



International
Serum Industry
Association

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TITLE: ISIA SERUM ORIGIN DEFINITIONS

The ISIA has developed definitions of origin, based on international guidelines set by the WTO, OIE, as well as the USDA and the EU. Since the word "origin" has several meanings and can cause confusion and controversy, the ISIA suggests the use of very precise wording whenever possible.

ISIA Origin Definitions

- **Country of Collection** - This is the country where the animal was slaughtered and the blood was collected or, in the case of donor animals, where the blood was collected. This includes animals born and raised in the country of collection, as well as imported animals, and may include animals imported for immediate slaughter. This is the country shown on the label as "origin". The Country of Collection is required to be shown on the Certificate of Analysis (CoA) and Certificate of Origin (CoO). The process of collecting blood and separating serum is considered substantial transformation.
- **Country of Manufacturing** - This is the country where filtration, bottling, and labeling occur and includes any other processes performed prior to filtration and bottling. Other acceptable terms include "Manufacturing Address" or "Site of Manufacture". This should be listed on the CoA. This is not considered substantial transformation.
- **Country of Further Treatment** – This is the country in which the product is treated after sterile filtration. Examples of further treatment are gamma irradiation or heat inactivation. These processes should be listed individually on the CoA and are not considered substantial transformation.
- The Country of Collection ("origin" on the label) does NOT change for import/export purposes. The Country of Collection can never change.

APPROVAL

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