

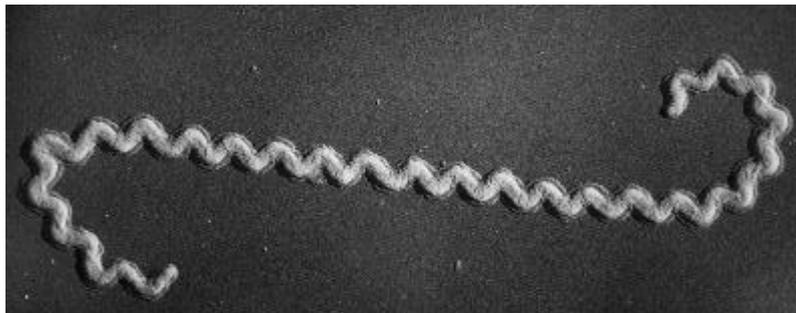


Department of  
AGRICULTURE  
FISHERIES &  
FORESTRY -  
AUSTRALIA



# **A SCIENTIFIC REVIEW OF LEPTOSPIROSIS AND IMPLICATIONS FOR QUARANTINE POLICY**

## **Review of submissions**



August 2001

Biosecurity Australia  
Agriculture, Fisheries and Forestry - Australia  
GPO Box 858  
Canberra ACT 2601  
AUSTRALIA

**TABLE OF CONTENTS**

- 1. DR. HUGH MILLAR, CHIEF VETERINARY OFFICER, VICTORIA..... 1
- 2. DR. ROGER MARSHALL, REPORT TO NEW ZEALAND MINISTRY OF AGRICULTURE,  
FISHERIES AND FORESTRY ..... 5
- 3. DR ALICK LASCELLES, CONSULTANT FOR NATIONAL FARMERS FEDERATION..... 8

**1. DR. HUGH MILLAR,  
CHIEF VETERINARY OFFICER, VICTORIA**

- 1.1 The draft report is a lengthy document at 89 pages. To elicit comment from interested parties, some form of cross-referencing between the precis report and the draft document would be helpful.

**Biosecurity Australia comment:** *Noted. The precis was useful during initial development of the review, by drawing out the main elements of the large body of information contained in the actual review. The precis has served its purpose and it is no longer feasible to maintain a precis as well as a review document. Consequently, the original precis has not been modified to reflect stakeholder comments and other changes to the review.*

- 1.2 I congratulate AQIS (now Biosecurity Australia) on producing an extremely thorough scientific review of leptospirosis.

- 1.3 However, I believe that recommendations in the draft report contain some extremely important implications for future quarantine policy development. In particular, the report embraces a provocative and challenging approach to determining Australia's acceptable level of protection, an approach that Victoria considers requires wider consultation and discussion as a separate issue.

**Biosecurity Australia comment:** *Agree. Biosecurity Australia supports further dialogue on the appropriate level of protection (ALOP). Animal Quarantine Policy Memorandum (AQPM) 1999/26 provides clarification of the concept of ALOP, as used in reports of import risk analyses in developing and reviewing quarantine policy.*

- 1.4 The report recommends that minimal risk reduction measures be implemented to prevent the introduction of exotic serovars of leptospirosis because:
- . while in some cases the entry/exposure risks may be moderate (expected to occur in half the cases),
  - . the consequence risk is low because leptospirosis in animals is not a notifiable disease of animals nationally and prevention and control are not mandatory in all states, BUT
  - . if uniform stricter notification requirements for leptospirosis were imposed nationally, the consequence assessments would be revised to moderate, and the projected risk may change in some cases to the extent where a risk reduction strategy may be appropriate.
- This statement is presented on page 71 of the report but not in the precis of the document.

**Biosecurity Australia comment:** *Noted. No longer necessary as Biosecurity Australia will not maintain an up-to-date precis of the review.*

- 1.5 In assessing the consequence risk, no account seems to have been taken of the fact that leptospirosis is a serious zoonosis (page 45), is of increasing importance as intensive farming practices increase (p4 of report) and a notifiable disease of humans in all States and Territories (page 12 of the report).

**Biosecurity Australia comment:**

*While the review acknowledges that leptospirosis is a notifiable disease of humans, it also clarifies that, compared to other zoonosis, it is not considered one of the most important public health risks in Australia: the Animal Industries Public Health Committee has not listed leptospirosis as one of the nine most critical current and emerging animal*

*industry public health issues in Australia and regard Q-fever as the most important of all zoonotic diseases.*

- 1.6 The fact that leptospirosis in animals is not notifiable nationally does not logically lead to the conclusion that the risk of entry, establishment and spread is “negligible to low”. In fact, the opposite is probably true.

**Biosecurity Australia comment:** *The observation that leptospirosis is not listed nationally as a notifiable disease in the review was made in relation to assessing the probability of adverse consequences arising from the entry, establishment and spread of exotic leptospirosis serovars. Of the 19 scenarios reviewed, the risk of entry, establishment and spread was assessed to be “moderate” in 12 cases, “low” in 5 cases and “negligible” in 2 cases.*

*A country classifies diseases that it considers significant by listing these as notifiable. The Commonwealth depends heavily on the States and Territories for advice on control and eradication programs of significant diseases in determining what sanitary measures should be applied on imports of animal and animal products, and hence what should be a notifiable disease. As leptospirosis is not a notifiable disease in all States and Territories, Biosecurity Australia concluded that the disease is not considered nationally significant and the introduction of an ‘exotic’ serovar will most likely have a negligible to low impact, as defined in Table 13 of the Review.*

- 1.7 The philosophy of the draft report suggests that the list of “nationally” notifiable diseases of animals (currently under review and development by VetComm) may be used in future to determine Australia’s acceptable level of protection and hence dictate quarantine policy. If this is to be so, VetComm needs to be advised officially, the issues debated and a consistent approach adopted. While this philosophy may be valid for quarantine policy relating to serovars that already exist in Australia, the level of protection traditionally adopted by States and Territories has been based on the assumption that Commonwealth import policy will prevent the introduction of exotic pathogenic serovars.

**Biosecurity Australia comment:** *VetComm will be advised officially so that these issues can be discussed [Vetcomm is a committee of State and Territory Chief Veterinary Officers (CVOs) and includes the CVO from New Zealand].*

- 1.8 Levels of protection adopted by States and Territories also depend on the prevalence of leptospirosis within their boundaries. For instance States with a high population of dairy cattle will be more concerned about leptospirosis than those with fewer dairy cattle.

**Biosecurity Australia comment:** *Generally agree. This is a State and Territory issue and may reflect the situation in some States and Territories, but not all. For example, Queensland has the highest number of human notifications for leptospirosis per year (216 notifications in 1999) in Australia with Victoria having 29 notifications during the same year. Leptospirosis is not a notifiable disease of livestock in Queensland. Yet Queensland does not have higher levels of protection against leptospirosis than Victoria.*

- 1.9 Lack of and inconsistent “regulatory” action is cited as another reason for low consequence risk. It should be noted that in the case noted on page 50 of the draft report, the State of Victoria was absolved of blame by the court on appeal.

**Biosecurity Australia comment:** *Noted. In the review it is stated that: “One claim resulted in a judgement of over \$400,000 but this was lost on appeal on grounds of responsibility. The claimant had filed claims only against the meat inspectors and not against the field veterinary service.” As stated by the Judge in handing down the*

*judgment, "The position may have been different in the case of officers of the Veterinary Field Service but the plaintiff's case was against the meat inspectors.*

- 1.10 Formal regulatory action (ie imposition of quarantine) is not always the most appropriate method of dealing with reports of leptospirosis in the first instance. Animal health authorities may offer guidance on management and vaccination strategies without invoking formal regulatory action.

**Biosecurity Australia comment:** *Agreed. The level and type of regulatory control imposed may vary from one jurisdiction to another.*

- 1.11 Current import requirements still reflect an era when animals were imported from only a few "safe" destinations. The modern global trading environment now requires that access requests from higher risk regions such as Africa, South America and the Caribbean be considered. How much do we know about what has entered under the current regime? Page 49 states "there is no evidence", one way or the other. Also page 39 of the report states "international movement of animals has led to a change in the distribution of animal hosts, the spread of leptospire and new host-leptospira relationships." This is surely a compelling reason for taking exotic serovars seriously rather than skewing the IRA by overemphasis on consequence risk, particularly when consequence is measured by current approach(es) to existing, rather than exotic, serovars.

**Biosecurity Australia comment:** *Australia is bound by international agreements to impose measures only when an exotic disease hazard can be identified in an exporting country. There is no evidence to date that any exotic leptospire serovar is more virulent than the serovars present in this country.*

- 1.12 This document highlights the need for uniformity amongst the states in notification of a potentially serious zoonosis such as leptospirosis. Further, if leptospirosis is a notifiable disease in all states in humans, it should be also a notifiable disease in all states in animals. The issue of whether leptospirosis is a notifiable disease also surely affects Australia's ability to accurately report on the leptospirosis status of Australia to the OIE (page 6), especially given that there is no national surveillance system in place for animals (page 7).

**Biosecurity Australia comment:** *See comment under 1.5. Biosecurity Australia supports uniform approaches to issues such as this.*

- 1.13 Victoria strongly supports revision of the OIE Code for leptospirosis.

**Biosecurity Australia comment:** *Noted. Biosecurity Australia is proposing changes to the OIE Code Chapter on leptospirosis.*

- 1.14 Options to facilitate negotiations on health conditions for export in the absence of streptomycin treatment receive only limited coverage in the report.

**Biosecurity Australia comment:** *Noted. A new chapter covering this topic has been added to the review and will include further information as it becomes available.*

- 1.15 Page 44, ii) Spread – the comment is made "...there is no evidence of sv zanoni infection spreading from northern Queensland despite lack of movement control". Given that the disease is not notifiable in either NSW or Queensland and there is currently no active surveillance system of animals in place, are we able to make this comment?

**Biosecurity Australia comment:** *Noted. Biosecurity Australia agrees that spread of this serovar may have occurred but without evidence of this we cannot include this information in the review. The Review has been amended to include this consideration.*

- 1.16 Table 14 page 46 “Progressive Likelihood Matrix” is difficult to understand and would benefit from some clarification in the text. Could there be some labelling (or at least clarification) of the columns in the table?

**Biosecurity Australia comment:** *Noted. This suggestion has been taken into account in the review.*

- 1.17 Page 50 “Thus the introduction of an ‘exotic’ serovar will most likely have a negligible to low impact”. This comment is possibly too broad brush. The consequence effect of an exotic serovar would have to depend on its pathogenicity and the potential adverse public health publicity.

**Biosecurity Australia comment:** *Refer to comment on point 1.5.*

- 1.18 It appears that there is little plan to change the policy to prevent the introduction of exotic serovars. The duty of care seems to be pushed back upon the states and this is potentially an issue that needs to be examined by VetComm so there is a higher degree of uniformity in notification. In this context, it needs to be emphasised that circulating an AQPM to CVOs is not synonymous with consultation with VetComm.

**Biosecurity Australia comment:** *The review supports the current policy of importing livestock and horses without sanitary measures for leptospirosis. The only policy that the review suggests be changed is to re-evaluate the need to test dogs for serovar canicola.*

*Biosecurity Australia agrees that creating a higher degree of uniformity in notification is desirable. Biosecurity Australia will put a proposal to VetComm for consideration on this issue.*

## 2. DR. ROGER MARSHALL, REPORT TO NEW ZEALAND MINISTRY OF AGRICULTURE, FISHERIES AND FORESTRY

- 2.1 This report by AQIS (now Biosecurity Australia) is a very satisfactory and complete review of leptospirosis. It covers the state of this disease, as it is understood today both in Australia and many other parts of the world. The complex nature of the taxonomy and genetic variations within and between organisms making up the pathogenic members of this group and what constitutes a serogroup, a serovar and a genomospecies is quite complex. This complexity leads to difficulties in trying to explain and in some cases understand their identity and therefore distribution. As an additional complication, organisms representing the same serovar may produce different clinical disease manifestations in different countries. For example hardjobovis appears to display a different clinical picture in Australia when compared with its New Zealand counterpart. How much of this variance is due to the different properties of the organism and how much to the host animal's management and to other environmental factors, is not known. Experiments bringing Australian strains of hardjobovis to NZ and determining whether or not they remain clinically typical in manifestation to those in their home country have not been undertaken. It is possible that animal management factors alone may account for differences in the clinical picture exhibited by infected animals. Another example is that of serovar copenhageni infection that is less severe in New Zealand compared with the infection in many other countries particularly those of the tropical regions. Serovar grippotyphosa constitutes an important cattle disease in some countries whereas in others it is apparently of little consequence. Presumably, variation in the virulence and pathogenicity of a particular strain is an important contributory factor and, if so, will require us to vary our projected risk for particular strains.

**Biosecurity Australia comment:** *Noted. Estimation of the probability of adverse consequences must be based on scientific evidence. Despite advances in scientific knowledge of leptospirosis, the occurrence of unusual outbreaks of leptospirosis in many countries and the appearance of more pathogenic strains of endemic serovars in several countries have had no significant adverse impact, eg. the disruption of trade or interference with the international movement of animals. In most cases these incidents have not resulted in changes to the import conditions for this disease, despite the inadequacy of risk measures to effectively prevent the introduction of exotic serovars or more pathogenic strains of endemic serovars. Past history does not provide support for the need to vary projected risk for particular strains.*

- 2.2 Another truism that is sometimes forgotten is that the level of knowledge for a particular country depends upon the amount and level of sophistication of scientific research conducted in that country. Indeed the level of knowledge and thus importance of this disease in a particular country is in some measure a function of the level of scientific research into leptospirosis. In large countries such as Australia, the level of knowledge may even vary from state to state. In some parts of Australia little or no investigative work has been carried out into leptospirosis and the climate and terrain in these areas may be different from those areas where a great deal is known. The absence of data about a particular serovar does not mean that this serovar is not present in that part of the country it may merely indicate that it has not been investigated.

**Biosecurity Australia comment:** *Accepted. However, as a member of the WTO, Biosecurity Australia must ensure that each measure "is based on scientific principles and is not maintained without sufficient scientific evidence...". The estimated risk*

*associated with importation of exotic leptospire serovars is based on currently available scientific information.*

- 2.3 When considering the risk of introducing new serovars/genomospecies New Zealand may be taken as a model. It must be remembered that probably all 8 presently isolated strains of leptospira that are in this country have been introduced in the last 1000 years (since Maori habitation). Indeed most are likely to have come into the country with domestic and wildlife mammalian species in the past 200 years (since European habitation). It is very likely that hardjobovis and pomona were both introduced into Australia with the introduction of domestic livestock. The large variety of native mammals makes it difficult to be sure just when and how the other strains came into that country. The establishment of some introduced serovars may have been, in the past, quite slow. For this reason one cannot be sure that there are not strains that are at the present time in the process of establishing themselves and that have the potential to become quite widespread through the animal and even human population.

**Biosecurity Australia comment:** See 2.2.

- 2.4 *Dr Marshall commented on a number of specific topics in the review, in particular*

- Chapter 1 - mild type leptospirosis in humans;
- Chapter 8 - serovar balcanica;  
- serovar medanensis;
- Chapter 9 - infection as a result of ingesting food and inhaling particles;  
- direct transmission;  
- factors affecting severity of leptospirosis;
- Chapter 10 - vaccination of animals;  
- evidence of spread of sv zanoni.

**Biosecurity Australia comment:** *Noted and taken into account in the review.*

- 2.5 In Chapter 11: “Risk evaluation”, the conclusion that... “when the projected risk is negligible or low, the animal product meets Australia’s acceptable level of protection without requiring risk reduction strategies,”.. may be correct but whether or not it should be correct is arguable. For example (Table 16) “Importing a dog from a country that reports dogs with antibody titres to svb batavia, bratislava, javanica and cynopteri, none of which has been reported in Australia,” is reported to be a moderate risk. This could lead to the introduction of one or more of these serovars into Australia and allow the organism/s to become established in one of the many wildlife species or a domestic animal. Introduced organisms might not act as they do in their country of origin and indeed might increase in virulence and pathogenicity. The wide range of wildlife species and the wide variation of environmental conditions prevailing in Australia could make that country vulnerable to such introductions.

**Biosecurity Australia comment:** *Noted. There is no evidence to suggest that these exotic serovars are of greater virulence than those already present in this country. Hence the imposition of measures is not required.*

- 2.6 In Chapter 13 “Implications for quarantine policy”, the statement “...if introduced, (exotic strains) may eventually adapt to a new host within the country and become impossible to eradicate” is indeed true and a point of which heed should be taken. There is no need even for the strain to adapt to a new host, it may find one closely related to that from whence it came. As I have already stated, most even perhaps all, strains found in NZ have been introduced and in Australia probably two have come in with domestic stock. Serovar pomona

has undoubtedly cost the pig industry a lot of money in both Australia and NZ, as has hardjo, the dairy industry. I believe that the risk assessments should be reconsidered in the light of these losses as well as factoring in the human health costs. Possibly some of the other serovars should also be reassessed.

**Biosecurity Australia comment:** *The paragraph from where this sentence originated states: "Risk reduction strategies should be based on scientific evidence. There is a school of thought that exotic strains, if introduced, may eventually adapt to a new host within the country and become impossible to eradicate. However, there does not appear to be any scientific evidence or pertinent information to support this hypothesis."*

*While serovars hardjobovis and pomona appear to have been introduced with domestic stock, they are widespread in most countries where these animals are found. Cattle and pigs are well recognised as long term carriers of sv hardjobovis and pomona respectively. Of the two serovars, only sv pomona has been isolated from Australian wildlife, namely Rattus fuscipes (bush rat). There is no report of adverse effects of this serovar in this species. While leptospirosis can affect animal production and farm profitability, analyses of animal health economics on the farm may not always justify the expense of a vaccination program, especially in beef cattle and sheep. As the human health costs have also been factored in the risk assessment, there is no need to reassess the risks.*

**3. DR ALICK LASCELLES,  
CONSULTANT FOR THE NATIONAL FARMERS FEDERATION**

- 3.1 AQIS (now Biosecurity Australia) experts have compiled an exhaustive review of leptospirosis and its implications with regard to future quarantine policy. The complexity of the leptospirosis story is such that there has been a reluctance in the past to take on the task of conducting a meaningful review and attempting to set quarantine conditions in a scientifically plausible way. This draft review is indeed comprehensive and the analysis of the review findings has been objectively and quite boldly presented.

**Biosecurity Australia comment:** *Noted.*

- 3.2 It is made clear that appropriate antibiotic treatment of semen and embryos virtually removes any quarantine risk in respect of leptospira, another illustration of the safety of semen and embryos as a means of trade in genetic material. On the other hand a case has been made that quarantine conditions for leptospirosis in the trade of domestic livestock imposed by a number of our trading partners are probably not doing the job intended.

**Biosecurity Australia comment:** *Noted.*

- 3.3 The table at appendix 1 provides a comprehensive list of serovars sorted by serogroup and genomospecies, which is entirely clear. The text from page 33 onwards I found a little confusing. Serogroup and genomospecies seem to be used interchangeably. Perhaps the author might check this out.

**Biosecurity Australia comment:** *Noted. Clarified in the Review (page 1 footnote).*