densome, components. Besides a list of infectious agents and toxins that can cause "substantial harm to human health," they include a requirement to register facilities dealing with these agents, to assess fees to cover costs, and to establish a process for tracking and documenting the transfer of such agents between shippers and duly registered institutions.

The pathogens and other materials on the CDC list consist of more than 40 named agents, including the following: viruses such as ebola, hantavirus, and yellow fever; bacterial pathogens such as *Bacillus anthracis*, *Chlamydia psittaci*, and *Y. pestis*; and toxins such as abrin, botulin, ricin, and shigatoxin. Infectious agents that are considered "less pathogenic," such as attenuated vaccine strains of viral agents on the list, are exempt from the rules. Moreover, clinical specimens being transferred for diagnostic and verification purposes are, for the most part, exempt, as are dilute solutions of toxins used for medical purposes or in biomedical research.

Although the "overall intent" of the proposals is good, many of the details are "vague," says Keith Bostian of Microcide Pharmaceuticals (Mountain View, CA). And, in some respects, the proposals are "weird," adds Alan Goldhammer of the Biotechnology Industry Organization (BIO, Washington, DC). Even if the rules do not represent "much of a burden to the industry" because few companies work with the materials that are specified, there are concerns over who will keep records and who will be responsible for meeting the reporting requirements. Goldhammer also says that the CDC rules could well prove more problematic for academic researchers than for those in industry.

The proposals are far from perfect, says Bostian, pointing to "inconsistencies, confusion, and lack of coherence from the different lists and multiple agencies" that companies and universities face. Parts of CDC's recently published list can be confused with other similar lists of restricted microorganisms that have been prepared by CDC for other purposes or by other federal agencies, including the Department of Commerce (DoC, Washington, DC), the US Department of Agriculture (USDA, Washington, DC), and the National Institutes of Health (NIH, Bethesda, MD).

The proposed regulations contain several important, potentially burdensome, components.

Thus, for instance, DoC officials, who have jurisdiction over exports of certain equipment and biological materials, including microorganisms, have recently taken steps to enforce tighter controls over potential biological warfare agents. Independently, the USDA issued guidelines for safe and appropriate handling of imported plant pathogens; the guidelines include a list and classification scheme for treating such organisms and procedures for notifying the USDA and obtaining permits for certain classes of pathogen. And the 1996 version of the *NIH Guidelines for Research Involving Recombinant DNA Molecules* contains a revised classification scheme for etiologic agents and guidelines for handling them.

Other federal agencies, such as the US Postal Service (Washington, DC), the Department of Labor (Washington, DC), and the Department of Transportation (Washington, DC), private sector organizations, including both national and international associations representing airline pilots, and the United Nations also have rules for packaging and transporting such materials.

The new framework may help to protect some companies against liability claims, points out Kenneth Berns of Cornell University Medical College (New York). Federal certification of containment equipment and institutional registration could be an advantage. However, there may be some who "feel uneasy" about provisions allowing federal officials to inspect facilities, even on a limited basis. Moreover, several items on the proposed list of pathogens are found widely in nature, raising questions about whether restricting their transfer will do anything but raise costs and increase the red tape for those who are doing legitimate studies.

When the assortment of federal and nonfederal rules for packaging and shipping pathogens is looked at broadly, "there is a perception that the regulations don't match the risks," points out Bostian. Indeed, some rules seem much worse by being more restrictive or arbitrary than others. Several interviewees claim that, in the past at least, confusion over the many disjointed elements of the overall system and the aggravation dealing with them has led many researchers to ignore the system and to quietly move cultures around in their briefcases and coat pockets.

Jeffrey L. Fox

Safer pertussis vaccines for adult use

The US Food and Drug Administration (FDA, Rockville, MD) is considering one version of a recombinant acellular pertussis vaccine as a primary product for use in young children; such vaccines are being used already either as boosters for children in the United States or more widely in Japan and Europe. However, momentum is building for a substantially increased use of these vaccines in adult populations—reflecting a growing belief that adult whooping cough cases, which usually go unrecognized, represent a reservoir for the disease to a greater extent than is generally recognized.

Officials at the National Institute for Allergy and Infectious Diseases (NIAID, Bethesda, MD) say they are now planning a study of pertussis in adult populations. Although data are scarce, some public health officials suspect that mild cases of pertussis—those that do not meet the strict criteria of the World Health Organization (Geneva)—in adolescents and adults help to maintain and spread the disease. Thus, wider use of these vaccines in older populations might curtail extended bouts of coughing from misdiagnosed "colds" among such older populations, but might also reduce the overall risk of developing the disease in the very young who are just beginning the usual course of childhood vaccinations.

Meanwhile, the debate about the appropriate makeup of acellular pertussis vaccines continues. The traditional vaccine consists of inactivated cells of the bacterial pathogen *Bordetella pertussis*. Although definitive proof is lacking, the whole-cell vaccine may be responsible for various side effects, from soreness to fever to more serious central nervous system damage. Several recombinant acellular pertussis vaccines have been formulated using one or more components derived from this bacterium, including pertussis toxin, filamentous hemagglutinin, and other antigens, to elicit a protective immune response.

Companies working on such products include Connaught Laboratories (Swiftwater, PA), SmithKline Beecham (Collegeville, PA and Rixensart, Belgium), Wyeth-Lederle Vaccines (Pearl River, NY), Pasteur Merieux (Marnes La Coquette, France), Chiron Biocine (Emeryville, CA), North American Vaccine (Beltsville, MD), and AMVAX (Beltsville, MD).

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