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February 9, 2015

USDA Animal and Plant Health Inspection Service

Re: Request for Comments on the Drafted Table of Contents of the Agriculture Biosafety/Biocontainment Manual (AgBMBL) – a companion to the NIH/CDC publication, “Biosafety in Microbiological and Biomedical Laboratories”

The American Biological Safety Association (ABSA) is an international group of biological safety professionals and is known as one of the world's foremost resources on biological safety practices. Member of ABSA have reviewed the Drafted Table of Contents of the AgBMBL and have the following comments.

- ABSA appreciates that the development of the AgBMBL will be collaborative and involve stakeholders and other knowledgeable persons.

Introduction:

- In the introduction, we recommend that the title of the section on history is changed to “History of Agriculture Biosafety and Biocontainment” and include information about the American Biological Safety Association (ABSA) involvement.
- Please include in the critical definitions the definition of biohazard, veterinary/farm/production biosecurity, medical surveillance, and respiratory protection.
- Please include in the introduction a section on ethics and responsibility.
- It will be extremely important to define the different ways in which the term “biosecurity” is used. The introduction might be a good place to set the standard for less confusing terminology by creating specific definitions for example, Veterinary Biosecurity, Plant Biosecurity, Criminal Biosecurity, etc.

BioRisk Analysis:

- For the introductory topic of biorisk management, we suggest referencing the “CEN Workshop Agreement” instead of including a section or chapter on it.
- We recommend that the biorisk management section included a template or fill-able form.
- For biorisk analysis, biorisk assessment we suggest including a section that covers human and/or animal health risk (zoonotic pathogens), economic risk (zoonotic and/or strict animal pathogens, plant pathogens, plant pests, GMOs), and security risk (select agents, DURC).
- Also, please add to biorisk assessment the concept of “One Health”.
- Please add to risk criteria, the risk criteria for insect/arthropod vectors of disease.
- Include individual risk vs public health risk vs environmental or agricultural risk description as part of the biorisk section instead of its own section.
- Add to the biorisk analysis chapter or appendix section guidance on biosafety for field work, for both veterinarians/farmers/ranchers and for those studying diseases in wildlife in their natural habitat. Include field practices for diseases or GMO plants.

Animals – Terrestrial:

- For the chapters on terrestrial animals and terrestrial plants, please clearly describe what the containment features and practices are doing (i.e., protecting personnel, protecting animals in the facility, protecting the public, protecting animals outside the facility).

- In the chapter on terrestrial animals, for the protective equipment section please address protective equipment for work with large animals that cannot be housed in primary caging for all AgABSL levels 1-4.
- Include animal allergies under occupational health programs.
- In animal care and use issues address the issue of bedding and the balance between biocontainment and animal comfort.
- For the agent summary statements include strict animal pathogens not included in BMBL.
- In the biosafety section for animals please mention the need for IBC and IACUC review and approval when work involves recombinant or synthetic nucleic acid molecules.
- In the decontamination section please address carcass disposal in its own section and not include it in the section on solid vs. liquid waste disposal.
- Under veterinary biosecurity, we recommend that integrated pest management systems are also discussed as part of the laboratory biosafety and biosecurity.
- Please keep the section on animal handling and restraint minimal and refer to restraint as a means of decreasing potential exposure. Reference other documents for extensive discussion of specific restraint methods.
- Please keep the section on animal surgery, necropsy and sampling methods minimal and refer to reference documents for more detailed discussions of these methods.
- For the section on design and construction references for livestock and wildlife for BSL-3Ag, the facility features are often only mandated in APHIS permit conditions and this should be mentioned in this section.
- Add a section under design and construction for countries where the disease is endemic vs. countries where the disease is exotic.
- Provide information on how to use/manage shared necropsy space in ABSL-3-BSL3 Ag containment.

Animals – Aquaculture:

- Since there is a section on aquatic pest plants, should there be a section on aquatic fish or shellfish such as zebra mussels or jumping Asian carp?
- Should this document include pest animals and plants? Maybe they belong in a separate document?

Plants – Terrestrial:

- For the section on terrestrial plants, describing the agents and their impact on agriculture we recommend splitting out a separate section for invasive species, parasitic plants, noxious weeds and a separate section for GMOs and transgenic organisms.
- Include routes of transmission in the section describing the agents and their impact on agriculture.
- Include arthropods and nematodes as disease vectors in plant health in the section describing the agents and their impact on agriculture.
- In the plant decontamination section, solid waste should describe usual solid lab wastes vs. liquid vs. plant vs. soil wastes.
- In the section on plant biosecurity, make it clear when talking about biosecurity whether you are talking about preventing spread of disease as opposed to preventing criminal access or use.
- In the plant design and construction references section, be clear about what is protecting the workers/public and what is protecting plants/economy.
- In the plant design and construction references, provide discussion that includes that often facility feature requirements, such as exit showers, for strict plant pathogens are only mandated in APHIS permit conditions.
- In the plant design and construction references add a section about endemic vs exotic status of the pathogen.

Plants – Aquatic:

- We recommend changing the title of the “Plants-Aquatic Plants” to “Plants- Aquatic Pest Plants”.
- In the section on aquatic plants for biosecurity, be clear about what definition of biosecurity is used.

Appendices:

- In the appendices, refer to the BMBL or the reference for “Biosafety Laboratory Competency”.

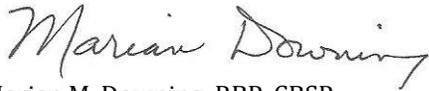
- We recommend for consistency, changing the title of the Appendix II to “Integrated Pest Management System”.

Other Comments:

- Please ensure that the topic of imports, exports, shipping, transporting, or receiving tissues, live animals, bacteria, viruses, or parasites from USDA regulated materials is addressed. USDA provides some information on their website and this information should be covered in the AgBMBL. For reviewing the source of the tissues or animals a form would be helpful that provides a checklist of diseases that the animals cannot be contaminated with or have.
- How will BMBL be referenced in this document or the appendices?

ABSA appreciates the opportunity to provide comments and information.

Sincerely,

A handwritten signature in cursive script that reads "Marian Downing".

Marian M. Downing, RBP, CBSP
President, American Biological Safety Association

