The Australian National Animal Health Laboratory – The Use of Live Exotic Animal Pathogens

1982
THE AUSTRALIAN NATIONAL ANIMAL HEALTH LABORATORY (ANAHIL)

The Use of Live Exotic Animal Pathogens

A REPORT TO THE PRIME MINISTER

by

THE AUSTRALIAN SCIENCE AND TECHNOLOGY COUNCIL

(ASTECE)

DECEMBER 1982

Australian Government Publishing Service
Canberra 1983
My dear Acting Prime Minister,

We have the honour to present to you a report on the Australian National Animal Health Laboratory (ANAHL) and the importation of exotic animal pathogens. This results from an inquiry undertaken at ASTEC's own initiative.

Australia needs a microbiologically secure laboratory and trained staff able to identify exotic animal diseases promptly and accurately. The main role of ANAHL will be in identification, but research and development work will be required to improve current diagnostic tests and to evolve new ones.

It may be necessary to import exotic animal pathogens to ANAHL if the Laboratory is to function at maximum efficiency. However, before any such importation is authorised, there should be general agreement that the potential benefits outweigh any risks involved. Our report includes recommendations on the procedures and consultation required to reach this position.

Foot-and-Mouth Disease has a special significance for Australia because our exports of meat, livestock and animal products depend upon maintenance of our complete freedom from the disease. ASTEC has concluded that Foot-and-Mouth Disease virus should not be imported for a period of five years, and our report includes proposals which would ensure that Australia's capability to identify this disease is upgraded in the meantime.

Yours sincerely,

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(J.H. Carver)  
Deputy Chairman

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Mr J.N. Davenport  
Dr L.W. Davies  
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1. **SUMMARY AND RECOMMENDATIONS**

1.1 The annual value of production of Australia's livestock industries is about $6,000 million; livestock and their products make up 20% of Australian exports by value. Due to Australia's geographical isolation, and more recently to importation and quarantine controls, the country has remained free from many of the most serious diseases of animals. However, these diseases are a continuing threat to the maintenance of both efficient animal production and exports, and the Australian National Animal Health Laboratory (ANAHL) has been established to help counter the danger from exotic livestock diseases.

1.2 Australia needs a microbiologically secure animal disease laboratory, and the underlying rationale for ANAHL has not diminished since the concept was developed in the early 1970's. The main role of the Laboratory should be to provide a secure Australian capability for primary diagnosis of exotic diseases of animals and for monitoring of any outbreak. In association with this function, ANAHL should also undertake appropriate research into exotic pathogens, with the overall objective of increasing Australia's ability for their prompt detection, identification and eradication. The role of the Laboratory in offering veterinary training, and in the production and testing of vaccines, is less clear-cut, and will depend upon the requirements for particular diseases. ANAHL should not, in general, undertake research into endemic diseases unless there are clear advantages in having particular programs carried out at the Laboratory rather than elsewhere.

1.3 In considering the important issue of whether animal pathogens should be imported for use at ANAHL prior to an outbreak of the relevant disease, it is necessary to consider both the additional risks involved and the potential benefits. The Council has not undertaken a risk analysis of ANAHL, and it is doubtful if such an exercise would yield an unequivocal answer because the probability of accidents, malfunctions or human errors leading to an escape cannot be predicted. There is general agreement within Australia, as well as overseas, that ANAHL has been designed and built to a very high standard, and its microbiological security is probably equal to, or better than, that of any other animal disease laboratory in the world.

1.4 No one is able to give a guarantee that there is absolutely no risk of an exotic pathogen escaping from ANAHL. Therefore, notwithstanding the excellent containment offered by ANAHL, the importation of an exotic pathogen to the Laboratory must be considered to represent an additional risk over and above that posed by its accidental or deliberate introduction by other means. For most diseases, and perhaps for all, the additional risk may be small compared with that already existing. However, there should be agreement on the likelihood of substantial benefits to offset any risks before deliberate importation of exotic pathogens is allowed. The responsibility for seeking such agreement should rest with CSIRO and, because of the varying characteristics of animal viruses and the diseases they cause, a separate case needs to be developed for each pathogen proposed for importation. However, several such cases for importation could be considered at the same time.
1.5 Furthermore, there is a clear need for an agreed procedure to ensure that full consultation takes place between CSIRO and Commonwealth and State authorities, producer organisations and other interested parties. CSIRO has developed a procedure for the introduction of exotic disease agents to ANAHL, in which application is first made by CSIRO to the ANAHL Consultative Committee and, if approval is given, is then submitted to the Animal Health Sub-Committee of the Standing Committee on Agriculture. The advice of the Sub-Committee will be considered by the Standing Committee and finally forwarded to the Australian Agricultural Council. This will ensure adequate consultation with government authorities, but it is important that all organisations with a legitimate interest be consulted at an early stage. ASTEC has concluded that the ANAHL Consultative Committee should have the responsibility to give formal notice, when an application for importation is made by CSIRO, to interested parties, including the National Farmers' Federation and the Australian Veterinary Association, and to transmit their advice and comments to the Minister for Health as well as to the Executive of CSIRO. In this way, independent groups can be consulted at an early stage and their views made available direct to the Minister, with whom rests the responsibility for final authorisation of importation.

**Recommendation 1**

(i) That, for each exotic pathogen which is proposed for importation to ANAHL, CSIRO prepare a brief summary of the reasons why importation is sought, as a basis for consultation and discussions;

(ii) That the ANAHL Consultative Committee be given the responsibility of providing formal notice of proposed importations of exotic animal pathogens to the National Farmers' Federation, the Australian Veterinary Association and other organisations that it considers appropriate, with a view to obtaining their advice and comments prior to completion of its own deliberations; and

(iii) That the advice and comments received by the ANAHL Consultative Committee be transmitted to the Minister for Health as well as to the Executive of CSIRO so that they may be taken into consideration when the Minister's approval is sought for the introduction of exotic animal pathogens.

1.6 In order that parties to the consultations are able to reach an informed judgement in a timely manner on the desirability or otherwise of each proposed importation, the cases prepared by CSIRO should specify the anticipated benefits of access to the live pathogen at ANAHL as well as the potential risks and costs associated with its importation. As indicated in the recommendations below, benefits and risks should be specified for diagnostic preparedness; veterinary training; production and testing of vaccines; and research.

**Recommendation 2**

That each case proposed by CSIRO for the importation of an exotic animal pathogen should include details of:

- potential benefits for diagnostic preparedness, the procedures accepted internationally for identification of the pathogen, the opportunities for developing new or improved procedures using inactivated reagents, low-virulence strains and non-pathogenic virus models, and the risks associated with manipulation of the pathogen in diagnostic procedures;
potential benefits for veterinary training, and the additional risks and costs associated with inoculation of cattle, sheep or pigs, the limitations for such training and the availability of other methods of training including attendance at courses and disease outbreaks overseas;

potential benefits and risks of manufacture and testing of vaccines, including the availability of supplies overseas and potential developments in genetically-engineered vaccines and in techniques for testing potency and safety which do not require live pathogens; and

potential benefits for research, including a broad description of the planned research programs and their objectives, and the associated risks.

1.7 Under current proposals, no importation of live pathogens will take place until the microbiological security of ANAHL has been tested rigorously and accepted by the ANAHL Security Assessment Group, established to advise the ANAHL Consultative Committee and through it the Executive of CSIRO. However, ANAHL is nearing completion, and recruitment of staff by CSIRO should proceed. ASTEC accepts the view put forward by CSIRO that it will be difficult to attract scientific staff of the required calibre if it is uncertain that the Laboratory will be permitted to import live pathogens. This is not a justification for importation, but progress needs to be made toward a decision, even though no importation is contemplated by CSIRO before the Laboratory's microbiological security has been tested and accepted, that is, before the end of 1984 at the earliest. Animal disease organisms of potential priority for introduction include Bluetongue, Newcastle Disease, Rabies, Swine Vesicular Disease, Vesicular Enanthema and Vesicular Stomatitis viruses. CSIRO should now determine which exotic pathogens, other than Foot-and-Mouth Disease virus, are of highest priority for early importation, and proceed to develop individual cases for importation, as outlined.

Recommendation 3
That CSIRO nominate exotic pathogens, other than Foot-and-Mouth Disease virus, considered to be of high priority for early importation to ANAHL following acceptance of its microbiological security, and proceed as soon as practical to prepare individual cases with a view to initiating consultation on the proposals through the ANAHL Consultative Committee and with the Australian Agricultural Council and its committees.

1.8 ASTEC has given separate consideration to the importation of live Foot-and-Mouth Disease (FMD) virus. It is important to understand that FMD has a special significance for Australia, greater than that of any other animal disease. A single outbreak would result in an immediate prohibition on most, if not all, of Australia's main animal exports. Major markets for beef would be closed and the domestic price would collapse; exports of live sheep and sheepmeat would also be seriously affected, and shipment of wool might also be banned by some countries. Furthermore, a proven disease-free period of six to twelve months after the last case might elapse before export markets were re-opened. It is clear, therefore, that FMD poses a special threat to Australia; there are few other countries with a major export industry dependent on freedom from the disease. Australia's major competitors in the international meat and livestock trade, for example countries in South America, are denied access to significant markets because they are not free of FMD.
1.9 A wide range of diagnostic tests has been developed for detecting FMD virus. Currently, access to the live virus would be advantageous for these tests in that it would enable staff to run positive controls (to provide confidence that negative results were due to absence of the pathogen rather than to faulty tests) and to check periodically that reagents are working satisfactorily. The advent of new diagnostic tests, some of which have been shown to be more sensitive than the traditional complement fixation test for the detection of FMD virus, may result in the adoption of different procedures for international standards and reduce the need for live virus. In general, these procedures can be checked adequately with inactivated antigen, and progress is being made toward the development of synthetic reagents.

1.10 Because of the supreme importance of reliability in the diagnosis of any vesicular disease in Australia, and the frequent difficulty of obtaining a clear cut result from specimens collected from recovering animals, diagnostic staff currently require access to all available tests. An argument can therefore be made today that a greater level of confidence is possible with access to live virus. However, ANAHL will not be in a position to import live FMD virus for at least two to three years, by which time there is a possibility that diagnostic tests which do not require live virus will be further developed and in use, and accepted by countries which import Australian meat and livestock. Australia has a particular interest in developing such tests and this should form a major part of the research at ANAHL.

1.11 At least until considerable experience and confidence has been gained in operating ANAHL over several years, the benefits gained from deliberate infection of pigs, cattle or sheep with live FMD virus to provide material for veterinary training courses are not sufficient to warrant the additional risks involved. The extra cost of sending Australians overseas to gain experience in recognition, laboratory manipulation or control of FMD or, if need be, of paying for the use of overseas facilities, is minor compared with the benefits of this course of action.

1.12 The suggested need for importation of live FMD virus in order to produce and test vaccines at ANAHL is not accepted by ASTEC. On present evidence, it seems unlikely that vaccination would be used in Australia to control the disease, save under the most exceptional circumstances; the Council is not convinced by arguments in favour of the so-called 'ring vaccination' technique. Even if vaccination were contemplated, it has not been demonstrated that adequate supplies could not be obtained, or made under contract, overseas and to standards of potency and safety acceptable to Australian authorities. The testing, at ANAHL, of vaccine obtained from overseas after the virus was shown to be present in Australia would pose a much lower level of risk than manufacture of vaccines at the Laboratory prior to an outbreak.

1.13 A high priority in the research programs of ANAHL should be given to developing new and improved diagnostic tests for FMD virus based on inactivated and synthetic reagents, and paying particular attention to the potential for simple tests which can be carried out 'on-farm' under favourable circumstances. Much of this research could be undertaken using inactivated antigen, but efficient development of new materials and procedures will require comparison with the standard tests using live virus. The research program should be initiated as soon as possible, but ANAHL will not be in a position to import the live virus for two to three years at least. Therefore, ASTEC proposes that the research program be carried out jointly by staff at ANAHL and by a small group of the Laboratory's
scientists located at an overseas laboratory where they would have ready access to the live virus. The ANAHL group would carry the main research load, with the overseas group being responsible for testing new reagents and procedures using the live virus and for preparing inactivated antigen for shipment to ANAHL.

1.14 These arrangements should be entered into as soon as practical and maintained for an initial period ending three years after completion of the 'setting-to-work' program, that is, about the end of 1987 on the current schedule. This arrangement would obviate the need to introduce live FMD virus into ANAHL for a period of five years or more, but would allow progress to be made in the meantime in developing diagnostic procedures for FMD while experience in operating the Laboratory is being gained. If, during this period, an outbreak of FMD were to occur in Australia, a satisfactory primary diagnosis could be undertaken by the ANAHL team using materials whose properties had been tested against the live virus by the overseas group. Samples could also be sent immediately to the ANAHL scientists overseas who would be able to provide assistance in the event of difficulties with the primary diagnosis. Once an outbreak is confirmed, the live virus is then available in the country; if required, it could be used at ANAHL to give greater confidence to secondary diagnoses. Identification of the sub-type of the virus is not required immediately (unless vaccination is proposed, which is unlikely) and could be undertaken by the overseas group as well as the World Reference Centre at Pirbright, United Kingdom. This proposal allows an immediate upgrading of Australian facilities for diagnosing FMD without the risks of importing the live virus.

1.15 Before the end of the initial period the question of importation of live FMD virus should be re-examined. New diagnostic techniques that do not require live virus may have been perfected and accepted internationally. On the other hand, if a need for the live pathogen can be demonstrated at that time, importation for restricted uses only might be agreed, as there would by then be considerably greater experience and confidence in the operation of the containment systems of the Laboratory. ANAHL will not be in a position to import live FMD virus until the end of 1984 at the earliest, but the proposed arrangements offer an opportunity for a rapid upgrading of Australia's capability to diagnose FMD, without the additional risks associated with importing the live virus into this country.

Recommendation 4

(i) That live Foot-and-Mouth Disease virus not be imported for use at ANAHL for a period of five years, that is, until the end of 1987;

(ii) That the research programs of ANAHL give priority to the development of new or improved procedures for the identification of Foot-and-Mouth Disease virus which do not require access to the live virus;

(iii) That, as a matter of urgency, CSIRO initiate discussions with appropriate authorities with a view to locating for an agreed period, and with appropriate costs borne by Australia, a small ANAHL research group within an overseas animal health laboratory which has access to live Foot-and-Mouth Disease virus;

(iv) That when this overseas group is established its main responsibility be to assist in the ANAHL research program, specifically by checking the efficacy of both standard and newly developed procedures and materials in use in Australia using the live virus where appropriate, and by preparing inactivated reagents for use at ANAHL; and
That this arrangement be entered into as soon as possible for an initial period ending three years after completion of the setting-to-work program at ANAHL, and the question of importing the live virus into Australia be re-examined before the end of that period.

2. INTRODUCTION

2.1 This report has been prepared by ASTEC because of the Council's concern that much of the current debate concerning the proposed importation into Australia of live, exotic animal pathogens has obscured important scientific and technical policy considerations. In the controversy over whether or not live Foot-and-Mouth Disease (FMD) virus should be introduced, the long-term objectives of the Australian National Animal Health Laboratory (ANAHL) have been neglected. In May 1982, ASTEC decided to undertake a study of the scientific issues involved in order to provide its advice to the Government.

2.2 This Section presents a brief background on the need for a national animal health laboratory, on the decisions leading to its construction, and on the facility itself and the schedule for its completion and commissioning. Section 3 discusses the role of ANAHL in the control of exotic diseases of animals and the diagnostic and research capabilities which will be required. Section 4 deals in a general way with the importation of live exotic pathogens, and Section 5 concentrates on the special problems associated with FMD and on whether live FMD virus is essential for the operation of ANAHL.

THE NEED FOR ANAHL

2.3 Agriculture remains an important part of Australia's economy. The total gross value of agricultural production in 1981-82 was approximately $12,500 million, equivalent to just under 8.4% of Gross Domestic Product. In the three years 1979-80 to 1981-82, items of rural origin accounted for about 43% of the value of all exports.

2.4 Within the rural sector, the livestock industries account for approximately half the total value of production. In 1981-82, Australia's livestock populations included 25 million cattle, 136 million sheep, and 2.4 million pigs. Exports of livestock and products, including meat, wool, milk and eggs, were worth around $3,800 million per year over the period 1979 to 1982, and made up 47% of the value of rural exports or 20% of total exports.

2.5 Among the many factors which have contributed to the establishment of efficient livestock industries in Australia is freedom from several of the most serious diseases of animals. In contrast to their counterparts in other countries, Australian producers are not faced with the costs of lost production and of control related to exotic diseases, the more important of which are listed in Table 2.1.
<table>
<thead>
<tr>
<th>Disease</th>
<th>Animals Affected</th>
<th>Nature of Disease</th>
<th>Distribution</th>
<th>Possible Mode of Entry into Australia (other than by infected livestock)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foot-and-Mouth Disease</td>
<td>Cattle, sheep, pigs, buffaloes, goats, deer</td>
<td>The most contagious of virus diseases. Severe production losses, disruption of trade in livestock and products</td>
<td>Europe, Africa, Asia, South America</td>
<td>Animal products, ships' garbage, contaminated soil and clothing</td>
</tr>
<tr>
<td>Rabies</td>
<td>All warmblooded animals, including dogs, birds and man</td>
<td>Virus disease, almost always fatal, spread through bites. Wildlife reservoirs make eradication difficult</td>
<td>Most countries</td>
<td>Infected dogs, cats and bats</td>
</tr>
<tr>
<td>Bluetongue</td>
<td>Sheep, cattle, goats</td>
<td>Insect transmitted virus, high mortality and loss of production, cattle are symptomless carriers</td>
<td>Africa, Middle East, India, United States of America</td>
<td>Insects, semen</td>
</tr>
<tr>
<td>Rinderpest</td>
<td>Cattle and buffaloes, occasionally sheep, pigs and goats</td>
<td>Virus, can cause devastating losses</td>
<td>Africa, Middle East, India, Asia</td>
<td>Animal products (only rarely)</td>
</tr>
<tr>
<td>Swine Fever (Hog Cholera)</td>
<td>Pigs</td>
<td>Serious epidemic viral disease</td>
<td>Europe, Asia, South America</td>
<td>Meat products from pigs</td>
</tr>
<tr>
<td>African Swine Fever</td>
<td>Pigs</td>
<td>The most serious epidemic disease of pigs, very high mortality</td>
<td>Africa, parts of southern Europe and central and south America</td>
<td>Most products from pigs, insect (tick) vector</td>
</tr>
<tr>
<td>Newcastle Disease</td>
<td>Poultry and other birds</td>
<td>Serious virus disease, worldwide epidemics with severe losses</td>
<td>Worldwide except Australia</td>
<td>Eggs, chicken meat, contaminated crates etc.</td>
</tr>
<tr>
<td>Rift Valley Fever</td>
<td>Cattle, sheep, goats, buffaloes, rodents, man</td>
<td>Mosquito transmitted virus, causing epidemics with high mortalities and abortion rates</td>
<td>Africa</td>
<td>Insects (mosquitoes), infected people</td>
</tr>
<tr>
<td>Disease</td>
<td>Affected Animals</td>
<td>Disease Description</td>
<td>Geographical Distribution</td>
<td>Source(s)</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>-------------------------------------------------------</td>
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<td>---------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Aujeszky's Disease</td>
<td>Mainly pigs, but also cattle, sheep, dogs, cats, rodents</td>
<td>Viral disease, causing high losses in young animals, fatal in cattle and sheep</td>
<td>Europe, Asia, Americas</td>
<td>Pig products</td>
</tr>
<tr>
<td>Swine Vesicular Disease</td>
<td>Pigs</td>
<td>Virus causing blisters on tongue and feet, may be confused with Foot-and-Mouth</td>
<td>Europe, Asia</td>
<td>Meat products from pigs, ships' garbage</td>
</tr>
<tr>
<td>Vesicular Exanthema</td>
<td>Pigs, marine mammals</td>
<td>Virus disease, may be confused with Foot-and-Mouth</td>
<td>North America</td>
<td>Meat products from pigs, marine mammals</td>
</tr>
<tr>
<td>Vesicular Stomatitis</td>
<td>Horses, cattle, pigs, sheep, goats</td>
<td>Virus disease, may be confused with Foot-and-Mouth</td>
<td>Americas</td>
<td>Insect vector, may occur in pasture plants</td>
</tr>
<tr>
<td>Scrapie</td>
<td>Sheep, goats</td>
<td>A slow 'virus' brain disease, always fatal</td>
<td>Europe, Africa, Asia, Americas</td>
<td>Semen or fertilised ova</td>
</tr>
<tr>
<td>Sheep Pox</td>
<td>Sheep</td>
<td>Virus causing high mortality in young animals</td>
<td>Africa, Middle East, Asia</td>
<td>Infective material on wool and hair</td>
</tr>
<tr>
<td>African Horse Sickness</td>
<td>Horses, donkeys</td>
<td>Insect transmitted virus, causing epidemics with high mortality</td>
<td>Africa, Middle East, India</td>
<td>Insects</td>
</tr>
<tr>
<td>Equine Viral Encephalomyelitis</td>
<td>Horses, donkeys, man; birds and reptiles act as reservoirs</td>
<td>Insect transmitted virus causing serious epidemics. Virus reservoir in water birds</td>
<td>North and South America</td>
<td>Insects (mosquitoes), infected migratory birds, reptiles</td>
</tr>
</tbody>
</table>

Sources: Submission by the Commonwealth Department of Health to Senate Committee on National Resources, Inquiry into Quarantine Services, 1978; 'ANAHL and Exotic Disease Control', Australian Bureau of Animal Health, Canberra, 1982.
The reasons for this fortunate situation include:

- Australia's geographical isolation as an island continent - isolation may have had both a direct effect, in reducing the likelihood of spread of pathogens by wind or insect or other vectors, and an indirect effect in that, until the advent of air travel, the time required to transport livestock to this country was such that seriously ill animals often perished on the journey;

- the absence, within native animals, of serious diseases transmissible to domestic livestock - in contrast to African countries for example;

- the low level of imports of meat or animal products - compared with the United Kingdom for example;

- the extensive nature of livestock industries in that part of the country closest to a neighbouring land-mass, with herds scattered and relatively isolated for much of the year, and

- climatic regimes which may be unfavourable to spread of animal pathogens during a large part of the year.

In more recent times, quarantine procedures have been established to help prevent the introduction of exotic animal diseases.

Despite these favourable aspects, some serious incursions of exotic diseases have occurred in the past. Contagious bovine pleuropneumonia entered Australia in 1858 and became widespread because effective control measures were not instigated; more than 100 years elapsed before this disease was finally eradicated. However, successful eradication campaigns were mounted quickly when Foot-and-Mouth disease appeared in 1800, 1803, 1871 and 1872, Rabies in 1866-7, Rinderpest (Cattle Plague) in 1923, Newcastle disease of poultry in 1930-32, Swine Fever in 1903, 1927, 1942 and in 1961, Scrapie in 1951 and Fowl Plague in 1978. Strains of Bluetongue virus, apparently non-virulent, were isolated in 1977 from insect vectors collected in northern Australia, although it was not clear if this represented a recent introduction.

The threat posed by exotic animal diseases is of continuing concern to animal producers and veterinarians. The number of people entering Australia each year has increased to a current level of about 2.3 million in 1981. Air travel makes it possible for someone who has been in contact with infected animals overseas to return to a rural area in Australia within 24 hours. Importation of uncertified or even prohibited animal products is a continuing problem, despite the vigilance of quarantine officers. Several tonnes of prohibited animal products including meat, cheese, milk products and rawhide are seized at Australia's major airports each year; quarantine authorities believe this represents about 85% of the total coming into the country, and have estimated that, in order to apprehend half the remaining 15%, it would be necessary to search nine out of every ten passengers.

Although accidental or deliberate importation of exotic diseases via commercial transport systems poses the greatest threat, there are other possible routes of introduction. Australia's sparsely populated northern coastline is visited illegally by travellers from countries to the north who not infrequently bring with them domestic animals and livestock. At certain seasons, there is a large
population of susceptible animals, including buffalo, within easy reach of these visitors, although the danger from this quarter may be reducing as animal diseases are brought under control in Indonesia and Papua New Guinea; for example, Foot-and-Mouth Disease has been eradicated in Bali and most parts of Indonesia through an Australian-sponsored vaccination program. The threat of direct movement of pathogens and their vectors to Australia from neighbouring countries remains. The importation of new genetic material for Australian livestock industries, whether by live animal, ova or semen, is another potential mechanism for spread of exotic diseases unless rigidly controlled.

2.10 The national campaign to eradicate the 1923 outbreak of Rinderpest resulted in an increased awareness of the need for co-operation and forward planning by the States and the Commonwealth to combat future incursions of exotic diseases. In the 1960s, steps were taken to improve the States' diagnostic facilities and to develop contingency plans to deal with foreign diseases. The eventual eradication of Contagious Bovine Pleuropneumonia in 1973 showed that exotic pathogens could be controlled, even in the most remote areas, and this gave added impetus to plans being developed for a highly-secure, national diagnostic laboratory.

THE DECISION TO CONSTRUCT ANAHL

2.11 The prime responsibility for control of infectious animal disease rests with the States, and programs for eradication of exotic diseases would be carried out under the authority of the Chief Veterinary Officer of each State. However, the Commonwealth also has a substantial role. The Australian Bureau of Animal Health, within the Primary Industry portfolio, is responsible for inspection and supervision of animal exports, and in association with this task carries out research and investigation into animal health matters, including exotic diseases. Quarantine is also a Commonwealth responsibility, and the control and co-ordination of such activities, including the importation of live exotic pathogens, is effected by the Quarantine Division of the Department of Health. Co-ordination of Commonwealth and State activities in animal health is achieved through the Australian Agricultural Council and its Standing Committee on Agriculture.

2.12 A major impetus for a national animal health laboratory came in 1964 when the Department of Health invited a senior veterinarian with the Food and Agriculture Organisation of the United Nations to visit Australia and advise on the country's preparedness to cope with outbreaks of foreign livestock diseases. The visit resulted in a recommendation that Australia establish a maximum security laboratory in which research and testing, using exotic pathogens, could be carried out, with a view to developing and providing diagnostic services and vaccine-testing facilities for use if an outbreak occurred.

2.13 This recommendation was examined by Commonwealth officials and by a Commonwealth-States Veterinary Committee. In 1970, the Australian Agricultural Council endorsed the recommendation of its Standing Committee that a maximum security animal virus laboratory be constructed to provide trained staff and facilities for:

- initial diagnosis of suspected exotic disease outbreaks;
continuing diagnosis during outbreaks;
- monitoring strains of virus isolated during outbreaks;
- definitively establishing freedom from disease when the outbreak is over;
- manufacture of vaccines;
- testing for safety and potency any imported or locally produced vaccines; and
- training Australian field and laboratory staff in the recognition and handling of exotic diseases.

2.14 A panel of senior representatives of the States, formed to consult with the Commonwealth on the protection of Australian livestock industries against exotic diseases, reached similar conclusions, and CSIRO was invited to examine the feasibility of staffing and managing the proposed laboratory. A Proposal Evaluation Team was established, and its members visited fifteen overseas animal disease laboratories to examine their facilities and evaluate methods of microbiological containment. In 1972, the Team reported that a suitable laboratory could be constructed in Australia to carry out the proposed functions without placing livestock at unacceptable risk. Of the exotic animal pathogens which might enter Australia, Foot-and-Mouth Disease virus was considered to be the most infective and readily spread, and it was therefore recommended that the laboratory be designed to the standard required for containment of this virus.

2.15 In October 1972, following a joint submission by the Ministers for Education and Science, Health, and Primary Industry, the Commonwealth Government agreed in principle to the construction of a maximum security, national animal disease laboratory, to be administered and operated by CSIRO. One year later, agreement was reached to site the laboratory at Geelong.

2.16 In 1974, the proposal to construct the laboratory was referred to the Parliamentary Standing Committee on Public Works for an investigation of the need and economic justification for the laboratory, the proposed functions and its microbiological security. Written submissions were invited and public hearings held. The Committee concluded that the laboratory was required to ensure prompt and reliable diagnosis of exotic animal diseases and was justified on economic grounds; that the proposed functions were appropriate; that the design principles would ensure the required microbiological security; and that construction and operation should proceed as a matter of urgency.

2.17 Despite the latter conclusion of the Public Works Committee, construction of the Laboratory did not begin immediately. In 1977, a serotype of Bluetongue virus was isolated from insects collected in northern Australia, and bans on the importation of Australian animals, meat, wool and hides were immediately introduced by many countries. This serotype was later shown not to cause clinical disease in cattle, and no clinical symptoms have been reported in sheep under field conditions. Most bans had been lifted within one to six months, but the threat to exports was sufficient to result in a submission to the Government by four major primary producer organisations calling for immediate commencement of construction. Building of the Laboratory, to be called the Australian National Animal Health Laboratory (ANAHL), began in March 1978.
2.18 The construction and commissioning of ANAHL is expected to be completed by the latter part of 1983. There will then be a setting-to-work period during which the Laboratory's microbiological security systems will be tested. This period should be completed by the end of 1984. The importation of exotic pathogens is envisaged only when such systems have been tested thoroughly and shown to operate satisfactorily.

2.19 The cost of the Laboratory was estimated at $67 million in 1974. The estimate at June 1982 was $145 million, which is within the earlier estimate if account is taken of inflation and additions to the project. The construction is being carried out under contract to the Department of Transport and Construction.

2.20 It is not proposed to give a detailed description of ANAHL, but some brief comments are pertinent. The Laboratory is designed on the box-in-box principle, in which the work area of highest security is located at the centre of the building and is surrounded by a series of 'boxes' of decreasing security classification. Microbiological security is achieved by careful sealing of all structural joints to make sure that each 'box' is airtight, together with maintenance of a gradation of differential negative air pressures, with the most secure area having the lowest pressure; should an air leak develop, air flows in toward an area of higher security.

2.21 The air flow through the Laboratory is separated from the outside atmosphere by high-efficiency filters, capable of retaining the smallest virus particles. Furthermore, air from high-risk areas is not only filtered, but is also heated to high temperature before passing to the outside. Liquid wastes will be subject to heat sterilisation, and solid wastes, including carcasses, will be steam-sterilised at high temperature before incineration at 1000°C.

2.22 The laboratory manipulation of pathogens, and the inoculation of small animals with high risk agents and their subsequent housing, will be undertaken in biological safety cabinets. All personnel working in high security areas will wear protective clothing and strict protocols, including changing clothes and personnel showering when required, have been developed to prevent the movement of infective agents from one area to another or to the outside of the Laboratory. High risk agents will be handled in designated areas containing totally enclosed cabinets where the operators work through gloved ports, and in other rooms in which operators will wear protective suits which are provided with their own independent air supply.

2.23 Some parts of the ANAHL containment systems use well-proven equipment and procedures. Where equipment of the required performance was not available and has had to be developed during the project, considerable effort has been given to building and testing prototypes before equipment was accepted for the Laboratory. A prototype animal room, similar to those within ANAHL, was built at the CSIRO Experimental Station at Maribyrnong, Victoria and used to test construction techniques for providing air-tight rooms, such as the development of air-tight doors, entry and exit of services and finishes on walls, floors and ceilings. A new concept in the design of air filter containers was developed and prototypes tested over a five-year period. This design permits the ready decontamination of filters, their replacement, and subsequent testing for efficiency after installation.
and for airtightness of the filter box. The system for monitoring and controlling air pressure gradient has also been extensively tested over a period of 18 months, and the performance of biological safety cabinets has also been improved and verified.

2.24 ANAHL will form part of the CSIRO Division of Animal Health, and its officer-in-charge will be responsible through the Chief of that Division to the Director of the Institute of Animal and Food Sciences and the CSIRO Executive. An ANAHL Consultative Committee has been established to advise the Executive of CSIRO on all aspects of the program and operations of the Laboratory. The Committee consists of the Secretaries of the Commonwealth Departments of Health and Primary Industry, the Chairman of CSIRO, the Director-General of the Victorian Department of Agriculture (representing the Australian Agricultural Council) and the President of the National Farmers' Federation. It usually operates through its alternates, who are the Director of the Australian Bureau of Animal Health (Chairman), Assistant Director-General (Animal Quarantine) of the Department of Health, the Director of CSIRO's Institute of Animal and Food Sciences, the Deputy Director-General of the Victorian Department of Agriculture, the Officer-in-Charge of ANAHL and the Executive Director of the National Farmers' Federation.

2.25 When fully operational, ANAHL will have a total staff of approximately 200, of whom 35 will be scientific staff, 100 scientific support staff, 45 operations and maintenance staff, and 20 administrative staff. The ratio of support staff to scientific staff will be much greater than in a conventional microbiological laboratory not operating under high-security conditions. The current proposals for ANAHL require 4.8 support staff to each scientist, whereas at the CSIRO Animal Health Research Laboratory, Parkville, the ratio is approximately 2.5 to one. In some overseas high-security laboratories the ratio approximates 8 to one.

2.26 The operation of complex security systems and the need for a high proportion of ancillary staff is expensive. The annual operating cost for ANAHL, when the Laboratory is fully functional, was estimated in April 1982 to be approximately $7 million, including salaries. The expenditure per research scientist or research program will be much greater than for other laboratories where a lesser degree of microbiological security is acceptable, and this is an important factor when considering what work is appropriate for ANAHL. The expenditure may also, however, be viewed as a relatively modest insurance premium against the value of Australian livestock industries and their exports. The significance of ANAHL for these industries is discussed in more detail in the next section.
3. FUNCTIONS AND OPERATION OF ANAHL

3.1 The underlying principle which led to the decision to construct ANAHL was the need to protect Australian livestock industries from exotic animal diseases. In order to put into perspective the current debate on whether or not live viruses, and other exotic pathogens, should be imported to ANAHL, it is necessary to consider, in detail, the nature of the threat posed by foreign diseases and how the Laboratory would help to alleviate their effects.

THE EFFECTS OF EXOTIC DISEASES

3.2 The effects of introduction of an exotic animal disease into Australia are likely to be twofold. First, there would be the 'internal' effects, perhaps including a large number of deaths of susceptible animals from disease and in slaughter-eradication programs before the outbreak was brought under control, reduced productivity and reproduction of animals which survived, and the costs of control and eradication, including compensation payments to producers. Secondly, and probably of more immediate economic significance, there is the possibility of 'external' effects through loss of export markets.

3.3 Exotic animal diseases can be classified into three broad categories according to their potential effects on exports. The first category includes diseases whose presence in Australia would result in the immediate cessation of exports because of the regulations imposed by importing countries. The most important member of this group, by far, is Foot-and-Mouth Disease, although there is also a possibility that some countries might ban imports of Australian livestock or animal products in the event of an outbreak of Rift Valley Fever; livestock might also be banned if virulent strains of Bluetongue virus were involved. Foot-and-Mouth Disease (FMD) is a special case because trading partners probably would not allow imports of Australian livestock or products to resume for at least six to twelve months after an outbreak was demonstrated to be eradicated. Estimates of the economic costs of an outbreak of FMD vary, but it is generally considered that lost export earnings in the year following discovery of the virus would be of the order of $2,500 to $3,000 million. Losses in the second year might exceed $1,000 million. Producers selling on the domestic market would also face a severe drop in income due to oversupply.

3.4 The second category comprises diseases which, although serious for producers, are unlikely to have as significant an effect on exports as an outbreak of FMD. This group would include most of the pig diseases, for example, African Swine Fever, Swine Fever (Hog Cholera), Swine Vesicular Disease and Vesicular Exanthema. They would be of great concern to pig producers and every effort would need to be made to eradicate an outbreak, but since the pathogens are confined to pigs, and Australian exports of pig meat and products are valued at less than $10 million annually, these diseases should be considered to represent a different level of risk to FMD. Similarly, although Newcastle Disease poses a most serious threat to the poultry industry and the entry of a virulent strain of the virus could result in major economic losses, including loss of exports, its overall economic impact would not be of the same magnitude as that of FMD. Many of the diseases listed in Table 2.1 fall into this category.
3.5 The third category contains diseases which are considered to be of lesser consequence. For example, Equine or Swine Influenza have a relatively minor effect on animal production and would not result in a significant loss of export markets. In some cases the cost of eradication may not be justified and producers would instead learn to live with the disease.

3.6 Each exotic disease has its own particular characteristics, but there are several essential factors which are common to any effective control program. These include:

- prompt recognition of clinical symptoms of disease, followed by quick and accurate identification of the pathogen involved;

- adoption of a well-prepared contingency plan agreed prior to the outbreak;

- initiation of appropriate control measures as soon as possible - in some cases control might be commenced on the basis of clinical symptoms alone, and the measures taken could include slaughter and disposal of exposed stock, disinfection of premises, restrictions on the movement of animals, people and goods, and control or elimination of insect vectors and feral animals;

- availability of sufficient trained personnel and adequate facilities to monitor the progress of the disease;

- access to veterinary products of proven efficacy and safety, including vaccines; and

- ability to determine with confidence that the disease has been controlled and/or eradicated.

3.7 Joint Commonwealth-State contingency plans have been developed for those exotic diseases considered to be the most threatening to Australia, and are tested from time to time in mock 'animal disease emergencies'. The plans involve the establishment of effective channels of communications, and the proper management and co-ordination of control programs. ANAHL will play a decisive role in these contingency plans. The responsibilities of the various organisations concerned are clearly specified, and emphasis is placed on producer understanding of what a disease emergency means and on ensuring their co-operation. Agreed cost-sharing arrangements have been formulated for the control programs and for payment of compensation to producers for stock and property destroyed.

FUNCTIONS OF ANAHL

3.8 The four main functions of ANAHL that were recommended by the Parliamentary Standing Committee on Public Works and approved by Parliament in 1974 were:
• provision of diagnostic service to support the control and eradication of exotic diseases of livestock should they be introduced into Australia, and to ensure that livestock imported through quarantine stations are free of exotic diseases;

• training field staff in the recognition and presumptive diagnosis of virus diseases, in particular exotic diseases of livestock, and laboratory staff in techniques for the isolation and identification of viruses;

• producing animal vaccines when required and testing for their safety and potency before release for use in field situations; and

• undertaking a continuing research program into indigenous and exotic diseases of livestock to ensure that staff are fully trained and ready to meet any emergency.

These functions, which remain those approved for the Laboratory, will now be discussed in more detail.

Diagnosis of Diseases and Identification of Pathogens

3.9 It is likely that initial suspicion of an exotic livestock disease will result from observation by the owner of the affected animals. Producers should therefore receive training in the identification of clinical symptoms of such diseases and be encouraged to report any suspicious circumstances immediately. Information programs of this sort have been promoted by State departments of agriculture for some years, and deserve continued emphasis in view of the significant benefits of early recognition. If a disease is not detected in its early stages and becomes established in the livestock population, and perhaps widespread among wildlife, insect vectors or feral animals, the difficulty of control and eradication is increased enormously.

3.10 Similar comments apply to the next line of defence, the State veterinary officers and veterinarians in universities and research laboratories, who would be called to investigate any unusual occurrence of animal disease. They need to be thoroughly familiar with the clinical symptoms of exotic diseases because the initial field diagnosis can determine whether or not control measures are instituted. For example, some veterinarians believe that the clinical symptoms of Foot-and Mouth Disease (FMD) in cattle can be readily recognised, at least in the early stages of the disease; in these instances, it is likely that a slaughter program would be initiated solely on clinical diagnosis, without waiting for confirmation by laboratory identification.

3.11 However, by no means all exotic diseases are identifiable from clinical symptoms. FMD may be difficult to detect in sheep, and its symptoms in pigs usually cannot be distinguished from those caused by Swine Vesicular Disease and Vesicular Exanthema; as already explained, the latter diseases carry quite different implications for Australia’s livestock exports, so a prompt and definitive identification is imperative.
3.12 In other instances, where clinical diagnosis is uncertain, an exact identification may be required before effective control programs can be selected and commenced. This is particularly important where vaccination is to be used. Many viruses occur in two or more serotypes and there may be little or no cross-immunisation between them; that is, only vaccine prepared against the specific serotype involved in the outbreak will be effective.

3.13 Accurate diagnosis is also an important requirement in respect of international trade. The need for complete confidence by Australia in a positive identification of an exotic pathogen in this country is obvious, but a similar confidence is also required for a negative result; Australia needs to be in a position to convince international trading partners that an unusual disease occurrence was not an outbreak of a serious exotic illness, or that if it was the disease has been eradicated.

3.14 World Reference Centres have been established for the more important animal diseases. For example, the Animal Virus Research Institute at Pirbright, UK, is the reference centre for Foot-and-Mouth Disease, the Plum Island Animal Disease Center in New York is the reference laboratory for African Swine Fever and Rinderpest, and the Onderstepoort Veterinary Research Institute in South Africa maintains reference facilities for Rift Valley Fever and Bluetongue. In the event of a suspected outbreak of an exotic disease in Australia, samples from suspect animals would be sent to the appropriate reference centre for identification of the causal organisms. However, reliance on this procedure for primary diagnosis is unacceptable, for several reasons.

3.15 Laboratory identification of animal pathogens is not always straightforward, especially for viruses. If the disease is detected only in its later stages most of the viral antigen may have been destroyed by the animal's reaction, and positive recognition of small amounts of antigen or of antibodies can be difficult. Furthermore, the primary diagnostic procedures currently in use are not completely reliable, and specimens may deteriorate even during the relatively short time of an international flight. For example, it has been found at Pirbright that the complement fixation test, when applied directly to field samples from cases of FMD, provided a positive result in 75% of samples from the UK and in less than 10% of those sent from overseas. Complement fixation is, at present, an internationally accepted primary test for FMD virus, and although there are several back-up tests which would be performed on any samples suspected of containing the virus many of these require 24 or 48 hours to give a result.

3.16 There is general agreement that in an ideal situation where FMD infection is detected quickly and specimens are taken early in the course of the disease, a presumptive diagnosis can be obtained within hours using inactivated diagnostic reagents. If the result is positive for FMD there is a high probability that it is correct. However, a negative result is of little value, and a wide range of tests will then be required to determine the causal agent of the observed disease. Animals suspected of having FMD will not always show characteristic symptoms, and furthermore may not, in fact, be infected by FMD virus. Thus it is absolutely essential that FMD be eliminated as a possible cause of any outbreak of vesicular disease and, if possible, the exact cause of the disease identified. Even if the herd is slaughtered on the basis of clinical symptoms alone, a diagnosis must be attempted to try to identify FMD or to eliminate it as the cause.
3.17 The example of FMD has been used to illustrate the problem, but similar difficulties could be experienced with other diseases. The causal agent of an unusual disease in pigs at Legana, Tasmania in 1979 could not be identified from samples sent to Pirbright, and the new Australian serotype of Bluetongue virus was not positively identified until a year after it was sent to the relevant reference laboratory. Reliance by Australia on overseas reference laboratories would result in considerable delays if a definitive diagnosis was not possible from the initial samples sent. If a control program had been initiated on the basis of clinical symptoms, as was the case at Legana, there would be no opportunity to send further material after animals had been slaughtered; the disease might have been eradicated, but there would still be a question mark over the incident. A much worse situation would occur if control programs were delayed because no authoritative diagnosis was available, and this enabled a disease to gain a substantial foothold.

3.18 One further point needs to be made concerning the need for an Australian capability in diagnosis. The international livestock trade is highly competitive, and not entirely apolitical. The Australian livestock industries and export authorities will be in a much stronger position for international trade discussions in the event of an exotic disease outbreak if they have quick and full access to detailed results of diagnostic tests. Comprehensive information can then be made available to trading partners from an unequivocal position. This is particularly important if the incident is a false alarm or the introduced pathogen proves to be a low-virulence serotype. The advantages of undertaking the diagnosis within an Australian laboratory are clear.

3.19 If the primary testing demonstrates that an exotic pathogen has entered Australia, an indigenous diagnostic facility will be required to deal with the many secondary identifications required. Even if the disease is confined to a single property and brought under control promptly, it will be necessary to monitor surrounding animals for some time to demonstrate that eradication has been achieved. If the disease is not controlled quickly, or if it is found to be already widespread when detected, monitoring its spread or distribution might require the testing of some hundreds of samples per day. It would be quite impractical to send such a large number for testing overseas, and in any case the world reference laboratories have no responsibility to carry out such work, nor could they be expected to make the necessary staff and facilities available at short notice.

3.20 There are, therefore, strong arguments for establishing a diagnostic facility for exotic diseases within Australia. It may be asked whether, since control of animal diseases is a State responsibility, the operation of diagnostic laboratories should not also be a matter for the States. Each State or Territory department of agriculture already operates its own laboratory in which identifications of samples from diseased animals may be carried out; similar diagnostic tests may be undertaken in university veterinary schools. However, it must be remembered that the present discussion concerns exotic pathogens, many of which are capable of causing very severe epidemics. Although State and university laboratories have, in some cases, been designed for a high level of microbiological security, none approaches the containment standards required for work with the most virulent and infectious organisms, for example, FMD virus.

18
3.21 It has been suggested that the need for ANAHL has been much reduced because of the development of techniques for rapid diagnosis of animal pathogens, perhaps on the suspect property, using inactivated reagents. ASTEC does not accept this view. Safe diagnosis carried out 'on-farm' using relatively simple procedures may be possible in the future, and the development and acceptance of such techniques should be promoted. Nevertheless, no single diagnostic test is completely reliable, and dependence upon serology alone for the initial identification of an exotic animal virus would be unwise. Primary diagnosis when an exotic disease is suspected, especially if it is one that carries serious implications for exports, needs as great a degree of certainty as is possible. Therefore, veterinary diagnosticians require access to all available test procedures in order to arrive at an authoritative identification, including inoculation of cell cultures, laboratory animals and livestock. ASTEC does not believe that satisfactory facilities for the whole range of diagnostic tests required could be established promptly within the affected area in the event of an outbreak of exotic disease. Secondary diagnosis, after an outbreak has been confirmed, might in the future be undertaken using simple serological tests if conditions are favourable (for example at a stage in the disease when the concentration of virus particles is at a maximum) but even so samples would need to be sent to ANAHL for verification or, if the results of serology were uncertain, for definitive identification.

3.22 Moreover, diagnostic tests may require the production of substantial amounts of viral antigen and antisera, and animals inoculated to multiply virus present in samples or to produce antisera become a potential source of the pathogen. As a consequence, a maximum-security laboratory is required for primary diagnosis. If on-farm serological tests using killed reagents were developed, the potency and purity of inactivated reagents would still need to be monitored at regular intervals under secure conditions. The possibility that livestock exports may have ceased immediately following primary diagnosis does not reduce the need for maximum-security for later tests; diagnostic procedures which result in multiplication of the virus in cell cultures or in animals should not be conducted under low-security conditions at the affected property because of the risk of spreading the infection. International acceptance that an exotic disease outbreak in Australia had been controlled and the pathogen eradicated would require application of the full range of diagnostic tests, and again a maximum-security laboratory is required.

3.23 The cost of a facility of the required standard is high, and there is no advantage in having a similar laboratory duplicated in each State. Furthermore, there are several exotic diseases for which Australia should be prepared, but in the past their occurrence has been sporadic or nil. There is no advantage in duplicating diagnostic readiness in each State if it can be done efficiently at a national level, thus allowing State personnel and facilities to deal with existing veterinary problems.
Training of Laboratory and Field Personnel

3.24 It has been pointed out in earlier paragraphs that prompt and accurate diagnosis of a suspected exotic disease can greatly facilitate control and eradication. Such diagnosis requires the availability of trained laboratory staff able to manipulate the initial samples to best advantage, and implies prior experience with the diagnostic tests to be used. This could be gained through work in overseas laboratories, but to achieve a satisfactory state of preparedness reagents and procedures need to be established prior to an outbreak and subjected to periodic testing to check their efficiency and to maintain the competence of laboratory staff. For some diseases this should be possible using killed antigen, non-pathogenic virus strains or even model virus systems, but in other cases the live pathogen may be required, necessitating the use of a maximum-security facility, that is, ANAHL. The staff of State diagnostic laboratories should have access to diagnostic systems established at ANAHL because they are likely to receive the first specimens from a disease outbreak if there is no intimation of an exotic pathogen.

3.25 The role of ANAHL in training field veterinarians will also vary with different diseases. The importance of recognition of exotic or unusual diseases by primary producers has already been mentioned. The training of State veterinary staff and private veterinarians is equally essential since they will probably be the first professionals called to investigate a suspicious disease occurrence. Because of Australia's long freedom from exotic diseases, there are only a small number of State veterinarians with first-hand experience in their recognition.

3.26 One way of obtaining experience is to make opportunistic use of major disease outbreaks overseas. This is often difficult to arrange; by the time staff arrive the outbreak may have been eradicated or infected animals slaughtered. There is the additional concern over re-entry of staff into Australia from infected areas. Nevertheless, Australian veterinarians have participated in the past in control of outbreaks of FMD, African Swine Fever and Newcastle Disease and, whenever possible, use should be made of such opportunities for training.

3.27 Another source of training is the courses conducted from time to time by overseas animal virus laboratories, including Pirbright and Plum Island. These are run only occasionally, there are usually few places available for foreign participants and the cost can be considerable. However, full use should be made of these courses whenever available. Veterinary staff can also receive training through lectures, using audio-visual presentations. These offer the advantage of showing a wide range of clinical symptoms, perhaps in several different host species, at the one session.

3.28 None of these training methods is entirely satisfactory on its own. An overseas epidemic may involve different hosts, symptoms and methods of spread to an outbreak in Australia. Laboratory courses have the advantage of enabling participants to follow the development of a disease from initial infection, through the whole range of symptoms to final autopsy, and offer an opportunity to gain experience in obtaining the best specimens for diagnosis at different stages. On the other hand, the symptoms shown by laboratory animals may differ significantly from those of animals under stress in the field, and there is limited scope for consideration of the herd picture, for example, the effects on animals of different ages. Audio visuals offer no 'hands-on' experience.
3.29 The small number of field veterinarians in Australia with experience in
the recognition and handling of exotic diseases is a matter of concern requiring
further consideration. It has been suggested that ANAHL could fill this need by
running courses based on livestock infected for the purpose, and, despite the
shortcomings mentioned above, this is certainly a possibility. However, many viral
diseases result in the excretion of very large quantities of infectious particles, so
that training courses, using deliberately infected livestock, probably represent the
greatest challenge to the microbiological security of ANAHL. This is particularly
so with respect to FMD virus, which is excreted in large amounts, may spread
readily as an aerosol, and requires a relatively small number of virus particles to
initiate an infection. The situation may be less critical for other pathogens; for
example, close contact between animals is required for the spread of Rinderpest
virus, and a simple barrier may prevent the spread of African Swine Fever
infection. However, for each disease, the benefits should be carefully weighed
against the risks before a decision is taken whether to infect livestock for training
purposes.

Vaccine Production and Testing

3.30 The main control methods for most of the diseases included in Table 2.1
(which is by no means an exhaustive list) are: prompt slaughter and sanitary
disposal of infected animals; disinfection of affected property; prevention of
movement of animals, animal products or other goods from adjacent areas; and
careful monitoring of surrounding animals. It is likely that vaccination would be
used in the control of Bluetongue and Rift Valley Fever, and, under certain
circumstances, Rabies and Newcastle Disease.

3.31 Most vaccines against virus diseases of animals are made of inactivated
virus particles in a suitable adjuvant. Manufacturing such vaccines is inherently
a high-risk procedure because it involves preparing and handling large quantities of
virus, and production therefore requires maximum-security facilities. ASTEC
considers that a case for production and storage of vaccine by ANAHL prior to an
outbreak can be made only if it is shown that vaccine would be required
immediately following positive identification of the particular disease under
discussion, and there is no possibility of obtaining suitable vaccine overseas or of
having it made and stored under contract. A further difficulty of prior
manufacture and storage may arise if the particular virus exists in several
serotypes which exhibit little cross-immunity. Vaccine against each serotype would
have to be maintained.

3.32 Similar arguments apply if vaccine is likely to be used only when
slaughter and quarantine of affected properties fail to control the disease. The
possibility of obtaining vaccine overseas should be explored thoroughly before
production within ANAHL is agreed. Having vaccine manufactured overseas under
contract may appear expensive, but, in fact, the vaccine is generally only a small
proportion of the total cost of an immunisation campaign. Rigorous testing would
be necessary to ensure the potency and safety of any vaccine obtained from
overseas. If manufacture within ANAHL is considered to be the only alternative
for a particular disease, collaboration should be maintained with the Common-
wealth Serum Laboratories which has over sixty years of experience in producing
and testing medical and veterinary vaccines. Experience suggests that about a
year would be needed to acquire competence in the use of new vaccine production
equipment on an industrial scale.
3.33 The role of ANAHL in testing vaccines is more clear. Any batch of vaccine would need to be checked for potency and safety before its use in an expensive immunisation program. Potency tests usually require that vaccinated animals and controls be challenged with the live virus. This is clearly a high-risk procedure (the controls should become infected and will excrete large amounts of virus); however, the implications of using live virus in the test are somewhat lessened once an outbreak has been identified. As well as potency, an inactivated virus vaccine, or a live attenuated vaccine, would need to be examined for innocuity, that is, to make sure the former does not contain active particles, or the latter virulent virus. It is also necessary to ensure the vaccines are free of 'passenger' viruses. All these tests should be carried out by ANAHL if a decision is taken to use vaccination in the control of an exotic disease.

3.34 During the last few years, attention has been given to developing new animal virus vaccines that are based not on inactivated whole virus but on pieces of virus protein. It may be possible to produce such vaccines in quantity by genetic engineering techniques, which offers the prospect of guaranteed innocuity and lower cost. The advent of such vaccines might reduce or remove the need for vaccine production at ANAHL under high-security conditions and possibly also for vaccine testing if a simple measure of antigen concentration was found to be a reliable indicator of potency.

Research

3.35 Even in the earliest consideration of the ANAHL concept it was recognised that although the Laboratory's prime function would be diagnosis, a major part of its operations would be related to research. This was the reason for the early invitation to CSIRO to consider staffing and managing the facility. The significant role of research arises mainly because of the need to improve current diagnostic techniques, and because the need for ANAHL's diagnostic services will, it is hoped, be episodic. Approximately three-quarters of the effort of overseas animal disease laboratories is directed to research.

3.36 ASTEC accepts that research will be a major part of ANAHL's operations. Nevertheless, careful attention should be given to what constitutes appropriate research for the Laboratory in view of the high costs associated with operation of its containment systems. In general, ANAHL should not undertake research on endemic animal diseases for which its high-security facilities are not required, unless it can be shown that such research is important and is not being taken up by other groups. Exceptions to this general proposition would include research on indigenous diseases during the initial period after commissioning but before exotic pathogens are introduced, the development of new or improved diagnostic tests required to distinguish between endemic and exotic organisms, and collaborative projects making use of specialised expertise or equipment at ANAHL. Furthermore, research programs on exotic diseases should be selected on the basis of Australian needs, bearing in mind the research being undertaken overseas. Consideration should be given to those foreign diseases which pose the most serious or immediate threat to Australian livestock, and to strengthening our ability to detect and control them.
Particular attention should be given to establishing collaborative projects involving the staff at ANAHL and other staff of CSIRO, Commonwealth animal health and quarantine authorities, State departments of agriculture, universities and research institutes. This will help to ensure that use is made of present expertise in exotic diseases, and will promote interaction between the relatively small group of scientists at ANAHL and those outside. It will encourage the flow of developments made at ANAHL to outside organisations who can also make use of them.

CONCLUSIONS

After careful consideration of the arguments outlined above, ASTEC has come to the following conclusions concerning the functions and operation of ANAHL:

- its main function should be to provide a microbiologically secure Australian facility for the primary diagnosis of exotic animal diseases, and for the continuing diagnostic services required during an outbreak;
- its role in providing veterinary training courses based on livestock infected in the Laboratory should be determined through risk-benefit decisions taken in respect of each particular disease;
- its role in the manufacture and testing of vaccines should be based upon the characteristics of particular diseases and pathogens - the potential for development of radically new types of vaccines may necessitate a re-appraisal of this role in three to five years time; and
- research will be an important part of the Laboratory's operations, and should be concentrated on improving Australia's capability to detect, identify and control exotic diseases of livestock.

The inferences to be drawn from these conclusions concerning the importation of live exotic pathogens are discussed in the next Chapter.

THE FINANCIAL RESOURCES ISSUE

It has been claimed that opposition both within and outside CSIRO to the proposed importation of live pathogens at ANAHL is based on a fear of reduced financial support for other veterinary groups once the Laboratory is operating. ASTEC does not accept that opposition to importation has been based solely on financial considerations; there are important technical and policy matters on which expert opinion is divided, although the Council has also identified a large middle ground of agreement. Nevertheless, some opposition is based on a fear of reduced financial support. It should be possible to allay such fears on the grounds that the main role of ANAHL is to undertake research and development on exotic diseases, with work on endemic organisms being only a minor part as stated in paragraph 3.36. There are many important veterinary problems in Australia
requiring investigation and the advent of ANAHL should not be a reason for slowing down such work. The anticipated operating expenditure of ANAHL is large compared with that of other animal research laboratories, and the current practice of identifying support for the Laboratory as a separate item should be maintained.

3.40 In respect of research outside CSIRO, for example in universities and research institutes, the proscriptions outlined in paragraph 3.36 would ensure that ANAHL does not come to dominate all veterinary research in Australia. Moreover, the number of research scientists proposed for ANAHL is not large in comparison with the staff of some veterinary schools, and the Laboratory offers opportunities for collaborative research with access to high-security laboratory facilities.

ANAHL AND QUARANTINE STATIONS

3.41 A specific objective proposed for ANAHL is to provide diagnostic services in support of Australia's animal quarantine stations. These include the Cocos Island high-security quarantine station, the medium-security establishment at Torrens Island, the proposed high-security poultry station at Torrens Island, and other regional stations. Some overseas sources of genetic material that could lead to improvements in Australian livestock have been identified, by panels appointed by the Standing Committee of the Australian Agricultural Council, but many are located in countries where diseases not present in Australia are endemic. Animals from these countries would be held in quarantine while specimens were checked for the presence of pathogens, or of antibodies indicating an infection. A thorough evaluation of these animals would require the diagnostic facilities and expertise available at ANAHL.

3.42 It has been claimed that the diagnostic tests which would be performed on animals held in quarantine might not show up all latent infections, and that therefore there is a risk in allowing such stock onto the mainland. This has led to the suggestion that importation of semen or fertilised ova would be a much safer procedure. However, there is evidence that certain viruses, for example Bluetongue virus, can be transmitted by this means also, and ANAHL is therefore likely to play an important role if new genetic material of livestock is to be introduced into Australia, no matter what form it takes.

4. THE IMPORTATION OF EXOTIC PATHOGENS - GENERAL DISCUSSION

4.1 This Section is concerned with the so called 'live virus issue', that is, whether or not exotic animal pathogens, in particular infectious viruses, should be imported for work at ANAHL prior to their occurrence in the form of a disease outbreak. The discussion deals in a general way with the importation of live exotic viruses; the next Section 5, considers the special problems associated with Foot-and-Mouth Disease (FMD).
4.2 The general approach adopted by ASTEC to investigating the proposed importation of animal viruses has been to weigh the additional risks posed by working with these organisms at ANAHL against the potential benefit derived from that work. Each aspect is now discussed in more detail.

ADDITIONAL RISKS FROM IMPORTING LIVE VIRUSES

4.3 The major factor determining the level of additional risk posed by importing a live virus pathogen prior to an outbreak of disease is the microbiological security of ANAHL. ASTEC has not attempted to carry out a thorough risk analysis of the Laboratory's security; it is doubtful if there is yet sufficient data available to undertake such a study, and in any event the results are unlikely to provide an unequivocal answer to the question 'what is the risk of an escape?'

4.4 Data have been collected on tests carried out on prototype equipment that has been specifically designed for ANAHL and tested at Maribyrnong and other establishments, and on components installed in ANAHL. An analysis of containment prepared by the Commonwealth Department of Transport and Construction derives criteria which need to be met by structures and items of equipment if security is to be maintained. These criteria are being used for acceptance testing during construction and will be used for routine testing during operation. Data obtained so far during construction indicate that a significantly higher standard is being achieved than that required by the acceptance criteria.

4.5 Another approach to risk assessment has been to assign arbitrary probability figures, considered to be excessive, to each step likely to be involved in escape of sufficient virus to result in an infection outside the Laboratory, and then to calculate an estimate of cumulative probability. This technique is also unable to provide an unequivocal estimate of risk.

4.6 Nor is much help to be gained by reference to overseas experience. All that can be said with certainty is that escapes of pathogens, including FMD virus, have occurred. Whether any parallels can be drawn with ANAHL is another matter. Research on FMD virus commenced at Pirbright in 1924 and no escape of this most infectious pathogen was detected for 34 years. In 1958 and again in 1960 the virus spread between groups of cattle housed within the Institute perimeter, and later in 1960 to cattle at Worplesdon about one mile from the boundary; at this time there was no provision for treatment of exhaust air in buildings where vaccines were being prepared and infected cattle housed. An apparent breach of security within the Institute in 1970 may in fact have originated from animals within the building concerned which were recovering from the disease and were potential carriers. An 'escape' within the boundaries of Plum Island Animal Disease Center in 1978 occurred when work involving FMD virus was continued during extensive modification of air filtration systems. Livestock will not be held at ANAHL outside the secure area, so that incidents comparable with those within the perimeters of Pirbright and Plum Island should not be possible. Escapes of other pathogens have invariably been associated with laboratories operating under containment conditions judged to be far less secure than those at ANAHL.
4.7 This is not to say that escapes from ANAHL can never occur; there is no reason to believe that the Laboratory will be immune from the errors and unusual circumstances which affect other supposedly 'safe' equipment. Two broad categories of risk can be identified. The first is failure of design or construction, with notable examples including: passenger aircraft, of which at least four designs brought into service in the past forty years have been shown to contain serious defects; motor vehicles, where new models are not infrequently recalled to have design faults rectified; nuclear power plants, for which there are several examples of design and construction errors leading to failures; spacecraft; steel bridges and so on. Errors continue to occur despite the large body of accumulated knowledge of design and safety factors for many of these items, and despite the generally incremental rate of design change. The second risk category is operational error, the 'human factor'. Examples may be drawn from aircraft and train crashes, escape of noxious chemicals from manufacturing plants, and failures at nuclear power plants. These errors carry heavy social and economic penalties, but continue to occur even though a great deal of effort is expended on their prevention.

4.8 It does not follow from these remarks that there will necessarily be a design or operational failure at ANAHL. Indeed, there is general agreement within Australia as well as overseas that ANAHL has been designed and built to a very high standard; several overseas scientists with experience in containment of animal pathogens have stated that its microbiological security will be better than that of any other existing animal disease laboratory. Nevertheless, this security cannot be guaranteed absolutely, nor, in ASTEC's view, can the risk of an escape of a particular pathogen be determined with sufficient accuracy to provide an estimate which would be useful to the present discussion.

4.9 It is worth remembering that overseas laboratories which are world reference centres for one or more animal diseases may be required to hold and work with pathogens which are not present in the host country, as well as accepting suspect specimens. For example, FMD virus is held at Pirbright and at Plum Island even though the United Kingdom and the United States of America are free of the disease. This implies that the risk of an escape of the virus is considered to be extremely small; the economic consequences of an escape of FMD could be very serious even though neither country is a major exporter of meat or livestock products.

4.10 Under the current proposals of CSIRO, no importation of live pathogens will be made until the microbiological security of ANAHL has been tested rigorously and accepted as satisfactory. This will include the commissioning period, during which all equipment including components of the containment systems will be examined to make sure they achieve design standards, and a longer period referred to as 'setting-to-work' in which systems are placed into normal service operations. The latter period, primarily a responsibility of CSIRO, will include tests of containment security using benign organisms, other reagents and possibly also indigenous animal viruses. An ANAHL Security Assessment Group has been established to advise the Executive of CSIRO, through the ANAHL Consultative Committee, of the adequacy of the Laboratory's security. The Group is chaired by the Commonwealth Department of Health (which has administrative responsibility for quarantine matters, including the importation of exotic pathogens) and includes representatives of the National Biological Standards Laboratory, the Victorian Department of Agriculture (also representing the Australian Agricultural Council) and CSIRO, together with a member of the executive of the
National Farmers' Federation, an independent veterinarian nominated by the Australian Veterinary Association and an overseas consultant with special expertise in microbiological containment systems.

4.11 The terms of reference of the ANAHL Security Assessment Group are:

- to develop protocols for testing individual containment systems, thus providing a basis for pronouncements on overall security;
- to supervise security tests;
- to determine how frequently such tests should be repeated;
- to develop security procedures to be adopted by personnel working in secure areas of ANAHL; and
- to monitor the continuing effectiveness of ANAHL's security systems and procedures, and to advise on any changes that ought to be made.

4.12 It has been suggested that because of the public controversy concerning importation of live exotic viruses, the security of ANAHL should also be subject to assessment by a competent group completely independent of all government agencies, and which would report direct to the Minister for Health whose authorisation is required before any pathogen can be imported. An independent assessment might help to increase confidence in ANAHL's security, but it is unlikely that any group would ever be in a position to give a complete guarantee that there was no risk whatsoever of an escape. Therefore, notwithstanding the excellent level of containment offered by ANAHL, the importation of an exotic pathogen to the Laboratory represents an additional risk over and above that posed by its accidental or deliberate introduction by other means. For some diseases, and perhaps for most, the additional risk may be small compared with that already existing. It is ASTEC's view, however, that there should be agreement on the likelihood of substantial benefits before deliberate importation of any pathogen is allowed. The responsibility for seeking such agreement should rest with CSIRO, and because of the varying characteristics of animal viruses and the diseases they cause, a separate case needs to be developed for each pathogen proposed for importation, although there is no reason why several such cases should not be considered at the same time.

4.13 Furthermore, there is a clear need for an agreed procedure to ensure that full consultation takes place between CSIRO and the relevant Commonwealth and State authorities, producer organisations and other interested parties, and for the results of that consultation to be forwarded to the Minister for Health. The Australian Agricultural Council, and its Standing Committee on Agriculture and technical sub-committees, provide a well-developed forum for consultation on matters affecting the rural industries, and these groups will be required to advise on any proposed importation of exotic animal pathogens. However, it will be necessary to consult fully with non-government organisations also, including the National Farmers' Federation and its commodity councils and the Australian Veterinary Association.
4.14 The following procedure has been developed by CSIRO for the introduction of exotic disease agents into ANAHL. Upon a report from the ANAHL Security Assessment Group that the microbiological security of the Laboratory has been tested thoroughly and accepted as satisfactory, application will be made by CSIRO to introduce exotic disease agents into ANAHL. A list of agents, along with the need for their introduction, will be submitted to the ANAHL Consultative Committee for its consideration and advice. If approved, the application will then be submitted to the Animal Health Sub-Committee of the Standing Committee on Agriculture. The advice of the Sub-Committee will be considered by the Standing Committee and finally forwarded to the Agricultural Council. If the application is supported, CSIRO will then place it before the Minister for Health, who in turn may seek advice from the Chief Quarantine Officers (Animals) Conference and from other interested groups. Final authorisation for importation rests with the Minister.

4.15 This lengthy procedure should ensure that adequate consultation occurs. However, non-government organisations should be involved at as early a stage as possible; to seek their views after the main consultative discussions are completed is not satisfactory. ASTEC therefore believes that the ANAHL Consultative Committee should have the responsibility, upon receipt of an application by CSIRO for importation of exotic animal pathogens, to give formal notice of the application to the National Farmers' Federation, the Australian Veterinary Association and other organisations the Committee considers appropriate, to seek their advice and comments prior to the completion of its own deliberations, and formally to transmit such advice and comments to the Minister for Health as well as to the Executive of CSIRO. In this way, independent groups can be consulted at an early stage and their advice made available direct to the Minister.

**ASTEC recommends:**

(i) That, for each exotic pathogen which is proposed for importation to ANAHL, CSIRO prepare a brief summary of the reasons why importation is sought, as a basis for consultation and discussions;

(ii) That the ANAHL Consultative Committee be given the responsibility of providing formal notice of proposed importations of exotic animal pathogens to the National Farmers' Federation, the Australian Veterinary Association and other organisations that it considers appropriate, with a view to obtaining their advice and comments prior to completion of its own deliberations; and

(iii) That the advice and comments received by the ANAHL Consultative Committee be transmitted to the Minister for Health as well as to the Executive of CSIRO so that they may be taken into consideration when the Minister's approval is sought for the introduction of exotic animal pathogens.

**POTENTIAL BENEFITS OF IMPORTING LIVE VIRUSES**

4.16 The potential benefits of importing a live pathogen prior to an outbreak will depend upon the particular characteristics of the organism and of the disease it causes. However, it is possible to make some generally applicable comments using the main functions of ANAHL (paragraph 3.38) as a reference.
Diagnosis

4.17 The prime function of ANAHL is diagnosis, so it is important to consider the potential benefits in this area. Many of the laboratory diagnostic tests which are accepted internationally as the standard for identification of dangerous animal viruses depend on serological and other procedures for which it is a great advantage to have live virus as a positive control. The efficiency of several of the serological tests, for example complement fixation, may be influenced by a wide range of factors and greater confidence is possible in a positive result, and perhaps more importantly in a negative, if controls using live virus can be run during the test to make sure it is operating correctly. Usually, additional confirmatory tests for identification are also carried out. These may involve inoculation of primary cell cultures and animals, and again access to live virus for use in controls gives a greater degree of confidence in the results obtained.

4.18 It has been claimed that international veterinary authorities have been overly cautious in recognising more modern methods for detecting and identifying virus particles, viral antigen or specific antibodies. Electronmicroscopy, immuno-electronmicroscopy and immunofluorescence are feasible for direct examination of samples but are not much used. Of perhaps greater potential are certain procedures now used routinely in immunological research and practice, including radioimmunoassay (RIA) and enzyme-linked immunosorbent assay (ELISA). These tests are quick and extremely sensitive, can be used to detect either antigen or antibody from infected animals, and offer a considerable increase in sensitivity over the traditional complement fixation test.

4.19 These newer procedures, and perhaps others such as the use of specific probes to identify nucleic acids, offer two particular advantages. All that is required to check that procedures are operating satisfactorily is a source of reasonably pure antigen or antibody. Improved techniques have been developed for inactivating live viruses without affecting their antigenic characteristics, so that a range of diagnostic tests which do not require the live pathogen is now possible; suitable antibody can be obtained from animals by injecting the inactivated virus. The second benefit is freedom from interference by anti-complementary effects. These two characteristics offer a promise of rapid, on-farm diagnosis using only inactivated reagents under favourable conditions (unfavourable conditions are discussed in paragraphs 3.15 to 3.17).

4.20 These new techniques are of special significance for Australia; the advantages of achieving preparedness for a diagnostic emergency without importation of live exotic pathogens are obvious. In addition, the development of simple methods of serological diagnosis, with back-up identification at ANAHL, would be of great assistance to control programs. Tests using only inactivated reagents would allow State laboratories to play a greater role in any disease emergency.

4.21 Unfortunately this situation does not yet exist; it is still only potential. Some work has been done overseas in adapting modern detection tests for veterinary use, for example the use of ELISA to identify Foot-and-Mouth Disease, but much more is needed before the currently accepted tests can be replaced with confidence. It may be several years before RIA, ELISA or similar tests win international acceptance as diagnostic standards. Furthermore, it is likely that authoritative diagnosis will continue to require access to the full range of tests, including inoculation of cell cultures and animals. These may require access to live pathogen if positive controls on procedures are to be maintained and there is no possibility of using related or model viruses.
4.22 The case for importation of a live exotic pathogen will need to give specific and detailed consideration to the potential benefits for diagnosis. The currently accepted international procedures for diagnosis should be clearly stated, together with the potential for using inactivated reagents. The likelihood of developing new tests based on inactivated reagents should be considered, as well as the use of low-virulence strains or non-pathogenic model viruses.

**ASTEC recommends:**
That each case for importation of an exotic animal pathogen include consideration of the potential benefits for diagnostic preparedness, specify the procedures accepted internationally for identification of the pathogen and the opportunities for developing new or improved procedures using inactivated reagents, low-virulence strains and non-pathogenic virus models, and comment on the risks associated with manipulation of the pathogen in diagnostic procedures.

**Training**

4.23 If reliable and rapid diagnostic tests can be developed that do not require live virus, there is clearly no advantage in prior importation of pathogens for training laboratory staff in diagnosis. The use of infected animals at ANAHL as an aid to training veterinarians is discussed in paragraphs 3.25 to 3.29. The need for veterinary officers to have prior experience of clinical symptoms of exotic diseases, and of how to collect and prepare specimens, is accepted. However, the benefits of having access to infected stock at ANAHL need to be balanced against the extra risk due to the excretion of large quantities of virus by infected animals, and the need for, and cost of, completely sanitary disposal of carcasses. The limitations of this training and the possible availability of other methods should be borne in mind.

**ASTEC recommends:**
That each case for importation of an exotic animal pathogen include consideration of potential benefits for veterinary training, and the additional risks and costs associated with inoculation of cattle, sheep or pigs, the limitations of such training and the availability of other methods of training including attendance at courses and disease outbreaks overseas.

**Vaccines**

4.24 Vaccination might be an important part of a control program for some exotic diseases, for example, Bluetongue and Rift Valley Fever, but in the main, quarantine and slaughter would be the chosen method of control of exotic disease outbreaks in Australia; vaccine would either not be used at all or only under special circumstances. Before a case can be made for production of vaccine within Australia prior to an outbreak, with its concomitant risks, it needs to be demonstrated that it would not be feasible to obtain supplies overseas at short notice or to have vaccine made and stored overseas under contract without prohibitive cost. Vaccine obtained from overseas would still require thorough testing for both potency and safety, but it might be possible for this to be carried out by the manufacturer to Australian requirements.
4.25 Traditionally, potency testing of vaccines involves the challenging of immunised livestock with live virus, but measurement of antibody response to the vaccine is in some instances regarded as adequate. The resistance to challenge of an immunised animal may give greater confidence than the measure of antibody, but even in a large laboratory such as ANAHL it is not possible to test more than a limited number of livestock, and moreover the reaction of stock under stress in the field may be different from that in the laboratory. Nevertheless, the likely cost of an immunisation campaign would be such that every effort should be made to verify the immunogenicity of the vaccine to be used before it is released. Once an exotic disease has been identified within Australia, the threat to livestock production and exports associated with any extra risk posed by testing a vaccine's potency through challenge of livestock at ANAHL may be small; the consequences of an escape would be far more serious when vaccine is to be tested prior to an outbreak.

4.26 The impending advent of genetically-engineered and synthetic vaccines opens further possibilities. These vaccines would contain a protein with the antigenic properties of the virus, but manufactured in quantity either by utilising a genetically-engineered culture organism (usually a bacterium) or by chemical synthesis. The protein is not derived directly from infective virus particles, and the product should therefore be much safer than current vaccines, which may contain incompletely inactivated particles or passenger viruses. However, these developments probably lie three to five years in the future, and Australia may wish to obtain the security provided by stocks of traditional vaccines meanwhile.

ASTEC recommends:
That each case for importation of an exotic animal pathogen include consideration of the potential benefits and risks of manufacture and testing of vaccines, including the availability of supplies overseas and potential developments in genetically-engineered vaccines and in techniques for testing potency and safety which do not require live pathogens.

Research

4.27 The important role of research in the operations of ANAHL is discussed in paragraphs 3.35 to 3.37. The key question is, are live pathogens necessary for such research?

4.28 A primary objective of research at ANAHL should be to strengthen Australia's ability to detect, identify and control possible outbreaks of exotic diseases. It follows from this that priority should be given to developing new and improved methods of diagnosis, especially those that provide increased sensitivity and reliability and allow on-farm testing using inactivated reagents. This work would be of particular benefit to Australia, and in fact there may be less impetus for it elsewhere. Animal disease laboratories overseas which already have access to live pathogens may view the development of diagnostic tests based on inactivated reagents as of lower priority than, say, progress in producing improved or cheaper vaccines.
4.29 Another area of high priority for research at ANAHL is the effects of exotic viruses on Australian livestock under local conditions, and the significance of these for control programs and animal production and export. Several exotic viruses which have been detected in Australia have been of low virulence although overseas strains are responsible for severe epidemics with high mortality. Examples include Swine Fever, Newcastle Disease and Bluetongue. It is not entirely understood why these viruses failed to produce serious disease in this country, but clearly an ability to distinguish between virulent and non-pathogenic strains may have an important bearing on Australia's disease-free status. Thus a case can be made for research at ANAHL into the molecular basis of infectivity and virulence of viruses.

4.30 Research to develop new diagnostic tests and assessment of virulence would require access to live pathogens, initially at least. In view of the importance to Australian livestock industries of access to prompt and accurate diagnosis of any suspected exotic disease, the potential benefits of developing improved procedures might in many cases outweigh the additional risks of importing the pathogen prior to an outbreak. However, as with other potential benefits, each case will need to be judged on its own merits.

ASTEC recommends:
That each case for importation of an exotic animal pathogen include consideration of the potential benefits for research, including a broad description of the planned research programs and their objectives, and of the associated risks.

4.31 If the cases for importation of live pathogens include the information specified in the recommendations made above, it should be possible for parties to the consultative process to reach an informed judgement of the desirability or otherwise of each proposal in a timely manner. In each case, it will be necessary to weigh the benefits claimed for importation against the risks. Without wishing to prejudge any case, it is ASTEC's view that strong arguments can be made for importation of several viruses in categories two or three of paragraphs 3.4 and 3.5. A more detailed examination will be necessary before any firm decisions can be made, but some candidates for early importation are listed in Table 4.1.

4.32 ANAHL should be completed by the latter part of 1983 and recruitment of staff by CSIRO should proceed if the Laboratory is to come into operation on schedule. ASTEC accepts the view put forward by CSIRO that it will be difficult to attract scientific staff of the required calibre if it is uncertain that the Laboratory will be permitted to import live pathogens. This is not a justification for importation, but progress needs to be made toward an early decision, even though no importation is contemplated before the microbiological security of ANAHL is tested and accepted as satisfactory by the ANAHL Security Assessment Group, that is, before late 1984 at the earliest. CSIRO should now determine which exotic pathogens, other than Foot-and-Mouth Disease virus, are of highest priority for early importation, and proceed to develop individual cases for importation, as already outlined.
<table>
<thead>
<tr>
<th>Disease</th>
<th>Justification for Importation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bluetongue</td>
<td>Low-virulence strains of bluetongue virus have been detected in northern Australia; there is no satisfactory explanation for the apparent absence of any disease in sheep. The potential for transformation to a virulent form is unknown. Vaccination would be an important component of any control program. Control of insect vector is not practical.</td>
</tr>
<tr>
<td>Newcastle Disease</td>
<td>World-wide distribution and very wide host range, including wild birds, suggest a high risk of entry into Australia. Virulent strains appear to be spreading. Vaccination might be used in control.</td>
</tr>
<tr>
<td>Rabies</td>
<td>World-wide distribution; notable exceptions are islands where quarantine controls have been effective, e.g. Australia, New Zealand. Vaccination would be an important part of control if the disease became widespread.</td>
</tr>
<tr>
<td>Swine Vesicular Disease</td>
<td>The first two are diseases of importance to the pig industry. The main significance of all three is that the clinical symptoms may be confused with those of Foot-and-Mouth Disease, so a capability for rapid and accurate diagnosis could assist early detection of the latter.</td>
</tr>
<tr>
<td>Vesicular Exanthema</td>
<td></td>
</tr>
<tr>
<td>Vesicular Stomatitis</td>
<td></td>
</tr>
</tbody>
</table>
ASTEC recommends:
That CSIRO nominate exotic pathogens, other than Foot-and-Mouth Disease virus, considered to be of high priority for early importation to ANAHL following acceptance of its microbiological security, and proceed as soon as practical to prepare individual cases with a view to initiating consultation on the proposals through the ANAHL Consultative Committee and with the Australian Agricultural Council and its committees.

5. IMPORTATION OF LIVE FOOT AND MOUTH DISEASE VIRUS

5.1 Most of the comments made in Section 4 can be applied to the proposed importation of live Foot-and-Mouth Disease (FMD) virus. However, separate discussion is warranted partly because the public controversy over FMD has overshadowed other considerations of ANAHL's role and operation, and also because there are special features of FMD which need to be taken into account.

5.2 FMD is an acute disease of cloven-footed animals. Clinical symptoms include fever and formation of blisters in the mouth and on the feet and teats. In young animals muscle lesions have been observed, especially in the heart, and these often cause death. The most severe signs are seen in highly productive domestic stock and milder lesions may occur in poor animals or in the wild. Cattle, pigs and sheep are the commonly affected domestic animals but goats are also susceptible. Pigs are the most efficient multipliers of the virus and constitute the worst source of infective material from amongst the domestic animals. The disease is endemic in most countries of Europe, Asia, Africa and South America. Disease-free areas include the USA, Canada, United Kingdom, Scandinavia, Australia, New Zealand, Japan and parts of Indonesia.

5.3 Animals may not exhibit obvious clinical symptoms until some time after they have become infective to others. Cattle may begin excreting virus particles at least 24 hours before the characteristic blisters appear, and for pigs the equivalent period can be as long as seven days. Therefore there is always a possibility that the infection has become more widespread than the distribution of animals with symptoms would suggest. Many wild species, both ruminants and swine, have been shown to act as reservoirs of the disease. In Australia, feral cattle, pigs and goats could spread the disease and constitute a reservoir, and it is known that the Cape Buffalo can be infected and may then become a carrier. Experimental work on native Australian fauna, including wallabies, kangaroos and wombats, has shown that only under very exceptional circumstances would these species be important in the epidemiology of the disease. No biological vector has been associated with spread of FMD.

5.4 FMD virus is known to exist in at least seven serotypes and more than 60 sub-types, and there is evidence that in some parts of the world a gradual drift occurs from one sub-type to another. Infection, or vaccination, by one serotype generally does not confer protection from another, and there may also be a low level of cross-protection between the sub-types of one serotype.
5.5 There are three principal pathways for the spread of FMD. The first is movement of infected livestock and their association with susceptible animals. Virus particles can be transmitted via the exhaled breath of an infected animal to the respiratory tract of a susceptible beast, or they may be ingested with contaminated food.

5.6 The second pathway of spread is the movement of contaminated animal products such as meat, milk, cheese, and hides, or of inanimate objects including footwear and vehicles. Under favourable conditions the virus can survive outside a host as a mechanical contaminant for 24 to 48 hours, and may be transmitted through indirect contact. FMD can infect humans but this happens rarely; the virus may, however, be carried passively in the nose or throat of humans for at least 24 hours and infection can be transmitted to livestock in this way. The risk of human transference of the virus would be greatest following close contact with infected livestock, unless protective suits with filtered or independent air supply are worn (as is planned at ANAHL). There should be little or no risk associated with laboratory use of the virus provided all manipulations are carried out in biologically secure cabinets. The role of birds in transmitting FMD, perhaps as a contaminant, is not certain.

5.7 The third method of spread involves air-borne particles which may be carried long distances by wind. There is strong circumstantial evidence that FMD virus has been carried up to 10 kilometres by this means, and occasionally very much further, and has then caused a new disease outbreak. It is believed that this mechanism requires liberation of a large 'parcel' of virus into a steady airstream, cool, humid conditions and absence of direct sunlight. This pathway differs from the first two in that movement of the virus is not controlled by import and quarantine restrictions.

5.8 The relative significance of the three means of spread under Australian conditions is not known. Experience with FMD in the tropics has shown that movement of infected animals is far the most important, but the possibility of air-borne spread during winter in temperate regions cannot be ruled out.

5.9 Considerable progress has been made in controlling FMD in many parts of the world. A control program based on vaccination was begun in western Europe in the late 1950s, and the number of outbreaks reported each year in countries such as France, the Netherlands, West Germany and Italy has fallen from several thousand to less than ten. An Australian-sponsored vaccination program was successful in controlling the disease in Indonesia and no clinical signs have been reported since 1979. Progress has also been made in South America, but outbreaks remain frequent in that region, in Africa, and in parts of Asia.

5.10 It is important to understand that FMD has a special significance for Australia, far greater than that of any other animal disease. An outbreak of Swine Fever or of Newcastle Disease would be serious, but the economic implications are limited because of the restricted host range and the fact that Australian livestock industries and exports are based primarily on species not affected by those diseases. An epidemic of virulent Bluetongue might cause serious economic losses, but a total ban on exports would be unlikely. In contrast, it is likely that a single outbreak of FMD would result in an immediate prohibition on most, if not all, Australia's main animal exports. The major markets for beef (the United States,
Canada, Japan and Korea) would be closed, resulting in a drastic fall in the
domestic price. Exports of live sheep and sheepmeat would also be seriously
affected, and shipment of wool might also be banned by some countries.
Furthermore, export markets might not re-open until six to twelve months had
elapsed after the last case of the disease and acceptance by importing countries
that Australia was again free of FMD.

5.11 It is unlikely that any other disease would have such a serious effect.
It is clear therefore that FMD poses a special threat to Australia, since there are
few other countries which rely on freedom from the disease to maintain a major
export industry. Some of Australia's competitors in the international livestock
trade, for example countries in South America, are denied access to significant
markets because FMD is endemic to them.

5.12 In addition to strengthening quarantine and import controls and checks
on illegal entry into isolated areas, priority should be given to improving
Australia's capability for rapid and accurate detection of FMD and its prompt
eradication. However, it must be recognised that an escape of this virus following
its importation to ANAHL would have the most serious consequences. Arguments
for and against importation are now considered in more detail.

ADDITIONAL RISK FROM IMPORTATION OF LIVE FMD VIRUS

5.13 FMD virus is one of the most infectious pathogens known. As few as
ten to a hundred infective doses are required to infect cattle by the respiratory
route, but between ten thousand and a million to infect cattle when the virus is
ingested (in this context an infective dose is the minimum amount of virus required
to infect cattle when virus is inoculated intradermally into the tongue using a
syringe and needle). This is one part of the rationale for designing ANAHL to a
standard expected to be sufficient to contain FMD virus. The comments made in
paragraphs 4.3 to 4.9 are pertinent, with added emphasis on the particular
seriousness of an escape of FMD virus.

5.14 The size of the risk associated with importing live FMD virus at
ANAHL will depend to some extent on what the organism is used for. Transport
of the virus into Australia, and then to ANAHL, constitutes one level of risk,
considered by many to be very small. Within the Laboratory, secure storage of the
virus with occasional use within a microbiologically secure cabinet to check the
accuracy of diagnostic reagents and procedures represents a low level of risk.
Inoculation of small laboratory animals for diagnostic purposes or to produce
antisera, and the attendant multiplication of the virus and need for careful disposal
of wastes, represents a somewhat higher level of risk. The inoculation of livestock,
for example cattle, sheep and pigs, to test vaccine or to provide material for
veterinary training programs would result in a much increased risk, as would the
inoculation of large scale tissue cultures to produce material for vaccines.
5.15 The infective nature of FMD virus has been taken into account in the design and construction of ANAHL, and will have a significant influence on how the virus is handled if introduced when ANAHL becomes operational. The virus would be stored in liquid nitrogen cabinets in areas that have been classified as high risk. Access to these areas would be confined to the microbiological security officer and one other person designated by the Officer-in-Charge. CSIRO proposes that, following an introduction of FMD virus into ANAHL, the use of the virus for various procedures would be staged. It would be used initially in laboratory procedures not requiring the inoculation of susceptible target species such as cattle, sheep and pigs. This stage would involve the inoculation of small laboratory animals, particularly guinea pigs, with inactivated and live virus for the production of anti-sera for diagnostic purposes, and the inoculation of tissue culture systems for the production of virus to be used in preparing inactivated reagents. The inoculation of laboratory animals with FMD virus presents a much lower risk than does the inoculation of susceptible target species. For example, an infected rat excretes in its urine and faeces only 0.00001% of the virus excreted by an infected cow by the same routes. Similar figures would be expected from the intramuscular inoculation of guinea pigs, and even less following the intraperitoneal inoculation of suckling mice. All of the in vitro manipulations and those involving small laboratory animals would be undertaken in high risk areas, utilising either totally enclosed highest-security facilities or rooms of equivalent security standard. Because of the possibility of airborne spread of virus, if animals are infected with FMD, or for that matter any other high risk agent, all exhaust air from cabinets and rooms would be passed through two high efficiency filters in series before being heated to 350°C for one second.

5.16 The inoculation of livestock would constitute the second stage in use of the virus, to be carried out only after further experience had been gained in operating the laboratory under high security conditions. The current plans of CSIRO require the inoculation of susceptible livestock species about twice a year for training and diagnostic purposes. Since this would always be an operation planned well in advance, the security containment systems would be tested and certified before it was carried out.

POTENTIAL BENEFITS OF IMPORTING LIVE FMD VIRUS

Diagnosis

5.17 A wide range of diagnostic tests have been developed for the identification of FMD virus, including:

- serological tests, including complement fixation, enzyme-linked immunosorbent assay and virus neutralisation, to detect and identify viral antigen or antibodies;
inoculation of sample material into cell cultures (including kidney cells and primary calf thyroid cells) or into baby mice in order to isolate any virus present in amounts too small to be detected by serological tests, so that it may be identified; and

inoculation of livestock in an attempt to reproduce the suspected disease so that further diagnostic and other tests can be carried out.

Access to live virus would be advantageous for these tests in that it would enable staff to run positive controls (to provide confidence in negative results) and to check periodically that reagents are working satisfactorily (for example that cell cultures are susceptible to the virus).

5.18 The advent of new serological tests, some of which have been shown to be more sensitive and reliable for the detection of FMD virus than the traditional complement fixation test, may result in the adoption of different procedures for international standards and reduce the need for live virus. Radioimmunoassay, enzyme-linked immunosorbent assay, immuno-electronmicroscopy and fluorescent antibody tests have all been used successfully for the detection of FMD. In general these procedures can be checked adequately with inactivated antigen, and progress is being made in the development of synthetic reagents. Further research is needed to demonstrate the reliability of these tests, for example, whether they result in false positives in animals which have not been exposed to FMD, and then to obtain their acceptance internationally.

5.19 Because of the supreme importance of reliability in the diagnosis of any vesicular disease in Australia, and the frequent difficulty of obtaining a clear cut result from specimens collected from recovering animals, diagnostic staff require access to all available tests. An argument can therefore be made today that a greater level of confidence is possible with access to live virus, for example, to monitor the sensitivity of cell cultures. However, ANAHL will not be in a position to import live FMD virus for at least two to three years, by which time there is a possibility that diagnostic tests which do not require live virus will be further developed and in use, and accepted by countries which import Australian meat and livestock. Australia has a particular interest in developing such tests and this should form a major part of the research at ANAHL.

5.20 Further options should also be considered. If, when it is accepted that ANHAL meets the design standards for containment and can accept exotic pathogens without undue risk, and if there is agreement that live FMD virus be included, a low-virulence or non-pathogen strain 'could be imported initially. Moreover, importation might be agreed only for periodic laboratory manipulation to check diagnostic procedures. These actions could help to reduce the risk attendant on importation of the live organism and provide a 'breathing space' while alternative tests are developed.

Training

5.21 The benefits, limitations and risks associated with infecting large animals at ANAHL to provide for veterinary training are discussed in paragraphs 3.25 to 3.29. It is ASTEC's view that, at least until considerable experience and
confidence has been gained in operating ANAHL over several years, the benefits are not sufficient to warrant deliberate infection of pigs, cattle or sheep with live FMD virus.

5.22 Emphasis should be given to other sources of training including audio-visual presentations and participation in overseas courses whenever possible. Arguments that overseas animal health laboratories will be unwilling to include Australian veterinarians in their training courses once ANAHL is completed are not convincing. Furthermore, urgent consideration should be given to participation by Australians in overseas training courses on FMD because ANAHL will not be in a position to provide such courses for several years. The additional cost of sending Australians overseas to gain experience in recognition, laboratory manipulation or control of FMD or, if need be, paying for the use of overseas facilities, is minor compared with the benefits of this course of action.

Preparation and Testing of Vaccines

5.23 There has been considerable debate on whether or not a vaccination program would be used to help control an outbreak of FMD in Australia. Vaccines have been used with great success in western Europe and more recently in Indonesia to reduce or eradicate the disease. However, there are some difficulties with vaccination, especially in relation to its use in Australia. An animal successfully immunised against a particular sub-type of the virus can later become a symptomless carrier if infected by another, and it is therefore virtually impossible to be sure that FMD is not present in the vaccinated region. This is not a great problem in many of the countries which have established vaccination programs since they are not large exporters of livestock or animal products (in South America the disease itself poses a far greater problem, hence control through vaccination is accepted as necessary). However, it would be a major problem for Australia whose most important export markets depend on our remaining free of the disease. Under most circumstances, any animals vaccinated in Australia would have to be slaughtered later, and it may be asked, why go to the trouble and expense of vaccination at all? A claimed advantage is that vaccination could be carried out more quickly than slaughter, because the proper disposal of carcasses is a time-consuming operation, but this suggestion is open to doubt, as discussed further below.

5.24 There are two situations in which it is claimed vaccination might be contemplated in Australia. The first would be when an outbreak was spreading so fast that the normal procedure of bans on movement and slaughter of infected animals was proving ineffective. It is suggested that vaccination of animals in a ring around the outbreak would prevent spread of the virus and enable the slaughter program to catch up.

5.25 The need for 'ring vaccination', or its effectiveness, is by no means certain. It is likely that over much of Australia, weather conditions during the greater part of the year would not favour rapid spread of the disease once movement of animals and goods was banned; this is the experience with FMD in the tropics. Favourable conditions could, however, occur in the south during winter. Livestock do not become immune until several days after injection of vaccine, so that in a fast spreading outbreak the 'ring' would need to be a long
way in front of the disease. Moreover, immunisation is not always complete and some animals might remain susceptible. It could therefore be argued that slaughter of animals where they stand would be quicker and more effective than roundup and vaccination of stock; because the animals in the 'ring' would not be infected, there would be no necessity for the immediate disposal of carcasses except on aesthetic grounds.

5.26 The other situation which might warrant a vaccination campaign would be if FMD were found to be already widespread when detected, for example in livestock and feral animals in northern Australia. This would present a very difficult problem. Movement of stock to the south would have to be prevented, while control was attempted. If movement of animals was the major means of spread, eradication without recourse to vaccination might be possible; again, slaughter might be quicker and more effective than vaccination.

5.27 To summarise, it seems that only in the most exceptional circumstances would FMD vaccine be used in Australia. The need for live virus for production and testing of vaccine is therefore in doubt. Even if the use of vaccine was considered likely, it would be necessary to show that no suitable supplies could be obtained or produced under contract overseas before agreement was given for this high-risk operation to proceed at ANAHL. The testing, at the Laboratory, of vaccines obtained from overseas after an outbreak of FMD had been confirmed in Australia represents a much lower risk than preparing and testing of vaccines prior to an outbreak. On the evidence presented, there is no case for stockpiling vaccine within Australia prior to an outbreak of FMD (a separate vaccine for each of the seven serotypes of the virus would have to be stored).

5.28 Recent developments have been made overseas in the production of synthetic vaccines, and it is quite possible that these will be available within three to five years. If this proves to be so, and they can be manufactured and tested adequately without the need for live virus, that is, with little or no risk, the role of ANAHL in relation to vaccines may need to be re-appraised.

Research

5.29 The importance of research to improve diagnostic procedures has already been discussed in paragraphs 4.28 and 4.30. This is especially true with respect to diagnosis of FMD, as new diagnostic techniques which do not require live virus would be of particular benefit to Australia. A high priority in the research programs of ANAHL should be given to developing new and improved diagnostic tests based on inactivated reagents, and paying particular attention to the potential for simple tests which can be carried out on infected or suspect properties under favourable conditions. Similar research is being undertaken at overseas laboratories, but it is unlikely to receive the same priority from non livestock-exporting countries or perhaps from a laboratory which has ready access to the live virus.

5.30 Much of this research could be undertaken using inactivated antigen, but efficient development of new materials and procedures will require comparison with the standard tests using live virus. The research program should be initiated as soon as possible, but, as already stated, ANAHL will not be in a position to import the live virus for two or three years at least. Therefore, ASTEC proposes that the research program be carried out jointly by staff at ANAHL and by a small
group of the Laboratory's scientists located at an overseas laboratory where they
would have ready access to the live virus. The ANAHL group would carry the main
research load, with the overseas group being responsible for testing new reagents
and procedures using the live virus and for preparing inactivated antigen for
shipment to ANAHL after it had been certified free of infectious particles.

5.31 These arrangements should be entered into as soon as practical and
maintained for an initial period ending three years after completion of the
'setting-to-work' program, that is, until about the end of 1987 on the current
schedule. Australia would pay appropriate expenses for the location of ANAHL
scientists overseas. This arrangement would obviate any need to introduce live
FMD virus into ANAHL over the next five years, but would allow progress to be
made in developing diagnostic procedures for FMD while, at the same time,
experience in operating the Laboratory is being gained. If, during this period, an
outbreak of FMD were to occur in Australia, a satisfactory primary diagnosis could
be undertaken by the ANAHL team using materials whose properties had been
tested against the live virus by the overseas group. Samples could also be sent
immediately to the ANAHL scientists overseas who would be able to provide
assistance in the event of difficulties with the primary diagnosis. Once an
outbreak is confirmed, the live virus is already available in the country if required
to give greater confidence to secondary diagnoses. Identification of the sub-type
of the virus, which could provide evidence of the source of the outbreak, is not
required immediately (unless vaccination is to be used, which is unlikely) and could
be undertaken by the overseas group as well as the World Reference Centre at
Pirbright. The additional expertise gained by the overseas group, which might
include strain differentiation through peptide/oligonucleotide mapping, hybridisation
and other tests, could be put to good use in the event of an outbreak.

5.32 Before the end of the initial period, the question of importation of live
FMD virus should be re-examined. If new diagnostic techniques have been
perfected and accepted internationally there may be little call for access to the
live virus. On the other hand, if a need for the live pathogen can be demonstrated,
importation for restricted uses only might be agreed as there would then be
considerably greater experience and confidence in the operation of the contain-
ment systems of the Laboratory.

5.33 ANAHL will not be in a position to import live FMD virus until the end
of 1984 at the earliest, but the proposed arrangements offer an opportunity for a
rapid upgrading of Australia's capability to diagnose FMD, without the additional
risks associated with importing the live virus into this country. Over the next five
years Australia's expertise and international credibility in diagnosis will increase
through the joint efforts of the two groups. It should be emphasised that these
arrangements are being proposed for a fixed term only; once ANAHL has been
fully operational for two years or so, the need for live FMD virus should be re-
examined so that a decision can be reached before expiry of the initial agreement
covering the overseas group.

5.34 It may be asked, what are the additional risks for Australia consequent
upon a decision not to import live FMD virus for five years? It is true that today,
December 1982, access to live FMD virus could be most advantageous in the event
of a difficult primary diagnosis. Whether the same will be true in December 1984,
about the earliest date that ANAHL could start laboratory work with the live
virus, will depend very much upon the progress made by the scientists located
overseas in developing new diagnostic procedures which do not require the live
pathogen. The value of access to live FMD virus in enabling a more rapid primary diagnosis of an outbreak of the disease, or a definitive identification when the disease is not FMD, is difficult to estimate; a slaughter-eradication program would probably be initiated on the basis of clinical symptoms without waiting for a positive identification, and confusion with other vesicular diseases could be avoided if the causal agents of the latter were available in Australia. Until several years experience have been gained in operating the Laboratory, the risks associated with working on live FMD virus at ANAHL outweigh the possible benefits.

5.35 There are several animal health laboratories where the small ANAHL overseas group could be located. Pirbright in the UK and Plum Island in the USA are obvious possibilities, but there are similar laboratories in other countries as well. It has been suggested recently that the FMD Vaccine Production Centre at Pak Chong in Thailand be strengthened to provide a regional reference laboratory, and this could be a suitable location for the ANAHL scientists. Field strains of FMD virus are available in Thailand for the testing of new procedures under natural conditions (field strains may have different characteristics to those acclimatised to the laboratory environment), and the work of the ANAHL group might be especially welcomed as contributing to control of the disease in South East Asia. If at all possible the group should be sited at a laboratory where their research program can contribute to that of the host institution. The potential benefits of this arrangement will more than outweigh the modest additional expenditure by Australia.

ASTEC recommends:
(i) That live Foot-and-Mouth Disease virus not be imported for use at ANAHL for a period of five years, that is, until the end of 1987;

(ii) That the research programs of ANAHL give priority to the development of new or improved procedures for the identification of Foot-and-Mouth Disease virus which do not require access to the live virus;

(iii) That, as a matter of urgency, CSIRO initiate discussions with appropriate authorities with a view to locating for an agreed period, and with appropriate costs borne by Australia, a small ANAHL research group within an overseas animal health laboratory which has access to live Foot-and-Mouth Disease virus;

(iv) That when this overseas group is established its main responsibility be to assist in the ANAHL research program, specifically by checking the efficacy of both standard and newly developed procedures and materials in use in Australia using the live virus where appropriate, and by preparing inactivated reagents for use at ANAHL; and

(v) That this arrangement be entered into as soon as possible for an initial period ending three years after completion of the setting-to-work program at ANAHL, and the question of importing the live virus into Australia be re-examined before the end of that period.
ASTEC appointed a Working Party in April 1982 to gather information on the proposed importation of live, exotic animal pathogens for use at the Australian National Animal Health Laboratory (ANAHL), and to prepare a draft report on the matter for consideration by the Council. The membership of the Working Party was:

- Sir Samuel Burston (Convenor), grazier, and a member of ASTEC;
- Professor W.I.B. Beveridge, formerly Professor of Animal Pathology at Cambridge University, United Kingdom;
- Sir Gustav Nossal, Director, Walter and Eliza Hall Institute of Medical Research, and a member of ASTEC;
- Professor P.A.P. Moran, Professor of Statistics, Institute of Advanced Studies, the Australian National University, and
- Sir John Wilson, Chairman, Australian Paper Manufacturers Limited, and a member of ASTEC.

Dr P. Price of the ASTEC Secretariat acted as Secretary to the Working Party.

Four members of the Working Party attended the ANAHL Forum, held at Geelong in August 1982, that was organised by the National Farmers' Federation. Following the Forum, the Working Party arranged a series of interviews of expert witnesses in order to explore particular scientific and technical issues in more detail. The participants at the interviews included:

- Dr K.V.L. Kesteven, formerly Director, Animal Production and Health Division, Food and Agriculture Organisation, United Nations;
- Dr A.J. Gibbs, Director, Viral Ecology Unit, Research School of Biological Sciences, the Australian National University;
- Dr R.V.S. Bain, formerly Associate Professor, School of Veterinary Science, the University of Sydney;
- Dr I. Littlejohns, Deputy Director, Glenfield Veterinary Research Station, Department of Agriculture, New South Wales;
- Professor P.C. Doherty, Head, Department of Experimental Pathology, The John Curtin School of Medical Research, the Australian National University;
- Dr B.M. Gorman, Chairman, Virology Department, Queensland Institute of Medical Research;
- Mr B.A. Woolcock, Director, Division of Animal Industry, Department of Primary Industries, Queensland;
Dr W.G. Laver, Senior Fellow, Department of Microbiology, The John Curtin School of Medical Research, the Australian National University;

Dr W.H. Southcott, formerly Assistant Chief, Division of Animal Health, CSIRO;

Dr K.A. Doyle, Assistant Director-General (Animal Quarantine), Commonwealth Department of Health;

Dr R.W. Gee, Director, Australian Bureau of Animal Health;

Dr W.A. Geering, Acting Assistant Director (Epidemiology), Australian Bureau of Animal Health;

Professor D.C. Blood, Head, Department of Veterinary Clinical Sciences, the University of Melbourne;

Dr E.L. French, formerly Chief Research Scientist, Division of Animal Health, CSIRO;

Professor B.P. Marmion, Director, Division of Medical Virology, Institute of Medical and Veterinary Science, South Australia;

Dr M.R. Branden, Senior Lecturer, Department of Veterinary Preclinical Sciences, the University of Melbourne;

Dr A.K. Lascelles, Chief, Division of Animal Health, CSIRO;

Dr M.J. Studdert, Reader, School of Veterinary Science, the University of Melbourne;

Mr W.A. Snowdon
Dr I.M. Parsonson
Dr A.J. Forman, respectively Officer-in-Charge, Senior Principal Research Scientist and Senior Research Scientist, the Australian National Animal Health Laboratory; and

Mr A. Kershaw, ANAHL Project Manager, Commonwealth Department of Transport and Construction.

A submission concerning the importation of live, exotic, animal disease viruses and the role of ANAHL was received from the Australian Veterinary Association.

Three members of the Working Party attended a further meeting at Geelong in November for discussions with research staff of the Laboratory and with officers of the Department of Transport and Construction.

The Working Party submitted a draft report to the Council on 9 November, and a revised version was presented to the December meeting of ASTEC. Further amendment resulted in the final Report submitted to the Government.