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GEN Exclusives

High-Quality FBS May Come from any Authorized Country of Origin

Adhering to the Highest Industry Standards and Regulatory Requirements Is Essential

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A recent article in GEN "Shifting Qualities of FBS May Impact Your Experiments" was very informative and correctly described the importance of FBS in cell culture. However, some information presented in the article is not based on the most recent scientific and regulatory information available, and can lead to inaccurate conclusions.

Traceability Confirms Transparency and Honesty in Labeling

It is correct that the International Serum Industry Association (ISIA) has started a traceability program in order to promote transparency and honesty in the processing and labeling of animal serum. But traceability is not aimed at identifying a higher or lower quality product based on its geographical origin. Rather, high-quality serum needed for the reproducibility of scientific research, can originate from any country, as long as it is collected, imported, and processed following all the applicable regulatory and industry requirements.

BSE Not a Disease of Concern for FBS

The article refers to bovine spongiform encephalopathy (BSE) as one of

the diseases of concern when selecting a country of origin for fetal bovine serum (FBS). Many FBS companies continue to promote certain countries of origin of FBS based on the obsolete Geographical BSE Risk Assessment (GBR) classification. In 2011 the World Organization for Animal Health (OIE), in an effort to put an end to misinformation about the trade risks associated with BSE, created a new BSE risk classification for countries based on three categories: "negligible risk", "controlled risk" and "undetermined risk". The OIE further clarified that blood and blood products do not play a role in the transmission of BSE[1]. The OIE also emphasized that regardless of the BSE status of the exporting country, blood and blood products should not be subject to any import restrictions relating to BSE[2].

The FDA[3] and USDA[4] have also both recently determined that BSE is not transmitted by FBS and should no longer be used as argument favoring certain geographical origins.

Australia Does Not Have the Lowest Viral Risks

Being an island and having strict importation regulations, does not mean that Australia enjoys the same fortunate animal health status as New Zealand. Many serum companies have erroneously put Australia in the same low viral risk status as New Zealand.

New Zealand has the distinction of being free of several cattle viruses, including Bluetongue, the Simbu serogroup viruses (Akabane and Aino), and Bovine Ephemeral Fever, all of which are present in Australia. FBS from New Zealand can be imported directly into the United States without safety testing, whereas Australian serum must be tested for the Bluetongue and the Simbu serogroup viruses. USDA also requires that imported "adult bovine serum" (ABS) from Australia, be tested for Bovine Ephemeral Fever[5].

Australia is the only origin of FBS where USDA safety testing must be done for two viruses (Bluetongue and Akabane). Imported FBS from New Zealand and Canada require no testing, and FBS from the other countries, allowed into the U.S., only require testing for one virus, i.e. Bluetongue. (Mexico, Central America, and Chile).

It should be noted that FBS from all countries, including New Zealand and Australian FBS must be tested and/or treated[6] for the same adventitious bovine viruses that are found in all regions of the world (BVD, PI3, Reo3, BAV, BPV, BRSV, and IBR)[7]. Neither New Zealand nor Australia are free from these adventitious bovine virus diseases.

All Major FBS Producing Countries Are Recognized Free of Foot and Mouth Disease (FMD)

The assertion that Australia and New Zealand are free of FMD is pointless, because all major serum producing countries are officially recognized by the OIE[8] as being free of FMD.

A recent 2015 article by Hawkes, entitled "Fetal bovine serum: geographic origin and regulatory relevance of viral contamination", gives further detailed information regarding of the presence of bovine viruses of regulatory concern, present in the major FBS producing regions of the world.[9]

Conclusion

High-quality FBS needed for the reproducibility of scientific research, can come from any country of origin, as long as regulatory and industry standards are adhered to. GEN

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