Serum Situation

To the editor:

John Hodgson's article, entitled "To Treat or Not to Treat: That is the Question for Serum" (*Bio/Technology* **13**:333-343, April), correctly describes the latest information received from Brussels on serum importation. In Europe, however, there are still some regulatory quirks. Currently, imports from South America are handled differently in the European countries. In Germany, we cannot import from South America, except from Chile. In contrast, France, the Netherlands, and Austria allow imports from Brazil. Here in Germany, we are trying, by all means—including talking to the German authorities—to set equivalent import regulations. Once South American material has been imported into countries such as the Netherlands, it may, in effect, be sold without restrictions in the European Union (EU) as internal customs clearance is not necessary.

The German delegate to the European Commission has said quite clearly to the serum industry that there seems to be little impetus from (industrial) lobby groups urging the Commission to harmonize regulations further.

An entirely separate point that deserves attention is the prohibitive nature of the present regulations in the U.S. As European suppliers, we cannot understand why the importation of U.S. material into the EU without treatment is even under discussion. The U.S. has Blue Tongue-disease in both sheep and cattle. For this reason alone (and to encounter the prohibitive U.S. regulations) we would argue that material from the U.S. should be treated like any other imported material with this disease profile.

"This pipe carries hydrogen, this pipe carries nitrate, and this big one just looks real good between the other two."

Since Germany has the strictest regulations as to imports, Kraeber concentrates its own production on EU origin materials.

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To the editor:

I would like to make the following comments on John Hodgson's article (*Bio/Technology* **13**:333-343, April): Even though agricultural and veterinarian regulations are in flux in Europe and are under consideration in the U.S., the importation of fetal bovine serum (FBS) by Life Technologies and other reputable suppliers has been, and continues to be, under tight control. Suppliers are required to obtain importation permits for individual countries through the appropriate government agencies. Further, certain governments require suppliers to sign compliance agreements which require suppliers to comply with processing, documentation, and audit requirements.

Life Technologies requires that its key collection and processing operations adhere to standard operating procedures, process controls, and levels of documentation that ensure the integrity of the serum and validity of the source. Contrary to the points suggested in the article, Life Technologies' collection technique does not "verge on the occult," and its supply chains are short and strictly controlled.

Viral inactivation of FBS, whether by gamma irradiation, heat, or other methods, generally is driven by customer requirements on performance, interpretation of regulatory requirements, and cost. Each method has its benefits and disadvantages.

It is not a question of "to treat or not to treat." It is a question of "informed choice." Whether in biopharmaceutical production or in research, each user of FBS has the right to the information that he or she requires to select a product to meet the need. This information includes product specifications, performance testing, source (including the traceability to back it up), and price. By requesting that the supplier has this information readily available, the user will receive a quality product. Further, by requesting this information, the user places value on it, which can only improve the controls that ensure the quality of FBS for everyone.

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