Product contamination

FDA sends in the marshals

Washington

US MARSHALS acting for the Food and Drug Administration (FDA) last week seized \$4 million-worth of tissue culture and related products belonging to Flow Laboratories Inc., a major supplier to clinicians and researchers. The FDA action was taken following an inspection in April that found numerous instances of bacterial contamination of products and violations of FDA's code of good practice.

A federal judge later allowed Flow to recover raw materials and products used only for research. Flow attorneys argued that the FDA action was unlawful because marshals took "everything they could lay their hands on", and that cell lines would quickly die without attention. The company had been forced by the FDA action to close its manufacturing facility at McLean, Virginia.

Flow does not dispute most of the hundred or so complaints listed by FDA in April, but, according to Douglas Poretz, director of corporate affairs, the company has since made vigorous efforts to comply with the FDA observations. The complaints originally made by FDA allege that procedures for testing contamination were inadequate, that "clean" and "dirty" areas were not kept separate and that sterilization equipment failed to work to specification. Several products were not routinely tested in the manner claimed and significant contamination was present in others. In some instances, according to FDA, the company had failed to notify customers after a faulty batch was detected.

Flow says that after the April inspection, several senior staff were fired and outside consultants were brought in. But problems continued, and more than 10 product recalls were made during July. An anonymous Flow employee telephoned FDA to say that some products known to be contaminated were being shipped to customers. FDA finally acted on the basis of the product recalls without carrying out a second inspection.

Flow General Inc., the parent company,

has been through a disastrous 2 years and has sold off parts of its operation after sustaining losses last year of \$10 million on sales of \$129 million. Legal difficulties over a defence contract led to many staff resigning, and Flow Laboratories' factory in Scotland had to recall many products because of mycoplasma contamination from the water supply. A trial to examine the legality of the FDA action will be held on 12 September.

Tim Beardsley

French nuclear energy

Overpowered

FRENCH pressurized water reactors (PWRs) now provide more than half of French electric power, and last year "had the best performance ever" after a rather worrisome year in 1982, according to a spokeswoman for Electricité de France (EDF), the French national utility.

In 1982, French reactors were troubled by problems with the radiation embrittlement of certain clips ("broches") which held fuel in place, which resulted in long shutdowns for repairs and consequently very poor operating figures for that year. It was feared that the French method of large batch production of a very small number of designs might have been cheap, but risky. If there were a fundamental flaw in the design, at worst all the reactors could go down, and French electricity production would be halved. What had seemed like sense began to seem like foolhardiness.

But all along EDF claimed that these were mere teething troubles. The French nuclear system had grown so rapidly, most of it was very new: the *broches* problem was a problem of running-in, said EDF (crossing its collective fingers meanwhile).

Now, however, the *broches* problem is past and all is well. In the first half of 1984, French PWRs have turned in availabilities (energy produced divided by energy theoretically capable of production, if the reactors all ran full-time) of over 80 per cent, compared with figures around and under 60 per cent a year earlier. West Germany and Japan are said to be showing similar good results.

But the problem in France now is what to do with all that electricity. The French Government, in announcing a slimmed-down nuclear construction programme last year, asked EDF to aim at increasing French electricity consumption by 40 per cent by 1990, a task which requires finding some inventive new uses for electricity. Domestic electricity consumption has indeed risen this year by about one per cent a month — but there are no obvious reasons why (the French economy has been stagnant). The other possible opportunity of filling the gap is export. Given the tardiness of the other European power programmes in substituting for coal and oil, this must be the greatest opportunity facing the French utility in 1990.

Robert Walgate

French universities

Now one for Le Havre

THE new French minister of education, M. Jean-Pierre Chevènement, is conforming to his old, expansionist style, and belief in investment in "grey matter". He has created a new university.

This will be the Université du Havre, a university for the channel port of Le Havre, the third port of Europe, the twentieth city in France and one that has been seeking university status for its various colleges for some fifteen years.

But "the university of where?" asked a surprised spokesman for the Centre National de la Recherche Scientifique (CNRS), France's principal source of funds for basic research, when confronted with the news on Monday. Admittedly the university had been created during her holiday (last Tuesday in fact), but this may be a small indication that the university is not immediately going to startle the world.

Actually, Le Havre will be the 64th French university, counting the vast 13-university University of Paris as one, to compare with 48 in Britain (counting the University of London as one), for about equal populations in the two countries. The comparison reflects the effects of the troubles of May 1968, when student pressure and political expediency led to the creation of many new universities in France and elsewhere on mainland Europe, but few in Britain.

The expansion might have been thought to be over in France, but that was reckoning without M. Chevènement — and the fact that the new Prime Minister, Laurent Fabius, owes his seat in the national assembly to the electorate of the Seine-Maritime department, which includes Le Havre.

The university is expected to concentrate on matters concerning international trade, and will begin with a £3 million cash grant to create a 6,300 sq. metre campus. It will combine an existing IUT (an institut universitaire de technologie, something like a British polytechnic) of 1,000 students, and other units that have previously depended on the Université de Rouen, 40 miles up the Seine. Its creation thus runs counter to policies observable in other countries (notably Britain), which tend towards a combination of facilities among universities.

According to figures collected by UNESCO, the United Nations Educational, Scientific and Cultural Organisation, France ranks fifth in the world in terms of the proportion of the population studying at university after the United States, Sweden, Japan and the Soviet Union. West Germany and Britain follow after France.

Robert Walgate