



# FedEx Regulatory News

## **Biologics, reagents, agricultural equipment, and farm machinery potentially subject to APHIS - Tips to avoid clearance delays**

March 1, 2021

### **Background information**

Importers of biologics, reagents, agricultural equipment, and farm machinery could require a change to their import documentation even if the products are determined not to be regulated by the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS).

### **What has changed?**

Although the APHIS regulations for these commodities have not changed, **effective March 15, 2021**, the importer must provide enough information to discern whether the item is APHIS regulated by providing **one** of the following:

- A detailed description that provides enough information to determine the product is **not** subject to APHIS
- A statement confirming the product does not have any plant or animal material and is **not** subject to APHIS
- Any applicable LPCO (License, Permit, Certification, Other) or required APHIS data elements if the product is subject to APHIS
- An updated product database with APHIS information or disclaims

### **What are the primary impacts of these changes?**

Shippers and importers of biologics, reagents, agricultural equipment, and farm machinery should ensure clearance paperwork or databases provide the broker with enough information for clearance. Failure to do so could result in clearance delays even for unregulated merchandise.

### **Biologics and Reagents**

These products are potentially regulated by USDA APHIS if they contain components of non-human, animal origin.

If your biologic or reagent product is classified under one of the Harmonized Tariff Schedule of the United States (HTSUS) codes indicated in **Appendix A** below, potential clearance delays may occur if a detailed description of the product is not provided.

**If your product contains no components of animal origin, please ensure that your shipment documents clearly indicate that no animal origin products are contained.** The following information is recommended for chemically synthesized materials classified under an AQ1 flagged HTSUS code:

- A statement identifying the material (name)
- A statement confirming the material is chemically synthesized
- A statement confirming the material does not contain any animal or cell culture derived products
- A statement confirming the material was not derived from any animal or cell culture derived products

**If your product contains components that are of animal origin, please provide the following information:**

- Common and scientific name of the animal from which the component was obtained
- Country and region of origin for the animal product component as well as the country of origin or production for the final product
- Intended use of the product
- Any licenses, permits, certificates, or other (LPCO) documents that USDA APHIS requires for the entry of your product.
  - Please refer to the [APHIS Guidelines](#) to determine if your product qualifies for an exemption from import permit requirements. Please include all required statements or paperwork indicated in the applicable guideline to minimize the chance of delay.
  - If you are unsure if your product requires a license, permit, or other document as a condition of entry, please refer to the [APHIS website](#) for additional information.

### **Agricultural Equipment and Farm Machinery**

Used farm machinery includes vehicles, equipment, and other implements used in agricultural and farming operations. These products are regulated by USDA APHIS to prevent the introduction of foreign disease vectors that may be harmful to the U.S. agricultural industry.

If your farm machinery product is classified under one of the HTSUS codes indicated in **Appendix B** below, clearance delays may occur if a detailed description of the product is not provided.

**For agricultural equipment and farm machinery, please ensure that your product description indicates if the product is in “new” or “used”.**

For all **used** farm machinery, the product must be cleaned and washed prior to entry with U.S. Customs and Border Protection. Additionally, if the used farm machinery is exported from a country or region affected with Foot and Mouth Disease (FMD), then a government certificate from the exporting country is also required or the product will be refused entry into the United States.

- For a list of regions affected by FMD, please refer to the [APHIS Animal Health Status of Regions website](#).
- For additional information on the government certificate requirements for used farm machinery exported from a region affected by FMD, please refer to the [APHIS website](#) for additional information.

**New** farm equipment is considered to be unrestricted by APHIS and will not be subject to their import requirements as long the product is clean and free of dirt or other particulates.

## References:

### [APHIS Manuals](#)

- [Animal Product Manual](#)
- [Animal Products That Do Not Require An Import Permit](#)
- [Fruits and Vegetables Import Requirements \(FAVIR\) Online Database](#)
- [Plants for Planting Manual](#)
- [Seeds Not for Planting Manual](#)
- [Miscellaneous Processed Products](#)
- [Cut Flowers and Greenery Import Manual](#)

### [APHIS Imports and Exports](#)

### [APHIS Core Message Set Questions and Answers](#)

## **Appendix A – AQ1 Flagged Reagent and Biologic Products**

<b>3002.11.0000</b>	Malaria diagnostic test kits
<b>3002.12.0090</b>	Other antisera and other blood fractions
<b>3002.13.0010</b>	Unmixed monoclonal antibodies, not in measured doses or packed for retail sale
<b>3002.13.0090</b>	Other unmixed immunological products, not in measured doses or packed for retail sale
<b>3002.14.0010</b>	Mixed Immunological products containing monoclonal antibodies, not in measured doses or packed for retail sale
<b>3002.14.0090</b>	Other mixed immunological products, not in measured doses or packed for retail sale
<b>3002.15.0010</b>	Diagnostic reagents based on an antibody test, put up in measured doses or packaged for retail sale
<b>3002.15.0090</b>	Other immunological products, put up in measured doses or packaged for retail sale
<b>3002.19.0000</b>	Other antisera, blood fraction, and immunological products not provided for elsewhere in the tariff schedule
<b>3002.20.xxxx</b>	Vaccines for human medicine
<b>3002.90.1000</b>	Ferments preparations (excluding yeasts)
<b>3002.90.5120</b>	Antiallergenic preparations
<b>3002.90.5150</b>	Other toxins, cultures of micro-organisms, and similar products not provided for elsewhere in the tariff schedule
<b>3006.20.0000</b>	Blood-grouping reagents
<b>3822.00.1010</b>	Diagnostic or lab reagents containing antigens or antisera, also containing methyl chloroform or carbon tetrachloride

<b>3822.00.1090</b>	Diagnostic or lab reagents containing antigens or antisera, not containing methyl chloroform or carbon tetrachloride
<b>3822.00.5050</b>	Diagnostic reagents based on a polymerase chain, not containing antigens or antisera
<b>3822.00.5050</b>	Other diagnostic or lab reagents not provided for elsewhere in the tariff schedule

**Appendix B – AQ1 Flagged Farm Machinery Products**

<b>8424.41.1000</b>	Agricultural or horticultural sprayers, Portable sprayers, Sprayers
<b>8424.41.9000</b>	Agricultural or horticultural sprayers, Portable sprayers, Other
<b>8424.49.0000</b>	Agricultural or horticultural sprayers, Other than Portable sprayers
<b>8424.82.0010</b>	Self-propelled, center pivot irrigation equipment
<b>8424.82.0020</b>	Other, irrigation equipment
<b>8424.82.0090</b>	Irrigation equipment, other
<b>8429.11.0090</b>	Track laying bulldozers, angledozers, used or rebuilt
<b>8429.19.0090</b>	Bulldozers, angledozers, other, used or rebuilt
<b>8429.20.0000</b>	Graders and levelers
<b>8429.30.0060</b>	Scrapers, used or rebuilt
<b>8429.51.1065</b>	Self-propelled bulldozers, angledozers, graders, levelers, scrapers, mechanical shovels, excavators, shovel loaders, tamping machines and road rollers: Mechanical shovels, excavators and shovel loaders: Front-end shovel loaders: Wheel-type: Used or rebuilt
<b>8429.51.5060</b>	Front-end loader other, used or rebuilt
<b>8429.52.1050</b>	Backhoes etc., used or rebuilt
<b>8429.52.5090</b>	Self-propelled bulldozers, angledozers, graders, levelers, scrapers, mechanical shovels, excavators, shovel loaders, tamping machines and road rollers: Machinery with a 360° revolving superstructure: Other: Used or rebuilt
<b>8429.59.1090</b>	Backhoes, shovels, etc., other, used or rebuilt
<b>8429.59.5080</b>	Mechanical shovels, excavators etc., other, used or rebuilt
<b>8432.10.0020</b>	Moldboard plows except listers
<b>8432.10.0040</b>	Disc plows
<b>8432.10.0060</b>	Plows, other, nspf
<b>8432.21.0000</b>	Disc harrows

<b>8432.29.0040</b>	Cultivators, tractor drawn or mounting
<b>8432.29.0060</b>	Rotary tillers, walk behind type
<b>8432.29.0080</b>	Cultivators, other, nspf
<b>8432.29.0090</b>	Scarifiers other, nspf
<b>8432.31.0010</b>	Planters and transplanters, No-till direct seeders, planters and transplanters
<b>8432.31.0090</b>	Seeders, No-till direct seeders, planters and transplanters
<b>8432.39.0010</b>	Planters and transplanters, other
<b>8432.39.0090</b>	Seeders, other
<b>8432.41.0000</b>	Manure spreaders
<b>8432.42.0000</b>	Fertilizer distributors
<b>8432.80.0010</b>	Machinery for soil prep, lawn, other, tow behind sweepers
<b>8432.80.0080</b>	Machinery for soil prep, lawn, etc., other, nspf
<b>8432.90.0010</b>	Agr mach prt,rd whl w/out tire
<b>8432.90.0020</b>	Ag mach pt,whl/tire assemblies
<b>8432.90.0040</b>	Plow parts
<b>8432.90.0050</b>	Harrows, scarifiers, cultivators, etc., parts
<b>8432.90.0060</b>	Seeders, planters, etc., parts
<b>8432.90.0081</b>	Machinery parts other, nspf
<b>8433.53.0000</b>	Root or tuber harvesting machines
<b>8433.59.0010</b>	Field forage harvesters
<b>8433.59.0090</b>	Harvesting and threshing machinery other, nspf
<b>8433.60.0010</b>	Harvesting or threshing machinery, including straw or fodder balers; grass or hay mowers; machines for cleaning, sorting or grading eggs, fruit or other agricultural produce, other than machinery of heading 8437; parts thereof: Machines for cleaning, sorting or grading eggs, fruit or other agricultural produce: Machines for cleaning, sorting or grading eggs
<b>8433.60.0090</b>	Harvesting or threshing machinery, including straw or fodder balers; grass or hay mowers; machines for cleaning, sorting or grading eggs, fruit or other agricultural produce, other than machinery of heading 8437; parts thereof: Machines for cleaning, sorting or grading eggs, fruit or other agricultural produce: Other

<b>8434.10.0000</b>	Milking machines
<b>8434.20.0000</b>	Dairy machinery
<b>8434.90.0000</b>	Milking machines and dairy machinery parts
<b>8436.21.0000</b>	Other agricultural, horticultural, forestry, poultry-keeping or bee-keeping machinery, including germination plant fitted with mechanical or thermal equipment; poultry incubators and brooders; parts thereof: Poultry-keeping machinery; poultry incubators and brooders: Poultry incubators and brooders
<b>8436.29.0000</b>	Other agricultural, horticultural, forestry, poultry-keeping or bee-keeping machinery, including germination plant fitted with mechanical or thermal equipment; poultry incubators and brooders; parts thereof: Poultry-keeping machinery; poultry incubators and brooders: Other
<b>8436.80.0040</b>	Barn and barnyard machines
<b>8436.80.0090</b>	Other agricultural, horticultural, forestry, poultry-keeping or bee-keeping machinery, including germination plant fitted with mechanical or thermal equipment; poultry incubators and brooders; parts thereof: Other machinery: Other: Other: Other
<b>8436.91.0080</b>	Machine parts for poultry keeping, other
<b>8436.99.0040</b>	Barn or barnyard machinery parts
<b>8438.50.0010</b>	Machinery, not specified or included elsewhere in this chapter, for the industrial preparation or manufacture of food or drink, other than machinery for the extraction or preparation of animal or fixed vegetable fats or oils; parts thereof: Machinery for the preparation of meat or poultry: Meat- and poultry-packing plant machinery
<b>8438.50.0090</b>	Machinery, not specified or included elsewhere in this chapter, for the industrial preparation or manufacture of food or drink, other than machinery for the extraction or preparation of animal or fixed vegetable fats or oils; parts thereof: Machinery for the preparation of meat or poultry: Other
<b>8438.80.0000</b>	Machinery, not specified or included elsewhere in this chapter, for the industrial preparation or manufacture of food or drink, other than machinery for the extraction or preparation of animal or fixed vegetable fats or oils; parts thereof: Other machinery
<b>8438.90.9060</b>	Machinery, not specified or included elsewhere in this chapter, for the industrial preparation or manufacture of food or drink, other than machinery for the extraction or preparation of animal or fixed vegetable fats or oils; parts thereof: Parts: Other: Of machinery for the preparation of meat or poultry
<b>8438.90.9090</b>	Machinery, not specified or included elsewhere in this chapter, for the industrial preparation or manufacture of food or drink, other than machinery for the extraction or preparation of animal or fixed vegetable fats or oils; parts thereof: Parts: Other: Other

<b>8453.10.0000</b>	Machinery for preparing, tanning or working hides, skins or leather or for making or repairing footwear or other articles of hides, skins or leather, other than sewing machines; parts thereof: Machinery for preparing, tanning or working hides, skins or leather
<b>8465.10.0050</b>	Machine tools (including machines for nailing, stapling, gluing or otherwise assembling) for working wood, cork, bone, hard rubber, hard plastics or similar hard materials: Machines which can carry out different types of machining operations without tool change between such operations: Other
<b>8465.20.1000</b>	Sawing machine tools, oth, nspf
<b>8465.20.8000</b>	Splitting mach tools, etc., oth
<b>8465.91.0091</b>	Sawing machine tools, oth, nspf
<b>8465.92.0091</b>	Planing, etc., mach tools, ot
<b>8465.95.0091</b>	Drilling/mort mach tools, other
<b>8465.96.0051</b>	Splitting mach tools, etc., oth
<b>8465.99.0250</b>	Machine tools (including machines for nailing, stapling, gluing or otherwise assembling) for working wood, cork, bone, hard rubber, hard plastics or similar hard materials: Other: Other: Other
<b>8479.20.00.00</b>	Machines and mechanical appliances having individual functions, not specified or included elsewhere in this chapter; parts thereof: Machinery for the extraction or preparation of animal or fixed vegetable fats or oils
<b>8701.30.10.90</b>	Track-laying tractor: used; suitable for agricultural
<b>8716.80.10.00</b>	Vehicle not mechanically propelled: farm wagon and cart
<b>8716.80.5090</b>	Nonmech. Propelled vehicle: other
<b>9801.00.1037</b>	U.S. goods returned:8419.31,8424.81,8424.90,8429.11,8429.19etc
<b>9801.00.1045</b>	Other U.S. goods returned: in chapter 84; not advanced in value
<b>9801.00.1063</b>	Other U.S. goods returned: in 8701; not advanced in value
<b>9801.00.1074</b>	U.S. Goods Provided For In Chapter 87, Others, Returning, Without Having Been Advanced In Value Or Improved In Condition By Any Process
<b>9817.00.5000</b>	Machinery, equipment & implements used for agriculture/horti

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