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Returning Refrigerated Transport Vehicles and Refrigerated Storage Units to Food Uses After Using Them to Preserve Human Remains Guidance for Industry

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You may submit either electronic or written comments regarding this guidance at any time. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA2017-D-0085.

For questions regarding this document as it relates to human food, contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-1200. For questions regarding this document as it relates to animal food, contact the Center for Veterinary Medicine (CVM) at 240-402-7002.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine**

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I. Introduction

FDA plays a critical role in protecting the United States from threats such as emerging infectious diseases.

During the Coronavirus Disease 2019 (COVID-19) pandemic, FDA was asked whether refrigerated food transport vehicles and refrigerated food storage units used for the temporary preservation of human remains subsequently can be used to transport and store human and animal food. In May 2020, FDA issued a previous version of this guidance to provide information and resources related to the cleaning and disinfection of such vehicles and storage units to address food safety before they are used again to transport and store food. The information in the guidance, however, also can be applied to situations where there is a temporary need for refrigerated food transport vehicles and refrigerated food storage units to temporarily hold human remains and where those vehicles and storage units are to be used subsequently to transport and hold human and animal food. Thus, we have revised the guidance so that it is no longer limited to the COVID-19 pandemic.

The recommendations in this guidance are intended to supplement existing food safety regulations and guidance.¹ Other aspects of cleaning and disinfection, such as worker, environmental, and

¹ For example, FDA's Sanitary Transportation of Human and Animal Food (21 CFR part 1 subpart O), Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (21 CFR part 117) and Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (21 CFR part 507) regulations contain requirements regarding the safe storage and transportation of human and animal food that also may apply.

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vehicle safety, are addressed by other federal agencies, such as the Occupational Safety and Health Administration (OSHA), Environmental Protection Agency (EPA), Centers for Disease Control and Prevention, and Department of Transportation (DOT), as well as State and local government agencies. Several additional resources related to these topics are included in Section IV of this document.

In general, FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidance means that something is suggested or recommended, but not required.

II. Background

On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency (PHE) related to COVID-19 under section 319 of the Public Health Service (PHS) Act and mobilized the Operating Divisions of HHS.² In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.³ The national emergency related to the COVID-19 pandemic ended on April 10, 2023⁴, and the PHE related to COVID-19 declared under the PHS Act expired on May 11, 2023⁵.

During the COVID-19 pandemic, additional refrigerated storage was needed for human remains. Refrigerated food transport vehicles and refrigerated food storage units ordinarily used for food preservation were used to preserve human remains temporarily. In response to questions about returning refrigerated food transport vehicles and refrigerated food storage units for use in food transport and storage, we issued guidance on how such refrigeration vehicles and refrigeration units could be safely used under certain circumstances.

The guidance, while issued during the COVID-19 pandemic, contained recommendations that would be applicable in most scenarios where refrigerated food transport vehicles and refrigerated food storage units ordinarily used for food preservation might be used to preserve human remains temporarily. Consequently, we have revised the guidance so that the recommendations can apply in most situations where refrigeration vehicles and refrigeration units that temporarily held human remains can be returned to use for food transport and storage.

² Secretary of Health and Human Services Alex M. Azar, Determination that a Public Health Emergency Exists. (originally issued on Jan. 31, 2020, and subsequently renewed), available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>.

³ Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at <https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>.

⁴ Joint Resolution terminating a National Emergency, available at <https://www.congress.gov/118/plaws/publ3/PLAW-118publ3.pdf>.

⁵ Fact sheet ending the PHE related to COVID-19, available at <https://www.whitehouse.gov/briefing-room/statements-releases/2023/05/09/fact-sheet-actions-taken-by-the-biden-harris-administration-to-ensure-continued-covid-19-protections-and-surge-preparedness-after-public-health-emergency-transition/>.

III. Discussion

Refrigerated food transport vehicles and refrigerated food storage units used for the temporary preservation of human remains subsequently can be safely used for food transport and food storage under certain circumstances. It is important that food is protected during transport and storage to ensure food is safe for humans and animals and that conditions do not exist that may adulterate the food. Before returning to service to transport or store human or animal food, refrigerated food transport vehicles and refrigerated food storage units used to hold human remains should be thoroughly cleaned and disinfected.⁶

The floors, walls, ceilings and other hard, non-porous surfaces on the interiors of refrigerated food transport vehicles and refrigerated food storage units are generally designed to be easily cleaned. After being cleaned, these surfaces should be disinfected to reduce the risks associated with pathogens. Appropriate Environmental Protection Agency (EPA) registered disinfectants (the EPA registration number is on the product's label) should be used to accomplish both goals. EPA registered disinfectants should be suitable for the intended material being disinfected.⁷

Disinfectants should be used in accordance with EPA-registered label use instructions to ensure safe and effective use of the product (for example, maintaining the required wetted contact time). Some surfaces may require repeat applications to ensure treatment for the required contact time. Also, because some disinfectants may not be effective at refrigeration temperatures (check the label), interiors may need to be brought to the appropriate temperature before disinfection. Further, note that certain chemicals, at concentrations known to be effective for proper disinfection, may damage the interior surfaces of the refrigerated food transport vehicles and refrigerated food storage units. When there is evidence that interior surfaces were in direct contact with blood or bodily fluids, FDA recommends that refrigerated food transport vehicles and refrigerated food storage units not be returned to service for transporting or storing food for humans or animals if any one of the following conditions exist:

- There are interior surfaces made of porous unfinished wood or other materials that are not suitable for cleaning and disinfection and that cannot be removed and replaced;
- There are interior surfaces that are damaged or compromised (e.g., cracked fiberglass, exposed seams) such that they are not able to be properly cleaned and disinfected;
- There are mechanical refrigeration components located within the storage areas that cannot be cleaned in place or removed for cleaning and/or replacement;
- The unit is permeated by offensive odors that cannot be eliminated through cleaning and disinfecting.

⁶ Disinfection describes a process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects. CDC Guideline for Disinfection and Sterilization in Healthcare Facilities (2008). (Available at: <https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html>)

⁷ EPA, Selected Registered Disinfectants, available at <https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants>.

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Under OSHA requirements, workers who conduct cleaning tasks must be protected from exposure to hazardous chemicals used in these tasks. In these cases, OSHA's Personal Protective Equipment (PPE) (29 CFR 1910 Subpart I) and Hazard Communication (29 CFR 1910.1200) standards may apply, and workers may need appropriate PPE to prevent exposure to the chemicals. If workers need respirators, they must be used in the context of a comprehensive respiratory protection program that meets the requirements of OSHA's Respiratory Protection standard (29 CFR 1910.134) and includes medical exams, fit testing, and training.

Cleaning chemicals' safety data sheets and other manufacturer instructions can provide additional guidance about what controls, including PPE, workers need to use the chemicals safely.

IV. Additional Resources

Additional information that may be helpful is provided below.

The Occupational Safety and Health Administration

29 CFR 1910.132 – Personal Protective Equipment (PPE)

Available at: <https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.132>

29 CFR 1910.134 – Respiratory Protection

Available at: <https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134>

29 CFR 1910.1030 – Bloodborne Pathogens

Available at: <https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030>

29 CFR 1910.1200 – Hazard Communication

Available at: <https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1200>

OSHA COVID-19 webpage

Available at: <https://www.osha.gov/coronavirus>

The Environmental Protection Agency

EPA Registered Disinfectants

Available at: <https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants>

Office of Land and Emergency Management – Medical Waste web page

Available at: <https://www.epa.gov/rcra/medical-waste>

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U.S. Department of Transportation

Handling and Disposing of COVID-19

Available at: <https://www.phmsa.dot.gov/transporting-infectious-substances/covid-19-information>

U.S. Department of Transportation

Title 49 CFR Parts 100-185 - Hazardous Materials Regulations

Available at: <https://www.phmsa.dot.gov/standards-rulemaking/hazmat/hazardous-materials-regulations>

How to Comply with Federal Hazardous Materials Regulation

Available at:

<https://www.fmcsa.dot.gov/regulations/hazardous-materials/how-comply-federal-hazardous-materials-regulations>

The Centers for Disease Control and Prevention (CDC)

When and How to Clean and Disinfect a Facility

Available at:

https://www.cdc.gov/hygiene/cleaning/facility.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fcommunity%2Fdisinfecting-building-facility.html

Guidelines for Disinfection & Sterilization in Healthcare Facilities

Available at: <https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html>

Cleaning and Waste Disposal Recommendations

Available at:

https://www.cdc.gov/hygiene/cleaning/facility.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fcommunity%2Fdisinfecting-building-facility.html

CDC National Institute for Occupational Safety and Health

Safety and Health Topic: Emergency Preparedness and Response Resources

Available at: <https://www.cdc.gov/niosh/emres/>

CDC National Center for Environmental Health

Available at: <https://www.cdc.gov/nceh/>

U.S. Army Public Health Center

Technical Guide 195A, November 2015 “Safety and Health Guidance for Mortuary Affairs Operations – Infectious Materials” Available at:

https://phc.amedd.army.mil/PHC%20Resource%20Library/TG195A_SafetyandHealthGuidanceforMortuaryAffairsOperations.pdf

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U.S. Department of Agriculture

Foreign Animal Disease Preparedness and Response Plan: Standard Operating Procedures: Cleaning and Disinfection Available at:

https://www.aphis.usda.gov/animal_health/emergency_management/downloads/sop/sop_cd.pdf

World Shipping Council

Joint Industry Guidelines for Cleaning of Containers

Available at:

https://www.google.com/url?sa=t&ret=j&q=&esrc=s&source=web&cd=&cad=rja&uact=8&ved=2ahUKEwivqMy50aqBAxXLF1kFHTDbD5IQFnoECBMQAQ&url=https%3A%2F%2Fwww.worldshipping.org%2Fnews%2Fnew-updated-version-released-of-pjoint-industry-guidelines-for-the-cleaning-of-containers&usg=AOvVaw2C124yNt7Jjyje7_CsIpZG&opi=89978449

Prevention of Pest Contamination of Containers: Joint Industry Guidelines for Cleaning of Containers (pest contamination includes contamination by organic material of animal origin)

Available at: https://www.worldshipping.org/s/Cleaning-of-Containers_Joint-Industry-Guidelines_EN.pdf