



INTERNATIONAL SERUM
INDUSTRY ASSOCIATION

ISIA Statement

Serum Importation from the USA into Mexico

Based on questions from several members, and with input from our legal team, ISIA has recommended to USDA that the word “any” be removed from the affidavit for import into Mexico.

The I-Reg statement currently is as follows:

*Blood products for use in research and diagnostics (098-22-1064-USA-USA)
revised September 2019*

*The product was subjected to the following treatment (indicate the
appropriate option):*

Physical treatment (ultrafiltration or triple filtration to 0.1 μ m):

Chemical treatment:

Radiation treatment:

Thermal treatment:

*which is designed to destroy, inactivate or eliminate any viruses, bacteria or
causal agents that can cause animal health risk.*

Of the two options listed which could be used for the treatment of serum, namely filtration and gamma irradiation, neither meet the criterion stated. Triple 0.1 filtration does not remove viruses and some mollicutes, and gamma irradiation is not effective against small non-enveloped viruses. It is the view of ISIA that signing this affidavit is misleading and constitutes a breach of the ethics policy.

We would ask that rather than sign this affidavit, members join us in working to convince SAGARPA and USDA to change the wording to:

*which is designed to destroy, inactivate or eliminate ~~any~~ viruses, bacteria or
causal agents that can cause animal health risk.*