

## **Withdrawal from the International Foot and Mouth Disease Vaccine Bank**

### **Introduction**

- 3.1 The International Foot and Mouth Disease (FMD) Vaccine Bank (IVB) commenced operation on 26 June 1985. According to a unanimous decision by the Commission, established under the Agreement, the Bank will cease operation on 30 June 2004. This is because, in the opinion of the Commission, ‘the Bank is no longer able to meet the needs of its members for the supply of high quality, safe and effective FMD vaccines.’<sup>1</sup>
- 3.2 Even though Australia’s rights and obligations will effectively end on this date, termination of the treaty terms is not automatic and the proposed treaty action is to ensure that Australia is not party to a meaningless agreement.

### **Background**

- 3.3 The IVB holds antigens of seven strands of FMD virus, sufficient to produce 50 000 doses of vaccine for each strain. It also has a small FMD vaccination formulation plant.

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1 National Interest Analysis (NIA), para. 7.

- 3.4 The Committee was informed that the main motivation behind reviewing the Bank's operation was the UK outbreak of bovine spongiform encephalopathy (BSE). According to Mr Merrilees
- since those outbreaks there have been concerns that any sort of biological material should be able to be demonstrated to not be sourced from animals that may have been subjected to BSE.<sup>2</sup>
- 3.5 The Committee understands that the first case of BSE was diagnosed in 1986 and the first case of variant CJD, attributed to the bovine disease, was announced in 1994.<sup>3</sup> Dr Tweddle, of AFFA, stated that
- from 1986 onwards, vaccine standards have been progressively tightened, and the primary standard for bovine vaccines is that no bovine material from a country that has a history of BSE can be in vaccines.<sup>4</sup>
- 3.6 AFFA stated that concerns were raised by Australia from the early 1990s and records were sought that could guarantee the safety and quality of the IVB. Dr Tweddle stated that because of the rationalisation which has occurred in the international vaccine industry, and the changing standards relating to the collection of information, such records are not available.<sup>5</sup>

## Consultations

- 3.7 The Committee understands that a wide range of participants from both industry and the government have been involved in the consultations leading to the proposed treaty action and the development of new FMD vaccine arrangements for Australia.
- 3.8 While the Commission resolved in May 2003 to cease the Bank's operation, Australia had been exploring possible alternatives for the supply of FMD vaccine since 2000. According to the National Interest Analysis (NIA), a study jointly commissioned by Australia and New Zealand recommended that Australia should leave the Bank and negotiate a new arrangement with a commercial vaccine producer.<sup>6</sup>
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2 Mr Dean Merrilees, *Transcript of Evidence*, 13 February 2004, p. 4.

3 Dr Neil Tweddle, *Transcript of Evidence*, 13 February 2004, p. 6.

4 Dr Neil Tweddle, *Transcript of Evidence*, 13 February 2004, p. 6.

5 Dr Neil Tweddle, *Transcript of Evidence*, 13 February 2004, p. 6.

6 NIA, para. 21.

An industry-government workshop and the Veterinary Committee of the Primary Industries Standing Committee considered this report in April 2001. It was noted that the Bank posed too great a risk and, as recommended in the report, that Australia should develop an independent FMD vaccine supply arrangement.<sup>7</sup>

- 3.9 In November 2001 Animal Health Australia (AHA) acquired the responsibility of developing a business plan and a tender document for the supply of an appropriate number of doses from a suitable supplier or suppliers.<sup>8</sup> Australia's involvement in the Bank would continue until new commercial arrangements were in place. These suggestions were endorsed by the Primary Industries Ministerial Council in May 2002.<sup>9</sup>
- 3.10 AHA conducted an industry-government meeting in November 2002. The meeting endorsed the specifications for an independent supply of FMD vaccine for Australia in an emergency response to an outbreak of FMD. At that meeting it was proposed that the vaccine arrangements be cost shared by industry (20 per cent) and government (80 per cent). This was agreed to by the Primary Industries Ministerial Council in April 2003 with the governments' contribution shared equally by the Commonwealth and the States and Territories.<sup>10</sup>

## Future FMD Vaccine Arrangements

- 3.11 As noted above, there have been investigations into alternative vaccine supplies for Australia. Through AHA, negotiations are taking place for commercial FMD vaccine arrangements. According to AFFA, the contract will provide for the progressive availability of antigens with full delivery in 12 months.<sup>11</sup>
- 3.12 The Commission has also initiated consultation with Participants in the current agreement on possible future international provisions for FMD vaccine supplies. AFFA informed the Committee that there is a meeting scheduled in London later in February 2004 to explore this possibility. It is envisaged that this operation would differ

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7 NIA, para. 21.

8 NIA, para. 22.

9 NIA, para. 22.

10 NIA, para. 24.

11 Mr Dean Merrilees, *Transcript of Evidence*, 13 February 2004, p. 4.

significantly from the current IVB and antigens would likely to be sourced from a commercial supplier.<sup>12</sup>

3.13 AFFA made an important observation in relation to these arrangements

... the purpose of entering into these sorts of agreements is to guarantee that we have ready access to at least an appropriate emergency supply of vaccine in the event that we have an outbreak in Australia ... we do not want to be left in the position of trying to obtain those sorts of supplies in an emergency.<sup>13</sup>

## Impact and costs of treaty action

3.14 The antigens that are currently held in the International Vaccine Bank (IVB) will continue to be available until the end of the agreement. AFFA informed the Committee that Australia has also negotiated temporary access and drawing rights to the European Commission FMD Bank, effective until 31 December 2004.<sup>14</sup>

3.15 When the Bank ceases operation, the only surviving right or obligation is that the participants will share in either excess monies or debts.<sup>15</sup> The assets will be disposed of and any surplus as a result of that disposal will be divided amongst Participants. AFFA stated that while there is uncertainty about whether there will be a surplus or a deficit, it is not expected to be a significant amount. The antigens are the major asset of the bank and do not hold any significant value considering the limitations in terms of their safety and quality.<sup>16</sup>

3.16 It is estimated that the costs for Australia are not expected to exceed \$50 000.<sup>17</sup> AFFA confirmed that this amount is in Australian dollars and added that this estimate would only apply in the worst case scenario, for example, if incineration of the antigens is required.<sup>18</sup>

3.17 In relation to this amount, AFFA pointed out that

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12 Mr Dean Merrilees, *Transcript of Evidence*, 13 February 2004, p. 4

13 Mr Dean Merrilees, *Transcript of Evidence*, 13 February 2004, p. 4.

14 Mr Dean Merrilees, *Transcript of Evidence*, 13 February 2004, p. 4.

15 NIA, para. 11.

16 Mr. Dean Merrilees, *Transcript of Evidence*, 13 February 2004, p.5.

17 NIA, para. 19.

18 Dr Neil Twedde, *Transcript of Evidence*, 13 February 2004, p. 5.

antigen is a very expensive and high-security, dangerous material. It is not really anticipated that it will be anywhere near that, but we can not really be sure until the British authorities go through the process of getting approval to dispose of it.<sup>19</sup>

## Implementation and entry into force

- 3.18 Denunciation takes effect with at least 12 months written notice, expiring on any anniversary of the date of commencement of the operation of the International FMD Vaccine Bank. As the bank commenced operating on 26 June 1985, any notice given before 26 June 2004 will take effect on 26 June 2005. Australia's rights and obligations under the agreement will effectively end, however, when the Bank ceases operating from 30 June 2004.<sup>20</sup>

## Conclusion

- 3.19 The Committee understands the implications of the risks outlined with the current International FMD Vaccine Bank and supports efforts to establish new arrangements for supply.
- 3.20 The Committee recognises that the supply of antigens is a specialised area and supports endeavours to secure an appropriate contract from a commercial supplier and negotiations with Participants for a continued international cooperation.

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19 Dr Neil Tweddle, *Transcript of Evidence*, 13 February 2004, p. 5.

20 NIA, para. 2.

**Recommendation 2**

**The Committee supports the proposed treaty action for Australia to denounce the *Agreement Establishing an International Foot and Mouth Disease Vaccine Bank, done at London 26 June 1985*, and recommends that binding treaty action be taken.**