

United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Washington, D.C.
20250

March 9, 1998

VETERINARY SERVICES NOTICE 98-03

Subject: Deregulation of Certain Monoclonal Antibodies

To: Directors, VS Regions
Area Veterinarians in Charge, VS
Veterinary Medical Officers, VS
Port Inspectors, Plant Protection and Quarantine (PPQ)

This Notice is to inform VS personnel and PPQ port inspectors of the new U.S. Department of Agriculture (USDA) policy regarding the importation of monoclonal antibodies. This new policy replaces that contained in VS Memorandum 593.1. A new VS Memorandum 593.1 containing updated information is being prepared.

Based on recent risk assessment results, certain monoclonal antibodies no longer require an import permit "U.S. Veterinary Permit for the Importation and Transport of Controlled Materials and Organisms and Vectors" (VS Form 16-6 and 16-6A.) The risk assessment concluded that monoclonal antibodies present negligible risk of introducing exotic animal disease agents into the United States if they meet the following criteria:

1. They are not directed against livestock or avian disease agents exotic to the United States;
2. They are intended for IN VITRO use; and
3. They are produced in a facility that does not work with exotic disease agents affecting livestock and avian species.

Therefore, monoclonal antibodies (including cell culture supernatants and ascitic fluid) that meet these criteria no longer require an import permit.

A "Guideline to Importation" for monoclonal antibodies is also being prepared and will be made available on the Animal Products Program automated document retrieval system.

Other classes of monoclonal antibodies (for example, those for IN VIVO use or from a laboratory that works with exotic disease agents affecting livestock and avian species) will still require an import permit.

Application forms (VS Form 16-3 and 16-7) may be obtained by calling our automated document retrieval system at: Area Code (301) 734-4952.

/s/

Joan M. Arnoldi
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Veterinary Services