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Fetal Bovine Serum – Country of Origin, Geographic Relevance, and Labeling

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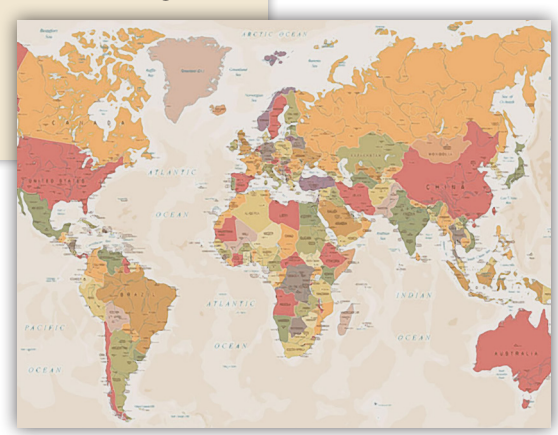
Abstract

With an ever-increasing number of countries involved in the collection, processing and marketing of serum, it is necessary to understand the relevance and rules relating to geographic region of origin. This article reviews and discusses the safety and quality of FBS, rules of origin, consumer market-motivated misinformation, and how mislabeled serum can be detected. The article concludes that high-quality serum needed for scientific research and biopharmaceutical products can originate from any country, as long as it is collected, imported, and processed following all the applicable regulatory and industry requirements.



1. Introduction

It is common for fetal bovine serum (FBS) to be collected in one country, then exported to a regional processing center in a second country, and sometimes exported to a third country for further sampling and testing, repackaging, and labeling prior to sale and distribution to customers worldwide. With an ever-increasing number of countries involved in the collection, processing, and marketing of serum, customers should be aware of marketing motives behind origin labeling and misconceptions that are often disseminated about the quality and safety of FBS from different geographical origins.

The geographical location where serum is collected and processed should not be an issue when selecting a serum supplier and country of origin, except as dictated by regulatory requirements. High-quality FBS can come from any country of origin, as long as regulatory and industry standards are adhered to.

This article will review and discuss the relevance of "*geographic origin*" as it relates to the safety and quality of serum, marketing-motivated country of origin labeling (COOL), and how identifying the origin of FBS is a mixture of regulatory requirements and industry marketing motives. The tools available to the serum industry and customers for detecting mislabeled serum will also be discussed.

2. Viral Safety and Quality

For many years, Oceania and the USA have been falsely promoted as having fewer cattle disease viruses and thus, having safer and higher quality serum. For example, a 2017 industry publication stated that FBS from Australia and New Zealand presents lower risks for pathogens, since both are free of foot-and-mouth (FMD) disease, have fewer cattle disease viruses than other countries, and neither have ever detected bovine spongiform encephalopathy (BSE).[1]

Another 2017 industry report gave distorted information, stating that "*serum from cows in places with low viral risk like New Zealand, Australia, and the United States, is more expensive than serum from higher-risk places like Brazil.*"[2] Yet another 2019 industry newsletter claimed "*serum sourced from Australia, New Zealand, and the US are deemed the highest quality with the lowest risk of viral contamination, while South America-sourced FBS is generally of a lower quality.*"[3] These statements are misleading.

2.1 BSE and Bovine Blood Products

In 2006, the World Organization for Animal Health (OIE) made it clear that blood and blood products do not play a role in the transmission of BSE.[4] The OIE also stressed that regardless of the BSE status of the exporting country, when proper slaughter and collection procedures are adhered to, blood and blood products should not be subject to any import restrictions relating to BSE.[5] The World Health Organization WHO[6], United States Department of Agriculture (USDA)[7], and US Food and Drug Administration (FDA)[8] have also come to the same conclusion that BSE is not transmitted by bovine blood products when cattle are properly slaughtered.

2.2 Viruses with Worldwide Distribution

Both the European Commission (EC) and the USDA have identified eight adventitious viruses and six additional viruses of importation concern that can cross the placental barrier from the mother to the fetus, thus necessitating virus testing

and/or inactivation treatments to assure the absence of these viruses in FBS.

A recent review by Hawkes in 2015[9] discussed the presence of regulatory viruses of concern for FBS in 30 major FBS-producing countries and compared the 2013 animal health status of the 30 countries. The conclusions drawn from this review are the same in 2018 as they were in 2013 (see **Table 1**). The USDA[10] and European Medicines Agency (EMA)[11] require that FBS from all 30 countries considered in this article be tested and/or treated for the same adventitious viruses of worldwide distribution.

2.3 Viruses of Limited Distribution

Regarding the six viruses of importation concern, all 30 countries shown in **Table 1** (except Colombia, which expects to recover their FMD-free status soon) are officially recognized by

TABLE 1. Comparison of animal health status of 30 countries of FBS origin – Regulatory diseases of concern for fetal bovine serum (2018)[12]

FBS Exporting Countries	Eight Adventitious Viruses of Concern									Six Viruses of Importation Concern							Total Viruses of FBS Concern
	Considered Worldwide Distribution by USDA[10] and EU[11]					Source: 2018 OIE Data[12]			Total Adventitious Viruses	Source: 2018 Data From OIE[12], USDA[13], and EC[14]						Total Viruses of Import Concern	
	Parainfluenza 3	Reovirus 3	Bovine Adenovirus	Bovine Parvovirus	Bovine Respiratory Syncytial Virus	Bovine Viral Diarrhea Virus	Infectious Bovine Rhinotracheitis	Rabies		Foot-and-Mouth	Vesicular Stomatitis 2014 OIE info[12]	Bluetongue	Akabane	Aino	Schmallenberg		
FINLAND	+	+	+	+	+	2010	1994	2007	5	1959	–	–	–	–	+	1	6
SWEDEN	+	+	+	+	+	2011	1995	1886	5	1966	–	2009	–	–	+	1	6
DENMARK	+	+	+	+	+	2017	2005	1982	6	1983	–	2009	–	–	+	1	7
NEW ZEALAND	+	+	+	+	+	+	+	–	7	–	–	–	–	–	–	0	7
NORWAY	+	+	+	+	+	2005	1992	+	6	1952	–	2010	–	–	+	1	7
BELGIUM	+	+	+	+	+	+	+	2008	7	1976	–	2008	–	–	+	1	8
CHILE	+	+	+	+	+	+	+	+	8	1987	–	-	–	–	–	0	8
IRELAND	+	+	+	+	+	+	+	1903	7	2001	–	-	–	–	+	1	8
NETHERLANDS	+	+	+	+	+	+	+	2012	7	2001	–	2009	–	–	+	1	8
URUGUAY	+	+	+	+	+	+	+	+	8	2001	–	-	–	–	–	0	8
ARGENTINA	+	+	+	+	+	+	+	+	8	2006	1986	+	–	–	–	1	9
CANADA	+	+	+	+	+	+	+	+	8	1952	1949	+	–	–	–	1	9
EL SALVADOR	+	+	+	+	+	+	+	2017	8	–	+	1997	–	–	–	1	9
DOMINICAN REPUBLIC	+	+	+	+	+	+	+	+	8	–	–	+	–	–	–	1	9
GERMANY	+	+	+	+	+	+	+	2005	7	1988	–	+	–	–	+	2	9
GUATEMALA *(2017 info)*	+	+	+	+	+	+	+	+	8	–	+	1998	–	–	–	1	9
HONDURAS	+	+	+	+	+	+	+	2015	8	–	+	2004	–	–	–	1	9
NICARAGUA	+	+	+	+	+	2016	+	+	8	–	+	2009	–	–	–	1	9
PARAGUAY	+	+	+	+	+	+	+	+	8	2012	–	+	–	–	–	1	9
PERU	+	+	+	+	+	+	+	+	8	2004	+	2004	–	–	–	1	9
POLAND	+	+	+	+	+	+	+	+	8	1971	–	–	–	–	+	1	9
COLOMBIA	+	+	+	+	+	+	+	+	8	2017	+	2007	–	–	–	2	10
AUSTRALIA	+	+	+	+	+	+	+	1867	7	1871	–	+	+	+	–	3	10
BRAZIL	+	+	+	+	+	+	+	+	8	2006	+	+	–	–	–	2	10
COSTA RICA	+	+	+	+	+	+	+	+	8	–	+	+	–	–	–	2	10
FRANCE	+	+	+	+	+	+	+	2015	8	2001	–	+	–	–	+	2	10
MEXICO	+	+	+	+	+	+	+	+	8	1954	+	+	–	–	–	2	10
PANAMA	+	+	+	+	+	+	+	+	8	–	+	*No Info*	–	–	–	2	10
SPAIN	+	+	+	+	+	+	+	2015	8	1986	–	+	–	–	+	2	10
UNITED STATES	+	+	+	+	+	+	+	+	8	1929	+	+	–	–	–	2	10

+ = Disease present **–** = Disease never reported **Year** = Year disease last reported **Year** = Year disease last reported, yet may be present ***No Info*** = Disease considered present

the OIE[15] as being free of FMD. These 30 countries are free of Akabane and Aino viruses, except Australia; only the European countries are affected by the Schmallenberg virus; only the Americas are affected by vesicular stomatitis virus; and all three continents represented are occasionally affected by different strains of bluetongue virus.

2.4 Quality

It is well known that no two batches of sterile FBS are the same, both in terms of their physical and biochemical analyses, or in their ability to support the growth of cells. These differences have never been shown to be related to the country of origin. Quality is related to the adherence of proper techniques and industry standards during collection, processing, safety testing, and clearing of contaminants.

Regardless of the country of origin, the same industry standards at collection and processing must be met in order for serum to be considered acceptable for use. The country where processing takes place is unimportant, as long as it is done in compliance with standards such as those specified in the United States Pharmacopeia (USP)[16] or the European Pharmacopeia (Ph. Eur.)[17], as well as other regulatory standards.

It can be concluded from **Table 1** that no one country has a real advantage over other FBS-producing countries as to the number of viruses to be testing for, since FBS from all countries needs to be tested and treated for the presence of multiple viruses. The most common treatment for eliminating viruses of concern in serum is gamma irradiation >25 kGy[18], and has absolute preference over geographical origin as an indicator of viral safety. Safe and high quality FBS can come from any country of origin.

3. Rules of Origin

3.1 Origin of Raw Serum

The "*origin of raw FBS*" is defined by the serum industry as the country where the animal is slaughtered and the serum is collected. Since raw sera from several abattoirs are pooled together, a typical FBS batch of 2,000–4,000 liters may represent animals coming from several hundred to over a thousand farms. This makes the traceability of FBS, beyond the slaughterhouse to the farms where the dams were born and raised, an impossible and meaningless task, especially when cattle are imported for slaughter. The cross-border trade of live cattle is a common practice on all continents, with the exception of Australia.

3.2 Processing

The processing of serum refers to several steps including centrifugation, sterile filtration, testing, packaging, and irradiation or heat treatment. These steps may take place in the same country where the blood was collected, or they may occur in processing centers in other countries.

The World Trade Organization (WTO), in its Rules of Origin, states: "*The country to be determined as the origin of a particular good is either the country where the good has been wholly obtained or, when more than one country is concerned in the production of the good, the country where the last substantial transformation has been carried out.*"[19]

The European Union (EU) and the USA follow the same rules of origin as the WTO. The EU Border Inspection Agency defines the origin of a product as the country where the last substantial, economically-justified processing or manufacturing of a product occurs.[20] The US Customs and Border Inspection Agency similarly defines the origin of a product to be the country where the product last went through a substantial change.[21]

Veterinary inspection authorities also designate the country of last processing as the country of origin on the export health certificate when exporting animal serum. Nevertheless, as part of the approval process prior to importation, the origin of the raw ingredients must also be identified (*e.g.*, as required by USDA[13] and EC[14] regulations.

When the finished product is ready for marketing and export, the country where processing occurred becomes the "*origin*," as defined by the WTO[19] above. This criteria is how the EU and US deal with, for example Mexican FBS processed in the USA and then exported to the EU as US FBS, and how the US and New Zealand deal with Australian FBS processed in New Zealand.

The rules of origin for imported animal serum can be summarized as follows:

- For raw serum, the country of origin is where the serum was collected.
- For finished serum, the country of origin is where the serum was last processed.

4. Consumer Market-Motivated Country of Origin Labeling

According to consumer marketing specialists, COOL is also known as country-based branding, and may use the "*nationality bias*" to influence consumer perceptions and behaviors, a marketing tool common in the serum industry. Marketing strategies take advantage of the tendency for customers to adopt a relative preference or affinity[22] toward products from certain origins, and a relative animosity[23] or aversion for products from other origins.

Marketing motivated labeling requirements on retail products can be declared discriminatory and in violation of international WTO trade agreements and obligations. An example of unfair marketing motivated labeling is the outcome of the WTO dispute resolution filed against the USA in 2009 by Canada and Mexico over the mandatory COOL retail labeling of beef and pork products.[24] The United States Department of Agriculture (USDA) Agriculture Marketing Service (AMS) conceded to withdrawing the mandatory COOL requirements for beef and pork products from Canada and Mexico in 2016 in order to avoid retaliatory trade tariffs authorized by the WTO.[25] The same arguments against mandatory labeling of retail products are also valid for serum products.

COOL can be used to generate misleading information and exaggerated price differences between origins, which in turn ends up contributing to economic incentives for deliberate mislabeling of origins and adulteration.

5. Mislabeling

5.1 Causes of Mislabeling

Even though the collection and processing of FBS has been standardized throughout the industry, trade requirements have not. The differences between the USDA and EU importation rules have split the worldwide serum market into two major markets. The main discrepancy between the two rule-making authorities is over the definition of "*FMD-free*" despite the fact that the major FBS-producing countries (with the exception of Colombia at the current time) are recognized by the OIE to be free of FMD. The EU allows the importation of FBS from countries recognized as free of FMD, either with vaccination, or without vaccination (*i.e.*, Europe, all the Americas, Oceania, and parts of Africa). In contrast, USDA restricts the importation of FBS to 11 countries from the Americas and Oceania, which are free of FMD-without vaccination (Canada, Mexico, Guatemala, El Salvador, Honduras, Nicaragua, Costa Rica, Panama, Chile, Australia, and New Zealand). It should be noted that USDA has not updated their import requirements for animal serum since 1998.[26] Therefore, even though European countries are free of FMD without vaccination, they still cannot export FBS to the US.

USDA's lack of harmonization of import requirements for animal serum with OIE standards has caused a great disparity in the international prices of serum. The price of FBS from USDA-approved countries is unnecessarily high, up to ten times higher than the same quality serum from some EU-approved origins. This price discrepancy not only causes researchers and pharmaceutical companies to overpay for FBS, but it also continues to be an incentive for mislabeling the origin of the product.

Expensive origins are among the sources most vulnerable to mislabeled origins as has been evidenced in Australia[27] and the US.[28] A recent 2013 case of adulterated and mislabeled-origin FBS caused the recall of 280,000 liters of FBS from the international market, and compromised the work of thousands of medical and life science researchers worldwide.[29] Since this recall also required replacement of the affected serum, the total amount of serum impacted represented more than half the FBS produced annually worldwide, which in turn caused a global shortage of FBS and higher prices.

5.2 Detecting Mislabeling

There are three basic tools for detecting mislabeled serum: external audits, geographic testing, and age testing. The purpose of external audits is to verify (or certify) that a producer or distributor's internal quality control processes are adequate, effective, and in compliance with government requirements, industry standards, and company policies. Most importantly, external audits verify if a company properly controls their supply chain. Such audits are commonly done by customers or certified auditors from organizations like Bureau Veritas, Société Générale de Surveillance (SGS), International Standards Organization (ISO), or the International Serum Industry Association (ISIA).

The ISIA traceability audit certification program was created to promote transparency and honesty in the processing and labeling of animal serum, aimed at bringing into compliance companies who do not control their supply chain.[30] Nevertheless, it should be noted that excessive emphasis on traceability may be used as a marketing tool to support the wrong perception that some geographic origins are superior to others.

In addition to procedural external audits, the geographical origin of the raw materials can be verified by isotope and trace element testing.[31] Age testing is used to determine the age of the animal from which blood was collected. Increased levels of immunoglobulin G and/or gamma-glutamyl transferase in a product labeled as FBS may indicate adulteration with neonatal calf serum, newborn calf serum, or adult bovine serum.[32]

Again, the purpose of geographical origin and age testing is directly related to the truthfulness in labeling of the product and not the quality or safety of the product because of its geographical origin.

6. Conclusion

High-quality serum needed for scientific research and biopharmaceutical products can originate from any country, as long as it is collected, imported, and processed following all the applicable regulatory and industry requirements. The geographical location where serum is collected and processed should not be an issue when selecting a serum supplier and country of origin, except as dictated by government regulatory agencies.

Serum users should base their selection of serum on an objective analysis of available alternatives and suppliers, focusing on control of supply chain, quality systems, scientific objectivity, transparency, and ethics. A commitment to providing clients with information that is accurate, fair, complete, and transparent is far more important than promoting geographic origin.

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