

corrective actions required at each level. Results for individual sampling events ranged from non-detect to 3.5 ug/cubic meter. Average quarterly lead concentrations for the Site did not exceed Federal and State of Oregon standard for lead (1.5 ug/cubic meter).

Groundwater samples were collected during six sampling events during construction activities from on-site and off-site wells. Sample results indicated that there were no exceedences of the 15 micrograms/liter action level for lead established under the Safe Drinking Water Act.

Surface soil (0 to 1ft depth) sampling was performed at the Site to identify soils exceeding 1,000 mg/kg total lead and confirm removal. Surface soils that required removal outside the footprint of the OCF were located in the lake area of the Rhone-Poulenc property and the eastern and southern portions of the Gould property. Surface soil inside the footprint of the OCF was also removed as part of the site preparation for the OCF. Contaminated surface soils from these areas were excavated and disposed of in the OCF. Confirmatory sampling was performed and sample analysis was conducted for areas outside the OCF footprint in accordance with the Quality Assurance Project Plan results were reviewed and approved by EPA representatives prior to backfilling with imported non-contaminated soil.

East Doane lake was divided into sampling quadrants and dredging depths were predetermined based on sample results. Post-dredging sampling was also conducted to evaluate whether dredging achieved the criteria of EP Toxicity for lead. Total lead levels were also collected for comparison purposes. Re-dredging of sediment in quadrants that did not meet the criteria was conducted until the sample results within the quadrant indicated the criteria was met and/or EPA approved backfilling the sample quadrant based on sample results in the quadrant and consideration of the practical limits of dredging. The East Doane lake remnant was then backfilled in accordance with the ROD and contract documents.

Two stockpiles of waste material were designated as principle threat waste, the lead fines stockpile and the screened excavation stockpile. This waste was treated by stabilization to achieve a RCRA waste characteristic level of less than 5 mg/l of lead. Quality control confirmatory samples were collected to verify that the results met the performance standard.

Operation and Maintenance

Operation and maintenance activities began in January 2000 in accordance

with the Final Remedial Design Report and Draft Operation and Maintenance Plan. The Final Operation and Maintenance Plan was completed November 6, 2001. It addresses activities, responsibilities and schedules for the following site components: OCF cover condition and stability, erosion and sedimentation controls, access roads, security fencing, storm water systems, leachate collection and removal, and groundwater monitoring. The plan also addresses monitoring and inspection frequency and responsibilities. Site inspections, maintenance and monitoring have been performed and will continue to be performed in accordance with the Operation and Maintenance Plan. EPA approved the Final Operation and Maintenance Plan on May 15, 2002.

Institutional Controls

Future use of the property is limited to industrial or other uses compatible with the cleanup under the terms of the Environmental Protection Restrictive Covenant and Easements that were granted by property owners to meet the requirements of the Consent Decree. EPA will evaluate the institutional controls at least every five years as part the five-year reviews that will be conducted at the Site.

Five-Year Review

Hazardous substances will remain at the Site above levels that allow unlimited use and unrestricted exposure after the completion of the remedial action. Pursuant to CERCLA Section 121(c) and provided in the current guidance on Five-Year Reviews, EPA must conduct a statutory five-year review to ensure that the remedy continues to provide adequate protection of human health and the environment. EPA conducted the first five-year review of the Gould Site on September 28, 1997, and the next five-year review is scheduled to be completed by September 28, 2002.

Community Involvement

EPA provided routine progress fact sheets to keep the public advised of site cleanup activities. There was not a great deal of interest in the excavation of waste materials and construction of the On-site Containment Facility (OCF) from the general public, but workers at an adjacent Metro waste transfer facility did raise concerns about the potential for off-site migration of lead-contaminated dust. Arrangements were made to provide air monitoring results directly to representatives from the transfer facility to keep workers advised

and provide assurances that lead levels were being adequately controlled.

Applicable Deletion Criteria

One of the three criteria for deletion specifies that EPA may delete a site from the NPL if "responsible parties have implemented all appropriate response actions required." EPA, with the concurrence of the State of Oregon, believe that this criterion for deletion has been met. There is no significant threat to human health or the environment and, therefore, no further remedial action is necessary. Subsequently, EPA is proposing deletion of this site from the NPL. Documents supporting this action are available in the deletion docket at the information repositories.

State Concurrence

In a letter dated August 8, 2002, from the Oregon Department of Environmental Quality (DEQ), DEQ concurs with the proposed deletion of the Gould Superfund Site from the NPL.

Dated: August 15, 2002.

Ronald A. Kreizenbeck,
Acting Regional Administrator, U.S. EPA,
Region 10.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 72, Appendix A

RIN 0920-AA08

Interstate Shipment of Etiologic Agents; Select Agents

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

ACTION: Notice of intent to issue regulations.

SUMMARY: On June 12, 2002, President George W. Bush signed Public Law 107-188, Public Health Safety and Bioterrorism Preparedness and Response Act of 2002. The Act specifies that the Secretary of the Department of Health and Human Services establish and maintain a list of biological agents and toxins that have the potential to pose a severe threat to public health and safety. The Secretary directed the Centers for Disease Control and Prevention (CDC) to convene an inter-agency work group to review the current list of biological agents and toxins found in 42 CFR part 72, Appendix A, and revise the list as necessary.

Prior to issuing the Interim Final Rule, as required by Public Law 107-

188, the CDC is interested in obtaining public comments on the revisions to 42 CFR part 72, Appendix A, that are under consideration. In addition to these revisions, the CDC is particularly interested in obtaining comments on whether there are biological agents and toxins that should be added to the list or removed from the list.

DATES: Submit comments on or before September 17, 2002.

ADDRESSES: Comments on the revisions to the list of select agents and toxins that are under consideration should be marked "Comments on Select Agents" and mailed to: Centers for Disease Control and Prevention, National Center for Infectious Diseases, Select Agent Transfer Program, 1600 Clifton Road NE., Mailstop E-79, Atlanta, Georgia 30333. Due to staff and equipment limitations, CDC cannot accept comments by facsimile or electronic mail.

FOR FURTHER INFORMATION CONTACT: For information concerning the revisions to the list of select agents and toxins that are under consideration should contact: Ms. Jennifer Brooks, National Center for Infectious Diseases, Office of the Director, 1600 Clifton Road NE., Mailstop C-12, Atlanta, Georgia 30333. Telephone: (404) 639-2763.

SUPPLEMENTARY INFORMATION:

Background

President George W. Bush signed the Public Health Safety and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188) on June 12, 2002. The Act specifies that the Secretary of the Department of Health and Human Services establish and maintain a list of biological agents and toxins that have the potential to pose a severe threat to public health and safety. The current list of select agents and toxins was published in the **Federal Register** on October 24, 1996, and appears as Appendix A to 42 CFR part 72. This notice of intent is part of the rule-making process that will culminate in the publication of an Interim Final Rule. CDC anticipates publishing this rule in coordination with the U.S. Department of Agriculture on or before December 9, 2002.

The Secretary directed the Centers for Disease Control and Prevention (CDC) to convene an inter-agency work group to review the current list of biological agents and toxins and revise the list as necessary. Members of the work group included representatives from the Department of Health and Human Services/Office of the Secretary (DHHS/OS), the Centers for Disease Control and Prevention (CDC), the National

Institutes of Health (NIH), the Food and Drug Administration (FDA), the Department of the Army (DoD/Army), the Department of the Navy (DoD/Navy), the Department of the Air Force (DoD/AF), the U.S. Department of Agriculture (USDA), the Environmental Protection Agency (EPA), the Agency for Toxic Substances and Disease Registry (ATSDR), the Department of Labor/Occupational Safety and Health Administration (OSHA), the National Institute of Occupational Safety and Health (CDC/NIOSH), the Department of Transportation (DoT), the Department of Commerce (DoC), Department of Energy (DoE), the Department of Justice (DoJ), the Federal Bureau of Investigation (FBI), the Central Intelligence Agency (CIA), the Defense Intelligence Agency (DoD/DIA), and the U.S. Postal Service (USPS).

The Current List of Select Agents and Toxins

The current list of select agents and toxins was previously published in the **Federal Register** on October 24, 1996 and appears as Appendix A to 42 CFR part 72. In June 2002, CDC convened an interagency working group to review the current list of select agents and toxins and develop recommendations regarding possible changes to the list. CDC has reviewed those recommendations and this notice of intent seeks to solicit comments from the public on potential changes to the current list of select agents and toxins. Of the 36 select agents and toxins on CDC's current list, 18 of these appear on the USDA list of agents and toxins required under Section 212(a) and located in 9 CFR 121.2(a). These 18 agents and toxins appear on both the CDC and USDA lists since they pose a risk to both human and animal health. Because the process of changing the list of select agents and toxins was in the initial stages when USDA published its interim rule on August 8, 2002 and when this CDC notice of intent is being published, the list of agents and toxins found in both 42 CFR part 72, Appendix A, and 9 CFR 121.2(a) reflects the select agent list promulgated by CDC in October 1996. The notification requirement for persons in possession of any select agent as published by CDC on July 12, 2002 and USDA on August 8, 2002, applies to the current list of agents and toxins and is unaffected by the information solicited by this notice.

Summary of Changes to Appendix A, 42 CFR Part 72, That Are Under Consideration

The following changes are being considered to the list of *Viruses*:

1. Rename "Equine Morbillivirus" to "Nipah and Hendra Complex viruses".

2. Change "Tick-borne encephalitis complex viruses" to "Tick-borne encephalitis complex (flavi) viruses (Central European Tick-borne encephalitis, Far Eastern Tick-borne encephalitis (Russian Spring and Summer encephalitis, Kyasanur Forest disease, Omsk Hemorrhagic Fever)".

3. *Delete:* "Viruses causing hantavirus pulmonary syndrome" and "Yellow fever virus".

4. *Add:* "Monkeypox virus" and "Herpes B virus".

5. *Remove:* exemptions list since exemptions will be covered in the Interim Final Rule.

The following changes are being considered to the list of *Bacteria*:

1. Remove "(Pseudomonas)" from the name of "Burkholderia (Pseudomonas) mallei" and "Burkholderia (Pseudomonas) pseudomallei".

2. Change "Clostridium botulinum" to "Botulinum neurotoxin producing strains of Clostridium".

3. *Remove the header:* Rickettsiae and combine these agents with the agents in the bacteria list.

4. *Remove:* exemptions list since this will be covered in the Interim Final Rule.

The following change is being considered to the list of *Fungi*:

1. Change *Coccidioides immitis* to *Coccidioides immitis, C. posadasii*.

The following changes are being considered to the list of *Toxins*:

1. *Remove:* "Aflatoxins".

2. Change "Botulinum toxins" to "Botulinum neurotoxins".

3. Change "Shigatoxin" to "Shigatoxin and Shiga-like toxins".

The following change is being considered for *Exemptions*:

1. Change "Exemptions: Toxins for medical use, inactivated for use as vaccines, or toxin preparations for biomedical research use at an LD<INF> 50 for vertebrates of more than 100 nanograms per kilogram body weight are exempt. National standard toxins required for biologic potency testing as described in 9 CFR part 113 are exempt." to "Exemptions: Toxin preparations containing ≤ 1 mg of Botulinum neurotoxins; ≤ 10 mg of Staphylococcal enterotoxins; or ≤ 100 mg of Abrin, Clostridium perfringens epsilon toxin, Conotoxins, Diacetoxyscirpenol, Ricin, Saxitoxin, Shigatoxin and Shiga-like toxins, Tetrodotoxin, or T-2 toxin, are exempt. Toxin preparation stored in more than one location within a facility must be aggregated in determining if the exemption applies. The medical use of toxins for patient treatment are exempt."

The following changes are being considered to *Recombinant Organisms/Molecules*:

1. Change title "Recombinant Organisms/Molecules" to "Genetic Elements, Recombinant Nucleic Acids, and Recombinant Organisms".

2. Change "1. Genetically modified microorganisms or genetic elements from organisms on Appendix A, shown to produce or encode for a factor associated with a disease. 2. Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed in this Appendix, or their toxic subunits." to:

"1. Full length nucleic acids (synthetic or naturally derived) of any of the viruses listed in Appendix A.

2. Nucleic acids (synthetic or naturally derived) of 100 nucleotides or more in length of Variola major virus (smallpox virus).

3. Nucleic acids (synthetic or naturally derived) of bacteria, fungi, or viruses listed in Appendix A that encode for either a functional toxin or virulence factor sufficient to cause disease if the nucleic acid is: (1) Expressed in vivo or in vitro; (2) in an expression vector or host chromosome; or (3) in a carrier plasmid.

4. Nucleic acids (synthetic or naturally derived) that encode for functional form of any of the toxins listed in Appendix A if: (1) Expressed in vivo or in vitro; (2) in an expression vector or host chromosome; or (3) in a carrier plasmid.

5. Microorganisms in Appendix A that have been genetically modified."

Finally, CDC is considering the following change to *Additional Exemptions*:

1. Remove the following text since exemptions will be addressed in the Interim Final Rule:

"1. Products subject to regulation under the Federal Insecticide Fungicide and Rodenticide Act (7 U.S.C. 136 *et seq.*) and the Toxic Substances Control Act (15 U.S.C. 2601 *et seq.*) are exempt.

2. Additional exemptions for otherwise covered strains will be considered when CDC reviews and updates the list of select agents and toxins in this Appendix. Individuals seeking an exemption should submit a request to CDC that specifies the agent or strain to be exempted and explains why such an exemption should be granted. Future exemptions will be published in the **Federal Register** for review and comment prior to inclusion in this Appendix."

List of Select Agents and Toxins

The following is the list of select agents and toxins that is being considered for adoption:

Viruses

1. Crimean-Congo haemorrhagic fever virus
2. Eastern Equine Encephalitis virus
3. Ebola viruses
4. Herpes B virus
5. Lassa fever virus
6. Marburg virus
7. Monkeypox virus
8. Nipah and Hendra Complex viruses
9. Rift Valley fever virus
10. South American Haemorrhagic fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito)
11. Tick-borne encephalitis complex (flavi) viruses (Central European Tick-borne encephalitis, Far Eastern Tick-borne encephalitis (Russian Spring and Summer encephalitis, Kyasanur Forest disease, Omsk Hemorrhagic Fever))
12. Variola major virus (Smallpox virus)
13. Venezuelan Equine Encephalitis virus

Bacteria

1. Bacillus anthracis
2. Brucella abortus
3. Brucella melitensis
4. Brucella suis
5. Burkholderia mallei
6. Burkholderia pseudomallei
7. Botulinum neurotoxin producing strains of Clostridium
8. Coxiella burnetii
9. Francisella tularensis
10. Rickettsia prowazekii
11. Rickettsia rickettsii
12. Yersinia pestis

Fungi

1. Coccidioides immitis
2. Coccidioides posadasii

Toxins

1. Abrin
2. Botulinum neurotoxins
3. Clostridium perfringens epsilon toxin
4. Conotoxins
5. Diacetoxyscirpenol
6. Ricin
7. Saxitoxin
8. Shigatoxin and Shiga-like toxins
9. Staphylococcal enterotoxins
10. Tetrodotoxin
11. T-2 toxin

Exemptions: Toxin preparations containing ≤ 1 mg of Botulinum neurotoxins; ≤ 10 mg of Staphylococcal enterotoxins; or ≤ 100 mg of Abrin, Clostridium perfringens epsilon toxin, Conotoxins, Diacetoxyscirpenol, Ricin, Saxitoxin, Shigatoxin and Shiga-like

toxins, Tetrodotoxin, or T-2 toxin, are exempt. Toxin preparation stored in more than one location within a facility must be aggregated in determining if the exemption applies. The medical use of toxins for patient treatment are exempt.

Genetic Elements, Recombinant Nucleic Acids, and Recombinant Organisms

1. Full length nucleic acids (synthetic or naturally derived) of any of the viruses listed in Appendix A.

2. Nucleic acids (synthetic or naturally derived) of 100 nucleotides or more in length of Variola major virus (smallpox virus).

3. Nucleic acids (synthetic or naturally derived) of bacteria, fungi, or viruses listed in Appendix A that encode for either a functional toxin or virulence factor sufficient to cause disease if the nucleic acid is: (1) Expressed in vivo or in vitro; (2) in an expression vector or host chromosome; or (3) in a carrier plasmid.

4. Nucleic acids (synthetic or naturally derived) that encode for functional form of any of the toxins listed in Appendix A if: (1) Expressed in vivo or in vitro; (2) in an expression vector or host chromosome; or (3) in a carrier plasmid.

5. Microorganisms in Appendix A that have been genetically modified.

Other Restrictions

The deliberate transfer of a drug resistance trait to microorganisms listed in this Appendix that are not known to acquire the trait naturally is currently prohibited if such acquisition could compromise the use of the drug to control these disease agents in humans or veterinary medicine.

Dated: August 9, 2002.

Julie Louise Gerberding,

Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018-AH08

Endangered and Threatened Wildlife and Plants; Designations of Critical Habitat for Plant Species From the Island of Molokai, HI

AGENCY: Fish and Wildlife Service, Interior.