NOTIFICATION

The following notification is being circulated in accordance with Article 10.4.

1. Party to Agreement notifying: SWITZERLAND

2. Agency responsible: Federal Veterinary Office

3. Notified under Article 2.5.2 [X], 2.6.1 [], 7.3.2 [], 7.4.1 [], other:

4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Immunological products for veterinary use (i.e. vaccines, antigens, toxins, anti-toxins, immunosera, immunoglobulins, immunomodulators)

5. Title and number of pages of the notified document: Ordinance on Immunological Products for Veterinary Use

6. Description of content: This new Ordinance concerns on one side the granting of production, importation and exportation for immunological products and on the other side the registration of immunological products.

7. Objective and rationale: Today, the regulation of the immunological products for veterinary use is part of the Animal Health Ordinance. Details are managed by the Ordinance on Production, Importation, Distribution and Examination of Immunological Products for Veterinary Use, issued on 1 May 1974 by the Swiss Federal Veterinary Office. As the Animal Health Ordinance is currently being revised, the above-mentioned regulations will be transferred into an ordinance promulgated by the Swiss Federal Council. In the meantime, the regulations will be assimilated to the regulations of the immunological products for human use.

The new Ordinance is equivalent to the essential safety requirements of the EC-regulation (90/677/EEC; 92/18/EEC). There still exist small differences on certain points of the safety requirements due to the small size of the manufacturers of immunological products for veterinary use in Switzerland. They concern only the Swiss production and will not create any barriers to trade.

8. Relevant documents: Swiss Law: The Ordinance is based on Article 27 of the Animal Health Law of 1 July 1966 (TSG; SR 916.40)

9. Proposed date of adoption and entry into force: 1 June 1995

10. Final date for comments: 20 February 1995

11. Texts available from: National enquiry point [X] or address and telefax number of other body: