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**NHMRC Special Expert Committee on
Transmissible Spongiform
Encephalopathies**

Report on activities in 2001



NHMRC

*National Health &
Medical Research Council*

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The strategic intent of the NHMRC is to provide leadership and work with other relevant organisations to improve the health of all Australians by:

- fostering and supporting a high quality and internationally recognised research base;
- providing evidence based advice;
- applying research evidence to health issues thus translating research into better health practice and outcomes; and
- promoting informed debate on health and medical research, health ethics and related issues.

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LIST OF ABBREVIATIONS

AFFA	Department of Agriculture, Fisheries and Forestry – Australia
ANZFA	Australia New Zealand Food Authority
AQIS	Australian Quarantine and Inspection Service
AVA	Australian Veterinary Association
BSE	bovine spongiform encephalopathy
cCJD	classical Creutzfeldt-Jakob disease
CJD	Creutzfeldt-Jakob disease
EU	European Union
DoHA	Commonwealth Department of Health and Ageing
FAO	Food and Agriculture Organisation of the United Nations
NHMRC	National Health and Medical Research Council
OIE	Office International des Epizooties, World Organization for Animal Health
SECTSE	Special Expert Committee on Transmissible Spongiform Encephalopathies
TGA	Therapeutic Goods Administration
TSE	transmissible spongiform encephalopathy
vCJD	variant Creutzfeldt-Jakob disease
WHO	World Health Organization

FOREWORD

Bovine spongiform encephalopathy (BSE) and variant Creutzfeldt-Jakob disease (vCJD) belong to the group of animal and human diseases known as transmissible spongiform encephalopathies (TSEs). The combined events of an outbreak of BSE in the UK, and the discovery that BSE could be transmitted to humans in the form of vCJD, an invariably fatal disease, lead to worldwide concern. There have been no cases of vCJD reported in Australia, nor have there been any cases of BSE in Australian cattle, but there is no room for complacency, and Australia responded to these developments by undertaking a whole-of-government, rigorous examination of its policies and preparedness to deal with potential cases of both BSE and vCJD. In September 2001 a case of BSE was reported in Japan, underscoring the need for a global approach to TSEs, and the need for sound policies underpinned by science.



Chair - Graeme Ryan

Addressing an issue as complex as TSEs involves many complex questions of science. The National Health and Medical Research Council Special Expert Committee on Transmissible Spongiform Encephalopathies (SECTSE) has been established as a principal source of independent, scientific advice for government, to review the scientific evidence on which policies aimed at minimising the risk should be based.

From a scientific perspective, there is much that is not yet known about TSEs. For example, while it is generally accepted that vCJD is caused by the transmission of the BSE agent to humans, the precise mechanism of transmission is not known. There is also no test that is conclusive in detecting vCJD before a person becomes symptomatic, and such a test could be some years away. The complexity is increased by the need to derive an appropriate balance between minimising the remote and unproven risk of transmission of vCJD and the real risk of harm to Australians if, for example, deferral of blood donors led to too few donors and insufficient blood products.

The first year of SECTSE's existence has been an intensely busy and productive one. The breadth of expertise of SECTSE's members has marshalled the scientific and technical advice needed to develop a body of scientific knowledge and expertise, and SECTSE has also consulted with the diversity of intra-government departmental parties and external parties involved in addressing the multiplicity of issues which are related to TSEs. The Committee has also been guided by international best practice in protecting against the risks of TSEs, including advice developed by

international organisations such as the World Health Organization (WHO) and the Office International des Epizooties, World Organization for Animal Health (OIE)

I would like to thank the SECTSE members and the officers of the various government agencies with whom the Committee has dealt for their energy and commitment to the Committee's work. The collaborative nature and concerted efforts in responding to this public health risk with a coordinated national response have been commendable. SECTSE will continue to provide expert scientific and technical advice to inform Australia's ongoing response to these issues.

Professor Graeme B. Ryan AC
Chair
NHMRC Special Expert Committee on
Transmissible Spongiform Encephalopathies

SECTSE'S ROLE

In December 2000 the Government invited the National Health and Medical Research Council to establish a Special Expert Committee on Transmissible Spongiform Encephalopathies (SECTSE). The Committee provides the government with independent specialist scientific advice on all matters necessary to prevent and limit the spread of TSEs in Australia. Its membership (provided in Appendix 1) includes some of Australia's leading experts in a range of human and animal health disciplines.

SECTSE'S TERMS OF REFERENCE

SECTSE's Terms of Reference require the Committee to provide expert and timely advice to Australian governments on all matters necessary to prevent and limit the spread of vCJD and other transmissible TSEs in Australia.

In particular to:

1. Take such steps as are necessary to provide prompt advice about TSE risks and measures to protect the health of Australians, having due regard to:
 - international best-practice in protection against the risks of TSEs, including advice developed by international organisations such as WHO and OIE;
 - assessment of any current or future TSE risks for the Australian population;
 - surveillance requirements for the earliest possible detection of any emerging risks;
 - research necessary to develop the evidence base on TSE risk for Australia;
 - professional education about TSEs; and
 - the most appropriate means for communicating information about levels of risk and preventive measures to the Australian public.
2. Receive and provide timely advice regarding reports from Australian governments, and from other relevant sources on:
 - measures implemented to limit TSE risk in the Australian population; and
 - results from all relevant surveillance, risk assessment and research activities.
3. Seek such other information from overseas and Australian sources as is necessary to discharge its advisory functions.
4. Assess the adequacy of the control measures implemented by Australian governments, and provide prompt advice about how these measures might be improved.
5. Provide formal reports on a regular basis to the Council.

CONDUCT OF MEETINGS AND COMMITTEE BUSINESS

SECTSE met on five occasions in 2001 and, between meetings, progressed its activities via teleconferences. Members are bound by the NHMRC's committee procedures, which require members of NHMRC committees, when accepting membership, to declare any conflict of interest in a matter being considered. At the beginning of each SECTSE meeting, members are asked to declare any conflicts of interest with respect to each agenda item as it is presented for discussion.

At the first meeting, members acknowledged the need to maintain open communication with the media and public on issues under consideration, and a media release is provided for this purpose following each meeting. The media releases are also posted on the NHMRC website (<http://www.nhmrc.gov.au>), together with other SECTSE information. They are reproduced in this report at Appendix 2.

THE WORK OF THE COMMITTEE IN 2001

At its first meeting, the Committee discussed the priority issues which are crucial to identifying and assessing risks to the Australian community from TSEs. There are three main routes of potential TSE transmission to humans: food, blood, and medical procedures/therapeutics.

SECTSE has proceeded to assess the level of risk in each of these areas and, based on scientific findings, has provided input to the development of a contingency plan for vCJD and national response plans for BSE and vCJD. These plans articulate an agreed approach in each area for minimising the risk to the community in the event of a confirmed case of BSE or vCJD.

In addition, a national TSE response plan is being developed with input from all agencies which seeks to list comprehensively all potential areas of TSE transmission and examine the evidence for transmissibility in each possible circumstance. It also serves to highlight any gaps in contingency plans developed to date.

The Committee has received submissions from a range of government agencies and provided scientific and technical advice on many aspects of government policy developed to prevent TSEs from gaining a foothold in Australia. Major activities are listed below.

MEDICINES, MEDICAL DEVICES AND THERAPEUTIC GOODS

The Committee endorsed the approach taken by the Therapeutic Goods Administration (TGA) in relation to minimising the potential risk of exposure to TSEs through the use of medicines and medical devices. The TGA requires that all new products included on the Australian Register of Therapeutic Goods which contain or use in their manufacture animal or human products, should be sourced only from BSE-free countries or, where this is not possible, requires evidence as to the safety from TSEs of the material used. The TGA is also well advanced in its review of all items on this Register to identify any BSE-related risk. Those medications that are derived from beef products have been identified and the manufacturers asked to provide evidence of their BSE-free origins. Medical devices are also being examined.

SECTSE also considered the TGA's re-evaluation of vaccines supplied into Australia. It endorsed TGA's view that, although a number of vaccines contain processed ingredients of bovine origin, any risk of potential transmission of BSE posed by vaccines supplied in Australia is extremely remote and far outweighed by the benefits of immunisation.

A detailed audit of bovine insulin used by diabetics in Australia showed that some bovine insulin available in Australia may contain small amounts of Dutch-derived bovine insulin. The vast majority of bovine insulin products in Australia are sourced from North America, which is classified as BSE-free, while a small number of cases

of BSE have been reported in the Netherlands. While there is no direct evidence to link bovine insulin to vCJD, as a precautionary measure the TGA moved to ensure that all stocks still held by the supplier had been quarantined, and that all future batches of bovine insulin are certified as sourced from BSE-free countries. SECTSE reviewed this information at the time and advised that the available evidence and evaluation of the manufacturing processes involved indicated there is a very low risk of BSE transmission through bovine insulin products, compared with the real risk to the health of diabetics if their treatment was disrupted.

SECTSE also noted and endorsed the work undertaken by TGA with regard to complementary medicines. TGA reviewed the origin and manufacture of existing approved products which may contain animal-derived ingredients, thereby ensuring that Australians are protected from risk of BSE exposure through these medicines.

Lyodura is lyophilised, irradiated human dura mater used primarily in neurosurgery. It was approved by the TGA for importation and use in Australia in 1972, but this licence was withdrawn in 1987 when a case of CJD was identified in a dura mater recipient in the USA in that year. Quantification of the number of Australians who may have been exposed to Lyodura has been undertaken. SECTSE is collaborating with the Royal Australasian College of Surgeons in addressing this issue.

BLOOD SUPPLY AND BLOOD PRODUCTS

While there is international consensus that the theoretical possibility exists that the agent for vCJD could be transferred by blood or blood products, there is no direct scientific evidence. As a precautionary measure, however, in December 2000 blood donors in Australia who lived in the United Kingdom between 1980 and 1996 for a period of 6 months or more were deferred from donating blood.

SECTSE has discussed further measures to protect the blood supply and has closely monitored overseas approaches, noting that the USA and Canada propose to extend their donor deferral measures to include donors who have travelled for extended periods to other countries where BSE has now been identified in cattle. The Committee endorsed a plan by the Australian Red Cross Blood Service to survey 16,000 blood donors to ascertain their travel histories. The results of the survey, due mid-2002, will be analysed by SECTSE, enabling Australian governments to make an informed decision about any extension of donor deferral measures.

The TGA has evaluated products derived from human blood products used in the treatment of blood disorders etc for potential TSE risks. To date they have found no products which present urgent concerns.

MEMBER PERSPECTIVE – DR TONY KELLER

Dr Tony Keller is the Director of the Australian Red Cross Blood Service's North West Region in Western Australia, and a member of SECTSE.



Dr Tony Keller

Australia has one of the safest blood supplies in the world, and our blood safety standards conform to international best practice. All volunteer blood donors are carefully screened before donating, and the collected blood then undergoes further rigorous testing.

Australia has responded quickly to new viral hazards such as hepatitis B, HIV and hepatitis C to ensure maximum safety of the blood supply, introducing new donor selection criteria and new tests as they became available.

The publication of scientific data suggesting that vCJD can be transmitted experimentally by blood in animals, presents a new challenge. There is no test available by which to screen and eliminate contaminated blood donations infected with vCJD, nor is there a treatment available for blood and blood products which can successfully deactivate the infectious agent giving rise to vCJD.

While there has not been a single documented case of vCJD transmitted by blood transfusion in Australia, or anywhere in the world, Australian Health Ministers agreed that persons who have lived for a cumulative period of six months or more in the UK between 1980 and 1996 inclusive should, for the time being, be deferred from donating blood. This action, which became effective on 21 December 2000, was taken as a precautionary measure in response to the potential risk of transmission of vCJD through blood.

Deferral of these donors has resulted in a reduction of over 5 per cent in all blood donations, and a range of strategies has been introduced by health authorities and the Australian Red Cross Blood Service to ensure that blood centres will have adequate supplies, in particular, the running of campaigns to recruit new donors to compensate for donations foregone.

The six month cut-off point is identical to that implemented by the United States of America, Canada and New Zealand. The number of cases of BSE occurring in countries other than the UK has been small, which is why there is no deferral policy for people who have lived or travelled in other countries. However, the issue is under active consideration by public health authorities in a number of countries, including Australia. In 2002, the Australian Red Cross Blood Service will conduct a donor travel survey to inform health authorities about any further decisions on donor deferral measures.

The approach that Australia has taken is a balanced one, which protects patients from an unknown and unproven risk without exposing them to the 'real' risk of harm if there was a shortage of blood or blood products.

ORGAN AND TISSUE DONATION

The Committee sought advice on organ transplantation policies in the USA and Canada to inform its deliberations in this area. The issue of life saving/major quality-of-life improvement for an organ donor recipient needs to be weighed up against the theoretical risk of transmission of vCJD. Unlike blood donations, where plasma is pooled and blood products are distributed to a large number of recipients, organ donation is effected on a one-on-one basis. As such, the issue of vCJD and organ donation is addressed on a case-by-case basis, with comprehensive screening of the potential organ donor being undertaken. The Committee undertook a survey of practices of organisations involved in organ and tissue transplantation in Australia, and in 2002 will investigate the need for uniform protocols in this area.

FOOD ISSUES

The risk of transmission of BSE via food can be minimised by banning or restricting the importation of cattle, beef, beef products or other products sourced from cattle from countries where BSE is present. In January 2001, Australia banned the importation of beef and beef products from all BSE-affected countries in Europe. Imports of beef and beef products from Japan were suspended in September 2001 following the confirmation of a BSE case in that country.

As yet, however, there is no test for BSE in processed beef which enables Australia to ensure that all beef products entering Australia for human consumption are derived from animals free from BSE. Australia relies on a system of certification by each exporting country that the appropriate steps have been taken to ensure that their cattle are free of BSE. SECTSE considered the scientific basis of these certification measures prior to their introduction by the Government in July 2001 via an amendment to the Food Standards Code. The measure is administered by the Australian Quarantine and Inspection Service (AQIS) on advice from the Australia New Zealand Food Authority (ANZFA) and came into full effect in November 2001. It is strongly supported by SECTSE.

SECTSE also provided technical and scientific advice to ANZFA's draft risk assessment on the scientific and technical aspects of human exposure to the BSE agent via the food chain.

MEMBER PERSPECTIVE – MS AMANDA HILL

Ms Amanda Hill is an immunologist employed by the Australia New Zealand Food Authority (ANZFA), and a member of SECTSE.

Variant Creutzfeldt-Jakob disease (vCJD), a rare and fatal human neuro-degenerative disorder, was first reported in the United Kingdom in 1996. The disease affects younger people (average age 29 years) and is characterized by neurological symptoms including psychiatric symptoms, difficulty in walking, involuntary movements and loss of speech.

There is a scientifically accepted association between the consumption of beef and beef products and the development of vCJD. Although an infectious oral dose of the BSE agent has not been determined for humans, experimental data indicate that a single dose is sufficient to cause BSE in cattle. Consequently the emergence of vCJD has caused worldwide concern about the use of bovine materials in the production of food for human consumption.



Ms Amanda Hill

ANZFA is a Commonwealth statutory authority responsible for the protection of public health and safety by maintaining a safe food supply. ANZFA has developed appropriate measures to manage the risk of human exposure to the BSE agent through the introduction into the Food Standards Code on 18 July 2001 requiring that all beef and beef products sold in Australia be derived from animals free from BSE. These restrictions do not include milk and dairy products, gelatine, fats and tallow, collagen from bovine skins and hides, and non-beef flavourings, as current scientific evidence indicates these products present a minimal risk for transmission of the BSE agent. As there is yet no test for BSE in food, the new standard relies on a new certification system that will determine the conditions under which beef and beef products may enter Australia. This new certification measure came into full effect on 16 November 2001. Countries with reported cases of indigenous BSE in their cattle populations have been allocated to the highest BSE-risk category and consignments of beef and beef products cannot be imported into Australia.

A comprehensive risk assessment has also been conducted by ANZFA to determine the risk of human exposure to the BSE agent through food consumption. The human exposure risk has been evaluated by determining the critical pathways for exposure to the BSE agent, the level of exposure and the effects of processing on inactivation of the BSE agent. The assessment considers countries that have or could have BSE in their cattle population and potentially could have exposed the public to infectious material from clinically healthy, BSE-infected, slaughtered animals.

AGRICULTURE

SECTSE has provided input to the contingency plan for BSE developed by the Commonwealth Department of Agriculture, Fisheries and Forestry (AFFA). The key purpose of the plan is to articulate an agreed policy for eradication, should there be an occurrence of BSE in Australia. The Committee has also provided advice to AFFA on the risk assessment it has prepared on the importation of cattle from Europe.

Australia imposed a ban on the import of stockfeed of animal origin in 1966, well ahead of studies which linked BSE to the feeding of meat and bone meal to cattle. Given the scientific uncertainties about the safety of feeding animal material to ruminants, SECTSE supported the decision in March 2001 by Australian Agriculture Ministers to extend the ban on the feeding of specified animal proteins to ruminant animals such as cattle and sheep, through the removal of exemptions which had previously allowed the feeding of pig, horse, kangaroo, poultry and fish material to ruminants. All Australian jurisdictions have effected legislative amendments to give effect to this decision. Audit and testing activities facilitate compliance with the legislation.

AFFA has implemented a National Transmissible Spongiform Encephalopathy Surveillance Program and ensures that Australia complies with the requirements of the OIE for monitoring BSE and other animal TSEs. The surveillance and monitoring program is designed to ensure that Australia remains free of BSE and scrapie. Scrapie is a naturally occurring TSE of sheep and goats. AFFA's surveillance activity and test results are included on the Animal Health Australia website (<http://www.aahc.com.au/surveillance/ntsesp/index.htm>).

SECTSE also endorsed a paper on quarantine policy for the importation of genetic material from TSE-susceptible species; and noted the decision of Agriculture Ministers to form a high level National Management Group to oversee preventive measures for BSE and foot and mouth disease.

The European Union (EU) undertakes geographical risk assessments of countries' BSE status. Australia is one of only eleven countries which meets the EU's 'level 1 status', which denotes that BSE is highly unlikely in a country. This is indicative of the sound basis of the preventive measures which Australia has adopted.

MEMBER PERSPECTIVE – DR KEVIN DOYLE

Dr Kevin Doyle is the National Veterinarian with the Australian Veterinary Association (AVA), a former Australian Deputy Chief Veterinary Officer, an expert in animal health, quarantine and risk analysis issues, and a member of SECTSE.



BSE is a chronic degenerative disease affecting the central nervous system of cattle. Affected cattle die of the disease, for which there is no treatment or vaccine, nor is there any certainty about its initial cause.

It has become clear that possible exposure to BSE through international trade in contaminated beef products could potentially pose a risk of vCJD in humans. Australia has been closely watching developments related to BSE. Increased testing and surveillance in many European countries, including countries that had not previously reported confirmed cases of BSE in their cattle, have demonstrated that BSE is more widespread than was initially thought. This is probably through trade in live animals and animal feed, and also via the feeding of contaminated ruminant meat and bone meal to other ruminants. The possible risk of spread of BSE to sheep in BSE-affected countries has the potential to affect consumption of, and trade in, sheep products, and there is also a need for monitoring of developments in TSEs of sheep.

The AVA has strong links with the universities and research community, as well as the Department of Agriculture, Fisheries and Forestry – Australia (AFFA) and Animal Health Australia. AVA is working with AFFA to research and implement animal health protection measures aimed at minimising the potential risk of introduction and transmission of TSEs through animals and animal feeding practices. AFFA also works closely with the beef and sheep industries through the industry-government SAFEMEAT coalition.

Australia is one of the world's leading producers of cattle, and is the world's largest exporter of beef. Timely action aimed at maintaining Australia's BSE-free status is vitally important to assure domestic and overseas consumers of the safety of Australian beef, and to maintain market access to trading partners.

This action includes strict controls and restrictions of imports of live animals, genetic material and animal feedstuffs; a ban on feeding meat and bone meal to ruminant animals; a national surveillance program; and strict quarantine measures.

Australia is one of only eleven countries judged by the European Union to meet 'Level 1' status, which indicates: *it is highly unlikely that domestic cattle are (clinically or pre-clinically) infected with the BSE-agent*. This result is attributable in no small part to these soundly-based preventive measures, and a cooperative approach by government and industry to their implementation.

Continuous monitoring of the effectiveness and appropriateness of these measures, in the event of new scientific findings or experience, will continue to be a primary focus of SECTSE's efforts.

INFECTION CONTROL

SECTSE has provided advice on a chapter on CJD for the NHMRC document *Infection control in health care settings: guidelines for the prevention of transmission of infectious diseases*. A discussion paper on the ethical issues pertaining to the higher risk groups has been developed, since familial CJD presents particular ethical difficulties in the context of effective infection control. The next step is to provide guidance for practitioners on these issues.

SECTSE also reviewed the published evidence for the transmission of TSE diseases following surgery, and noted the scientific uncertainty surrounding the risk of transmission of vCJD/CJD through the re-use of surgical instruments. Further work on these issues will continue in 2002.

INTERNET SHOPPING

SECTSE cautioned Internet users on the potential risks of contracting vCJD associated with some products that are available via the Internet, and which contain or use material of animal origin from overseas in their manufacture and are offered as nutritional supplements. In doing so, it noted that AQIS had mounted a public awareness campaign to highlight the potential threat of introducing unwanted, and even dangerous, pests and diseases through importing materials via the Internet. AQIS also instituted inspection of international mail items arriving in Australia to address these pest and disease risks.

COMMUNICATING THE POTENTIAL RISK TO THE PUBLIC

It is important to public trust and understanding that measures that have been implemented to manage the potential risk of TSEs and protect the public, are widely disseminated. In doing so, it is also important to convey the magnitude of risk – noting that it is still a theoretical risk – in a meaningful way.

It was noted earlier that SECTSE issues media releases after each of its meetings, which are also posted on the NHMRC website (<http://www.nhmrc.gov.au>), together with other SECTSE information.

In addition, consumer versions of contingency plans are being developed. Similarly, a consumer/media version of the clinical response plan, which outlines how the health system will respond should a case of vCJD be diagnosed in Australia, is also being developed. ANZFA is drafting a public version of its risk assessment on the scientific and technical aspects of human exposure to the BSE agent via the food chain.

AFFA's surveillance activity under its National Transmissible Spongiform Encephalopathy Surveillance Program, and test results, are included on the Animal Health Australia website (<http://www.aahc.com.au/surveillance/ntsesp/index.htm>).

MONITORING INTERNATIONAL DEVELOPMENTS; INTERNATIONAL LINKS

It is of vital importance that SECTSE regularly reviews its approach to minimising the risk of TSEs and to consider whether new scientific knowledge, or new international developments, suggest a revised approach in any of the areas under consideration. This ensures that Australia's approach is aligned to best practice overseas. For example, late in 2001 there was conjecture in both the scientific literature and media reports about the theoretical possibility that BSE is in the UK sheep population. However, currently there is no scientific evidence that BSE is present in sheep flocks in the UK or anywhere else in the world. SECTSE will continue to closely monitor the situation and respond if necessary.

On the animal health and food side, the work of WHO on TSEs provides guidance to both the OIE and the Food and Agriculture Organisation of the United Nations (FAO) in establishing standards and policies, and is closely followed by AFFA and ANZFA in their work.

On the health side, in addition to WHO guidance, SECTSE also monitors the deliberations of the US Food and Drug Administration's TSE Program. Professor Colin Masters, a member of SECTSE, is also a member of the UK's Spongiform Encephalopathy Advisory Committee, enabling a valuable exchange of information. The Chair of New Zealand's BSE Expert Science Panel has attended a SECTSE meeting in an observer capacity, and there are plans to formalise such links.

MEMBER PERSPECTIVE – PROFESSOR COLIN MASTERS

Professor Masters is in the Department of Pathology at the University of Melbourne, a recognised international expert in prions and TSEs, and a member of SECTSE.

His membership of the United Kingdom's Spongiform Encephalopathy Advisory Committee (SEAC) has facilitated the acknowledged need to address the complex issues that TSEs raise on a global, collaborative basis.

SEAC's terms of reference are very similar to SECTSE's: it is the expert panel assisting Government in relation to all manner of issues relating to TSEs. In contrast to the UK, there have been no cases of vCJD reported in Australia, nor have there been any cases of BSE in Australian cattle, but the issues are similar, as is the need to be clear on the facts, and the uncertainties, around aspects of the science of TSEs.



Professor Colin Masters

In addition to the sharing of expertise, Professor Masters' membership of SEAC facilitates timely access to new research findings and insight into how other countries are approaching this important public health issue.

Elsewhere in this report, the importance of maintaining international links is noted, together with details of the main international organisations, the deliberations of which are integral to SECTSE's work. The Australian National Creutzfeldt-Jakob Disease Registry (ANCJDR) provides a further mechanism for international collaboration in relation to TSE epidemiology and surveillance activities. Dr Steven Collins, also a member of SECTSE, plays a pivotal role in the Registry's activities. The ANCJDR has been involved in EUROCID since 1997, and is currently associated with two European Commission Concerted Actions: "Human Transmissible Spongiform Encephalopathies; the neuropathology network (PRIONET)" 2000-2003; and "Creutzfeldt-Jakob Disease: epidemiology, risk factors and diagnostic tests (EUROCID)" 2000-2003. This latter group is focussing on the clinical and epidemiological surveillance of TSEs in France, Germany, Italy, Spain, the Netherlands and the UK.

Active association with EUROCID requires attendance at their meetings, at which individual countries report their most recent national surveillance experience, followed by specific items of interest. Dr Collins attends these meetings. In 2001, such items included preliminary analysis of all prospective CJD cases (totalling around 1000 patients) from France, Germany, Spain, Italy, UK, Austria, Australia and the Netherlands; and discussion concerning treatment of CJD with quinacrine and chlorpromazine. Many European surveillance registries are aware of, or are conducting, open observational studies of the utility of these treatments.

The ANCJDR is also involved in a new European Commission Concerted Action application aimed at evaluating novel diagnostic techniques for human TSEs such as protease-resistant prion protein detection in urine, new CSF diagnostic markers, and capillary electrophoresis of blood for protease-resistant prion proteins.

The ANCJDR also participates, on an ad hoc basis, in activities at the request of various WHO agencies. Currently it is involved in a project auspiced by the National Institute for Biological Standards and Control attempting to standardise the nomenclature for human brain protease-resistant prion protein glycoforms. The ANCJDR has also been invited by the WHO to become a Regional Reference Centre for TSEs.

It is still too early to predict how the BSE and vCJD epidemics will evolve, but it is of vital importance to Australians that through these links we have forged, SECTSE is attuned to emerging research, and to developments in other countries.

FUTURE WORK

SECTSE will continue to review the epidemiology of TSEs. Scientific knowledge on TSEs continues to evolve, but ongoing research is needed to better understand the infective agent and to develop needed diagnostic tools, therapies and preventive measures for humans and animals. SECTSE will continue to monitor international developments and scientific findings so that, if warranted, it can re-assess its advice to governments, ensuring that Australia is well prepared to meet this challenge to public health.

RESEARCH
INDICATED

APPENDIX 1: SECTSE MEMBERSHIP IN 2001

Professor Graeme Ryan	Chair; Expert in pathology
Professor Michael Alpers	Expert in prions and TSEs
Dr Chris Baldock	Expert in agricultural and veterinary epidemiology
Dr Steven Collins	Expert in neurology
Dr Kevin Doyle	Expert in quarantine and risk analysis
Professor Lyn Gilbert	Expert in communicable diseases and quarantine testing
Professor Adele Green	Expert in medical epidemiology
Ms Amanda Hill	Expert in food safety
Dr Terri Jackson	Expert in health economics
Professor John Kaldor	Expert in human risk assessment
Dr Anthony Keller	Expert in blood transfusion
Professor Peter McDonald	Expert in communicable diseases
Associate Professor Paul McNeill	Expert in human ethics
Professor Colin Masters	Expert in prions and TSEs
Associate Professor Peter Reilly	Expert in surgery/neurosurgery
Professor Trang Thomas	Representative of consumer interests

APPENDIX 2: MEDIA RELEASES IN 2001



MEDIA RELEASE

1 February, 2001

NHMRC Special Expert Committee on TSE's sets strategic directions

AUSTRALIA'S peak public health advisory and medical research body, the National Health and Medical Research Council (NHMRC), has established a special expert committee to advise Government on issues relating to Transmissible Spongiform Encephalopathies (TSEs), including Bovine Spongiform Encephalopathy (BSE) – commonly known as “mad cow disease” and its human equivalent, variant Creutzfeld Jakob Disease (vCJD).

The Committee met for the first time on Tuesday 30 January, discussing its Terms of Reference and priority issues crucial to identifying and assessing risks to the Australian community from TSE's.

Professor Graeme Ryan, Chair of the Special Expert Committee, said:

“the Committee will immediately begin work to evaluate the risks relating to TSE's and the Government has asked us to investigate such issues as blood and organ donation, animal feeding practices, food and medicines.

Professor Ryan also said the Committee's risk assessment processes will focus on ways through which BSE, vCJD, scrapie and other TSEs may enter Australia and could be transmitted to humans within Australia.

“We must also explore the requirements for, and possible impediments to, effective surveillance systems in Australia for BSE and its human equivalents.,” Professor Ryan said.

“The Committee will be commenting on emerging technologies that may inform risk assessment and risk management, as well as on the control measures and policies already introduced by the Government. We will also provide advice on surveillance and research, as well as action to minimise all identified or potential risks to the Australian population.” Professor Ryan said.

At its first meeting the Special Expert Committee also agreed that within two weeks of every meeting, the NHMRC would provide a media release summarising key issues. Media releases would also be posted on the NHMRC web site with other relevant documents. “It is important that we maintain open communication with the media and public on these matters.” said Professor Ryan.



MEDIA RELEASE

5 April 2001

RISK OF 'MAD COW' DISEASE REDUCED BY EARLY RESPONSE IN AUSTRALIA

Early response and continuing risk management have provided a significant degree of protection for Australia from Bovine Spongiform Encephalopathy (BSE) and its human equivalent, variant Creutzfeldt-Jakob Disease (vCJD), but there are no grounds for complacency, the chair of the National Health and Medical Research Council's Special Expert Committee on TSEs (SECTSE), Professor Graeme Ryan, said today.

Speaking after the second meeting of SECTSE, held in Melbourne today, Professor Ryan said the global issue of BSE in cattle had entered a new dimension and, while Australia was one of the few countries in the world that was BSE-free, it was essential to keep ahead of international standards.

"SECTSE has been given the task of providing the scientific basis for Australia's approaches to BSE, vCJD and other transmissible spongiform encephalopathies (TSEs) and to give expert advice to inform Australia's ongoing response to these issues," he said.

Professor Ryan said the Committee today considered current scientific evidence and information provided by the Therapeutic Goods Administration (TGA), the Australia New Zealand Food Authority (ANZFA), the Department of Agriculture, Fisheries, Forestry Australia (AFFA) and the Australian Red Cross Blood Service (ARCBS).

The Committee endorsed the approach taken by the TGA in relation to minimising the potential risk of exposure to TSEs through the use of medicines and medical devices.

In particular:

- the TGA will continue to require that all new products included on the Australian Register of Therapeutic Goods which contain or use in their manufacture animal or human products, should be sourced only from BSE-free countries or, where this is not possible, evidence as to the safety from TSE of the material used; and

- the TGA will continue its review of existing medicines and medical devices to identify any potential risks of exposure to TSEs with a view to removing the use of animal or human products sourced from non-BSE-free countries, except where such use can be fully justified.

In addition the Committee noted that the TGA has reviewed:

- *Vaccines* supplied in Australia. The Committee considered the TGA's assessment of these products and agrees that, although a number of vaccines contain processed ingredients of bovine origin, any risk of potential transmission of BSE posed by vaccines supplied in Australia is extremely remote and far outweighed by the benefits of immunisation; and
- *Bovine insulin*. A detailed audit of bovine (beef derived) insulin used in Australia has shown that some beef insulin available in Australia may contain small amounts of Dutch-derived bovine insulin. The vast majority of bovine insulin products in Australia are sourced from North America, which is classified as BSE-free, while a small number of cases of BSE have been reported in the Netherlands. Nowhere in the world is there any direct evidence to link bovine insulin to vCJD. The TGA estimated that the risk of contracting vCJD from this insulin was that, in the worst case, one person could be infected for every 100 million treated for one year. As a precautionary measure however, the TGA has moved to ensure that all stocks still held by the supplier (Aventis) have been quarantined and that all future batches of bovine insulin be certified as sourced from BSE-free countries. This was communicated to the public by the Commonwealth Chief Medical Officer in March this year.

“The Committee reviewed this information at the time and advised that available evidence and evaluation of the manufacturing processes involved indicate there is a very low risk of BSE transmission through bovine insulin products,” Professor Ryan said.

On food issues:

- The Committee noted that the food authority was working on a certification arrangement that will apply globally to all imports of beef or beef products into Australia. Under this arrangement beef and beef products will not be allowed into Australia for sale unless ANZFA, as the Australian food regulator, is satisfied that they are safe.
- The Committee also noted the formation by ANZFA of an expert panel to assist the authority to more accurately determine the risk to human health resulting from exposure to BSE through the consumption of beef and beef products.

On agriculture issues:

- The Committee noted the recent decision by Australian Agriculture Ministers to extend the ban on the feeding of specified animal proteins to ruminant animals, such as cattle and sheep, through the removal of exemptions which had previously allowed the feeding of pig, horse, kangaroo, poultry and fish material to ruminants.

“The Committee supports this decision given the scientific uncertainties about the safety of feeding animal material to ruminants,” Professor Ryan said.

- The Committee also noted the recent decision of Agriculture Ministers to form a high level National Management Group (NMG) to oversee preventative measures for BSE and foot and mouth disease.

On blood issues:

- In view of the expanding epidemic of BSE in Europe and the on-going epidemic of vCJD in the UK, the Committee has discussed further measures to protect blood supply. The Committee is assisting the Australian Red Cross Blood Service (ARCBS) to plan a comprehensive survey of blood donor travel history between 1980 and 2001 inclusive. This survey will build on previous ARCBS surveys and provide a basis for decisions on possible future extension of donor deferral, which might be necessary to maintain the safety of the blood supply.

“One lesson from the UK’s BSE Inquiry is the vital importance of sound and timely scientific advice,” Professor Ryan said.

“My committee will keep fully abreast of overseas developments and learn from the UK experience to ensure that our advice is of the highest quality and makes a valuable contribution to Australia’s response to these and other TSEs.”



MEDIA RELEASE

1 June, 2001

NHMRC warns of 'mad cow disease' risk in Internet shopping

THE National Health and Medical Research Council's Special Expert Committee on Transmissible Spongiform Encephalopathies today cautioned Internet surfers on the availability of products containing overseas animal ingredients that may pose a risk of transmitting the human form of 'mad cow disease', variant Creutzfeldt-Jakob Disease (vCJD).

The Chair of the Committee, Professor Graeme Ryan, also announced the endorsement of an Australian Red Cross Blood Service (ARCBS) proposal to conduct a comprehensive survey of Australian blood donors to gain a clearer picture of their travel histories.

The following two issues emerged from the Committee's meeting in Melbourne, yesterday.

Internet warning:

"The Committee believes consumers need to be aware of the potential risks of contracting vCJD associated with some products that are available via the Internet, and which contain or use material of animal origin from overseas in their manufacture," Professor Ryan said.

"Indeed, we note that the Australian Quarantine and Inspection Service (AQIS) is engaged in a public awareness campaign to highlight the potential threat of introducing unwanted, and even dangerous, pests and diseases through importing materials via the Internet. AQIS is also instituting 100% inspection of international mail items arriving in Australia to address these pest and disease risks.

"Our Committee is aware of products listed for sale at various international sites on the Internet that contain raw bovine brain or pituitary, and other, glands, which are offered as nutritional supplements.

"These products have not been assessed by the regulatory authorities in Australia and, therefore, the potential risk of transmission of Bovine Spongiform Encephalopathy to humans through such products is unknown. Consumers are, therefore, advised to take particular care when considering purchasing products via

the Internet and to only use products which have been shown to meet Australian regulatory requirements.”

Professor Ryan said medicinal products meeting Australian requirements can be identified by an AUST L or AUST R number on the label.

Blood donor survey

At the direction of the Australian Health Ministers, the ARCBS introduced a blood donor deferral policy in December 2000 for donors who had lived in the UK for a cumulative period of six months or more between 1980 and 1996.

“This action was a precautionary measure to protect people from the theoretical risk of transmission of vCJD through blood,” Professor Ryan said. “It was also in line with countries such as the USA, Canada and New Zealand.

“Since that time, the American Red Cross, which supplies about half the whole blood collected in the US, has decided to extend its deferral of donors to those who lived in the UK for three months or more from 1980 up to the present day.

“The American Red Cross will also defer donors who lived in other European countries for six months or more, over the corresponding period. The American Red Cross’s move will become effective in the US in September 2001. Other blood collection agencies in the US have not followed suit, while the US Food and Drug Administration has not announced any decisions.

“It is important to ascertain the impact on our national blood supply should a similar extension be considered in Australia. This information will be gained through the ARCBS’s survey, encompassing the overseas travel history of Australian donors from 1980 to the present, and will add to the body of information required for Australian governments to make informed decisions.”



MEDIA RELEASE

6 August, 2001

Committee supports beef safety measures

The Special Expert Committee on Transmissible Spongiform Encephalopathies (SECTSE) has strongly supported new certification measures announced by the Federal Government in July to protect the Australian public from Bovine Spongiform Encephalopathy (BSE), commonly known as Mad Cow Disease.

The SECTSE, established by the National Health and Medical Research Council to advise the Government on Transmissible Spongiform Encephalopathies including BSE, met for the fourth time last week.

At this meeting the Committee considered the scientific basis of the measures designed to protect consumers from possibly contaminated beef and beef products entering Australia, and supported the policy as an appropriate response to the protection of public health.

Committee chair Professor Graeme Ryan said the Committee had noted that a rigorous scientific risk assessment of the BSE safety of beef production would be undertaken for every country wishing to export beef products to Australia.

"Countries will be categorised according to their BSE risk and will only be permitted to export products to Australia if they can certify that products have been derived from animals which were not exposed to BSE risk," Professor Ryan said.

Professor Ryan said that Australia was one of the few countries in the world that was BSE-free, and it was essential that high standards were maintained for the protection of the Australian public.

At last week's meeting the Committee also noted that a comprehensive survey of Australian blood donors was about to begin, to investigate their travel history from 1980 to the present.

The survey, commissioned by the Australian Red Cross Blood Service and funded by the Commonwealth Department of Health and Aged Care, is expected to report by the end of this year.

After expert analysis of the results, the SECTSE will advise the Government on the range of measures to be considered concerning blood donations from donors who

lived in certain European countries at times when they may have been at risk of BSE exposure.

The Committee also commended the Therapeutic Goods Administration (TGA) for the work it was carrying out to minimise the risk of transmission of BSE through complementary medicines.

“We strongly support the TGA’s review of the origin and manufacture of existing approved products which may contain animal-derived ingredients,” Professor Ryan said.

“The TGA’s rigorous approach is vital in helping to ensure that Australians are protected from risk of BSE exposure through medicines,” Professor Ryan said.



MEDIA RELEASE

19 November 2001

SECTSE congratulates AFFA and TGA on safeguards towards keeping Australia BSE-free

The National Health and Medical Research Council's (NHMRC's) Special Expert Committee on Transmissible Spongiform Encephalopathies (SECTSE) today acknowledged the important contribution Agriculture, Forestry and Fisheries Australia (AFFA) and the Therapeutic Goods Administration (TGA) are making to safeguard Australia in remaining BSE-free.

Chair of the SECTSE, Professor Graeme Ryan, noted, at its November 8 meeting in Canberra, that the Committee

had favourably reviewed AFFA's progress to date, including measures to preclude the feeding of meat and bone meals, including meals of poultry and fish origin, to ruminant animals.

"The SECTSE is very pleased to note the substantial progress made by State and Territory jurisdictions in effecting legislative amendments to give effect to this extension of existing ruminant feeding controls, which are key elements in safeguarding against BSE risks," Professor Ryan said.

"The rapid action of agriculture ministers, at federal, State and Territory levels, in strengthening these preventative measures, is to be commended."

Professor Ryan also paid tribute to the TGA in taking a proactive approach to ensuring that any potential risk of transmission of bovine spongiform encephalopathy (BSE, otherwise known as 'mad cow disease') through the use of medicines and medical devices in Australia, is minimised.

"The TGA's actions reflect those being taken in other leading international regulatory agencies," Professor Ryan said.

"It is continuing to require that all new products submitted to it for inclusion on the Australian Register of Therapeutic Goods (ARTG), which contain or use in their manufacture animal or human ingredients, are sourced from BSE-free countries or show evidence as to the safety from BSE of the material used.

“The TGA is also conducting an ongoing review of existing products to identify any potential risks of exposure to BSE with a view to removing the use of animal or human products sourced from non-BSE-free countries, except where such use can be fully justified.

“The TGA, as part of a systematic risk-based strategy to minimise exposure to therapeutic goods containing TSE transmitting agents, wrote to sponsors seeking information on at-risk animal origin ingredients. This was done in a staged manner based on identified risk.

“In meetings with the Industry, the TGA indicated its intention to undertake a full and comprehensive review of TSE safety and develop a Guidance document to minimise the risk of transmission of agents causing TSE via therapeutic goods.”

The National Health and Medical Research Council

The National Health and Medical Research Council (NHMRC) is a statutory authority within the portfolio of the Commonwealth Minister for Health and Ageing, established by the *National Health and Medical Research Council Act 1992*. The NHMRC advises the Australian community and Commonwealth, State and Territory Governments on standards of individual and public health, and supports research to improve those standards.

The NHMRC advises the Commonwealth Government on the funding of medical and public health research and training in Australia and supports many of the medical advances made by Australians.

The NHMRC also develops guidelines and standards for the ethical conduct of health and medical research.

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