



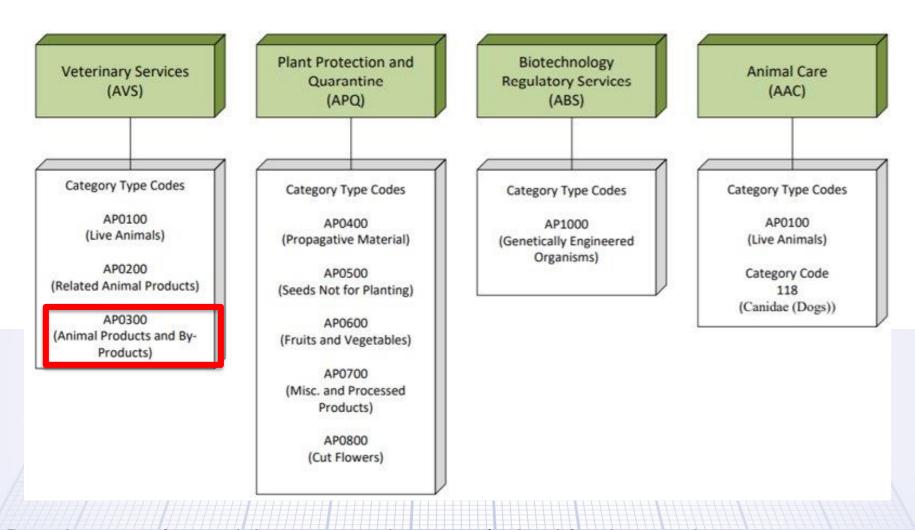
Using the Automated Commercial Environment (ACE) to Submit APHIS-Required Import Data for Animal Product Commodities

February 20, 2020

Exemptions from APHIS Core PGA Data

- APHIS Veterinary Services Live Animals
 - https://www.aphis.usda.gov/aphis/ourfocus/animalhea
 lth/animal-and-animal-product-import-information/live-animal-imports/import-live-animals
- Select Agents
 - https://www.selectagents.gov/
- Hand-carried Material (unless filing in ACE)
 - http://cbp.gov/biologicals

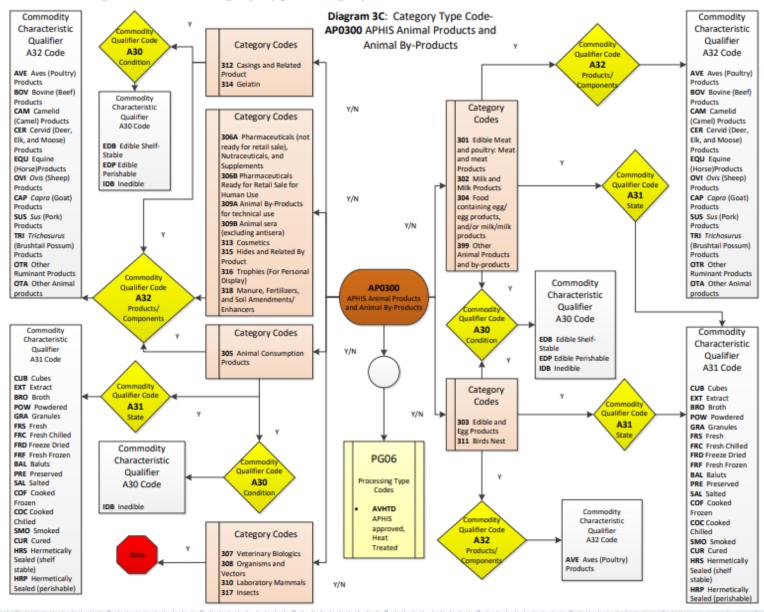




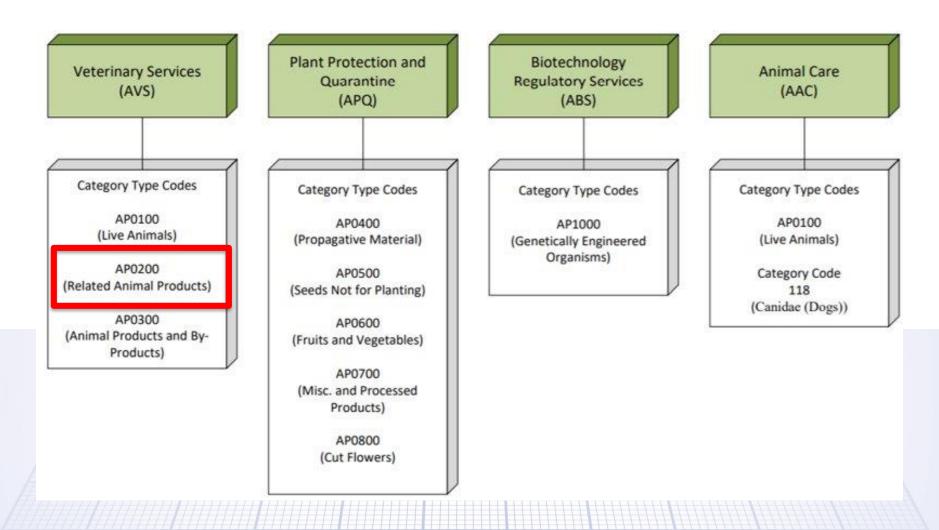
Broad scope of materials: meat products, pet/animal foods, veterinary biologics (vaccines, test kits), pharmaceuticals, fertilizers, and many other commodities that contain animal origin material.

United States Department of Agriculture

AP0300 Business Rule Diagram - PG10 Category Type, Category, and Characteristics





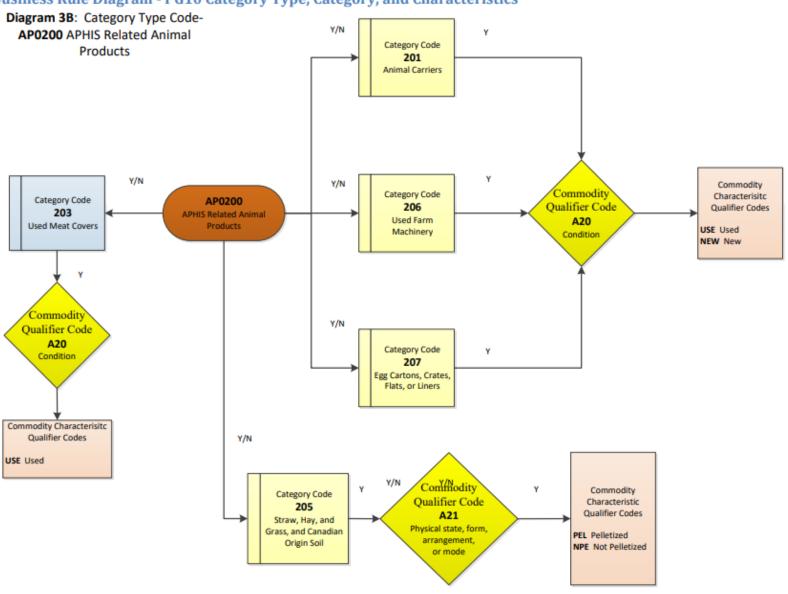


Commodities that may have come into contact with animal products or be contaminated with animal products.



United States Department of Agriculture

AP0200 Business Rule Diagram - PG10 Category Type, Category, and Characteristics



Data Elements That "Drive" the Message Set

- HTS Code
- Government Agency Code: APH
- APHIS Program Code: AVS
- Government Agency Processing Code: A01
- PG 10:
 - Category Type Code: AP0200 or AP0300
 - Category Code: 2XX or 3XX
 - Commodity Characteristics
- LPCO Type and Identifier (Number)
- Country of origin and/or export
- Permitted Destination Address



VS Form 16-6a Permit: LPCO Type Code A24

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VS FORM 16-6A (MAR 95)

Replaces VS Form 16-3A and 16-28 which are obsolete

Page 1 of 2



APHIS 2006 Permits: LPCO Type Code A06, APHIS DIS Doc Code APH03

United States
Department of Agriculture

UNITED STATES VETERINARY BIOLOGICAL PRODUCT PERMIT

RESEARCH AND EVALUATION

Permit #

Dates valid

NO. *VB-161105*

Issued at Washington, D.C. on

6/21/2017

This parmit is issued pursuant to the torms of the Act of Congress approved March 4, 1913 (37 state 837), governing the preparation, sale, batter, exchange, anipment, and importation of veterinary biological products. So far as the jurisdiction of the U.S. Department of Agriculture is concerned.

IMA Importer University Research Facility 4700 River Road

Importer/consignee

Riverdale, MD 20737
is authorized to import

Bovine Coronavirus Test Kits

This is an unlicensed experimental test kit imported for research only in our facility. It will not be sold or further distributed in the U.S.

prepared by

Biologics Manufacturing Inc Brussels, Belgium

Producer/exporter

into the United States through the port of Any U.S. Port

Importation shall be made subject to the following special conditions:

This importation is authorized in accordance with Title 9, Code of Federal Regulations, Part 104 for evaluation at the research/containment facility or diagnostic laboratory specified in the application filed with the Animal and Plant Health Inspection Service. All unused portions of imported materials must be autoclaved or incinerated before disposal.

Imported materials have not been approved by the USDA for sale and distribution. Therefore any claims regarding the prevention, diagnosis, management or cure of animal diseases have not been proven.

A COPY OF THIS PERMIT MUST BE INCLUDED WITH THE SHIPMENT FOR PORT INSPECTION.

This permit may be revoked if the permittee violates or fails to comply with said Act, the regulations made thorounder, or the conditions specified herein.

6/21/2016

Donna L Malloy

Donna L. Malloy for Director, Center for Veterinary Biologics
Animal and Flant Health Inspection Service

United States Department of Agriculture UNITED STATES VETERINARY BIOLOGICAL PRODUCT PERMIT SALE AND DISTRIBUTION no permit # Issued at Washington, D.C. on Expires: Not Applicable This permit is issued pursuant to the terms of the Act of Congress approved March 4, 1913 (37 Stat. 832), governing the preparation, sale, barter, exchange, shipment, and importation of veterinary biological products. So far as the jurisdiction of the U.S. Department of Agriculture is con Importer/consignee/ 601 West Cornhusker Highway Lincoln, Nebraska 68521 quarantine facility is authorized to import Parapox Ovis Virus Immunomodulator, Code 9330.00 Zoetis, Belgium S.A. Exporter/consignor Rue Laid Burnait, 1 B-1348 Louvain la Nueve. Belgium Any Port Importation shall be made subject to the following special conditions: The producer/permittee agrees to submit to periodic reinspections of the production facility under terms to be specified in a Cooperative Agreement between the parties. The permittee agrees to be responsible for all costs associated with these inspections. See attached restriction(s). This permit may be revoked if the permittee violates or fails to comply with said Act, the regulations made thereunder, or the conditions specified herein March 27, 2013 Center for Veterinary Biologics Director Animal and Plant Health Inspection Service



Certificate(s): LPCO Type Code A03

- Must submit in original, paper form
- Enter the certificate number in ACE





Other: Manufacturer's statement ("STATs") LPCO Type Code A25, APHIS DIS Doc Code APH01.

Manufacturer's Statement Example

I. Identification of product Brownies from the grocery store		
Date of production: August 01, 2019		
Type of packaging: Plastic	Number of packages: 1 (one)	
Condition of storage and transport: room temperature, automobile	Net weight (kg) 0.68 kg	
Name, address and approval number of producing establishment : Giant Food of North America		
Manufacturer's Declaration:		
I, Example Person 1, hereby certify that:		

SIGNATURE (Digital or ink)
DATE

1. The product contains lactose as the only animal origin ingredient.



EXAMPLES



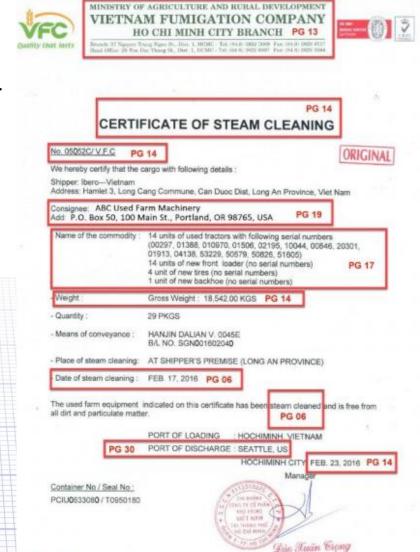
Example 1: Feathers for Stuffing

- 10 digit HTS Code: 0505.10.00.XX
- Category Type Code: AP0300 Animal Products
- Category Code: 315 Hides and related by products
- Country of Export
- Country of Origin
- Importer Name and Address
- Exporter Name and Address
- Permit Number
- Health certificate number, if required



Example 2: Used Farm Equipment

- Includes equipment used in the production of livestock or crops, slaughter machinery, tractors, but not automobiles and trucks.
- Country of Export
 - Foot-and-Mouth Disease affected?
- HTS: many may apply
- Category Type Code: AP0200 Related Animal Products
- Category Code 207
- PG10 Commodity Qualifier A20
 "Condition"= Used
- PG 14 Type Code A05 Treatment Certificate





Example 3: Veterinary Biologics

- All veterinary biologics require an APHIS permit: APHIS Form 2006
 - PG14 Type Code A06, DIS document Code APH03
- 10 digit HTS Code: 3002.30.0000 (veterinary vaccines)
 - Other codes may apply if not a veterinary vaccine
- PG02 APHIS Veterinary Biologics Product Code (AVB)
 - for sales and distribution veterinary biologics
- Category Type Code: AP0300 Animal Products
- Category Code: 307 Veterinary Biologics
- Producer/Manufacturer Name and Address
- Destination/Quarantine Address

Veterinary biologics are vaccines, bacterins, diagnostics, etc. which are used to prevent, treat, or diagnose animal diseases. These products generally work through some immunological method or process.

USDA

Example 4: Commodities for Human Consumption

- 10 digit HTS Code: XXXX.XX.XX.XX
- Category Type Code: AP0300 Animal Products
- Category Code:
 - Meat/poultry = 301
 - Milk/milk products = 302
 - Egg/Egg products = 303
 - Food containing egg/egg products and/or milk/milk products = 304
 - Nutraceuticals/Supplement= 306A

- Permit number, if required
- Meat/sanitary certificate number
- manufacturer's statement (DIS)
- Country of Export
- Country of Origin
- Country of Processing
- Commodity Type (i.e. ham, sausage, etc) and animal species



USDA FSIS may also regulate these products.

Example 5: Pet Food/Animal Feed Ingredients

- 10 digit HTS Code: 23XX.XX.XX.XX
- Category Type Code: AP0300 Animal Products
- Category Code: 305 Animal Consumption Products
- Permit Number
- Manufacturer's Statement (DIS)/Health Certificate Number, if required by permit
- Country of Export and/or Origin
- All species from which animal origin materials contained within the product are derived from



Example 6: Inedible Gelatin

- 10 digit HTS Code: **3503.00.XX.XX** or **9602.00.10.XX**
- Category Type Code: AP0300 Animal Products
- Category Code: 314 Gelatin
- Species (Ovine, Bovine, Caprine, etc.)
- Most gelatin requires only a health certificate (no permit)
 - Health Certificate number
 - Manufacturer's statement (DIS), if required
 - Permit number, if required
- Country of origin



Example 7: Fertilizer

- 10 digit HTS Code: 3101/3102/3105.XX.XX.XX
- Category Type Code: AP0300 Animal Products
- Category Code: 318 Manure, Fertilizers, and Soil Amendments/Enhancers
- Permit number
- Health Certificate number
- Country of Export
- Country of Origin



Fertilizer containing plant material and/or chemicals may also be regulated by other federal agencies.



Example 8: Cell Cultures and Their Products

- 10 digit HTS Code: XXXX.XX.XX
- Category Type Code: AP0300 Animal Products
- Category Code: 309A Animal
 By-Products for Technical use
- Species (Ovine, Bovine, Caprine, etc.)
- Manufacturer's Statement (DIS) as required

- Health Certificate- if required
- Permit Number- permit required
- Country of Export and Origin
- Importer Name and Address
- Exporter Name and Address
- Destination Address

 Guideline 1120: Cell Cultures/Lines, Recombinant Cell Cultures/Lines, and Their Products (for in vitro use)

Including:

Monoclonal antibodies, cell culture supernatants, ascitic fluid, cell extracts, hybridomas, cell cultures/lines which are not derived from livestock*.

Not including:

Cell lines of livestock* and their products, microbial cultures and their products.



Guidance and Disclaims



- APHIS HTS flagging is based on the tariff code description, including explanatory notes
- Country or commodity-specific restrictions may not require an LPCO
- Tariff code flagging cannot account for country or commodity-specific restrictions
- With AQ2 HTS flag, APHIS data must be filed, even if no LPCO is required for APHIS.
- Example: edible lamb meat originating from New Zealand has no APHIS-required LPCO. This lamb requires "proof of origin".

Element	NZ lamb
Entry Number	varies
Entry Line Number	varies
OI - Commercial Description	Lamb meat
PG01 - PGA Line Number	1
PG01 - Government Agency Code and Program Code	APH AVS
PG01 - Confidential Information Indicator	Υ
PG01 - Intended Use Code	230
PG02 - Item Type	P
PG06 - Source Type Code and Country Code	267 or 39: NZ
PG10 - Commodity Category Type and Category	AP0300, 301
PG13/14 if LPCO exists ("conditionally mandatory")	Not submitted
PG17 - Common Name Specific	Lamb Meat
PG19 - Entity Role Code, Name, Address information	IM/CB/UC
PG21 - Individual Qualifier, Name and contact information	Varies
PG26 - Packaging Qualifier, Quantity, UOM	Varies
PG27 - Container Number, Type, Length	Varies
PG30 - Inspection Status, arrival date, arrival location information	I, CBP Port Code
PG32 - Commodity Routing Type Code and Country Code	198 NZ



- APHIS Veterinary Services has guidance on commodities that do not require an import permit
 May still require LPCO, such as certificate or manufacturer's statements
 - Guidelines for Importation:
 - https://www.aphis.usda.gov/aphis/ourfocus/animalheal th/animal-and-animal-product-importinformation/import-live-animals/no-import-permit-req
 - Low Risk/Exempted Animal Products
 - https://www.aphis.usda.gov/animal_health/downloads/i mport/list-of-low-risk-and-exempted-animal-originingredients-and-products.pdf

- If No LPCO is required:
 - Disclaim Code A (not regulated) or B (data not required as per PGA guidance)
 OR
 - File a message set

Example:

- for APHIS, rabbit meat only requires "proof of species".
 Disclaim using Disclaim Code B and be sure to include a correct cargo description showing the material is "rabbit meat"
- 2. Fire extinguishers (3813.00.50.00) or non-animal origin biodiesel (3826.00....). Disclaim using Disclaim Code A, as there is no animal origin material.

Even with Disclaim, filers can also submit DIS document to support disclaim if you choose not to file PGA data. Example: ingredients list

Disclaim: Plain Bovine Rawhide Pet Chews

- Multiple HTS codes may apply
- Guidelines: Animal Products That Do Not Require An Import Permit https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/import-live-animals/no-import-permit-req
- APHIS Guideline for Importation #1119 <u>may apply</u>
 - For plain (not ground, not flavored, not colored)
 bovine rawhide, can disclaim using Disclaim Code B.
 - Proof of "it is what it is"



These materials do not require a USDA import permit, but will be reviewed at the port of entry.

- ✓ Guideline 1100: Human And Veterinary Pharmaceuticals and Vaccines
- ✓ Guideline 1101: Non-Human Primate Material (excluding cell cultures)
- Guideline 1102: Feline and Canine Material
- Depending on the guideline, LPCO (certificate, manufacturer's statement) may be required
 - Disclaim code B if no LPCO

✓ Guideline 1119: Pet Chews and Treats Made of Antlers or Rawhide

Effective March 31, 2016

Introduction:

Material derived from any animal is potentially subject to U.S. Department of Agriculture (USDA) regulations and must be cleared by Department of Homeland Security, Customs and Border Protection (DHS, CBP) Agricultural Specialists at the U.S. port of arrival before entry into the United States is authorized. A USDA import permit is required for animal material that may pose a risk of introducing foreign animal diseases into the United States.

Rawhide and antlers intended for use as pet chews/treats may be imported without a USDA VS Import Permit provided the conditions of this guideline are met.

Entry:

1. Rawhide:

Plain rawhide intended for use as pet chews/treats (may be cut, molded, or in sheets) which has not been ground, flavored, basted, colored, or otherwise processed is allowed entry without a VS Import Permit. All shipments are subject to inspection by CBP personnel at the U.S. port of arrival.

Rawhide which does not meet the above requirement must be accompanied by a USDA VS Import Permit.

*Note: Rawhide is defined as untanned cattle skin made into leather by dehairing, drying, liming, and other processes. Products which do not meet this description, such as pork hides labelled as "rawhide" require a VS Import Permit.

Disclaim or PGA data: Retail-ready Cosmetics

- Multiple HTS codes may apply
- Cosmetics may have several animal-origin ingredients; however, if cosmetics are packaged and ready for sale, they are unrestricted
 - No LPCO required
 - Proof showing "it is what it is".
 - Note: does not apply to cosmetic ingredients being imported for further manipulation
- Can disclaim using Disclaim Code B
 OR
- Submit a message set for APHIS Core.

Disclaim or PGA data: Retail-ready Cosmetics

Element	Cosmetic
Entry Number	varies
Entry Line Number	varies
OI - Commercial Description	Retail cosmetic
PG01 - PGA Line Number	1
PG01 - Government Agency Code and Program Code	APH AVS
PG01 - Confidential Information Indicator	Υ
PG01 - Intended Use Code	130
PG02 - Item Type	Р
PGUD - Source Type Code and Country Code	267 or 39: [country code]
PG10 - Commodity Category Type and Category	AP0300, 313
PG13/14 if LPCO exists ("conditionally mandatory")	Not submitted
PG17 - Common Name Specific	Cosmetic
PG19 - Entity Role Code, Name, Address information	IM/CB/UC
PG21 - Individual Qualifier, Name and contact information	Varies
PG26 - Packaging Qualifier, Quantity, UOM	Varies
PG27 - Container Number, Type, Length	Varies
PG30 - Inspection Status, arrival date, arrival location information	I, CBP Port Code
PG32 - Commodity Routing Type Code and Country Code	198 [country code]

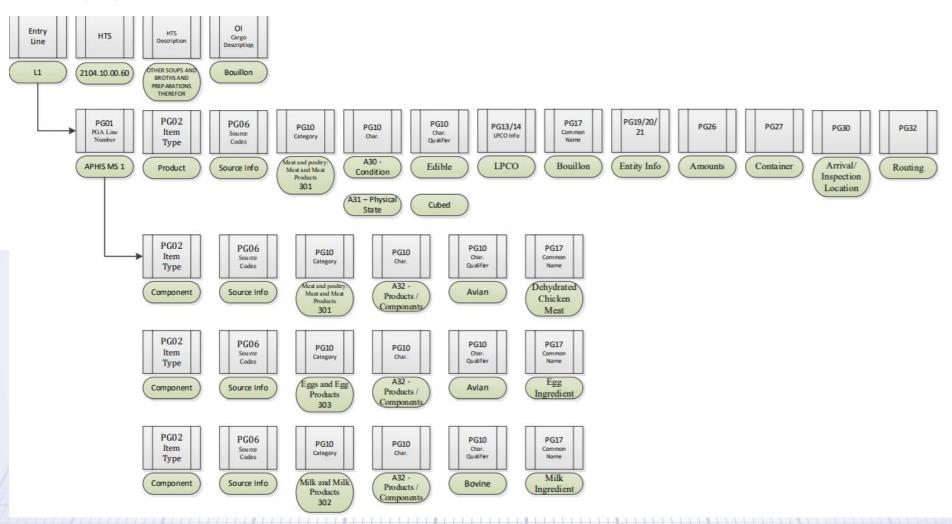


Guidance: Product-level versus Component-level Data

- Product=commodity itself (whole item)
- Components=ingredients of the product/item
- Reporting of components is not required and not enforced; however, best practice to report components
 - Animal Product permits are issued for 1 year, but may not always be shipment-specific
 - Shipment-specific component data will be on the LPCO (certificate, statements) and/or ingredients list.
 - Report to best of your ability



Guidance: Product-level versus Component-level Data





Guidance: Product-level versus Component-level Data

- If choosing not to report ingredients as components:
 - Report product level data (PG02) AND repeat PG10 multiple times

Or

 [Less preferred method]: If too many ingredients, report product level data (PG02) and complete PG10 once, indicating "multiple animal origin ingredients" in PG17.





Resources

- Contact <u>ACE.ITDS@usda.gov</u> regarding APHIS Core Message Set
- More guidance available on the APHIS ACE Website (<u>www.aphis.usda.gov/ace</u>)
 - Exemptions
 - Entry types where APHIS Core flagging is enforced
 - Full list of CBP Appendices referenced for APHIS Core Message Set
- APHIS' Import/Export web page or call the APHIS
 Customer Service Center at 1-844-820-2234.
- Coming Soon: APHIS eFile