



Regulations and Standards

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The concept of this column is to provide information on new, revised, or proposed regulations, guidelines, and standards that may be of interest to the biosafety professional and other safety professionals who have responsibilities for biosafety. By its very nature, the timeliness of such information is subject to many factors including when information becomes available, how it comes to the attention of the editors, and the publication schedule of this journal. My primary source of information will be through the ABSA Technical Review Committee, currently chaired by Bill Homovec and by monitoring the biosafety listserv. In most cases, I'll reprint summaries obtained directly from the primary source of information. If such information is not available, I'll write my own summary. Following the detailed summaries, I'll provide basic source material that readers may use to find additional information on the topic or published work. I welcome readers' feedback on whether this format works and how to make it better meet their needs. Please send your comments by e-mail to don_callihan@bd.com or to the Editor, Ira F. Salkin, at irasalkin@aol.com.

Antimicrobial Pesticides

<http://www.epa.gov/oppad001/>
(updated March 7, 2002)

AGENCY: United States Environmental Protection Agency, Office of Pesticide Programs

SUMMARY: This web site provides registration information to the antimicrobial regulated community and other stakeholders interested in better understanding requirements, policies, procedures, and future directions that affect how the U.S. Environmental Protection Agency (EPA) regulates antimicrobial pesticides. Since much of the information contained on this web site is technical, the following background provides a brief history of how the Agency ensures the protection

of the public's health and the environment through its antimicrobial registration program.

EPA regulates pesticides under the statutory authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The registration requirements for antimicrobial pesticides differ somewhat from those of other pesticides. For example, EPA requires special tests to ensure the efficacy of public health pesticides when the pests are invisible disease-causing microbes, rather than insects or rodents that may be harboring disease organisms. Similarly, determining human and ecological risks from exposure to antimicrobial pesticides requires different types of measurements and models than those needed for pesticides largely applied to crops and other plants. In view of these and other differences, EPA decided that its regulations governing pesticide registration requirements should also incorporate special antimicrobial sections.

Author's Note

Some of the following release dates have passed, but this is the information available on the web site.

Presently, EPA's proposed 40 CFR Part 152 and 156 are nearing completion and are projected to be released between the end of 2000 and early 2001. In proposing these and other changes, EPA's goal is to improve protection of public health and the environment while minimizing the data burdens on applicants. There will also be ongoing opportunity for all interested groups and individuals to submit comments once the proposal for 40 CFR Part 158 is officially released for data requirements. You will find more information on these regulations, the Federal Acts, and more as you browse through this web site.

Antimicrobial pesticides, such as disinfectants and sanitizers, are pesticides that are intended to "(i) disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms; or (ii) protect inanimate objects (for example, floors and walls), indus-

trial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime." This category does not include certain pesticides intended for food use, but does encompass pesticides with a wide array of other uses. For example, antimicrobial pesticides act as preserving agents in paints, metalworking fluids, wood supports, and many other products to prevent their deterioration.

Antimicrobials are especially important because many are public health pesticides. They help to control microorganisms (viruses, bacteria, and other microorganisms) that can cause human disease. Antimicrobial public health pesticides are used as disinfectants in medical settings, where they are present in products used to clean cabinets, floors, walls, toilets, and other surfaces. Proper use of these disinfectants is an important part of infection control activities employed by hospitals and other medical establishments.

Antimicrobial Chemical/Registration Number Indexes

<http://www.epa.gov/oppad001/chemregindex.htm>
EPA ANTIMICROBIALS LIST
(updated May 22, 2002)

Lists A through F are EPA's registered antimicrobial products effective against tubercle bacteria, human HIV-1 virus, or Hepatitis B virus, as well as products classified as sterilants and products used for medical wastes. The lists are organized alphabetically by product name and represent the most current data as of March 2, 2002.

- List A: EPA's Registered Antimicrobial Products as Sterilants.
- List B: EPA Registered Tuberculocide Products Effective Against *Mycobacterium* spp.
- List C: EPA's Registered Antimicrobial Products Effective Against Human HIV-1 Virus.
- List D: EPA's Registered Antimicrobial Products Effective Against Human HIV-1 and Hepatitis B virus.
- List E: EPA's Registered Antimicrobial Products Effective Against *Mycobacterium* spp, Human HIV-1, and Hepatitis B virus.
- List F: EPA's Registered Antimicrobial Products for Medical Waste Treatment.

Only antimicrobial products from the primary registrants are included in the lists. All EPA's registered pesticides must have an EPA registration number (EPA Reg#). The EPA Registration number for primary regis-

trants consists of two sets of numbers separated by a hyphen (-), for example EPA Reg#001234-000012. The first set of numbers refers to the registrant's identification number and the second set to the product identification number. A distributor's product may use a different name, but must have the first two sets of EPA Reg# of the primary registrant, plus a third set of numbers that represents the Distributor/Relabeler Identification number, for example EPA Reg#001234-000012-000567. An establishment number (EPA Est#) is the place where the pesticide, formulation, or device is produced; it is indicated by a set of codes consisting of the registrant's number followed by the State where the product is made and the facility number.

The approved label of a particular antimicrobial product can be found in the Pesticide Product Label System (PPLS) using the EPA registration number of the primary product.

For additional information contact the Antimicrobials Division hotline at 703-308-0127, 703-308-6467 (fax), or send an e-mail to info_antimicrobial@epa.gov.

Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps): Draft Guidance

Federal Register: June 25, 2002 (Vol. 67, No. 122, pp. 42789-42790). Available from the *Federal Register* Online via GPO Access [wais.access.gpo.gov] DOCID: fr25jn02-65.

AGENCY: Department of Health and Human Services, Food and Drug Administration

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)" dated June 2002. The draft guidance document provides information to assist manufacturers of human cellular and tissue-based products in minimizing the risk of transmitting CJD/vCJD by HCT/Ps through deferral of donors with possible exposure to the agents of CJD and vCJD. Since there is no readily available

demographic information about the HCT/P donor population, FDA encourages establishments to submit with their comments study data concerning the effect that implementation of these recommendations could have on the HCT/P supply. Submit written or electronic comments by December 23, 2002.

Hazardous Materials: Retention of Shipping Papers; Final Rule

49 CFR Parts 172, 174, 175, 176, and 177 [Docket No. RSPA-01-10568 (HM-207B)] RIN 2137-AC64. *Federal Register*: July 12, 2002 (Vol. 67, No. 134, pp. 46123-46129). From the *Federal Register* Online via GPO Access [wais.access.gpo.gov] DOCID: fr12jy02R

AGENCY: Research and Special Programs Administration (RSPA), DOT

SUMMARY: RSPA is amending the Hazardous Materials Regulations to require shippers and carriers to retain a copy of each hazardous material shipping paper, or an electronic image thereof, for a period of 375 days after the date the hazardous material is accepted by the carrier.

DATES: This final rule is effective August 12, 2002.

Hazardous Materials: Revision to Standards for Infectious Substances; Final Rule

49 CFR Parts 171, 172, 173, 177, and 178 [Docket No. RSPA-98-3971 (HM-226)] RIN 2137-AD13. *Federal Register*: August 14, 2002 (Vol. 67, No. 157, pp. 53117-53144). From the *Federal Register* Online via GPO Access [wais.access.gpo.gov] DOCID: fr14au02-30.

AGENCY: Research and Special Programs Administration (RSPA), DOT

SUMMARY: RSPA is revising transportation requirements for infectious substances, including regulated medical waste, to adopt defining criteria and packaging requirements consistent with international standards, revise the current broad exceptions for diagnostic specimens and biological product, and authorize bulk packaging options for regulated medical waste consistent with requirements in international standards and DOT exemptions. These revisions will ensure an acceptable level of safety for the transportation of infectious substances and facilitate domestic and interna-

tional transportation.

DATES: This final rule is effective February 14, 2003.

Actions Resulting from Enactment of the Public Health Security and Biodefense Preparedness and Response Act of 2002 (Public Law 107-188)

Since the last issue, there has been a lot of regulatory activity focusing on efforts to identify those who possess Select Agents. The CDC Office of Health and Safety's Laboratory Registration/Select Agent Transfer Program now has all of the information needed for notification posted on its web site at <http://www.cdc.gov/od/ohs/lrsat.htm>.

Notification of Possession of Select Agents: OMB Approval of Data Collection; Notice

Federal Register: August 6, 2002 (Vol. 67, No. 151, pp. 51058-51064). From the *Federal Register* Online via GPO Access [www.access.gpo.gov] DOCID: fr14au02-30.

AGENCY: Centers for Disease Control and Prevention, Department of Health and Human Services

SUMMARY: The purpose of this Notice is to announce OMB approval of data collection, "Notification of Possession of Select Agents," under the Paperwork Reduction Act of 1995 (PRA). The OMB Control Number for this data collection is 0920-0561. The data collection will expire January 31, 2003.

DATES: All persons in possession of any "Select Agent" must notify the Secretary of the Department of Health and Human Services (DHHS) by September 10, 2002.

Agricultural Bioterrorism Protection Act of 2002; Listing of Biological Agents and Toxins and Requirements and Procedures for Notification of Possession

7 CFR Part 331 and 9 CFR Part 121 [Docket No. 02-082-1] RIN 0579-AB47. *Federal Register*: August 12, 2002 (Vol. 67, No. 155, pp. 52383-52389). From the *Federal Register* Online via GPO Access [www.access.

gpo.gov] DOCID:fr12au02-2.

AGENCY: Animal and Plant Health Inspection Service, USDA

ACTION: Interim rule and request for comments

SUMMARY: In accordance with the Agricultural Bioterrorism Protection Act of 2002, we are establishing, by regulation, an initial list of biological agents and toxins determined to have the potential to pose a severe threat to animal or plant health, or to animal or plant products. The Act requires that all persons in possession of any listed biological agent or toxin must, within 60 days of the publication of this interim rule, notify the Secretary of such possession. This interim rule establishes the initial list of biological agents and toxins and provides guidance on the manner in which the required notice is to be provided.

DATES: This interim rule became effective August 12, 2002. Submit comments on or before October 11, 2002.

Assistant Editor's Note

Information included in this article was that available as of August 16, 2002. In this rapidly evolving regulatory environment, readers are urged to join ABSA's Biosafety Discussion List, *BIOSAFETY*. For instructions on how to subscribe, go to <http://www.absa.org/resources/list.htm>. Another way to monitor changes in U.S. government laws and regulations is to subscribe to the *Federal Register* Table of Contents service, FEDREGTOC-L by visiting <http://listserv.access.gpo.gov/>.

For more information:

Title	Status	Organization	Additional information
ABSA Biosafety Discussion List (BIOSAFETY)	Ongoing	American Biological Safety Association	http://www.absa.org/resources/list.htm
Antimicrobial Chemical/Registration Number Indexes	Ongoing	U.S. Environmental Protection Agency	http://www.epa.gov/oppad001/chemregindex.htm
Antimicrobial Pesticides	Ongoing	Office of Pesticide Programs, U.S. Environmental Protection Agency	http://www.epa.gov/oppad001/
Agricultural Bioterrorism Protection Act of 2002; Listing of Biological Agents and Toxins and Requirements and Procedures for Notification of Possession	Interim	USDA, APHIS, Veterinary Services, National Center for Import and Export	http://www.aphis.usda.gov/ppd/rad/webrepor.html Section 213(b) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 requires all persons in possession of any "High Consequence Livestock Pathogens and Toxins" notify the Secretary of the Department of Agriculture (USDA) by October 8, 2002. A machine-readable version of the form may be obtained by calling 1-866-567-4232. An alternate version of the form is available on the Internet at http://www.aphis.usda.gov/vs/ncie .
Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease...Draft Guidance	Draft	Department of Health and Human Services, Food and Drug Administration	Copies of this draft guidance are available from the Office of Communication, Training and Manufacturers Assistance (HFM-40), 1401 Rockville Pike, Rockville, MD 20852-1448, or by calling 1-800-835-4709 or 301-827-1800, or from the Internet at http://www.fda.gov/cber/guidelines.htm Submit written or electronic comments by December 23, 2002.
Federal Register Table of Contents Service: FEDREGTOC-L	Ongoing	U.S. National Archives and Records Administration, College Park, MD, 1-866-272-6272	http://listserv.access.gpo.gov/ http://www.archives.gov/federal_register/index.html
Hazardous Materials: Retention of Shipping Papers	Final	Office of Hazardous Materials Safety, Research and Special Programs Administration, U.S. Department of Transportation	http://hazmat.dot.gov/ Effective August 12, 2002
Hazardous Materials: Revision to Standards for Infectious Substances; Final Rule	Final	Office of Hazardous Materials Safety, Research and Special Programs Administration, U.S. Department of Transportation	http://hazmat.dot.gov/ Effective October 1, 2002
Laboratory Registration/Select Agent Transfer Program	Final	Centers for Disease Control and Prevention, Office of Health and Safety	http://www.cdc.gov/od/ohs/lrsat.htm . Section 202(a) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("The Act") requires that all persons in possession of any "Select Agent" notify the Secretary of the Department of Health and Human Services (DHHS) by September 10, 2002. Call 866-567-4232 to obtain additional copies of the notification form. This form and a Guidance Document are viewable on the Internet at http://www.cdc.gov/od/ohs/lrsat/possess.htm