/CORRESPONDENCE

BST: Science and politics*To the editor:*

Russ Hoyle's article (*Bio/Technology* 12:570-571, June) on the U.S. Food and Drug Administration's (FDA, Rockville, MD) bovine somatotropin (BST) policy unwittingly strikes at the heart of the dilemma posed by the assessment of veterinary medicinal products and production aids.

Of course, the blame for the latest confusion does not lie with the Clinton administration as Mr. Hoyle supposes nor exclusively with any of the pharmaceutical companies, but is part of a wider debate relating to whether or not it is desirable to use production aids to increase yield.

Quite aside from the fact that scientists are not always as objective as some may suppose, the fact that BST has been given a clean bill of health by the FDA need not automatically qualify the product for use.

While the standard three criteria of quality, safety, and efficacy may be sufficient for veterinary medical products, it must be borne in mind that BST is not used for this purpose. That is why the European Parliament's Committee on the Environment, Public Health, and Consumer Protection advocated

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REASONS

"The good news, however, is that thanks to Dr. Prebish we can implant in you the genes of someone I won't yearn to fire."

a further criterion for cases where animal pharmaceuticals are used as production aids, that of a "fourth hurdle."

The fourth hurdle requires, in addition to the three above-mentioned criteria, a socioeconomic and environmental impact assessment of the product in question. In the case of BST, it is clear that its use is potentially uneconomic and this was a factor recognized by the European Commission in its consideration of the moratorium on its use in the European Union. At the same time it was also recognized that its use could result in "negative consumer reaction... and... related effects on consumption." Small wonder that some American dairy producers have seen a niche in the market for a premium "BST-free product."

While it is important to keep an open mind as to the value of products produced with the aid of biotechnology, there is little point in introducing a product that has both the potential to destabilize the already fragile market and, in addition, the power to lower consumption levels.

The FDA's reaction therefore may be considered

as nothing more than the inevitable result of applying the wrong criteria to the licensing application. Instead of considering all possible aspects of BST's use, the FDA only looked at the three criteria of safety, quality, and efficacy. Having judged these to be met, it then licensed the product. The subsequent confusion is a belated recognition of both the importance of socioeconomic factors and of the primacy of consumer protection—even from unfounded fears.

This is why, in addition to any lingering doubts over the product's safety, quality, and efficacy, the moratorium was introduced and subsequently extended in the European Union.

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To the editor:

In the June edition of *Bio/Technology*, Russ Hoyle describes how "FDA's BST policy wreaks havoc in the market" (12:570-571). Europeans dealing with registration of animal health products in Europe generally consider the FDA system an example for European regulators: Once the FDA approves a product automatically the product can be sold. This is not yet the case in the European Union (EU).

BST is still not sold in the EU member states, even though the EU regulators (Committee of Veterinary Medicinal Products, Brussels) recommended approval (in effect) of two BST products (Monsanto's and Eli Lilly's) early in 1992. This is because, in 1993, the European Commission proposed a seven-year moratorium, ending in 2000, on the use of BST. But at the end of last year, the Council of Ministers, under the presidency of Belgium, decided to change the moratorium within one year. There were two main reasons for this: GATT agreements had just forced the members to abandon any nonscientific trade barrier; and early in November in the U.S., the FDA had just approved Posilac, Monsanto's BST. Before the end of 1994, under the presidency of Germany, the Council of Ministers will decide whether to end or to continue the moratorium.

So, throughout 1994, the Commission and the Council of Ministers are watching the U.S. situation very carefully, particularly the sales of milk. It seems that despite huge negative campaigns after the launch of BST, the sales of milk did not change. U.S. consumers appear to remain confident in their regulators. But all other news from the U.S. is scrutinized by the Commission and by those who oppose an end to the moratorium: Any campaign against BST (e.g., potential labeling) is reported widely in the press and brought to the attention of those in power.

As I pointed out in an earlier article in *Bio/Technology* (10:148-149, February, 1992), there is an internal struggle within the European Commission over BST