Serum Quality Guarantees

To the editor:

Bio/Technology (''Checking Sources: Serum Supply Secrets,'' December 1991; ''Fetal Bovine Serum Revisited,'' January 1993) does not, perhaps, go far enough into the problems in the fetal bovine serum (FBS) market. The concepts and arguments over serum origins are less scientifically objective and specific than one might expect. One needs to look beyond origins.

For years, the large Anglo-Saxon (U.S., U.K., Australia, New Zealand. . . .) companies have used serum origins as the main plank of their commercial strategies. Those strategies are underwritten by strict regulations. But those regulations are disparate, the consequence of which is that FBS prices vary greatly with origin. Legislation which favors certain sources only—U.S., New Zealand, Australia—and thus only a few players, creates prices hikes which are tantamount to fraud. Thus in Europe, serum accepted by the American legislation is two to three times more expensive than other sources. The situation is artificial: it is of no real value to the European end-user that serum from Latin America, for example, has been validated by the Department of Agriculture in Miami: it is only of value to those who pocket the profit. This situation is an invitation to all sorts of malpractice, which can (and does) occur at all levels, from abattoir to final distribution.

Strengthening the rules on origins seems a totally obvious solution for law-abiding people. Simply ban certain origins. But banning, for example, South American products would cut over 100,000 liters from the world FBS supply, encouraging further price hikes. Reasonably priced FBS has been a driving force in pharmaceutical research and production; increasing costs could threaten this activity. It is clear who benefits from the elevated prices—and it is not the end-user nor the wider public.

Tightening the rules would not stop those who cheat; they, by definition, already break the law or at best exploit its inconsistencies. Stopping them, even if the rules were applied less erratically than at present, would require immense efforts. No, tightening the rules, thereby increasing prices, would only serve to encourage fraudsters still further.

Nowhere in the two articles were the questions of serum quality for cell growth and public health raised. Is serum origin the only guarantee of its quality?

For pharmaceutical raw materials, many countries, including the U.S. and Germany, permit manufacturers to import products of animal origin from countries which are not acceptable as sources of FBS. The only requirement on the manufacturer concerns the specifications of the final product. Why not adopt the same approach for FBS?

The U.S. allows imports of Central American FBS following strict controls. This correlates more with the final use of FBS—helping to guarantee improved cell growth and the safety of manufactured products. This approach has, in addition, the advantage of encouraging responsibility in distributors and of guaranteeing product quality, not by a certificate of origin, but by exact and controllable specifications.

EUROBIO adheres to European standard ISO 29002 for "Quality assurance in production and installation." This applies not only to process control and good laboratory practice, but also to control and quality in procurement. The identification, traceability, and verification of purchased products are specified. We audit our serum suppliers for good practice in collection, treatment, storage, and documentation of serum. Those with whom we do business, including Latin American suppliers, have as high standards as anyone in the world. We believe that continuity, long-standing commercial relationships, and our work in QA all benefit our clients. Naturally, we take the greatest care to verify our documentation, too.

IMAGE UNAVAILABLE FOR COPYRIGHT REASONS

"Somehow I was hoping genetic engineering would take a different turn."

By focusing only on the laxness of the rules, *Bio/Technology*'s articles ignore the activities of a handful of international players which the scientific community distrusts—having already suffered from their speculation. Serum users could do better to trust local professionals whom they know, whose knowledge and honesty are established, and who have been a long time in the field.

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EC and the Pending Patent Law

To the editor:

I refer to your article on the draft European Council Directive on the Legal Protection of Biotechnological Inventions *(Bio/Technology*, December 1992). The European Commission has issued an amended text for the draft directive, together with an explanatory memorandum. A number of points in your article require clarification, particularly in the light of this amended text.

First, it is not accurate to say that the draft directive intends to exclude all animals from patentability. Rather, the draft sets out exceptions which one hopes will be narrowly construed. Thus, Article 2.3 of the current draft states "Inventions shall be considered unpatentable where publication or exploitation thereof