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Comments and opinions on editorials, articles, and research in Bio/Technology *are welcome. Letters to the Editor may be addressed to: 345 Park Ave. South New York, NY 10010 fax: 212 696 9635 (e-mail: m.ginsberg@natureny.com).*

Changing serum's mind-set

To the editor:

To understand the urgent need for new regulations for fetal bovine serum (FBS), you have to look at the history of demand, supply, and pricing. The demand for FBS has grown steadily for years, even though researchers have developed techniques to get more cells out of each liter of serum

When it was first used as a medium supplement, FBS seemed to be in unlimited supply, at least in the U.S. Any new demand was satisfied simply by extending its collection to new abattoirs. The U.S. limit was reached in the late 1970s, after which first Canada and Mexico and then other nations became FBS producers. The supply has grown by an average of 15,000 liters per year during the last 30 years. Total world production peaked at 500,000 liters per year, and is now falling because of lower per capita meat and dairy product consumption, and higher outputs per animal. FBS can be divided into four groups, based on the health status of the cattle as defined by USDA.

In the 1980s, the combination of growing demand and decreasing supply turned FBS from a commodity in unlimited supply at stable, low prices into an item where demand and supply were closely matched. Consequently, new demand caused price explosions; crashes followed when new sources became available or the demand disappeared. Currently, virtually all countries that can produce are producing, so any future growth in demand will inevitably cause FBS price increases.

These may be the rules of the market, but as far as FBS is concerned, it is a market that is somewhat artificially maintained. Producers from "old" FBS countries—like the U.S., New Zealand, or Canada—have used the lack of clear rules and definitions on serum quality to make geography synonymous with quality. This strategy is unjustified by both scientific and—apart from group IV serum—U.S. regulatory criteria, but has provided substantial commercial gains for certain suppliers by creating price differentials between FBS of different origins.

The price differentials within FBS origins in groups I-III are only 10-15%. However, group IV serum is dangerously cheap. Why? Largely because these sources, particularly the South American ones, have, or have been given, a bad name. *Bio/Technology* used the headline "USDA Welcomes Infected FBS" (*Bio/Technology* **13**:333-343) when it reported the proposal from the USDA that FBS from foot-and-mouth or rindepest-endemic (but BSE-free) countries could be imported into the U.S. if subjected subsequently to gamma-irradiation treatment.

Bio/Technology's headline and the false perception of the market for FBS that it reflects obscure a number of basic truths. The first is that, just because a country is not free from a particular virus, this does not mean that its products are infected: Live animals in South America are vaccinated and controlled; killed animals are inspected ante and post-mortem. Furthermore, authorities in both the U.S. and Europe permit the importation of meat, beef casings for sausages, and glands (for insulin production) from South America. So why not FBS?

Then there is the arbitrary distinction between "good" viruses (including blue tongue virus), which are found in the group I-III countries, and the "not-so-good" viruses (including foot-and-mouth disease), which are found in group IV countries. This distinction has been eliminated from EU proposals on animal component importation. What people who use FBS for cell culture actually want is no virus at all!

Third, the fact that there are ways both of detecting and inactivating virus in serum is overlooked. And finally, there is the question of BSE. If BSE is a risk factor, as the USDA proposals suggest, then the extensive, grass-fed nature of cattle operations in South America should count in the their favor.

The consequence for the market of ignoring these facts has been the price differential of 50% for the group IV sera, a differential which is clearly a danger. Misuse of FBS is definitely more likely to stem from smuggling and misrepresentation (for which there is currently a huge financial incentive) than it is from legalizing importation under the stringent control of agricultural authorities.

I believe that the proposals that have come from the USDA and the EC will move things in the right direction by opening up markets and clarifying rules. They will reduce price differentials and reduce the problems associated with them. It is difficult to see the downside. The use of FBS from blue tongue or FMD-endemic countries is risk-free as long as users are aware of the origin and take the right precautions before, during and after the use of the product. Coordination of the new rules between the USDA and EC as well as clarification by FDA of their acceptance criteria for FBS of different origins would further help to make the market more transparent.

As the proposals stand (or, at least, as they started) everyone—producers, filterers, distributors, end users and official authorities—should benefit from these new, straightforward rules. The only losers will be those well-connected "specialists" who, in the past, have made fortunes by turning serum of whatever origin they could buy into serum of whatever "sophisticated" origins they needed for their patrons.

This change can happen—if the rules are kept simple and easy to control. And that is why I hope that the final decisions about new rules on both sides of the Atlantic will be made soon, and will be made objectively, based on scientific criteria applied to the real world, and without undue political or commercial considerations.

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