

# A Guide to Shipping Samples

From European Union to the USA

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  - Refer to: Guidance on regulations for the Transport of Infectious Substances 2009-2010, World Health Organization (can be found on the Web)
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  - Accugenix Identification Request Forms
  - Commercial Invoice
  - Consignment Note
  - CDC Permit (obtain from Accugenix)
- Recommended Packaging

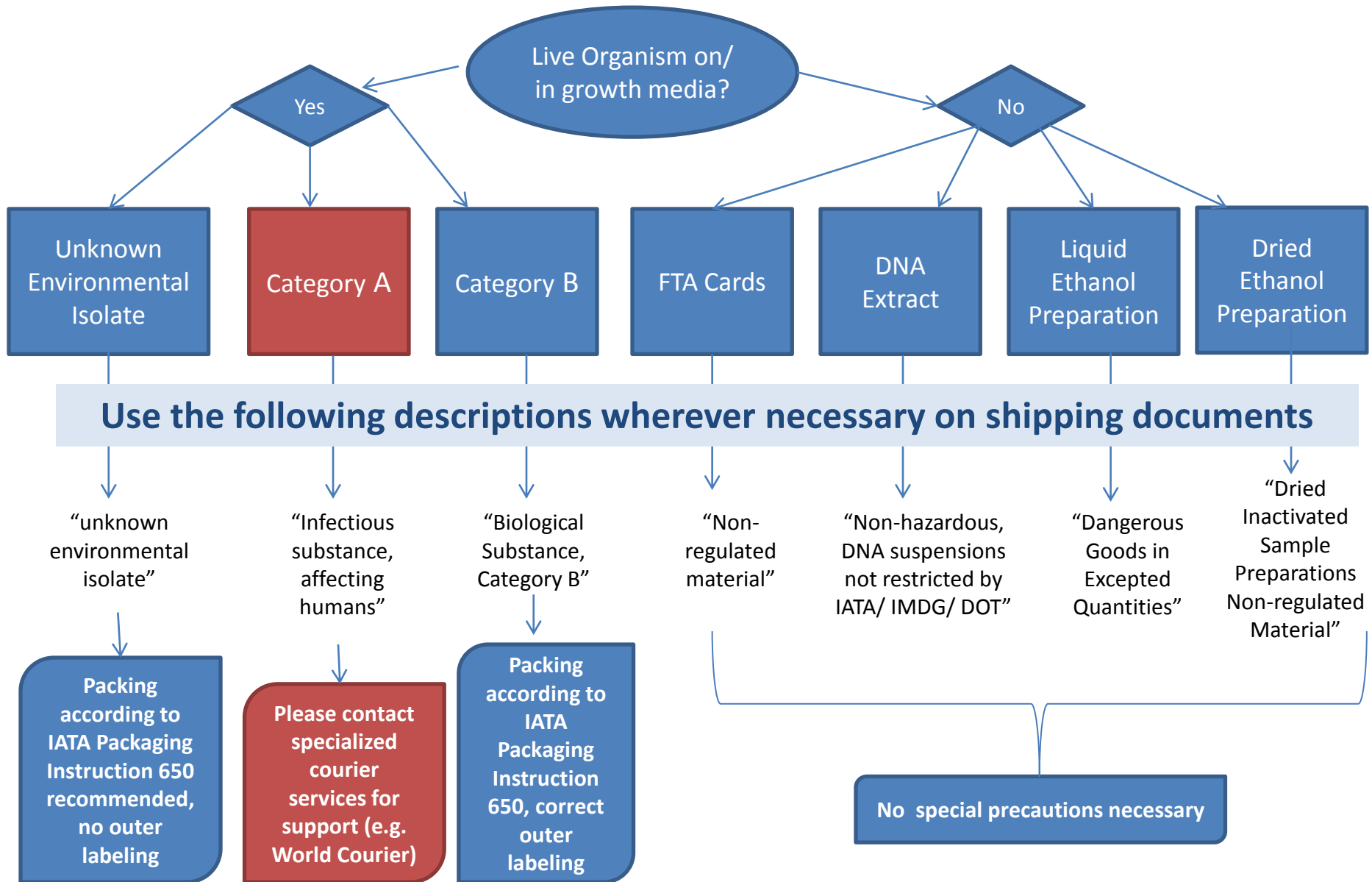
# What type of sample are you sending?

- Unknown Environmental Isolate
- Known Infectious Substance
  - Category A\*
    - *An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals.*
    - Infectious Substance, Affecting Humans (UN 2814) OR Infectious Substance, Affecting Animals (UN 2900).
    - **Accugenix requires special permits to allow the import of certain Category A microorganisms. Please contact Accugenix if you believe you have a Category A sample.**
  - Category B
    - *An infectious substance which does not meet the criteria for inclusion in Category A.*
    - Biological Substance, Category B (UN 3373)

\*Refer to Annex 2, “Examples of infectious substances included in Category A,” Guidance on regulations for the Transport of Infectious Substances 2009-2010, World Health Organization.

- FTA Card
- DNA Extract
- Liquid Ethanol Preparation
- Dried Ethanol Preparation

# Labeling and Packaging Requirements



# Shipping Documents Required for International Shipments to the U.S.

Required Shipping Documents	Sample Types					
	Live Cultures (Unknown)	Live Cultures (Category B)	FTA Cards	DNA Extract	Liquid Ethanol Preparation	Dried Ethanol Preparation
<b>Accugenix Identification Request Form</b> (IRF can be found on Accugenix's website)	Yes Inside	Yes Inside	Yes Inside	Yes Inside	Yes Inside	Yes Inside
<b>Airway Bill</b> (i.e. FedEx, UPS, DHL)	Yes Outside	Yes Outside	Yes Outside	Yes Outside	Yes Outside	Yes Outside
<b>Commercial Invoice</b> (Document attesting to the monetary value of the shipment)	Yes Outside Description of Goods State: "Unknown Environmental Isolates"	Yes Outside Description of Goods State: "Biological Substance, Category B"	Yes Outside Description of Goods State: "Non-regulated material"	Yes Outside Description of Goods State: "Non-hazardous DNA suspensions. Not restricted by IATA/IMDG/ DOT"	Yes Outside Description of Goods State: "Dangerous Goods in Excepted Quantities"	Yes Outside Description of Goods State: "Dried Inactivated Sample Preparations Non-regulated Material"
<b>Shipper's Declaration of Dangerous Goods</b>	Not Required	Yes Outside	Not Required	Not Required	Not Required	Not Required
<b>CDC Permit</b> (Accugenix will provide a copy of our CDC Permit)	Yes Outside	Yes Outside	Yes Outside	Yes Outside	Yes Outside	Yes Outside
<b>Biohazard Label</b> (Order from preferred vendor)	Not Required	Yes Secondary Container	Yes Affix to Multi-barrier Pouch	Not Required	Not Required	Not Required

# Identification Request Forms\* —

## Place the appropriate form inside the box

For AccuPRO-ID®

For Sequencing and RiboTyping

**Accugenix** The Leader in Genetic Microbial Identification  
 223 LAKE DRIVE, NEWARK, DE 19702 PHONE 302.292.8888 FAX 302.292.8468

ACCOUNT # \_\_\_\_\_ LOGGED \_\_\_\_\_ CALLED \_\_\_\_\_  
FOR ACCUGENIX USE ONLY

**CUSTOMER ACCOUNT INFORMATION**

**SHIP REPORTS TO**  
 COMPANY \_\_\_\_\_ CONTACT NAME \_\_\_\_\_ QUOTE # \_\_\_\_\_  
 ADDRESS \_\_\_\_\_ CITY \_\_\_\_\_ STATE \_\_\_\_\_  
 ZIP/MAIL CODE \_\_\_\_\_ COUNTRY \_\_\_\_\_ PHONE \_\_\_\_\_

**BILL TO**  
 SAME AS SHIPPING  
 INVOICING CONTACT \_\_\_\_\_ DEPARTMENT \_\_\_\_\_ PHONE \_\_\_\_\_ FAX \_\_\_\_\_  
 ADDRESS \_\_\_\_\_ CITY \_\_\_\_\_ STATE \_\_\_\_\_  
 ZIP/MAIL CODE \_\_\_\_\_ COUNTRY \_\_\_\_\_ EMAIL ADDRESS \_\_\_\_\_

**PAYMENT INFORMATION**  
 PURCHASE ORDER # \_\_\_\_\_  
 If using a POB, send a signed copy via email to [technicalsupport@accugenix.com](mailto:technicalsupport@accugenix.com), or fax to 302.292.8468.  
 CREDIT CARD # \_\_\_\_\_  VISA  MASTERCARD  AMERICAN EXPRESS  
 CARDHOLDER NAME \_\_\_\_\_ EXPIRATION DATE \_\_\_\_\_ CSC CODE (3 OR 4 DIGIT) \_\_\_\_\_

**DELIVERY OF ID REPORTS ON DUE DATE**  
 VIA EMAIL - PROVIDE ALL APPLICABLE ADDRESSES)  
 VIA FAX - PROVIDE FAX NUMBER

**DELIVERY OF HARD COPY ID REPORTS**  
 SEND HARD COPY REPORTS OVERNIGHT (ADDITIONAL FEE APPLIES)  
 DO NOT SEND HARD COPIES (ACCUGENIX WILL ARCHIVE)

**SAMPLE DISPOSITION** **MUST CHOOSE ONE.** Samples will be discarded 3 calendar weeks from sample due date.  
 Discard Sample  Return Sample (Customer FedEx # Required)  Customer FedEx# \_\_\_\_\_

**AUTHORIZATION**  
 AUTHORIZED SIGNATURE (REQUIRED) \_\_\_\_\_ DATE \_\_\_\_\_

**PROTEOTYPIC BACTERIAL IDENTIFICATION**

**TEST CODES:** The number in each code refers to the desired turnaround time in business days from when the sample is received and meets the sample shipping requirements as stated in the Terms & Conditions.  
 MALDIBac-0  
 MALDIBac-1  
 MALDIBac-2  
 MALDIBac-5  
 MALDIBac-10

For Direct Samples, both temperature and time are critical factors that will affect result. Samples should not be exposed to or stored at temperatures below room temperature. Ship samples at room temperature. NO ICE PACKS! The total time from sample inoculation to arrival at Accugenix should not exceed 48 hours, otherwise subculture will be required (check below). Record inoculation date and time information for each Direct Sample submitted.  
 \*Ethanol Extracted Samples are not time sensitive nor affected by temperature fluctuations.

When more than one colony type is present:  ID DOMINANT COLONY ONLY  ID ALL DISTINCT COLONY TYPES  ID CIRCLED COLONY ONLY

ACCUGENIX USE ONLY	CUSTOMER SAMPLE ID	SUBSTRATE	DATE	TIME	EXTRACT	TEST CODE	COMMENTS
	1						
	2						
	3						
	4						
	5						
	6						
	7						
	8						
	9						
	10						

\* Check only if sample is recovered from marketed product source. \*\* Only Direct Samples can be sub-cultured. 1 OF 2 SOP-GEN-058.3 EFF. 11MAR10

**Accugenix** The Leader in Genetic Microbial Identification  
 223 LAKE DRIVE, NEWARK, DE 19702 PHONE 302.292.8888 FAX 302.292.8468

ACCOUNT # \_\_\_\_\_ LOGGED \_\_\_\_\_ CALLED \_\_\_\_\_  
FOR ACCUGENIX USE ONLY

**CUSTOMER ACCOUNT INFORMATION**

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 ADDRESS \_\_\_\_\_ CITY \_\_\_\_\_ STATE \_\_\_\_\_  
 ZIP/MAIL CODE \_\_\_\_\_ COUNTRY \_\_\_\_\_ PHONE \_\_\_\_\_

**BILL TO**  
 SAME AS SHIPPING  
 INVOICING CONTACT \_\_\_\_\_ DEPARTMENT \_\_\_\_\_ PHONE \_\_\_\_\_ FAX \_\_\_\_\_  
 ADDRESS \_\_\_\_\_ CITY \_\_\_\_\_ STATE \_\_\_\_\_  
 ZIP/MAIL CODE \_\_\_\_\_ COUNTRY \_\_\_\_\_ EMAIL ADDRESS \_\_\_\_\_

**PAYMENT INFORMATION**  
 PURCHASE ORDER # \_\_\_\_\_  
 If using a POB, send a signed copy via email to [technicalsupport@accugenix.com](mailto:technicalsupport@accugenix.com), or fax to 302.292.8468.  
 CREDIT CARD # \_\_\_\_\_  VISA  MASTERCARD  AMERICAN EXPRESS  
 CARDHOLDER NAME \_\_\_\_\_ EXPIRATION DATE \_\_\_\_\_ CSC CODE (3 OR 4 DIGIT) \_\_\_\_\_

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 Discard Sample  Return Sample (Customer FedEx # Required)  Customer FedEx# \_\_\_\_\_

**AUTHORIZATION**  
 AUTHORIZED SIGNATURE (REQUIRED) \_\_\_\_\_ DATE \_\_\_\_\_

**TEST INFORMATION**

The number in each code refers to the desired turnaround time in business days from when the sample is received. Use "0" test codes for same-day service.  
 Microbial Characterization is performed using a standard two enzyme analysis (BacRI). A single enzyme analysis (BacRES) is offered for special circumstances.

**BACTERIAL ID (16S 500bp)**  
 BacSeq-0  
 BacSeq-1  
 BacSeq-2  
 BacSeq-5  
 BacSeq-10

**MOLD and YEAST ID (ITS)**  
 FunRI-0  
 FunRI-1  
 FunRI-2  
 FunRI-5  
 FunRI-10

**BACTERIAL ID (16S 1500bp)**  
 FunSeq-0  
 FunSeq-2  
 FunSeq-5

**MICROBIAL CHARACTERIZATION (RiboPrinter®)**  
 BacRib-1  
 BacRib-2  
 BacRib-5  
 BacRib-10  
 BacRib-20

**GRAM STAIN**  
 GS-1  
 GS-5

**MICROSCOPIC ID (Filamentous Fungi)**  
 FunMic-5

When more than one colony type is present:  ID DOMINANT COLONY ONLY  ID ALL DISTINCT COLONY TYPES  ID CIRCLED COLONY ONLY

ACCUGENIX USE ONLY	CUSTOMER SAMPLE ID	BACTERIAL	YEAST	TEST CODE	COMMENTS
	1				
	2				
	3				
	4				
	5				
	6				
	7				
	8				
	9				
	10				

\* Check only if sample is recovered from marketed product source. 1 OF 2 SOP-GEN-011 EFF. 19JAN09

\* Available on Accugenix website or contact Technical Support at +1.302.292.8888

# Commercial Invoice

- EU to United States – REQUIRED

•Fill in the **Description of Goods** section with the following:

**For Known Organisms -**  
“Biological Substance, Category B”

**For Unknown cultures–**  
“Unknown Environmental Isolate”

**For FTA Cards –**  
“Non-regulated materials”

**For DNA Extract –**  
“Non-hazardous DNA suspensions not restricted by IATA/IMDG/DOT”

**For Liquid Ethanol Preparation –**  
“Dangerous Goods in Excepted Quantities”

**For Dried Ethanol Preparation –**  
“Inactivated Sample Preparations  
Non-regulated Material”

- Affix to outside of box

•Your courier service will support you in preparing a commercial invoice

•Adhere to regulations of shipping company and local government

•Templates can be found on-line from shippers

## Commercial Invoice

Consignee:	Date: _____	Export Reference #: _____
Shipped by:		

Country of Ultimate Destination: \_\_\_\_\_

Customs Broker: \_\_\_\_\_

Haz mat	Marks & Numbers	Country of Origin	# of Cases	Detailed Description of Goods	Weight	Quantity	Unit Value US\$	Total Value US\$
Total Number of Cases:					Total Weight:			Total Value:

These commodities are licensed for the ultimate destination shown.  
Diversion contrary to the United States Law is prohibited.

*"I hereby declare that the information on this invoice is true and correct. I hereby authorize the freight carrier to execute any additional documents as may be necessary to export the goods."*

Name of Shipper: \_\_\_\_\_ Title: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_


## Consignment Note

- Example of a blank consignment note for Category B, UN 3373


- Affix to outside of box

- Your courier service will provide you with blank forms

Special Service Consignment	
<b>Sender</b> AccNo. : Name : FIRMA ABC Address : PC/City : Contact : Tel.No. : Fax :	
<b>Receiver</b> AccNo. : Name : AGENOLAB GMBH&CO KG Address : KESSELSTR. 17 PC/City : DE 70327 STUTTGART Contact : Tel.No. : Fax :	
<b>Pickup</b> AccNo. : Name : Address : Coun/PC : City : Contact : Tel.No. : Fax :	<b>Delivery</b> AccNo. : Name : Address : Coun/PC : City : Contact : Tel.No. : Fax :
<b>Airfreight/WEF</b> <input type="checkbox"/> door to door <input type="checkbox"/> door to Airport	<b>Dangerous Goods</b> <input type="checkbox"/> Dangerous Goods Class: Pack.-Group: UNNr. : <input type="checkbox"/> Limited Quantity
<input checked="" type="checkbox"/> Invoice to Receiver Sender liable for unpaid charges	



0



The Conditions of Carriage of TNT Express GmbH will apply to all assignments, valid in the most recently amended version. Registered office 53842 Troisdorf. Siegburg District Court HRB 6113, Directors: Thomas Kraus (chair), Thomas Lock, Jürgen Seifert, Dr. Roland Schütze

Special Instructions	
<b>Reference</b> : Pickup-Date : <input type="checkbox"/> Self pickup Delivery-Date:Delivery-Time:	
Goods Description	
Items	Description Weight(kg)
0	0
Value :	0,00 EUR
Dimensions	
Colli	Lengths Width Height Volume
0	0,000 m 0,000 m 0,000 m 0,000 m3
0	0,000 m 0,000 m 0,000 m 0,000 m3
0	0,000 m 0,000 m 0,000 m 0,000 m3
MOID SPS 116	
Date	Signature

# Permit to Import or Transfer Etiological Agents or Vectors of Human Disease

## PHS PERMIT NO. 2010-03-117

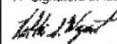
- Permit allows Accugenix to receive isolates and DNA of Etiologic Agents from international clients
- Renewed every year
- States conformance requirements with 49 CFR Sections 171-180
- *Not* approved for select agents (42 CFR 73)
- Accugenix provides document
- Affix to outside box

MAR. 26. 2010 3:15PM IMPORT PERMITS NO. 356 P. 1/3

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
Centers for Disease Control and Prevention  
Office of Health and Safety, MS A-16  
Atlanta, Georgia 30333  
TEL: 404-718-2077; FAX: 404-718-2093

**CDC**  
SAFER · HEALTHIER · PEOPLE™

**Permit to Import or Transfer Etiological Agents or Vectors of Human Disease**  
In accordance with 42 CFR Section 71.54 of the Public Health Service Foreign Quarantine Regulations, cited on the bottom of this permit, permission is granted the permittee to import into any port under control of the United States, or to receive by transfer within the United States, the material described in item 1 below.

PHS PERMIT NO.	2010-03-117	
DATES	ISSUED: Monday, March 22, 2010	EXPIRES: Tuesday, March 22, 2011
1. DESCRIPTION OF MATERIAL	ISOLATES OF ETIOLOGIC AGENTS (LIST ON FILE AT CDC).	
2. PERMITTEE (NAME, ORGANIZATION, ADDRESS)	BETH H. BURKE ACCUGENIX, INC. 223 LAKE DRIVE NEWARK, DE 19702	TEL: 302-292-8888 FAX: 302-292-8468
3. SOURCE OF MATERIAL (NAME, ORGANIZATION, ADDRESS, COUNTRY)	WORLDWIDE	
4. TYPE OF PERMIT AND INSTRUCTIONS FOR USE	<input checked="" type="checkbox"/> Multiple Importation into the US <input checked="" type="checkbox"/> Multiple Transfer Within the US A. Record of each importation shall be maintained on permanent file by permittee. B. Enclosed label(s) must be forwarded to the shipper(s). C. One label shall be affixed to shipping container. Enclosed labels may be photocopied.	
5. CONDITIONS OF ISSUANCE ITEMS APPLICABLE WHEN CHECKED	<input type="checkbox"/> A. Subsequent distribution, within the U.S., of the material described in this permit is prohibited without prior authorization by the Public Health Service. <input checked="" type="checkbox"/> B. All materials for laboratory use only. Not for use in the production of biologics for humans or animals. <input checked="" type="checkbox"/> C. All material is free of tissues, serum and plasma of domestic and wild ruminants, swine and equines. <input type="checkbox"/> D. Additional Requirements: <input type="checkbox"/> File APHIS/CDC Form 2 for select agents as defined in 42 CFR 73 <input type="checkbox"/> IATA Packaged to preclude escape. <input type="checkbox"/> USDA permit may be required (Telephone: 301-734-3277). <input checked="" type="checkbox"/> E. Work with the agent(s) described shall be restricted to areas and conditions meeting requirements in the CBQNH publication, "Biosafety in Microbiological and Biomedical Laboratories." <input checked="" type="checkbox"/> F. Packaging must conform to 49 CFR Sections 171-180. <input type="checkbox"/> G. Select Agent. Receiving facility must be registered under 42 CFR Part 73.	
6. COPY SENT TO	7. Signature of issuing officer	
<input checked="" type="checkbox"/> U.S. QUARANTINE STATION	 Robbin Weyant, PhD, CAPT, USPHS, Etiologic Agent Import Permit Program	

CDC 0728 (F 13.00) REV. 2-91

42 CFR 71.54. Etiological agents, hosts, and vectors

(a) A person may not import into the United States, nor distribute after importation, any etiological agent or any arthropod or other animal host or vector of human disease, or any exotic living arthropod or other animal capable of being a host or vector of human disease unless accompanied by a permit issued by the Director.

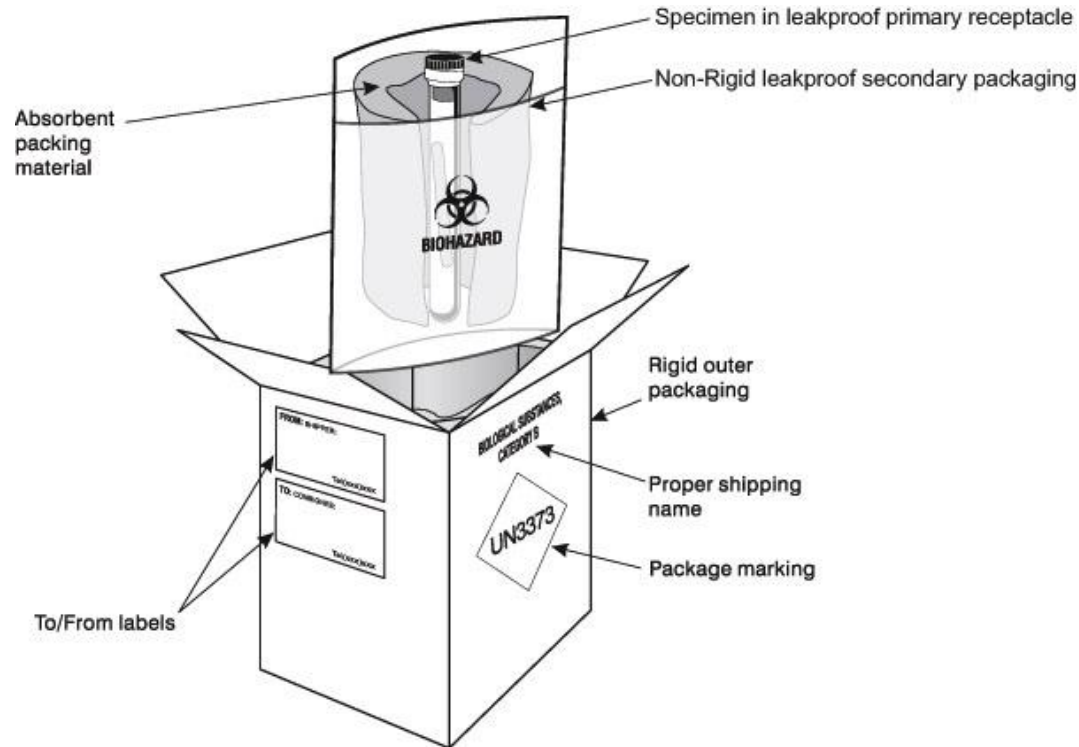
(b) Any import coming within the provisions of the section will not be released from custody prior to receipt by the District Director of the U.S. Customs Service of a permit issued by the Director.

Note: Other permits may be required.

# Packaging – Triple Containment

In accordance with IATA Packing Instruction 650

- Required for UN3373, Biological Substance, Category B
- Recommend for non-regulated “unknown environmental isolate”



# Accugenix Recommendations

- Ship agarose plates at ambient temperature
  - Do not send blue ice packs/ dry ice
  - Ship overnight via traceable courier
- Choose your descriptions *carefully*...
  - Known infectious substance: “Biological substance, Category B”
  - Unknown organisms: “Unknown environmental isolates”
  - FTA cards: “Non-regulated Material”
  - DNA extract: “Non-hazardous DNA suspensions not restricted by IATA/ IMDG/ DOT”
  - Liquid ethanol preparation: “Dangerous Goods in Excepted Quantities”
  - Dried ethanol Preparation: ““Non-regulated Material - Dried Inactivated Sample ”
- ***Do not use for description of goods...***
  - Pharmaceuticals, Bacteria, Genetic Material, Baby Formula, DNA, etc. Or sample(s) will be delayed!