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Returning Refrigerated Transport Vehicles and Refrigerated Storage Units to Food Uses After Using Them to Preserve Human Remains During the COVID-19 Pandemic

Guidance for Industry

May 2020

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

Preface

Public Comment

This guidance is being issued to address the Coronavirus Disease 2019 (COVID-19) public health emergency. This guidance is being implemented without prior public comment because the Food and Drug Administration (FDA or Agency) has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to <https://www.regulations.gov>. All comments should be identified with the docket number FDA-2020-D-1139 which is the specific general docket for the Center for Food Safety and Applied Nutrition and complete title of the guidance in the request.

Additional Copies

Additional copies are available from the FDA webpage titled "COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders," *available at* <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>, the FDA webpage titled "Search for FDA Guidance Documents," *available at* <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

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This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

FDA plays a critical role in protecting the United States from threats such as emerging infectious diseases, including Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support response efforts to this pandemic.

FDA has been asked whether refrigerated food transport vehicles and refrigerated food storage units used for the temporary preservation of human remains during the COVID-19 pandemic subsequently can be used to transport and store human and animal food. FDA is issuing 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 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 vehicle safety, are addressed by other federal agencies, such as the Occupational Safety and Health Administration (OSHA), the Environmental Protection Agency (EPA), The Centers for Disease Control and Prevention, and the Department of Transportation (DOT), as well as State and local government

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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agencies. Several additional resources related to these topics are included in Section IV of this document.

Given this public health emergency, and as discussed in the Notice in the *Federal Register* of March 25, 2020, titled “Process for Making Available Guidance Documents Related to Coronavirus Disease 2019,” available at <https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf>, this guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the FD&C Act and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with our good guidance practices.

In general, FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s 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 Agency guidance means that something is suggested or recommended, but not required.

II. Background

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named “SARS-CoV-2” and the disease it causes has been named “Coronavirus Disease 2019” (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 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

During the COVID-19 pandemic, additional refrigerated storage is needed for human remains. Therefore, refrigerated food transport vehicles and refrigerated food storage units ordinarily used for food preservation may be temporarily used to preserve human remains. When additional refrigerated storage is no longer needed, industry may wish to return the trailers and storage units to use for food transport and storage.

III. Discussion

Refrigerated food transport vehicles and refrigerated food storage units used for the temporary preservation of human remains during the COVID-19 pandemic 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

² Secretary of Health and Human Services Alex M. Azar, Determination that a Public Health Emergency Exists. (Jan. 31, 2020, renewed April 21, 2020), 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://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>.

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food, refrigerated food transport vehicles and refrigerated food storage units used to hold human remains during the COVID-19 pandemic should be thoroughly cleaned and disinfected.⁴

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 SARS-CoV-2 virus and foodborne 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. We recommend that only EPA-registered disinfectants effective against SARS-CoV-2 (i.e., disinfectants on List N⁵) and foodborne pathogens be used.

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.

Under Occupational Safety and Health Administration (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.

⁴ 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>)

⁵ EPA, List N: Disinfectants for Use Against SARS-CoV-2, available at <https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2>.

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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.

OSHA recommends that compressed air or water sprays not be used to clean potentially contaminated surfaces, as these techniques may aerosolize infectious material.⁶

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

List N: Disinfectants for Use Against SARS-CoV-2

Available at: <https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2>

Reopening America Guidance: Cleaning and Disinfection

<https://www.epa.gov/coronavirus/guidance-cleaning-and-disinfecting-public-spaces-workplaces-businesses-schools-and-homes>

The Environmental Protection Agency

Office of Land and Emergency Management – Medical Waste web page

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

The Environmental Protection Agency

Coronavirus Frequently Asked Questions page.

Available at: <https://www.epa.gov/coronavirus/frequent-questions-about-waste-and-coronavirus-covid-19>

U.S. Department of Transportation

Handling and Disposing of COVID-19

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

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⁶ OSHA, Environmental Services Workers and Employees, available at: <https://www.osha.gov/SLTC/covid-19/environmental-services.html>.

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Title 49 CFR Parts 100-185 - Hazardous Materials Regulations

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

U.S. Department of Transportation

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)

Cleaning and Disinfecting Your Facility

<https://www.cdc.gov/coronavirus/2019-ncov/community/disinfecting-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/coronavirus/2019-ncov/hcp/guidance-postmortem-specimens.html#waste-disposal>

Cleaning and Disinfection for Non-Emergency Transport Vehicles

https://www.cdc.gov/coronavirus/2019-ncov/community/organizations/disinfecting-transport-vehicles.html?deliveryName=USCDC_1191-DM25966

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

U.S. Department of Agriculture

Foreign Animal Disease Preparedness and Response Plan: Standard Operating Procedures: 15.

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: <http://www.worldshipping.org/industry-issues/safety/joint-industry-guidelines-for-cleaning-of-containers>

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: [http://www.worldshipping.org/industry-issues/safety/Pest Contamination Cleaning Guidelines Feb 2017.pdf](http://www.worldshipping.org/industry-issues/safety/Pest%20Contamination%20Cleaning%20Guidelines%20Feb%202017.pdf)