Risk Group Classification for Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)

Final Statement

This updated statement confirms the official risk group classification for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus responsible for coronavirus disease 2019 (COVID-19).This statement is aimed principally at laboratories carrying out diagnostic testing for SARS-CoV-2 because of the 2020 pandemic and research and development laboratories working with, using or handling SARS-CoV-2.

The Legal Background

The Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 (S.I. No. 572 of 2013) (hereafter referred to as the Biological Agents Regulations) apply to work activities where there is existing or potential, whether deliberate or incidental, exposure to a biological agent. In laboratories such as research, development, teaching or diagnostic laboratories, where work is to be carried out which involves the handling of a biological agent, the employer must determine the containment level and implement the containment measures as specified in the code of practice for the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013. The biological agent must be handled only in working areas corresponding to at least the containment level specified in this code of practice. For example, if a biological agent is assigned to risk group 3 in the code of practice then containment measures must comply at a minimum with the containment level 3 measures as outlined in Schedule 2 of the code of practice. This legally means that at a minimum a containment level 3 laboratory must be used when handling a risk group 3 biological agent. The employer must conduct their risk assessment taking account of the work that is planned and the workers that may be exposed. Based on the findings of the risk assessment, the employer must determine whether the minimum containment measures provide adequate worker protection or whether additional or enhanced containment measures or even a higher containment level is required.

Where laboratories are handling materials and they are unsure whether a biological agent that may cause human disease is present and the laboratory does not have as their aim working with, cultivating or concentrating a biological agent, then the work may be carried out in a containment level 2 laboratory. Examples of such laboratories may be water treatment laboratories, quality control laboratories and routine diagnostic laboratories. Where it is known or strongly suspected that a hazard risk group 3 (or 4) biological agent is present, then a containment level 3 (or 4) laboratory must be used even if there is no intention to deliberately propagate or concentrate the agent.

Certain biological agents classified in the code of practice as group 3(*) present a limited risk of infection for workers because they are not normally infectious by the airborne route and subject to a full risk assessment, certain containment measures may be dispensed with. Schedule 4 of the code of practice outlines specific risk group 3(*) biological agents which have dispensations from the minimum containment measures. Dispensation permits certain physical containment measures to be changed or dispensed with based on risk assessment. It does not automatically mean that the work can be carried out at a lower containment level. As the biological agent is still classified as a risk group 3 agent, occupational exposure lists, specific instruction, information and training with regard to working safely with a risk group 3 agent in addition to a high level of supervision and management will still be required.

Official Risk Group Classification for SARS-CoV-2

The European Commission has classified SARS-CoV-2 as a **risk group 3 biological agent.**

A risk group 3 biological agent "means one that can cause severe human disease and presents a serious hazard to employees and which may present a risk of spreading to the community, though there is usually effective prophylaxis or treatment available".

However, in order to ensure sufficient testing capacity as well as continuity of testing for COVID-19, the European Commission has included a footnote with the risk group classification. This footnote states that non-propagative diagnostic laboratory work involving SARS-CoV-2 should be conducted at a facility with procedures equivalent to at least containment level 2. Propagative work involving SARS-CoV-2 should be conducted at a containment level 3 laboratory with air pressure negative to atmosphere.

The European Commission have stated that in the context of SARS-CoV-2, that non-propagative diagnostic work involves routine laboratory procedures, such as polymerase chain reaction (PCR) analyses on clinical specimens from patients who are suspected or confirmed to be infected with SARS-CoV-2. In the context of SARS-CoV-2 non-propagative diagnostic work has been extended to cover research and development with SARS-CoV-2 using routine laboratory procedures.

The Commission further stated that the handling of materials with high concentrations of live virus or large volumes of infectious materials should be performed by properly trained and competent personnel in a containment level 3 laboratory with air pressure negative to atmosphere.

Implementation of European Legislation

- European legislation sets down the minimum requirements for the protection of workers. When implementing European legislation, Member States are entitled to adopt more stringent requirements for the protection of their workers should they wish to do so.
- As SARS-CoV-2 has been classified as a risk group 3 biological agent this would normally mean that under Irish law, where it is known or strongly suspected that SARS-CoV2 is present then a containment level 3 laboratory should be used.
- However, in light of the COVID-19 pandemic, Ireland has decided to adopt the European Commission's footnote when implementing this legislation in order to ensure sufficient testing capacity and associated support of the National testing programme.
- The Biological Agents' code of practice will be updated to accommodate the inclusion of SARS-CoV-2. This update will simultaneously take account of Commission Directive (EU) 2019/1833 updating and restructuring the list of biological agents and aligning containment measures with the Genetically Modified Organisms (Contained Use) Regulations 2001 to 2010. The Code of Practice will be subject to the Health and Safety Authority's public consultation process.
- Until finalisation of the code of practice, work involving SARS-CoV-2 must take account of this statement, in line with Regulation 7(1)(e)(v) of the Biological Agents Regulations.
- Note that the concessionary footnote relates only to SARS-CoV-2. For other biological agents that are classified as risk group 3, the Biological Agents Regulations require that where it is known or strongly suspected that a risk group 3 agent is present then containment level 3 measures must be used, irrespective of the laboratory techniques being used and even if there is no intent to propagate the agent.

Minimum Required Containment Measures for SARS-CoV-2

- Laboratories carrying out non-propagative diagnostic work in relation to SARS-CoV-2, for example, sequencing or nucleic acid amplification test [NAAT], may subject to appropriate risk assessment, carry out the work at a minimum of containment level 2.
- Laboratories carrying out research and development in relation to SARS-CoV-2, where the work involves similar non-propagative laboratory work techniques may subject to appropriate risk assessment, carry out the work at a minimum of containment level 2.
- Initial sample processing (before virus inactivation) must take place in a validated Biological Safety Cabinet.
- Any work involving the handling of material with high concentrations of live virus or large volumes of infectious materials must be carried out at a minimum of containment level 3 (BSL-3).
- Propagative work (for example, virus culture, isolation, deliberate propagation or neutralization assays) and animal infection work using SARS-COV-2 must be carried out at a minimum of containment level 3 (BSL-3). Use implies the deliberate/intentional use of the biological agent and must be notified to the Health and Safety Authority. In certain areas of work there may be a transition from non-intentional use to intentional use and in such cases, notification will then be required.
- Further information on notification can be found here. Notifications should be sent only via email (no postal notifications) to bioagents_notif@hsa.ie. When notifying, sufficient information should

be provided about the risk assessment and preventative measures in order to demonstrate that the employer has identified the hazards associated with SARS-CoV-2 in conjunction with the work that is being carried out.

Risk Assessment

- Risk assessments must take into account the published guidance from the World Health Organization (WHO) [1] and any relevant updates.
- Factors to consider in conducting the risk assessment include:
    - the work activity,
    - the volume and concentration/viral titre,
    - the presence of any other biological agents,
    - whether there is potential for exposure – (creation of splashes, droplets or aerosols of infectious materials, spillages etc.),
    - the frequency and duration of exposure,
    - who may be affected by the work - are there vulnerable or sensitive persons who may be particularly affected; and
    - the capability of the staff conducting the work.
- Based on the findings of the risk assessment, it must be determined whether the minimum containment level provides adequate worker protection for the planned work. Enhanced containment measures or a higher containment level may be required based on the outcome of the risk assessment.
- Other factors may also need to be taken account of in conducting the risk assessment, for example, biosecurity.
- The risk assessment must be kept under regular review. The risk assessment must be updated if working conditions change in a way that affects the worker's exposure or if new working equipment, new processes or procedures are introduced.
- In line with Regulation 14(1)(d) of the Biological Agents Regulations, the Authority must be immediately notified of any accident or incident which may result in the release of SARS-CoV-2. Notification can be done via the on-line reporting system. Containment measures and containment levels must be immediately reviewed in the case of a laboratory-acquired infection (LAI).

References

1. World Health Organization: Laboratory biosafety guidance related to coronavirus disease 2019 (COVID-19).