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Centers for Disease Control and Prevention  
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Ladies and Gentlemen,

The American Biological Safety Association (ABSA) is an international group of biological safety professionals known as one of the world's foremost resources on biological safety practices. ABSA reviewed the proposed revisions to the Foreign Quarantine; Etiological Agents, Hosts, and Vectors standard announced in the Federal Register on October 14, 2011. ABSA has the following comments to share regarding the proposed revisions:

In general, ABSA commends this rule making initiative. It seeks to simplify and clarify some issues that may arise during the permitting process. Please consider the specific comments which follow:

71.54 (a)

**Definitions**

The term, "infectious substance" is used once in the proposal, specifically in 71.54(b)(4) where the text is, "The importer is in compliance with all applicable laws regarding the packaging and shipping of infectious substances". Since the expectation, as stated, is that shipments of infectious biological agents or infectious materials coming into the United States are to be properly prepared as per the applicable transportation standards, we suggest that the definition for "infectious substance" used in those standards be provided for reference in the definitions section. Doing so would provide consistent, proper guidance to permit holders on the expectations of your agency on this matter, and would keep with current practices as per guidance related to possible applicable transportation requirements currently posted on your Etiologic Agent Import Permit Program web site.

We suggest the following definition for this section: "*Infectious Substance*": Infectious substance defined under Class 6, division 6.2 in 49 CFR 173.134 of the U.S. Department of Transportation's Hazardous Materials standards."

The term, "biosafety measures" is discussed in the preamble of the proposed standard in detail. In the text of the proposed standard it is used five times although the context lacks the detail provided in the preamble to the proposed standard. Since the text of the standard will not include the supporting discussion, we suggest that a definition of "biosafety measures" be added to the definitions section. Given that it will be the point of reference for possible inspections of permit applicants, and given that these inspections have not ever been conducted regarding this standard, provision of a clearer point of reference would be beneficial to parties accessing and reading this standard.

We suggest the following definition for this section:

*“Biosafety measures”*: Standard microbiological practices, special practices, safety equipment (primary and personal protective equipment) and laboratory facilities (secondary barriers) as noted in the current edition of *“Biosafety in Microbiological and Biomedical Laboratories (BMBL)”* and additional safeguards as provided in the NIH Guidelines for recombinant and synthetic DNA, appropriate for the material as determined by risk assessment.”

Section 71.54 (b)

The proposed text moves some of the explanation of the permit preparation guidance into the text of the standard. Doing so could help some importers to be reminded of their responsibilities under this program. Consider keeping the current text in the permit preparation guidance as well, so permit applicants have two opportunities to know their responsibilities and your agency’s expectations.

Section 71.54(b)(4)

The text on your Etiologic Agent Import Permit Program web site indicates, “The importer is legally responsible for assuring that the foreign personnel package, label, and ship the infectious materials according to Federal and International regulations.” Since hazardous material transportation requirements are determined by regulatory standards, it is suggested that the text of this provision in the revised standard be edited to read, “The importer is in compliance with all applicable laws and standards concerning the packaging and shipping of infectious substances.” It is also suggested that the text of the updated standard indicate, “The importer is legally responsible for assuring that the foreign personnel are in compliance with all applicable laws and standards regarding the packaging, labeling, marking, and shipment of infectious substances.” As with the comments regarding section 71.54(b), consider keeping the final text of this section in the permit preparation guidance to provide multiple opportunities for your agency’s expectations to be known to permit applicants.

Section 71.54 (f)(1)

We support the exclusion of CDC Select Agents and Toxins imported under the provisions of the CDC/APHIS Select Agents and Toxins standards from the need to seek an importation permit under this standard. The purpose and intent of the Select Agents and Toxins standard is to address many of the same concerns this standard seeks to address. A registered entity correctly observing those standards when obtaining these materials will be providing for the public’s safety and health.

We appreciate the opportunity to provide this information in response to this proposed rulemaking.

Sincerely,



LouAnn Crawford Burnett, MS, CBSP  
President  
American Biological Safety Association