Explanatory Memorandum

The Health and Safety Authority is conducting a targeted consultation on the 2020 Code of Practice for the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 and 2020. This consultation will run from Tuesday 11 August to 5.00pm Friday 28 August 2020.

Reason for Update of the Code of Practice

The code of practice (see attached) is being updated to take account of Commission Directive (EU) 2019/1833 of 24 October 2019 and Commission Directive (EU) 2020/739 of 3 June 2020. These directives amend the original biological agents' directive (Commission Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000) which lays down the minimum requirements for protection of the health and safety of workers exposed to biological agents at work. The implementation date for the directives and this code of practice has been expedited due to the SARS-CoV-2 (COVID-19) pandemic. The implementation date for this code of practice is Tuesday 24 November 2020. Failure to implement European directives by the required timelines can result in Ireland being subject to fines. The code of practice will be supported by an amendment to the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013

Main Changes in the Draft Code of Practice

In this, the third version of the code of practice, the main changes are:

- Addition of definitions, clarifications and guidance.
- Schedule 1 sees:
    - Updates to nomenclature, for example *Actinomyces pyogenes* is now listed as *Truperella pyogenes*
    - Updated taxonomy with viruses now listed according to Order, Family and Genus.
    - Addition of biological agents, for example, the inclusion of *Clostridium difficile*, *Helicobacter* spp., *Aspergillus flavus,* MERS and SARS-CoV-2 viruses.
    - Deletion of some biological agents, for example, Human pegivirus (Hepatitis G virus) and *Mycoplasma caviae*, which are now considered risk group 1 biological agents, have been removed from the list.
    - Changes in classifications, for example, *Rickettsia canadensis (*formerly *R.canada*) was risk group 3* and is now risk group 2, Poliovirus type 2 was risk group 2 and is now risk group 3.

    - Addition of notes to some biological agents, for example, *Streptococcus pneumoniae* is now annotated with V and T (indicating effective vaccine available and registered within the EU and toxin production).
    - Helminths and protozoa, which were separated out in the previous version of the code of practice, are now combined together under parasites, in line with the EU directives.
- Schedules 2 and 3 changes include:
    - Realignment to ensure consistency with each other and with the Genetically Modified Organisms (Contained Use) Regulations 2001 to 2010. For example, containment measures have been restructured, additional headings and definitions added and the word "recommended" is now used in both Schedules.
    - The addition of a new control measure. "Personnel should shower before leaving the contained area" has been added to Schedule 2.
    - Update of descriptions for some containment measures. For example, "the workplace is to be sealable to permit disinfection" is now "the workplace is to be sealable to permit fumigation" and "incinerator for disposal of animal carcasses" is now "validated inactivation process for the safe disposal of animal carcasses".
- Schedule 4 has been updated to reflect nomenclature changes and to include dispensations for diagnostic testing for SARS-CoV-2.

Submissions in Relation to the Code of Practice

You are invited to submit your comments in relation to the code of practice. Submissions should be sent via email to bioagents_notif@hsa.ie. In making your submission, points to consider are:

- European directives set 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. Ireland has implemented the minimum requirements of the European Directives with the exception of the requirement for a biohazard sign at containment level 2 in Schedule 3 of this code of practice, which has been made mandatory - the directive only recommends this measure.

  Are there other containment measures that you believe should be made mandatory?

- Definitions that are defined within the European directives or within Irish law cannot be altered. However, Ireland has added additional definitions to the code of practice in an attempt to improve clarity, for example definition of industrial process, diagnostic work, diagnostic laboratory and isolation facility. Taking account of the definitions:
  Are there definitions in the code of practice that you believe are incorrect or can be improved on?

- Dispensations from minimum containment measures are included in Schedule 4. The dispensations (with the exception of SARS-CoV-2) are carried over from the previous version of the code of practice. In the previous version of the code, the dispensations were based on the dispensations granted by the Health and Safety Executive in the United Kingdom for diagnostic laboratories and animal rooms in the United Kingdom. Taking account of Irish laboratories, the work being carried out within them and the aim for Ireland to be one of the safest countries within the European Union for workers:
  Do you agree with the dispensations? Should additional information be added to ensure improved worker safety?

This consultation is an opportunity for you to have your say with regard to biological agents and contribute to improved worker safety within Ireland. In addition to the above points any general comments, corrections with respect to typographical errors and so on are invited.

The closing date for receiving submissions is 5.00pm on Friday 28 August 2020.