



**America's Blood Centers**<sup>®</sup>  
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July 17, 2005

Dockets Management System  
U.S. Department of Transportation  
400 Seventh Street, SW  
Nassif Building, Room OK-401  
Washington, DC 20590-0001

Re: Docket No. PHMSA-2004-16895 (HM-226A) RIN 2137-AD93 Hazardous Materials: Infectious Substances; Harmonization with the United Nations Recommendations; Proposed Rule

Dear Docket Officer:

America's Blood Centers (ABC) appreciates the opportunity to comment on the Department of Transportation Pipeline and Hazardous Materials Safety Administration's (DOT PHMSA) proposed rule on hazardous materials; infectious substances and the harmonization effort with the United Nations recommendations. We applaud DOT PHMSA for taking a strong step toward assuring safety for the transportation of infectious substances while also facilitating domestic and international transportation.

For your information, ABC is a national network of locally controlled, not-for-profit community blood centers that collect almost half of the US blood supply from volunteer donors. Many ABC members are actively involved in the collection, processing, storage, and distribution of blood and blood components.

ABC supports all recommended changes of the proposed rule with one exception. There is concern that conflicting statutory requirements will be established by the proposed security requirements for select agents currently controlled by other federal agencies. Specific comments are listed below. We feel the proposed changes simplify the requirements for both shippers and carriers by recognizing that not all infectious substances pose the same risk and that risk is very much dependent upon form of the material. Your recommendations for labeling will simplify the process reducing risk of error by either party. We concur with DOT PHMSA's recommendation to follow the International Civil Aviation Organization's (ICAO) rules requiring point of contact information for Category B Infectious Substances on the packaging. These changes should result in reduced complications and detrimental delays in the shipment of infectious material.

Our specific comments on the proposed rule follow.

**Section IV, Paragraph 1-B [Security Requirements for Select Agents]**

*“Currently, persons who offer for transportation or transport certain infectious substances in commerce must develop and implement security plans in accordance with Subpart I of Part 172 of the HMR. ...For infectious substances, the security plan requirements apply to shipments of select agents and toxins regulated by CDC under 42 CFR Part 73. The CDC regulations identify select agents and toxins affecting humans (“HHS Select Agents and Toxins”) and select agents and toxins affecting both humans and animals (“Overlap Select Agents and Toxins”). The USDA*

*regulations at 9 CFR Part 121 identify select agents and toxins affecting animals, in addition to the Overlap Select Agents and Toxins that are listed in the CDC Regulations. USDA regulations at 7 CFR Part 331 identify agents and toxins affecting plants. Select agents and toxins affecting animals only are not currently subject to the security plan requirements. Biological agents and toxins affecting plants only do not meet the definition of an infectious substance under the HMR. ... As proposed, persons who offer for transport any of the materials regulated under 9 CFR Part 121 would be required to develop and implement security plans that conform to HMR requirements."*

**ABC Comments: While we support security requirements for persons who offer for transport certain infectious substances, as well as the select agents and toxins that pose a risk to humans, animals and plants; there is concern about multiple federal agencies establishing conflicting statutory requirements. We would recommend the appropriate portions of 42 CFR Part 73 and 7 CFR Part 331 be revised to include this requirement.**

Yours truly,

A handwritten signature in black ink that reads "Celso Bianco". The signature is written in a cursive, slightly slanted style.

Celso Bianco, MD  
Executive Vice President