Making the right connections

Whistle blowers aren't always welcomed, of course. But one would expect that when government officials are alerted to the possibility that products that they themselves have designated as being a danger to animal health had entered the country, they would take some action. Not necessarily so says David Murray, founder and former Managing Director of serum collection and processing company, Seralab (Crawley Down, UK).

In January 1989, before he sold Seralab to Porton International (London, UK), Murray was offered a 2,400 litre consignment of "very dubious" FBS. The accompanying veterinary certificate specified that the batch had come from an abattoir which, from recent dealings, Murray knew could produce only 20 or so litres of FBS a week: that one batch would have represented around two years' collection. So was this consignment really UK serum?. His subsequent investigation of the company which had offered the serum revealed them to be a "shell" operating from a hut. Murray dismissed the company from his mind but he was still concerned about the veterinary certificate. The company could have forged it. Alternatively, and perhaps more seriously, the local veterinarian could have made a false declaration.

Murray wrote, in January 1989, to the local Ministry of Agriculture, Fisheries and Food (MAFF) office outlining his concerns that certificates issued in the Ministry's name were being misused. He telephoned the office on February 1 and, on being told that there was no cause for action, stressed that he was "seriously disturbed" about the possibility that the certificate was of doubtful origin. Some action ensued when Murray suggested that he should take the matter up with MAFF head office in London: he recieved a letter from the local office telling him that the principal of the veterinary practice was on holiday. On the March 8, another letter arrived, this time saying simply that the local MAFF officials had spoken to the vet.

All went quiet until June 12 when a third letter came from MAFF. It said "The facts indicate that there may have irregularities ...". At last, something seems to be happening. It was a false dawn. On July 31, a circular was sent out to serum companies throughout Europe, including Seralab, offering large quantities of certified UK serum: it came from the same company which had offered Murray the 2,400 litre consignment in January. It appeared that the veterinarians had signed more certificate and that the Ministry had, again, turned a blind eye. Murray believes that veterinary malpractice of this kind is not uncommon: "There is no doubt that it does go on.", he says. And he attributes the feebleness of the investigation by MAFF to the presence of an "old-boy network" linking vets in commercial practices with Ministry officials with veterinary

presto chango, ten times more kosher serum. The photocopier, like the magician's cape, is used to obscure the deceit. There is at least one reasonably well-documented example of the use of the "zero option": an original consignment of 200 litres of New Zealand, routed through Switzerland, arrived in Germany as 2,000 litres. Fortunately, the end-user uncovered the con. There are two easy counters to the "zero option". At one end, the customer should insist on original certificates. At the other, the exporter should simply write the original volume in both words and numbers. Scandalously, that simple safeguard is not standard practice.

The one paper trail racket that is not so easily preventable is "the bent vet." The authenticity of the paper trail and of the consignment itself depends heavily on ethical behaviour from veterinarians. But with a single signature worth, say $100,000 (for a 2,000 litre consignment of South American FBS "converted" to "European"), the frailties of officialdom can clearly come into play. Rarely, intimate market knowledge and luck may lead to the uncloaking of the fraud (Box 2). More usually, however, "the bent vet" can only be discovered by physically retracing the paper trail for the shipment of interest back to the original source. In essence, an investigator will need to answer the question "Is it probable that all the documented events actually took place?"

Healthcare companies are beginning to recognise the need to undertake such detective work. The quality assurance manager at a major monoclonal antibody manufacturer said that his company had always performed customer audits on suppliers' premises and followed batches of serum through the chain. "For batches of serum that we receive or have on reserve, we use copies of the veterinary certificates released by the processor, go back through their records and trace how [the batch] arrived on their side. We have rejected a number of processors in the past on that basis. ... Its not something you can afford to relax on." The company, however, doesn't pursue the trail all the way to the abattoir although it may do soon. Wellcome (Beckenham, UK) does, with quality assurance staff making trips on a twice-yearly basis to New Zealand to follow the audit trail of the adult bovine serum it uses for vaccine production. That may have to become a routine task for major uses of foetal bovine serum unless the supply industry can straighten its act out itself.

Recommendations

Those in the FBS supply industry have their own ideas about how it might be tightened up. Some suggestions, like the call for greater diligence and more intense scrutiny by serum users, are outside the industry's control. So, too, is the call from Moregate's Elizabeth Meixner that the importation of FBS from South America into Europe should simply be banned—because of animal disease. It would probably be very difficult politically to enact such a ban and almost impossible to enforce. Indeed, it would have the effect of raising the price differential between European and South American products and might encourage scurrilous dealers.

Formal licensing of all serum traders and processors in Europe would be another way forward. It would bring Europe into line with the US, it would force supply companies to adopt standard protocols and it would give serum users an official stamp of approval to look for in selecting a supplier. Understandably, since Life Technologies is already FDA-licensed, Tom Coutts is enthusiastic about the idea; "If [government] took a more proactive interest, then many of the people who have thrived by bending the rules will be out of business." The difficulty will be harmonising the rules across Europe. Another wrinkle on the same theme might be the formation of an industry association which sets its own standards and polices its members. Self-regulation, however, is not something on which the FBS supply industry has a very good record.

Perhaps the most practical suggestion, at least in terms of protecting the FBS supply in New Zealand and Australia, would be to process the serum "down under." Following the UK BSE scare, Neville Pope relocated his adult serum processing to New Zealand. He has a 1250 litre per day filtration capacity which he intends to use for FBS soon. If FBS was exported in sterile form to users, it could be supplied directly—cutting out at a stroke much of the scope for criminal activity. It wouldn't stop South American FBS entering Europe: it would, however, help users to know what they were getting. And by cutting out some of the middlemen, it might even bring the price down.