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The Availability of Foot-and-Mouth Disease Vaccine for Emergency Vaccination in Europe
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1. Introduction

A review of the availability of vaccine and inactivated antigen for emergency vaccination use was called for during the 62nd Session of the Executive Committee of the European Commission for the Control of Foot and Mouth Disease at their meeting in Lysebu, Norway in November 1998. This report is intended to be used as an update to the comprehensive report prepared by Dr. Garland for the 32nd Session of the European Commission for the Control of Foot-and-Mouth Disease.[1]

Foot and mouth disease (FMD) vaccines banks are of two types: those holding reserves of fully formulated and tested vaccine ready for immediate use but with limited shelf life, and those holding reserves of tested antigen of long shelf life which can be formulated into vaccine and filled as required. This paper is only concerned with antigen banks in Europe.

Stockpiles of FMD antigen have been in existence for over 20 years. The first was created in Denmark in 1976 while international banks were formally inaugurated in North America in 1982 and in Europe in 1985. National banks have also been created. Commercial manufacturers provide much of the antigen for these banks and also hold stocks in their own right.

To date stocks of antigen in international banks have been called upon to supply emergency vaccine rather rarely i.e. from the European Commission Vaccine Bank to the Balkans in 1996.

The threat of FMD persists and the risk of spread is exacerbated by political and economic developments, expanding free trade areas and ever more rapid movement of animals, animal products and people around the globe. In the European context the continuing risk from FMD is emphasised by the presence of endemic disease in Anatolian Turkey and recent outbreaks in North Africa and the Caucasian countries.

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2. Existing FMD Vaccine Banks

There are essentially three existing types of FMD vaccine bank.

- International, Government administered and financed banks.
- National, Government administered and financed vaccine banks.
- Commercially maintained vaccine banks.

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2.1. International Governmental Vaccine Banks

Appendixes

- *2.1.1. The International Vaccine Bank (IVB)*

  The IVB came into being in 1985. The founder members were comprised of seven countries, all of which were free of FMD at the time and which have since maintained that freedom, namely: Australia, Finland, The Republic of Ireland, New Zealand, Norway, Sweden, and the United Kingdom. Malta joined the bank as an associate, non-voting member in 1995.

  The bank is located at the UK Institute of Animal Health (IAH) Laboratory at Pirbright, England, which is also the World Reference Laboratory (WRL) and European Reference Laboratory for FMD. Antigens are purchased according to open tender from commercial sources. The IVB is unique among the FMD vaccine banks in having its own facilities for the formulation and filling of vaccines in dedicated premises under licensed conditions and in compliance with Good Manufacturing Practice.
  The choice of antigens is determined according to the prevalent epidemiological conditions world wide and to reflect the likely needs of member countries in Europe and Australasia The selection process takes cognisance of the latest information available from the WRL, the Office International des Epizooties (OIE) and the Food and Agriculture Organisation (FAO) of the United Nations. It has not been deemed necessary to change the selection of antigens since the previous report in 1997. Currently the stocks include antigens equivalent to half a million doses of finished vaccine of each of the types and subtypes of virus and of the potencies shown in table 1.

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Table 1 : IVB Vaccine Stocks and Potency Values

Vaccine Type and Strain			PD50 value as most recently assayed in 1996[2]
Type A15	Thailand	>	112 PD50 per dose
Type A22	Iraq		75 PD50 per dose
Type A24	Cruzeiro		18 PD50 per dose
Type O1	Lausanne		41 PD50 per dose
Type O1	Manisa	>	112 PD50 per dose
Type C1	Oberbayern	>	112 PD50 per dose
Type Asia1	India 8/79		61 PD50 per dose

The bank is maintained in a constant state of readiness and has the capability of formulating, filling and despatching up to 500,000 doses of vaccine within three days of receiving a request from a member state. Both aqueous-saponised and oil adjuvanted vaccines can be formulated.

- *2.1.2. The European Union Vaccine Bank (EUVB)*
  The establishment of the European Union Vaccine Bank (also earlier referred to as the European Commission Vaccine Bank) was formally

authorised in 1991 by EC Decision 91/666/EEC [5]. This Decision stipulated that the bank would eventually hold antigen equivalent to at least five million doses of vaccine of ten subtypes, these being specified in Annex 1 of the Decision. The Directorate General VI of the EC in Brussels manages the bank with technical advice from the FMD Sub-group of the Scientific Veterinary Committee of the Commission of the European Communities and the Standing Veterinary Committee.

Antigens are purchased from European manufacturers with a minimum acceptance level of 6.0 PD50 per dose. For ease of geographical access and for reasons of security the inactivated concentrates are divided between at least two of three designated storage locations situated at: Pirbright in the UK; the Laboratoire de Pathologie Bovine du Centre National d'Etudes Veterinaire et Alimentaire at Lyon in France; and the Instituto Zooprofilattico Sperimentale di Brescia in Italy

The current quantities and locations of antigen in the EUVB are shown in Table 2.

Table 2: EUVB antigen stocks and locations

Virus type and subtype	Quantity	Location
O1 Tur 1/78 (Manisa)	2,500,000	Brescia
C1 Europe (Noville)#	2,500,000	Brescia
Asia1 (Asia 1 Shamir)#	2,500,000	Brescia
A22 Iraq 24/64	2,500,000	Brescia
O1 Tur 1/78 (Manisa)	2,500,590	Lyon
O1 BFS	2,500,692	Lyon
A24 Cruzeiro	2,500,874	Lyon
A22 Iraq	3,887,124#	Lyon
O1 BFS	2,500,000	Pirbright
A24 Cruzeiro	2,500,000	Pirbright

(strain x) => Closest strain to those recommended by EuFMD Research Group Vienna, Sept. '94. See Appendix 1

= items changed since the 1997 report

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- *2.1.3. The All Russian Research Institute for Animal Health (ARRIAH) Vaccine Bank*

The ARRIAH Institute at Vladimir near Moscow has for many years supplied vaccine for a number of regions within Russia and for countries

formerly included in the USSR prior to the break up of the soviet block. The Institute is recognised by OIE as a Regional Reference Laboratory for FMD for the countries of Eastern Europe, Central Asia and Transcaucasia, including the function of acting as the vaccine bank for these regions. ARRIAH has negotiated contracts for the supply of vaccine to Bulgaria, Ukraine, Kazakhstan, Belarus, Moldavia and Turkmenistan [5, 6]. Its role in the co-ordination of FMD Control in the Caucasian countries (Russia, Armenia, Georgia, and Azerbaijan) has recently been defined by the EuFMD/OIE/EC mission to the Caucasian countries and ARRIAH Vladimir. (see item 5).

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2.2. National Government Vaccine Banks (NGVB)

The status of NGVBs was reviewed in an international context by Callis in 1994 [6] and in an European context by the EuFMD Commission in 1993 [7], 1995 [8]. and again in 1997[1]. The latter three reviews utilised a questionnaire sent to all member countries - including both members and non members of the European Union - and a number of associated countries. This exercise was repeated in January 1999 and the detailed results are given in Appendix 2.

Summary of Results of the Questionnaire of NGVB in Europe in 1999

Questionnaires were despatched to the 33 member countries and replies were received from all 33 countries, giving a 100% response rate.

- Six countries (18%) have made no arrangements for the supply of emergency vaccine.
- Seventeen countries (52%) have made one arrangement - either through a national vaccine bank, through a contract with a commercial supplier or as a member of an international vaccine bank - for the supply of emergency vaccine.
- Ten countries (30%) have made more than one arrangement for the supply of emergency vacccine.

In total there are 11 national banks among the member countries, and they vary in their arrangements. Seven of the 11 banks (64%) are maintained by private manufacturers under contract; the remainder are with national institutes. Seven of the eleven banks (64%) consist of inactivated antigens only, 1 bank consists of formulated vaccine only and 3 banks include both.

Five countries (15%) maintain contracts for the supply of formulated vaccine in an emergency either from a commercial supplier or from a national institute.

Six countries (18%) are members of the International Vaccine Bank. The 15 (45%) EU members are all entitled to access the EU vaccine bank. However, nine of the fifteen (60%) have an additional arrangement, 4/15 are also members of the IVB and 5/15 maintain national vaccine banks. Of the ten countries who maintain more than one arrangement, 9 are EU countries.

Nine countries have changed their position since the previous report.

Six of these changes involved changes to a national vaccine bank. There was 1 new contract, a change in the terms of another contract and the final change was related to changes in the European Union vaccine bank.

Of the changes to the National vaccine banks, five of the six included a change in the profile of serotypes represented, four of the six increased the overall quantities and in general the changes reflected a trend towards more inactivated antigen than formulated vaccine.

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2.3 Commercial Vaccine Suppliers:

Three commercial companies are currently engaged in FMD vaccine manufacture within the EU namely: Bayer AG in Germany; Intervet in the Netherlands; and Merial in England and in France.[1]
Vaccine manufacturers outside the EU include: the government ARRIAH facility in Russia and regional vaccine plants in Shelkovo and Povrov [8]; the Dyntec company at Terezin in the Czech Republic; the government SAP Institute in Ankara and the new, private Vetal company at Adiyaman in Turkey.[1]
On contacting these manufacturers the amount of additional information to that provided by Dr. Garland in his previous report is very little.[1] Some manufacturers reported that due to the current outbreak of FMD type O in North Africa, very little type O vaccine was available for quick delivery, but this vaccine is still available from other suppliers.

3. Summary

The IVB holds antigen equivalent to 3.5 M doses of formulated vaccine of seven serotypes and is accessible to 6 commission members. The EUVB antigen stocks are equivalent to 26.4 M doses of six serotypes and are accessible to the 15 EU member countries (and possibly other countries on a case by case basis). National vaccine banks in member countries currently hold antigens equivalent to 38.3 M doses of formulated vaccine and cover 17 serotypes. The full break down of Serotypes can be found in Table 3. Thus there are antigen stocks capable of producing some 68.2 M doses in member countries, excluding some stocks maintained by commercial firms and the antigens held in the ARRIAH bank.

Table 3: Details of Emergency Vaccine Stocks

Serotype	IVB	EUVB	NGVB	Totals
O	1,000,000	10,001,282	10,778,718	21,780,000
A	1,500,000	11,387,998	13,599,002	26,487,000
C	500,000	2,500,000	6,800,000	9,800,000
Asia 1	500,000	2,500,000	5,240,000	8,240,000
SAT1			1,000,000	1,000,000
SAT2			1,000,000	1,000,000
Total	3,500,000	26,389,280	38,417,720	67,307,000

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4. References:

- 1. Garland A.J.M. (1997) The Availability of Vaccines for Emergency

Vaccination in Europe. Report of the 32nd Session of the European Commission for the Control of Foot and Mouth Disease, Rome, Italy 2-4th April 1997. Appendix 8, pages 89-111.

- 2. Pastoret P-P. (1996) Report on the Control of Foot and Mouth Disease in the European Union. Directorate General VI, European Commission, Brussels.
- 3. Anon.(1991) Council Decision of 11th December 1991. establishing Community Reserves of Foot and Mouth Disease vaccines (91/666/EEC).
- 4. Anon. (1994) Virus Strains for Vaccine Banks. European Commission for the Control of Foot and Mouth Disease. Session of the Research Group of the Standing Technical Committee, Vienna, Austria, 15-22nd September 1994. Item 8, pages 8-9.
- 5. Zakharov V.M., Baibikov T.Z., Rakhmanov and Dudnikov A.I. (1995) Foot and Mouth Disease Control Strategies in the Russian Federation and in Ex-USSR Countries. European Commission for the Control of Foot and Mouth Disease. Meeting of the Research Group of the Standing Technical Committee, Vladimir, Russian Federation, 20-22 September 1995. Appendix 13, pages 81-83.
- 6. Callis, J. (1994) Vaccine Banks: Present Status and Future Development. In the Proceedings of the 62nd General Session of the Office International des Epizooties. Paris, 16-20 May 1994. Report 62/SG 10, pages 1-6.
- 7. Anon.(1993)
  (a) Foot and Mouth Disease Prophylaxis in Europe 1991-92.
  (b) Vaccination programme 1991-1992. Report of the 30th Session of the European Commission for the Control of Foot and Mouth Disease, Rome, Italy, 27-30 April 1993. Appendix 3, pages 28-35.
- 8. Leforban Y. (1995) Availability of Vaccines for Emergency Vaccination in Europe. Report of the 31st Session of the European Commission for the Control of Foot and Mouth Disease, Rome, Italy 5-7th April 1995. Appendix 9, pages 60-65.

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Appendix 1

FMD virus strains recommended for inclusion in the European Vaccine Bank by the Research Group of the EuFMD at its Session held in Vienna from 19-22 September 1994.

Vaccine strains recommended for inclusion in the European Vaccine Bank:

High priority

0 Manisa
O BFS or Lausanne
A22 Iraq
A24 Cruzeiro
Asia 1 Shamir
C Noville

Medium priority

SAT 2 Zimbabwe
A15 Bangkok related strain
A87 Argentina related strain
A Saudi Arabia
SAT 1 South Africa
C Philippines
A Turkey

Low priority

SAT2 Kenya
SAT1 Kenya
SAT3 Zimbabwe

O Thailand
A Kenya
0 Hong Kong

(not in order of importance)

Strain not Circulating at the time of the recommendations above:

A Iran/96

Appendix 2

Strategic Reserves of FMD Vaccine and Antigen held by Member countries as of as of March 1999. Click **here** for the table.

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