. 13 (4)) provides that the notification to competent authorities referred to in Article 13 must include (b) the name and capabilities of the person responsible for safety and health at work. A similar requirement is included in Article 7 (1) (d). Other provisions of the directive also refer to the person responsible for health and safety.

Information of workers: The Directive contains specific requirements concerning the information of workers and this is closely linked to the training requirements (see point below). There is also a specific requirement that employers must immediately inform workers (and/or their representatives) of any accident or incident, which may have resulted in the release of a biological agent and which could cause severe human infection and/or illness.

Training of workers: The Directive provides that information and instructions must be given to workers to facilitate their training on a) potential risks to health, b) precautions to be taken to prevent exposure, c) hygiene requirements, d) wearing of protective equipment and clothing and e) steps to be taken by workers in the case of incidents and to prevent incidents. The Directive also provides that training shall be given at the beginning of work, and shall be adapted and repeated periodically if necessary.

Health surveillance: The Directive includes provisions on the obligation of employers to make available, when necessary, effective vaccines for those workers who are not already immune to the biological agent to which they are exposed; as well as the obligation of the authorities involved in health surveillance to propose any protective or preventive measures to be taken in respect to the individual worker and the requirement to provide information to workers regarding HS that they may undergo.

Consultation of workers: The Directive does not provide more detailed requirements regarding consultation of workers, but refers to the relevant article in the Framework Directive (art. 11).

In addition, the Directive provides for a number of other KRs, which are listed and explained in Table 2-2. Most importantly, the Directive builds on a hierarchy of measures whereby the first priority is to avoid the use of biological agents altogether, the second is to substitute dangerous substances with less dangerous ones, and, thirdly, if this is not possible, to introduce measures that reduce the exposure to biological agents.
Unlike other OSH Directives, the Biological Agents Directive does not include specific exposure limits for the classified biological agents. This is because there was still limited knowledge about the agents and their effects at the time of drafting the Directive (and this knowledge is still under development), but also because different persons react to different agents in different ways.

### Table 2-2 CPMs and KRs (Biological Agents Directive)

| Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work (biological agents) |
|---|---|---|---|---|---|---|
| **Key requirements: Scoping and definitions** | **Scope of application** | Arts. 1, 2 and 3 (1) | The Directive applies to activities in which workers are or are potentially exposed to biological agents as a result of their work. Biological agents are defined as microorganisms, including those which have been genetically modified, cell cultures and human endoparasites which may be able to provoke any infection, allergy or toxicity. Biological agents are classified in four risk groups. |
| **Key requirements: Common processes and mechanisms** | **CPM** | Conducting a risk assessment | Preventive and protective services | Information of workers | Training of workers | Health surveillance | Consultation of workers |
| **Relevant Articles** | 3 (2) (3), 7(1)<sup>12</sup> | 13 (4) | 9, 10 | 9 | 14 | 12 |
| **Key requirements: Directive-specific provisions** | **Substitution** | Art. 5 | The Directive requires that the use of a harmful biological agent is avoided if the nature of the activity permits it. The harmful agent should be replaced by an agent which is not dangerous or is less dangerous to workers' health. |
| **Measures to avoid and reduce exposure** | Art. 6 | The Directive requires the exposure of the workers to harmful biological agents to be prevented and, when this is not possible, the introduction of measures to reduce the level of exposure as low as necessary in order to protect adequately the health and safety of the workers concerned. |
| **Information for the competent authority** | Art. 7(1) | Where the results of the risk assessment reveal risk to workers' health or safety, employers shall upon request make available to the competent authority information specified in Art. 7(1). |
| **Information for the competent authority (accidents and incidents)** | Art. 7(2) | Employers shall inform the competent authority of any accident or incident which may have resulted in the release of a biological agent, which could cause severe human infection and/or illness. |
| **Information to competent authorities** | Art. 7(3) | The list of exposed workers along with the medical record shall be made available to the competent authority in cases where the undertaking ceases to exist. |
| **List of exposed workers** | Art. 11 | Employers shall keep a list of workers exposed to the biological agents in groups 3 and 4, keep such a list for a prescribed period of time and make this available to the competent authorities for health and safety at work. |

<sup>12</sup> This provision concerns the information the employer is required to communicate to the competent authority, including on the results of the risk assessment.
<table>
<thead>
<tr>
<th><strong>Prior notification to competent authorities</strong></th>
<th><strong>Art. 13</strong></th>
<th>The first time use of groups 2-4 of biological agents must be notified to the competent authorities at least 30 days before the commencement of the work.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Measures in health and veterinary care facilities</strong></td>
<td><strong>Art. 15 (2)</strong></td>
<td>Appropriate measures shall be taken in health and veterinary care facilities, including specifying appropriate decontamination and disinfection procedures and implementing procedure regarding waste handling and disposal.</td>
</tr>
<tr>
<td><strong>Special measures for industrial processes, laboratories and animal rooms</strong></td>
<td><strong>Art. 16</strong></td>
<td>The Directive lays down a set of measures to ensure appropriate containment and thus minimisation of the risk of infection to be taken in laboratories and in rooms for laboratory animals which have been deliberately infected with group 2, 3 or 4 biological agents or which are or are suspected to be carriers of such agents.</td>
</tr>
<tr>
<td><strong>Classification of biological agents in groups 1-4</strong></td>
<td></td>
<td>The Directive provides an overview of the biological agents classified in risk groups 1-4. These define the requirements for the application of the provisions of the Directive.</td>
</tr>
</tbody>
</table>

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### 2.4 Intervention logic

**Impact logic**

Figure 2-1 illustrates the logical steps of the Biological Agents Directive represented by its KRs – leads to impact, i.e.:

- **CPMs and other KRs** are as discussed above the provisions of the Directive that during the analysis have been identified as the ones that in particular need to be addressed when assessing impacts. The figure illustrates that, because of the multifaceted nature of the Directive, it is not possible to identify how each of the KRs in itself will have an impact. In other words, the KRs work in tandem to produce impacts and, consequently, are analysed as such.

- **Workplace impacts** constitute the direct changes/improvements that occur at the workplace as a result of implementing the KRs. For instance, better safety and health surveillance, organisational changes, higher awareness among workers about potential safety and health issues, etc. These changes come at a cost to the workplace, but are also the drivers by which the safety and health impacts occur.

- **Safety and health impacts** constitute the actual elimination and/or reduction in safety and health risks arising from exposure to biological agents. These impacts occur as a result of the Directive (KRs) through the above-mentioned workplace impacts.

- **Broader impacts** constitute the impacts that may occur more broadly speaking as a result of the above mentioned safety and health impacts.

**Impact storyline**

Figure 2-1 shows that the Biological Agents Directive is expected to lead to increased assessment of the risks of exposure to biological agents. The increased knowledge arising from this assessment should then lead employers to adopt various measures to reduce the risk of exposure, in particular as regards biological agents in groups 2-4. First and foremost, it is expected that the use of biological
agents is avoided where possible and, where this is not possible, substituted with other less dangerous biological agents. Where it is not possible to avoid or substitute the biological agents, the employers should ensure that the risk of exposure of workers is reduced through a series of preventive and protective measures, including organising the work processes in an appropriate way, making available equipment and personal protection devices (and vaccines where appropriate), which ensure the protection of the individual workers. Workers should be informed about the risks involved and trained in the work processes and use of equipment. This should lead to safe handling of biological agents and appropriate behaviour in circumstances where there is a risk of exposure, which again should reduce (eliminate) the incidence of exposure.

The Directive also requires employers to keep records of cases of exposure and the associated medical records. This should lead to increased knowledge about biological agents and the associated work related health effects. This can then provide input to better risk assessments as well as design of appropriate measures – and consequently, reduced levels of exposure.

Ultimately, reduced levels of exposure should lead to decreases in the incidence of work-related infections and illnesses stemming from exposure to biological agents.

For types of activities, where there is a special risk, e.g. health care, laboratories and animal rooms, special measures should be adopted regarding decontamination, disinfection, waste handling and containment. This should lead to safe handling of the biological agents at the work place and thus protection of the workers involved, but it should also reduce the risk of dangerous biological agents being released and causing a risk to the population at large.
EVALUATION OF THE PRAXICAL IMPLEMENTATION OF THE EU OCCUPATIONAL SAFETY AND HEALTH (OSH) DIRECTIVES IN EU MEMBER STATES

Figure 2.1 Intervention logic

Key requirements

<table>
<thead>
<tr>
<th>CPMs</th>
<th>Workplace impacts</th>
<th>Safety and health impacts</th>
<th>Broader impacts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducting a risk assessment</td>
<td>Workplace impacts are measurable changes that occur at the workplace as a result of the Directive.</td>
<td>Safety and health impacts are measurable changes that result from the Directive through workplace changes.</td>
<td>Assessed at acquis level</td>
</tr>
<tr>
<td>• [5 and 7]: nature, degree and duration of exposure to be assessed on the basis of all available information and reviewed regularly and when changes occur.</td>
<td>• Share of workplaces conducting risk assessments including assessment of exposure to biological agents.</td>
<td>• Reduced incidence of work-related infections.</td>
<td>Broader impacts are assessed across all Directives and include:</td>
</tr>
<tr>
<td>• [1 - 3]: person responsible for safety and health information of workers.</td>
<td>• Workers’ self-assessed level of information and training.</td>
<td>• Reduced incidence of work-related illnesses caused by infections or other contact with biological agents (number of persons contracting illness - sick days).</td>
<td>• Employment growth.</td>
</tr>
<tr>
<td>• [9 and 10]: information necessary to meet training requirements and information on actions in case of accidents/incidents.</td>
<td>• Health surveys focusing on biological agent exposure.</td>
<td>• Reduced number of work-related deaths caused by illnesses.</td>
<td>• Economic growth.</td>
</tr>
<tr>
<td>• [11]: training: a) potential risks to health, b) precautions to be taken to prevent exposure, c) hygiene requirements, d) wearing of protective equipment and clothing and steps to be taken by workers in case of incidents and to prevent incidents.</td>
<td>• Higher degree of awareness and implementation of preventive and protective measures among workers.</td>
<td>•</td>
<td>• Increased productivity.</td>
</tr>
<tr>
<td>• [14]: Make vaccines available, propose protective and preventive measures for the individual worker.</td>
<td>• Decrease in the use of biological agents in a classification 2-4 (decrease in notifications of first use).</td>
<td>•</td>
<td>• Improved quality of products and services.</td>
</tr>
<tr>
<td>Consultation of workers</td>
<td>• Introduction of new equipment which offers better protection against exposure.</td>
<td>•</td>
<td>• Improved well-being and job satisfaction.</td>
</tr>
</tbody>
</table>

Other KR:

Substitution

• [5]: replace dangerous biological agents with non or less dangerous ones.

Avoid and reduce exposure

• [6]: measures to avoid and, if not possible, to reduce exposure.

Information for competent authority

• [7]: make all available information on risk assessment/ exposure, accidents/ incidents, medical records.

Keep list of exposed workers

• [8]: list of workers exposed to BAs, group 3 and 4. Prior notification to competent authorities.

• [10]: notify before first use of groups 2-4 BAs.

Measures in health and veterinary care facilities

• [11]: procedures for decontamination/disinfection and waste handling and disposal.

Special measures for industrial processes, laboratories and animal rooms

• [12]: containment according to levels specified in Annex V.
2.5 Measuring impacts

In continuation of the above impact storyline, the assessment of whether the initial impact hypotheses prove to be correct takes place via analysing impacts at three levels; namely (i) workplace impacts; (ii) safety and health impacts; and (iii) broader impacts. There are two important considerations in regard to the above:

1. While workplace impacts do not necessarily say anything about specific improvements concerning occupational accidents, work-related diseases or levels of exposure to risks, they provide important indications about these; i.e. relating to the fact that the safety and health impacts from the Directive stem from the associated changes at the workplace.

2. As indicated in the intervention logic, the broader effects of the Directive are assessed at the acquis level, and for the Framework Directive (see Main Report). It is thus not addressed specifically for the Biological Agents Directive and therefore not reflected in this report.

Table 2-3 lists indicators for workplace as well as safety and health impacts that ideally should be considered in the evaluation of the Directive. Measuring the precise impacts of the Directive on this basis requires that the indicators used for the analysis are quantifiable via available statistics – and this is not always possible.

<table>
<thead>
<tr>
<th>Impact indicators</th>
<th>Workplace Impacts</th>
<th>Safety and health impacts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Share of workplaces where there is a risk of exposure to biological agents conducting a risk assessment (with emphasis on biological agents)</td>
<td>Reduction in the incidence of work-related infections arising from work involving biological agents</td>
<td></td>
</tr>
<tr>
<td>Share of workplaces with a risk of biological agents which conduct health surveillance and use it as an instrument in assessing risks and planning measures</td>
<td>Reduction in the incidence of occupational diseases occurring as result of exposure to biological agents at work [indicated by the number of workers suffering from cancer, respiratory diseases, diseases of the sensory organs, skin diseases and infections]</td>
<td></td>
</tr>
<tr>
<td>Share of workplaces where employers provide clear information/instructions/training</td>
<td>Reduction in work-related deaths caused by diseases occurring as a result of occupational exposure to biological agents</td>
<td></td>
</tr>
<tr>
<td>Share of establishments providing for consultation/participation of workers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Degree of use of personal protective equipment (PPE) by workers who are required to use it</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Share of workplaces which introduce appropriate preventive and protective measures in accordance with the Directive</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Share of workplaces which have prevented or reduced the use of biological agents$^{13}$</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

$^{13}$ This may be different from the share of workplaces which introduce measures, as the introduction of measures may not – in itself – lead to prevention/reduction.
It should be noted that the fact that an indicator is potentially quantifiable does not necessarily mean that data exists which can fully inform the indicator. Hence, Table 2-3 should be seen as a list of indicators for which potential data sources could exist. Table 2-4 provides an overview of identified statistical data variables and sources that are used in this report to provide useful quantified information on the above indicators in the evaluation of the Directive.

We also seek to shed light on indicators for which quantitative data for the EU-27 does not exist through using available quantitative data for some Member States combined with qualitative data (mainly stakeholder perceptions and relevant reports and academic studies), but this evidence is not as strong as quantified EU-27 statistical information on the indicators.

Table 2-4: Available data

<table>
<thead>
<tr>
<th>Workplace Impacts</th>
<th>Variable</th>
<th>Data source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information of workers</td>
<td>Share of workers who report that they are very well informed, well informed, not well informed, not at all well informed about health and safety risks relating to performance of their job.</td>
<td>Eurofound: EWCS (2010), Q30**</td>
</tr>
<tr>
<td>Personal Protective Equipment (PPE)</td>
<td>Share of workers who report that they are required to wear PPE and who actually use it when required to.</td>
<td>Eurofound: EWCS (2010), Q28/29**</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Safety and health impacts</th>
<th>Variable</th>
<th>Data source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure to biological agents</td>
<td>Share of workers who report that they are exposed at work to handling or being in direct contact with materials which can be infectious.</td>
<td>Eurofound: EWCS (2010), Q23, b**</td>
</tr>
<tr>
<td>Health affected by biological agents</td>
<td>Share of workers who report that their work affects their health: 1) Mainly positively, 2) mainly negatively, 3) no effect on health</td>
<td>Eurofound: EWCS (2010), Q67**</td>
</tr>
<tr>
<td></td>
<td>Share of workers who report that their work affects their health and the health effect is skin problems, headaches, respiratory difficulties, injuries.</td>
<td>Eurofound: EWCS (2010), Q69**</td>
</tr>
<tr>
<td></td>
<td>Share of workers who report that they consider their health to be at risk due to their work.</td>
<td>Eurofound: EWCS (2010), Q66**</td>
</tr>
<tr>
<td></td>
<td>Share of workers who report that they have had an illness caused by or made worse by work, infectious disease (virus, bacteria).</td>
<td>Eurostat Search Database: LFS 2007 ad hoc module - hsw_pb (483) LFS 1999 ad hoc module - hsw_healthpb</td>
</tr>
<tr>
<td>Absence from work due to health problems</td>
<td>Share of workers who report that they have been absent from work for specified periods of time</td>
<td>Eurofound: EWCS (2010), Q72**</td>
</tr>
</tbody>
</table>

14 See the list of references enclosed in Appendix A.
** And similar questions in previous EWCS when available (all workplace indicator data cross-tabulated with Q23 (i), so that only responses from those who indicated that they are exposed to infectious materials ¼ of the time to all of the time are included)

** Data challenges

Data to inform us about the extent to which workplace impacts and health and safety impacts have been achieved is very limited. The data itself is reported in Chapter 5. Below, some of the main constraints are highlighted.

In relation to workplace impacts, the evaluation assessed that it was not relevant to use ESENER data as it would not be possible to extract data which would give a sufficiently precise picture of the situation in establishments where there is a risk of exposure to biological agents. It is not possible to drill down to a relevant NACE sector level in the data set. It is not possible to do a meaningful cross-tabulation within the ESENER data set either, as this would only enable us to identify establishments where ‘dangerous substances’ in general is a concern (ref. ESENER questions M200/ER250).

As shown in the table above, EWCS data can provide some insight into compliance with certain requirements. However, the only meaningful way to extract data is to focus on respondents who indicate that they are exposed to infectious materials. This is a problem, firstly because biological agents comprise much more than infectious materials, and secondly, because we do not know whether the responses provided refer to that exposure or some other factor in the respondent’s work environment.

Concerning accidents, the ESAW data set from Eurostat contains information on number of accidents by type of injury, which enables an overview of the accidents involving poisonings and infections. The ESAW data provides the number of accidents at work and is not incidence based, i.e. does not take the size of the workforce into account.

There is an issue with definitions of accidents and diseases in relation to this Directive, which has also been mentioned in some national implementation reports. It is not clear whether an infection is regarded as an accident or a disease – or both. This can potentially lead to both under and over reporting and confusion about data.

Considering occupational diseases resulting from exposure to biological agents is a complex exercise for several reasons:

› Exposure to biological agents can give rise to many different health effects, many of which can also be related to other factors than exposure to biological agents.
Infectious diseases, which occur due to biological agents, do not follow a stable pattern but can be related to outbreaks and epidemics, which means it does not render itself to time-series based analysis of incidence data.

Furthermore, EU-level data is extremely scarce. While national data exists for some countries, it is not directly comparable as the rules of recognition and reporting of occupational diseases vary between the Member States.

The European Centre for Disease Control and Prevention (ECDC) has a database (CISID) which holds data on infectious diseases in the countries in the European Region collected through standardised reporting forms. Indicators include the number of cases in each country and the incidence per 100,000 population. The annual epidemiological reports from the ECDC provide information on a number of cases for a number of diseases. However, these statistics do not record whether the cases are work-related or not and therefore cannot be used in this context. That being said, the incidence of infectious diseases in general does give an indication of the level of risk of exposure that workers in the health care sector are exposed to.

The EODS data set from Eurostat contains some standardised information from the years 2001-2005 relating to some of the diseases, which can be seen as directly related to the Biological Agents Directive. However, the data set is not officially available and the data is associated with considerable uncertainties.

Interview data can only to a very limited extent be used to make up for the lack of availability of statistical information. Firstly, because of its qualitative nature, but also because relatively few interviewees have provided detailed comments on the implementation of the specific Directive. The interview data and the associated methodological challenges and choices are discussed in the Main Report.

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Which are also reported in EU-OSHA: Working Paper: Biological Agents and Pandemics: review of the literature and national policies, 2009
3 Implementation in the Member States

As part of the evaluation, a mapping exercise of the implementation of the 24 Directives in the Member States has been conducted. This has been done via seven mapping questions (MQs). This chapter provides a summary of the findings of the mapping exercise relevant for the Biological Agents Directive. The main basis for the findings presented below is the information collected from 27 Member States, including the NIRs, and documented in the evaluation’s Country Summary Reports (CSRs). In addition, EU level information sources have been used where relevant.

The chapter is structured in accordance with the seven mapping questions. For the purpose of presenting information across Member States, country codes are used in the tables in this chapter.

3.1 MQ1: Transposition

MQ1. Across the Member States, how are the different Common Processes and Mechanisms foreseen by the Directives put in place, and how do they operate and interact with each other?

The first mapping question focuses on the six CPMs (ref. section 2.3 above), i.e. the requirements to conduct a risk assessment, to ensure internal and/or external preventive and protective services, to inform workers, to train workers, to carry out health surveillance, and to consult workers. We look into how the CPMs have been transposed in the Member States, and whether there have been any infringement proceedings or inconsistencies in relation to transposition. We also consider the extent to which the Member States have implemented more detailed or stringent requirements than those directly specified in the Directive.

16 Eurostat country codes: Austria (AT), Belgium (BE), Bulgaria (BG), Czech Republic (CZ), Denmark (DK), Germany (DE), Estonia (EE), Ireland (IE), Greece (EL), Spain (ES), France (FR), Italy (IT), Cyprus (CY), Latvia (LV), Lithuania (LT), Luxembourg (LU), Hungary (HU), Malta (MT), the Netherlands (NL), Poland (PL), Portugal (PT), Romania (RO), Slovenia (SI), Slovakia (SK), Finland (FI), Sweden (SE), the United Kingdom (UK)
According to the information gathered from the Member States, all Member States have transposed the Directive. Based on the lists of infringement proceedings provided by the Commission, it can be concluded that several infringement proceedings were launched for non-communication of national measures for the transposition of Directive 90/679/EEC and the amending Directives (Directive 93/88/EEC, Directive 95/30/EC, Directive 97/59/EC and Directive 97/65/EC). All these cases were closed further to the transmission of the national implementing measures. No infringement proceedings were launched for incorrect transposition or application of the Biological Agents Directive.

As part of the analysis of the national implementation, the evaluation has looked for observed discrepancies between the Directive’s requirements and the transposing legislation. This covers instances where the text of the national transposing legislation is different from the transposed Directive’s provisions. This difference could lead to the non-application or partial application of the relevant CPM due to contradiction between the national provision and the corresponding one in the Directive.

Some observed discrepancies have been identified in terms of information for workers in the Netherlands.

- First of all, written instructions and, if appropriate, display notices should be available at the workplace and should at least set out the procedures to be followed whilst working. This includes regulations for safely handling and transporting biological agents within the business or establishment, as well as an effective contingency plan in case of accidents or incidents involving biological agents. No explicit mention is made of handling a group 4 biological agent.
- Secondly, no explicit obligation exists to provide workers, at their request, with the information for Competent Authorities.
- Finally, information about accidents, serious accidents and anonymous collective information is not available to workers, only to the Works Council or

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the staff representation body or, in the absence thereof, the interested workers.

The comparison of the Directive key requirements with the transposing national legislation indicates that the majority (25 of 27) of the Member States have implemented more detailed or stringent requirements than those specified in the Directive. The most prevalent national requirements (where the national legislation in nine or more Member States comprises such requirements) include:

- The content or form of information to workers is further specified in national legislation (9 Member States).
- The national legislation sets more stringent requirements on health surveillance (e.g. individual medical records must be kept more than 10 years) (9 Member States).
- The arrangements for health surveillance records are specified in the legislation (11 Member States).
- The periodicity of health surveillance is provided in national law (13 Member States).22

3.2 MQ2: Derogations and transitional periods

MQ2: What derogations and transitional periods are applied or have been used under national law under several of the Directives concerned?

In the case of the Biological Agents Directive, no derogations or transitional periods have applied.

3.3 MQ3: Compliance

MQ3: What are the differences in approach to and degree of fulfilment of the requirements of the EU OSH Directives in private undertakings and public-sector bodies, across different sectors of economic activity and across different sizes of companies, especially for SMEs, microenterprises and self-employed?

Data from EWCS can provide an indication of levels of compliance with some requirements of the Directive. The data provided below are based on responses from those respondents who have indicated that they are exposed at work to handling or being in direct contact with materials which can be infectious. It thus gives an indication of compliance, but it is not known whether the basis for responses is the exposure/handling of biological agents or other factors.

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22 The Directive requires ‘regular intervals’ – the Member States providing the periodicity have stated in their national legislation what the required interval is.
Regarding wearing of personal and protective equipment (PPE), the EWCS data shows that 90% of the selected respondents indicate that they wear PPE when it is required (data only for 2010, ref EWCS survey Q28 and 29).

With respect to provision of information, the EWCS data shows that the share of selected respondents who considered themselves very well informed or well informed about the health and safety risks related to the performance of their job was 85% in 2005 and 88% in 2010.

All in all, the EWCS data indicates that the level of compliance is in the 80-90% range, however, this is limited to a few requirements and the data is uncertain as described in section 2.5.

Data from NIRs

In the National Implementation Reports, the Member States have provided more qualitative assessments of implementation of the Directive. The manner in which the Member States have responded to questions in the NIRs differs considerably making it difficult to extract a consistent assessment of compliance. Member States were not asked directly to provide data on compliance in the NIRs, except for the question ‘Do SMEs have particular difficulties in following the requirements of the Directive?’. Some Member States have, nevertheless, provided some information, which gives an impression of the degree to which requirements are complied with in general. Out of 27 NIRs, 11 provided an indication. Out of these 11, 7 reports highlighted various general implementation difficulties or inspection data, which indicate problematic compliance. However, this data is not necessarily indicative of the general situation, as it is not known what the 16 Member States, who did not touch upon this subject, would have answered if questioned directly on compliance.

In respect to the question on whether SMEs face particular difficulties in implementing the Directive, 25 Member States provided an answer to this question. 11 Member States answered that this was not the case, 5 Member States considered ‘yes’ and the remaining 9 Member States did not provide a conclusive answer.

Some Member States providing more elaborate answers highlight various shortcomings and difficulties in implementation. The shortcoming most often mentioned relates to inadequate knowledge of biological risks and several Member States emphasise that while laboratories and health care facilities have a general good awareness and management of the risks, the situation is different in other sectors, such as agriculture, fisheries, forestry and waste management. It is mentioned by several stakeholders that sectors with intentional users of biological agents are more compliant than the unintentional users (but it is not specified which sectors or activities are considered to belong to each of these groups).

Another issue raised in several NIRs relates to lack of recognised methods for measuring biological agents and lack of standard limit values establishing when occupational exposure to certain agents become a risk to human health. This also means that it is difficult to perform a risk assessment.
A view offered by several Member States is that while awareness might be relatively high, there is still a tendency for measures employed to be insufficient and to focus on protective measures rather than preventive measures. On the other hand, it is also emphasised that the Directive has contributed to a clearer picture of the relevant risks, exposures, sectors and types of work processes in respect to biological agents.

Other national data

As part of preparing the CSRs, data on compliance was gathered from national sources. It was only possible to gather data in seven Member States: Belgium, Lithuania, the Netherlands, Poland, Romania, Slovakia and Spain. The data from these countries indicates that, generally, the compliance with the CPM requirements in the Directive seems to be at a medium level, however, this is based on information from a limited number of Member States. Also, there is considerable variance in levels of compliance for individual Member States and individual requirements.

Data from interviews at Member State level is also very scarce as few interviewees have commented directly on the Biological Agents Directive – most have referred to the Framework Directive and explained that the situation is considered the same or have indicated that it is not possible to provide a detailed assessment. Based on responses from four Member States, the impression is that the Directive has had an impact on the behaviour of establishments, but mostly so when it comes to large establishments. However, the data basis is very small.

EU stakeholders

Data from interviews with employers’ and workers’ organisations at EU level is relatively limited as few of the organisations interviewed had opinions on the Biological Agents Directive. When assessing the level of compliance with the Directive’s requirements, the interviewees were asked to rate the level on a scale from 1-5 where 1 was ‘very low’ and 5 was ‘very high’. The average score based on interviews with four organisations was 3.6. The majority of the interviewed organisations consider that compliance is higher in large establishments and lower in SMEs.

Combined assessment

All in all, the evidence on level of compliance with the Directive is weak and fragmented. The data indicates that compliance is generally at a medium to high level with 50-90% compliance. Based on the data, it seems that the level of compliance relies to an extent on sectors rather than on size of establishment, with the sectors being intentional users or handlers of biological agents (laboratories, health care facilities, etc.) being most aware and thus most in compliance.

Based on the data we have very limited information about how performance in work places has developed over time and thus it is also difficult to establish whether the medium-high levels of compliance are caused by the Directive or whether the same would have been the case without the Directive. Stakeholders who assess the importance of the Directive, generally recognise that the Directive has played a role, but some NIRs also consider that national measures were in place before the adoption of the Directive.
3.4 MQ4: Accompanying actions

MQ4: What accompanying actions to OSH legislation have been undertaken by different actors (the Commission, the national authorities, social partners, EU-OSHA, Eurofound, etc.) to improve the level of protection of safety and health at work, and to what extent are they actually used by companies and establishments to pursue the objective of protecting safety and health of workers? Are there any information needs that are not met?

When answering the fourth mapping question we distinguish between accompanying actions taken at Member State level – mainly based on information presented in the Country Summary Reports developed within the present evaluation, and accompanying actions taken at EU level – mainly based on information obtained through desk research and interviews with EU level stakeholders.

3.4.1 Accompanying actions at Member State level

We have looked into the existence of different types of accompanying actions taken at Member State level to encourage the implementation of and compliance with the Biological Agents Directive. This is illustrated in Table 3-1, which shows the existence of guidance documents and support tools.

Table 3-1  Guidance documents and support tools

<table>
<thead>
<tr>
<th>No guidance doc.</th>
<th>No support tools</th>
<th>1-2 support tools</th>
</tr>
</thead>
<tbody>
<tr>
<td>AT, BG, HU, IE, LT</td>
<td>CZ</td>
<td></td>
</tr>
<tr>
<td>1-10 guidance doc.</td>
<td>DK, EE, EL, FI, IT, LU, LV, MT, NL, PT, RO, SE, SI, SK</td>
<td>BE, CY, FR, PL, UK</td>
</tr>
<tr>
<td>Above 10 guidance doc.</td>
<td>DE, ES</td>
<td></td>
</tr>
</tbody>
</table>

Source: Country Summary Reports.

Table 3-1 shows that this investigation has led to the identification of a number of guidance documents and support tools – including IT tools. It shows that most countries have developed guidance documents – and this has been combined with support tools in some countries, but only a minority.

A few Member States have also made use of more active accompanying actions such as awareness-raising campaigns, and the education and training of employers and workers within the establishments as shown in Table 3-2.
### Table 3-2: Awareness-raising campaigns, and education and training activities

<table>
<thead>
<tr>
<th>No campaigns</th>
<th>No education and training activities</th>
<th>1 or more education and training activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>No campaigns</td>
<td>AT, BG, CZ, DE, DK, EE, EL, ES, FI, FR, HU, IE, IT, LU, LV, PT, SE, SI, SK, UK</td>
<td>LT</td>
</tr>
<tr>
<td>1 or more campaigns</td>
<td>CY, MT, NL, RO</td>
<td>BE, PL</td>
</tr>
</tbody>
</table>

Source: Country Summary Reports

The above information does not necessarily indicate that the available guidance documents, support tools and awareness raising activities are sufficient. In fact, several stakeholders consulted via the development of the Country Summary Reports state that they are not always sufficient. In this context, Table 3-3 shows that information gaps in relation to the Biological Agents Directive, some of which are especially relevant for SMEs, are considered to exist in most Member States.

### Table 3-3: Information gaps

<table>
<thead>
<tr>
<th>No information gaps</th>
<th>Information gaps – some specifically SME-related</th>
<th>Information gaps – none specifically SME-related</th>
</tr>
</thead>
<tbody>
<tr>
<td>DE, DK, HU, IE, SE, UK</td>
<td>BE, BG, FR, IT, LV, MT, PT, SI, SK</td>
<td>AT, CY, CZ, EE, EL, ES, FI, LT, LU, NL, PL, RO</td>
</tr>
</tbody>
</table>

Source: Country Summary Reports.

### Financial incentives

The data from national data collection indicates that only one Member State – the Netherlands – has made use of financial incentives for establishments to comply with safety and health provisions related specifically to the Biological Agents Directive. It should be noted that several countries have general arrangements for financial incentives – these are described in the Directive report on the Framework Directive.

#### 3.4.2 Accompanying actions at EU level

Contrary to the situation for many of the other OSH Directives, no overall guidance document has been developed by the Commission on the Biological Agents Directive. Referring to the NIRs, quite a few Member States regard the development of such a guidance document as important. It should be mentioned that the guide to prevention and good practice in the health care sector contains a useful chapter on biological risks.

However, the EU has initiated a number of accompanying actions to support the implementation of the directive, including several publications by EU-OSHA:

- Factsheet 41 – Biological Agents, 2003

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› E-Facts 29: Occupational safety and health in Europe’s forestry industry, 2008

› E-Facts 53: Risk Assessment For Biological Agents, 2010

› Factsheet100: Legionella and legionnaires’ disease: European policies and good practices, 2011

In addition, the members of the European Surveillance Scheme for Travel Associated Legionnaires’ Disease and the European Working Group for Legionella Infections have produced the European Guidelines for Control and Prevention of Travel Associated Legionnaires’ Disease in 2005.

3.5 MQ5: Enforcement

**MQ5**: What are the enforcement (including sanctions) and other related activities of the competent authorities at national level and how are the priorities set among the subjects covered by the Directives?

Authorities and strategies

The data from the national analysis shows that the Member States typically have a general enforcement authority responsible for OSH enforcement and inspections related to all or the majority of OSH matters, including biological agents. The same can be said about enforcement strategies. Thus, the national studies have not led to the identification of special enforcement authorities, enforcement strategies or types of sanctions, which are focusing in particular on compliance with national legislation pertaining to the Biological Agents Directive. Reference is therefore made to the Framework Directive Report and the Main Report, which describe the general enforcement frameworks applied in the Member States, including sanctions, activities and how priorities are set.

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29 Reference is made to the Directive report on implementation of the Framework Directive, which provides a summary of the general systems in force.
30 In Slovakia (SK) some of the OSH Directives, including the Biological Agents Directive, can be enforced under the Public Health Act, whereas the Framework Directive and a group of OSH Directives are enforced/sanctioned under the Labour Inspection Law. Reference is made to the Country Summary Report for Slovakia, section 1.2.2.
3.7 MQ6: Vulnerable groups

MQ6: What are the differences of approach across Member States and across establishments with regard to potentially vulnerable groups of workers depending on gender, age, disability, employment status, migration status, etc., and to what extent are their specificities resulting in particular from their greater unfamiliarity, lack of experience, absence of awareness of existing or potential dangers or their immaturity, addressed by the arrangements under question?

The findings from the national studies show that most Member States have general approaches to vulnerable groups, which are not targeted at specific Directives (except those Directives, which are specifically designed to address vulnerable groups).

Pregnant and breastfeeding workers represent a vulnerable group, which is covered by various guidance documents and tools in the majority of the Member States. It is not always clear from the titles listed as part of the work of identifying such tools in the country summary reports, whether biological agents is addressed specifically, but this is likely to be the case in most instances.

Estonia has developed a guideline particularly addressing pregnant workers: Biological risk factor in the working environment.

3.8 MQ7: SMEs and Microenterprises

MQ7: What measures have been undertaken by the Member States to support SMEs and microenterprises (e.g. lighter regimes, exemptions, incentives, guidance, etc.)?

The data collected from the Member States shows that the Member States have generally not developed specific measures to support SMEs which are only relevant to the Biological Agents Directive. Some Member States have general measures in support of SMEs, which come under the Framework Directive and are described in the Framework Directive report. It should also be mentioned that a number of Member States have developed general guidance on implementation of requirements related to Biological Agents, which they regard as equally applicable by large enterprises and SMEs (ref. NIR reports).

The data collected has shown one example of a particular exemption in Germany. Here, micro-enterprises can be exempted on request from documenting the risk assessment when only working with biological agents in risk group I.

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Assessment of Relevance

In this section, the relevance of the Directive in relation to the coverage of workforce and Member States, and the severity and extent of risks covered is investigated. The conclusions from the five parameters used to assess relevance are summarised in the table below.

### Table 4-1 Summary of the five relevance parameters

<table>
<thead>
<tr>
<th>Coverage of Workforce and Member States</th>
<th>Severity and extent of risks covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Member States where the Directive is potentially relevant</td>
<td>Proportion of EU workforce to whom the Directive is potentially relevant</td>
</tr>
<tr>
<td>Fatal accidents at work (per 100,000 employed)</td>
<td></td>
</tr>
<tr>
<td>Non-fatal accidents at work (per 100,000 employed)</td>
<td></td>
</tr>
<tr>
<td>Work-related health problems</td>
<td></td>
</tr>
<tr>
<td>27</td>
<td>20.4%</td>
</tr>
</tbody>
</table>

**Coverage of Member States**

This Directive has been transposed into national legislation in all Member States according to evidence from the NIRs\(^{32}\). According to EU-OSHA, exposure to biological agents can occur whenever people are in contact at work with natural or organic materials such as: soil, clay, plant materials (hay, straw, cotton, etc.), substances of animal origin (wool, hair, etc.), food, organic dust (e.g. flour, paper dust, animal dander), waste, wastewater, blood and other body fluids. They are therefore potentially encountered in a wide variety of occupational groups represented in all Member States and so the Directive remains relevant in all Member States.

**Workforce relevance**

Turning to the labour market, determination of the proportion of the labour market covered by the provisions of this Directive is therefore a matter of establishing the number of persons employed within the appropriate sectors. The Directive is relevant to all such workers.

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\(^{32}\) Individual NIRs
Consideration of NACE coding of economic sectors suggests that primary Code A (agriculture, forestry and fishing) is an obviously category for inclusion. Selected sub-categories of manufacturing (NACE Code C), involving the handling of plant or animal products were also selected (C10, C11, C12, C13, C14, C15) as were pharmaceutical products (C21). Finally, NACE Codes E (water supply, sewerage, waste management and remediation activities) and Q (human health and social work activities) were also selected for inclusion.

LFS data documents that, for 2012, a total of 215,678,600 people were employed within the EU-27 (15-74 years). Out of these, 10,495,500 were employed within the agriculture, forestry and fishing sector (NACE Code A); 1,663,700 within water supply etc. (NACE Code E); and 22,861,300 in health care etc. (NACE Q). Turning to the subcodes of category C, the SBS database indicates that there are 7,245,300 workers in the relevant sub-sections out of a total of 30,000,000 workers employed in manufacturing (22%). Applying the 22% to the 37,814,400 workers in the same (manufacturing) sector according to the LFS data yields a total of 8,297,487 workers. Combining these numbers with those employed in the other three sectors gives a total of 43,980,487 workers or 20.4% of the EU workforce. The Biological Agents Directive can therefore be regarded as potentially relevant to at least 20.4% of the EU workforce.

4.1 EQR1: Current relevance

**EQR1: To what extent do the Directives adequately address current occupational risk factors and protect the safety and health of workers?**

**Fatal accidents at work**

Although exposure to biological agents can result in fatal illnesses, it will not lead to accidental death and therefore no fatal accidents were considered relevant to this Directive. However, fatalities arising from exposure and infection are clearly of relevance (see non-fatal accidents).

An EU-OSHA Risk Observatory report, published in 2009 provides an extensive overview of a variety of different specific infectious agents and the extent of resulting ill-health (including fatalities). One of its conclusions was that:

«There are only limited data on occupational exposure to infectious biological agents in the EU. Statistical information concerning occupational diseases (it means cases that were accepted as an occupational disease by the national compensation or other competent authorities) do exist in the most countries, however not all work – related infectious diseases are registered as

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33 Employment by sex, age and economic activity (from 2008 onwards, NACE Rev. 2) - 1 000
Ifsa_egan2
34 Annual enterprise statistics by size class for special aggregates of activities (NACE Rev. 2)
sbs_sc_sca_r2
35 Biological agents and pandemics: review of the literature and national policies.
occupational diseases. The rules of recognition and notification of occupational diseases vary between the Member States." (p45)

In many instances, the incidence of ill-health (including fatalities) can be associated with specific isolated ‘outbreaks’ rather than a more generalised exposure. However, the report does serve to illustrate that, despite the shortcomings in data sources, there are identifiable fatalities from work-related acquisition of infectious diseases amongst EU workers.

The Health Council of the Netherlands estimates that 5,000 workers in the European Union die each year as a result of occupational exposure to biological agents. The council suggests that the number who fall ill due to occupational exposure to biological agents is probably much higher, but is difficult to estimate because there is no specific monitoring in this field and the reported data are insufficient.

According to one estimate, fatalities due to communicable disease represent 3% of work-related fatalities annually in the EU compared to over half (57%) attributable to cancer.

**Non-fatal accidents at work**

The Eurostat ESAW database includes accidents at work resulting in more than three days at work arising from ‘poisonings and infections’. It is not possible to differentiate between these two causes. Across the EU-27 the database shows that, in 2012, there were 11,211 incidence of such accidents (including fatalities). From the same database, excluding fatalities there were 11,113 accidents, indicating that there were 98 fatalities. These figures should be seen against the total figure of 2,482,415 accidents of which 3,465 were fatalities. The fatality figures are consistent with the estimate of 3% fatalities referred to earlier. However, as these data include poisonings and do not necessarily include infections not recorded as ‘accidents’, too much significance should not be placed on this similarity.

**Work-related health problems**

The LFS 2007 database includes statistics relating to those who report having had what they perceive as a work-related health problem within the last 12 months. Although this database includes workers in the appropriate sectors, there are no details of the nature of those problems. It is not possible to conclude firmly on the extent to which these problems are associated with biological agents.

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36 Advisory letter on Health-based recommended occupational exposure limits for biological agents. Gezondheidsraad (Health Council of the Netherlands), December 2012
38 Accidents at work by type of injury and severity (NACE Rev. 2, A, C-N) [hsw_mi07]
39 Persons reporting one or more work-related health problems in the past 12 months, by sex, age and economic activity sector - % [hsw_pb6]
However, another tabulation of data from the same source provides a breakdown of health problems by type of problem, including an entry ‘infectious diseases’\(^{40}\). From this, 1.8% of the respondents indicated that their most serious work-related problem over the preceding 12 months had been an infectious disease. It is not possible to restrict the data to those reports originating from those workers likely to have been exposed to biological agents as part of their work and so the possibility that such problems were acquired through other avenues (e.g. an infection acquired from a work colleague) cannot be excluded.

Finally, from the same database, information is presented categorised by the diagnosis group of health problems experienced\(^{41}\). However, although some of the groups, especially pulmonary disorders, could be caused by exposure to biological agents, the potential causes are too diverse to enable any realistic picture to be formed of the relevance of this Directive from this source.

Data from the EWCS survey (2007) identifies reported exposures to physical risk factors (chemical, biological, ergonomic, noise, temperature; etc.)\(^{42}\). One specific question asks "Are you exposed at work to - Handling or being in direct contact with materials which can be infectious?" (Variable q23i). Given the fact that even transient exposures to infectious agents can result in illness it seems appropriate to consider all those who consider that they might be exposed to such potentially infectious materials at some time. The database records that 78.8% of respondents stated that they never encountered such exposures. By default therefore, it is assumed that 21.2% might, at some time, be exposed.

Clearly this only includes overtly infectious materials and does not encompass other less apparent sources. In some such cases (such as infectious agents contaminating a hide or other material), a positive response probably depends on the knowledge of the individual. Nevertheless, it does provide some insight into the extent of current exposures of relevance.

The Risk Observatory report cited previously presents data from a wide variety of sources, whilst acknowledging that the occupational nature of any particular infection cannot always be established and that recognition of such infections as occupational varies between Member States. There was a clear need, both for greater consistency in data collected, and for better collection and collation of such data across the EU. As with fatalities, ‘clusters’ of ill-health could often be associated with specific outbreaks of a disease and these tended to be geographically isolated and defined by the source of the outbreak. However, some diseases, such as blood-borne diseases like viral hepatitis and human immunodeficiency virus (HIV) are more widespread. The challenge here is that occupation as the source of the infection is not always recorded in statistics.

\(^{40}\) Persons reporting their most serious work-related health problem work in the past 12 months, by type of problem - % [hsw_pb5]

\(^{41}\) Standardised prevalence rate of work-related health problems by diagnosis group, economic activity of the employer and age [hsw_hp_dinag]

Information from National Implementation Reports (NIRs)

The questionnaire for the NIRs included two questions in respect to relevance: (1) “In the light of practical experience, knowledge, technological, social and cultural developments, are the provisions of the Directive still appropriate?”; and (2) “Does the Directive need adaptation to take account of the pattern of accidents or ill health?”

In respect to the first question, a lot of Member States answered with a simple ‘yes’ and very limited (if any) additional rationale provided (17 Member States). Some answered that the provisions are appropriate, but updates are needed (6 Member States). Only one Member State considered the provisions inappropriate (Poland). For three Member States, the answer was inconclusive.

In respect to the second question, six Member States indicated clearly in their answer that the Directive needs adaptation. Some Member States consider that the annex with the list of biological agents needs to be updated – some consider that this can be done without updating the provisions of the Directive, whereas others consider an update of the provisions to be necessary. In total, ten Member States indicated that they considered the classified list (Annex III) to be out of date and referred to adding new agents to this list of hazardous biological agents. Clearly, this would improve the relevance of the Directive considering that the list has not been updated since the adoption of the Directive in 2000. This is also in conflict with the Directive itself, which in Annex III, Note 6 states that the list will be updated as soon as it no longer reflects the latest state of knowledge. This issue was explored in depth in a report on classification of biological agents from the Netherland’s National Institute of Public Health and the Environment (see below).

In addition to those Member States which consider an update of the provisions to be necessary, four Member States have offered the opinion that there is a need for guidelines on the implementation of the Directive and that this would be sufficient to address current shortcomings.

In their answers to the questions, the Member States often refer to the lack of data on patterns of accidents or ill-health, which makes it difficult to form a strong conclusion on whether or not there is a need for an update of the Directive. For example, the United Kingdom NIR states:

“It is not possible to obtain reliable data on the numbers of infections at work caused by incidental exposure to biological agents (including in healthcare). There were 100 accidents/incidents reported in Great Britain (under the requirements of Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995) during the period of August 2006 to August 2010 related to high hazard work with biological agents. This constitutes in the region of 30 accidents per year for deliberate work with biological agents. In the same period, 12 cases of ill-health were reported.”

One other Member State (Bulgaria) also presented data relating to occupational diseases caused by exposure to biological agents indicating that they had records of 14 cases in the (5 year) reporting period, with one to four new cases of occupational diseases recorded annually.
In both instances these appear to relate to those infections amongst those actively working with biological agents as opposed to others (such as health workers) exposed as a corollary to their work.

In 2012, the Netherlands' National Institute for Public Health and the Environment published a report on classification of biological agents, which reviewed the Biological Agents Directive in respect to classification of biological agents. The report included a comprehensive review of Annex III of the Directive and concluded that:

"the European list with classifications is dated and needs to be updated and expanded. The current list contains conceptual and textual omissions. There is a lack of information on animal pathogens, opportunistic pathogens, genetically modified organisms, attenuated strains, toxins and biological agents with high risk for human health in particular situations (e.g. pregnancy). This is seen as an important drawback of the current European list."

The report further highlighted uncertainties and lack of clarity in procedures concerning biological agents which are 'pending classification' (ref. Art. 18 of the Directive), where the Member States are obliged to classify these agents. Further, the report found that the procedure for adopting and amending the list in Annex III leaves little opportunity to respond promptly to new developments in science and in the word, including natural outbreaks of infectious diseases or bioterrorism.

The report recommended to remove the appendices with classifications from the Directive, in order to be able to maintain the list on a more frequent basis. It suggested that a centralised database be set up based on available online and interactive tools with a central curator of such a resource, for instance the European Centre for Disease Prevention and Control (ECDC) and/or the European Agency for Safety and Health at Work (EU-OSHA). The report also raised the subject of links between the classification/risk assessment and the containment measures arguing that the model prescribed in the Directive (ref. Annex V) is too simplistic and that more attention should be put on gearing the measures in accordance with the risk assessment. This is an argument against the prescriptive element of the Directive Annex V and in favour of a goal-oriented approach. The UK NIR made a comment along similar lines concerning one of the measures prescribed in Annex V, which requires animal carcasses to be incinerated. The NIR suggests that other equally effective means are now available to ensure that any biological agent in a carcass has been destroyed. It suggests that it would be better if the Directive allowed the duty-holder to select the most effective and appropriate disposal method for their circumstances, according to the risks involved.

Not all Member States provided a specific opinion on the relevance of this Directive (often restricting their view to the relevance of the whole OSH acquis). However, amongst those five who did, all considered that the Directive remained relevant (in some Member States highly relevant).

Report on classification of biological agents

Interviews with Member State stakeholders

Some isolated comments included suggestions of limit values (1 Member State) and the addition of new agents (2 Member States) as a means of improving the current relevance of the Directive, although such views were by no means widespread among the interviewees.

However, the suggestion for the introduction of limit values for some organisms has also been advocated by a specialist group from one Member State (Health Council of the Netherlands),\textsuperscript{44} which suggested that limits could be introduced for biological agents giving rise to toxic and/or allergic effects (but not infectious diseases). Such a measure could possibly impact on both the relevance and effectiveness of this Directive. Whilst no doubt other agencies might produce a contrary view there does seem to be some merit in at least exploring this as a possibility.

Interviews with EU stakeholders offered few opinions on the relevance of the Biological Agents Directive although one stakeholder (worker) advocated the introduction of limit values (although it was not clear that this specifically related to the Biological Agents Directive).

Despite the shortcomings of the data, the cumulative evidence from ill-health associated with infection from biological agents, as demonstrated by the contents of this report, is that biological agents remain a significant potential cause of work-related ill-health. Also, there is a very strong case that the list of biological agents in Annex III to the Directive is outdated and in need of being updated – and the procedure for updating the list is too cumbersome to live up to the Directive’s own target: That the list will be updated as soon as it no longer reflects the latest state of knowledge. There is also evidence to suggest that the prescriptive approach to identifying correct measures in Annex V is not suitable and a more flexible approach scoping the measures in accordance with the results of the risk assessment would be more appropriate.

4.2 EQR2: Future relevance

EQR2: Based on known trends (e.g. new and emerging risks and changes in the labour force and sectoral composition), how might the relevance of the Directives evolve in the future, and stay adapted to the workplaces of the future in light of the horizon of 2020? Does the need for EU level action persist?

Only a few interviewees (EU or Member State) and no NIRs offered specific opinions on the future relevance of the Biological Agents Directive. However, stakeholders from one Member State expressed the view that new biological factors (new viruses and microorganisms), to which the society is not prepared, could possibly emerge (meaning that a need for EU level action persisted).

\textsuperscript{44} Advisory letter on Health-based recommended occupational exposure limits for biological agents. Gezondheidsraad (Health Council of the Netherlands), December 2012
This comment can be related to the observation above that a number of Member States regarded the classified list of infectious agents to be out of date. Updating this would clearly improve the current relevance of the Directive. However, to maintain its future relevance, it would seem that an efficient mechanism needs to be devised to enable this list to be updated regularly and easily.

In 2007, an EU-OSHA Risk Observatory report\(^{45}\) concluded:

“Occupational risks related to global epidemics are the biggest emerging issue identified in this forecast, with a high level of consensus among the respondents. Even in the 21st century, we are still confronted with the emergence of new pathogens, such as severe acute respiratory syndrome (SARS) or avian influenza, and the re-emergence of outbreak-prone diseases such as cholera and yellow fever.”

Other factors identified in this report were:

- The emergence of drug-resistant organisms.
- Risks resulting from poor risk assessment.
- The lack of information on biological risks in the workplace, including the lack of information passed on to workers — i.e. the inadequate provision of OSH training to workers.
- Poor maintenance of water and air systems.
- Combined exposure to biological agents and chemicals.
- Exposures to endotoxins and indoor moulds.
- Occupational risks linked to waste treatment.

A further EU-OSHA report in 2009\(^{46}\) identified disease pandemics as a recognisable and ongoing problem. With increasing global social mobility the risk of such problems is likely to persist, presenting foreseeable risks, especially to health care and social sector workers.

It is noted that some Member State stakeholders have also expressed concerns regarding some of these factors (e.g. antimicrobial resistance as a specific form of drug-resistant organism).

Some of these, such as poor risk assessment and inadequate training and information appear to reflect poor implementation of the existing OSH provisions rather than any need to consider change. Others, such as working with drug-resistant organisms should already be covered by the existing provisions.

In order to retain its relevance, the Directive needs to respond to those emerging risks (and others which might develop) which should be within the scope of the Biological Agents Directive. However, the emergence of such new risks means that the Directive is likely to remain relevant against a horizon of 2020.

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\(^{45}\) Expert forecast on emerging biological risks related to occupational safety and health, EU-OSHA 2007

\(^{46}\) Outlook 1 - New and emerging risks in occupational safety and health
Some NIRs have included comments relating to a specific question in the NIR template regarding whether or not the Directive needed adaptation to take account of the pattern of accidents or ill-health. Attention to relevant aspects of these comments would clearly increase the future relevance of this directive.

The most frequent comment (apart from no comment) was the suggestion from several MSs of a need to update the classification (and lists) of pathogens. This is a clear and important need and it is suggested that this should be explored as a priority. Poland in particular commented at length on this need and suggested an approach for determining the most appropriate quantitative exposure standards. The UK NIR suggests that improved compliance is a more urgent priority than amendment. Nevertheless, it does identify a series of issues which it suggests need to be addressed. One of these is the need to update the list and the classification of biological agents.

Estonia included a comment regarding making a distinction between what can be perhaps best summarised as working with biological agents (e.g. in a laboratory) and work where workers might be exposed to such agents (e.g. working with infectious patients, incidental exposures to moulds, etc.). The Netherlands echoed this view, introducing the concept of “reasonable prospect of exposure”. Other sources also refer to intentional versus unintentional users.

France drew attention to the large numbers of self-employed workers not covered by the provisions of the Directive. This is a wider issue than just this Directive and reference is made to the Framework Directive report.
5 Assesssment of effectiveness

The assessment of the Biological Agents Directive takes its point of departure in the impact storyline presented in Chapter 2 of this report. On the basis of data gathered from statistics, studies and interviews, we examine whether the intentions and associated hypotheses regarding the impacts of the Directive can be confirmed. We do this by looking into the data on the impact indicators defined in Chapter 2.

The evaluation encompasses seven questions on effectiveness. These questions form the structure of this chapter. Reflecting the methodology of the evaluation, not all questions are addressed at the level of the individual Directives. In these cases, reference is made to the overall evaluation report, which provides an analysis of these questions at the overall acquis level.

5.1 EQE1: Effect on occupational safety and health

EQE1: To what extent has the Directive influenced workers' safety and health, the activities of workers' representatives, and the behaviour of establishments?

This first evaluation question on effectiveness concerns a key element in relation to effectiveness – the impact of the Directive. In line with the intervention logic shown in Chapter 2, we present the assessed impacts by firstly looking into workplace impacts – i.e. the direct changes/improvements that occur at the workplace as a result of implementing the KRs, and secondly by looking into the improvement in the safety and health situation arising from the workplace impacts.

5.1.1 Workplace impacts

The workplace impacts are concerned with the changes that take place as a result of implementing the Directive in the individual workplaces. I.e. that the workplaces perform the tasks and live up to the requirements specified in the Directive. This is already described in Chapter 3.3 on compliance in this report.
In summary, this section concluded that the evidence on level of compliance with the Directive is weak and fragmented. The data indicates that compliance is generally at a medium to high level with 50-90% compliance. Based on the data, it seems that level of compliance relies to an extent on sectors rather than on size of establishment, with the sectors being intentional users or handlers of biological agents (laboratories, health care facilities, etc.) being most aware and thus most in compliance.

Based on the data, we have very limited information about how performance in work places has developed over time and thus it is also difficult to establish whether the medium-high levels of compliance are caused by the Directive or whether the same would have been the case without the Directive. Stakeholders who assess the importance of the Directive, generally recognise that the Directive has played a role, but some NIRs also consider that national measures were in place before the adoption of the Directive.

5.1.2 Health and safety impacts

There is limited data on the extent to which workers are exposed to biological agents during their work. Data from EWCS can provide an indication about the degree to which workers are exposed to infectious materials; however, biological agents include much more than that. EWCS data from 2005 and 2010 is consistent and shows that 4-5% of workers consider that they are exposed to infectious materials all of the time or almost all of the time. 88-90% of workers indicate that they are never or almost never exposed and the remaining group indicates that they are exposed ¼ to ¾ of the time.\(^{47}\)

Hence, there is no indication that exposure to biological agents has diminished and thus that prevention of workers’ exposure has taken place to a large degree. However, it is not known what the level of exposure would have been without the Directive, and hence, it is not possible to make any firm conclusions about the effects of the Directive on level of exposure.

Data from EWCS shows that, among those who indicated that they are exposed to infectious materials ¼ to all of the time, the perceived work-related health risks have decreased slightly in the period 2005-2010\(^{48}\). However, first of all, the change is relatively small, and secondly, changes in perceived risks can be related to many other factors than infectious materials. Thus, it does not give any firm indications about effects of the Directive. If anything, it again indicates that no radical changes have taken place due to the Directive.

Table 5-1 shows data from EWCS on perceived health effects of work for four different types of health effects showing responses from those who are to some degree exposed to infectious materials and those who are never or almost never exposed.

\(^{47}\) EWCS, responses to question 23, category I: ‘Are you exposed at work to - Handling or being in direct contact with materials which can be infectious?’

\(^{48}\) EWCS, responses to question 66: ‘Do you think your health or safety is at risk because of your work?’
Table 5-1  Perceived health effects according to EWCS

<table>
<thead>
<tr>
<th>Does your work affect your health</th>
<th>Exposed to infectious materials (1/4 to all of the time)</th>
<th>Never or almost never exposed to infectious materials</th>
</tr>
</thead>
<tbody>
<tr>
<td>- skin problems</td>
<td>16%</td>
<td>8%</td>
</tr>
<tr>
<td>- headaches</td>
<td>46%</td>
<td>39%</td>
</tr>
<tr>
<td>- respiratory difficulties</td>
<td>11%</td>
<td>6%</td>
</tr>
<tr>
<td>- injuries</td>
<td>16%</td>
<td>8%</td>
</tr>
</tbody>
</table>

Source: EWCS 2010, answers to question 69

Table 5-1 shows that for all four types of health effects (skin problems, headaches, respiratory difficulties, and injuries), the respondents who are to some degree exposed to infectious materials consider to a larger degree that their health is affected by their work than those who are never or almost never exposed. However, it is not known whether this is related to the exposure to infectious materials (or to other biological agents) or to other factors.

When looking at data on reported absence due to health problems, a similar picture emerges as shown in Table 5-2.

Table 5-2  Reported absence according to EWCS

<table>
<thead>
<tr>
<th>Exposed to infectious materials (1/4 to all of the time)</th>
<th>Never or almost never exposed to infectious materials</th>
<th>% change</th>
<th>% change</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>2010</td>
<td>% change</td>
<td>2005</td>
</tr>
<tr>
<td>Never</td>
<td>70%</td>
<td>51%</td>
<td>-27%</td>
</tr>
<tr>
<td>1 to 4 days</td>
<td>6%</td>
<td>14%</td>
<td>139%</td>
</tr>
<tr>
<td>5 to 9 days</td>
<td>6%</td>
<td>12%</td>
<td>93%</td>
</tr>
<tr>
<td>10 to 19 days</td>
<td>8%</td>
<td>12%</td>
<td>43%</td>
</tr>
<tr>
<td>20 to 49 days</td>
<td>6%</td>
<td>8%</td>
<td>27%</td>
</tr>
<tr>
<td>50 days or more</td>
<td>4%</td>
<td>4%</td>
<td>1%</td>
</tr>
</tbody>
</table>

Source: EWCS 2010, answers to question 72

Table 5-2 shows that workers exposed to infectious materials report higher levels of absence in all categories compared to those never or almost never exposed. Furthermore, in the period 2005-2010, the level of absence has reportedly increased more for those exposed to infectious materials compared to those never or almost never exposed. Again, it is not known whether the absence is due to exposure to infectious materials or to other factors.
As explained in Chapter 2.5 there are considerable challenges in relation to data on occupational accidents and diseases due to exposure to biological agents. Below, the data which does exist is presented.

The advisory letter from the Health Council of the Netherlands on health-based recommended occupational exposure limits for biological agents estimates that approximately 5,000 workers in the EU die each year as a result of occupational exposure to biological agents and that the number who fall ill due to occupational exposure is probably much higher but difficult to estimate. The same estimate can also be found in the report on emerging biological risks from EU-OSHA’s risk observatory. However, none of these sources make an assessment of the effects of the Directive and the estimate is derived from a global review from 2005, which means that it underlines the relevance of regulating risks from biological agents, but it says nothing about the effectiveness of the regulation.

Accidents

The ESAW data set on accidents at work provides data per type of injury for the period 2008 and onwards. The data on accidents involving poisonings and infections are shown in Table 5-3 below.

Table 5-3  Number of accidents involving poisonings and infections

<table>
<thead>
<tr>
<th></th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>European Union (27 countries)</td>
<td>16,259</td>
<td>14,964</td>
<td>:</td>
<td>12,260</td>
<td>11,211</td>
</tr>
</tbody>
</table>

Source: ESAW data, hsw_mi07

Table 5-3 shows a decreasing trend in number of accidents involving poisoning and infections in the period 2008-2012. According to the data, Italy accounts for about two thirds of these accidents and the decreasing trends is also particularly clear in the case of Italy, whereas for other countries it is more varied. It is not clear why there is such a considerable difference between Italy and other countries, but it does give an indication that data reliability is questionable. Furthermore, it is important to note that the displayed data is not incidence-based and thus does not take changes in the size of the workforce into account.

Diseases

The EODS data provides some information on the incidence of hepatitis B and C and tuberculosis, where analysis of time-series data could potentially give meaningful results. These are illustrated in Figure 5-1 and Figure 5-2 below, which are replicated from the EU-OSHA working paper. In addition, there is data on a number of other diseases, which are rare and with no or very few entries in the database and thus not meaningful to analyse in this context. The EODS data is associated with uncertainty and according to Eurostat it is considered that there is a substantial level of underreporting. The data is therefore not officially accessible and the database has not been available to the evaluation, which is why the only

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data that can be presented is that extracted from working paper. The data is not incidence based and thus does not take into account changes in the size of the workforce.

*Figure 5-1  Number of work-related cases of viral hepatitis B and C in the EU-15*

![Number of work-related cases of viral hepatitis B and C in the EU-15](https://example.com/fig1)


*Figure 5-1* indicates that the number of work related cases of viral hepatitis B and C have decreased in the period after adoption of the Directive.

*Figure 5-2  Number of work-related cases of tuberculosis in the EU-15 by year*

![Number of work-related cases of tuberculosis in the EU-15 by year](https://example.com/fig2)


*Figure 5-2* indicates a fairly stable situation in respect to the number of cases of tuberculosis. The EU-OSHA working paper also included data from national sources (displayed in Table 5-4 below).
Table 5-4   Number of recognised cases of tuberculosis per country and year (national data sources)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>DK</td>
<td>3</td>
<td>2</td>
<td>6</td>
<td>6</td>
<td>3</td>
<td>7</td>
<td>6</td>
<td>4</td>
<td>5</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>FI</td>
<td>7</td>
<td>7</td>
<td>10</td>
<td>10</td>
<td>6</td>
<td>9</td>
<td>16</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FR</td>
<td>17</td>
<td></td>
<td>51</td>
<td>63</td>
<td>61</td>
<td>85</td>
<td>50</td>
<td>83</td>
<td>96</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PL</td>
<td></td>
<td></td>
<td>192</td>
<td>151</td>
<td>131</td>
<td>100</td>
<td>93</td>
<td>93</td>
<td>86</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ES</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>0</td>
</tr>
</tbody>
</table>


Table 5-4 provides a mixed picture across countries with no clear overall trend.

**NIR data on effects of the Directive**

For the National Implementation Reports, the Member States were not asked to provide data or views on number of accidents and diseases which can be linked to occupational exposure to biological agents. However, six Member States (Estonia, the Netherlands, Portugal, Romania, Slovenia and the United Kingdom) have mentioned some data on this or views on the effects of the Directive. There is no clear trend emerging from these entries.

**Interview data on effects of the Directive**

The data from the few interviews at EU level, where respondents were able to provide an assessment of the Biological Agents Directive, shows that these respondents have quite differing views on the extent to which the Directive has had an effect on the level of health and safety in the EU. Broadly speaking, they all agree that some effect has been achieved, but the assessments range from a low-medium level to high. In the case of national interviews, the number of respondents who have commented directly on the Directive and its effects on health and safety of workers is too limited to justify presentation in this report.

**Combined assessment**

In summary, the data does not allow for firm conclusions about the effect of the Biological Agents Directive on safety and health. Referring to section 3.3 workplace impacts are assessed as medium-high and there is there is good reason to believe that the Biological Agents Directive has also led to positive safety and health impacts. However, based on the available data it is not possible to quantify this impact.

### 5.2 EQE2: Derogations and transitional periods

**EQE2:** What are the effects on the protection of workers’ safety and health of the various derogations and transitional periods foreseen in several of the Directives concerned?

As also mentioned in Section 3.2, no derogations or transitional periods have been applied or have been used under national law under the Biological Agents Directive. Hence, there is nothing to report under this evaluation question.
5.3 EQE3: Effect of Common Processes and Mechanisms

EQE3: How and to what extent do the different Common Processes and Mechanisms that were mapped contribute to the effectiveness of the Directives?

There is very limited data on the importance of the different CPMs in relation to effectiveness of the Directives. Due to the general lack of statistical data on workplace and safety and health impacts, it is also not possible to establish any quantifiable evidence concerning the contribution of the CPMs.

Among the interviewees at EU and Member State level, the following CPMs have been mentioned as contributing: Risk assessment, health surveillance, information and training. However, for both groups, there are none of these CPMs, which are mentioned consistently in the majority of the interviews.

Looking at the data presented in Chapter 3.3, we do not have an indication that some CPMs are significantly more effectively implemented than others. This indicates that the CPMs contribute in combination and in an equal way to the implementation of the Directive.

When looking at the information provided by Member States in the National Implementation Reports, the implementation issues discussed often revolve around the CPMs, which, indirectly, is an indication of the perceived importance of the CPMs in relation to an effective implementation of the Directive. However, the NIRs also illustrate that other KRs are important – in particular the requirements for substitution (art. 5) and measures (art. 6).

Considering the various accompanying actions on how to address risks associated with biological agents (guidelines, information material, etc.), it is very clear that there is an emphasis especially on risk assessment as a point of departure for identifying the risks and devising and implementing the correct measures (which also include information and training of workers). The EU-OSHA risk observatory report on emerging biological risks emphasised that poor risk assessment in itself is an important issue and that there is a need to develop better tools and techniques for measurement as well as criteria and protocols for assessing exposure to hazardous biological substances. The report also called for more data to help establish occupational exposure limits. In addition, issues in relation to information and training of workers were also highlighted. Box 5-1 provides key extracts from the report.
Box 5.1 Key issues related to CPMs identified in the EU-OSHA risk observatory report on biological risks

Risks resulting from poor risk assessment are the second most important of the emerging issues. Directive 2000/54/EC lays down the principles for the management of biological risks and assigns to employers the duty of assessing the risks posed by biological agents in the workplace. But the state of knowledge on biohazards is still relatively immature and, in practice, proper assessment of biological risks is difficult. In order to produce a proper exposure assessment, better tools for the detection of biological agents and measurement of their concentrations need to be developed. These should be based on non-culture techniques because culture methods have proven to be of limited use. The validation of measurement methods and international harmonisation of those methods are also necessary if laboratory results are to be comparable. Such harmonisation should include the definition of commonly approved criteria and accepted protocols for assessing exposure to biological hazardous substances; including concise and uniform guidelines on sampling, storage, extraction and analytical procedures. This, together with more epidemiological and clinical data, is the basis for understanding better the relationships between exposure and occupational health effects. Of course, the actual effect depends on an individual’s susceptibility. Information on dose-effect relationships would also help to establish occupational exposure limits (OELs), which, conversely, would support the proper interpretation of measurement results in a risk assessment procedure. As at October 2006, although some Member States have formulated recommendations and set indicative values, very few obligatory OELs have been set for airborne microorganisms or their associated toxins.

The lack of information on biological risks in the workplace, which makes risk assessment difficult, has been treated as an emerging risk in a separate item, especially in the office workplace and the agriculture sector. Furthermore, the lack of information passed on to workers—i.e. the inadequate provision of OSH training to workers, especially in local authorities—has also been raised.

A further emerging risk, with a rather high consensus among the experts, is the poor maintenance of water and air systems. This puts workers — and the general population—at risk of legionella. Moreover, this again illustrates the consequences of having insufficient information on biohazards. Indeed, the experts comment that some ill-health symptoms observed in indoor workers are often wrongly assumed to be flu-like diseases. In fact, they are caused by biological agents that have developed in poorly maintained air-conditioning systems. Recent findings on legionella will help establish a correct diagnosis of such symptoms.

Taken together, the data indicates that the CPMs are very important to the implementation of the Directive and to the achievement of its objectives. In

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particular, performing the risk assessment is a fundamental requirement. However, there are a number of challenges in relation to the implementation of the requirement to perform the risk assessment, which relate to lack of agreed standards and methods, which again reflects a situation where the knowledge of biological agents and the ways in which they affect human health is still fairly limited.

5.4 EQE4: Effect of enforcement

**EQE4**: To what extent do sanctions and other related enforcement activities contribute to the effectiveness of the Directives?

The data collected through the national studies does not indicate that the legislation implementing the Biological Agents Directive is subject to a particular enforcement focus in the Member States. Establishments where workers are exposed to biological agents are subject to a similar inspection and control regime as other establishments. However, there is a link to legislation and enforcement systems concerning biosafety and concerning public health, which is evident in some NIRs, for example. Reference is made to the Main Report, which provides a general analysis of the effect of enforcement on the effectiveness of the Directives.

The interviews with the stakeholders at the EU level who have commented specifically on the Biological Agents Directive indicate that enforcement and sanctions is considered to contribute to a high degree to play a role in ensuring compliance, however, this reflects in particular the relevant workers’ organisations, whereas the employers’ organisations typically give medium scores. Interview data from the Member States is too scarce to be taken into consideration.

5.5 EQE5: Benefits and costs

**EQE5**: What benefits and costs arise for society and employers as a result of fulfilling the requirements of the Directives?

This question is addressed in the Main Report in a cross-Directive perspective.

5.6 EQE6: Broader impacts

**EQE6**: To what extent do the Directives generate broader impacts (including side effects) in society and the economy?

This question is addressed in the Main Report in a cross-Directive perspective.
5.7 EQE7: Objective achievement

**EQE7**: To what extent are the Directives achieving their aims and, if they are not, what cause could play a role? What factors have particularly contributed to the achievement of the objectives?

The objective of the Directive is stated in art. 1: *This Directive has as its aim the protection of 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.*

Both national and EU stakeholders were asked to score the extent to which the Directives fulfilled its objective on a scale from 1-5 (where 1 equalled a very low extent and 5 equalled a very high extent). The average score based on 4 EU stakeholders interviews was 3.3 and the respective score based on 15 Member State interviews (covering 5 Member States) was 4. The limited interview data thus shows that these stakeholders – on average – consider objectives to be achieved to a fairly high degree, with EU stakeholders being somewhat more sceptical than the national stakeholders.

The evaluation indicates that there is a medium to high level of compliance with the Directive's requirements. This in itself indicates that workers are – to a relatively high degree – protected against the risks associated with biological agents. The data indicates that implementation is strongest where biological agents are intentionally used, which points to a high degree of objective achievement in the sectors and work places handling biological agents as part of the work processes, e.g. health care sector, test laboratories, etc.

The Directive (art. 15 and 16 and associated annexes) provides specific measures for containment in respect to these types of work places (health and veterinary facilities, industrial processes, laboratories and animal rooms), whereas for other sectors, the Directive is much less specific about the measures to be applied. This in itself could potentially be part of the explanation why awareness and compliance is considered to be higher in these sectors. However, it is also likely that awareness and compliance in these sectors are higher precisely because these sectors comprise intentional users of biological agents or professionals who through their occupation and training are aware of the risks (e.g. doctors, nurses, laboratory workers).

However, as mentioned in the chapter on relevance, the Directive does not encompass all biological agents, and as such, it does not provide for an all-encompassing protection against risks associated with biological agents. The Directive makes provision for possible technical adjustment to the Annex containing the list of biological agents. However, no such adjustment has taken place since the Directive was adopted.

In addition, the Directive does not include limit values for exposure to various biological agents (and neither does it include methods for measuring biological
agents), which gives rise to uncertainty about whether workers are sufficiently protected. This situation reflects that knowledge about biological agents and their effects on human health is still limited (when it comes to biological agents which are not infectious diseases).
6 Assessment of coherence

This chapter provides the findings in respect to internal coherence (i.e. coherence between the Biological Agents Directive and the other OSH Directives) in section 6.1, and external coherence (i.e. coherence between the Directive and non-OSH regulation) in section 6.2.

6.1 EQC1: Coherence and complementarity between Directive 2000/54/EC (biological agents) and the other OSH Directives (Internal coherence)

EQC1: What, if any, inconsistencies, overlaps, or synergies can be identified across and between the Directives (for example, any positive interactions improving health and safety outcomes, or negative impact on the burdens of regulation)?

Scope of application

This Directive applies to activities in which workers are or are potentially exposed to biological agents as a result of their work. Biological agents are classified into four groups according to their level of risk. The Framework Directive fully applies without prejudice to more stringent and/or specific provisions under Directive 2000/54/EC (biological agents).

Risk assessment

Similarly to all directives that regulate worker risks from specific agents, Directive 2000/54/EC (biological agents) contains a detailed risk assessment procedure. Despite the differences between chemical agents and biological agents (properties and hazards) and the differences on the risk control measures for these two distinct agents several requirements under Directive 98/24/EC (chemical agents) could also apply to the risk assessment of biological agents as they are not specifically tailored for chemical agents:

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The effect of preventive measures taken or to be taken must be included in the risk assessment procedure.\(^{54}\)

The employer shall obtain additional information which is needed for the risk assessment from the supplier or from other readily available sources.\(^{55}\)

The risk assessment must take into account conclusions to be drawn from any health surveillance already undertaken.\(^{56}\)

Certain activities within the undertaking or establishment, such as maintenance, in respect of which it is foreseeable that there is a potential for significant exposure, or which may result in deleterious effects to safety and health for other reasons, even after all technical measures have been taken, shall be included in the risk assessment.

The risk assessment may include a justification by the employer that the nature and extent of the risks make a further detailed risk assessment unnecessary.

Risk management measures derived from the risk assessment

Directive 2004/54/EC (biological agents) sets a very different approach with regard to the derived risk management measures compared to the Physical and Chemical agent Directives. Under this Directive, the type of risk management measures depend on the result of the risk assessment but also the type of biological agents workers are exposed to. For example, in case the risk assessment concerns group 1 biological agents and health risks to workers have been identified, almost all risk management measures under this Directive do not apply (e.g. replacement, reduction of risk, information to the competent authority), apart from Annex VI requiring that for group 1 biological agents, the principles of good occupational safety and hygiene should be observed. No coherence issues were identified here these risk management measures are very specific and cannot be replicated to other agents.

Preventive and protective services

Directive 2000/54/EC (biological agents) does not contain any provision on internal and or external preventive and protective services. This CPM is very linked to undertakings/establisments, so having a relevant provision in risk-specific Directives used within establishments/undertakings would not be consistent with the nature of the requirement to appoint preventive and protective services for each establishment/undertaking.

\(^{54}\) Recitals 8 of Directive 2000/54/EC (biological agents) mentions that preventive measures should be taken for the protection of the health and safety of workers exposed to biological agents.

\(^{55}\) Certain biological agents such as bacteria can be sold to laboratories for research purposes.

\(^{56}\) Note that Directive 2000/54/EC (biological agents) under Article 14 requires that workers must undergo health surveillance prior to exposure which would implicitly mean that the result of health surveillance is taken into account for the risk assessment. Furthermore the risk assessment under Directive 2000/54/EC requires taking into account knowledge of a disease from which a worker is found to be suffering and which has a direct connection with his work.
Directive 2000/54/EC (biological agents) provides two types of information requirements. One general requirement applying to all workers exposed to biological agents (e.g. information and training on potential risks to health, hygiene requirements), the other one more specific requiring employers to provide written instruction to workers in case of serious accident or incident or in case of handling a group 4 biological agents. Some of these information requirements could apply to all workers independently of the occupational risks (e.g. information on hygiene requirements, information in case of accidents and incidents) (See Framework Directive Report).

Several physical agent Directives contain an employer obligation to inform on how to detect health effects of exposure and how to report them. Since there are adverse health effects of exposure to biological agents, such information obligation could also apply for biological agents.

The training requirements are combined with the information requirements under Directive 2000/54/EC (biological agents).

Both the Framework Directive and Directive 2000/54/EC (biological agents) require that training must be adapted to take account of new or changed risks and must be repeated regularly. Such overlaps do not lead to double regulation in practice.

Directive 89/656/EEC (PPE) requires employers to arrange for training and ‘if appropriate, organise demonstrations in the wearing of personal protective equipment’. Directive 2000/54/EC (biological agents) also requires training concerning wearing and use of protective equipment and clothing. This is a potential overlap that does not lead to double regulation in practice. However, for better clarity the training requirements on PPE could be streamlined under Directive 89/656/EEC (PPE) (See Directive Report).


The three chemical agent Directives and the Biological Agent Directive have quite a similar approach to health surveillance (e.g. they all include an Annex comprising practical recommendations for the health surveillance/clinical assessment of workers). Among the detailed requirements on health surveillance some of them are very specific to chemical or biological agents, other could be replicated under the Framework Directive and apply to all workers independently of the risk covered (see Framework Directive-Specific Report for further details).

Similarly to most chemical agents directives, Directive 2000/54/EC (biological agents) contains requirements relating to health records in the provisions on health surveillance. This is however not the case for several other Directives that set provisions on health surveillance (notably the Framework Directive). This is considered as a potential inconsistency (see Framework Directive Report).

Among the Directives that sets health record requirements, Directive 2000/54/EC (biological agents) does not explicitly require to keep them up to date as is the
case under the Chemical Agents Directives. Neither does it specify that the health records must contain the summary of the results of health surveillance like other Directives, but mentions that health records must contain the medical and occupational history which is considered quite similar and does not lead to inconsistencies.

**Consultation of workers**

Directive 2000/54/EC (biological agents) provides that consultation and participation of workers and/or their representatives in connection with matters covered by this Directive shall take place in accordance with Article 11 of Directive 89/391/EEC.

**Workers at particular risk**

The introductory notes under Annex III on classification of biological agents provides that the list of classified agents is based on the effect of those agents on healthy workers and that 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 breastfeeding. It adds that additional risk to such workers should be considered as part of the risk assessment required by the Directive. This is in line with the provision of the Framework Directive on workers requiring that particularly sensitive risk groups must be protected against the dangers which specifically affect them.

**Other aspects**

**Reporting obligations**

Directive 2000/54/EC (biological agents) contains several reporting obligations. Employers must inform the competent authority in case of identified risk during the assessment, in case of accident or incident which may have resulted in the release of a biological agent and which could cause severe human infection and/or illness. Employers must also submit to competent authorities a list of exposed workers. Finally, employers must provide a prior notification to the competent authority prior to the use for the first time of Categories 2, 3, and 4 biological agents. Such specific reporting obligations are justified by the hazards and contagious effects of biological agents that may also have an impact on public health.

**Inspection and enforcement measures**

The Directive does not include any provisions relating to inspections or penalties.

6.2 **EQC2: Coherence between Directive 2000/54/EC (biological agent) and other EU measures and policies/international instruments (External coherence)**

**EQC2:** How is the interrelation of the Directives with other measures and/or policies at European level also covering aspects related to health and safety at work, such as EU legislation in other policy areas (e.g. legislation: REACH, Cosmetics Directive, Machinery Directive, policy: Road Transport Safety, Public Health, Environment Protection), European Social Partners Agreements or ILO Conventions?
In the NIR, one Member State identified some overlaps between Directive 2000/54 (biological agents) and Directive 2009/41/EC (on the contained use of genetically modified micro-organisms) in relation to the control of exposure to biological agents. They mention that Article 16 on special measures for industrial processes, laboratories and animal rooms along with Annexes V and VI (containment for industrial processes) under Directive 2000/54/EC should be aligned with the containment requirements of Directive 2009/41/EC on the contained use of genetically modified micro-organisms.

The definition of biological agents under Directive 2000/54/EC includes micro-organisms that have been genetically modified. However, according to Article 1 of Directive 2000/54/EC (biological agents), it applies without prejudice to Directive 90/219/EEC on contained use of genetically modified micro-organisms. These Directives both set containment measures to avoid the dispersion of these biological agents in the environment. These measures are not entirely similar in their approach, content and scope. Overlaps and double regulation should however be avoided by the application of the without prejudice clause under Directive 2000/54/EC (biological agent).

Directive 2010/32/EC (sharp injuries)

Directive 2010/32/EU was adopted in order to implement, in accordance with Article 155 (2) TFEU, the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by the EU social partners EPSU (European Public Services Union) and HOSPEEM (European Hospital and Healthcare Employers’ Association) on 17 July 2009. The Directive aims at achieving the safest possible working environment through the prevention of workers’ injuries caused by all medical sharps, including needle-sticks.

The Directive applies to individuals who work in the hospital and healthcare sector directly related services and activities. The Directive sets up an integrated approach to prevent sharp injuries. It contains provisions in relation to risk assessment and prevention, use of safe equipment, participation and information of workers, training and awareness raising, health assessment and health records.

It builds upon several provisions of Directive 2000/54/EC (biological agents). It provides that the hierarchy of general principles of prevention according to Articles 3, 5 and 6 of Directive 2000/54/EC is applicable. It requires that the risk assessment must be in compliance with Articles 3 and 6 of Directive 2000/54/EC and health surveillance in compliance with Article 14 of Directive 2000/54/EC.

Finally, Clause 6 of the Directive provides that if the assessment reveals that there is a risk to the safety and health of workers due to their exposure to biological agents for which effective vaccines exist, workers shall be offered vaccination.

57 This Directive was repealed by Directive 2009/41/EC on the contained use of genetically modified micro-organisms
Such provision already exists under Article 14(3) and Annex VII to Directive 2000/54/EC. Such overlap does not lead to double regulation in practice.

One EU stakeholder identified potential coherence issues with the sharp injury Directive.

Despite these close links with Directive 2000/54/EC (biological agents), the scope of Directive 2010/32/EU does not cover all the categories of workers that might be exposed to infection through sharp injuries (e.g. workers dealing with special/contaminated waste management treatments, cleaners, police or researchers in laboratories). The broadening of the scope to all workers exposed to sharp injuries could have a positive impact on limiting worker exposure to biological agents.

No comprehensive international instrument covering biological agents has been identified. The ILO Safety and Health in Agriculture Convention 2001 (No 184) states, in Article 14, that “National laws and regulations shall ensure that risks such as those of infection, allergy or poisoning are prevented or kept to a minimum when biological agents are handled, and activities involving animals, livestock and stabling areas, comply with national or other recognized health and safety standards”.
7 Conclusions and recommendations

7.1 Relevance

According to EU-OSHA, exposure to biological agents can occur whenever people are in contact at work with natural or organic materials such as: soil, clay, plant materials (hay, straw, cotton, etc.), substances of animal origin (wool, hair, etc.), food, organic dust (e.g. flour, paper dust, animal dander), waste, wastewater, blood and other body fluids. They are therefore potentially encountered in a wide variety of occupational groups represented in all Member States and so the Directive remains relevant in all Member States.

The Biological Agents Directive can be regarded as potentially relevant to at least 20.4% of the EU workforce. According to the NIRs, the Directive has been transposed into national legislation in all Member States.

Despite the shortcomings of the data, the cumulative evidence from ill-health associated with infection from biological agents, as demonstrated by the contents of this report, is that biological agents remain a significant potential cause of work-related ill-health.

However, it is apparent that the classified list of infectious agents is out of date and should be updated to improve the current relevance of the Directive. To maintain its future relevance, it would seem that an efficient mechanism needs to be devised to enable this list to be updated regularly and easily. There is also evidence to suggest that the prescriptive approach to identifying correct measures in Annex V is not suitable and a more flexible approach scoping the measures in accordance with the results of the risk assessment would be more appropriate.

7.2 Effectiveness

The data does not allow for firm conclusions about the effect of the Biological Agents Directive on occupational safety and health. Workplace impacts are assessed as medium-high and there is good reason to believe that the Biological Agents Directive has also led to positive safety and health impacts. However, based on the available data it is not possible to quantify this impact.
The data indicates that implementation is strongest where biological agents are intentionally used, which points to a high degree of objective achievement in the sectors and work places which handle biological agents as part of the work processes, e.g. health care sector, test laboratories, etc.

The Directive (art. 15 and 16 and associated annexes) provides specific measures for containment in respect to these types of work places (health and veterinary facilities, industrial processes, laboratories and animal rooms), whereas for other sectors, the Directive is much less specific about the measures to be applied. This in itself could potentially be part of the explanation why awareness and compliance are considered to be higher in these sectors. However, it is also likely that awareness and compliance in these sectors are higher precisely because these sectors comprise intentional users of biological agents or professionals who through their occupation and training are aware of the risks (e.g. doctors, nurses, laboratory workers).

However, the Directive does not encompass all biological agents, and as such, it does not provide for an all-encompassing protection against risks associated with biological agents. The Directive makes provision for possible technical adjustment to the Annex containing the list of biological agents. However, no such adjustment has taken place since the Directive was adopted.

In addition, the Directive does not include limit values for exposure to various biological agents (and neither does it include methods for measuring biological agents), which gives rise to uncertainty about whether workers are sufficiently protected. This situation reflects that knowledge about biological agents and their effects on human health is still limited (when it comes to biological agents which are not infectious diseases).

### 7.3 Coherence

Similarly to all directives that regulate worker risks from specific agents, Directive 2000/54/EC (biological agents) contains a detailed risk assessment procedure. Despite the differences between chemical agents and biological agents (properties and hazards) and the differences on the risk control measures for these two distinct agents several requirements under Directive 98/24/EC (chemical agents) could also apply to the risk assessment of biological agents as they are not specifically tailored for chemical agents.

Several physical agents Directives contain an employer obligation to inform on how to detect health effects of exposure and how to report them. Since there are adverse health effects of exposure to biological agents, such information obligation could also apply to biological agents.

Among the Directives that set health record requirements, Directive 2000/54/EC (biological agents) does not explicitly require to keep them up to date as is the case under the chemical agents Directives. Neither does it specify that the health records must contain the summary of the results of health surveillance like other Directives, but mentions that health records must contain the medical and
occupational history which is considered quite similar and does not lead to inconsistencies.

The definition of biological agents under Directive 2000/54/EC includes microorganisms that have been genetically modified. However according to Article 1 of Directive 2000/54/EC (biological agents) must apply without prejudice to Directive 90/219/EEC on contained use of genetically modified micro-organisms. These Directives both set containment measures to avoid the dispersion of these biological agents in the environment. These measures are not entirely similar in their approach, content and scope. Overlaps and double regulation should however be avoided by the application of the without prejudice clause under Directive 2000/54/EC (biological agent).

There are overlaps between the Biological Agents Directive and Directive 2010/32/EU (sharps injuries) concerning obligations to offer vaccines to workers, however, these do not lead to double regulation in practice. Despite the close links with Directive 2000/54/EC (biological agents), the scope of Directive 2010/32/EU (sharps injuries) does not cover all the categories of workers that might be exposed to infection through sharp injuries (e.g. workers dealing with special/ contaminated waste management treatments, cleaners, police or researchers in laboratories). The broadening of the scope to all workers exposed to sharp injuries could have a positive impact on limiting worker exposure to biological agents.

7.4 Recommendations

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 to 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. This could entail a strengthening of the Directive's provisions of the principle that the risk assessment should be used to establish the most appropriate measures safeguarding workers against the risks of exposure and that such measures should be appropriate in handling the risks.

› 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.

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58 This Directive was repealed by Directive 2009/41/EC on the contained use of genetically modified micro-organisms
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.

To enhance the coherence of the Biological Agents Directive with other Directives, it could be considered to:

- 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, to obtain additional information from suppliers, to take into account conclusions to be drawn from health surveillance, to include activities with foreseeable exposures in the risk assessment and include a justification by the employer that the nature and extent of the risks make a further detailed assessment unnecessary.

- 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.
Appendix A  References

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