

# 2023

## UNITED STATES CBP ENFORCEMENT OF BIOLOGICAL SUBSTANCES

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# **US CBP ENFORCEMENT OF BIOLOGICAL SUBSTANCES**

## **Agenda**



**Enforcement Overview**

**Impact for Shippers & Receivers**

**Key Takeaways**

**FAQs**

**External Links**

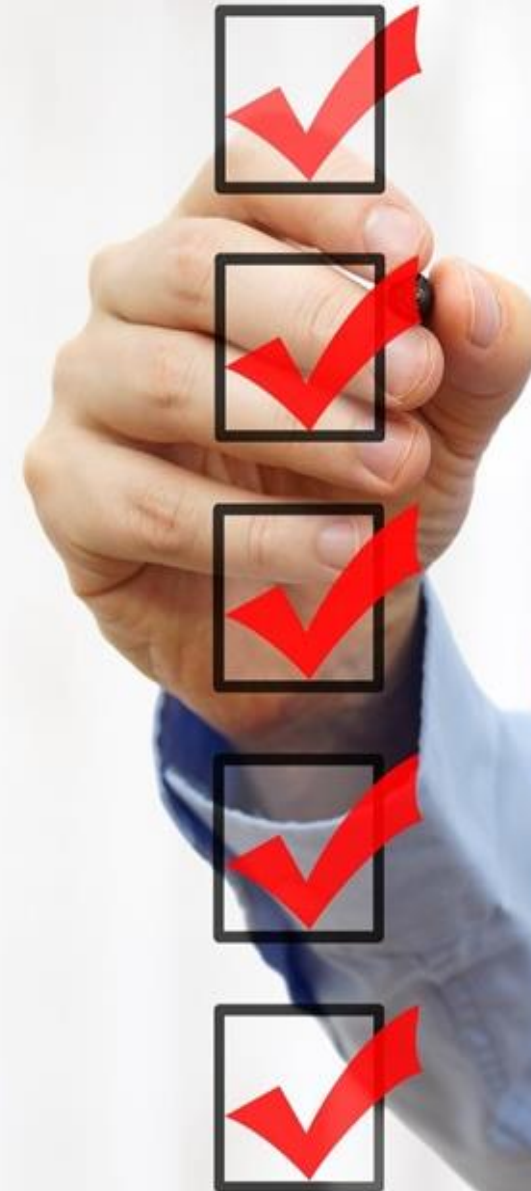
# United States CBP ENFORCEMENT OF BIOLOGICAL SUBSTANCES Overview

## Enforcement Overview

United States (U.S.) Customs and Border Protection (CBP) is enforcing the regulations and requirements regarding biological substance shipments.

**Requirements:** Import shipments of biological substances must be clear on the contents in the commodity description in the commercial invoice and airwaybill. Based on the commodity the Centers for Disease Control and Prevention (CDC) requires additional documentation outlined below for biological materials coming into the U.S.

1. Human specimens:
  - a. For infectious human biological shipments/ **UN3373 Biological Substances Category B:** A permit needs to be attached to the actual shipment and the package must be labeled with the UN3373 diamond symbol and with the text "Biological Substances Category B" marked adjacent to it.
  - b. For non-infectious human biological shipments/**Exempt Human Specimen:** The waybill description **must state** Exempt Human Specimen and the outside of the box should have markings or distinguish the shipment as containing Exempt Human Specimens. **A Statement Letter needs to be attached to the actual shipment** as well as included with the imaged work.
2. Animal specimens:
  - a. For infectious animal biological shipments/**UN3373 Biological Substances Category B:** A permit needs to be attached to the actual shipment and the package must be labeled with the UN3373 diamond symbol and with the text "Biological Substances Category B" marked adjacent to it.
  - b. For non-infectious animal biological shipments/**Exempt Animal Specimen:** The waybill description **must state** Exempt Animal Specimen and the outside of the box should have markings or distinguish the shipment as containing Exempt Animal Specimens. These types of shipments **require a permit**.



# United States CBP ENFORCEMENT OF BIOLOGICAL SUBSTANCES Overview

## Enforcement Overview - continued

Please see below a detailed description of the requirements:

### 1. Human:

- a. UN3373 Biological Substances Category B:  
Infectious UN 3373 Biological substance, Category B shipments are subject to International Air Transport Association (IATA) Dangerous Goods (DG) shipping regulations. Additionally, a CDC permit is required when the shipper knows that the shipment is infectious (hence, they declare it as UN 3373 Category B), or shipper does not know it is infectious. In both instances, a permit is needed. **A copy of the permit needs to be attached to the actual shipment.** Permit's holder details must match with receiver details on the shipment paperwork.

The package must be labeled with the UN3373 diamond symbol and with the text "Biological Substances Category B" marked adjacent to it. The words Human Specimen, although not strictly required, are highly encouraged in order to reduce inspection rates. If the shipment has a proper Human Specimen description and meets all requirements, CDC may not need to examine the shipment and may only spot check for compliance, thus improving transit time.

- b. Exempt Human Specimens:  
Eligible for manifest clearance under Sec. 321 – no import permit required. The waybill description **must state** Exempt Human Specimen and the outside of the box should have markings or distinguish the shipment as containing Exempt Human Specimens.
- ✓ **A Statement Letter needs to be attached to the actual shipment** as well as included with the imaged work. The Statement Letter must have the following:
    - ✓ Signed by the importer
    - ✓ Written on official letterhead
    - ✓ A detailed description of the imported material. The description of goods in the Statement Letter needs to match with the description of the goods on the shipment paperwork (tissue, plasma, blood, etc...) An affirmation that the material is not known or suspected to contain an infectious biological agent. This statement should:
      - Explain how you know that the specimen does not contain an infectious biological agent OR
      - Basis of the belief that there is no reason to suspect that the specimen does not contain an infectious biological agent OR
      - A detailed description of how the material was rendered noninfectious
    - ✓ Explanation of how the material will be used (i.e., testing, etc.)



# United States CBP ENFORCEMENT OF BIOLOGICAL SUBSTANCES Overview

## Enforcement Overview - continued

### 2. Animal:

Permits are required for all animal biological products (infectious or non-infectious), including samples and must be attached to the shipment and included with the imaged paperwork.

#### a. UN3373 Biological Substances Category B:

- ✓ Infectious UN 3373 Biological substance, Category B shipments are subject to International Air Transport Association (IATA) Dangerous Goods (DG) shipping regulations. Additionally, a CDC permit is required when the shipper knows that the shipment is infectious (hence, they declare it as UN 3373 Cat B), or shipper does not know it is infectious, and in the case of animal specimens, even when the shipment is non-infectious. In all instances, a permit is needed. **A copy of the permit needs to be attached to the actual shipment.** Permit's holder details must match with receiver details on the shipment paperwork.
- ✓ The package must be labeled with the UN3373 diamond symbol and with the text "Biological Substances Category B" marked adjacent to it. The words Animal Specimen, although not strictly required, are highly encouraged because authorities seek to examine all shipments of animal specimens, and this would support them in identifying those shipments.

b. Exempt Animal Specimens: Non-infectious animal biological shipments waybill description **must state** Exempt Animal Specimen and the outside of the box should have markings or distinguish the shipment as containing Exempt Animal Specimens. These types of shipments **require a permit** and should follow the permit requirements stated immediately above.



# US CBP ENFORCEMENT OF BIOLOGICAL SUBSTANCES

## Impact for Shippers & Receivers



### Impact for Shippers and Receivers (from Rest of World to the United States)



Shippers from Rest of World to the United States shall be aware that:

Noncompliant shipments will result in denied admissibility by U.S. CBP. This includes not having all the required documents on the shipment at the time of presentation to U.S. CBP. In most cases U.S. CBP will allow the shipment to return to origin but in some cases, U.S. CBP will request destruction of noncompliant shipments.

#### HOW CAN SHIPPERS FROM REST OF WORLD TO UNITED STATES AVOID DELAYS

Shippers from Rest of World to the United States shall:

- ✓ Shippers should place all documents on the shipment for review during inspection. All documents should align with the contents of the shipments, permits, proper description, labeling, marking, and packaging. If all paperwork is aligned and meets regulations, the package should be released after inspection or avoid inspection.
- ✓ Shippers must not use UN 3373 Biological Substances Category B for goods that are not infectious and use the correct description of Exempt Human Specimen or Exempt Animal Specimen as applicable. They must use the correct packaging and correct description.
- ✓ Stating on the Invoice that Exempt Human Specimen is not infectious **does not suffice for CDC**. It must have the Statement Letter of non-infectious with the details outlined above.
- ✓ UN 3373 Biological Substances Category B should have the CDC Permit and **should not have** the Statement Letter of non-infectious, as it is contradictory.
- ✓ Permit's holder details must match with receiver details on the shipment paperwork. The CDC permit functions to ensure that infectious substances are going to a lab that can handle infectious substances and not a home lab. Customers can always add other names under the permit.

## KEY TAKEAWAYS

### About The CBP Enforcement of Biological Substances

- ✓ Import shipments of biological substances must be clear on the contents in the commodity description in the commercial invoice and airwaybill.
- ✓ **For infectious Human biological shipments/ UN3373 Biological Substances Category B:** A permit needs to be attached to the actual shipment and the package must be labeled with the UN3373 diamond symbol and with the text "Biological Substances Category B" marked adjacent to it
- ✓ **For Exempt Human Specimens, a Statement Letter needs to be attached to the actual shipment** The waybill description **must state** Exempt Human Specimen and the outside of the box should have markings or distinguish the shipment as containing Exempt Human Specimens.
- ✓ **For infectious Animal biological shipments/UN3373 Biological Substances Category B:** A permit needs to be attached to the actual shipment and the package must be labeled with the UN3373 diamond symbol and with the text "Biological Substances Category B" marked adjacent to it.
- ✓ **For non-infectious Animal biological shipments/Exempt Animal Specimen:** The waybill description **must state** Exempt Animal Specimen and the outside of the box should have markings or distinguish the shipment as containing Exempt Animal Specimens.
  - **Permits are required for all animal biological products (infectious or non-infectious), including samples** and must be attached to the shipment and included with the imaged paperwork.
- ✓ Infectious UN 3373 Biological substance, Category B shipments (containing **Animal or Human** specimens) are subject to International Air Transport Association (IATA) Dangerous Goods (DG) shipping regulations.
- ✓ Infectious UN 3373 Biological substance, Category B shipments require a **copy of the permit to be attached to the actual shipment**. Permit's holder details must match with receiver details on the shipment paperwork.





# US CBP ENFORCEMENT OF BIOLOGICAL SUBSTANCES

## Frequently Asked Questions (FAQs)

### Frequently Asked Questions (FAQs)

#### What are the package labeling requirements?

Label requirements can be found here:

##### Job Aid for Packing

[https://www.cdc.gov/labtraining/docs/job\\_aids/packing\\_and\\_shipping/Step\\_3\\_Job\\_Aid\\_Final\\_v2\\_052322.docx](https://www.cdc.gov/labtraining/docs/job_aids/packing_and_shipping/Step_3_Job_Aid_Final_v2_052322.docx)

##### Label Aid

[https://www.cdc.gov/labtraining/docs/job\\_aids/packing\\_and\\_shipping/Step\\_4\\_Job\\_Aid\\_Final\\_v2\\_072422\\_508.docx](https://www.cdc.gov/labtraining/docs/job_aids/packing_and_shipping/Step_4_Job_Aid_Final_v2_072422_508.docx)

#### Are there any changes regarding Permits, Licenses, and Certificates requirements?

- There are no changes to the regulation. The permit requirements under CDC regulations continue to apply.
- Permits are required for all Animal specimens **UN3373 Biological Substance, Category B (infectious) and Exempt Animal Specimens (non-infectious)**, including samples and must be attached to the shipment and included with the imaged paperwork. Permit's holder details must match with receiver details on the shipment paperwork.
- For Human, **UN3373 Biological Substances Category B**: a CDC permit is required when the shipper knows that the shipment is infectious (hence, they declare it as UN 3373 Category B), or shipper does not know it is infectious. In both instances, a permit is needed. **A copy of the permit needs to be attached to the actual shipment.** Permit's holder details must match with receiver details on the shipment paperwork.



# US CBP ENFORCEMENT OF BIOLOGICAL SUBSTANCES

## External Links

### External Links

For additional information, please consult the following website below:

[www.CDC.gov](http://www.CDC.gov)



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