Submissions Received in Relation to the Targeted Consultation on the Code of Practice for the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 and 2020 (The Biological Agents Code of Practice).

Submission 1

From: EHS Officer, Biomarin

I forwarded this to the full biosafety group within IBEC (which should cover off most of the biopharma chem sector)

I have read over same and just wanted to compliment the work- as it's very considered.

Other Relevant Legislation Enforced by Other Departments or Agencies Legislation enforced by other Government Departments and Agencies may also be applicable and may need to be taken account of with respect to biological agents such as the Genetically Modified Organisms (Contained Use) Regulations 2001 to 2010 (S.I. No.73 of 2001 as amended), which is enforced by the Environmental Protection Agency. As legislation is always under regular review, check the status of legislation on the Attorney General's website at www.irishstatutebook.ie.

On the above section just wondering should we add the department of agriculture also – as they have requirements around destruction of animal derived material etc -such as type of inactivation- also requirements around security and access control etc -the 3 key regulators for our sector would be the HSA, EPA GMO section and also the DOA (DAFM). All three have requirements around inactivation etc.

On the 3 key questions posed -I have nothing further to add except to say that the controls in place from Irish regulators are very robust and well thought out to ensure excellent levels of protection.

HSA Response to Submission 1

- Agreed in principle - but after contacting the Department of Agriculture there would appear to be several pieces of legislation that could be included. Believe this is best addressed in guidance with assistance from the Department where required.

Submission 2

From: Biological Safety Advisor, University College Cork

Hello,

Thanks for including me on the consultation list regarding the revised Code of Practice for the Biological Agents Regulations – I have also forwarded it to a number of other interested parties. All seems mostly good to me – thanks for the effort you have gone to! I have the following minor comments:

- Good to see alignment with the GMO containment measures – we have implemented whichever was the more stringent to date.
- P20: suggest changing "…..relevant Genetic Modification legislation….." to "…….relevant genetic modification legislation……"

- P20: suggest changing “principally the Contained Use legislation” to “principally the GMO (Contained Use) Regulations”.
- P20: “Group II GMM” should be “Class 2 GMM”.
- P24: Splitting hairs perhaps but I would remove “and the proper use of PPE” from the vaccination section. As written I think this places too much emphasis on use of PPE as a control measure when it really is a last resort control and not something to be relied upon. It would also, presumably, be covered by the “safe working procedures” referred to immediately prior.
- I have not gone through the agent list in detail but presume it’s in alignment with the EU Directives.
- Schedule 4, point 22: in the context of SARS-CoV-2 dispensations for research and development this refers to “work in direct support of the National testing programme”. However, the HSA final statement on SARS-CoV-2 simply refers to “research and development in relation to SARS-CoV-2” with no qualifiers relating to the work being associated with testing, nor for it to be in “direct support” of the national programme. I think this point should be modified to bring it to congruence with the final statement.

HSA Response to Submission 2

- Noted.
- Agreed - changed to lower case lettering.
- Agreed - reworded to principally the Genetically Modified Organisms (Contained Use) Regulations
- Agreed - terminology corrected.
- Agreed - reworded in line with hierarchy of control.
- Yes the list is as per EU Directive but takes account of typographical errors in the Directive.
- Agreed - work in direct support of the National testing programme removed. Reason for dispensation still remains on page 47.

Submission 3:

From: Irish Congress of Trade Unions

2020 Code of Practice for the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 and 2020

Response to Consultation

Congress welcomes the opportunity to respond to the consultation on the proposed COP for regulations on Biological Agents, and supports the relative urgency with which it is planned to implement it.

We have a number of general observations, and suggestions for some minor changes in the text.

1. With the exception of SARS-CoV-2, we do not see anything to comment on in the organisms’ classifications or containment categories themselves.

2. On the matter of biological containment levels, often when the term “recommended” is in place for measures for containment level 3, it is interpreted as meaning that the measure is an ideal to be aspired to rather than the measure that should be in place if possible / reasonably practicable. It would be in the interests of all employees exposed to biological agents for the code of practice to state that “recommended” means something a bit stronger than an optional extra and that all processes require ongoing risk assessment and access to resources when new risks are identified e.g. arising from emerging pathogens, new technologies or workload increases.

3. In addition, what can also hamper laboratories’ correct adherence to containment measures can be a severe lack of space to separate and segregate different work streams at different containment levels. Diagnostic laboratories in hospitals are often very cramped spaces and space is at a premium in a busy hospital environment. What was sufficient space for the demands of the service when the laboratory was first planned can very quickly become insufficient as technology becomes more elaborate, automation takes up bench space, specimen numbers increase constantly and staff numbers grow to cope with demand. As an example, the urgent need to implement testing for COVID-19 caused huge problems for diagnostic hospital laboratories not just in terms of getting the testing up and running but also in finding the space in which to do it safely. It should be recognised that environments where biological agents are not just present, as is the case throughout the hospital, but are being manipulated and propagated deserve special consideration of the space requirements to operate safely. Behind-the scenes workplaces like clinical laboratories tend to be last on the list for additional space allocation and are expected to just fit new and expanding services into existing spaces but there is a limit to what can be achieved while still maintaining safety.

4. Furthermore, workers in a clinical laboratory cannot eat or drink at their workspace and most provide a 24/7 service with scientists working long hours on call. Staff require access to convenient rest areas where they can take their breaks throughout the day and night. These rest spaces are often seen as luxuries rather than a requirement and they are often the first spaces to be targeted by management when extra laboratory space is required.

5. Congress believes it is essential that the Health and Safety Authority increases inspections of hospital laboratories to ensure that the Code of Practice is implemented properly and also that staff have adequate welfare facilities provided.

6. Congress notes that the proposed COP follows the EC position in relation to the classification of SARS-CoV-2. We regret the decision at European level to classify this as Group 3 rather than Group 4. According to Article 2, Directive 2000/54/EC:

    a. 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;
    b. 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.

    The explanatory note accompanying the draft COP refers to the on-going search for vaccines. However, we do not currently have any vaccine and nobody can predict the effectiveness of whatever may emerge. In our view therefore, there is simply no effective prophylaxis or treatment available and SARS-CoV-2 should have been classified as group 4.

Article 18 further states that *"If the biological agent to be assessed cannot be classified clearly in one of the groups defined in the second paragraph of Article 2, it must be classified in the highest risk group among the alternatives*". The fact that it was not requires that there be a review of the classification system in our view. One of the arguments against a group 4 classification was that it would require too rigid a framework for laboratories to effectively do their work. Yet derogations are always possible, as this Draft COP itself demonstrates.

7. Finally, we have only one minor amendment to suggest in the text. This relates to Part 4 – Notification and Record-keeping (Regulations 14 and 15) where employer responsibilities are listed, page 13 of the current document. At bullet point 3 we would suggest that the phrase "resulting in a release" be deleted. This would both avoid any ambiguity about what constituted a "release" and also confer a broader obligation to report any incidents that could cause serious illness.

August 2020

HSA Response to Submission 3:

1. Noted.
2. Agreed - the HSA also has concerns that there is often a tendency to risk assess downwards to suit the facilities available and agree with the strengthening of wording. The wording "should in principle" has been replaced by the word "must" and the word "indicate" has been changed to "prove" in both Schedule 2 and 3.
3. Noted - the workplace and requirements for space are legally covered under Chapter 1 Part 2 of the Safety, Health and Welfare at Work (General Application) Regulations 2007 to 2020 (S.I. No. 299 of 2007) rather than under the Biological Agents' Regulations. This should be addressed in laboratory guidance for biological agents (design, review of risk assessment etc.).
4. Noted - legal requirements regarding welfare and rest areas already exist. Regulation 9(a) of the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 requires that employees do not eat or drink in any location within a place of work where there is a risk of contamination by a biological agent. This reinforces Regulation 18(f) of the Safety, Health and Welfare at Work (General Application) Regulations 2007 to 2020 (S.I. No. 299 of 2007) which prohibits the taking of meals at any location in the place of work where there is likely to be a risk to safety, health or welfare. Whilst Regulation 19 covers rest rooms and rest areas. As the code does not only apply to laboratories, this would best be addressed in laboratory guidance for biological agents (design and welfare).
5. Noted - the Authority's intent is to prepare specific laboratory guidance for biological agents in conjunction with interested parties. On completion, an inspection programme would follow to promote the guidelines.
6. Noted - the classification was agreed at EU level and will remain as a risk group 3 biological agent in line with fellow Member States. Derogations are usually only provided for risk group 3* biological agents but a special dispensation on foot of the pandemic was provided for SARS-CoV-2. A derogation would never be granted for a risk group 4 agent to be handled at containment level 2. Although a vaccine does not exist for this disease (note: the explanatory memo does not refer to this – possibly the submission is referring to point 10 of the preamble to the directive?) there are prophylactic measures that can be taken to prevent the disease such as social distancing, good hygiene procedures and correct use of personal

protective equipment. The mortality rate is mainly in susceptible persons or persons with pre-existing conditions. The risk group classification criteria are based on the effect on healthy workers only, although it may be a serious hazard to elderly workers and those with underlying medical conditions or chronic disease. A risk group 4 biological agent is an agent that would produce life-threatening disease in all infected. SARS-CoV-2 does not result in all infected persons developing signs and symptoms of the disease. It should be noted that Ireland does not have any appropriate containment level 4 laboratory or healthcare facilities, which are highly specialized facilities.

7. Noted - this wording reflects the legal wording within the Biological Agents Regulations.

Submission 4

From: Environmental Protection Agency

Schedules 2 and 3 have been updated and realigned to ensure consistency with each other and the GMO (Contained Use) Regulations 2001-2010

I refer in particular to Schedule 2.
Containment measure no 13 refers to the "validated inactivation process for the safe disposal of animal carcasses" but this does not cover the inactivation of biological waste in general, particularly with regard to RG3 and RG4 contaminated waste.
Therefore I think schedule 2 would benefit from the inclusion of a measure covering the inactivation of contaminated material and waste, (similar to measure no 17 in Table 1A "Containment measures for contained use of GMMs in a lab" under Part B of the Fourth Schedule of the GMO (Contained Use) Regulations, 2001-2010 - attached) since waste from high risk group activities in particular cannot be removed off site without first being inactivated. For the purposes of facilitating inactivation I would suggest the inclusion of a measure covering the availability of an autoclave under equipment.

I would also suggest the inclusion of measures to cover the following:

- Suitable protective clothing be worn, including gloves and glasses where the risk assessment shows it to be required;
- The use of biohazard signs

Finally, the inclusion of a clarification that nominated workers are trained workers.

I note that the above mentioned measures are not in Directive 2019/1833 and perhaps there is a reason for that but I think their inclusion would help to strengthen national legislation and provide workers with increased protection.

Table 1A

Containment measures for contained use of genetically modified

micro-organisms in a laboratory

Measures		Containment levels			
		1	2	3	4
1	Laboratory suite: isolation	Not required	Not required	Required	Required
2	Laboratory: sealable for fumigation	Not required	Not required	Required	Required
Equipment					
3	Surfaces resistant to water, acids, alkalis, solvents, disinfectants, decontamination agents and easy to clean	Required for bench	Required for bench	Required for bench and floor	Required for bench, floor, ceiling and walls
4	Entry to laboratory via airlock	Not required	Not required	Optional	Required
5	Negative pressure relative to the pressure of the immediate environment	Not required	Not required	Required	Required
6	Extract and input air from the laboratory should be HEPA-filtered	Not required	Not required	Required	Required for input and extract air
7	Microbiological safety cabinet	Not required	Optional	Required	Required
8	Autoclave	On site	In the building	En suite	Double-ended autoclave in laboratory
System of work					
9	Restricted access	Not required	Required	Required	Required
10	Biohazard sign on the door	Not required	Required	Required	Required
11	Specific measures to control aerosol dissemination	Not required	Required to minimise	Required to prevent	Required to prevent

12	Shower	Not required	Not required	Optional	Required
13	Protective Clothing	Suitable protective clothing	Suitable protective clothing; footwear optional	Suitable protective clothing and footwear	Complete change of clothing and footwear before entry and exit
14	Gloves	Not required	Optional	Required	Required
15	Efficient vector control (e.g. for rodents and insects)	Optional	Required	Required	Required

Measures		**Containment levels**			
		1	2	3	4
Waste					
16	Inactivation of genetically modified micro-organisms in effluent from hand-washing sinks or drains and showers and similar effluents	Not required	Not required	Optional	Required
17	Inactivation of genetically modified micro-organisms in contaminated material and waste	Optional	Required	Required	Required
Other Measures					
18	Laboratory to contain its own equipment	Not required	Not required	Optional	Optional
19	Observation window or alternative to enable occupants to be seen	Optional	Optional	Optional	Required

For the purpose of this Table:

(1) In measure 1, "isolation" means that the laboratory is separated from other areas in the same building or is in a separate building.
(2) In measure 4, "airlock" means that the entry must be made through a chamber isolated from the laboratory. The clean side of the airlock must be separated from the restricted side by changing or showering facilities, or by interlocking doors.
(3) In measure 5, "negative pressure relative to the pressure of the immediate environment" is only required for a class 3 contained use where airborne transmission can occur.
(4) "HEPA" means high efficiency particulate air.
(5) In measure 6, where viruses which are not capable of being retained by HEPA filters are used in class 4 contained use, extra requirements shall be provided for extract air.
(6) In measure 8, "en suite" means that where the autoclave is located outside the laboratory in which the contained use is being carried out but within the laboratory suite, validated procedures shall be in place to ensure the safe transfer of material into the autoclave and to provide a level of protection equivalent to that which would be achieved if the autoclave were in the laboratory.

HSA Response to Submission 4

- Noted - the realignment is principally in the headings and the associated layout. This Schedule's focus is principally on containment and not all available prevention measures. As the schedule also applies to animal rooms, veterinary and healthcare isolation rooms, changing the schedule may impact on these other areas. The Authority is of the opinion that the issues raised are best addressed in guidance.

Submission 5

From: Head of Safety, Trinity College Dublin

28th Aug 2020

Re: Feedback on the Draft of Code of Practice for the Safety, Health and Welfare at Work (Biological Agents) Regulations 2020

In reference to your email dated 11th Aug 2020 whereby Health and Safety Authority was seeking targeted consultation on the updated Code of Practice for the Safety, Health and Welfare at Work (Biological Agents) Regulations, please find herewith comments on the draft of the code of practice.
Under Schedule 3 of the Code of Practice -we would like to see more specifics in relation to the waste handling, especially with high risk organisms such as SARS-CoV-2. Inactivation and disposal down any sink are not sufficient methods.
We have advised our researchers that all work that is being carried out on SARS-CoV-2 must either dispose deactivated liquid waste directly to a municipal drain or through a waste stream with a registered waste provider. Explanation: *Microbial trafficking occurs in wastewater pipe networks in biofilm, in air currents travelling behind liquid waste being discharged down pipework and in air currents generated when partial vacuums are generated behind columns of discharged liquid. Air currents can also be caused from distant wastewater pipework in the municipal system. It happens all the time in wastewater networks and is a known mechanism of dispersal of pathogenic microbes around wastewater networks. Many hospital outbreaks have developed in this way.*
Pouring bleach down traps has very little effect on biofilms resident in wastewater drains, traps and pipes and a lot of components are not impacted by bleach in the first place.

*If a **wastewater network** from a lab is physically connected to other rooms and laboratories, microorganisms will traffic. Wastewater networks are generally not considered when designing laboratories or in hospitals. The result is that people get infected.*

In addition, the following comments are suggested together with highlights within the draft documents (attached):
On page 18, Section Minimum Containment Levels and the lines which have been highlighted in the attached document: There is a query regarding the Minimum Containment Levels requirement, i.e. CL3 is required for handling risk group 3 organisms. Non propagative work of SARS-Covid-2 was allowed in CL2 previously, is it still valid now? If not, then most of the diagnostics works/non-propagative work in most universities/institutes which have predominantly CL2 facilities, may have issues in continuing research. As per the most recent HSA statement regarding SARS-Covid-2, propagative work could be done in CL3 with -VE PRESSURE but the paragraph of Minimum Containment Levels requirements creates confusion and needs clarification.
Page 45: Equipment, second row, it was stated by HSA that propagative work must be carried out at CL3 lab with -ve pressure. The present statement of this draft which says the controlled area should be maintained at an air pressure negative to atmosphere as Recommended. This statement creates confusion.
Page 49, the statement on *Mycobacterium microti*, which needs CL3, should be highlighted.
Page 2 of Explanatory Memorandum: The addition of a new control measure. "Personnel should shower before leaving the contained area" has been added to Schedule 2. Is it that all CL3 must have shower systems? Although this will is an extra safety measure it may not be feasible for all universities and institutes to have the shower systems now to commence work. Can this be clarified?
In addition, is it possible to mention/include 'research work/activities' wherever they talk about diagnostic work for COVID-19), for example on Page 43: (This special dispensation is primarily in order to ensure sufficient testing capacity and continuity of testing *and research activities)*.
If you require any clarifications on our comments, please do not hesitate to contact me.

HSA Response to Submission 5

- Noted - Schedule 3 is for industrial processes as defined. "Effluent from sinks and showers should be collected and inactivated before release" refers to waste water from wash hand basins and showers being collected. Clarification on this schedule is best addressed in guidance.
- Noted - the derogation is for non-propagative laboratory work techniques. It is for SARS-CoV-2 only and not a blanket derogation for all biological agents and non-propagative work in general.
- Agreed – additional sentence added in under minimum containment levels page 18-19, namely "Schedule 4 of this code details where appropriate dispensations for laboratories and animal rooms from minimum containment measures for specified biological agents. The use of any such dispensation must be subject to a full and thorough risk assessment".
- Noted - page 45 relates to industrial processes and not laboratories. The biological agent is contained in a closed system for example, a fermenter. The fermenter is then located within a controlled area which is under negative pressure. There is no dispensation for SARS-CoV-2 and industrial processes.
- Agreed - page 49 relevant sentence has been underlined as dispensation is for animal rooms only.
- Noted – for places of work that are already operational it would not be expected that showers be installed. However, if introducing new agents, the risk assessment should identify whether

shower facilities are required and if not in situ and are required, then work with that agent should not commence.

- Disagreed – the special dispensation for SARS-CoV-2 was only made because of the pandemic (see point 7 Commission Directive (EU) 2020/739). This agent is a risk group 3 biological agent and would have no dispensation except there is an on-going pandemic. The dispensation is not for all research and development work using SARS-CoV-2 and is only for research using non-propagative laboratory work techniques and this is subject to risk assessment. Where large volumes of infectious material or material with high concentrations of virus are being used then containment level 3 must be used. Page 6 has been reworded but not as suggested.

Submission 6

From: Biological Safety Committee, Dublin City University

B.S.C. Feedback: 19.08.2020

General Comments:

1. The amendment to the Safety, Health and Welfare at Work Act (Biological Agents 2013; S.I. no 572 of 2013) is welcome, especially due to the current global pandemic - and with more research groups undertaking laboratory-based work to elucidate the mechanisms involved in the pathogenicity of the SARS-CoV-2 virus. Notably, in the precursor document, members of the Family *Coronaviridae* (subfamily *Coronavirinae*) were assigned to Hazard Group 2 (HG2), while members of the Genus *Betacoronavirus*, including SARS-related Coronavirus, were identified as falling into HG3. It is important to note that, in this updated document, SARS-CoV-2 (the biological agent; Family *Coronaviridae* and Genus *Betacoronavirus*) remains classified as a HG3 biological agent, e.g. one that can cause severe human disease and presents a serious hazard to employees, and may present a risk of spreading to the community; though there is usually effective prophylaxis or treatment available. This aligns with recommendations from companion entities, such as the U.K. Advisory Committee on Dangerous Pathogens (ACDP).
2. Specific to this, and with the potential for different strains of Coronavirus and related viruses to be identified, the inclusion of a more comprehensive taxonomic system, comprising the detailing of Order, Family and Genus, is most welcome – and makes sense to incorporate.
3. With reference to proposed research on SARS-CoV-2, and from the perspective of (redacted), it is important to note **recommendations 21-24**, inclusive, which state:

- 21: Non-propagative diagnostic laboratory work (for example sequencing, nucleic acid amplification test [NAAT]), involving SARS-CoV-2 subject to written risk assessment, can be conducted at a facility using procedures equivalent to at least containment level 2. Heightened control measures may be required based on the written risk assessment.
- 22. Research or development work in direct support of the National testing programme using non-propagative laboratory work techniques may be carried out at minimum of containment level 2 subject to written risk assessment and heightened control measures where required.
- 23. Handling of materials with high concentrations of the live virus or large volumes of infectious materials must be carried out at containment level 3.
- 24. Propagative work (for example, virus culture, isolation or neutralisation assays) involving SARS-CoV-2 must be conducted at a containment level 3 laboratory with air pressure negative to atmosphere.

It is imperative to emphasise that activities pertinent to recommendations 23 and 24 would not be supported by Containment Levels (CL) currently accessible in (redacted), where laboratories primarily fall into the CL2 category. Therefore, the undertaking of projects involving live virus or propagative work in would be, in my opinion, inadvisable. Furthermore, it would be imperative for all COVID-related projects to undertake **rigorous biohazard/operational Risk Assessment** as part of a formal Biological Safety Committee (BSC) submission, in the event that they satisfy the requirements of recommendations 21 and 22.

4. In support of the above point, the inclusion of clear guidance on **minimum** Containment Level definition and critically – **what HG can be accommodated within; adhering to a Safe System at Work** – is a very welcome addition. While a Risk Assessment would typically direct this, clear guidance is a very useful tool in formulating a laboratory-based workplan.
5. The definitions content is more comprehensive than in the precursor document (Biological Agents 2013; S.I. no 572 or 2013), and this is another welcome addition. Here, definitions primarily focussed on components such as (1) authority, (2) biological agents, (3) cell culture, (4) micro-organism, (5) PPE and (6) spp. (species), so it is positive to note the inclusion of additional definitions of key importance, specific to the use of biological agents, such as animal room, containment measures, controlled area, HEPA, opportunistic infection and prophylaxis etc. as such definitions align well with current laboratory practices involving the use of biological agents. In parallel to this, it is encouraging to see that key definitions remain largely

unchanged, e.g. for Biological Agents, Hazard Group (HG) containment levels and PPE (personal protective equipment).

6. Specific to bacterial pathogens, and given the importance of understanding the mechanisms of disease associated with emerging strains such as *Clostridium difficile* through the undertaking of laboratory work, it is very welcome to see the classification of a new cohort of bacterial biological agents, in addition to fungi (e.g. *Aspergillus spp.*). Here, *C. difficile* is assigned to HG2 (e.g. one that can cause human disease, and might be a hazard to employees – although it is unlikely to spread to the community – and effective prophylaxis is available). It is noted that where applicable, the presence of an available vaccine is flagged, alongside where the biological agent is a producing strain of a toxin. Again, this is very helpful. (redacted) comment on toxins (e.g. substances that are toxic, and of biological origin) is correct, in that they are not specifically biological agents, but producing bacterial (*e.g. Clostridium botulinum spp*.) and fungal strains would fall under this remit.
7. The inclusion of additional guidance on undertaking Risk Assessments with biological agents in facilities such as animal rooms (Regulations 16 and 17) is informative, and directly relevant to work undertaken at DCU.
8. There are some amendments to HG classification, but the species of interest do not appear to be relevant to work that is currently being undertaken at DCU.

Recommendations:

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

1. Yes. Here, it may be useful to discuss in more detail guidelines pertinent to the **shipping** of biological samples containing SARS-CoV-2. It would be reasonable to assume that this material would fall into a Category A material, identified by Packaging Instruction PI620. In the event that projects are approved where samples are to be sent to laboratories with the correct level of containment, having clear guidelines on this would be useful, on the basis that capturing this information is within the scope of this (updated) Code of Practice.
2. While not specifically-related to containment, it may also be useful to mention the relevance of ensuring that disinfectants selected to clean areas where laboratory work is to be undertaken (where there is a risk of SARS-CoV-2 presence) should comply with EN 14476 (the standard used to determine the virucidal properties of disinfectants, through a quantitative suspension test), or EN1276 (for bacterial) or EN 13697 (for fungi).

Are there definitions in the code of practice that you believe are incorrect or can be improved on?

1. As stated above, it's reassuring to see additional definitions included, and that key definitions remain largely unchanged, specific to the previous version of this document. My only recommendations would be to expand on **animal room** to include **animal facility**, given the inclusion of additional information on undertaking work in such facilities – which is a welcome addition.
2. While the definition of Genetically-Modified Organism is alluded to (on page 9), and referenced correctly with the correct (contained use) guidelines (S.I. no 73 of 2001; 442 of 2010), it may be useful to include this here; e.g. those in which genetic material is altered in such a way that does not occur in nature, e.g. through mating, natural recombination or both.

Do you agree with the dispensations? Should additional information be added to ensure improved worker safety?

1. The guidelines provide guidance on minimum containment levels to be implemented, which makes sense. Specific to work involving SARS-CoV-2, it is absolutely correct to highlight that **dispensation does not mean that work can automatically be carried out at containment level 2**, and that in order to ensure compliance, a Risk Assessment must be conducted.
2. In support of this point, it may be important to state that in the case of work to be undertaken with SARS-CoV-2 (and related biological agents, of course), that all activities must only be initiated subject to approval from a local Biological Safety Committee, such as that residing in [redacted].

oOo

HSA Response to Submission 6 (Section Above)

• Noted - comments are noted. • Noted - the code of practice supports the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013. The Carriage of Dangerous Goods by Road cover the shipping of such agents. The code would not deal with specific details on shipping for specific agents. This would be covered best in guidance or advice from a DGSA may be required. • Noted - this is best addressed in guidance specific for laboratories. • Noted - the inclusion of animal facility is a broader definition than that of the Directive. More research would be required prior to including this and due to time restraints this is currently not feasible.
• Agreed - Definition expanded on. • Noted – comments are noted. • Noted - not all places of work will have a biological safety committee. This is a legal requirement under GMO legislation. This would best be addressed as a local rule or in a guidance for laboratories.

Reviewer 1

Comments on the draft 2020 Biological Agents' Code of Practice

Definitions

Decontamination: insert 'of' after 'reduction' to improve the clarity of this sentence.

Also, it would be helpful if the document contained an explanatory note on what is meant by 'reduction to a level that does not pose a risk to health'. How is this level determined for different Biological Agents?

A similar note could be included to clarify disinfection to a level that they no longer pose a risk of infection

Fumigation: uses a different statement that is not aligned with that used for decontamination, despite being a form of the latter.

Also, in the definition of fumigation, 'atmosphere' is used to refer to (presumably) the enclosed environment within the contained area but later, in Schedule 2, the same word is used to refer to the environment outside the contained area. Such ambiguity is confusing.

Toxins: the statement should include a reference to toxins produced by genetically-modified organisms, which may not be natural products.

General

The section on unlisted Biological Agents is very welcome, especially with respect to identifying that Risk Group 1 is not the default for unlisted agents and the strengthened statement on the need for risk assessment to determine classification.

Risk Assessment (p20)

This section should include 'Containment level 2 plus measures usually only applied at higher containment levels' as an alternative to upgrading classification fully to level 3. Although this might seem to be implicit throughout the document, in many references to the specified containment measures for each containment level being the minimum requirements, it is never explicitly stated as an option.

I am unclear on the statement "Employees or their safety representatives must have access to the collective information in the occupational exposure list provided the information is not identifiable to any one employee"

HSA Response to Submission 6 (Reviewer 1 Comments):

- Agreed – but definition changed on foot of other comments. Due to the wide range of biological agents it would be impossible to include the determination of level. The risk assessment for the agent should consider disinfection and ensure there is a validated means of disinfection.
- Agreed - terminology for decontamination, disinfection and fumigation changed.
- Noted - the code relates to the biological agents regulations. GMMs are regulated by the EPA. In conducting a risk assessment, the employer must take account of toxic effects and this would relate to taking account of genetically modified micro-organisms and any toxic effects.

- Noted - comments are noted.
- Disagreed - there is no such level as containment level 2 plus. Page 6 refers to the employer must determine whether the minimum containment level and containment measures provide adequate worker protection for the planned work or whether enhanced or heightened control measures or a higher containment level is required.
- Noted - this means that employees and safety representatives have access to anonymised date, for example, 5 people are working with SARS-COV-2, the average exposure time is ….etc. but names of the people are not given. This can be addressed further in guidance.

Reviewer 2

It is noted that toxins of biological origin are not considered "biological agents" for the purposes of the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013, which provide the following definition:

"biological agent" means 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, classified into 4 risk groups according to their level of risk of infection.

HSA Response to Submission 6 (Reviewer 1 Comments):

- Noted - the Biological Agents Regulations refer to biological agents, which may provoke toxicity. So the toxic potential of the agent must be considered in written risk assessments. Where the toxin is not associated directly with the agent it falls under the Safety, Health and Welfare at Work (Chemical Agents) Regulations 2001 and 2015.

Reviewer 3

I welcome the updates to the list of classified biological agents (Schedule 1), updates to minimum containment measures for labs including diagnostic labs, animal rooms and animal isolation facilities (Schedule2). The mandatory requirement for a biohazard sign at containment level 2 and the additional definitions to the CoP that improve clarity of the document are noted.

I welcome notes 21-24 in relation to dispensations and requirement for risk assessment and agree with the dispensations from minimum containment measures for diagnostic testing for SARS- Cov-2 that are included in Schedule 4.

HSA Response to Submission 6 (Reviewer 1 Comments):

- Noted - comments are noted.

Submission 7

From: Individual

A chara,

Thank you for extending the deadline for submissions. My main concern is the use of the word "exposure". It is used in a number of different contexts and can cause confusion. The phrase "deliberate or incidental exposure" "intentional or deliberate exposure" is used throughout the document. To me deliberate or intentional exposure suggests a deliberate or intentional action to expose an individual e.g. bioterrorism. It is explained on page 9 that this refers to working directly

with a biological agents. However it would avoid confusion if this was the phrase use e.g. "The deliberate intention to work with a biological agent."

I have worked as a microbiologist over many years and as manager of CL3 facilities. If someone is exposed to a biological agent of any group it is classed as a serious incident and investigated appropriately.

I am happy to discuss this with you at any time.

HSA Response to Submission 7

Noted - intentional exposure could be taken as relating to biosecurity and malicious intent to release a pathogen. However, as explained in section 2 of the code these definitions are for the Biological Agents Regulations and the Biological Agents' code of practice only and selected terms are explained in that context. The term exposure is used in the Biological Agents Regulations and the EU Directive. Regulation 3(1) of the Biological Agents Regulations refers to …apply to activities where existing or potential, whether deliberate or incidental, exposure to a biological agent has occurred or may occur. The European Agency for Safety and Health also refer to exposure, intentional and unintentional exposure. As the terms are used widely throughout occupational health and safety, the terminology will not be changed.

Submission 8

From: Comments from Department of Agriculture, Food and the Marine Laboratories on the Draft 2020 Code of Practice (Biological Agents) Regulations 2013 and 2020 as requested by the Health and Safety Authority via email on the 12th August 2020

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

In schedule 2 page 43, specific mention of biosafety cabinets and decontamination of clinical waste by autoclaving should be included- see below under point 3.c. with other suggestions.

2. **Are there definitions in the code of practice that you believe are incorrect or can be improved on?**

Page 18 bullet 4: The definition of CL2 in the form presented is ambiguous and contradicts the first bullet point with reference to CL2. A CL2 diagnostic laboratory may and will intentionally amplify a RG 2 agent for diagnostic purposes but should not intentionally amplify a RG3 (or higher) agent. We suggest a wording along the following lines which are paraphrased from BMBL5 and the Australian/ new Zealand standard **(ref 1& 2 - see appendix 1 for BMBL5 & Aus/NZ text)** .

CL2 containment: Practices, equipment, and facility design and construction are applicable to clinical, diagnostic, teaching, and other laboratories in which work is done with the broad spectrum of indigenous moderate-risk agents that are present in the community and associated with human disease of varying severity (e.g. Risk Group 2 microorganisms). With good microbiological techniques, these agents can be used safely in activities conducted on the open bench. Procedures with aerosol or high splash potential that may increase the risk of such personnel exposure must be conducted in primary containment equipment, or in devices such as a BSC or safety centrifuge cups. Personal protective equipment should be used as appropriate, such as splash shields, face protection, gowns, and gloves. P*ropagation and culture manipulation of RGs higher than RG2 (e.g. mycobacterium bovis) are performed at higher containment.*

Page 35 genus influenzavirus A (H5) : note that some Eurasian strains of highly pathogenic avian influenza (HPAI) virus of the subtype H5 are not considered zoonotic, e.g. the H5N8 and H5N6. We recommend that they are included as ** or dispensations from minimum containment measures indicated. Should the zoonotic risk change, appropriate additional containment measures can be applied as identified by risk assessment.

3. Do you agree with the dispensations? Should additional information be added to ensure improved worker safety?

Two areas that should be considered in dispensations in the code of practice or noted as guidance are the containment requirements for the receipt and handling of diagnostic samples in clinical laboratories and the containment requirements for necropsy rooms. Paragraphs **on receipt of samples** and **necropsy rooms** below are paraphrased from the referenced documents. *Text in Italics are our additions for clarity*.

a. Receipt of samples (see ref 2)

Clinical laboratories, especially those in health care facilities and medical *& veterinary* diagnostic laboratories receive clinical specimens with requests for a variety of diagnostic and clinical support services. Typically, the infectious nature of clinical material is unknown, and specimens are often submitted with a broad request for microbiological examination for multiple agents (e.g. samples submitted for "routine," acid-fast, and fungal cultures). Except in extraordinary circumstances (e.g. *certain suspected RG3 & 4 agents*), the initial processing of clinical specimens and identification of isolates can be done safely at BSL-2. Primary barriers such as BSCs (Class I or II) should be used when performing procedures that might cause splashing, spraying, or splattering of droplets *whereas propagation and culture manipulation of RGs higher than RG2 (e.g. mycobacterium bovis) are performed at higher containment as determined by risk assessment.*

b. Animal Necropsy Facilities (see ref 3):

Animal necropsy facilities: Animal necropsy facilities can function at BSL-2 with an option for BSL-3 practices when warranted by a case-by-case risk assessment (considering, for example availability of Class II biological safety cabinet (BSC) and downdraft necropsy tables) and appropriate PPE, such as eye and face protection). The attending pathologist, is responsible for risk assessment and for consideration of limited necropsy procedures and subsequent acceptable risk level to personnel before each necropsy. Use of necropsy facilities with engineering controls such as class II BSCs *(or down drafts)* should be considered where practical for small animal necropsies of carcasses with suspected zoonotic agents and as indicated by a case-by-case risk analysis. However, because necropsy of large animal carcasses suspected to be infected with zoonotic agents is not practical in BSCs therefore appropriate PPE, practices and, where practical, engineering controls developed through risk analysis and on a case by case basis where appropriate, should be applied.

c. Minimum Containment requirements :

Would suggest addition of the following where appropriate

	BSL 1	BSL 2	BSL 3	BSL 4

Biosafety cabinet		Yes (Class I or II)	Yes (Class I or II or III)	Yes (class II or III)
Liquid waste capture & treatment			Yes	Yes
Personnel Change room at containment boundary			Yes	Yes
Shower Available at boundary of containment facility			Recommend (YES for animal facility)	yes
Liquid disinfectant present in U-bends or P-traps (sinks /drains)		recommend	Yes	yes
Backflow prevention (liquid, gas lines)			recommend	yes
Windows			Sealed and closed	Sealed and closed
Sewer & vent lines protected by HEPA or similar hydrophobic filters			Recommend (as required by risk assessment)	Yes
Single pass (no recirculation of air)		recommend	yes	Yes
Pressure gradient/pressure cascade			yes	yes
Autoclave or other similar validated for waste treatment (needs to go with point (13) page 43		Yes (on or off site)	Yes – autoclave at containment boundary of lab	Yes – autoclave at containment boundary of lab
Staff Welfare area (e.g. WC, drinking water, rest away from lab, etc.)			Recommend	Yes

4. <u>Further comment</u>

More clarity is required in Introduction on which directive it refers to in the text.

<u>References:</u>

1. Australian New Zealand Standard 2243.3-2002 Safety in Laboratories; Microbiological aspects of containment facilities. : section 4.2

2. Biosafety in Microbiological and Biomedical Laboratories , 5th Edition

3. CDC: 2012- Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories: Recommendations of a CDC-convened, Biosafety Blue Ribbon Panel; Centres for Disease control and Prevention- Morbidity and Mortality Weekly Report MMWR Supplement vol. 61

APPENDICES

Appendix 1 Definition of CL2 (containment level 2)

Comment 2.1 –

- Definition from the Australian New Zealand Standard 2243.3-2002 Safety in Laboratories - Microbiological aspects of containment facilities. : section 4.2

PHYSICAL CONTAINMENT LEVEL 2 (PC2)
This level of facility with its practices and equipment is applicable to clinical, diagnostic, Industrial, teaching and other premises where work is carried out with microorganisms or Material likely to contain microorganisms which may be present in the community, where the microorganism may be associated with animal, plant or human disease of moderate severity, e.g. Risk Group 2 microorganisms. With good microbiological techniques, work with these agents may be carried out on the open bench. If there is a significant risk from the production of aerosols, a biological safety cabinet shall be used.

- Definition from BMBL 5 (Biosafety in Microbiological and Biomedical Laboratories , 5th Edition

Biosafety Level 2 practices, equipment, and facility design and construction are applicable to clinical, diagnostic, teaching, and other laboratories in which work is done with the broad spectrum of indigenous moderate-risk agents that are present in the community and associated with human disease of varying severity. With good microbiological techniques, these agents can be used safely in activities conducted on the open bench, provided the potential for producing splashes or aerosols is low. Hepatitis B virus, HIV, the salmonellae, and *Toxoplasma* spp. are representative of microorganisms assigned to this containment level. BSL-2 is appropriate when work is done with any human-derived blood, body fluids, tissues, or primary human cell lines where the presence of an infectious agent may be unknown. (Laboratory personnel working with human-derived materials should refer to the OSHA *Bloodborne Pathogen Standard* 2 for specific required precautions).

Primary hazards to personnel working with these agents relate to accidental percutaneous or mucous membrane exposures, or ingestion of infectious materials. Extreme caution should be taken with contaminated needles or sharp instruments. Even though organisms routinely manipulated at BSL-2 are not known to be transmissible by the aerosol route, procedures with aerosol or high splash potential that may increase the risk of such personnel exposure must be conducted in primary containment equipment, or in devices such as a BSC or safety centrifuge cups. Personal protective equipment should be used as appropriate, such as splash shields, face protection, gowns, and gloves.

Secondary barriers such as hand washing sinks and waste decontamination facilities must be available to reduce potential environmental contamination.

Appendix 2 **Sample Reception/ Sample handling**

- From BMBL 5 (Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th Edition

CLINICAL LABORATORIES

Clinical laboratories, especially those in health care facilities, receive clinical specimens with requests for a variety of diagnostic and clinical support services. Typically, the infectious nature of clinical material is unknown, and specimens are often submitted with a broad request for microbiological examination for multiple agents (e.g., sputa submitted for "routine," acid-fast, and fungal cultures). It is the responsibility of the laboratory director to establish standard procedures in the laboratory that realistically address the issue of the infective hazard of clinical specimens.

Except in extraordinary circumstances (e.g., suspected haemorrhagic fever), the initial processing of clinical specimens and serological identification of isolates can be done safely at BSL-2, the recommended level for work with bloodborne pathogens such as HBV and HIV.

The containment elements described in BSL-2 are consistent with the OSHA standard*, "Occupational Exposure to Bloodborne Pathogens."* This requires the use of specific precautions with **all** clinical specimens of blood or other potentially infectious material (Universal or Standard* Precautions).Additionally, other recommendations specific for clinical laboratories may be obtained from the Clinical Laboratory Standards Institute (formerly known as the National Committee for Clinical
Laboratory Standards).

BSL-2 recommendations and OSHA requirements focus on the prevention of percutaneous and mucous membrane exposures to clinical material. Primary barriers such as BSCs (Class I or II) should be used when performing procedures that might cause splashing, spraying, or splattering of droplets. Biological safety cabinets also should be used for the initial processing of clinical specimens when the nature of the test requested or other information suggests the likely presence of an agent readily transmissible by infectious aerosols (e.g., *M. tuberculosis*), or when the use of a BSC (Class II) is indicated to protect the integrity of the specimen.

HSA Response to Submission 8

- Noted – point 3 in schedule 2 refers to safety cabinet which is defined in the definitions as a biological safety cabinet. This schedule also applies to other sectors such as healthcare so an autoclave would not be applicable to all.
- Noted - the referred to “definition” of CL2 is not actually a definition. This is a specific Regulation within the biological agents regulations and comes from the EU Directive. The first bullet refers to handling a known group 2 biological agent whilst the fourth bullet point refers to handling material where it is not known whether such an agent is present and there is no intention to grow a specific known agent.
- Noted – the wording is from the EU Directive – Ireland can increase risk group classifications but cannot decrease risk group classification. This addition refers to “Highly Pathogenic Avian Influenza Viruses HPAIV (H5), e.g. H5N1” – as an example is given this means it does not include all strains of this subtype so if there are strains that are not pathogenic then they are excluded.

- Noted – this would be best covered in guidance. Subject to legal opinion, the Authority would consider that necropsy rooms do not fall under the definition of animal room or veterinary care and would instead fall under the general requirements of the Biological Agents Regulations rather than the schedules.
- Noted – schedule 2 also applies to animal and human isolation rooms so modifying the schedule to cover further laboratory requirements would dilute the essential containment measures. Further prevention measures can be covered in guidance for laboratories for example – design criteria for laboratories.
- Agreed – reworded as amending directives.