

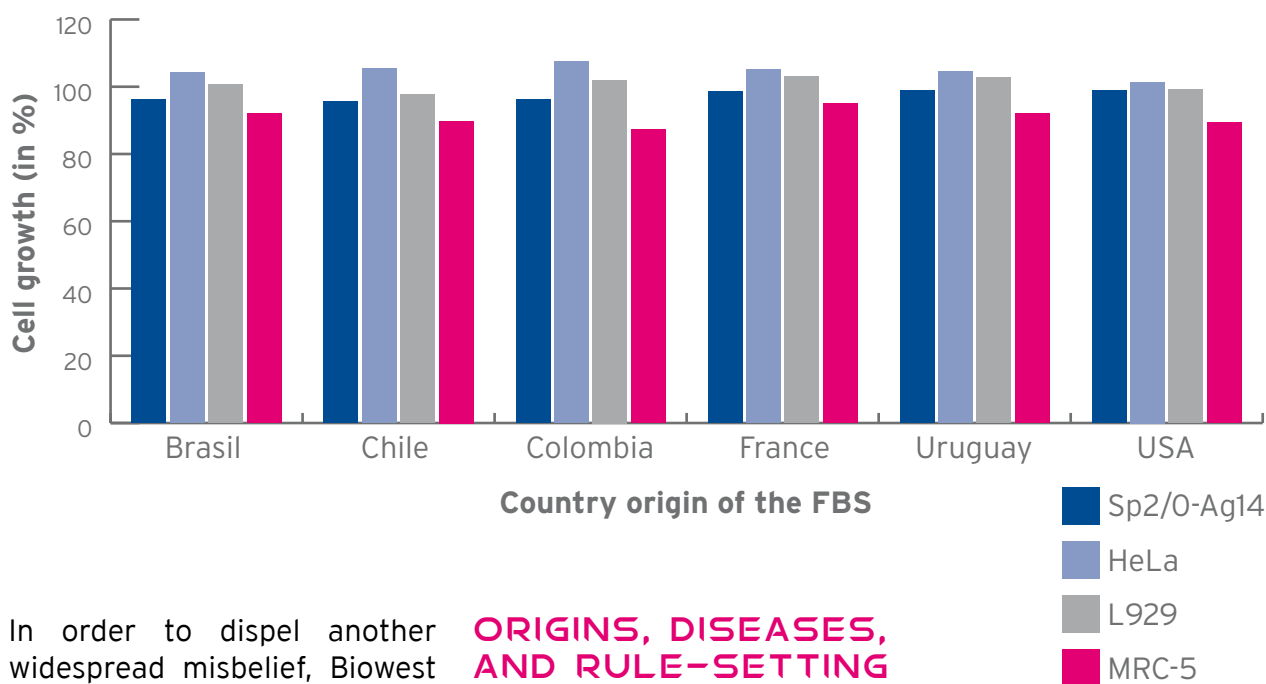
FBS Quality vs. Countries of Origin

SINCE THE EARLY DAYS OF FETAL BOVINE SERUM (FBS) USE FOR CELL CULTIVATION, GEOGRAPHICAL ISOLATION AND PURPORTED FAVORED ANIMAL HEALTH STATUSES OF A FEW FBS COUNTRIES OF ORIGIN HAVE BEEN USED AS COMMON SALES ARGUMENTS. THESE ARGUMENTS HAVE BEEN USED SO MUCH THAT, WITHIN THE FBS INDUSTRY AND AMONG USERS, THERE IS A PERSISTENT BELIEF THAT THE HIGHEST QUALITY FBS NECESSARILY COMES FROM NEW ZEALAND AND AUSTRALIA.

With its many years of experience in serum manufacturing and after conducting numerous research studies, Biowest has demonstrated beyond any doubt that the quality (adaptability to cell lines) of FBS is in no way related to its country of origin, but rather to how the FBS is collected, processed, cleared of contaminants, and safety and quality tested.

On behalf of Biowest, serum specialist Leonel Del Cid in 2014 studied 244 batches of FBS coming from six countries representing three continents, analyzing the correlation between the physical and biochemical parameters and cell growth. The results showed no observable difference in cell growth performances among the six FBS source countries for Sp2/O - Ag14, HeLa, L929 and MRC-5 cell lines. See Table 1.

Table 1 - Comparison of Cell Growth Performance for Different Origins of FBS.



In order to dispel another widespread misbelief, Biowest compared the latest animal health status of 30 FBS-producing countries, using OIE¹, USDA², and EU³ data sources. The purpose was to identify which diseases of concern for FBS were actually present and which were absent, country by country. The results shown in Table 2 are surprising and demonstrate the lack of rationality and scientific basis of the assumptions about good-quality FBS origins.

This lack of information has serious consequences for FBS prices. Currently, Australian serum is sold at a price sometimes ten times higher than FBS from other origins, even though their growth performances are equal. Paradoxically, serum from Australia and the US actually contains the greatest number of viruses of concern for importation.

ORIGINS, DISEASES, AND RULE-SETTING

Not all countries qualify to export FBS because of certain diseases in their cattle populations and of unavailability of material. At this time, there are only 30 countries in the world where FBS is collected. Restrictions are imposed, not because of how the FBS from that country will perform in cell cultures, but mainly because of the animal health status of the exporting country. The purpose of import requirements is to guarantee the absence of viruses of concern, by either prohibiting importation or by other measures, such as safety testing, and gamma irradiation.

Since the two largest global markets for animal-derived products are the USA and Europe, the import requirements from the USDA and the European Commission (EC), to a great extent, have become the veterinary control standards for the FBS industry.



Since the 1980s, the principal source countries for FBS are from North, Central and South America, Oceania, and Europe. As BSE is no longer considered to be transmitted by blood and blood products⁴, FBS is no longer subject to import restrictions related to the BSE status of the exporting country, provided that a proper slaughter method is used⁵. The cattle diseases of concern for FBS are those which cross the placental barrier of the cow and infect the calf fetus. From a

geographic perspective, some of these viruses (adventitious viruses) have a worldwide distribution, and others (viruses of import concern) are limited to certain regions of the world. Table 2 compares the disease status of 16 of the 30 FBS exporting countries for eight adventitious viruses and for six viruses of importation concern. The sources for this information are the World Animal Health Organization (OIE), the USDA, and the EU. See Table 2.

Table 2 - Regulatory Diseases of Concern for FBS - Comparison of Animal Health Status of Countries of FBS Origin.

FBS exporting countries	Adventitious Viruses of concern								Total Adventitious Viruses	Viruses of Importation Concern						Total No. Viruses of FBS Concern	
	Considered worldwide distribution by USDA and EU					Source: 2013 OIE data				Source: 2013 data from OIE, USDA and EU							
	Parainfluenza 3	Reovirus 3	Bovine Adenovirus	Bovine Parvovirus	Bovine Respiratory Syncytial Virus	Bovine Viral Diarrhea (BVD)	Infectious Bovine Rhinotracheitis (IBR)	Rabies		Foot and Mouth Disease (FMD)	Vesicular Stomatitis (VS)	Bluetongue (BT)	Akabane	Aino Virus	Schmallenberg Virus		Total viruses of import concern
FINLAND	+	+	+	+	+	2010	1994	2007	5	1959	-	-	-	-	+	1	6
NORWAY	+	+	+	+	+	2005	1992	2011	5	1952	-	2010	-	-	+	1	6
SWEDEN	+	+	+	+	+	2011	1995	1886	5	1966	-	2009	-	-	+	1	6
DENMARK	+	+	+	+	+	+	2005	2002	6	1983	-	2009	-	-	+	1	7
NEW ZEALAND	+	+	+	+	+	+	+	-	7	-	-	-	-	-	-	0	7
CHILE	+	+	+	+	+	+	+	+	8	1987	-	-	-	-	-	0	8
URUGUAY	+	+	+	+	+	+	+	+	8	2001	-	-	-	-	-	0	8
CANADA	+	+	+	+	+	+	+	+	8	1952	1949	+	-	-	-	1	9
COLOMBIA	+	+	+	+	+	+	+	+	8	2009	+	2007	-	-	-	1	9
HOLLAND	+	+	+	+	+	+	+	+	8	2001	-	2009	-	-	+	1	9
MEXICO	+	+	+	+	+	+	+	+	8	1954	+	2010	-	-	-	1	9
PARAGUAY	+	+	+	+	+	+	+	+	8	2012	-	Unkwn	-	-	-	1	9
AUSTRALIA	+	+	+	+	+	+	+	1867	7	1871	-	+	+	+	-	3	10
BRAZIL	+	+	+	+	+	+	+	+	8	2006	+	+	-	-	-	2	10
FRANCE	+	+	+	+	+	+	+	+	8	2001	-	+	-	-	+	2	10
UNITED STATES	+	+	+	+	+	+	+	+	8	1929	+	+	-	-	-	2	10

(year) indicates year disease last reported
 (+) disease is present
 (-) disease has never been reported

Sources: OIE Animal Health Status / USDA 9 CFR 113.46-53 / EMEA-CPMP-BWP-1793-02

