Specialist Medical Review Council

Reasons for Decisions

Section 196W
Veterans' Entitlements Act 1986

Re: Statements of Principles Nos. 28 and 29 of 2005
In Respect of Malignant Neoplasm of the Prostate
Matter Nos. 2011/3 & 4
Requests for Review Declaration No. 17

SUMMATION

1. In relation to the Repatriation Medical Authority (the RMA) Statement of Principles No. 28 of 2005 in respect of malignant neoplasm of the prostate and death from malignant neoplasm of the prostate, made under subsection 196B(2) of the *Veterans' Entitlements Act 1986* (the VEA), the Specialist Medical Review Council (the Council) under subsection 196W of the VEA:

> DECLARES that there is sound medical-scientific evidence on which the RMA could have relied to amend the Statement of Principles to include the factors set out below;
>
> DIRECTS the RMA to amend Statement of Principles No 28 of 2005 by including the following factors in respect of tobacco smoking:
>
> > For current smokers only smoking at least 40 pack years of cigarettes or the equivalent thereof in other tobacco products before the clinical onset of malignant neoplasm of the prostate.
> >
> > Smoking at least 15 pack years of cigarettes or the equivalent thereof in other tobacco products before the clinical worsening of malignant neoplasm of the prostate, and where smoking has ceased, the clinical worsening has occurred within 10 years of cessation.

2. In relation to the RMA Statement of Principles No. 29 of 2005 in respect of malignant neoplasm of the prostate and death from malignant neoplasm of the prostate, made under subsection 196B(3) of the VEA the Council under subsection 196W of the VEA:

> DECLARES that there is sound medical-scientific evidence on which the RMA could have relied to amend the Statement of Principles to include the factor set out below;
>
> DIRECTS the RMA to amend Statement of Principles No 29 of 2005 by including the following factor in respect of tobacco smoking:
>
> > Smoking at least 40 pack years of cigarettes or the equivalent thereof in other tobacco products before the clinical worsening of malignant neoplasm of the prostate, and where smoking has ceased, the clinical worsening has occurred within 10 years of cessation.
>
> DECLARES that the sound medical-scientific evidence available to the RMA is insufficient to justify any amendment to the Statement of Principles to include as factors exposure to potable water or any other factor.

THE SPECIALIST MEDICAL REVIEW COUNCIL

3. The Council is a body corporate established under section 196V of the VEA, and consists of such number of members as the Minister for Veterans' Affairs determines from time to time to be necessary for the proper exercise of the function of the Council as set out in the VEA. The Minister must appoint one of the Councillors to be the Convener.

4. When a review is undertaken 3 to 5 Councillors selected by the Convener constitute the Council. When appointing Councillors, the Minister is required to have regard to the branches of medical-science expertise that would be necessary for deciding matters referred to the Council for review.

5. Clinical Associate Professor Jonathan Phillips FRANZCP was the Convener of the Council for this review until 30 June 2012 when his appointment as Convener expired. Professor Guest, the new Convener of the Council, appointed Professor Phillips as Presiding Councillor for this review on and from 1 July 2012. Professor Phillips is a psychiatrist involved in three separate areas of practice, offering consultancy advice to health services and other bodies. Professor Phillips has a substantial clinical practice and offers medico-legal advice and opinion, and holds academic positions at three universities. He is a past President of the Australian & New Zealand College

of Psychiatrists and a past Chair of the Committee of Presidents of the Australian Medical Colleges. The other members of the Council were:

(i) Professor Albert Frauman FRACP who is Professor of Clinical Pharmacology & Therapeutics, University of Melbourne, Professorial Fellow of the Baker IDI and Medical Director, Austin Centre for Clinical Studies, has a career spanning over 30 years in clinical research; and is an expert in drug trials and pharmacokinetic studies. Professor Frauman has longstanding activities in clinical medicine, teaching and research as a hospital and academic physician and sits on a number of key State and Commonwealth therapeutics committees as a clinical pharmacologist; and

(ii) Professor John Funder AO FRACP, who is Professor, Department of Medicine, Monash University and Professorial Associate at the Centre for Neuroscience, The University of Melbourne and Honorary Professor, Institute of Molecular Biosciences, The University of Queensland; and

(iii) Professor Robert Cumming FAFPHM, who is Professor of Epidemiology and Geriatric Medicine at the University of Sydney, based at the School of Public Health and the Centre for Education and Research on Ageing at Concord Hospital; and

(iv) Professor David Handelsman FRACP, who is the inaugural Professor/Director, ANZAC Research Institute and Head, Andrology Department, Concord Hospital. His expertise and research are in male reproductive health, medicine and biology.

THE LEGISLATION

6. The legislative scheme for the making of Statements of Principles is set out in Parts XIA and XIB of the VEA. Statements of Principles operate as templates that are ultimately applied by decision-makers in determining individual claims for benefits under the VEA and the *Military Rehabilitation and Compensation Act 2004* (the MRCA) [1].

[1] See sections 120, 120A and 120B of the VEA and sections 335, 338 and 339 of the MRCA.

7. Fundamental to Statements of Principles is the concept of 'sound medical-scientific evidence', which is defined in section 5AB(2) of the VEA. Information about a particular kind of injury, disease or death is taken to be sound medical-scientific evidence if:

(a) the information

(i) is consistent with material relating to medical science that has been published in a medical or scientific publication and has been, in the opinion of the Repatriation Medical Authority, subjected to a peer review process; or

(ii) in accordance with generally accepted medical practice, would serve as the basis for the diagnosis and management of a medical condition; and

(b) in the case of information about how that injury, disease or death may be caused meets the applicable criteria for assessing causation currently applied in the field of epidemiology. [2]

8. The functions of the Council are set out in section 196W of the VEA. In this case, the Council was asked (under section 196Y of the VEA) to review the contents of:

– Statement of Principles No. 28 of 2005, in respect of malignant neoplasm of the prostate and death from malignant neoplasm of the prostate, being a Statement of Principles determined by the RMA under section 196B(2) [3] of the VEA ('the reasonable hypothesis test'); and

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[2] This has been held to mean 'information which epidemiologists would consider appropriate to take into account' see *Repatriation Commission v Vietnam Veterans' Association of Australia NSW Branch Inc* (2000) 48 NSWLR 548 (the New South Wales Court of Appeal decision) per Spigelman CJ at [117].

[3] Section 196B(2) provides:

> If the Authority is of the view that there is sound medical-scientific evidence that indicates that a particular kind of injury, disease or death can be related to:
>
> (a) operational service rendered by veterans; or
>
> (b) peacekeeping service rendered by members of Peacekeeping Forces; or
>
> (c) hazardous service rendered by members of the Forces; or
>
> (caa) British nuclear test defence service rendered by members of the Forces; or
>
> (ca) warlike or non-warlike service rendered by members;
>
> the Authority must determine a Statement of Principles in respect of that kind of injury, disease or death setting out:
>
> (d) the factors that must as a minimum exist; and
>
> (e) which of those factors must be related to service rendered by a person;
>
> before it can be said that a reasonable hypothesis has been raised connecting an injury, disease or death of that kind with the circumstances of that service.

– Statement of Principles No. 29 of 2005, in respect of malignant neoplasm of the prostate and death from malignant neoplasm of the prostate, being a Statement of Principles determined by the RMA under section 196B(3) [4] of the VEA ('the balance of probabilities test').

9. Specifically, the President of an organisation representing veterans, members of the Forces, and members of Peacekeeping Forces (the Applicant) and a person eligible to make a claim for a pension (Mr M), respectively contended that there was sound medical-scientific evidence upon which the RMA could have relied to include:

9.1. 'tobacco smoking' as a factor for each of clinical onset and clinical worsening in each of Statements of Principles 28 and 29 of 2005;

9.2. in Statement of Principles No. 29 of 2005 a factor in the same or similar terms to existing factor 5 (b) (iii) in Statement of Principles No. 28 of 2005 which provides:

> being:
>
> (iii) on board a vessel and consuming potable water supplied on that vessel, when the water supply had been produced by evaporative distillation of estuarine Vietnamese waters,
>
> for a cumulative period of at least 30 days, at least five years before the clinical onset of malignant neoplasm of the prostate.

10. In conducting its review, the Council must review all the information that was available to (before) the RMA at the time it determined, amended, or last

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[4] Section 196B(3) provides:

> If the Authority is of the view that on the sound medical-scientific evidence available it is more probable than not that a particular kind of injury, disease or death can be related to:
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> (a) eligible war service (other than operational service) rendered by veterans; or
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> (b) defence service (other than hazardous service and British nuclear test defence service) rendered by members of the Forces; or
>
> (ba) peacetime service rendered by members;
>
> the Authority must determine a Statement of Principles in respect of that kind of injury, disease or death setting out:
>
> (c) the factors that must exist; and
>
> (d) which of those factors must be related to service rendered by a person;
>
> before it can be said that, on the balance of probabilities, an injury, disease or death of that kind is connected with the circumstances of that service.

amended the Statements of Principles (the relevant times) and is constrained to conduct its review by reference to that information only. [5]

11. Under section 196W of the VEA, the Council can only reach the view that a Statement of Principles should be amended on the basis of sound medical-scientific evidence.

BACKGROUND

12. On 19 September 2005, the RMA under subsections 196B(2) and (3) of the VEA determined Statements of Principles being Instruments respectively numbered 28 and 29 of 2005 in respect of malignant neoplasm of the prostate.

13. On 21 September 2005, in accordance with section 42 of the *Legislative Instruments Act 2003* the Statements of Principles were*:*

- registered;
- tabled in the House of Representatives on 10 October 2005 and in the Senate on 5 October 2005.

14. On 28 October 2005, the Council received an Application dated 17 October 2005 for review of Statements of Principles Numbers 28 and 29 of 2005. Specifically the Application was concerned with the decision of the RMA of 19 September 2005 not to include 'tobacco smoking' as a factor in the Statements of Principles.

15. Pursuant to section 196ZB of the VEA, the Council published in the Gazette a Notice of its Intention to carry out a review of all the information available to the RMA about malignant neoplasm of the prostate, and inviting persons or organisations authorised so to do, to make submissions to the Council. [6] The Council gazetted five subsequent notices as to the dates by which written submissions must be received by the Council. [7]

16. The Council in its Gazette Notice of 20 January 2010 advised that the closing date for written submissions was 29 October 2010. The Council subsequently discovered that its website specified 31 December 2010 as the closing date for written submissions. The Council determined on procedural fairness grounds to accept written submissions received by 31 December

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5 *Vietnam Veterans' Association (NSW Branch) Inc v Specialist Medical Review Council and Anor* (full Federal Court decision) (2002) 72 ALD 378 at [35] per Branson J.

6 Gazette number 50 of 21 December 2005 (p. 3140).

7 Gazette Notice 23 of 14 June 2006, (p. 1371); Gazette Notice 4 of 31 January 2007, (p. 454); Gazette Notice 32 of 15 August 2007, (p. 2184); Gazette Notice 30 of 5 August 2009, (p. 1960); and Gazette Notice 2 of 20 January 2010, (p. 94).

2010, as opposed to 29 October 2010, and the Council's website maintained the publication of 31 December 2010 as the closing date for submissions.

The information sent by the RMA to the Council

17. The RMA is obliged under section 196K of the VEA to send to the Council all the information that was available to it (the RMA) at the relevant times. That comprises all the information that was available to the RMA when it determined the original Statements of Principles in 1995, and all the information subsequently available at all times when the Statements of Principles have been amended, or revoked and replaced, up to and including that information which was available in September 2005 when the RMA determined the Statements of Principles under review. In other words, within 28 days after being notified that the Council has been asked to conduct a review, the RMA must send to the Council all the information in respect of malignant neoplasm of the prostate which was in the possession of the RMA at the time it (the RMA) made the decision that triggered the Council's review.

18. Within the 28 day period specified in section 196K of the VEA, the RMA sent to the Council the information the RMA advised was available to (before) it at the relevant times and provided to the Council lists of that information.

19. Subsequently the RMA sent to the Council further information which the RMA said was available to (before) it at the relevant times, and provided various confirmatory lists of the information that was so available to the RMA. Ultimately, by letter dated 19 December 2008, in accordance with arrangements agreed between the RMA and the Council, the RMA re-sent to the Council via electronic access through a service provider known as FileForce, the information that was available to (before it) at the relevant times and provided the Council with lists of that information.

20. Copies of the information forwarded to the Council by the RMA from time to time were provided by the Council to the participants to the review on various dates. Ultimately, by correspondence dated 17 April 2009 and 19 October 2009 respectively, the Council provided to the Applicant and the representative of the Commissions electronic access to the information which the RMA advised was available to (before) it at the relevant times.

21. By correspondence dated 5 and 21 August 2009 the Council provided to a(nother) person eligible to make a claim for a pension (Mr C) electronic access to the information sent by the RMA to the Council on 19 December 2008 via FileForce. [8]

22. By correspondence on or about 13 December 2010 the Council provided to Mr M electronic access to the information sent by the RMA to the Council on 19 December 2008 via FileForce. [9]

PROPOSED SCOPE OF REVIEW AND PROPOSED POOL OF INFORMATION

Preliminary Decisions on the Proposed Scope of Review and Proposed Pool of Information

First preliminary decision on scope of review

23. On 24 November 2010, the Council wrote to the Applicant, Mr C, and the Commissions advising them of the Council's preliminary decision on the proposed scope of the review. [10]

24. The Council's preliminary decision on the proposed scope of review was that without limiting the scope of the Council's review (of some or the whole of) the contents of the Statements of Principles, the Council then proposed:

24.1. to have particular regard to whether there was sound medical-scientific evidence upon which the RMA could have relied to amend either or both of the Statements of Principles in either or both of the following ways, i.e. the possible inclusion of 'tobacco smoking' as a factor for clinical:

(a) onset; and/or

(b) worsening

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8 Mr C had contacted the Council on 20 May 2009 seeking access to the information so he could make a written submission to the Council on herbicides and dioxin exposure in Vietnam. He made a written submission to the Council dated 17 October 2010. In respect of the submission, which ultimately was determined by the Council not to be within the scope of this review, see [24.2].

9 On 1 December 2010 Mr M contacted the Council in reliance on the statement on the Council's web site that the due date for the receipt of written submissions was 31 December 2010 to determine whether he could make a written submission to the Council as summarised in [9.2]. Mr M's written submission was dated 29 December 2010 see [108].

10 The Council did not at this stage make a preliminary decision on the proposed pool of information.

of malignant neoplasm of the prostate (the contended smoking factor); and

24.2. not to include exposure to herbicides within the proposed scope of review as requested in Mr C's submission, a copy of which was enclosed, because in the Council's preliminary view, Mr C's submission:

- was not a submission about any information that was available to the RMA at the relevant time as required by section 196ZA of the VEA; and
- sought a policy or legislative change.

25. The Applicant, Mr C and the Commissions were invited to make any written comments as to the Council's preliminary decision on scope by close of business on 15 December 2010, and to make any oral comments at the hearing of oral submissions complementing the written submissions.

26. No written comment was received by the Council on its preliminary decision on the proposed scope of review (including the preliminary decision not to include Mr C's submission on herbicides as within scope). On 15 December 2010 the Applicant confirmed by telephone that he was asking the Council to review the Statements of Principles only in respect of the contended tobacco smoking factor.

Second preliminary decision on proposed scope of review

27. On 9 March 2011 the Council wrote to the Applicant, Mr M, Mr C and the Commissions advising of the Council's second preliminary decision on the proposed scope of the review.

28. The Council's second preliminary decision on the proposed scope of review was to include within scope:

28.1. the contended smoking factor;

28.2. the contention that existing factor 5(b) (iii) of Statement of Principles No. 28 of 2005 should be amended, or a new factor added to Statement of Principles No. 28 of 2005, to include exposure to alleged contamination arising from the absorption of dioxins by bitumastic paint, which it was contended is or was used to seal water tanks in Navy ships (the contended bitumastic paint factor);

28.3. the contention that a factor in the same or similar terms to existing factor 5(b) (iii) in Statement of Principles No. 28 of 2005 should be included in Statement of Principles No. 29 of 2005;

28.4. the contended bitumastic paint factor should be included in Statement of Principles No. 29 of 2005;

28.5. existing factors 5(a), 5(b)(i) and 5(b)(ii) in Statement of Principles No 28 of 2005 together with the relevant definitions in [8] of that Statement of Principles; and

28.6. whether some or all of the existing factors or a factor or factors in similar terms to factors 5(a), 5 (b)(i) and 5(b)(ii) together with the relevant definitions in [8] of Statement of Principles No. 28 of 2005 should be included in Statement of Principles No. 29 of 2005.

First preliminary decision on the proposed pool of information

29. The Council's first preliminary decision on the proposed pool of information as advised on 9 March 2011 was that the pool of information should be identified from the information that was available to (before) the RMA at the relevant times, sent to the Council by the RMA under section 196K (via FileForce in December 2008) and should comprise sound medical-scientific evidence as defined in section 5AB(2) of the VEA being information which:

- epidemiologists would consider appropriate to take into account; and
- in the Council's view, 'touches on' (is relevant to) the revised proposed scope of review.

30. A copy of the first preliminary list of the proposed pool of information was forwarded to the Applicant, Mr M, Mr C and the Commissions.

31. The Applicant, Mr M, Mr C and the Commissions were invited to make any written comments as to the Council's second preliminary decision on the proposed scope of the review and first preliminary decision on the proposed pool of information by close of business on 15 April 2011; to make any written submissions regarding the matters within the second preliminary scope of review by 13 May 2011; and to make any oral comments at the hearing of oral submissions complementing the written submissions.

32. On 9 May 2011 the Council received from the Commissions a written submission regarding the matters within the second proposed scope of review other than the contended smoking factor (see [102] - [107]). The Commissions submitted that the first proposed pool of information did not include three of the studies referenced in their submission. [11]

33. On 13 May 2011 the Department of Veterans' Affairs (DVA) received from the Applicant a further written submission regarding the matters within the second proposed scope of review including the contended smoking factor which was forwarded to the Council on 17 May 2011 (see [82] - [83] below).

Third preliminary decision on proposed scope of review

34. On 26 - 27 May 2011, the Applicant, the representative of the Commissions and Mr M made oral submissions, complementing their respective written submissions (see [43] - [44] below). Mr M clarified his contentions to the Council. He said that he sought no amendments to Statement of Principles No. 28 of 2005. Nor did he seek a bitumastic paint factor in either Statement of Principles. Rather, he contended that a factor in the same or similar terms to existing factor 5 (b) (iii) in Statement of Principles No. 28 of 2005 [12] (the contended potable water factor) should be included in Statement of Principles No. 29 of 2005, with appropriate amendment to a potential exposure timeframe.

35. On 24 June 2011 the Council, on the basis of the oral submissions complementing the written submissions, wrote to the Applicant, Mr M, Mr C and the Commissions advising of further revision of its preliminary decision on the proposed scope of the review (ie the third preliminary decision on the proposed scope of the review) and revision of its preliminary decision on the proposed pool of information (the second preliminary decision on the proposed pool of information). The Council's third preliminary decision on the proposed scope of review was that:

> Without limiting the scope of the Council's review of (some or the whole of) the contents of the Statements of Principles, the Council presently proposes to have particular regard to whether there was sound medical-scientific evidence upon which the Repatriation Medical Authority (the RMA) could have relied to amend:

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[11] 32524 Akhtar, FZ et al. 2004, 'Cancer in US Air Force veterans of the Vietnam War', *Journal of Occupational & Environmental Medicine*, vol. 46, no. 2, pp. 123-136.

36638 Australian Institute of Health & Welfare 1993, *Cancer incidence study, Australian Veterans of the Korean War*, AIHW, catalogue, no. PHE, 48, Canberra.

37771 Harrex, WK et al. 2003, *Mortality of Korean War Veterans, the Veteran Cohort Study*, *A report of the 2002 retrospective cohort of Australian veterans of the Korean War*, Department of Veterans' Affairs, Canberra.

[12] See [9.2].

1. Statement of Principles No. 28 of 2005 by the possible inclusion of the contended smoking factor.

2. Statement of Principles No. 29 of 2005 in any or all of the following ways for the clinical:

   – onset; and/or

   – worsening

   of malignant neoplasm of the prostate:

   (a) the possible inclusion of the contended smoking factor;

   (b) the possible inclusion of the contended potable water factor

which in the Council's preliminary view, may include a need for the Council to determine whether the sound medical-scientific evidence in the pool of information concerning exposure to dioxins (if found to exist in a particular case) could provide a relevant connection between malignant neoplasm of the prostate or death from malignant neoplasm of the prostate and relevant service according to a standard of satisfaction on the balance of probabilities. [13]

Second preliminary decision on proposed pool of information

36. The Council's second preliminary decision on the proposed pool of information as advised on 24 June 2011 was that the pool of information should include the information that was available to (before) the RMA at the relevant times and which satisfied the other criteria set out in [29].

37. A copy of the revised list reflecting the Council's second preliminary decision of the proposed pool of information was forwarded to the Applicant, Mr M, Mr C and the Commissions, and is attached at **Appendix A**.

38. The Council's second preliminary decision on the proposed pool of information included in the proposed pool the three articles referred to in the Commissions' May 2011 written submission. [14]

39. The Council advised that it did not propose to include in the proposed pool of information a copy of the 1994 DVA submission to the RMA on Lung Cancer and Herbicides (the 1994 DVA paper), [15] a copy of which was provided by

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[13] Mr M seemingly contended that potable water had been contaminated by dioxins, and that that contamination continued to affect adversely service personnel after the relevant ships left Vietnamese waters. Accordingly, the Council was of the preliminary view, as had been previously advised in its letter of 9 March 2011, that it may not be possible to consider the contended potable water factor without first considering whether exposure to dioxins by any mechanism could provide a relevant connection on the balance of probabilities**.**

[14] See footnote 11.

[15] Horsley, KW 1994, *Supplementary submission on lung cancer and herbicides*, a report to the Repatriation Medical Authority by the Department of Veterans' Affairs, Canberra, pp. 1-14.

the Applicant in its written submission received 13 May 2011. The Convener of the Council stated at the hearing on 26 May 2011 that the Council would confirm with the RMA the status of the 1994 DVA paper and the information to which it referred. The Council's Secretariat wrote to the RMA by letter dated 10 June 2011 to ascertain whether the 1994 DVA paper was available to the RMA at the relevant times, and the status of the information to which it referred. The RMA responded by letter dated 16 June 2011 that the 1994 DVA paper was not available to the RMA at the relevant times, and that the information available to the RMA at the relevant times was as previously advised. [16]

40. The Applicant, Mr M, Mr C and the Commissions were invited to make any written comments as to the Council's third preliminary decision on scope and second preliminary decision on the proposed pool of information by close of business on 8 July 2011.

41. The Applicant responded to the Council by letter dated 15 July 2011, submitting that:

> we still maintain that the [1994 DVA paper] is [the] basis of the exposure factors contained in the definitions of exposure to herbicides in Vietnam in SOP 95 of 1995 and is the genesis of the 30 day service in Vietnam factor contained [in] the SOP no 28 of 2005.

42. No comment was received by the Council from the Commissions, Mr M or Mr C regarding its third preliminary decision on the proposed scope of review and second preliminary decision on the proposed pool of information.

ORAL SUBMISSIONS COMPLEMENTING THE WRITTEN SUBMISSIONS

43. As mentioned in [34], the Council held a meeting to hear oral submissions complementing the written submissions on Thursday 26 and Friday 27 May 2011, at which the Applicant, Mr M and a Medical Officer with the DVA representing the Commissions made oral submissions complementing their respective written submissions. The Applicant's complementary oral submissions were made by Mr McC and Dr Peter John McCullagh.

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[16] Copies of the following articles referred to in the 1994 DVA paper were sent by the RMA to the Council via Fileforce on 19 December 2008:

3236 MacLennan, R and Smith, P 1994, *Veterans and agent orange, Health effects of herbicides used in Vietnam*, Report prepared for Department of Veterans' Affairs commenting on the NAS report, pp.1-18.

3312 Blair, A Hoar Zahm, SH Pearce, NE Heineman, EF and Fraumeni, Jr JF 1992, 'Clues to cancer etiology from studies of farmers', *Scand Journal Work Environ Health*, vol. 18, pp. 209-215.

44. Mr C did not make a written submission other than his initial submission which the Council considered was not a submission about any information available to the RMA as required under section 196ZA of the VEA, but rather suggested policy or legislative change. Mr C did not make an oral submission, notwithstanding he was afforded the opportunity to do so.

PREVIOUS COUNCILS' REVIEWS OF STATEMENTS OF PRINCIPLES IN RESPECT OF MALIGNANT NEOPLASM OF THE PROSTATE

45. The Council has previously considered the contended smoking factor in previous reviews of now revoked Statements of Principles in respect of malignant neoplasm of the prostate. The Minister appointed, and the Convener selected, a newly constituted Council to conduct this review, to ensure that there was no apprehension of bias or prejudgement. [17]

46. On 22 December 1995 a previously constituted Council published its Declaration and Reasons for Decision in respect of now revoked Statements of Principles 95 and 96 of 1995. [18] On 2 August 2001, another previously constituted Council published its Declaration and Reasons for Decision in respect of Instruments Numbered 191 and 192 of 1996. [19]

47. The Council holds a copy of the two previously constituted Councils' Declarations and Reasons for Decision, and a copy of the previously constituted Council's 22 December 1995 Declaration and Reasons for Decision was included in the information sent by the RMA to this Council. [20] However, the Council took the view that it should not rely on either or both of the two previously constituted Councils' Reasons (noting that only the 1995 Decision was available to the RMA at the relevant times), but that it should consider for itself all the information that was before the RMA at the relevant times.

48. The Council was cognisant that not all the information before it had been before the previously constituted Councils when they had considered the now revoked Statements of Principles. Importantly, both the previously constituted Councils' Reasons for Decision were drafted before the full Federal Court had settled the way in which the Council carries out its functions. Thus, this Council and the previously constituted Councils were

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17 None of the Councillors on this Council was a member of either of the previously constituted Councils reviewing Statements of Principles in respect of malignant neoplasm of the prostate.

18 The previous Council's 22 December 1995 Declaration was published by Gazette Notice 4 of 31 January 1996, p 456.

19 The previous Council's 2 August 2001 Declaration was published by Gazette Notice 32 of 15 August 2001, p 2360.

20 Previous Council's 22 December 1995 Declaration at FileForce Item ID 8494 and Reasons for Decision at ID 8506.

operating within a different legal and administrative framework when undertaking their respective reviews. [21]

49. Accordingly, the Council approached its task without any preconceptions, applying the two-stage process discussed below to the entirety of the information that was before the RMA at the relevant times.

THE APPLICANT'S SUBMISSIONS

50. In its Application of 17 October 2005, the Applicant stated that the grounds for review were as follows:

> Rejection of the smoking factor for Prostate cancer.
>
> [The] RMA failed to accept the best and strong animal and epidemiology (sic) evidence that supports the Reasonable Hypothesis and Balance of Probabilities onus of proof.

51. The Applicant made a number of comprehensive written submissions:

51.1. dated 12 December 2006 with attachments:

a. paper by Dr. Peter John McCullagh dated 3 July 2006;

b. paper by Professor Gabriel A. Kune dated 1 October 1996;

c. report by Total Environment Centre Inc, per Ben Cole 'Association Between Smoking and Prostate Cancer' dated 28 August 2003;

d. report by Dr David Douglas dated 3 June 2003; and

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[21] The Council was cognizant that the previously constituted Councils':

- 22 December 1995 decision concerning Statements of Principles Nos 95 and 96 of 1995 (the first decision) had been set aside as void by James J on the basis of a denial of procedural fairness (with respect to excision of the then existing herbicides factor in Statement of Principles No. 95 of 1995) and, with respect to the then contended smoking factor, because it (the Council) was found to have incorrectly applied the reasonable hypothesis test.

  The NSW Court of Appeal declared void the first decision so far as it related to Statement of Principles No. 95 of 1995.
- 3 August 2001 decision concerning Statements of Principles Nos. 95 and 96 of 1995 as amended by Instruments 191 and 192 of 1996 (the second decision) was set aside by the full Federal Court, on the basis that the Council had lost jurisdiction to complete the review once the Statements of Principles had been revoked by the RMA and replaced with Statements of Principles Nos. 84 and 85 of 1999 (noting too that the Council's Decision incorrectly referred to amending instruments, rather than to the Statements of Principles as amended).
- commenced but not completed re-review of Statements of Principles Nos. 95 and 96 of 1995 (the third review) was terminated by the Council in accordance with comments by the full Federal Court on the basis that the Council had lost jurisdiction due to the revocation by the RMA of those Statements of Principles by Statements of Principles Nos. 84 and 85 of 1999 (see Gazette Notice 7 of 19 February 2003, page 559).

e. Hickey, K et al. 2001. [22]

51.2. undated and received by DVA on 13 May 2011 with attachments:

a. the 1994 DVA paper; [23]

b. copy of revoked RMA Statement of Principles No. 95 of 1995 in respect of malignant neoplasm of the prostate, pages 1-3;

c. Muller, J et al. 2002; [24]

d. Huncharek, MPH et al. 2010. [25]

51.3. dated 15 July 2011, making comment on the Council's third preliminary decision on the proposed scope of review and second preliminary decision on the proposed pool of information.

and oral submissions by Mr McC and Dr McCullagh complementing the written submissions.

52. The Applicant:

52.1. contended that the paper by Dr Peter McCullagh supported its contention that there was a:

> link between tobacco products and prostate cancer.

52.2. drew the Council's attention to the paper by Professor Kune and the report by Mr Cole as:

> Identify[ing] 24 epidemiological studies showing a positive link between tobacco products and prostate cancer. [26]

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22 Hickey, K et al. 2001, 'Smoking and prostate cancer', *Epidemiologic Reviews*, vol. 23, no. 1, pp. 115-125.

Unless otherwise stated, all the articles referred to in submissions to the Council were available to the RMA at the relevant times and sent to the Council by the RMA via Fileforce (see Appendix B).

23 As mentioned above (see [39]) this paper was not available to the RMA at the relevant times, and so could only be considered by the Council as new information.

24 Muller, J et al. 2002, *Examination of the potential exposure of Royal Australian Navy (RAN) personnel to polychlorinated dibenzodioxins and polychlorinated dibenzofurans via drinking water*, The National Research Centre for Environmental Toxicology NRCET (ENTOX), A report to the Department of Veterans' Affairs, Australia, pp. 1-75.

25 Huncharek, MD et al. 2010, 'Smoking as a risk factor for prostate cancer: A meta-analysis of 24 Prospective Cohort Studies', *Research and Practice*, vol. 100, no. 4, pp. 693-701.

This article was not available to the RMA at the relevant times, and so could only be considered by the Council as new information.

26 The Council noted that Professor Kune's report pre-dated the full Federal Court decision. It does not reflect the Council's two-step process in applying the reasonable hypothesis test as set down by the full Federal Court (see [113] - [114]).

52.3. contended that the paper by Professor Kune, the report by Dr Douglas and the Hickey et al. 2001 article supported a biologic/plausible link between cadmium and prostate cancer:

> Cadmium is found in tobacco products. Strong scientific evidence exists linking the exposure to cadmium and the development of prostate cancer...Hickey et al. discuss the role of smoking and prostate cancer... One of the biologic/plausibility (sic) discussed is the link between cadmium and prostate cancer.
>
> We submit that is (sic) is plausible that cadmium contained in tobacco products is a cause of prostate cancer.

53. The comments and passages highlighted in the Applicant's written submissions and complementary oral submissions at the Council's meeting on 26-27 May 2011 are extracted below. [27]

Paper by Dr. Peter John McCullagh dated 3 July 2006

54. Dr McCullagh's paper, submitted to the Council on behalf of the Applicant, examined the medical-science published since 1996. While he endorsed the conclusions of Professor Kune based on earlier medical-science with respect to incidence/onset (see [64] - [73] below), Dr McCullagh focused in his written and complementary oral submissions upon clinical worsening:

> …my submission I hope is sufficiently clear that it was directed specifically and exclusively to the proposition of the impact of current smoking on the progress of prostate cancer.

55. Dr McCullagh took as his starting point the RMA 1996 Consensus Conference Statement: [28]

> 1. There is inadequate evidence that smoking is causally related to the occurrence of prostate cancer.
>
> a. There is limited evidence that smoking is associated with increased mortality attributed to prostate cancer.
>
> b. There is inadequate evidence that smoking is associated with prostate cancer incidence.

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27 Regardless of the way in which articles were referenced by the participants in the review, the Council has provided the full citations of articles in footnotes in accordance with the 'Author-date' system described in the Commonwealth of Australia 2002, *Style manual*, 6th edn, John Wiley & Sons Australia Ltd, pp. 187-232.

A key defining statistical and other terms used in submissions to the Council and these Reasons is at pages 113-116.

28 Golditz, GA ed. 1996, *Repatriation Medical Authority Consensus Conference Prostate Cancer*, Commonwealth Government Printing Service, Canberra ACT.

2. A plausible inference from these statements is that smoking may be associated with poorer survival.

and submitted that since 2003:

> …adequate evidence has accumulated pointing to an association between prostate cancer of the higher grades of malignancy and smoking … The hypothesis, pointed to by the most recent evidence, namely that smoking constitutes a significant contributing factor in development of the more malignant forms of prostate cancer, is presented without prejudice to resolution of the question of whether smoking is a contributing factor in the development of prostate cancer of **any** degree of malignancy.

56. Dr McCullagh acknowledged that:

> …conflicting reports…have been published [and submitted that] several possibilities should be recognised:
>
> a) there may be multiple factors that can contribute to…prostate cancer…so effectively confounding epidemiological studies,
>
> b) the aggregation of all cases…may disguise stronger and more readily detectable associations between one or more subcategories of that disease and associated factors,
>
> c) 'lumping' of a heterogeneous population of affected individuals may similarly obscure legitimate associations…

57. Dr McCullagh noted that uncertainties arise from the biology and natural history of the disease:

> …prostate cancer…becomes increasingly frequent with advancing age…mortality rates do not keep pace with…incidence…it is more common to die *with* than it is to die *of* prostate cancer…
>
> The capacity to detect prostate cancer by non-invasive blood testing has…introduced more potential confusion into identification of causative factors.

58. Dr McCullagh in his oral submission referred to what in his view was an increasing recognition in the literature of the possibility of a difference between initiation (onset) and promotion (worsening) of prostate cancer. Further, he put the view that incidence of prostate cancer is now recognised as a better indicator of the initiation of a prostate tumour, with mortality as reflecting the influence of promoting factors, and submitted that the focus in articles on whether tobacco smoking was an initiating factor for prostate cancer had led to confusion and a lack of focus on its role as a promoting factor.

59. Dr McCullagh made submissions on the basis of his interpretation of the following articles touching on:

59.1. 'dissociation' between incidence and mortality rates, which he contended had confounded earlier attempts to identify a potential association:

a. Breslow, RA et al. 1977 [29]

> …notwithstanding a similar frequency of small latent prostate cancer in 7 geographically different locations, the incidence of clinically presenting cases of prostate cancer varied markedly between these locations.

b. Yatani, R et al. 1988 [30]

> …examined the frequency of detection of latent (infiltrative and noninfiltrative) prostate cancer… They observed that, whereas the increase in frequency of noninfiltrative cancer between the two periods was barely significant ($p = 0.045$), there was a highly significant ($p < 0.0001$) increase in occurrence of latent infiltrative prostate cancer.
>
> As with…Breslow, cited above, these findings were consistent with the interpretation that some causative factors could be operative at two stages…both during initial development and again during transition to higher grades of malignancy (i.e. from a noninfiltrative to an infiltrative stage).

59.2. smoking as an additional risk factor for the development of more aggressive prostate cancers:

a. Hussain, F et al. 1992 [31]

> …undertook a retrospective analysis of the degree of differentiation of the prostate cancers of 670 patients. The frequency of smokers v non-smokers among men with well differentiated carcinoma 15.04% v 37.1%, moderately differentiated carcinoma 27.07% v 45.16% and poorly differentiated carcinoma 57.89% v 17.74% differ significantly ($p < or = 0.00005$). Prostate cancers in smokers were both of higher grade and more invasive than those in non-smokers.

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29 Breslow, RA et al. 1977, 'Latent carcinoma of prostate at autopsy in seven areas', *International Journal of Cancer*, vol. 20, pp 680-688.

This article was not available to the RMA at the relevant times, and so could only be considered by the Council as new information.

30 Yatani, R et al. 1988, 'Trends in frequency of latent prostate carcinoma in Japan from 1965-1979 to 1982-1986', *Journal of the National Cancer Institute*, vol. 80, pp. 683-687.

This article was not available to the RMA at the relevant times, and so could only be considered by the Council as new information.

31 Hussain, F et al. 1992, 'High grade adenocarcinoma of prostate in smokers of ethnic minority groups and Caribbean Island immigrants', *International Journal of Radiation Oncology Physics,* vol. 24, pp. 451-461.

b. Daniell, HW 1995 [32]

Stage D disease was found to be independently related to smoking (OR 2.1, p = 0.0015). When 5 year tumour-specific mortality rates of patients with Stage D2 disease were compared, smokers (88%) were significantly (p <0.05) more likely than non-smokers (63%) to have died. Similarly, among patients with metastatic disease, smokers (39%) were much more likely (p <0.001) than non-smokers (17%) to have died. This has been interpreted as pointing to association between smoking and progression to higher grades of malignancy independent of contribution to initial tumour development.

c. Rodriguez, C et al. 1997 [33]

…a prospective study of 450,279 men…The relative risk among participant smokers…when compared with non-smokers was 1.44. The authors concluded…that smokers with prostate cancer had a shortened survival time.

d. Cerhan, JR et al. 1997 [34]

…a cohort of 1155 men…When compared with men who had never smoked, current smokers of < 20/day had relative risks of 2.0 and 4.7 respectively for localised and regional/disseminated prostate cancer and current smokers of > 20/day had relative risks of 2.9 and 8.7. There was a dose/response relationship between the number of cigarettes currently smoked and the risk of invasive cancer.

The authors identified a possible bias in their results…current smokers might have more frequent health care contact and…might be more likely to be diagnosed earlier.

…these authors observed that : *There is approximately a 50-fold difference between populations with a high incidence (e.g. U.S., Sweden) and a low incidence (e,g. China, Singapore) of prostate cancer*. *However, autopsy studies reveal that the prevalence of histological prostate cancer in men over 50 is between 15% and 30%, and this prevalence rate appears to be consistent across populations.…initiating events for carcinogenesis may be relatively common across different populations, but there are likely to be large differences in exposure to factors which promote growth, invasion or metastasis leading to clinically evident prostate cancer.*

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32 Daniell, HW 1995, 'A Worse Prognosis for Smokers with Prostate Cancer', *Journal of Urology,* vol. 154, no. 1, pp. 153-157.

33 Rodriguez, C et al. 1997, 'Smoking and fatal prostate cancer in a large cohort of adult men', *American Journal of Epidemiology*, vol. 145, no. 5, pp. 466-475.

34 Cerhan, JR et al. 1997, 'Association of smoking, body mass, and physical activity with risk of prostate cancer in the Iowa 65+ rural health study (United States)', *Cancer Causes & Control*, vol. 8, pp. 229-238.

e. Giovannucci, E et al. 1999 [35]

…the possible influence of smoking on prostate cancer should be considered both in relation to initial causation and contribution to continued progression…

f. Kobrinsky, NL et al. 2003 [36]

…11,716 cases…The relative risk of current smokers (relative to 'never' smokers) that prostate cancer was metastatic at the time of diagnosis was 1.53 (p = 0.003) whilst the RR of regional invasion was 1.83 (p = 0.03).

g. Roberts, WW et al. 2003 [37]

…men (< 55 years of age) with prostate cancer that was undifferentiated (assessed as Gleason 7 and higher) and/or had spread to an extraprostatic location…

[of] 352 patients undergoing prostatectomy…5.4% of men were current smokers and 44.6% were former smokers. Compared with the remainder of participants (who had never smoked) the OR for extraprostatic cancer and/or a tumour of Gleason 7 or higher grade were 3.85 (95% CI 1.44-10.33) and 3.17 (95% CI 1.13-8.85) respectively. The risk of having extraprostatic cancer increased in proportion to the cumulative number of 'pack-years' smoked (p = 0.005) as also did the risk of having a tumour graded at Gleason 7 or higher (p = 0.003).

h. Plaskon, LA et al. 2003 [38]

Cases with more aggressive cancers (regional or distant stage disease or Gleason score 8-10) were compared with controls…The results were… *Although the odds ratios in current smokers were similar for men with more aggressive disease (OR=1.5) and those with less aggressive disease (OR=1.4), stronger associations with smoking history, measured as either smoking duration, number of cigarettes smoked per day, or total number of pack years smoked, were observed in men with more aggressive prostate cancer. For example, men who had a greater than 40 pack year history of smoking had a 40% increase in risk (95% CI 1.0-2.0) of less aggressive disease, but a 100% increase in risk (95% CI 1.3-3.1) of developing more aggressive prostate cancer relative to non-smokers.*

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35 Giovannucci, E et al. 1999, 'Smoking and risk of total and fatal prostate cancer in United States health professionals', *Cancer Epidemiology, Biomarkers & Prevention,* vol. 8, pp. 277-282.

36 Kobrinsky, NL et al. 2003, 'Impact of smoking on cancer stage at diagnosis', *Journal of Clinical Oncology,* vol. 21, no. 5, pp. 907-913.

37 Roberts, WW et al. 2003, 'Association of cigarette smoking with extraprostatic prostate cancer in young men', *The Journal of Urology,* vol. 169, pp. 512-516.

38 Plaskon, LA et al. 2003, 'Cigarette Smoking and Risk of Prostate Cancer in Middle-Aged Men', *Cancer Epidemiology, Biomarkers & Prevention,* vol. 12, pp. 604-609.

60. Dr McCullagh submitted that there were a number of credible biological mechanisms for the way in which smoking could accelerate the development of prostate cancer, in particular contending that smoking is associated with an increase in the blood levels of male sex hormones. [39]

61. Dr McCullagh concluded in his oral submission that the findings in articles by:

- Roberts, WW et al. 2003 (RR of 3.85) for current smokers;
- Kobrinsky, NL et al. 2003 (RR of 1.5 for metastatic disease and 1.8 for regional disease) for current smokers;
- Hussain, F et al. 1992 (high grade and advanced tumour association) with ever smoking; and
- Daniell, HW 1995 (association with ever smoking and advanced stage tumours)

were most persuasive of an association for the development of prostate tumours on the balance of probabilities – ie that an association is more likely than not.

62. Dr McCullagh noted the inconsistency of findings in epidemiological studies, and submitted that it was explicable by what was being measured.

63. In conclusion Dr McCullagh:

> …request[ed] the [Council] consider the significance of smoking as a factor, not only in initiating prostate cancer, but also as a most significant contributor to the degree of malignancy when this condition develops. I also request that consideration be given…in the Statements of Principles…that the histologically determined degree of anaplasia and the extent of extraprostatic spread can reflect a contribution by smoking to the progression of individual cases of prostate cancer.

Paper by Professor Gabriel A. Kune dated 1 October 1996

64. The Applicant relied upon a paper by Professor Kune which had also been submitted on behalf of the Applicant to a previously constituted Council in its (the previously constituted Council's) review of Statements of Principles 95 and 96 of 1995 then in force. Professor Kune did not make a complementary oral submission to the Council in this review.

65. Due to the state of the medical-science at the date of Professor Kune's paper, it focussed on clinical onset, contending that there were 15 epidemiological studies which found a statistically significant association

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[39] See Dai, WS et al. 1988, 'Cigarette Smoking And Serum Sex Hormones In Men', *American Journal of Epidemiology*, vol. 128, no. 4, pp. 796-805.

between smoking and prostate cancer. [40] He identified the 250,000 US veteran cohort as the main epidemiological study. [41]

66. On the basis of his interpretation of the study referred to in [65], Professor Kune submitted that:

66.1. The relative risks [for smoking and prostate cancer] in the several reports of this cohort have decreased from 2.2 by Dorn in 1959 to 1.7 by Kahn in 1966, to 1.2 in the reports of Rogot and Murray in 1980 and also of Hsing and co-workers in 1991.

66.2. the decrease in the risk over this period could be attributed to misclassification of smokers, as an estimated 40% of the cohort would have stopped smoking, and background risk factors would have increased over the period.

66.3. the important aspects in the results of this cohort were:

Elevated risks are statistically significant;
There is a positive dose-response effect;
Former smokers also had a statistically significant elevation of risk;

and that:

Confounding aetiological factors have not been corrected for.

67. Professor Kune's paper made submissions on the basis of his interpretation of the following articles in respect of risk and smoking:

a. Schuman, LM et al. 1977 [42]

…small population based case-control study of 40 cases…elevated risk of 1.5.

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40 See Appendix C.

41 Subjects in:

Dorn, HF 1959, 'Tobacco Consumption and Mortality From Cancer and Other Diseases', *Public Health Reports,* vol. 74, no. 7, pp. 581-593.

Kahn, HA 1966, 'The Dorn Study of Smoking and Mortality Among U.S. Veterans: Report on Eight and One-Half Years of Observation', *National Cancer Institute Monograph,* vol. 19, pp. 1-61 and pp. 63-123.

Rogot, E & Murray, JL 1980, 'Smoking and Causes of Death Among U.S. Veterans: 16 years of Observation', *Public Health Reports*, vol. 95, no. 3, pp. 213-222.

Hsing, AW et al. 1991, 'Tobacco use and prostate cancer: 26 year follow-up of US veterans', *American Journal of Epidemiology*, vol. 133, no. 5, pp. 437-441.

42 Schuman, LM et al. 1977, 'Epidemiologic study of prostatic cancer: Preliminary report', *Cancer Treatment Reports*, vol. 61, no. 2, pp. 181-186.

b. Honda, GD et al. 1988 [43]

…a community based case-control study in which a statistically significant relative risk of 1.9 was noted and…a positive dose-response effect.

c. Hsing, AW et al.1990 [44]

…an important cohort from the Lutheran Brotherhood Study in the USA…149 cases…statistically significant relative risk of 1.8.

d. Ross, RK et al. 1990. [45] In Wald, N and Baron, J eds. 1990

'Leisure world's' cohort…Southern California…14 cases with a statistically significant relative risk of 2.2.

…other subgroups of smokers were not at elevated risk.

e. Akiba, S & Hirayama, T 1990 [46]

…well-known large Japanese cohort in which a threefold statistically significant elevation of relative risk was noted for smokers of a few cigarettes, up to four per day, and of smokers of more than 35 cigarettes per day, and in which a total of only 13 cases have been identified in these sub-groups of smokers.

…other subgroups of smokers were not at elevated risk.

f. Mills, PK & Beeson, WL 1992 [47]

…the data the authors refer to comes from the Seven Day Adventist cohort…the authors reviewed their data and found an elevation of risk in ex-smokers with a rise in the relative risk in ex-smokers according to duration of smoking, that is they found a dose-response effect among ex-smokers.

g. Daniell, HW 1993 [48]

…statistically significantly more cases of prostate cancer were current smokers than those with benign prostatic enlargement when a smoking history of almost 400 men who have previously had a prostatectomy was reviewed.

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43 Honda, GD et al. 1988, 'Vasectomy, cigarette smoking and age at first sexual intercourse as risk factors for prostate cancer in middle-aged men', *British Journal of Cancer*, vol. 57, pp. 326-331.

44 Hsing, AW et al. 1990, 'Diet, tobacco use and fatal prostate cancer: Results from the Lutheran Brotherhood Cohort Study', *Cancer Research*, vol. 50, pp. 6836-6840.

45 Ross, RK et al. 1990, *Effects of cigarette smoking on 'hormone-related' diseases in a Southern California retirement community*, in N Wald, & J Baron eds., *Smoking and Hormone-Related Disorders*, Oxford: Oxford University Press, pp. 30-54.

46 Akiba, S & Hirayama, T 1990, 'Cigarette smoking and cancer mortality risk in Japanese men and women - results from reanalysis of the six-prefecture cohort study data', *Environmental Health Perspectives*, vol. 87, pp. 19-26.

47 Mills, PK & Beeson, WL 1992 [LETTER] Re: Hsing, AW et al. 1991 - See footnote 41 - a review of the data in Mills, PK et al. 1989, 'Cohort study of diet, lifestyle and prostate cancer in Adventist men', *Cancer,* vol. 64, pp. 598-604.

48 Daniell, HW 1993, 'More Stage A prostatic cancers, less surgery for benign hypertrophy in smokers', *The Journal of Urology*, vol. 149, pp. 68-72.

h. Nakata, S et al. 1993 [49]

…population based case-control study of almost 300 prostate cancer patients…a statistically significant elevated risk…with a past history of smoking.

i. Hiatt, RA et al. 1994 [50]

…large prospective cohort of over 43,000 men… 238 cases of prostate cancer…it was found that smoking one or more packs of cigarettes per day was associated with a statistically significant elevation of relative risk of 1.9 after statistical adjustment for alcohol consumption, and vasectomy, but no adjustments…for dietary factors and hormonal factors.

j. van der Gulden, JW et al. 1994 [51]

…case control comparison of almost 350 prostate cancer patients…a statistically significant elevated risk of 2.12 for those individuals who had smoked at any time…A dose-response was not obtained…the risk among ex-smokers was not different from the risk among current smokers.

k. Hayes, RB et al. 1994 [52]

…study of almost 1000 men with prostate cancer…in three parts of USA, overall no risk [ ]elevations were noted…statistically significant risk elevations were noted for smokers of 40 or more cigarettes per day, both among current smokers (RR = 1.5) and among former smokers (RR = 1.4).

l. Wegner, HE et al. 1994 [53]

…cohort of over 1400 men with prostate cancer, 14 cases of primary bladder cancer were observed…compared to the expected 6 cases, with a relative risk of 2.3. Cigarette smoking was noted as the single most important risk factor…

m. Rodriguez, C et al. 1996 [54]

…large cohort conducted by the American Cancer Society of over 350,000 men after 9 years follow-up, “current” smoking was statistically significantly positively

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49 Nakata, S et al. 1993, 'Study of Risk Factors for Prostatic Cancer', *Acta Urology Japan*, vol. 39, pp. 1017-1025.

50 Hiatt, RA et al. 1994, 'Alcohol consumption, smoking, and other risk factors and prostate cancer in a large health plan cohort in California (United States)', *Cancer Causes and Control,* vol. 5, pp. 66-72.

51 van der Gulden, JW et al. 1994, 'Smoking and drinking habits in relation to prostate cancer', *British Journal of Urology,* vol. 71, pp. 382-389.

52 Hayes, RB et al. 1994, 'Tobacco use and prostate cancer in Blacks and Whites in the United States', *Cancer causes and control,* vol. 5, pp. 221-226.

53 Wegner, HE et al. 1994, 'Bladder cancer following prostate cancer - an analysis of risk factors', *Int J of Urology and Nephrology*, vol. 26, pp. 43-51.

This article was not available to the RMA at the relevant times, and so could only be considered by the Council as new information.

54 Rodriguez, C et al. in Press, [ABSTRACT] 'Smoking and fatal prostate cancer in a large cohort of adult men', (see footnote 33) in Golditz, GA ed. 1996 (see footnote 28).

associated with fatal prostate cancer, and had a relative risk of 1.35 (95% CI 1.16-1.58).

n. Coughlin, SS et al.1996 [55]

> …almost 350,000 US men after 16 years of follow-up, current smoking was statistically significantly positively associated with fatal prostate cancer, with a relative risk of 1.31 (p >0.01).There was also a statistically significant dose-response trend.

68. Professor Kune also listed 23 studies in 24 reports which he stated had found no association. [56] He submitted that the absence of association in a study could be due to the design of that study, and did not necessarily indicate an absence of association. He stated:

> …there are several aspect of the studies which have not found an association between previous smoking and prostate cancer which may explain in most why no association was found…either small study numbers, or flawed design of the case control study using hospital based controls or assessing smoking habit after diagnosis.

69. Professor Kune submitted that evidence on cessation of smoking was important supportive evidence. He reasoned that:

> …even after two decades of cessation of smoking, a risk elevation can still be present. This finding is similar to our knowledge of cessation of smoking and lung cancer in the study of smoking habits of British physicians performed by Sir Richard Doll and [c]olleagues, in which…even after 15 years of cessation of smoking, there was still a twofold risk elevation relative to non-smokers.

70. Professor Kune made submissions on the basis of his interpretation of the following articles concerning increased risk after cessation of smoking:

a. Hsing, AW et al. 1991 [57]

> In the US Veterans' Study…the questionnaire was dated 1954 or 1957…follow-up of mortality was performed in 1980, so that their status was known for at least 23 years. If the status remained unchanged, they found that there were 817 cases of prostate cancer in ex-smokers, with a relative risk of 1.13 which was statistically significant.

b. Hsing, AW et al. 1990 [58]

> …The Lutheran Brotherhood Study…questionnaire in 1966 with a follow-up of mortality in 1986…20 years later…they identified 52 cases of prostate cancer in

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55 Coughlin, SS et al. 1996, 'Cigarette smoking as a predictor of death from prostate cancer in 348,874 men screened for the multiple risk factor intervention trial', *American Journal of Epidemiology,* vol. 143, no. 10, pp. 1002-1006.

56 See Appendix C.

57 See footnote 41.

58 See footnote 44.

those who in 1966 said they were occasional or ex-smokers, with a relative risk of 1.9 which was statistically significant.

c. Mills, PK et al. 1989 [59]

…in a questionnaire of 1976 and a follow-up of prostate cancer outcomes in 1982 … identified 79 ex-smokers with a relative risk of 1.24 and this elevation was not statistically significant.

d. Mills, PK & Beeson, WL 1992 [60]

…a further analysis…in 1992 of these ex-smokers showed a dose-response effect among ex-smokers according to duration of smoking.

71. Professor Kune submitted that there was evidence for 4 possible biological mechanisms whereby smoking may be related to prostate cancer:

…exposure of the prostate to…cadmium contained in tobacco and tobacco smoke, changes in the metabolism of N-nitroso compounds, an elevation in the level of male sex hormones, including testosterone, in response to smoking, and mutation of the p53 gene.

72. Professor Kune made submissions on the basis of his interpretation of the following articles which touched on:

72.1. cadmium exposure as one of the potential mediators of smoking induced prostate cancer:

a. IARC Monographs, no. 38 [61]

Each cigarette contains a variable amount of cadmium…estimated to be between 0.007 and 0.35 ug per cigarette:

A statistically significant relationship has been found between the amount of cadmium in the body of smokers and the number of years of smoking…a heavy smoker on average has more than twice the total amount of cadmium in the body compared to a non-smoker…

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59 Mills, PK et al. 1989, 'Cohort Study of Diet, Lifestyle and Prostate Cancer in Adventist Men', *Cancer*, vol. 64, pp. 598-604.

60 See footnote 47.

61 IARC Monographs 1986, *Evaluation of the carcinogenic risk of chemicals to humans, Tobacco Smoking*, International Agency for Research on Cancer, Monograph vol. 38, IARC, Lyon, France, pp. 115-116.

This monograph was not available to the RMA at the relevant times, and so could only be considered by the Council as new information.

b. Fuestel, A et al. 1987 [62]

…elevated levels of cadmium have been found in prostatic cancer tissue.

c. IARC Monographs, no. 58 [63]

[cadmium exposure is] accepted by the World Health Organisation…..as a category 1 human carcinogen.

d. Kolonel, LN & Winkelstein, W Jr 1977 [64] and Elghany, NA et al. 1990 [65]

In these two studies dietary cadmium alone did not give rise to elevated risks; only when the occupational exposure and smoking were both added to this index.

e. Waalkes, MP & Rehm, S 1994 [66]

Occupational exposure to cadmium has been linked with prostate cancer…among alkaline battery workers, in welding and electroplating and among cadmium production workers in general.

…cadmium has been found to be carcinogenic in experimental animals and a recently published review of animal models strongly suggests a role for cadmium in the cause of human prostate cancer.

72.2. N-nitroso compounds:

a. IARC no. 38, 1986 [67]

b. Magee, PN 1989 [68]

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62 Fuestal, A et al. 1987, 'Zinc, cadmium and selenium concentrations in separated epithelium and stroma from prostate tissues of different histology', *Urologic Research*, vol. 15, pp. 161-163.

This article was not available to the RMA at the relevant times, and so could only be considered by the Council as new information.

63 IARC Monographs 1993, *Evaluation of the carcinogenic risk of chemicals to humans, Beryllium, Cadmium, Mercury and exposure in the glass manufacturing industry*, International Agency for Research on Cancer, Monograph vol. 58, IARC, Lyon, France, pp. 66-103.

64 Kolonel, LN & Winkelstein, W Jr 1977, 'Cadmium and Prostatic Carcinoma', *The Lancet - September 10, 1977,* pp. 566-567.

65 Elghany, NA et al. 1990, 'Occupation, Cadmium Exposure and Prostate Cancer', *Epidemiology*, vol. 1, no. 2, pp. 107-115.

66 Waalkes, MP & Rehm, S 1994, 'Cadmium and prostate cancer', *Journal of Toxicology and Environmental Health* vol. 43, pp. 251 - 269.

67 See footnote 61.

68 Magee, PN 1989, 'The experimental basis of the role of nitroso compounds in human cancer, *Cancer Surveys*, vol. 8, pp. 207-239.

This article was not available to the RMA at the relevant times, and so could only be considered by the Council as new information.

c. Hecht, SS & Hoffman, D 1989 [69]

d. Pour, P 1981 [70] and Pour, PM 1983 [71]

and concluded from their findings that:

> The ability of N-nitroso compounds, including nitrosamines to cause the development of cancers at sites far distant from their site of absorption or administration has been well documented in experimental animals...expert opinion [is] that several smoking related cancers such as cancer of the pancreas and urinary tract are induced in this manner. Thus, if the association between smoking and prostate cancer is causal, it is reasonable to suggest…that N-nitroso compounds are one of the mediators of this effect.

72.3. male sex hormones:

a. Dai, WS et al. 1981 [72]

b. Dyslypere, JP & Vermeulen, A 1984 [73]

c. Anderson, AN et al. 1984 [74]

d. Vermeulen, A & Dyslypere, JP 1985 [75]

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69 Hecht, SS & Hoffman, D 1989, 'The relevance of tobacco specific nitrosomines (sic) to human cancer', *Cancer Surveys*, vol. 8, pp. 273-294.

This article was not available to the RMA at the relevant times, and so could only be considered by the Council as new information.

70 Pour, P 1981, 'A new prostatic cancer mode, systemic induction of prostatic cancer in rats by nitrosamines', *Cancer Letters*, vol. 13, pp. 303-308.

This article was not available to the RMA at the relevant times, and so could only be considered by the Council as new information.

71 Pour, PM 1983, 'Prostatic cancer induced in MRC rats by N-nitrosobis(2-oxopropyl)amine and N-nitrosobis(2-hydroxypropyl)amine', *Carcinogenesis*, vol. 4, no. 1, pp. 49-55.

72 Dai, WS et al. 1981, 'The epidemiology of plasma testosterone levels in middle-aged men', *Am J of Epidemiology*, vol. 114, pp. 804-816.

This article was not available to the RMA at the relevant times, and so could only be considered by the Council as new information.

73 Dyslypere, JP & Vermeulen, A 1984, 'Leydig cell function in normal men, effect on age, life-style, residence, diet and activity', *J of Clin Endocrinology and Metabolism*, vol. 59, pp. 955.

This article was not available to the RMA at the relevant times, and so could only be considered by the Council as new information.

74 Anderson, AN et al. 1984, 'Prolactin and pituitary-gonadal function in cigarette smoking in fertile patients', *Andrologia*, vol. 16, pp. 391-396.

This article was not available to the RMA at the relevant times, and so could only be considered by the Council as new information.

75 Vermeulen, A & Dyslypere, JP 1985, 'Testicular endocrine function in the ageing male', *Maturitas*, vol. 7, pp. 273-279.

This article was not available to the RMA at the relevant times, and so could only be considered by the Council as new information.

e. Lichtenstein, MJ 1987 [76]

f. Dai, WS et al. 1988 [77]

and concluded from their findings that:

> …there is satisfactory evidence that elevation of male sex hormones including testosterone levels, caused by smoking, may be one of the ways of mediating prostate cancer among smokers.
>
> Testosterone levels have been particularly high in young black US males and in the population of US black males, there is the highest recorded rate of prostate cancer in the world.

and noted further that prostate cancer had been induced in experimental animals by administering testosterone. [78]

72.4. mutation of the p53 gene:

a. Vogelstein, B & Kinzler, KW 1992 [79]

b. Greenblatt, MS et al. 1994 [80]

c. Brennan, JA et al. 1995 [81]

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76 Lichtenstein, MJ 1987, 'Sex hormones, insulin, lipids and prevalent ischemic heart disease', *Am J of Epidemiology*, vol. 126, pp. 647-657.

This article was not available to the RMA at the relevant times, and so could only be considered by the Council as new information.

77 See footnote 39.

78 See Noble, RL 1977 'The development of prostatic adenocarcinoma in *N*b rats followed prolonged sex hormone administration', *Cancer Research*, vol. 37, pp. 1929-1933; and

Pour, P & Stepan, K 1987 'Induction of prostatic carcinoma and lower urinary tract neoplasms by combination treatment of intact and castrated rats with testosterone propionate and *N*- nitrosobis (2 - oxypropyl) amine', *Cancer Research,* vol. 47, pp. 5699-5706.

Neither of these articles were available to the RMA at the relevant times, and so they could only be considered by the Council as new information.

79 Vogelstein, B & Kinzler, KW 1992, 'Carcinogens leave finger prints', *Nature (London)*, vol. 355, pp. 209-210.

This article was not available to the RMA at the relevant times, and so could only be considered by the Council as new information.

80 Greenblatt, MS et al. 1994, 'Mutations in the p53 tumor suppressor gene, clues to cancer etiology and molecular pathogenesis', *Cancer Research*, vol. 54, pp. 4855-4878.

This article was not available to the RMA at the relevant times, and so could only be considered by the Council as new information.

81 Brennan, JA et al. 1995, 'Association between cigarette smoking and mutation of the p53 in squamous cell carcinoma of the head and neck', *New England J of Medicine*, vol. 332, pp. 712-717.

This article was not available to the RMA at the relevant times, and so could only be considered by the Council as new information.

d. Navone, NM et al. 1993 [82]

e. Brookstein, R et al. 1993 [83]

f. Visakorpi, T et al. 1992 [84]

and concluded from the findings in the articles above that:

> …mutations in p53 are due to specific environmental exposures such as smoking, diet and others.
>
> … p53 mutations are seen in aggressive prostate cancers…[which] is consistent with the presence of environmental mutagens, such as smoking or diet, apparently influencing the transformation of a relatively indolent prostate cancer to a highly aggressive prostate cancer…
>
> This finding could also have some other explanation, such as non-specific adverse effect of smoking on survival, or lower rates of screening and surveillance among smokers compared to non-smokers.

73. Professor Kune submitted that the evidence examined by him met epidemiological criteria and that a reasonable hypothesis can be raised between smoking and service and the subsequent development of prostate cancer. [85] He placed particular emphasis on the studies that he contended showed a statistically significant positive association, the studies in which a dose-response was noted, and the evidence regarding mediation of the smoking effect, which he said gave strong biological plausibility and coherence. Professor Kune submitted that while the evidence did not reach the medical-scientific level of proven to the 95 percentile level this was because the positive associations found were not strong and may be explained by confounding and bias. However, Professor Kune noted the reasonable hypothesis test, and submitted that the contended association between smoking and prostate cancer could not be said to be theoretical, remote, tenuous or fanciful.

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82 Navone, NM et al. 1993, 'p53 Protein Accumulation and Gene Mutation in the Progression of Human Prostate Carcinoma', *Journal of the National Cancer Institute*, vol. 85, no. 20, pp. 1657-1669.

83 Brookstein, R et al. 1993, 'p53 is mutated in a subset of advanced-stage prostate cancers', *Cancer Research*, vol. 53, pp. 3369-3373.

This article was not available to the RMA at the relevant times, and so could only be considered by the Council as new information.

84 Visakorpi, T et al. 1992, 'Small subgroup of aggressive, highly proliferative prostatic carcinomas defined by p53 accumulation', *Journal of the National Cancer Institute,* vol. 84, no. 11, pp. 883-887.

85 See footnote 26.

Report by Total Environment Centre Inc, per Ben Cole 'Association Between Smoking and Prostate Cancer' dated 28 August 2003

74. The Applicant relied upon a report by Mr Cole which reviewed studies published in two periods of time 1996 to 1999 and 2002 to 2003. Mr Cole did not make a complementary oral submission.

75. In his report, Mr Cole submitted that:

> higher death rates from prostate cancer in current cigarette smokers, and inconsistent findings in incidence studies suggest that smoking may adversely affect survival in prostate cancer patients.

and made submissions on the basis of his interpretation of the following articles, which he submitted:

75.1. were in support of a positive association:

1996 to 1999

a. Cerhan, JR et al. 1997 [86]

> …n = 3,673…In a multivariate model, age, smoking (relative risk [RR] = 2.9 for currently smoking 20 or more cigarettes per day compared with never smoking…) … were independent predictors of prostate cancer, and these associations were stronger for regional or disseminated disease at diagnosis.
>
> The author's (sic) concluded that their findings suggested that smoking…are risk factors for prostate cancer.

b. Yu, GP et al. 1997 [87]

> …n = 25,436…A dose-response effect was found between ever-smoking and cancer patient survival. The predictive effect of smoking on survival was significant for patients with…prostate cancers…

c. Coughlin, SS et al. 1996 [88]

> …n = 348,874…men… screened as part of the Multiple Risk Factor Intervention Trial. Among cigarette smokers, there was some evidence of a dose-response relation (p = 0.20). The relative risk for those who reported they smoked 1-25 cigarettes per day compared with non-smokers was 1.21 (p = 0.04); the relative risk for those who reported smoking > or = 26 cigarettes per day compared with non-smokers was 1.45 (p = 0.0003).

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86 See footnote 34.

87 Yu, GP et al. 1997, 'Smoking History and Cancer Patient Survival: A Hospital Cancer Registry Study', *Cancer Detection and Prevention*, vol. 21, no. 6, pp. 497-509.

88 See footnote 55.

The authors concluded the findings did add to the limited evidence that cigarette smoking may be a risk factor for prostate cancer.

d. Rodriguez, C et al. 1997 [89]

… large prospective mortality study of 450,279 men… Current cigarette smoking was associated with fatal prostate cancer (rate ratio = 1.34, 95% confidence interval (CI) 1.16-1.56). The ratio was greater at younger ages, decreasing from 1.83 (95% CI 1.04-3.24) among men below the age of 60 years to 1.11 (95% CI 0.79-1.58) among men aged 80 years and above (p trend = 0.16).

No trend in risk…with the number of cigarettes per day or with the duration of smoking among current smokers at baseline, and no increased risk…among former smokers.

2002 to 2003

e. Plaskon, LA et al. 2003 [90]

…753 cases…current smokers had an increased risk (OR = 1.4, 95% CI 1.0 - 2.0) relative to non-smokers…Men who smoked for more than 40 years had a modest elevation in risk (OR = (95% CI = 1.0 – 2.2) (sic) [91]as did those who smoked an average of over 40 cigarettes a day (OR = 1.5, 95% CI = 0.8 – 2.8).

Length of smoking was…found to increase the risk…OR's for 10 pack years were 1.07, 20 pack years 1.14 and 30 pack years 1.22.

Strong associations were also found with more aggressive prostate cancer and smoking duration, number of cigarettes smoked per day, or total number of pack years smoked…men who quit smoking appeared to reduce their risk of prostate cancer approximately ten or more years after quitting.

The authors concluded that their study demonstrated a modest, positive association …

f. Kobrinsky, NL et al. 2003 [92]

…11,716 cases… An increase in metastatic disease and regional disease was found…(RR, 1.53; p = .003) and (RR, 1.83; p = .030) respectively.

g. Roberts, WW et al. 2003 [93]

…352 men who underwent radical prostatectomy…risk of extraprostatic (p = 0.005) and a Gleason sum 7 or greater/extraprostatic (p = 0.003)

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89 See footnote 33.

90 See footnote 38.

91 See at page 605 of Plaskon, NL et al. 2003 (OR = 1.5, 95% CI = 1.0 - 2.2).

92 See footnote 36.

93 See footnote 37.

disease increased with increasing cumulative pack-years smoked. Higher cumulative smoking in the 10 years before surgery was associated with an increased risk of extraprostatic (p = 0.004) and a Gleason sum 7 or greater/extraprostatic (p = 0.005) disease. Men who smoked more than 40 pack years had greater than 3 times the risk of extraprostatic and Gleason sum 7 or greater/extraprostatic disease compared to men who never smoked.

The authors concluded that a statistically significant dose dependent relationship between cigarette smoking and extraprostatic and Gleason sum 7 or greater/extraprostatic disease was identified… The authors suggested that this data supported the hypothesis that carcinogens in cigarette smoke may act as promoters of prostate cancer.

75.2. had found a negative or inconclusive association:

1996 to 1999

a. Villeneuve, PJ et al. 1999 [94]

…n = 1,623…the risk of prostate cancer was inversely related to the number of cigarettes smoked daily (p = 0.06) and cigarette pack years (p < 0.01)…no association…between the total number of smoking years or the number of years since smoking cessation.

The authors concluded that the analysis was limited by the absence of data related to tumour severity and screening history.

b. Furuya, Y et al. 1998 [95]

…case control study…329 patients with untreated prostate cancer and 188 patients with benign prostate hyperplasia (control patients)…

Smoking…found not to be [a] risk factor[ ]…odds ratio 0.986; 95% CI 0.69 -1.41…

c. Lumey, LH et al. 1997 [96]

…1,097 prostate cancer cases and 3,250 matched controls…several ordinal measures of lifetime smoking were compared to look for dose-response or threshold associations.

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94 Villeneuve, PJ et al. 1999, 'Risk factors for prostate cancer: results from the Canadian National Enhanced Cancer Surveillance System', *Cancer Causes & Control*, vol. 10, pp. 355-367.

95 Furuya, Y et al. 1998, 'Smoking and obesity in relation to the etiology and disease progression of prostate cancer in Japan', *International Journal of Urology*, vol. 5, no. 2, pp. 134-137.

96 Lumey, LH et al. 1997, 'Cigarette Smoking and Prostate Cancer: No Relation With Six Measures of Lifetime Smoking Habits In a Large Case-Control Study Among U.S. Whites', *The Prostate,* vol. 33, pp. 195-200.

No association was seen between prostate cancer and former or current smoking, age started smoking, number of years smoked, cigarettes per day…number of years since quitting, and lifetime tar exposure.

d. Rohan, TE et al. 1997 [97]

…case control…408 cases and 407 controls…there was little variation in risk…with pack years of cigarette consumption…little variation in risk by years since first smoked or (for ex-smokers) by years since quitting. The author's (sic) concluded…little support for an association between cigarette smoking and prostate cancer risk.

e. Ilicacute, M et al. 1996 [98]

…one hundred and one patients…202 hospital controls…smoking was found to be independently related to prostate cancer. [99]

f. Lumey, LH 1996 [100]

All published case-control and cohort studies…were collected.

The study found that neither a clinical nor a statistically significant association…seems likely, but it cannot be ruled out entirely.

g. Adami, H-O et al. 1996 [101]

…135,006 male construction workers in Sweden…as of December 1991 2,368 incident cases of prostate cancer and 709 deaths due to this disease had occurred.

The study found no convincing association between current smoking status, number of cigarettes smoked or years since onset and risk of prostatic cancer. The age-adjusted incidence RR among previous smokers was 1.09 and among current smokers 1.11 compared to non-smokers.

Weak and inconsistent trends were seen with increasing number of cigarettes smoked per day and increasing duration among current

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97 Rohan, TE et al. 1997, 'Cigarette smoking and risk of prostate cancer: a population-based case-control study in Ontario and British Columbia Canada', *European Journal of Cancer Prevention,* vol. 6, pp. 382-388.

This article was not available to the RMA at the relevant times, and so could only be considered by the Council as new information.

98 Ilicacute, M et al. 1996, 'Case-control study of risk factors for prostate cancer', *British Journal of Cancer,* vol. 74, pp. 1682-1686.

This article was not available to the RMA at the relevant times, and so could only be considered by the Council as new information.

99 While Mr Cole listed this as a negative study, the Council understood this to be a (positive) study in support of the relevant association.

100 Lumey, LH 1996, 'Prostate Cancer and Smoking: A Review of Case-Control and Cohort Studies', *The Prostate*, vol. 29, pp. 249-260.

101 Adami, H-O et al. 1996, 'A prospective study of smoking and risk of prostate cancer', *International Journal of Cancer*, vol. 67, pp. 764-768.

smokers…smoking is most likely not causally linked to the occurrence of prostate cancer. [102]

2002 - 2003

h. Kuper, H et al. 2002 [103]

From a literature review the authors concluded that the incidence of prostate cancer was unlikely to be linked to tobacco use.

76. Mr Cole's conclusion from his interpretation of the findings in the articles above that:

> …reports published between 1996 and 1999 found seven reports support[ing] a negative or inconclusive association…with four studies showing a positive association.

but submitted that

> …the weight of evidence…(Feb 2002 – August 2003) has supported the existence of a positive relationship…Most importantly Packson (sic – Plaskon) et al. (2003) and Roberts (2003) provided evidence for two key associations;
>
> 1) Length of time smoking was associated with higher risk of being diagnosed with prostate cancer; and
>
> 2) Increased length of time smoking was associated with more aggressive (life-threatening) cancers.

3 June 2003, Report by Dr David Douglas

77. The Applicant relied upon a report by Dr Douglas which related to a claimed exposure of a veteran to cadmium compounds. In support of that claim Dr Douglas submitted a review of literature on occupational exposure to cadmium and the development of prostate cancer. Dr Douglas did not make a complementary oral submission to the Council.

78. Dr Douglas noted his interpretation of the results in the following articles which touched on exposure to cadmium**:**

a. Potts, CL 1965 [104] and Kipling, MD & Waterhouse, JA 1967 [105]

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102 While Mr Cole listed this as a negative study, the Council understood from the RR figures that it was a weak positive study in support of the relevant association (see [142] - [150])

Further, the Council considered that the reference in Mr Cole's submission to 'not causally linked' did not reflect the Council's two-step process as set down by the full Federal Court (see [113] - [114]).

103 Kuper, H et. al 2002, 'Tobacco use and cancer causation: association by tumour type', *Journal of Internal Medicine*, vol. 252, pp. 206-224.

104 Potts, CL 1965, 'Cadmium proteinuria. The health of battery workers exposed to cadmium oxide dust', *Annals of Occupational Hygiene*, vol. 8, pp. 55-61.

105 Kipling, MD & Waterhouse, JA 1967, [LETTER] 'Cadmium and prostatic carcinoma', *The Lancet,* April, pp. 730-731.

… The number of cases reported was small, but the relative risks for prostate cancer were high among those heavily exposed to cadmium dusts for at least one year.

b. Sorahan, T & Waterhouse, JA 1985 [106]

…2,559 British cadmium battery workers…a small increase in prostate cancer overall, but in those heavily exposed for more than one year, the risk was four times that of non-exposed workers.

c. Elinder, C et al. 1985 [107]

…a small overall excess of prostate cancer in cadmium exposed men, but the excess risk increased greatly in those exposed for five or more years and with at least twenty years latency…

d. Elghany, NA et al. 1990 [108]

…a small increased relative risk...most apparent for aggressive tumours…

79. Dr Douglas cited and discussed a number of reports of animal research [109] which he submitted strongly supported the role of cadmium in causing prostate cancer in animal test systems.

80. Dr Douglas also referred to the 1993 IARC monographs' [110] conclusion that:

…cadmium and cadmium compounds are carcinogenic to humans (Group 1).

This was based on sufficient evidence from scientific studies of humans and experimental animal systems.

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106 Sorahan, T & Waterhouse, JA 1985, 'Cancer of the prostate among nickel-cadmium battery workers', *The Lancet*, vol. 1, p. 459.

107 Elinder, C et al. 1985, 'Cancer mortality of cadmium workers', *British Journal of Industrial Medicine*, vol. 42, pp. 651-655.

108 See footnote 65.

109 Waalkes, MP et al. 1992, 'Cadmium exposure in rats and tumours of the prostate' *Toxicology and Carcinogenicity* vol. 118, pp. 391-400.

Waalkes, MP & Rehm, S 1994, See footnote 66.

Waalkes, MP et al. 1999, 'Chronic toxic and carcinogenic effects of oral cadmium in the noble (NBL/Cr) RAT: induction of neoplastic and proliferative lesions of the adrenal, kidney, prostate, and testes', *Journal of Toxicology & Environmental Health*, vol. 58, pp. 199-214.

Waalkes, MP 2000, 'Cadmium carcinogenesis in review', *Journal of Inorganic Biochemistry*, vol. 79, pp. 241-244.

110 See footnote 63.

Hickey, K et al. 2001 [111]

81. As mentioned above, the Applicant provided a copy of this article and submitted that it supported the biological plausibility of a link between smoking and prostate cancer due to cadmium exposure.

Submission received by DVA on 13 May 2011 and the Council on 17 May 2011 – Exposure to Herbicides by Australian Defence Force personnel whilst in Vietnam

82. With respect to Statement of Principles No. 28 of 2005 the Applicant submitted that:

- any herbicides factor should maintain the 30 day exposure requirement, and
- the definition of 'being exposed to herbicides' should replicate that in the now revoked Statement of Principles No. 95 of 1995.

83. The Applicant re-confirmed reliance on its submission dated 12 December 2006 in respect of prostate cancer and tobacco products as set out above, and provided a copy of some new information, [112] asking the Council, if it did not direct an amendment to the Statements of Principles, to refer the study to the RMA.

84. The Applicant submitted that Australian troops in Vietnam were exposed to a 'significant amount of TCCD'. Further, the Applicant contended that the literature associated with the use of herbicides in Vietnam was extensive.

85. As mentioned above, the Applicant submitted two papers in support:

- the 1994 DVA paper [113]
- Muller, J et al. 2002. [114]

86. The Applicant noted the Executive Summary of the Muller, J et al. 2002 paper and contended that the:

> overall finding of this study demonstrates that evaporative distillation of water does not remove but enriches certain contaminants such as dioxins in drinking water… the authors…state TCDD exposure via drinking water may have been substantial, exceeding the recommended levels of European authorities and draft recommendations of the NHMRC of Australia. Further the authors state that personnel on board ships were exposed to biologically significant quantities of dioxins.

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111 See footnote 22. The Council's analysis is at [212]-[218].

112 See footnote 25.

113 See [39] and footnotes 15 and 16.

114 See footnote 24.

THE COMMISSIONS' SUBMISSIONS

87. The Commissions made comprehensive written submissions, dated:

- November 2009 on smoking and malignant neoplasm of the prostate; and
- May 2011 on Herbicides, Dioxin and TCDD exposure via potable water,

and oral submissions complementing the written submissions.

88. A Medical Officer with the Department of Veterans' Affairs represented the Commissions at the Council's meeting on 26 and 27 May 2011, and was the principal author of the Commissions' written submissions to the Council.

89. In the Commissions' submission:

> original epidemiological studies provide the most important information. Summary reports and reviews of such studies are of lesser value.

Smoking

90. The Commissions identified more than 100 reports of cohorts and case-control studies containing epidemiological data on smoking and prostate cancer and noted the large number of studies that had been available to the RMA. The Commissions further noted that a number of studies had reported statistical associations between smoking and prostate cancer. However, the Commissions contended that the extent and quality of data on smoking and risk of prostate cancer varied considerably, and that:

> the nature of prostate cancer, with its tendency to remain a sub-clinical disease, its low mortality rate, its age and race dependent incidence, together with the usual range of problems that can arise when studying associations with smoking, mean that studies of prostate cancer and smoking are very prone to having methodological shortcomings, notably various forms of bias and also confounding.

91. The Commissions contended that in respect of smoking and prostate cancer the overall picture based on the data from incidence studies was that some were positive studies; there were some statistically significant negative studies; and there were many studies showing no association. The data from mortality studies in the Commissions' view showed a consistent pattern of weak associations for fatal prostate cancer and smoking. The Commissions further suggested that the positive incidence studies were consistent with the mortality data and the evidence that there was a connection between more aggressive forms of prostate cancer and smoking, but not with prostate cancer incidence overall or less aggressive incidental forms of prostate cancer.

92. The Commission provided the Council with numerous summary tables and forest plots showing the results of epidemiological studies of the relation between smoking and prostate cancer. Meta-analyses conducted by the Commission showed non-significant relative risks for current smoking and onset of prostate cancer of 1.08 for cohort studies (14 studies), 0.94 for nested case-control studies (7 studies) and 0.97 for population-based case-control studies (12 studies). Meta-analysis of 9 cohort studies of current smoking and death from prostate cancer gave a statistically significant relative risk of 1.22.

93. The Commissions submitted that the dominant study in terms of size was Adami, H-O et al. 1996, [115] which they submitted:

> reported a small excess risk of prostate cancer in smokers, of borderline statistical significance and without convincing dose-risk trends. The authors noted that the association could easily be due to confounding or bias. The study was unable to control for a range of potential confounders, most notably dietary fat intake.

94. The Commissions submitted that there was good evidence that dietary fat intake was associated with prostate cancer risk, as evidenced by the existing animal fat consumption factors in both Statements of Principles.

95. Other limitations with the Adami et al. study as submitted by the Commissions were surveillance bias, and that smoking data was collected only at baseline.

96. The Commissions submitted that the best study, methodologically, was Giovannucci, E et al. 1999, [116] which had controlled for a range of potential confounders including dietary fat, and which updated smoking status every two years. The Commissions submitted that the results of this study indicated that smoking was not related to prostate cancer incidence.

97. The Commissions submitted that:

> In contrast to the incidence data, the studies looking at prostate cancer mortality do show a fairly consistent association with current smoking…

with evidence of positive dose-response trends for number of cigarettes per day and duration of smoking.

98. The Commissions also submitted that the evidence was reasonably consistent in showing that current (or recent) but not former smoking was associated with more advanced stage disease once cancer is present.

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115 See footnote 101.

116 See footnote 35.

99. The Commissions noted that a number of biological mechanisms had been suggested as explaining how smoking may initiate or progress prostate cancer, however submitted that none of these suggested mechanisms were well supported by the available evidence.

100. The Commissions also noted in their oral submissions complementing their written submissions their interpretation of the results from the following incidence studies:

a. Cerhan, JR et al. 1997 [117]

> …quite a small study of [people from rural Iowa] finding a positive association between smoking and prostate cancer…they would be less likely to come to be receiving regular healthcare…and to be undergoing any sort of screening…it would seem …that they're more likely to have a higher proportion of aggressive prostate cancer…and that might be a possible explanation for that positive association.

b. Plaskon, LA et al. 2003 [118]

> That was an odds ratio in current smokers of 1.4, borderline statistical significance, confidence interval of 1 to 2… it's an under 65 population…we're looking at perhaps a higher proportion of aggressive disease in that group…the fact that the odds ratio only became increased when they adjusted for PSA screening…they're really saying current heavy smokers have an increased risk in that group with a higher rate of more aggressive disease because of their age…

c. Andersson, S-O et al. 1996 [119]

> …a reporting odds ratio of 1.8…there doesn't seem to have been any screening program in that population, so we're looking at symptomatic or locally advanced

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117 See footnote 34.

In their written submission the Commissions said of Cerhan, JR et al. that:

> given the relatively small size of the study, the unrepresentative population and other methodological shortcomings, the Commission does not rate this as an important or persuasive study.

118 See footnote 38.

In their written submission the Commissions said of Plaskon, LA et al. that it:

> Reported an increased risk in current smokers and found a positive trend for pack years of smoking and a decreasing risk with time since cessation of smoking. This study involved subjects younger than typical prostate cancer patients (subjects were <65 years of age). The increased risk in current smokers (OR 1.4) seen in this study was only manifest after adjustment for [PSA] screening status. The OR increased from 1.03 to 1.43 when PSA screening was added to the regression model used in the study.

119 Andersson, S-O et al. 1996, 'Lifestyle Factors and Prostate Cancer Risk: a Case-Control Study in Sweden', *Cancer Epidemiology, Biomarkers & Prevention*, vol. 5, pp. 509-513.

In their written submission the Commissions said of Andersson, S-O et al. that it was:

> a smaller study [which] also found a statistically significant association in current cigarette smokers, but not pipe smokers. No trend was found with number of cigarettes smoked per day and no regular trend was seen for duration of smoking.

perhaps cases…possibly consistent with some sort of association with aggressive prostate cancer rather than prostate cancer overall.

d. Adami, H-O et al. 1996 [120]

…which is the biggest study…the lack of any dose-response data…even though it has found a significant elevated risk of 1.1, relative risk…as the authors of that study note, bias or confounding could well account for that association that they have reported.

…we have got evidence both for stage of disease and for grade of disease…it's not consistent but it's more indicative of an association between at least regional metastatic or distant metastatic disease and smoking but not locally invasive disease, but there seems to be an association there for stage of disease but not so much for grade of disease…

…other crucial evidence…what you see in ex-smokers…when you stop smoking the risk for more advanced disease seems to fall away sharply and you don't see the risk in ex-smokers, and I think that's consistent with a conclusion that smoking is having a role in progression of disease but not in any sort of initiation or not in causing the disease, not in instigating it…

…it appears that current smoking, current heavy smoking, is causing progression of existing disease, aggressive disease, and even more so fatal disease.

e. Giovannucci, E et al. 1999 [121]

…perhaps the best analysis and best data…with both incidence and mortality data…the findings in that paper are of a dose-response effect for recent smoking and risk of metastatic and fatal cancer. They found a positive association between lifetime pack years and distant metastatic disease, but that goes away when you control for recent smoking. …that seems to establish that it's particularly heavy recent smoking causing progression of disease and they found no association at all between early smoking and the later development of disease.

101. The Commissions submitted that a factor for clinical worsening could be included in Statement of Principles 28 of 2005. While the Commissions' written submissions said that 'the Commission[s] do[ ] not support the inclusion of a worsening factor' in Statement of Principles 29 of 2005, at the hearing of oral submissions complementing the written submissions, the representative of the Commissions said that the evidence 'could go either way' in support of a clinical worsening factor for Statement of Principles 29 of 2005.

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120 See footnote 101 and [93] - [95]

121 See footnote 35 and [96].

Herbicides, Dioxin and TCDD exposure via potable water

102. The Commissions' submission included a contended history of the use of pesticides and herbicides in Vietnam, and claims about the possible health effects and possible exposures. The Commissions contended:

> Concerns about adverse health consequences from exposure to herbicides in Vietnam have centred on TCDD. This is because of its demonstrated toxicity and carcinogenicity in animals. Experimental data supporting the carcinogenicity of the other herbicide constituents used in Vietnam are considerably weaker. [122]
>
> Exposure of Australian personnel to [Agent Orange and the other colour coded herbicides (Agents White, Blue, Purple, Pink and Green)] …came from being in areas that had been sprayed by US forces or via other pathways such as contaminated food.

103. The Commissions noted their interpretation of the Muller, J et al. 2002 paper, which they submitted was the main basis for existing factor 5 (b)(iii) in Statement of Principles No. 28 of 2005:

– Muller, J et al. 2002 [123]

> …[the] study found that an evaporative distillation process used on Navy ships in the Vietnam era to produce potable water did not remove, but rather would have enriched certain contaminants, including dioxins. That is, if dioxins including TCDD were present in the source water, their concentration would likely be increased in the potable water that was produced…
>
> The study did not examine whether the herbicides 2,4-D or 2,4,5-T could be similarly co-distilled. These herbicides readily degrade in the environment, TCDD is persistent in the environment…In water bodies it is found in sediment and suspended solids. It is highly but not completely insoluble in water.
>
> Australian Navy ships are understood to have used estuarine water in Vietnam for evaporative distillation. Such water could have been polluted by TCDD consequent to 2,4,5-T spraying in Vietnam. On that basis it is possible that Navy personnel were exposed to TCDD via the consumption of contaminated water.
>
> In the [Muller paper] an attempt was made to quantify exposure via this pathway. The [paper] derived an estimate of the estuarine water level of TCDD using:
>
> (i) contemporary records of TCDD levels in fish that were caught in Vietnamese waters; and
>
> (ii) experimental models of bioaccumulation of TCDD in fish placed in deliberately contaminated water.
>
> That level was combined with other parameter assumptions to produce an estimated exposure. A high degree of uncertainty surrounds the resulting estimate.

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122 See footnotes 138 and 142.

123 See footnote 24.

and concluded that:

> The actual quantity of TCDD in the estuarine water and in the potable water that was produced are unknown. Other parameters concerning the consumption of potentially contaminated water are also uncertain. Consequently, the possible dose of TCDD received via this pathway can only be loosely estimated.

104. The Commissions submitted that the potential inclusion of the contended potable water factor in Statement of Principles No. 29 of 2005 would first require that a link be found at the balance of probabilities standard between TCDD (specifically) and prostate cancer.

105. The Commissions' submission thus included a review of the information in the pool which touched on whether it was more probable than not that the relevant connection existed between TCDD exposure and prostate cancer based on the evidence from industrially exposed chemical workers' studies, environmental studies, occupational studies, veteran studies and others.

106. The Commissions submitted that the best available evidence concerning TCDD exposure and cancer risk was contained in those studies concerning industrial exposure, and Bertazzi PA et al. 2001 [124] (concerning the Seveso accident). The Commissions noted their interpretation of the following:

106.1. industrial exposure studies:

a. IARC 1997 [125]

> …best available evidence concerning TCDD exposure and cancer risk comes from studies of workers involved in the production of phenoxy herbicides and chlorophenols…[this is] the largest such study on dioxin and cancer risk…[it is a] co-ordinated multi-centre historical cohort mortality study of phenoxy herbicide and chlorophenol production workers and sprayers…36 cohorts from 12 countries and comprised 21,863 subjects and approximately ½ million person-years of follow-up.
>
> …the study reported mortality rates slightly higher than expected for cancer overall with an (sic) standardised mortality ratio (SMR) of 1.12 (95% CI, 1.04 to 1.21). For workers exposed to TCDD or higher chlorinated dioxins the prostate cancer SMR was 1.11 (95% CI, 0.81 to 1.50, 43 cases). For workers exposed to phenoxy herbicides or chlorophenols but not to TCDD or higher chlorinated dioxins the prostate SMR was 1.10 (95% CI, 0.71 to 1.62, 25 cases).

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124 Bertazzi, PA et al. 2001, 'Health effects of dioxin exposure: a 20-year mortality study', *American Journal of Epidemiology*, vol. 153, no. 11, pp. 1031-1044.

125 Kogevinas, M et al. 1997, (IARC 1997) 'Cancer Mortality in Workers Exposed to Phenoxy Herbicides, Chlorophenols, and Dioxins. An Expanded and Updated International Cohort Study', *American Journal of Epidemiology,* vol. 145, no 12, pp 1061-1075.

b. Steenland, K et al. 1999 [126]

> …provided an update on the largest of the individual cohorts in the IARC study. This cohort comprised 5,132 production workers…involved in the production of TCDD-contaminated products, including Agent Orange… In this cohort there were 28 deaths from prostate cancer, with an SMR of 1.17 (95% CI, 0.78 to 1.69).

c. Bodner, KM et al. 2003 [127]

> …added 10 years of follow-up to earlier reports on mortality in a cohort of 2,187 male chemical production workers…who had had substantial exposure to TCDD…the SMR was reported to be 1.7 (95% CI, 1.0 to 2.6).

106.2. environmental studies:

a. Bertazzi, PA et al. 2001 [128]

> …[this study] reported on the 20 year mortality of the Seveso cohort. For subjects in the highly exposed zone A there were no deaths from prostate cancer, versus 0.8 expected. In the less contaminated zone B, there were 8 deaths from prostate cancer versus 6.7 expected (relative risk 1.2, 95% CI, 0.6 to 2.4).

b. Revich, B et al. 2001 [129]

> …reported on public health in Chapaevsk in the Samara region in Russia…Residents…exposed to a wide range of environmental pollutants, particularly dioxins, from chemical plants. Significantly elevated levels of TCDD were detected on serum analysis, as well as in human and cow's (sic) milk, soil and drinking water... For prostate cancer the age adjusted incidence rate was lower in the city (7.0/100,000) than in the region (22.0) or in Russia overall (19.6).

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126 Steenland, K et al. 1999, 'Cancer, heart disease, and diabetes in workers exposed to 2,3,7,8-Tetrachlorodibenzo-dioxin', *Journal of the National Cancer Institute*, vol. 91, no. 9, pp. 779-786.

127 Bodner, KM et al. 2003, 'Cancer risk for chemical workers exposed to 2,3,7,8-tetrachlorodibenzo-p-dioxin', *Occup Environ Med*, vol. 60, pp. 672-675.

128 See footnote 124.

129 Revich, B et al. 2001, 'Dioxin exposure and public health in Chapaevsk, Russia', *Chemosphere*, vol. 43, pp. 951-966.

106.3. Ranch Hand veteran studies:

a. Akhtar, FZ et al. 2004 [130]

> …assessed cancer incidence and mortality in 1,009 Ranch Hand veterans…In white Air Force veterans the standardised incidence rate (SIR) for prostate cancer was elevated in the Ranch Hand veterans (SIR 1.46, 95% CI, 1.04 to 2.00, 36 cases), but also in the non-exposed veterans (SIR 1.62, 95 % CI, 1.23 to 2.10, 54 cases). In a sub-analysis there was some evidence of a dose-response effect across three categories of serum dioxin level, but this was based on small case numbers.

b. Ketchum, NS et al. 1999 [131]

> …found no increase in prostate cancer incidence in Ranch Hand veterans versus the comparison group (odds ratio 1.0) and no dose-response effect across background, low and high exposure categories.

c. Kayajanian, GM et al. 2001 [132]

> …using the Ranch Hand cohort…Among white men, the prostate cancer relative risk did not significantly change as a function of dioxin body burden…

106.4. other occupational studies:

a. Alavanja, MCR et al. 2003 [133]

> …examined the relationship between prostate cancer incidence and pesticides in a prospective cohort…of 55,332 male pesticide applicators in Iowa and North Carolina…data on…exposure parameters was obtained for a range of pesticides including 2,4,5-T and 2,4-D. No exposure response association with prostate cancer was seen with either herbicide, although the data were not provided.

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130 Akhtar, FZ et al. 2004, 'Cancer in US Air Force Veterans of the Vietnam War', *Journal of Occupational & Environmental Medicine*, vol. 46, no. 2, pp. 123-136.

131 Ketchum, NS et al. 1999, 'Serum dioxin and cancer in veterans of operation Ranch Hand', *American Journal of Epidemiology*, vol. 149, no. 7, pp. 630-639.

132 Kayajanian, GM et al. 2001, 'Dioxin body burdens in operation Ranch Hand veterans: Promotion blocking and cancer causation', *Ecotoxicology and Environmental Safety*, vol. 50, pp. 167-173.

133 Alavanja, MCR et al. 2003, 'Use of agricultural pesticides and prostate cancer risk in the agricultural health study cohort', *American Journal of Epidemiology*, vol. 157, pp. 800-814.

106.5. other Vietnam veteran studies:

a. AIHW 1999 [134]

> …an exercise to validate the presence of diseases that had been self-reported…The number of estimated validated prostate cancer cases in Vietnam veterans was 211, versus 147 expected based on national rates (95% CI, 123 to 173).

b. AIHW 2003 [135]

> …Korean war veterans… In the cancer incidence study there were 731 prostate cancers observed versus 619 expected, giving an SIR of 1.18 (95% CI, 1.09 to 1.27). In the mortality study the corresponding SMR was 1.29 (95% CI, 1.10 to 1.48).

c. Giri, VN et al. 2004 [136]

> …a pilot case-control study…examined the risk of prostate cancer from self-reported Agent Orange exposure. There were 47 prostate cancer cases…cases were more likely to report past Agent Orange exposure than controls (OR 2.06, 95% CI, 0.81 to 5.23).

d. Zafar, MB and Terris, MK 2001 [137]

> Prostate cancer was found in 13 of the exposed patients (41%) and 33 of the controls (34.4%). Agent Orange exposure was not statistically associated with prostate cancer detection (p = 0.15) nor PSA score (p = 0.9) or cancer grade (p = 0.41).

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134 Australian Institute of Health & Welfare 1999, *Morbidity of Vietnam Veterans. A study of the health of Australia's Vietnam veteran community - Validation study*, vol. 3, AIHW.

135 Australian Institute of Health & Welfare 2003, *Cancer incidence study: Australian Veterans of the Korean War*, AIHW Cat. No. PHE 48, Canberra.

136 Giri, VN et al. 2004, 'Association between Agent Orange and prostate cancer: a pilot case-control study', *Urology,* vol. 63, no. 4, pp. 757-760.

137 Zafar, MB & Terris, MK 2001, 'Prostate cancer detection in veterans with a history of agent orange exposure', *The Journal of Urology*, vol. 166, pp. 100-103.

106.6. other articles:

a. NAS IOM [138] 2000, [139] 2002, [140] 2004 updates [141]

> Updates 2000, 2002 and 2004 all affirmed the conclusion made in earlier …reports that there was limited or suggestive evidence of an association [142] between exposure to at least one of the chemicals of interest (2,4-D, 2,4,5-T or its contaminant TCDD, picloram or cacodylic acid) and prostate cancer.
>
> The [NAS IOM updates] also address biological plausibility, noting that no animal studies have reported an increased incidence of prostate cancer…The reports observe that plausibility of a casual relationship could be argued on the basis that the prostate is hormonally responsive and that TCDD has been shown to be an endocrine disrupter.

107. The Commissions concluded from their interpretations of the findings in the articles above that:

> The evidence from industrially-exposed chemical workers, with the highest exposure and best exposure assessment, could be seen to be weakly supportive of an

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138 On 6 February 1991 the Congress of the United States of America directed the US Secretary of Veterans' Affairs to request the National Academy of Sciences (NAS) to conduct a comprehensive review and evaluation of the available scientific and medical information regarding the health effects of exposure to Agent Orange and other herbicides used during the Vietnam conflict.

The NAS is a non-governmental organisation dedicated to the furtherance of science and technology and to their use for the promotion of general public welfare. The first review in 1992 of the published scientific literature in respect of Veterans and Agent Orange resulted in the publication of 1994. To conduct each subsequent review resulting in a release of an update, the NAS Institute of Medicine (IOM) establishes a new committee with some common members from its previous review. Committee members are selected because they are leading experts in their fields, have no conflicts of interest with regard to the matter under study, and have taken no public positions concerning the potential health effects of herbicides in Vietnam veterans or related aspects of herbicide or TCDD exposure. As with all reports from the IOM, the Committee's work was reviewed by an independent panel of distinguished experts (NAS IOM update 2002 from the Preface, pages ix-xi).

139 Institute of Medicine 2001, *Veterans and Agent Orange: update 2000*, 'Committee to review the health effects in Vietnam veterans of exposure to herbicides (third biennial update)', The National Academic Press, Washington DC.

140 Institute of Medicine 2003, *Veterans and Agent Orange: update 2002,* 'Committee to review the health effects in Vietnam veterans of exposure to herbicides (fourth biennial update)', The National Academic Press, Washington DC.

141 Institute of Medicine 2005, *Veterans and Agent Orange: update 2004*, 'Committee to review the health effects in Vietnam veterans of exposure to herbicides (fifth biennial update)', The National Academic Press, Washington DC.

142 The Council notes that the methodology of the NAS is to determine whether a statistical association exists; the increased risk of each disease for those US forces exposed during Vietnam service; and whether a plausible biologic mechanism or other evidence of a causal relationship exists (see page 6 of the 2004 update).

This methodology does not reflect the Council's two-step process in applying the reasonable hypothesis test as set down by the full Federal Court (see [113] - [114]).

> association… In the Commissions' view, the available evidence falls well short of establishing that it is more probable than not that prostate cancer can be caused by TCDD exposure…
>
> The Commissions' summary view is that there is more support in the available evidence for TCDD-contaminated chemical agents as a cause of prostate cancer than for TCDD alone, but that the evidence still falls well short of the balance of probabilities standard of proof.
>
> The evidence could also be interpreted as offering some (limited) support for an association between phenoxy herbicides and prostate cancer, as well as for herbicides generally, and for certain occupations, such as farming. Disentangling the various strands of evidence and reaching solid conclusions based on the available data is very difficult.

Mr M'S SUBMISSIONS

108. Mr M made a written submission to the Council dated 29 December 2010 concerning the contended potable water factor and made an oral submission complementing his written submission.

109. As mentioned above [143] at the Council's hearing of oral submissions complementing the written submissions Mr M clarified that he was seeking the addition of a factor to Statement of Principles 29 of 2005 in recognition of possible service related exposures similar to those contained in subsection 5 (b)(iii) of Statement of Principles 28 of 2005. He submitted there was sound medical-scientific evidence of the relevant association, given exposure to potable water which continued beyond Vietnam war service.

110. Mr M submitted that his contentions concerning bitumastic paint were an attempt to provide an explanation and biological mechanism for how dioxin might exist in ships' water tanks for a period longer than as stated in Statement of Principles No. 28 of 2005, that is, evidence in regard to dioxin in potable water that might extend the period of exposure beyond the Vietnam period of service. However, he accepted that any dioxin contaminated potable water from distilled Vietnamese water would have been gradually diluted as the ships' tanks were partially emptied and refilled over time.

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143 See[9.2] and [34].

111. In support of his contentions, Mr M referred to his interpretation of the following articles:

a. Muller, J et al. 2002 [144]

> …the study confirmed that TCDDs could be co-distilled in significant quantities when contaminated water was processed by ship distillation units. The study estimated that the daily body burden through drinking water and cooking water may have been 12-200 pg /kg bw /day of TCDDs.

b. Kayajanian GM, et al. 2001 [145]

> …Operation Ranch Hand personnel…found that the actual rates of PCa, [146] compared to the expected rates were "a surprise given the relative youth of the veterans" and the relative risk for PCa didn't change as a function of dioxin body burden.

c. Wilson, EJ et al. 2005 [147]

> A retrospective study of nearly 60,000 men followed for 38 years.
>
> Mortality from cancer 6% higher than expected among Vietnam veterans compared to the Australian male population (Scenario 1 (excluding veterans whose status is unknown) SMR 1.06 95% CI 1.02-1.11).
>
> For prostate cancer there was an increase in mortality of borderline significance – Vietnam veteran cohort. There were 107 deaths with an SMR of 1.23 (0.99-1.46). Table 6-7. Data by Service for Scenario 1 is provided at Tables D6-8 for Navy and prostate 1.29 (0.75-1.82). For Army and prostate 1.17 (0.89-1.46). For RAAF and prostate 1.38 (0.81-2.10).
>
> In conclusion the authors claimed that strengths of the study were its size, a study population that was racially homogenous, only male subjects, and minimal distortion effect of subjects with unknown vital status. Limitations include the existence of diseases and aspects of health that were not measured (by any mortality study), little information on exposures, particularly the amount of any exposure and healthy worker effect.
>
> In the chapter on perceptions and recollections of Vietnam service it is noted that there were different types of distillation systems in different ships. The recollections include the following:

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144 See footnote 24.

145 See footnote 132.

146 Prostate cancer.

147 Wilson, EJ et al. 2005, *The Third Australian Vietnam Veterans' Mortality Study*, Department of Veterans' Affairs, Canberra.
This article was not available to the RMA at the relevant times, and so could only be considered by the Council as new information.

- When tanks were open for inspection they were covered in 'browny yellow, greasy, slippery wet' coating;
- …use [of] an anti-fouling emulsion in the tanks;
- … the ships' tanks were emptied and cleaned with wire brushes;
- Fresh water tanks were sealed with "bitumastic paint", and tank cleaning and repainting would take place every 32 months...coating inside the tanks started peeling (about once a year) then the tanks were painted inside with bitumastic paint…some remember the name as "Caroline Black" which veterans recalled being used in the early 1960's. Later a red lead powder, and then Silvereen were used;
- For the Small Ship Squadron, recollections include that of extensive herbicide spraying along the riverbanks (p. 202).

d. Endo, S et al. 2008 [148]

This paper evaluates 'coal tar-water partitioning coefficient estimation methods and solute-solvent' molecular interactions in tar phase.

I understood from my communication with Professor Goss that the equations in that paper would enable both the absorption and the desorption of dioxin from coal tar or the bitumastic substance to be calculated.

e. NAS IOM 2008 -11, [149] Blue Water Navy Vietnam veterans and Agent Orange exposure

This paper includes a summary of the Muller paper and a further independent analysis to determine the likelihood of co-distillation of TCDD, using a different (batch distillation) theoretical model.

The NAS Committee's calculation was that 'the concentration of TCDD in the distillate is 400 ng/L (40/0.1)'. The authors claim that is in general agreement with the experimental results reported in the Muller paper (75-95% co-distillation).

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148 Endo, S et al. 2008, 'Evaluating coal tar-water partitioning coefficient estimation methods and solute-solvent molecular interactions in tar phase', *Chemosphere*, pages 532-538. Professor Goss, K-U is a co-author of this article.

This article was not available to the RMA at the relevant times, and so could only be considered by the Council as new information.

149 NAS IOM 2011, *Blue Water Navy Vietnam Veterans and Agent Orange Exposure*, Washington, DC, National Academies Press, accessed via www.nap.edu, by the Council's Secretariat.

This article was not available to the RMA at the relevant times, and so could only be considered by the Council as new information.

f. NAS IOM Veterans and Agent Orange Update 2008: [150]

> The committee responsible for this update, concluded that… the additional information available to it did not change the conclusion … there was limited or suggestive evidence of an association between exposure to chemicals of interest and prostate cancer… [151]
>
> The current committee engaged Steven Hawthorne…to review the Muller et al. (2002)…He affirmed the findings of the Australian study. [152]

g. Chamie, K et al. 2008 [153]

> a…cohort of approximately 6000 and the conclusions of that paper…
>
> Individuals who were exposed to Agent Orange had an increased incidence of prostate cancer, developed the disease at a younger age and had a more aggressive variant than their unexposed counter parts. Consideration should be made to classify this group of individuals as high risk, just like men of African American heritage and men with a history of prostate cancer. [154]

112. Mr M concluded from his interpretation of the findings in the articles above that:

> For the reasons stated above, Statement of Principle (sic) 29 of 2005 should be amended to include a factor related to TCDD… but within a time period where it could be expected that the dioxin would be reduced to essentially safe levels in the potable water, viz:
>
> > on board a vessel and consuming potable water supplied on that vessel, when within the last three (3) years, the water supply had been produced by evaporative distillation of estuarine Vietnamese waters.

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150 NAS IOM 2009, *Veterans and Agent Orange*, *Update 2008*, Washington, DC, National Academies Press, accessed via www.nap.edu by the Council's Secretariat.

This article was not available to the RMA at the relevant times, and so could only be considered by the Council as new information.

151 Previous IOM Committees reached the same conclusion – 1994, and updates 1996 to 2006.

See footnote 142 – This methodology does not reflect the Council's two-step process in applying the reasonable hypothesis test as set down by the full Federal Court (see [113] - [114]).

152 See footnote 150; NAS IOM Update 2008 at page 55.

153 Chamie, K et al. 2008, 'Agent Orange exposure, Vietnam War veterans, and the risk of prostate cancer, *Cancer,* vol. 113, no. 9, pp. 2464-70, as cited in NAS IOM 2009, *Veterans and Agent Orange*, *Update 2008*, Washington, DC, National Academies Press and Abstract accessed via www.ncbi.nlm.nih.gov/pubmed/18666213, by the Council's Secretariat.

This article was not available to the RMA at the relevant times, and so could only be considered by the Council as new information.

154 All Vietnam War veterans who received their care in the Northern California Veterans Health system were stratified as either exposed (n=6214) or unexposed (n=6930) to Agent Orange. The odds ratio for exposed men identified with prostate cancer vs unexposed was OR =2.19 (95%CI 1.72 -2.75) – Abstract, Results at page 1.

REASONS FOR THE COUNCIL'S DECISION

The Council's Task

113. In conducting a review the Council follows a two-step process. It first identifies the pool of information, ie by identifying from all the information that was available to the RMA when it determined, amended, or last amended the Statements of Principles the sound medical-scientific evidence (as that term is defined in section 5AB(2) of the VEA (see [7] above)) which touches on (ie is relevant to) the issue of whether a particular kind of injury, disease or death can be related to service.

114. The second step requires the Council to determine whether the sound medical-scientific evidence in the pool of information:

114.1. points to (as opposed to merely leaves open) [155] the relevant possibility (whether tobacco smoking (if found to exist in a particular case) could provide a link or element in a reasonable hypothesis connecting malignant neoplasm of the prostate or death from malignant neoplasm of the prostate to relevant [156] service). [157] The Council had to find that the hypothesis contended for was reasonable, and not one which was 'obviously fanciful, impossible, incredible or not tenable or too remote or too tenuous'. [158]

114.2. concerning tobacco smoking and/or the contended potable water factor (if found to exist in a particular case) could provide a relevant connection between malignant neoplasm of the prostate or death from malignant neoplasm of the prostate and relevant [159] service according to a standard of satisfaction 'on the balance of probabilities', or as being 'more probable than not'.

115. In these Reasons the association for both the reasonable hypothesis test ([114.1]) and the balance of probabilities test ([114.2]) are respectively referred to as the 'relevant association'.

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155 See full Federal Court decision at [49] per Branson J.

156 Relevant service here refers to operational, peacekeeping and hazardous service, British nuclear test defence service, and warlike and non-warlike service as those terms are defined in the VEA and the MRCA.

157 See *Vietnam Veterans' Association of Australia (NSW Branch) Inc v Specialist Medical Review Council and Anor* (2002) 69 ALD 553 (Moore J decision) per Moore J at [29].

158 See the full Federal Court decision in *Repatriation Commission v Bey* (1997) 79 FCR 364 which cited with approval these comments from Veterans' Review Board in *Stacey* (unreported 26 June 1985), all of which were in turn cited with approval in the Moore J decision at [33].

159 Relevant service here refers to eligible war service (other than operational service), defence service (other than hazardous service and British nuclear test defence service), and peacetime service as those terms are defined in the VEA and the MRCA.

116. It was with these tests firmly at the forefront of its collective mind that the Council considered the sound medical-scientific evidence in the pool of information and the submissions made by the Applicant, Mr M and the Commissions referable to the contended factors.

117. In forming its judgement of whether the sound medical-scientific evidence pointed to the relevant association, the Council was conscious that the reasonable hypothesis test is 'a test of possibility' [160] and 'an unusually light burden'. [161] If the reasonable hypothesis test was found not to be met, the balance of probabilities test necessarily could not be satisfied.

SCOPE OF REVIEW

118. As mentioned [28.2] - [28.4], the Council initially understood from Mr M's written submission that he sought amendments to Statement of Principles No. 28 of 2005. At the hearing of oral submissions on 26 - 27 May 2011, Mr M clarified his contention to the Council. He stated that his only contention was that a factor in the same or similar terms to existing factor 5(b)(iii) in Statement of Principles No. 28 of 2005 should be included in Statement of Principles No. 29 of 2005 (see [34]).

119. The Council's third preliminary decision on the proposed scope of review, as set out at [35] included the contended potable water factor. The Council's preliminary view noted that this may include a need for the Council to determine whether the sound medical-scientific evidence in the pool of information concerning exposure to dioxins (if found to exist in a particular case) could provide a relevant connection between malignant neoplasm of the prostate or death from malignant neoplasm of the prostate and relevant service according to a standard of satisfaction on the balance of probabilities.

120. The Council had regard to Mr M's oral submissions complementing his written submissions, and to the fact that the existing factor 5(b)(iii) in Statement of Principles No. 28 of 2005 is a stand-alone factor, the elements of which are:

- being on board a vessel; and
- consuming potable water supplied on that vessel;
- when the water supply had been produced by evaporative distillation of estuarine Vietnamese waters;

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160 See full Federal Court decision at [49] citing with approval Spigelman CJ in the New South Wales Court of Appeal decision at [111].

161 See full Federal Court decision at [55] per Branson J.

– for a cumulative period of at least 30 days, at least five years before the clinical onset of malignant neoplasm of the prostate. [162]

The Council's final view was that the contended potable water factor did not require the Council to consider whether exposure to dioxins could provide the relevant connection on the balance of probabilities. [163]

121. However, against the possibility that the contended potable water factor somehow incorporated contamination by dioxins, the Council also considered whether the sound medical-scientific evidence in the pool of information concerning exposure to dioxins, herbicides and/or pesticides impacted on whether the contended potable water factor should be included in Statement of Principles No. 29 of 2005.

122. The Council's final decision on the scope of the review was:

122.1. whether the contended smoking factor (clinical onset and/or clinical worsening) should be included in either or both of Statements of Principles Nos. 28 and 29 of 2005; and

122.2. whether the contended potable water factor for clinical onset should be included in Statement of Principles No. 29 of 2005.

123. Given the Council's final decision on the scope of review (which was not to include any extant or contended dioxin related factor in Statement of Principles No. 28 of 2005):

123.1. Mr C's written submission dated 17 October 2010 (see [24.2]); and

123.2. the Applicant's written submission received by DVA on 13 May 2011 so far as it related to herbicides and Statement of Principles No. 28 of 2005 (see [82])

were not relevant to any issue within (the final) scope.

POOL OF INFORMATION

124. As mentioned above, the first step for the Council was to determine the pool of information from the information that was available to (before) the RMA at the relevant times, as sent to the Council by the RMA under section 196K (via File Force in December 2008).

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162 See [9.2]

163 Exposure to dioxins is covered in existing factor 5(a) in Statement of Principles No. 28 of 2005.

125. As set out in [29] and [36] above, the Council's first and second preliminary decisions were that the pool of information should comprise sound medical-scientific evidence as defined in section 5AB(2) of the VEA being information which:

- epidemiologists would consider appropriate to take into account; and
- in the Council's view, 'touches on' (is relevant to) either or both of tobacco smoking and the contended potable water factor and which has been evaluated by the Council according to epidemiological criteria, including the Bradford Hill criteria.

126. The Council's final view on the pool of information was that it should comprise the sound medical-scientific evidence the Council had identified on a preliminary basis (**Appendix A**). In reaching this decision the Council took into account the written submissions and complementary oral submissions and considered whether any of the information to which it was referred should be in the pool.

COUNCIL'S INTRODUCTORY COMMENTS

Prostate Cancer

127. Prostate cancer is the most frequently diagnosed internal cancer of Australian men with nearly 20,000 cases diagnosed and 3,000 deaths per year. One in four men who live till their 80's will have prostate cancer diagnosed.

128. Prostate cancer develops very slowly and remains asymptomatic for decades as a localised, pre-malignant form within the prostate of the majority of middle-aged and older men. In a minority of older men, for unknown reasons, prostate cancer becomes more aggressive and spreads beyond the prostate gland when it is then incurable.

Screening for Prostate Cancer

129. The long latency and existence of an indolent, pre-malignant and localised form in the prostate gland provides the opportunity for effective screening for prostate cancer. This requires a sensitive and specific detection test together with localised treatment of the prostate that can effectively and safely eliminate the cancer. The development of the blood PSA test in the 1980's provided the first possibility of population screening for prostate cancer during its long (asymptomatic) pre-clinical period. Until very recently, high quality, large-scale, randomised clinical trials of population screening by blood PSA testing for prostate cancer failed to show any benefit in reduced deaths to balance the expected increase in treatment-induced side-effects.

However, the latest randomised trial suggests a small reduction in mortality as a result of PSA screening.

130. This supports national policies that have not adopted population screening by blood PSA testing for prostate cancer, due to dilution by low-grade, indolent prostate cancers that might not threaten life but may lead to unnecessary treatment. Nevertheless adoption of PSA screening is relatively common with as many as 50% of Australian men undergoing ad hoc PSA screening. As a result prostate cancer rates of diagnosis far exceed rates of death, indicating substantial over-diagnosis. This is manifest as rising rates of prostate cancer diagnosis with no change in overall prostate cancer mortality.

Prostate Cancer aetiology

131. The cause(s) of prostate cancer remain unknown despite a variety of epidemiological and clinical clues. Prolonged exposure to adult male levels of serum testosterone and genetic mutations are both necessary but not sufficient to develop prostate cancer. Additional possible contributions towards the origins and/or progression of prostate cancer include: ethnic/racial disparities in rates of fatal prostate cancer evident in geographical differences and migration effects; epigenetic and dietary factors; sexually transmitted infections and chronic prostatic inflammation; and heavy metals, for example cadmium.

132. With respect to cadmium, the Council noted a number of studies in the pool that touched on cadmium. The Council was of the view that the experimental evidence in favour of cadmium as a biological mechanism was not supported by clinical studies.

Stage and grade - Prostate Cancer

133. The severity of prostate cancer is defined by its stage, which reflects the extent of its spread from within the gland (organ-confined and potentially curable) to disseminated (local, regional or metastatic spread and incurable). This corresponds with the risk of life-threatening disease and/or its histological grade which gives the so-called Gleason score (the sum of the two highest gradings of malignancy in a multi-punch prostate biopsy, on a semi-quantitative 1-5 scale).

THE COUNCIL'S ANALYSIS OF THE INFORMATION IN THE POOL

Should There Be A ‘Tobacco Smoking’ and/or contended 'Potable Water' Factor?

134. Having settled the pool of information, the second question for the Council to consider was whether the sound medical-scientific evidence in the pool of information:

134.1. points to a potential ‘tobacco smoking’ factor as a link or element in a reasonable hypothesis connecting malignant neoplasm of the prostate to relevant service (see [114.1]) and if so, whether the relevant association exists on the balance of probabilities [114.2]; and

134.2. concerning the contended potable water factor has the relevant connection with malignant neoplasm of the prostate and relevant service on the balance of probabilities [114.2].

135. The Council considered all the evidence in the pool. However, given the large number of articles in the pool, the Council in these Reasons focuses upon its analysis of those articles that it considered most pertinent to the issues before it.

136. Ultimately, matters of weight are questions for the Council in the exercise of its expertise and scientific judgement, noting that the Councillors are appointed to a particular review because of their specialist expertise in the particular condition (in this case malignant neoplasm of the prostate).

COUNCIL'S ANALYSIS OF SALIENT ARTICLES IN THE POOL TOUCHING ON TOBACCO SMOKING

137. The Council took into account all the submissions made to it, both written and oral. [164] However, the Council's task is to determine whether the sound medical-scientific evidence available to the RMA at the relevant times:

137.1. 'points to' the relevant association, [165] and if so,

137.2. satisfies the balance of probabilities test. [166]

138. For the Council, consideration of the statistical data was a necessary, but not sufficient consideration of whether the different tests were met. The Council considered all the studies, both individually and collectively, to consider whether the sound medical-scientific evidence available to the RMA at the relevant times 'pointed to' as opposed to merely leaving open the relevant association, and if so, whether it satisfied the balance of probabilities test. [167] The Council having closely analysed all the information in the pool, placed particular weight on the articles discussed in detail below.

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[164] From the Applicant at [50] - [86].
From the Commissions at [87] - [107].
From Mr M at [108] - [112].

[165] See [114.1].

[166] See [114.2].

[167] See [114].

139. The Council noted a group of studies, [168] all of which were considered by the Council to be unpersuasive because they all dealt with:

139.1. organ confined cancers, the majority of which could only have been diagnosed because of PSA screening; and

139.2. a particular type of treatment.

140. In the Council's view all of these studies were affected by selection and other biases.

141. The Council noted too that it was difficult to interpret ex-smoker data in the studies. In some studies, ex-smoker was not defined. In others, an ex-smoker could have quit smoking at anytime up to the last 5 years.

Adami, H-O et al. 1996, 'A prospective study of smoking and risk of prostate cancer', *Int J Cancer*, vol. 67, pp. 764–768

142. This occupational cohort study collected smoking information in 1971-1975 from a nationwide cohort of 135,000 male construction workers in Sweden. As of December 1991, 2,368 incident cases of prostate cancer and 709 deaths due to prostate cancer were identified.

143. Registration of newly diagnosed cancers was considered to be 96% complete and 98% of prostate cancers were confirmed by histopathology or cytology. Mortality from prostate cancer was based on The Cancer Registry and National Death Registry where prostate cancer (ICD-7: 77) was coded as the underlying cause of death. Follow-up was for an average of 18 years.

144. The authors' findings [169] were:

> There were slightly elevated risks for previous and current smokers compared with never-smokers…a weak, but statistically significant, positive association (current

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[168] Pickles, T et al. 2004, 'The Effect of Smoking on Outcome Following External Radiation for Localised Prostate Cancer' *The Journal of Urology,* vol. 171, pp. 1543-1546.

Roberts, WW et al. 2003, See footnote 37.

For Applicant's submission see [59.2.g] and [75.1.g].

Spitz, MR et al. 2000, 'Epidemiologic Determinants of Clinically Relevant Prostate Cancer' *Int J Cancer (Pred Oncol),* vol. 89, pp. 259-264.

Daniell, HW 1993, See footnote 48.

For Applicant's submission see [67.g].

Merrick, GS et al. 2004, 'Effect of Cigarette Smoking on Biochemical Outcome after Permanent Prostate Brachytherapy', *Int J Radiation Oncology Biol Phys,* vol. 58, pp. 1056-1062.

[169] See at pages 765 - 766 and Table II at page 766.

smokers RR = 1.11 (95% CI 1.01-1.23)) between smoking and the risk of developing prostatic cancer.

A weak relationship between number of cigarettes smoked per day and the risk of prostatic cancer (*p* for trend = 0.04). Among smokers of more than 14 cigarettes, RR, was 1.12 (95% CI 0.98-1.27); however in smokers of 25 or more cigarettes per day, the risk was unity (RR = 1.00 (95% CI 0.72-1.38)).

No obvious trend [was found] with duration of smoking.

Among men who had been smokers for 30 years or longer…compared to never-smokers RR's were:

1.04 among smokers of 1-4 cigarettes per day;
1.06 among smokers of 5-14 cigarettes per day; and
1.30 (95% CI 1.06-1.59) among smokers of 15 or more cigarettes per day.

145. The authors' mortality findings [170] were:

Among smokers, the mortality RR was slightly higher than the incidence RR…Former smokers had essentially the same risk of dying from prostatic cancer as never smokers (RR 1.03), while current smokers had a statistically significant 26% (RR=1.26 (95% CI 1.06-1.50)) excess risk (Table III).

No trend with increasing number of cigarettes smoked per day…Among current smokers…a general 19-41% excess mortality rate from prostatic cancer but without any trend with duration of smoking (Table III).

146. The authors considered the strengths of their study included:

– the careful data collection with a combination of self-administered questionnaires and face-to-face interviews by nurses;
– that few men who were non-smokers later took up smoking and few heavy smokers and long term smokers quit during follow-up.

147. The authors in summary stated that they had found:

…a small excess risk of borderline significance and without convincing dose-risk trends. Potential confounding and bias seem more likely to have entailed slightly exaggerated, rather than under-estimated, relative risks in smokers. [171]

Council's comments

148. The Council considered this a persuasive study due to its large size (although it was not the largest of those commented upon by the Council) and as the incidence data was followed by mortality data for the same cohort. However, the study importantly did not adjust for confounders, for example

170 See at page 766 and Table III at page 767.

171 See at page 767.

diet ('increasing animal fat consumption' is an existing factor in Statement of Principles No. 28 of 2005 in respect of prostate cancer).

149. The Council noted the statistically significant RR's for both incidence (1.11 (95% CI 1.01-1.23)) and mortality (1.26 (95% CI 1.06-1.50)) showed a small increase of risk, with the mortality finding the stronger of the two. However, there was no clear dose-response between amount smoked and either incidence or death. There was no trend with duration of smoking.

150. The Council considered that this study:

- did not point to, but merely left open the possibility of, the relevant association for clinical onset (and so necessarily did not satisfy the balance of probabilities test for clinical onset);
- pointed to the relevant association for clinical worsening; and
- did not satisfy the balance of probabilities test for clinical worsening.

Akiba, S & Hirayama, T 1990, 'Cigarette Smoking and Cancer Mortality Risk in Japanese Men and Women - Results from Reanalysis of the Six-Prefecture Cohort Study Data', *Environmental Health Perspectives,* vol. 87, pp. 19–27. [172]

151. This was a large Japanese prospective cohort study, with 265,000 men followed for 15 years via cancer registers and self-report by questionnaire on smoking, drinking, dietary habits, occupation and marital status.

152. The authors found that:

> statistically nonsignificant elevations of the RRs for cancers of the … prostate in the group smoking 35 or more cigarettes per day [173] [35 + cigarettes per day - RR = 3.0 (95% CI 1.0 - 7.1)]. [174]

153. Further data for daily cigarette consumption and prostate cancer were included in Table 1 (at page 21) with relative risks of about 1.0, except for 1 - 4 cigarettes per day RR of 3.1 (95% CI 1.4 - 6.4) and 35+ as discussed above.

Council's comments

154. The Council noted that this was a large prospective study which looked at all cancers, not just prostate cancer. The study found there was no association between smoking and prostate cancer deaths.

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172 For Applicant's submission see [67.e].

173 At page 20.

174 See at Table 1, page 21.

155. The Council considered that the study:

- was non-contributory for clinical onset;
- did not point to, but merely left open the possibility of the relevant association so far as clinical worsening was concerned (and so necessarily did not satisfy the balance of probabilities test for clinical worsening).

Cerhan, JR et al. 1997, 'Association of smoking, body mass, and physical activity with risk of prostate cancer in the Iowa 65+ Rural Health Study (United States)', *Cancer Causes and Control*, vol. 8, pp. 229–238. [175]

156. This prospective cohort study of lifestyle factors, including smoking, and any potential association with the onset of prostate cancer, was conducted across a rural population of 3,673 between 1982 and 1993. The study featured prospective Registry data (part of the National Cancer Institute's Surveillance, Epidemiology and End Results (SEER) program) with confirmation by biopsy as to the extent of the disease, and occurred prior to PSA screening.

157. The findings referable to smoking were that:

> men who were current smokers at baseline had over a doubling of risk compared with non-smokers (Table 3) [RR 2.2 (95% CI 1.2 - 4.4)], while former smokers had only a 20% elevation in risk which was not statistically significant. [176] There was a dose-response with pack-years of smoking [177] …and number of cigarettes currently smoked…but most of the excess risk appeared to be associated with current smoking, as risks for former smokers remained only slightly elevated and were not associated consistently with time since quitting smoking. [178]

158. The authors also considered whether smoking (and other environmental factors) were associated with more aggressive tumours (defined as tumours with: regional or distant stage at diagnosis; unknown stage with poorly or undifferentiated grade; or local stage with undifferentiated grade). [179] They

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175 For Applicant's submissions see [59.2.d] and [75.1.a].
For Commissions' submission see [100.a].

176 See Table 3 on page 232.

177 See at Table 3 on page 232:
<31 pack years: RR = 1.3 (95% CI 0.7 - 2.5)
31 - 55 pack years: RR = 1.3 (95% CI 0.7 - 2.7)
>55 pack years: RR = 2.0 (95% CI 1.1 - 3.8).

178 See at page 233.

179 See at page 233.

concluded that there was a stronger association with clinical worsening than clinical onset: [180]

> For all prostate cancers - RR 2.9 (95% CI 1.3 - 6.7)
>
> For localised prostate cancer - RR 2.5 (95% CI 0.9 - 7.1)
>
> For aggressive prostate cancers - RR 8.7 (95% CI 1.9 - 40).

159. The authors noted that their findings were inconsistent with case-control studies (noting that only two of at least 15 such studies had found positive associations). The authors considered the different outcomes may be explained by a possibility of bias, given the over-representation of smokers in hospital-based control groups.

160. They also noted that results from prospective cohort studies had shown positive associations in 3 of 7 mortality studies, and 2 of 6 incidence studies. The authors considered that their cohort of older men may have been a contributing factor to their results being higher than previously reported. [181]

161. The authors speculated that the biological mechanisms for the positive association they had found between cigarette smoking and cancer may have been linked to hormonal changes (elevated levels of endogenous testosterone or estradiol and/or adrenal androgen androstenedione) and/or the tobacco constituents themselves (for example, N-nitroso compounds). They noted, however, that dietary factors may be confounding, given that smokers have been reported to have lower vegetable consumption, and higher intakes of total fat and meat than non-smokers. [182]

Council's comments

162. The Council considered that this was a relatively small study, which reduced the weight that could be attached to its findings. The authors identified 71 cases of confirmed prostate cancer.

163. The Council noted that the data in Table 3 showed a doubling of risk for current smokers versus never smoked (RR = 2.2 (95% CI 1.2-4.4)), and there was a clear dose-response relationship with pack years and number of cigarettes smoked per day.

164. A more detailed examination of the data showed (Table 5) that the increased risk (current smokers who smoke more than 20 cigarettes a day) is more due to regional / distant prostate cancer (RR = 8.7 (95% CI 1.9-40, a *p* trend

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180 See Table 5 at page 234.

181 See at page 235.

182 See at page 235.

= 0.004)) than localised prostate cancer. There was no dose-response curve for localised disease (RR = 2.5 (95% CI 0.9 - 7.1, a *p* trend = 0.09)).

165. The Table 5 data generally, and in particular, that a dose-response for localised disease was not quite statistically significant, cast some doubt upon whether the balance of probabilities test for clinical onset had been satisfied. Nevertheless, taking the evidence overall, the Council concluded that to be so. The Council considered that an RR of 8.7 for current smokers who smoke more than 20 cigarettes was striking, and strongly supported the relevant association for clinical worsening as being more probable than not.

166. The Council considered that this study:

- pointed to the relevant association for clinical onset,
- satisfied the balance of probabilities test for clinical onset;
- pointed to the relevant association for clinical worsening; and
- satisfied the balance of probabilities test for clinical worsening.

Coughlin, SS et al. 1996, 'Cigarette Smoking as a Predictor of Death from Prostate Cancer in 348,874 Men Screened for the Multiple Risk Factor Intervention Trial', *American Journal of Epidemiology,* vol. 143, pp. 1002–1006. [183]

167. This was a prospective cohort study to identify potential predictors of mortality due to prostate cancer. As smoking history was not obtained, never smokers could not be differentiated from ex-smokers. 37% of the cohort said they smoked cigarettes at the time of screening, with an average of 26 cigarettes smoked per day.

168. A positive association with cigarette smoking was observed. Cigarette smoking was associated with a 31% increased risk of death (RR=1.31 (95% CI 1.13-1.52)). Evidence of a dose relationship (a graded increase in risk with increasing numbers of cigarettes) was not strong. However, the risk of death from prostate cancer relative to non-smokers for those who smoked 1 - 25 cigarettes per day was 1.21 (95% CI 1.01-1.46), and for smokers who smoked > 26 cigarettes per day, was 1.45 (95% CI 1.19-1.77). [184]

169. The authors considered that the large cohort size of their study increased its statistical power for detecting weak associations, and that the on average younger age of the subjects was less likely to confound results with other mortality risks. The lack of information on duration of smoking, and changes

[183] For Applicant's submission see [67.n] and [75.1.c].

[184] See at page 1003.

in smoking status were important constraints, however were considered likely to render risk estimates conservative. [185]

170. The authors said that:

> although the results of the present study (and the collective results of all studies reported to date) do not implicate cigarette smoking as a causal factor in prostate cancer, the association is biologically plausible… the results of this study add to the limited evidence that suggests that cigarette smoking is associated with a modest elevation in risk of prostate cancer mortality. Although the results of studies carried out to date have been inconsistent, a weak association with cigarette smoking could have been overlooked in studies with relatively few prostate cancer cases or other design limitations… [186]

Council's comments

171. The Council considered this was a persuasive study, given its very high numbers in respect of death, with nearly 350,000 men followed for an average of 16 years.

172. The study found that those who were current smokers (defined as smokers at the start of the study) had a 31% higher risk of death from prostate cancer than non-smokers (see Table 2). [187] The Council considered that the authors' interpretation of the data was conservative, given that the conflation of never smokers and ex-smokers was likely to have understated the results.

173. The Council noted that the results were adjusted for several confounders, [188] which in the Council's view, supported the validity of its findings.

174. This was a study where the outcome was death. It did not measure incidence. Accordingly, in the Council's view it was a study which was non-contributory in terms of initiation/onset. Therefore, it neither pointed to, nor satisfied the balance of probabilities test for clinical onset.

175. The Council considered that the study:

- pointed to the relevant association;
- satisfied the balance of probabilities test

for clinical worsening.

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185 See at page 1005.

186 See at page 1005.

187 See at page 1004.

188 Age, race, income, diabetes and serum cholesterol. The study could still have been confounded by socio-economic factors, dietary factors or other exposures more directly related to risk of fatal prostate cancer (see at page 1005).

Daniell, HW 1995, 'A Worse Prognosis for Smokers with Prostate Cancer', *The Journal of Urology,* vol. 154, pp. 153–157. [189]

176. Hospital records were used in the study of 359 men with prostate cancer.

177. This study noted the outcomes of previous prospective studies, which generally demonstrated a lower incidence and higher mortality rate among smokers with prostate cancer, suggesting a higher mortality to incidence ratio for prostate cancer in men who smoke. [190] The authors noted that this would indicate more aggressive early growth or metastasis of tumours in men who smoke. Their study examined both potential associations.

178. This study confirmed more aggressive tumour advance in smokers, [191] and a worse prognosis. Consistent with other prospective studies, the results confirmed a higher mortality to incidence ratio to prostate cancer among smokers (for stage D tumours among men with non-stage A prostatic cancer and smoking OR = 2.1 (95% CI 1.3 - 4.3). For all men with non-stage A prostatic cancer five year tumour specific mortality rate was greater in smokers than non-smokers (39% versus 17%)). [192]

179. Delayed diagnosis was considered likely to have contributed to the advanced tumours among smokers in this study. Younger age and slender stature were relevant. Inherently more aggressive tumour tissue in the prostate cancers of smokers was not indicated. [193]

180. The authors recognized that a shortcoming with their study was that it relied upon retrospective chart review to determine smoking habit. This was considered 'less reliable' than the authors would have wished. [194]

Council's comments

181. The Council noted that the percentage of smokers was higher in men with more advanced disease, and mortality rates were higher in smokers than non-smokers. However, smokers had more advanced disease at diagnosis, and the study did not take into account level of medical care or socio-economic status.

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189 For Applicant's submission see [59.2.b].

190 See at page 153.

191 A higher percentage of stage D tumours - see Figure 1 and Table 1 both on page 154.

192 See at page 155; Table 4 at page 155; Figure 4 at page 156.

193 See at page 156.

194 See at page 156.

182. The Council's view was that this study:

- was non-contributory for clinical onset;
- pointed to the relevant association for clinical worsening;
- satisfied the balance of probabilities test for clinical worsening.

Giles, GG et al. 2001, 'Smoking and Prostate Cancer: Findings from an Australian Case-control Study', *Annals of Oncology,* vol. 12, pp. 761–765.

183. This was a large, population-based, case-control study, with 1,498 cases (aged less than 70 years, and with an histopathologically-confirmed diagnosis of adenocarcinoma of the prostate, excluding tumours that were well differentiated) and 1,434 controls randomly selected from men on the electoral roll, over the period 1994 - 1998. [195] Men with moderate-grade tumours were analysed separately from men with high-grade tumours.

184. Data were collected by interview and questionnaires:

> The smoking questions related only to cigarettes, and ascertained current smoking status at time of interview, age at commencement, age at stopping, time since stopping, periods of stopping, total years smoked and average daily consumption. A smoker was defined as having smoked at least one cigarette a day for at least a year. [196] … Total lifetime consumption of cigarettes was computed from total years smoked and the average daily consumption and was divided into tertiles based on the distribution in the controls (the tertile cut points were approximately 15 and 35 pack years). The reference group was men who had never smoked. [197]

185. The authors found that: [198]

> the ORs of ever smoking and current smoking were less than unity and the upper limits of their confidence intervals were in excess of but close to unity. The OR for ex-smokers was virtually unity. In analyses of age smoking started, years since quitting, duration of smoking, number of cigarettes smoked per day and total pack years smoked, all ORs were close to unity and the lower limits of all confidence intervals were less than unity while the upper limits excluded all but weak positive effects. There was no evidence of any dose-response relationships… ever smoking had a weak but not significant positive association with high-grade tumours and a weak but not significant negative association with moderate grade tumours…
>
> Ever smoked OR 0.96 (95% CI 0.81 - 1.14);
>
> Current smoker OR 0.82 (95% CI 0.65 - 1.05); and

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195 See page 761.

196 See page 762.

197 See page 762.

198 See Table 2 at page 763.

Ex-smoker OR 1.02 (95% CI 0.85 - 1.22). [199]

186. The authors concluded that:

> We have failed to identify any strong associations of smoking history with either moderate- or high-grade prostate cancer in men under the age of 70. Our findings are consistent with the conclusions of major reviews of this topic, which have been that smoking probably has little to do with the incidence of [prostate cancer] but may have modest effects on the progression of, and mortality from, this disease…[200]

187. In concluding that their study provided *'no persuasive evidence of an association between smoking and prostate cancer'*, the authors considered the possibility that their results may be due to chance, bias, and prostate specific antigen testing (which probably resulted in any moderate-grade tumours being identified which would otherwise not have been the case). [201]

Council's comments

188. The Council considered this was a very good case-control study, and the best Australian study of the potential association. However, the Council noted that it was conducted after PSA testing became commonplace.

189. The Council noted that the data in Table 2 [202] showed no association (see particularly the key findings in the top four rows of the 'all subjects' column) with narrow confidence intervals. It was, therefore, a solidly negative study concerning clinical onset and somewhat ambivalent concerning clinical worsening.

Giovannucci, E et al. 1999, 'Smoking and Risk of Total and Fatal Prostate Cancer in United States Health Professionals', *Cancer Epidemiology, Biomarkers and Prevention,* vol. 8, pp. 277–282. [203]

190. This was a prospective cohort study of 50,000 US health professionals, followed for about eight years, conducted by questionnaire. When prostate cancer was diagnosed (which occurred in 1,369 cases), hospital records and

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199 See at pages 762 - 3 and Table 2 on page 763.
For moderate grade tumours ORs ranged from 0.74 - 1.13 none of which had a statistically significant 95% CI.
For high grade tumours ORs ranged from 1.00 - 1.54 but only one had a statistically significant 95% CI.

200 See at page 764.

201 See at pages 764-765.

202 See at page 763.

203 For Applicant's submission see [59.2.e].
For Commissions' submission see [100.e].

pathology reports were obtained, and the cancers categorised by stage. [204] A cigarette pack year history for each participant was compiled. [205]

191. The authors found that there was no association between smoking and onset of prostate cancer (see Table 1, with a relative risk for current smoking and onset of prostate cancer of 1.04 (95% CI 0.85-1.27)).

192. The authors further investigated the potential relationship between smoking and onset of prostate cancer by considering whether smoking early in life (before age 30) might be associated with initiation of prostate cancer. They found that:

> Analyses of total pack-years smoked prior to the age of 30 years did not yield an association with total prostate cancer incidence (age-adjusted RR of 1.08 (95% CI, 0.92-1.27), for >10 versus 0 pack-years).

193. The authors also conducted a detailed analysis of the relationship between smoking and advanced prostate cancer, defined in two ways: distant metastatic prostate cancer and fatal prostate cancer. They found a clear dose-response relationship between smoking and both distant metastatic and fatal prostate cancer. They concluded that:

> Total lifetime cigarette pack-years was a risk factor for distant metastatic prostate cancer (RR, 1.14 (95% CI, 1.01-1.30) for a 20 pack-year increment) and fatal prostate cancer (RR, 1.18 (95% CI, 1.01-1.37)).

194. The results of the study were not affected by confounding by other risk factors for prostate cancer. In the multivariate models reported in the tables in the paper, the authors adjusted for age, body mass index at age 21, and intakes of calcium, total fat, vitamin E and lycopene. They also stated that:

> Further control for other potential confounders by including individually vasectomy, physical activity, alcohol, race, energy intake, and body mass index in 1986 in the basic multivariate model did not alter the results for smoking variables appreciably. [206]

Council's comments

195. The Council considered this to be the best study methodologically of the potential association. The Council considered it a very good, important and persuasive prospective study. It was a large study and had been thoroughly conducted. It included a detailed smoking history, and adjusted well for confounders, including for body mass index and several dietary variables, particularly dietary fat intake (Table 2).

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204 See at page 278.

205 A pack year was defined as the equivalent of smoking 20 cigarettes a day for one year, see at page 278.

206 At page 279.

196. The Council noted that the study found no association between smoking and the onset of prostate cancer. However, the study did find an association between smoking and distant metastatic/fatal prostate cancer (see Table 2). [207]

197. In the Council's view, the data in this study:

- was negative in respect of the relevant association for clinical onset;
- pointed to the relevant association for clinical worsening;
- satisfied the balance of probabilities test for clinical worsening.

Hayes, RB et al. 1994, 'Tobacco use and prostate cancer in Blacks and Whites in the United States', *Cancer Causes and Control,* vol. 5, pp. 221–226. [208]

198. This was a population based case-control study of 981 pathologically confirmed cases of prostate cancer, designed to ascertain whether the higher incidence of prostate cancer among black Americans was linked to tobacco use. Information about tobacco use was obtained by interview.

199. The authors found that:

199.1. risks for prostate cancer were not elevated for former or current cigarette smokers in either blacks or whites, although an increase in risk was noted for smokers of 40 or more cigarettes per day among former (OR = 1.4 (95% CI 1.0 - 1.5)) and current smokers (OR = 1.5 (95% CI 1.0 - 2.4)); [209]

199.2. there was no association between duration of cigarette use and exposure (pack years).

Odds ratios for all cancers ranged from 0.9 to 1.2, [210] which were not statistically significant, and there was no dose-response relationship, i.e. no trend of increased risk with increased exposure. [211]

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207 At page 279. See Table 2 at page 279: For 15 or more pack years of cigarettes:
for distant metastic prostate cancers: RR = 1.81 (95% CI 1.05 - 3.11)
for fatal prostate cancers: RR = 2.06 (95% CI 1.08 - 3.90).

208 For Applicant's submission see [67.k].

209 See at pages 221 and 223, and see Table 1 at page 222, which also specified for current smokers an OR = 1.4 (95% CI 1.0 - 1.9).

210 See Table 2 at page 223.

211 See at page 223.

200. No overall increase in risk was identified for age groups 60 - 69 [212] and 70 years or more. However, for age group 40 to 59, an elevated risk was found for both former and current cigarette smokers. The relevant findings were: [213]

> For former smokers 40 - 59 years with any cigarette use:
> OR = 1.7 (95% CI 1.1 - 2.6)
>
> For current smokers 40 - 59 years with any cigarette use:
> OR = 1.5 (95% CI 1.0 - 2.3)
>
> For current smokers 40 - 59 years of 40 + cigarettes per day:
> OR = 1.9 (95% CI 1.0 - 3.6)
>
> For duration smoked age 40 - 59 years:
> 20 - 39 years OR = 1.8 (95% CI 1.2 - 2.6)
> 45 + pack years OR = 1.9 (95% CI 1.2 - 3.0)

but with no clear dose-response relationship. [214]

201. The authors concluded that tobacco use probably is not a risk factor for prostate cancer:

> the risks associated with any use of cigarettes were not elevated, for either Blacks or Whites. There was evidence of increased risk in subjects who usually smoked 40 or more cigarettes per day but there was no evidence for increased risk in smokers of less than this amount. Additionally, duration of cigarette use and cumulative amount of cigarette use were not associated with prostate cancer risk …
>
> Increased risks for prostate cancer were found for men aged 40 to 59 years associated with both former and current cigarette use, but examination of usual daily amount smoked, duration of use, and cumulative amount of cigarettes smoked in this age group, showed no increase in risk with increase in exposure. In particular, the pattern of increased risk with usual use of 40 or more cigarettes per day, found in the total group, was not apparent in the age-specific analysis. The finding of an overall increase in risk for prostate cancer in younger men who smoked, but the lack of a dose-response, may indicate that smoking is associated with an unexamined risk-factor for prostate cancer. A possible selection bias for non-smokers among younger controls may have occurred, due to differential non-response… [215]
>
> The results of the present study may be consistent with a small excess risk for prostate cancer associated with tobacco use, but the lack of consistent findings in population

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212 Except for former smokers of 1 - 10 cigarettes per day: OR = 2.3 (95% CI 1.1- 4.8) (Table 3 at page 224).

213 See at Table 3 at page 224 and Table 4 at page 224.

214 See at page 223.

215 See at page 225.

subgroups and the lack of a clear dose-response relationship argue more strongly that no causal association exists. [216]

Council's comments

202. The Council considered this was a reasonably good case-control study, which analysed data in age groups.

203. The study only considered any association between smoking and clinical onset. It did not consider progression of disease or death, so it was not relevant to clinical worsening.

204. The Council noted that the study found no association between smoking and the onset of prostate cancer.

205. The Council considered that this study:

- did not support the relevant association for clinical onset; and
- was non-contributory for clinical worsening.

Hiatt, RA et al. 1994, 'Alcohol consumption, smoking, and other risk factors and prostate cancer in a large health plan cohort in California (United States)', *Cancer Causes and Control*, vol. 5, pp. 66–72. [217]

206. This was a prospective cohort study of 43,432 men of whom 238 developed prostate cancer. It was designed to consider any association between prostate cancer development and environmental factors, primarily alcohol and smoking. Information, including on smoking, was obtained by questionnaire.

207. The authors found that:

> Persons who reported smoking one or more [packs of cigarettes per day] had a significantly elevated, age adjusted [relative risk] of prostate cancer of 1.8 (95% CI = 1.1 - 2.8) compared with persons who never smoked… [218]
>
> … we found a significant relation between prostate cancer and smoking one or more [packs of cigarettes per day]; this relation persisted after adjustment for age, race, marital status, and education, and was evident for both White men and Black men. The results of the case-control comparison, which was a matched analysis using a subset of

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216 See at page 226. The Council considered that the reference to 'no causal relationship' did not reflect the Council's two-step process as set down by the full Federal Court (see [113] - [114]).

217 For Applicant's submission see [67.i].

218 See Table 1 and [2] of column 2 on page 68. After adjusting for age, alcohol consumption, smoking status, race and education the multivariate RR was 1.9 (95% CI 1.2 - 3.1).

the noncases in the cohort, suggested the same finding but were not statistically significant. [219]

208. The authors acknowledged that their findings could have been confounded by failing to control for dietary fat intake. [220]

Council's comments

209. The Council considered this was a persuasive study, particularly because:

209.1. it was a large study with 43,000 men followed for an average of 4.6 years;

209.2. of the confidence intervals, which were more than 1 against never smokers; and

209.3. the data were not confounded by PSA screening.

210. The study found that men who smoked at least one pack a day at baseline had nearly twice the risk of prostate cancer diagnosis during follow-up.

211. The Council considered this study:

- pointed to the relevant association for clinical onset, but did not satisfy the balance of probabilities test for clinical onset.
- was non-contributory in terms of clinical worsening.

Hickey, K et al. 2001, 'Smoking and Prostate Cancer', *Epidemiologic Reviews,* vol. 23, no. 1, pp. 115–125. [221]

212. This paper was a review of the outcomes of previous studies.

213. The review authors summarised the findings of the studies included in the review as follows: [222]

a. in respect of 23 prospective cohort studies (of which 3 produced positive association findings that were statistically significant, and a dose-response relationship), 5 nested case-control studies, 1 retrospective cohort study and 36 case-control studies:

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219 See at page 69.

220 See at page 70.

221 For Applicant's submission see [81].

222 See at pages 115-116.

> The reported associations between current smoking and prostate cancer ranged in magnitude and direction, from negative, 0.38…to positive, 2.9…
>
> The association between past smoking and prostate cancer also ranged from negative, 0.6…to positive 1.9…

b. most of the prospective cohort studies and all of the nested case-control studies that used incident cases as the outcome:

> …found no association between current smoking and prostate cancer.

c. the majority of the prospective studies that used death from prostate cancer as the outcome:

> …found a positive association between current smoking and prostate cancer…The strength of the association observed between current smoking and fatal prostate cancer was weak-in the order of approximately a 30 percentage increase.

The review authors noted that 4 of these studies did not find a positive result and 1 study produced a dose-response relationship between current smoking and fatal prostate cancer. Also 1 study found that:

> …men who smoked 15 or more pack years of cigarettes within the preceding 10 years were at a higher risk of distant metastatic prostate cancer (RR = 1.81: 95% CI: 1.05 - 3.11) and fatal prostate cancer (RR = 2.06: 95% CI: 1.08 - 3.90) relative to non-smokers. This study also found a significant dose-response relation between smoking over the prior 10 years and distant metastatic and fatal prostate cancer.

d. 10 of 15 population based case-control studies and 12 of 16 hospital based case-control studies:

> …produced essentially null results with regard to current smoking and prostate cancer…Five other case-control studies used hospital cases…four of these studies produced null findings.

214. The view was expressed that mortality studies (that use death from prostate cancer as the outcome) may have overstated the association between smoking and fatal prostate cancer, because smokers are more likely to die, especially from tobacco related diseases. This overstated effect would be exacerbated if prostate cancer were incorrectly recorded as the underlying cause of death. [223]

215. Other potential shortcomings were identified as:

- surveillance bias, given that smokers may have more contact with medical practitioners; [224]

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223 See at page 116.

224 See at page 116.

- uncontrolled confounding for dietary fat; [225]
- potentially different treatment between smokers and non-smokers; [226]
- failure to separate former smokers from current or never smokers, or smoking status otherwise being poorly defined; [227] and
- failure to update smoking status despite long follow-up periods. [228]

Council's comments

216. The Council considered that this was high-quality review of the literature on smoking and prostate cancer published to March 2000. The authors concluded that prospective cohort studies based on new cases of prostate cancer had not found associations with smoking, but that prospective cohort studies of fatal prostate cancer had found such an association. Overall, the authors concluded that smoking is associated with fatal prostate cancer, but they were unable to determine whether this was a genuine association between smoking and more aggressive cancer, or due to bias.

217. The Council considered there was a further potential explanation, not considered by the authors, being that smokers were less healthy generally, particularly so far as lung and cardiovascular disease were concerned.

218. Whilst the Council noted the views of the authors of this review paper, including those summarised at [213], it considered that the studies reviewed by the authors (which the Council noted were not necessarily the same as the studies considered salient by the Council) potentially supported the relevant association on the basis of the reasonable hypothesis test, at least so far as clinical worsening was concerned, but did not satisfy the balance of probabilities test.

Honda, GD et al. 1988, 'Vasectomy, cigarette smoking, and age at first sexual intercourse as risk factors for prostate cancer in middle-aged men', *Br J Cancer,* vol. 57, pp. 326–331. [229]

219. This was a population based case-control study of men aged 60 or less, to assess any association between prostate cancer and cigarette smoking among other exposures. The authors found that:

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225 See at page 116.

226 See at page 116.

227 See at page 121.

228 See at page 121.

229 For Applicant's submission see [67.b].

> Cigarette smoking was associated with moderately increased prostate cancer risk. The RR (ever v. never smoked) was 1.9 ([95%] CI = 1.2 - 3.0). There was a positive relationship between prostate cancer risk and smoking duration (trend test, 1-sided p = 0.001). Men who had smoked at least 40 years had 2.6 times the risk [RR 2.6 (95% CI 1.4 - 4.9)] of men who had never smoked. [230]
>
> The major findings of this study are the moderately strong relationships between prostate cancer risk and cigarette smoking duration… [231]

Council's comments

220. The Council considered this was a reasonably sound study, with cancers histologically confirmed.

221. The Council noted that the study found that smoking was associated with a risk of prostate cancer, [232] and that there was a clear dose-response relationship with years of smoking, ie the risk increased with years of smoking. [233] The Council considered that a doubling in risk indicated a strong relationship and was very unlikely to be due to chance.

222. The Council considered that this study:

- pointed to the relevant association for clinical onset;
- satisfied the balance of probabilities test for clinical onset;
- was non-contributory for clinical worsening.

Hsing, AW et al. 1990, 'Tobacco Use, and Fatal Prostate Cancer: Results from the Lutheran Brotherhood Cohort Study', *Cancer Research,* vol. 50, pp. 6836–6840. [234]

223. This was a self-selected prospective cohort study of 17,633 insured white males [235] at 20 year follow-up (from 1966 - 1986) to consider any associations with the risk of fatal prostate cancer, from which there had been 149 deaths. Information, including about tobacco use, was obtained from questionnaire completed at commencement only. While it was recognized that as many as 40% of the cohort could have ceased smoking since 1966, it was considered this would lead to an under-estimation of any association. [236]

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230 See at page 327 and see Table 3 at page 328.

231 See at page 328.

232 See [2] of column 2 at page 327.

233 See Table III at page 328.

234 For Applicant's submission see [67.c] and [70.b].

235 Being those white male policy holders of the Lutheran Brotherhood Insurance Society who were at least 35 years of age in 1966.

236 See at page 6839.

224. The authors found that:

> All forms of tobacco use were associated with an increased risk of prostate cancer… Risks were significantly elevated among persons who ever used any form of tobacco (RR = 1.8 95% CI, 1.1 - 2.9), [237] both among cigarette smokers and users of smokeless tobacco…. There was no clear dose-response with amount of cigarettes smoked, and there was little difference, after adjustment for the use of smokeless tobacco. Among current smokers, however, the risk was elevated among those who inhaled compared to those who did not (RR = 2.0 95% CI, 0.7 - 5.8)… [238]

225. The authors considered that the difference in their results from those of other studies may have been due to the high prevalence of cigarette smoking among the control groups drawn from hospital patients. [239]

Council's comments

226. The Council noted that the study found that smoking was associated with an increased risk of prostate cancer (see Table 3), [240] but that there was no dose-response relationship (see Table 4). [241] The data pre-dated PSA screening.

227. The Council considered this study was fairly persuasive. The confidence intervals were similar to those found in previous studies, being 1.1 - 2.9 overall, with a relative risk of 1.8 for all forms of tobacco (see [224]).

228. The Council considered that this study:

- was non-contributory for clinical onset;
- pointed to the relevant association for clinical worsening;
- did not satisfy the balance of probabilities test for clinical worsening.

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237 See Table 3 on page 6838.
For cigarette smoking only RR 2.0 (95% CI 1.1 - 3.7)
For smokeless tobacco only RR 4.5 (95% CI 2.1 - 9.7)

238 See at page 6837.

239 See at page 6839.

240 At page 6838.

241 At page 6838.

Hsing, AW et al. 1991, 'Tobacco Use and Prostate Cancer: 26-year Follow-up of US Veterans', *American Journal of Epidemiology,* vol. 133, pp. 437–441. [242]

229. This was a 26-year mortality follow-up by questionnaire of Dorn's cohort of nearly 250,000 US veterans, of whom 4,607 had died from prostate cancer, as ascertained from death certificates.

230. The authors found that:

> For cigarette smokers, the overall increases in risk were small but statistically significant among both ex-smokers (RR = 1.13) [95% CI 1.03 - 1.24] [243] and current smokers … (RR = 1.18) [95% CI 1.09 - 1.28]. [244] Moreover, the risk of prostate cancer increased steadily with the number of cigarettes smoked per day, with smokers of more than 40 cigarettes per day having a 51% increase in risk [RR 1.51 (95% CI 1.20 - 1.90)]. [245] The risks associated with cigarette smoking from the 26-year follow-up were lower than those from earlier follow-ups… The effect of age started smoking … was unrelated to risk of prostate cancer, while the number of years smoked was significantly related to risk, after adjustment for the amount smoked. [246]

231. The authors considered that the large number of prostate cancer deaths increased the force of their study. A continuing trend of decreasing relative risk over the duration of the study was ascribed to subjects ceasing to smoke since the completion of the initial questionnaire (answered in 1954 and 1957, and not repeated). The authors concluded that their risk ratios for the current smokers were therefore likely to be under-estimated.

232. The authors identified an increased risk among both current and former smokers. They considered that the differences in their results from those of other studies were referable to:

- a limited number of prostate cancer deaths in other cohorts; and
- that case-control studies:
  - were not designed specifically to evaluate smoking; and
  - usually used hospital controls, among whom the prevalence of smoking often exceeds the level in the general population, thus potentially masking a comparatively weak smoking effect. [247]

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242 For Applicant's submission see [70.a].

243 Table 1 at page 438.

244 ibid.

245 ibid.

246 See Table 2 at page 439.

247 See at page 440.

Council's comments

233. The Council considered this follow-up of the Dorn cohort the most relevant, as it was the most recent. [248] The study considered only death from prostate cancer, and so was non-contributory with respect to initiation/onset.

234. The Council noted that the study found that current smokers (those who were smokers at baseline) had a small (18%) increased risk of prostate cancer death, with a weak dose-response relationship (see Table 1). [249] Ex-smokers also had a small (13%) increased risk of prostate cancer death.

235. The Council noted that Table 1 showed a decrease over time in the magnitude of the association between smoking and prostate cancer. The Council considered that this was probably due to the fact that smoking was only assessed at baseline, and that many of those who had originally smoked (and so were classified as smokers) would have quit.

236. In the Council's view, the study was persuasive. It considered a quarter of a million people and 5,000 cases of prostate cancer.

237. In the Council's view the study:

- was non-contributory for initiation/clinical onset;
- pointed to the relevant association for clinical worsening;
- did not satisfy the balance of probabilities test for clinical worsening.

Hussain, F et al. 1992, 'High Grade Adenocarcinoma of Prostate in Smokers of Ethnic Minority Groups and Caribbean Island Immigrants', *Int J Radiation Oncology Biol Phys,* vol. 24, pp. 451–461. [250]

238. This study, conducted from 1980 to 1990, was of 670 patients with histologically confirmed adenocarcinoma of the prostate gland. Smoking

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248 Previous studies of the same cohort, all of which were considered by the Council, were:

Dorn, HF 1959, 'Tobacco Consumption and Mortality From Cancer and Other Diseases', *Public Health Reports,* vol. 74, no. 7, pp. 581-592, which was a prospective cohort study following 250,000 US veterans from 1954 to 1956

Kahn, HA 1966, 'The Dorn Study of Smoking and Mortality Among U.S. Veterans: Report on Eight and One-Half Years of Observation', *National Cancer Institute Monograph,* vol. 19, pp. 1-61 which was a mortality study, not limited to prostate cancer, being a follow-up at 8 1/2 years of the Dorn study, including data from respondents to questionnaires issued in 1954 and 1957. Dorn had reported findings after 2 1/2 years, using data only from those who answered the 1954 questionnaire.

Rogot, E and Murray, JL 1980, 'Smoking and Causes of Death Among U.S. Veterans: 16 years of Observation' *Public Health Reports,* vol. 95, no. 3, pp. 213-222 which was a 16 year follow-up of the Dorn cohort.

249 At page 438. See [230].

250 For Applicant's submission see [59.2.a].

history was collected from hospital and medical records. The results were as follows:

> 65.4% were smokers and 34.6% were non-smokers on aggregate. Smokers had 15.04%, 27.07% and 57.89% well, moderate, and poorly differentiated carcinoma, respectively, while non-smokers had 37.10%, 45.16% and 17.74% well, moderate, and poorly differentiated carcinoma of prostate, respectively. [251]

239. The level of exposure to smoking was related to the degree of differentiation of tumour. Most of the patients in the cohort were black, and black patients had the highest rate of high-grade and high stage tumours. [252] It was noted that blacks smoke heavier tar cigarettes than whites.

240. The authors concluded that their findings:

> …indicate that smoking is directly associated with degree of tumour differentiation and leads to high grade and more invasive carcinoma of prostate. Overall median survival with well, moderately, and poorly differentiated prostatic carcinoma was 86.24, 78.55 and 42.8 months, respectively… there is a statistically significant difference … in tumour stage of smokers compared to non-smokers … Tumour stage is also directly correlated with the median survival. [253]

241. The authors contended that their study:

> …conclusively proves the correlation of smoking and degree of differentiation of prostatic carcinoma. [254]

Council's comments

242. The Council noted that the study showed that those who smoked tended to have more advanced prostate cancer (i.e. a higher percentage of poorly differentiated tumour) than non-smokers (see Table 6). [255]

243. The Council considered this study was persuasive because of the findings set out at [240]. The study clearly differentiated median survival between smokers and non-smokers.

244. In the Council's view, this study:

- was non-contributory for clinical onset;
- pointed to the relevant association for clinical worsening;

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251 See at page 454.

252 See at page 459.

253 See at pages 455 - 456.

254 See at page 460.

255 At page 453.

– satisfied the balance of probabilities test for clinical worsening.

Kobrinsky, NL et al. 2003, 'Impact of Smoking on Cancer Stage at Diagnosis', *Journal of Clinical Oncology,* vol. 21, pp. 907–913. [256]

245. This cancer registry-based study identified 11,716 cases and was designed to consider any potential association between cigarette smoking and the spread of various cancers, including prostate cancer.

246. For a number of cancers, including prostate cancer, metastatic disease was most prevalent in current smokers, less prevalent in previous smokers, and least prevalent in non-smokers. This indicated a possible dose-effect between cigarette smoking and stage of disease (for metastatic disease - 17% for current smokers, 10.6% for previous smokers, and 11.4% for never smoked). [257]

247. The authors found that current smokers had an increased risk of developing metastatic disease compared with non-smokers, as well as an increase in the regional spread of prostate cancer at diagnosis. [258]

> For prostate cancer, 3.4% of non-smokers versus 5.8% of current smokers had regional disease and 11.4% of non-smokers versus 17.0% of current smokers had metastatic disease at diagnosis. [259]

248. The authors considered that the regional spread may have been confounded by age, although they noted that the difference between the three groups (current, previous and non-smoker) of 2 years was not clinically significant. [260]

249. The authors found a strong association with stage at diagnosis for prostate cancer.

> Compared to never smoked, current smokers had an increase in:
> - regional spread of disease at diagnosis – RR = 1.83 (95% CI 1.09-3.06); and
> - metastatic spread of disease at diagnosis – RR = 1.53 (95% CI 1.17-2.02). [261]

However, the authors said that their study did:

> not determine whether smoking in fact increases cancer spread and adversely affects the patterns of metastatic behaviour at diagnosis, or whether smoking is closely

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256 For Applicant's submission see [59.2.f] and [75.1.f].

257 See Table 2 at page 909.

258 See at pages 909-910.

259 See at page 910.

260 See at page 910.

261 See Table 3 at page 910.

associated with a population of patients far less likely to seek medical attention until symptoms are advanced.

These data identify an important public health issue that requires further research. If smoking facilitated cancer spread before diagnosis, smoking cessation at diagnosis would clearly be warranted. Although smoking is an important risk marker, further study is required to determine whether smoking may also be a risk factor or part of a complex causal mechanism for cancer spread…

In summary, smoking is associated with cancer spread at diagnosis. This finding … offers support for the notion that, with regard to cigarette smoking, 'it's never too late to quit.' [262]

Council's comments

250. The Council noted that many different types of cancer were studied, including 2,311 prostate cancers. The authors found that current smokers, but not ex-smokers, were more likely to have metastatic or invasive cancers than never smokers (for prostate cancer see [246] - [249] and Table 3). [263] The Council noted the authors did not look for a dose-response.

251. The Council considered that this study:

- was non-contributory for clinical onset.
- pointed to the relevant association for clinical worsening;
- did not satisfy the balance of probabilities test for clinical worsening.

Plaskon, LA et al. 2003, 'Cigarette Smoking and Risk of Prostate Cancer in Middle-Aged Men', *Cancer Epidemiology, Biomarkers and Prevention,* vol. 12, pp. 604 - 609. [264]

252. This was a population based case-control study. Smoking history of 753 subjects was elicited from interview. Prostate cancer diagnosis was confirmed by biopsy, and stage and grade were clinically available.

253. The authors found that current smoking was associated with a 40% increase (OR 1.4, 95% CI = 1.0 - 2.0) in prostate cancer risk relative to non-smokers. [265] Former smokers were not at an increased risk of prostate cancer when compared with non-smokers. [266] Stronger associations were discerned between smoking and aggressive prostate cancer. Earlier

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262 See at page 912.

263 See at page 910.

264 For Applicant's submission see ([59.2.h] and [75.1.e].
For Commissions' submission see [100.b].

265 See at page 605.

266 See at page 606.

commencement age for smoking also was found to be a risk factor for more aggressive tumours: [267]

> Men who smoke before age 15 years had an OR = 1.1 (95% CI 0.8 - 1.5) for having aggressive [prostate] cancer and an OR = 1.8 (95% CI 1.2 - 2.7) for more aggressive disease. [268]

254. The authors concluded that their study suggested that smoking is a risk factor for prostate cancer. They found current smokers at moderately increased risk relative to non-smokers, and a dose-response relationship, including a decline in risk upon cessation of smoking. [269]

255. The authors posited two primary mechanisms by which smoking may increase the risk of prostate cancer - by hormonal changes (increased bioavailable testosterone, and decreased bioavailable estradiol) and exposure to cadmium, and its interaction with the androgen receptor. [270] However, they concluded that the exact relationship between smoking and prostate cancer remained unclear.

256. They commented that the conflicting results in other studies (which had found no association) may be due to limited sample size, and possible confounding. Screening was identified as a strong negative confounder, on the basis that non-smokers generally lead healthier lifestyles, and are more likely to be screened, biasing results toward the null. [271]

257. The authors considered that a strength of their study was its adjustment for numerous potential confounders, including prostate screening. Further, they considered that their study of younger men (aged 40 to 64 years) may have strengthened their ability to detect modest associations that otherwise may have been overlooked. [272]

258. The authors said:

> …current smokers appear to be at moderately increased risk (OR = 1.4) for this disease relative to non-smokers. There also is a dose-response relationship, with a significant increase in risk estimates observed as the number of pack-years smoked increases. This is most pronounced in men with > 40 pack years of cumulative exposure who are

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267 See at pages 606-607.

268 See at page 607.

269 See at page 607.

270 See at pages 607-608.

271 See at page 608.

272 See at page 608.

> 1.6 times more likely to have prostate cancer and are at a 2-fold increased relative risk of developing more aggressive forms of the disease. [273]

and concluded that:

> The current population-based study demonstrates a modest positive association between smoking and risk of prostate cancer. In particular, current smokers, smokers of > 40 years duration, and those with > 40 pack years of exposure have a 40 - 60% [274] elevation in risk of prostate cancer relative to non-smokers [See Table 3 - for > 40 pack years OR = 1.4 (95% CI 1.0 -2.0) for less aggressive cancers and OR = 2.0 (95% CI 1.3 - 3.1) for more aggressive prostate cancer. There was an increase in risk for more aggressive prostate cancers in those who smoked 21 - 30 pack years, but it was not statistically significant: RR = 1.3 (95% CI 0.8 - 2.2)]. Moreover, these positive associations are stronger in men with clinically more aggressive forms of prostate cancer. Men who quit smoking appear to reduce their risk of prostate cancer - 10 or more years after cessation. [275]

Council's comments

259. The Council considered this was a sound study. It was reasonably well designed and analysed. It contained good quality and detailed smoking history data, and persuasive quit data, and differentiated between degrees of disease. The Council considered that these issues were well handled.

260. The Council noted that the study found that current smokers had a 40% higher risk of prostate cancer than never smokers, and that smoking was more strongly associated with more aggressive cancers than with less aggressive cancers. [276] Further, the Council noted that the study found a dose-response relationship. While the absence of a dose-response relationship does not, in the Council's view, indicate necessarily the absence of an association, the presence of a dose-response relationship is supportive evidence that the relevant association exists.

261. The Council considered that this study:

- pointed to the relevant association for clinical onset, but did not satisfy the balance of probabilities test for clinical onset;
- pointed to the relevant association for clinical worsening, and satisfied the balance of probabilities test for clinical worsening.

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273 See at page 607.

274 The authors define less aggressive (localised stage with a Gleason score ≤ 7) and more aggressive (regionalised stage or Gleason score 8-10) prostate cancer, at page 605.

275 See at pages 608-609.

276 See [258] above and Table 3 at page 607.

Rodriguez, C et al. 1997, 'Smoking and Fatal Prostate Cancer in a Large Cohort of Adult Men', *American Journal of Epidemiology,* vol. 145, pp. 466–475. [277]

262. This prospective cohort study of 450,279 US men in the Cancer Prevention Study II examined any relationship between smoking and the risk of fatal prostate cancer. All participants in the study were cancer free at enrolment in 1982. Men were followed for nine years, and there were 1,748 deaths from prostate cancer.

263. Current cigarette smoking was found to have a 34% elevation in risk for fatal prostate cancer (RR = 1.34 (95% CI 1.16 - 1.56) adjusted for age, race, education, family history of prostate cancer, vasectomy, exercise, body mass index, alcohol use and vegetable and fat meat intakes. The risk was greater at younger ages. [278] No trend in risk was observed with the number of cigarettes per day, nor with the duration of smoking among current smokers, and no increased risk was found among former smokers. [279]

264. The authors found no association between ever cigarette smoking (defined as men who reported smoking at least one cigarette per day for at least 1 year, and who did not smoke a pipe or cigars), [280] RR = 1.02 (95% CI 0.92 - 1.14) or former cigarette smoking (defined as ever cigarette smokers who indicated when they had quit smoking), [281] RR = 0.99 (95% CI 0.87 - 1.12) and the risk of fatal prostate cancer. [282]

265. The authors noted that an alternative explanation for their findings was that the association between smoking and fatal prostate cancer was due to reduced overall survival rate among smokers, and reliance on death certificates. It was noted that the validity of prostate cancer as the true underlying cause of death had not been assessed, and therefore the association could be overstated. [283]

266. The size and prospective design of the study were considered by the authors to be strengths, while they considered the once-only collection of data on smoking status was a limitation.

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277 For Applicant's submission see [59.2.c], [67.m] and [75.1.d].

278 See Table 5 at page 473.

279 See Table 4 at page 472.

280 See at page 469.

281 Ibid.

282 See at page 470.

283 See at pages 473 - 474.

267. Almost 50% of male current smokers at commencement of the study had quit in the follow-up 10 year period. However, this was considered likely to understate the risk estimates, such that the association between smoking and fatal prostate cancer may be stronger than had been found. [284]

Council's comments

268. The Council noted that the study found that smoking at baseline was associated with a 34% increased risk of death from prostate cancer, even after adjusting for a large number of confounders (see last column of Table 4). [285] However, no dose-response relationship was found.

269. The Council considered that this study was persuasive, despite the diagnoses occurring post-mortem, and the lack of a dose-response relationship. The Council considered that the methodological imperfections were overcome by the size of the study and the magnitude of the increase found.

270. The Council considered that this study:

- was non-contributory for clinical onset;
- pointed to the relevant association for clinical worsening;
- did not satisfy the balance of probabilities test for clinical worsening.

Ross, RK et al. 1990, *Effects of Cigarette Smoking on 'Hormone-related' Diseases in a Southern California Retirement Community*, in Wald, N and Baron, J eds, 1990, *Smoking and Hormone-Related Disorders,* Oxford University Press. [286]

271. This was a report on a prospective cohort study of approximately 14,000 subjects, in which relevant information was obtained by questionnaire.

272. The authors found that men who smoked for more than 30 years had a statistically significant reduced risk of prostate cancer compared to lifetime non-smokers (RR = 0.6 (95% CI 0.4 - 0.97)). [287] On the other hand, risk in short duration smokers was significantly increased (RR = 2.2 (95% CI 1.2 - 3.9)). [288]

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284 See at page 474.

285 At page 472.

286 For Applicant's submission see [67.d].

287 See at page 41.

288 Ibid.

Council's comments

273. The Council noted that the study comprised 5,106 men, and that 138 new prostate cancers occurred in about five years of follow-up. The Council considered that the study was well conducted.

274. The Council noted that:

- no association was found between smoking status (never, ex and current) and prostate cancer;
- an association was found between smoking and prostate cancer for duration smoked of 1 - 10 years; [289]
- no association was found thereafter and it appeared that men who had smoked for longer were at lower risk. [290] The Council noted the finding that men who had smoked for more than 30 years had a statistically significant reduced risk of prostate cancer compared with non-smokers, and noted further that this finding was not consistent with other studies in the pool; and
- no association was found between smoking and prostate cancer for number of cigarettes per day.

See Table 3.7. [291]

275. This was a negative study for both clinical onset and clinical worsening. However, the Council considered that at least the findings concerning duration of smoking of 1 - 10 years could potentially be due to random error or chance.

Slattery, ML and West, DW 1993, 'Smoking, alcohol, coffee, tea, caffeine and theobromine: risk of prostate cancer in Utah (United States)', *Cancer Causes and Control,* vol. 4, pp. 559–563.

276. This was a population-based case-control study conducted in Utah between 1983 and 1986. The subjects were white men aged 45 to 74 years, with histologically confirmed, first primary prostate cancer. [292]

277. The authors found that:

> Cigarette smoking as assessed by pack-years smoked was not associated with prostate cancer risk (Table 1) [> 28.6 pack years < 67 years = OR 1.24 (95% CI 0.86 - 1.80) and

289 RR = 2.2 (95% CI excludes 1.0) see Table 3.7 at page 47.

290 At page 47.

291 At page 47.

292 See at page 560. 75% of the subjects were Mormons, for whom smoking is proscribed.

> 28.6 pack years > 67 years = OR 1.22 (95% CI 0.81 - 1.85)], [293] although a slight elevation in risk was observed for older men with aggressive tumours [> 28.6 pack years < 67 years = OR 1.07 (95% CI 0.51 - 2.22) and > 28.6 pack years > 67 years = OR 1.50 (95% CI 0.77 - 2.88)]. [294]

278. The authors noted that their study had limited statistical power to evaluate associations with aggressive tumours.

Council's comments

279. The Council considered this was a reasonable case control study, although it had limited statistical power, and there was no definition of ex-smoker.

280. The Council noted that the data in the study showed no differences between the groups examined.

281. The Council considered this a neutral study, as it found no relevant association with either clinical onset or clinical worsening (see Table 1). [295]

THE COUNCIL'S CONCLUSIONS ON THE CONTENDED SMOKING FACTOR

282. The Council considered that the relevant association must be analysed on the basis of the whole body of information in the pool. The Council closely analysed all the information in the pool which touched on the contended smoking factor (clinical onset and clinical worsening). However, it placed particular weight on the articles discussed in detail above.

283. The critical question for the Council was whether the sound medical-science *'points to, as opposed to merely leaves open, the possibility of the relevant association.'* [296] It is only if the Council answered that question in the affirmative, that it needed to consider whether the relevant association was established on the balance of probabilities.

284. The Council considered its task a very difficult question of judgement, and acknowledged that its decisions on whether the relevant tests had been met were necessarily a question of expert and professional judgement, and matters in respect of which reasonable minds may differ. For the Council, consideration of the statistical data was a necessary, but not sufficient consideration of whether the different tests were met. The Council

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293 See Table 1 at page 560.

294 See at pages 560-561.

295 See at page 560.

296 See full Federal Court decision at [49] per Branson J and [114.1] above.

considered all the studies, both individually and collectively, in concluding whether the sound medical-scientific evidence available to the RMA at the relevant times 'pointed to' as opposed to merely leaving open the relevant association, and if so, whether it satisfied the balance of probabilities test. [297]

285. The Council considered that the question of whether the sound medical-scientific evidence available to the RMA 'pointed to' the relevant association for clinical onset was finely nuanced. There were negative studies in the pool, which, as discussed above, the Council found were methodologically sound and persuasive. [298] Ultimately, though, the Council, being always cognisant that the reasonable hypothesis standard is a '*test of possibility'* and *'an unusually light burden',* considered that the combined effect of the studies by:

- Cerhan, JR et al. 1997
- Hiatt, RA et al. 1994
- Honda, GD et al. 1988
- Plaskon, LA et al. 2003

'pointed to' (as opposed to merely leaving open) the relevant association, but did not satisfy the balance of probabilities test. The Council had some doubt that the paper by Cerhan, JR et al. 1997 satisfied the balance of probabilities test. While the Council considered that Honda, GD et al. 1988 did satisfy the balance of probabilities test, when the combined effect overall of the positive studies was taken into account, the Council considered that the balance of probabilities test was not met for clinical onset.

286. The Council noted that the Applicant and the Commissions were in agreement that the sound medical-scientific evidence available to the RMA at the relevant times was sufficient to justify an amendment to include clinical worsening in Statement of Principles No. 28 of 2005. The Council agreed.

287. While acknowledging the Commissions':

287.1. written submission (against); and

287.2. complementary oral submission (that the evidence 'could go either way')

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297 See [114].

298 Ross, RK at el 1990;
Giles, GG et al. 2001;
For clinical onset only:
Giovannucci, E et al. 1999;
Hayes, RB et al. 1994.

concerning a clinical worsening factor in Statement of Principles No. 29 of 2005, the Council was of the view that the combined effect of the studies by:

- Adami, H-O et al. 1996
- Cerhan, JR et al. 1997
- Coughlin, SS et al. 1996
- Daniell, HW 1995
- Giovannucci, E et al. 1999
- Hsing, AW et al. 1990
- Hsing, AW et al. 1991
- Hussain, F et al. 1992
- Kobrinsky, NL et al. 2003
- Plaskon, LA et al. 2003
- Rodriguez, C et al. 1997

not only pointed to the relevant association, but also satisfied the balance of probabilities test for clinical worsening. A key question for the Council in assessing the relevant studies was whether death was found to be due to prostate cancer, or whether prostate cancer was only a contributory factor. The data in the relevant studies on prostate cancer related deaths indicated that the deaths were due to prostate cancer.

288. Given the Council's decision, it was of the view that there was no need for it to consider any of the 'new information' with respect to the contended smoking factor, in order to form a view as to whether any directions or recommendations should be made to the RMA with respect to the conduct of any future investigation encompassing the contended smoking factor.

Formulation of factors to be included in Statements of Principles Nos. 28 and 29 of 2005

289. The Council's decision was that there was sound medical-scientific evidence on which the RMA could have relied to amend the Statements of Principles, and the Council should thus direct the RMA to amend:

- Statement of Principles No. 28 of 2005 to include tobacco smoking as a separate factor for each of clinical onset and clinical worsening;
- Statement of Principles No. 29 of 2005 to include tobacco smoking as a factor for clinical worsening only.

290. By letters dated 22 June 2012, the Council provided the Applicant, the Commissions and Mr M with an opportunity to comment by close of business on 27 July 2012 on the wording of proposed new factors in respect of active tobacco smoking for:

290.1. clinical onset and clinical worsening in Statement of Principles No. 28 of 2005; and

290.2. clinical worsening in Statement of Principles No. 29 of 2005.

291. The proposed new factors were:

291.1. in Statement of Principles No 28 of 2005:

> For current smokers only smoking at least 40 pack years of cigarettes or the equivalent thereof in other tobacco products before the clinical onset of malignant neoplasm of the prostate.
>
> Smoking at least 15 pack years of cigarettes or the equivalent thereof in other tobacco products before the clinical worsening of malignant neoplasm of the prostate, and where smoking has ceased, the clinical worsening has occurred within 10 years of cessation.

291.2. in Statement of Principles No. 29 of 2005:

> Smoking at least 40 pack years of cigarettes or the equivalent thereof in other tobacco products before the clinical worsening of malignant neoplasm of the prostate, and where smoking has ceased, the clinical worsening has occurred within 10 years of cessation.

292. The Applicant wrote to the Council by letter dated 12 July 2012, received by DVA on 26 July 2012, and said relevantly:

> The results from a recent mega study … generally supports 40 packs factor. We accept the SMRC conclusions…[299]

293. The Commissions made no comment on the wording of the proposed new factors.

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[299] The Council understands that in making this comment the Applicant relied upon the meta-analysis set out in the paper by Huncharek MD et al. 2010. From that paper the Applicant attached a copy of Table 1: Smoking and Prostate Cancer Risk: Overview of 24 Cohort Studies.

This paper was new information, and was not taken into account by the Council in this review (see footnote 25) and [288].

294. Mr M advised by e-mail dated 12 July 2012 that he intended to make no comment on the wording of the proposed new factors.

295. The Council took into account the responses it received from the Applicant, the Commissions and Mr M.

296. In formulating the factors the Council considered that the best directly relevant data for:

296.1. clinical onset was in the Plakson, LA et al. 2003 paper, Table 3 of which showed a statistically significant relative risk for less aggressive prostate cancer and >40 pack years of smoking. While the Cerhan, JR et al. 1997 paper did not provide data on pack years or duration of smoking for localised disease, it did so for all prostate cancers combined. Table 3 in the Cerhan, JR et al. 1997 paper showed a statistically significant relative risk for >55 pack years for all prostate cancers.

296.2. clinical worsening were the papers by Giovannucci, E et al. 1999 and Plaskon, LA et al. 2003. Both showed that risk for ex-smokers only increased within 10 years of quitting smoking. For Statement of Principles 28 of 2005, the Council relied upon Table 2 of the paper by Giovannucci, E et al. 1999 which showed a statistically significant increased risk of both metastatic and fatal prostate cancer for men who smoked 15 or more pack years. For Statement of Principles 29 of 2005 the Council relied upon the Plaskon, LA et al. 2003 paper, Table 3 of which showed a statistically significant increased risk only for those who smoked > 40 pack years. There was an increase in risk for those who smoked 21 to 30 pack years, but it was not statistically significant.

297. The Council thus directed the RMA to include the following factors in:

297.1. Statement of Principles No. 28 of 2005:

> For current smokers only smoking at least 40 pack years of cigarettes or the equivalent thereof in other tobacco products before the clinical onset of malignant neoplasm of the prostate.
>
> Smoking at least 15 pack years of cigarettes or the equivalent thereof in other tobacco products before the clinical worsening of malignant neoplasm of the prostate, and where smoking has ceased, the clinical worsening has occurred within 10 years of cessation.

297.2. Statement of Principles No. 29 of 2005:

> Smoking at least 40 pack years of cigarettes or the equivalent thereof in other tobacco products before the clinical worsening of malignant neoplasm of the prostate, and where smoking has ceased, the clinical worsening has occurred within 10 years of cessation.

THE CONTENDED POTABLE WATER FACTOR

298. As stated above, the contended potable water factor is that a factor in the same or similar terms to existing factor 5(b)(iii) in Statement of Principles No. 28 of 2005 should be included in Statement of Principles No. 29 of 2005.

299. Existing factor 5 (b)(iii) in Statement of Principles No 28 of 2005 provides as follows:

> being:
>
> (iii) on board a vessel and consuming potable water supplied on that vessel, when the water supply had been produced by evaporative distillation of estuarine Vietnamese waters,
>
> for a cumulative period of at least 30 days, at least five years before the clinical onset of malignant neoplasm of the prostate…

300. Relevant terms are defined in clause 8 of Statement of Principles No. 28 of 2005, viz:

- 'estuarine Vietnamese waters' means at least one of the waterways or harbours in the relevant areas described in Items 4 and 8 of Schedule 2 of the VEA; and
- 'potable water' means water used for drinking water, food preparation and beverage production.

301. The only paper within the pool of information which the Council considered 'touched on' (was relevant to) the contended potable water factor was that by Muller, J et al. 2002, as analysed below.

Muller, J et al. 2002, *Examination of the potential exposure of Royal Australian Navy (RAN) personnel to polychlorinated dibenzodioxins and polychlorinated dibenzofurans via drinking water*, The National Research Centre for Environmental Toxicology NRCET (ENTOX), A report to the Department of Veterans' Affairs, Australia, pp. 1-75. [300]

302. This study investigated the potential for exposure of sailors on Australian Navy ships and Army small ships to contaminants via potable water. Laboratory experiments were carried out to assess whether sailors could have been exposed to herbicides and pesticides through drinking water. Specifically, experiments were carried out to ascertain whether PCDD/Fs [301] and DMA [302] could co-distil in significant quantities in the distillation units of ships. The study also evaluated the potential exposure level and pathways.

303. The authors described the distillation process which was used during the Vietnam conflict:

> In general, sea water was fed into an evaporator where the water was boiled by a combination of heating and reduced pressure (vacuum) and the vapour was condensed in the condenser from which it was pumped into feed tanks. [303]

304. The authors aimed to reproduce this distillation process, and to assess the potential for co-distillation of chemicals in the distillation unit, using water from the Brisbane River.

305. The Phase One findings of the study included the following:

> These results clearly demonstrated that organochlorines and dioxins have the potential to co-distill relatively rapidly… [304]
>
> Interestingly in this first experiment 2,3,7,8-tetrachlorodibenzodioxin, the most toxic of all PCDD/Fs and the main contaminant in Agent Orange, was found at about 85% of the quantity observed in the non-distilled samples and thus co-distilled the most. [305]

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300 For Applicant's submission see [85] & [86].
For Commissions' submission see [103].
For Mr M's submission see [111.a].

301 PCDD/F's - polychlorinated dibenzodioxins and dibenzofurans. Agent Orange…was contaminated with up to ~ 45 ppm of 2,3,7,8-TCCD and traces of 1,2,3,7,8-PeCDD (Young et al. 1978, quoted in IOM 1999, update 1998). At p. 11. A list of the chemicals, including physico-chemical properties, used in the Muller, J et al. 2002, experiments is provided in Table 1 of that study (at page 15).

302 Agent Blue herbicide was the third most commonly used herbicide in Vietnam and consisted of an aqueous solution of Dimethylarsenic acid (DMA). At page 9.

303 See Figure 1 at page 11.

304 See at page 20.

305 See at page 21.

> A compounds' co-distillation decreased with increasing levels of suspended solids in the water. [306]
>
> Co-distillation of dioxins and organochlorines from water collected from the Brisbane River (water was added to known amount (sic) of chemicals of interest) demonstrated that the process is reproducible using estuarine water. [307]

306. The Phase 2 findings (the aim of which was to evaluate the co-distillation of Agent Blue, which was used as a contact herbicide) was suggestive that Agent Blue was:

> …unlikely to have been consumed in substantial quantities through drinking water that was produced by distillation. [308]

Although doubt remained as to its potential as a contaminant in food, particularly fish.

307. The authors noted methodological difficulties with their experiment. These included an inability to measure exposure, and difficulty replicating the temperature of distillation units that would have been used on board ship (the difference between that and the laboratory experiment was 50°C). In attempting to measure levels of exposure, the authors noted the uncertainty of many of the input factors.

> Due to the lack of information on water concentrations of PCDD/Fs from the period and at sites of interest, we attempted to calculate water concentrations from concentrations in fish from Vietnam waters taken during the relevant period. [309]
>
> The distillation experiments carried out in the present study show that, if we assume that about 50% of the water is distilled and the rest is discharged, distillation would result in an enrichment of TCDD by about a factor of 2 … Recent information suggests that possibly only 5-10% of the water was distilled which would increase this enrichment factor to approximately 10 - 20, depending on the TSP [310] of the water.
>
> We assumed that on average sailors consumed on average 5 L of this water per day. The direct consumption of this water would lead to a daily body burden of about 0.4 – 7 ng/day. The water was also used to prepare food and as a result of the hydrophobic character of the dioxins the TCDD would also accumulate in the food. Hence we may

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306 See at page 6.

307 See at page 6.

308 See at page 31.

309 See at page 33.

The authors' reference to 'concentrations in fish' is followed by a reference to Baughman and Meselson, 1973. This article was not available to the RMA at the relevant times and so could only be considered by the Council as new information. The full citation is:

Baughman, R & Meselson, M 1973, 'An analytical method for detecting TCDD (Dioxin): Levels of TCDD in samples from Vietnam', *Environmental Health Perspective*, vol. 5, pp. 27-35.

310 TSP means total suspended particles. See at page 33.

estimate the total exposure due to water contaminating food was similar to that of the direct consumption of drinking water- another 0.4 – 7 ng/day. [311]

For a 70 kg person the body burden would be in the range of 12 – 200 pg / kg bw per day for a 14 day period in addition to the background exposure through TCDD and other dioxin-like chemicals in the food and in the environment. [312]

308. The authors concluded that:

Overall the findings of this study demonstrate that evaporative distillation of water does not remove but rather enriches certain contaminants such as dioxins in drinking water. The study provides some evidence that use in the distillation process of water contaminated with TCDD would result in contamination of potable water. Subsequent ingestion by sailors on board ships (as well as soldiers and airmen, who were passengers) is thus a vector for exposure to these chemicals. [313]

The effect of salinity on co-distillation could not be determined, but the studies indicated that suspended particles or a sorption compartment in the water reduced the tendency for co-distillation. However, enrichment of TCDD in the distilled water was still high at 1.4 g TSS L-1. [314]

Council's comments

309. The Council noted that the authors attempted to replicate, by experimentation in laboratory conditions, water concentrations of contaminants on the basis of concentrations of contaminants in fish in Vietnamese waters. The Council considered this was a major methodological flaw.

310. The Council noted that the authors gave no indication of what the concentration of TCDD was in the water, as opposed to the concentration in the fish, noting that the fish concentrations were low.

311. In the Council's view it was to be expected that the concentrations of dioxin in fish, particularly fatty fish, would be higher that the ambient concentrations of dioxin in water due to the hydrophobic character of dioxin. The Council considered that the concentration in fish may be very significantly higher than the concentration in water. In the Council's view, neither the concentration of dioxin in water nor fish singularly nor in combination, satisfied the more probable than not standard.

311 See at page 33.

312 See at page 35.

313 See at pages 7-8.

314 TSS means total suspended sediments. See at page 38.

COUNCIL'S CONCLUSIONS ON MULLER, J et al. 2002 PAPER

312. The Council's view is that the data in this study do not satisfy the more probable than not standard for clinical onset or at all. Accordingly, to the extent it is correct to consider this study in isolation, the Council decided that the sound medical-scientific evidence in the pool of information was insufficient to justify inserting the contended potable water factor into Statement of Principles No. 29 of 2005.

SUBMISSIONS REGARDING DIOXINS

313. For the reasons stated above, the Council considered that the sound medical-scientific evidence in the pool of information concerning the contended potable water factor was insufficient to justify its inclusion in Statement of Principles No. 29 of 2005.

314. However, the Council was conscious that the submissions made to it concerning the contended potable water factor included submissions concerning exposure to dioxins. Further, the Muller, J et al. 2002 paper itself sought to ascertain whether water from the Vietnamese estuarine waters was likely to be contaminated, including by dioxin.

315. The Council considered it was possible, therefore, that Mr M's contentions related to inserting into Statement of Principles No. 29 or 2005 a factor of being on board a vessel and consuming potable water contaminated by dioxins. To the extent that was so, or to the extent it may be relevant to the contended potable water factor in any event, the Council considered the articles in the pool concerning exposure to dioxins, herbicides and pesticides.

316. As a threshold proposition, the Council noted that it was very difficult to ascertain from the studies which touched on such exposure the precise nature of the exposure, i.e., whether it was to dioxins, herbicides, pesticides, or a combination.

317. The Council considered all the studies in the pool. However, it identified from the pool those studies it considered most methodologically sound and persuasive. One study was initially strongly negative (Ketchum, NS et al. 1999), and subsequently weakly positive, but only for a specified sub-group (Akhtar, FZ et al. 2004). The two remaining studies the Council considered most persuasive were strongly negative (Bertazzi, PA et al. 1997 and 2001 and Kogevinas, M et al. 1997). The Council's analysis of the articles it considered most important regarding exposure to dioxins (and/or herbicides and/or pesticides) is summarised below.

Akhtar, FZ et al. 2004, 'Cancer in US Air Force Veterans of the Vietnam War', *Journal of Occupational & Environmental Medicine*, vol. 46, no. 2, pp. 123–136. [315]

318. The authors noted the conclusion of the National Academy of Sciences [316] that there is limited/suggestive evidence of an association between dioxin or herbicide exposure and cancer of the prostate. [317]

319. This study is an update to the Ranch Hand veterans' study of Ketchum, NS et al. 1999, with results from examinations of the subjects in 1997 included, over 35 to 40 years of post war follow-up. The study also included some internal cohort contrasts and external contrasts of cancer incidence and mortality, with the expected experience derived from national cancer rates. [318]

320. To address veterans' concerns that the controls (who had served in South East Asia (SEA) but who had not sprayed herbicides) and the Ranch Hand veterans may have increased cancer risk the authors included:

> …internal cohort contrasts, which adjusted for time spent in SEA and for the percentage of time spent in Vietnam. [319]
>
> …we assigned each veteran to…"Before 1962 or after 1972" (when no herbicide was sprayed), "1962-1965" (pre-Agent Orange), "1966-1970" (predominantly Agent Orange), and "1971-1972" (Post Agent Orange). We attempted to isolate a "Vietnam effect" in two ways: by 1) restricting time spent in SEA to at most 2 years, and 2) by restricting comparison veterans to those who spent 0% and Ranch Hand veterans to those who spent 100% of their SEA service in Vietnam. [320]
>
> We expected to find evidence of increased cancer risk among Ranch Hand veterans who served during the period of heaviest spraying, at most 2 years in the SEA region and among those who spent 100% of their SEA service in Vietnam. [321]

321. The results were:

> No significant increase in the incidence of all cancers combined relative to national rates were found in white veterans…

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315 For Commissions' submissions see [106.3.a].

316 NAS IOM 1994 and update 2000. See at footnotes 138 and 139 and Akhtar, FZ et al. 2004, at page 131.

317 At page 123.

318 Data covering the period 1950-2000 from the Surveillance, Epidemiology, and End Results (SEER) program of the National Cancer Institute. At page 124.

319 At page 124.

320 At page 125.

321 At page 131.

However, the incidence of…cancer of the prostate (SIR = 1.46, 95% CI = 1.04 to 2.00, *p* = 0.03) was significantly increased in White Ranch Hand veterans.

No significant increases in all-site cancer incidence were found among black veterans. Without regard to race, no significant increase in the incidence of all-site cancer was found in either cohort. [322]

322. The results of the external contrasts with national cancer rates included:

Restriction to veterans whose tour ended between 1966 and 1970 (Table 5), the period of heaviest Agent Orange spraying, revealed that the incidence of…cancer of the prostate (SIR = 1.68) was significantly increased in white Ranch Hand veterans. The incidence of cancer of the prostate (SIR 1.64)…was significantly increased in white Comparison veterans who served during the same period. [323]

Restriction to white veterans with at most 2 years in South East Asia (Table 6) …The risk of prostate cancer was borderline significantly increased in Ranch Hand veterans (SIR = 1.54, 95% CI = 0.98 - 2.32, *p* = 0.06) but not in Comparison veterans (SIR = 0.68) and this variation…was significant (*P* = 0.05). [324]

Restriction to white Ranch Hand veterans who spent 100% of their South East Asia service in Vietnam and comparison veterans who spent 0% of the South East Asia service in Vietnam (Table 6) revealed a significant increase in the incidence of…cancer of the prostate (SIR = 1.66, 95% CI = 1.00 - 2.60, *P* = 0.05). [325]

The risk of death from cancer (Table 7) was significantly decreased in both white and non-white veterans in both cohorts [Ranch Hand and Comparison]. [326]

323. The results of the internal contrasts included:

Restriction to white veterans who spent at most 2 years in South East Asia (Table 8) …the risk of cancer of the prostate (RR = 6.04, *P* = 0.01) was significantly increased in the high category among white veterans. There was no significant increase in the risk of cancer in any of the three Ranch Hand dioxin categories among white veterans whose tour in South East Asia was more than 2 years in length (data not shown). [327]

324. The authors noted the following qualifications to the findings in their study:

– the increased SIR for prostate cancer could have been at least partially explained by the level of medical examination;

– statistical power was limited;

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322 At page 128.

323 At page 128.

324 At page 129.

325 At page 129.

326 At pages 129-130. In respect of prostate cancer standardised mortality ratios (SMR) Ranch Hand cohort SMR = 0.70, 95% CI 0.12 - 2.33 and Comparison cohort SMR = 0.77, 95% CI 0.20 -2.09. See at Table 7, page 130.

327 At page 130.

– uncertainties regarding dioxin exposure, as measurements were made up to 30 years after the exposure, and extrapolated back using an assumed half life. Background levels of exposure could not be determined; and

– both cohorts comprised veterans of the Vietnam war.

Council's comments

325. The Council noted that the authors had found an increased incidence of prostate cancer among white males. The Council noted that the study was supportive of an association of an increased incidence, but not an increased risk of death.

326. The Council noted a border-line significant increase in incidence for service periods less than 2 years, but in the high exposure group the increase was statistically significantly elevated (a six fold increase). Where service was greater than 2 years there was no increase in incidence, including for any exposure sub-group.

327. The Council was of the view that the data which related to only one sub-group could not be interpreted properly. The Council concluded that the data in this study were supportive of an association at the reasonable hypothesis standard (noting that a factor concerning exposure to dioxins is included in Statement of Principles No. 28 of 2005, and was not within the scope of this review), but did not satisfy the balance of probabilities standard. If the results had been consistent across every sub-group (i.e. if every sub-group had had an increased incidence overall), the Council may have been satisfied that the balance of probabilities test had been met in the study. [328] However, that was not the case.

[328] Had this been the case, this study would have had to have been considered taking into account the other studies in the pool that touched on the contended potable water factor (and exposure to dioxins/herbicides/pesticides) to determine overall whether the balance of probabilities test had been satisfied.

Ketchum, NS et al. 1999, 'Serum dioxin and cancer in veterans of operation Ranch Hand', *American Journal of Epidemiology*, vol. 149, no. 7, pp. 630–639. [329]

328. In the authors' view:

> Generalised increases in cancer risk associated with dioxin exposure are considered plausible because this pattern is consistent with animal experiments in which dioxin has been demonstrated to cause cancer in multiple anatomic locations (23, 24). [330]

329. The authors summarised the study of cancer and exposure to 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (dioxin) in veterans of Operation Ranch Hand.[331]

> These results were accumulated during the post-service period from each veterans' departure from South East Asia to July 10, 1997, in men participating in the ongoing Air Force Health Study, a 20 year prospective study of the health, mortality and reproductive outcomes of Ranch Hand veterans.

330. The authors compared the Ranch Hand veterans with a comparison group of other Air Force veterans who had served in South East Asia during the same period, but who were not involved with the spraying of herbicides. In 1982, 1985, 1987, and 1992 the study subjects were examined and medical records were assessed. In 1987 and 1992 blood was collected and assayed for dioxin.

331. Overall, the authors found that:

> Without regard to anatomic location, no association was found between the prevalence of non-skin cancer and dioxin category.
>
> No association was found between any cancer (all sites and any type) and dioxin category. [332]

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329 For Commissions' submissions see [106.3.b].

330 The citations at (23) and (24), both of which in this review were new information (ie not available to the RMA at the relevant times) were:

(23) Birnbaum, LS 1994, 'The mechanism of dioxin toxicity: relationship to risk assessment,' *Environ Health Perspect*, vol. 102, suppl. 9, pages 157-194

(24) Institute of Medicine 1994, *Veterans and Agent Orange*, National Academy Press, Washington DC.

331 "…Operation Ranch Hand [was] the unit responsible for the aerial spraying of herbicides, including Agent Orange, in Vietnam from 1962 to 1971." At pages 630 - 631.

332 Page 635 and Table 4.

> Small numbers prevented us from analysing malignancies by all anatomic locations; however we found no excessive risk of prostate cancer among Ranch Hand veterans in any exposure category. [333]

332. The authors considered the strength of the study included high participation, a well matched comparison population, the length of follow-up, and the focus on cancer incidence rather than cancer mortality. However, they expressed concerns about small numbers and confounding, and uncertainties regarding dioxin exposure, given that the estimates of exposure were made up to 30 years after the exposure had occurred, calculated on the basis of an assumed constant half-life (which may not be appropriate given that decay rate may depend on body fat). [334]

333. In respect of cancer latency the authors concluded that:

> the risk of cancer at sites other than the skin within 20 years of service was increased in Ranch Hand veterans with elevated dioxin levels, but the pattern was inconsistent with that of another study, suggesting that the excess risk may not have been caused by dioxin exposure. [335] Overall, we found no consistent evidence of a dose-response gradient and no significant increase in cancer risk in the High dioxin exposure category, the subgroup of greatest a priori interest. [336]

Council's comments

334. The Council considered this was an important study, as it dealt with the group thought to have been most highly exposed to dioxin contaminated herbicides, and over a long follow up. The Council considered the data in Table 4 (that there was no association between exposure to dioxins and prostate cancer) was telling.

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333 Page 635 and see Table 4.
For prostate cancer:
For 7 background exposure cases: OR = 0.4 (95% CI 0.1 - 0.8)
For 8 low exposure cases: OR = 0.6 (95% CI 0.3 - 1.5)
For 4 high exposure cases: OR = 0.7 (95% CI 0.2 - 2.2).

334 See at page 637.

335 See Table 6 at page 636.
Cancer sites other than skin; less than 20 years' service:
For 7 background exposure cases: OR = 1.0 (95% CI 0.4 - 2.8)
For 13 low exposure cases: OR = 3.4 (95% CI 1.5 - 8.0)
For 6 high exposure cases: OR = 2.7 (95% CI 0.9 - 8.0).

336 At pages 637 - 8.

335. The Council considered that this was a persuasive and strongly negative study, and so did not satisfy the balance of probabilities test. [337]

Bertazzi, PA et al. 1997, 'Dioxin Exposure and Cancer Risk: a 15-Year Mortality Study after the Seveso Accident', *Epidemiology,* vol. 8, no. 6, pp. 646–652.

Bertazzi, PA et al. 1998, 'The Seveso Studies on Early and Long-Term effects of Dioxin Exposure: A Review', *Environmental Health Perspectives*, vol. 106, (suppl. 2), pp. 625–633.

Bertazzi, PA et al. 2001, 'Health effects of dioxin exposure: a 20-year mortality study', *American Journal of Epidemiology*, vol. 153, no. 11, pp. 1031–1044. [338]

336. These 2 studies and a literature review all concerned the effects of the 1976 Seveso (Italy) accident in which:

> … an uncontrolled exothermic reaction caused the release into the atmosphere of some 2,900 kg of organic matter, including TCDD, that settled over an inhabited territory. [339]

337. The study examined cancer mortality from 1976 to 1991. The area of Seveso was divided into three zones (A = highest exposure to dioxin, B the next & C the lowest of decreasing contamination). The population of the surrounding non-contaminated area was used as a reference group (Zone R). [340]

338. Time in the contaminated areas was analysed and age adjusted in each zone with those in the reference zone. Estimates of the expected number of deaths by cancer site, gender, and separate analyses by calendar year, duration of residence (exposure period), years since first exposure (latency period), and residence on the day of the accident were conducted. [341]

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337 While the findings in Ketchum, NS et al. 1999, were moderated somewhat in Akhtar, FZ et al.'s 2004 update of the findings on the Ranch Hand veterans' data, for the reasons stated above, the Council considered that Akhtar did not satisfy the balance of probabilities test.

338 For Commissions' submission see [106.2.a].

339 At page 646.

340 At page 646 and at page 647 (Zone A, n = 805; Zone B, n = 5,943; Zone R, n = 38,625; Zone Reference, n = 232,747; Total n = 278,120).

341 At page 647.

339. The strengths of the study were stated by the authors to be that the exposure to dioxin was:

> …relatively pure and substantial; its distribution in the environment was measured, and estimates of blood levels were available; the exposed population was fairly stable and included both genders and different ages; a local population provided valid reference figures; excellent conditions for the enumeration and follow-up of the study cohort existed. Nevertheless, the study had to cope with several limitations, mainly linked to exposure categorisation, time elapsed since exposure, and small size. [342]

340. The 1998 literature review cited a range of studies with a focus on the health effects of the exposures related to the Seveso accident including the findings of the earlier 1997 study, including those specific to prostate cancer. [343] The authors concluded that:

> …the mortality rate for death from all causes did not differ appreciably in any of the three TCDD contaminated zones from that for the reference population. [344]

341. The authors noted limitations of the study at the time of the accident and subsequently.

342. The 2001 study extended the follow up period to 1996 and prostate cancer deaths for the total study period. [345]

343. The authors concluded that the:

> …accident failed to reveal an overall increase in all–cause and all-cancer mortality. However, it suggested that those residents living in the highly contaminated territory were at increased risk from some causes. [346]

For the authors' findings on prostate cancer see footnote 345.

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342 At page 649.

343 At pages 625-633.

344 At page 628.

345 At page 1034, Table 4.

Deaths from prostate cancer in each of Zones A, B and R:

Zone A: no RR due to insufficient data

Zone B - RR = 1.2 (95% CI 0.6 - 2.4)

Zone R - RR = 1.1 (95% CI 0.5 - 2.2).

At page 1040, Table 7: Number of deaths from prostate cancer since first exposure

0 - 4 years: RR 2.0 (95% CI 0.6 - 6.3)

5 - 9 years: RR 1.2 (95% CI 0.3 - 4.9)

10 - 14 years: RR 0.5 (95% CI 0.1 - 3.6)

15 - 20 years: RR 0.9 (95% CI 0.2 - 3.5)

0 - 20 years: RR 1.1 (95% CI 0.5 - 2.2).

346 At page 1037.

Council's comments

344. The Council noted that this study was of a large population exposed to a large amount (dose) of chemicals including dioxin. The Council considered the findings were convincing and strongly negative to the relevant association. No association was found in circumstances where a lot of people were heavily exposed.

345. The Council's view is that the data in this study does not satisfy the balance of probabilities test.

Kogevinas, M et al. 1997, 'Cancer Mortality in Workers Exposed to Phenoxy Herbicides, Chlorophenols, and Dioxins. An Expanded and Updated International Cohort Study', *American Journal of Epidemiology,* vol. 145, no. 12, pp. 1061-1075. [347]

346. This study described an International Agency for Research on Cancer (IARC) study of 21,863 herbicide workers in 36 cohorts in 12 countries. The subjects were followed from 1939 to 1992, with exposure being reconstructed using job records, company exposure questionnaires, and serum and adipose tissue dioxin levels. [348]

347. The cohort included workers employed in production and in spraying herbicides.

348. In the total cohort of exposed workers all cause mortality was slightly lower than expected (men SMR = 0.97 and women SMR = 0.98), mainly due to low mortality from circulatory and respiratory diseases. [349] The findings relevant to prostate cancer were that there was no increased risk from exposure to the substances considered in the study. [350]

349. The authors noted doubts as to the evaluation of exposure to herbicides and dioxins, and the potential for confounding by other occupational exposures and lifestyle factors such as smoking. However, they considered any exposure misclassification probably lead to an underestimation of the true risk. [351]

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347 For Commissions' submission see [106.1.a].

348 At Abstract, page 1061.

349 At page 1066.

350 At page 1068, Table 4: Standardised mortality ratios for prostate cancer compared to exposure

Exposed to TCDD: SMR 1.11 (95% CI 0.81 - 1.5)

Not exposed to TCDD: SMR 1.10 (95% CI 0.71 - 1.62)

Exposed to any phenoxy herbicides or chlorophenols: SMR 1.10 (95% CI 0.85 - 1.39).

351 See at page 1072.

Council's comments

350. In the Council's view this was the most comprehensive study of occupational exposure to herbicides and dioxins in the pool. It was a strongly negative paper, with findings of no increased risk of prostate cancer, and no support for the relevant association for onset or worsening on the basis of the reasonable hypothesis test (and so necessarily no relevant association at the balance of probabilities standard).

THE COUNCIL'S CONCLUSIONS ON WHETHER THERE SHOULD BE A POTABLE WATER FACTOR

351. For the reasons stated above, the Council concluded that the information available to the RMA at the relevant times touching on the contended potable water factor, when considered in isolation, was insufficient to justify an amendment to Statement of Principles No. 29 of 2005.

352. To the extent the information available to the RMA at the relevant times touching on exposure to dioxins was relevant to the contended potable water factor, the Council concluded that it was insufficient to justify any amendment to Statement of Principles No. 29 of 2005.

353. The findings of the various studies in the pool included a statistically non-significant slightly elevated increase of risk of prostate cancer in respect of exposure to multiple chemicals and not solely dioxins (Bodner, [352] Ott, [353] Hooiveld [354], Steenland [355] and Kogevinas [356]). The collective data combining the data from the above studies in Kogevinas, M et al. 1997, was strongly against the relevant association. The Council considered that the accidental exposure to chemicals including dioxin in the Sevaso study (and others) was of a dose that should have shown an association to the relevant standard if one existed.

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352 Bodner, KM, et al. 2003, 'Cancer risk for chemical workers exposed to 2,3,7,8-tetrachlorodibenzo-p-dioxin', *Occup Environ Med*, vol. 60, pp. 672-675.

353 Ott, MG & Zober, A 1996, 'Cause specific mortality and cancer incidence among employees exposed to 2,3,7,8-TCDD after a 1953 reactor accident', *Occupational and Environmental Medicine*, vol. 53, pp. 606-612.

354 Hooiveld, M et al. 1998, 'Second Follow-up of a Dutch Cohort Occupationally Exposed to Phenoxy Herbicides, Chlorophenols, and Contaminants', *American Journal of Epidemiology*, vol. 147, no. 9, pp. 891-901.

355 Steenland, K et al.1999, 'Cancer, heart disease, and diabetes in workers exposed to 2,3,7,8-Tetrachlorodibezo-dioxin', *Journal of the National Cancer Institute*, vol. 91, no. 9, pp. 779-786.

356 Kogevinas, M et al. 1997, 'Cancer Mortality in Workers Exposed to Phenoxy Herbicides, Chlorophenols, and Dioxins. An Expanded and Updated International Cohort Study', *American Journal of Epidemiology*, vol. 145, no. 12, pp. 1061-1075.

354. The Council's view was that the individual studies analysed above were the strongest and most persuasive within the pool of information. In the Council's view, those studies taken:

- individually; and/or
- collectively; and
- taking into account the other studies in the pool that touched on the contended potable water factor (and exposure to dioxins/herbicides/pesticides)

did not satisfy the balance of probabilities test.

NEW INFORMATION ON CONTENDED POTABLE WATER FACTOR

355. The Council considered the 'new information' in **Appendices D** and **F** (ie information that was not available to (not before) the RMA at the relevant times) to which it was referred with respect to the contended potable factor. The new information was not taken into account for the purposes of the review, but rather was considered to determine whether, in the Council's view, it warranted the Council making any directions or recommendations to the RMA.

356. In the Council's view, any such direction or recommendation should only be made if it were to form the view that the new information:

- comprised sound medical-scientific evidence as defined in section 5AB(2) of the VEA, being information which epidemiologists would consider appropriate to take into account; which
- in the Council's view 'touches on' (is relevant to) the contended potable water factor; and
- has been evaluated by the Council according to epidemiological criteria, including the Bradford Hill criteria; and
- potentially could satisfy the balance of probabilities test.

357. The Council was not sufficiently persuaded of the matters in [356] to make any recommendation or direction to the RMA concerning the undertaking of a fresh investigation specifically on this basis. However, in the event of any future investigation by the RMA, the purview of which included the contended potable water factor, the Council considered it would be appropriate for the RMA to take the new information into account.

DECISION

358. The Council made the declarations summarised in **paragraphs 1 and 2** above.

EVIDENCE BEFORE THE COUNCIL

Documents

359. The information considered by the Council (being the information that was available to (before) the RMA and sent to the Council by the RMA in accordance with section 196K of the VEA) is listed in **Appendix B**.

360. As mentioned above, the information upon which the Applicant, Mr M and the Commissions relied (being information that was available to (before) the RMA and sent to the Council by the RMA in accordance with section 196K of the VEA is listed in **Appendices C, E and G** respectively.

361. The information to which the Applicant and Mr M referred (being information which was not available to (not before) the RMA, and so was not considered by the Council in reaching its decision) is listed in **Appendices D and F** respectively.

TABLE OF ARTICLES UPON WHICH COUNCIL COMMENTS

F Force Item ID	RMA ID / Reference Numbers	Title
Contended Tobacco Smoking factor:		
7340	16355	Adami, H-O et al. 1996, 'A prospective study of smoking and risk of prostate cancer, *Int J Cancer*, vol. 67, pp. 764-768.
7085	7148	Akiba, S & Hirayama, T 1990, 'Cigarette smoking and cancer mortality risk in Japanese men and women - results from reanalysis of the six-prefecture cohort study data', *Environmental Health Perspectives*, vol. 87, pp. 19-26.
7223 7265	16660 16587	Cerhan, JR et al. 1997, 'Association of smoking, body mass, and physical activity with risk of prostate cancer in the Iowa 65+ rural health study (United States)', *Cancer Causes & Control*, vol. 8, pp. 229-238.
7238	16621	Coughlin, SS et al. 1996, 'Cigarette smoking as a predictor of death from prostate cancer in 348,874 men screened for the multiple risk factor intervention trail', *American Journal of Epidemiology*, vol. 143, no. 10, pp. 1002-1006.
7016 7335	7500 16339	Daniell, HW 1995, 'A Worse Prognosis for Smokers with Prostate Cancer', *Journal of Urology*, vol. 154, no. 1, pp. 153-157.
6538	29017	Giles, GG et al. 2001, 'Smoking and prostate cancer: findings from an Australian case-control study', *Annals of Oncology*, vol. 12, pp. 761-765.
7288 7297	16585 17143	Giovannucci, E et al. 1999, 'Smoking and risk of total and fatal prostate cancer in United States health professionals', *Cancer Epidemiology, Biomarkers & Prevention*, vol. 8, pp. 277-282.
6998	3265	Hayes, RB et al. 1994, 'Tobacco use and prostate cancer in Blacks and Whites in the United States', *Cancer causes and control*, vol. 5, pp. 221-226.

6992	3316	Hiatt, RA et al. 1994, 'Alcohol consumption, smoking, and other risk factors and prostate cancer in a large health plan cohort in California (United States)', *Cancer Causes and Control*, vol. 5, pp. 66-72.
6673	28471	Hickey, K Do, KA and Green, A 2001, 'Smoking and prostate cancer', *Epidemiologic Reviews*, vol. 23, no. 1, pp. 115-125.
7197	3308	Honda, GD et al. 1988, 'Vasectomy, cigarette smoking and age at first sexual intercourse as risk factors for prostate cancer in middle-aged men', *British Journal of Cancer*, vol. 57, pp. 326-331.
7188	3309	Hsing, AW et al. 1990, 'Diet, tobacco use and fatal prostate cancer: Results from the Lutheran Brotherhood Cohort Study', *Cancer Research*, vol. 50, pp. 6836-6840.
7176	3309	Hsing, AW et al. 1991, 'Tobacco use and prostate cancer: 26 year follow-up of US veterans', *American Journal of Epidemiology*, vol. 133, no. 5, pp. 437-441.
6504	17448	Hussain, F et al. 1992, 'High grade adenocarcinoma of prostate in smokers of ethnic minority groups and Caribbean Island immigrants', *International Journal of Radiation Oncology Physics*, vol. 24, pp. 451-461.
6899	28875	Kobrinsky, NL et al. 2003, 'Impact of smoking on cancer stage at diagnosis', *Journal of Clinical Oncology*, vol. 21, no. 5, pp. 907-913.
6663	28497	Plaskon, LA et al. 2003, 'Cigarette Smoking and Risk of Prostate Cancer in Middle-Aged Men', *Cancer Epidemiology, Biomarkers & Prevention,* vol. 12, pp. 604-609.
7047 7350	10918 16357	Rodriguez, C et al. 1997, 'Smoking and fatal prostate cancer in a large cohort of adult men', *American Journal of Epidemiology*, vol. 145, no. 5, pp. 466-475.
6965	7210	Ross, RK et al. 1990, 'Effects of cigarette smoking on 'hormone-related' diseases in a Southern California retirement community', in Wald, N & Baron, J (eds.) 1990, *Smoking and Hormone-Related Disorders*, Oxford University Press, pp. 30-54.

7012 3266 Slattery, ML & West, DW 1993, 'Smoking, alcohol, coffee, tea, caffeine and theobromine: risk of prostate cancer in Utah (United States)', *Cancer Causes and Control*, vol. 4, pp. 559-563.

Contended Potable Water factor:

6664 27791 7916 28736 Muller, J et al. 2002, *Examination of the potential exposure of Royal Australian Navy (RAN) personnel to polychlorinated dibenzodioxins and polychlorinated dibenzofurans via drinking water*, The National Research Centre for Environmental Toxicology NRCET (ENTOX), A report to the Department of Veterans' Affairs, Australia, pp. 1-75.

7627 32524 Akhtar, FZ et al. 2004, 'Cancer in US Air Force veterans of the Vietnam War', *Journal of Occupational & Environmental Medicine*, vol. 46, no. 2, pp. 123-136.

7287 16739 Ketchum, NS et al. 1999, 'Serum dioxin and cancer in veterans of operation Ranch Hand', *American Journal of Epidemiology*, vol. 149, no. 7, pp. 630-639.

7425 12982 Bertazzi, PA et al. 1997, 'Dioxin Exposure and Cancer Risk: a 15-Year Mortality Study after the "Seveso Accident"', *Epidemiology*, vol. 8, no. 6, pp. 646-652.

6955 14329 Bertazzi, PA et al. 1998, 'The Seveso Studies on Early and Long-Term effects of Dioxin Exposure: A Review. *Environmental Health Perspectives*, vol. 106, (suppl. 2), pp. 625-633.

6632 25817 Bertazzi, PA et al. 2001, 'Health effects of dioxin exposure: a 20-year mortality study', *American Journal of Epidemiology*, vol. 153, no. 11, pp. 1031-1044.

7074 11115 Kogevinas, M et al. 1997, 'Cancer Mortality in Workers Exposed to Phenoxy Herbicides, Chlorophenols, and Dioxins. An Expanded and Updated International Cohort Study', *American Journal of Epidemiology*, vol. 145, no. 12, pp. 1061-1075.

7841 34854 Bodner, KM et al. 2003, 'Cancer risk for chemical workers exposed to 2,3,7,8-tetrachlorodibenzo-p-dioxin', *Occup Environ Med*, vol. 60, pp. 672-675.

7059 9920 Ott, MG & Zober, A 1996, 'Cause specific mortality and cancer incidence among employees exposed to 2,3,7,8-TCDD after a 1953 reactor accident', *Occupational and Environmental Medicine*, vol. 53, pp. 606-612.

7015 14595 Hooiveld, M et al. 1998, 'Second Follow-up of a Dutch Cohort Occupationally Exposed to Phenoxy Herbicides, Chlorophenols, and Contaminants', *American Journal of Epidemiology*, vol. 147, no. 9, pp. 891-901.

6601 19352 Steenland, K et al. 1999, 'Cancer, heart disease, and diabetes in workers exposed to 2,3,7,8-Tetrachlorodibezo-dioxin', *Journal of the National Cancer Institute*, vol. 91, no. 9, pp. 779-786.

Key defining statistical and other terms [357]

Note: that this key is referred to in footnote 27 of the Reasons.

Statistical Terms

Ordinal measures	Classification into ordered qualitative categories, where the values have a distinct order, but there is no natural or numerical distance between their possible values.
RR	Relative risk – the ratio of the risk of disease or death among the exposed to the risk among the unexposed – is synonymous with risk ratio. Alternatively, the ratio of the cumulative incidence rate in the exposed to the cumulative incidence rate in the unexposed – ie the rate ratio. Has also been used synonymously with odds ratio.
OR	Odds ratio – the ratio of two odds. For example: for exposure – the odds ratio for a set of case control data – the ratio of the odds in favour of exposure among the cases to the odds in favour of exposure among noncases; and for disease – the odds ratio for a cohort or cross-sectional study is the ratio of the odds in favour of disease among the exposed to the odds in favour of disease among the unexposed. for risk – the ratio of the odds in favour of getting the disease, if exposed, to the odds in favour of getting the disease if not exposed.
SIR	Standardized incidence ratio – the ratio of the incident number of cases of a specified condition in the study population to the incident number that would be expected if the study population had the same incidence rate as the standard or other population for which the incidence rate is known. Usually expressed as a percentage.

[357] The definition of statistical terms, unless otherwise stated is from:
Last, JM ed. 2001, A Dictionary of Epidemiology, 4th Edition, *Oxford University Press.*

SMR	Standardized mortality rate - the ratio of the number of deaths observed in the study population to the number that would be expected if the study population had the same specific rates as the standard population, multiplied by 100. Usually expressed as a percentage.
CI	Confidence interval - The computed interval with a given probability. e.g 95%, that the true value of a variable such as a mean, proportion, or rate is contained within the interval.
Statistically significant	An estimate of the probability of the observed or greater degree of association between independent and dependant variables. Usually is stated by the p value.
p value	Probability – that the difference observed could have occurred by chance if the groups were really alike. In most biomedical and epidemiological work, a study result whose probability value is less than 5% ($p < 0.05$) or 1% ($p < 0.01$) is considered sufficiently unlikely to have occurred by chance – is statistically significant.
Incidence	The number of newly diagnosed cases during a specific time period. (http://www.cancer.gov/statistics/glossary)
prevalence	The number of cases alive on a certain date. (http://www.cancer.gov/statistics/glossary)
Carcinogen	An agent that can cause cancer. The IARC classifies carcinogens as follows: [358] *Sufficient evidence*. A positive causal relationship has been established between exposure and occurrence of cancer. *Limited evidence*. A positive association has been observed between exposure to the agent and cancer, for which a causal interpretation is credible, but chance, bias, or confounding cannot be ruled out. *Inadequate evidence*. Available studies are of insufficient quality, consistency, or statistical power to permit a conclusion regarding the presence or absence of a causal relationship.

[358] As noted in footnote 142 with respect to NAS reviews, this is not consistent with the Council's two stage test as set out in [114].

	Evidence suggesting lack of carcinogenicity. Several adequate studies covering the full range of doses to which humans are known to be exposed are mutually consistent in not showing a positive association between exposure to the agent and any studied cancer at any level of exposure.

Other Terms

Stage of Disease	The extent of a cancer within the body. If the cancer has spread, the stage describes how far it has spread from the original site to other parts of the body
Grade of Disease	The severity of the cancer
Gleason score or sum	A numerical score employed to determine the severity of a prostate cancer. It is based upon microscopic tumour patterns that are measured by the pathologist, based on a prostate biopsy. The Gleason Score is the sum of the two histopathological ratings on a 1 - 5 scale so that the sum can be between 2 - 10. The higher the number the more aggressive the prostate cancer (see [133]. (http://gleasonscore.net)
Well differentiated – Poorly differentiated	Small, uniform glands – lack of glands, sheets of cells. From low to high Gleason score. (http://gleasonscore.net)
Metastatic disease	Cancer cells spread to other parts of the body (http://gleasonscore.net)
PSA	Prostate-specific antigen
TCDD	Dioxin 2,3,7,8-tetrachlorodibenzo-*p*-dioxin unintended contaminate generated during the production of 2,4,5-T.
2,4-D	2.4 dichlorophenoxyacetic acid
2,4,5-T	2,4,5-trichlorophenoxyacetic acid
Agent Orange	Herbicide – (a 50:50 mixture of 2,4-D and 2,4,5-T)

Appendices

Appendix A	Second preliminary list of the proposed pool of information, as advised to the Applicant, Mr M, Mr C and the Commissions by letters dated 24 June 2011 (see [37] and the final pool of information see [126].
Appendix B	Information available to (before) the RMA and sent to the Review Council by the RMA under section 196K by FileForce on 19 December 2008.
Appendix C	Information upon which the Applicant relied (being information which was available to (before) the RMA and sent to the Review Council by the RMA in accordance with section 196K of the VEA).
Appendix D	The information to which the Applicant referred (being information which the RMA advised was 'new information', that is, information which was not available to (not before) the RMA at the relevant times, and so was not considered by the Review Council in reaching its review decision).
Appendix E	Information upon which Mr M relied (being information which was available to (before) the RMA and sent to the Review Council by the RMA in accordance with section 196K of the VEA).
Appendix F	The information to which Mr M referred (being information which the RMA advised was 'new information', that is, information which was not available to (not before) the RMA at the relevant times, and so was not considered by the Review Council in reaching its review decision).
Appendix G	Information upon which the Commission relied (being information which was available to (before) the RMA and sent to the Review Council by the RMA in accordance with section 196K of the VEA).

APPENDIX A

FForce Item ID	RMA ID / Reference Numbers	Title
6661	28679	Achanzar, WE et al. 2001, 'Cadmium-induced malignant transformation of human prostate epithelial cells', *Cancer Research,* vol. 61, pp. 455-458.
7285	16744	Acquavella, J et al. 1998, 'Cancer among farmers: a meta-analysis', *Annals of Epidemiology*, vol. 8, no. 1, pp. 64-74.
6505	17445	Acquavella, JF 1999, 'Farming and prostate cancer', *Epidemiology*, vol. 10, no. 4, pp. 349-351.
7340	16355	Adami, H-O et al. 1996, 'A prospective study of smoking and risk of prostate cancer', *International Journal of Cancer*, vol. 67, pp. 764-768.
8343 8370	29534	Agency for Toxic Substances & Disease Registry (ATSDR) 2002, *Toxicological profile for 1,4-Dichlorobenzene*, Health Effects, US Dept of Health & Human Services, Public Health Service, ch. 2, pp. 11-148.
8162 8163	29535	Agency for Toxic Substances & Disease Registry (ATSDR) 2002, *Toxicological profile for Chlorpyrifos*, Health Effects, US Dept of Health & Human Services, Public Health Service, ch. 2, pp. 9-99.
8160 8161	29536	Agency for Toxic Substances & Disease Registry (ATSDR) 2002, *Toxicological profile for Chlorfenvinphos*, Health Effects, US Dept of Health & Human Services, Public Health Service, ch. 2, pp. 7-114.
8182	29539	Agency for Toxic Substances & Disease Registry (ATSDR) 2002, *Toxicological profile for Malathion*, Relevance to Public Health, US Dept of Health & Human Services, Public Health Service, ch 2, pp. 13-22.

8170 8171 8173 8181 8192 29544 Agency for Toxic Substances & Disease Registry (ATSDR) 2002, *Toxicological profile for DDT, DDE & DDD*, Relevance to Public Health, Health Effects, References, US Dept of Health & Human Services, Public Health Service, ch. 2, pp. 15-395.

8017 29523 Agency for Toxic Substances & Disease Registry (ATSDR) 2002, *Toxicological profile for Adrin/Dieldrin*, US Dept of Health & Human Services, Public Health Service.

8404 32376 Agency for Toxic Substances & Disease Registry September 2002, *Draft for Public Comment, Toxicological Profile for Chlorine dioxide and chlorite*, Department of Health & Human Services, viewed 5 October 2004, www.atsdr.cdc.gov/toxprofiles/tp160.html

7627 7872 32524 Akhtar, FZ et al. 2004, 'Cancer in US Air Force veterans of the Vietnam War', *Journal of Occupational & Environmental Medicine*, vol. 46, no. 2, pp. 123-136.

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8032 29275 Alavanja, MCR et al. 2003, 'Use of agricultural pesticides and prostate cancer risk in the agricultural health study cohort', *American Journal of Epidemiology,* vol. 157, pp. 800-814.

7017 14300 Alavanja, MCR et al. B 1988, 'Mortality among agricultural extension agents', *American Journal of Industrial Medicine*, vol. 14, pp. 167-176.

8088 29110 Alavanja, MCR Rush, GA Stewart, P Blair, A 1987, 'Proportionate mortality study of workers in the grain industry', *Journal of the National Cancer Institute,* vol. 78, no. 2, pp. 247-252.

7056 14116 Alberghini, V et al. 1991, 'Mortality Among Male Farmers Licensed to use Pesticides', *La Medicina del lavoro,* vol. 82, pp. 18-24.

8081 29130 Albertsen, K & Gronbaek, M 2002, 'Does amount or type of alcohol influence the risk of prostate cancer?', *The Prostate,* vol. 52, pp. 297-304.

7024 7432 Amoateng-Adjepong, Y Sathiakumar, N Delzell, E & Cole, P 1995, 'Mortality among Workers at a Pesticide Manufacturing Plant', *Journal of Occupational and Environment Medicine*, vol. 37, no. 4, pp. 471-478.

7155 12174 Andersson, S-O et al. 1996, 'Lifestyle Factors and Prostate
7415 16267 Cancer Risk: a Case-Control Study in Sweden', *Cancer Epidemiology, Biomarkers & Prevention*, vol. 5, pp. 509-513.

7418 15741 Anttila A et al. 1998, 'Cancer incidence among Finnish workers exposed to aromatic hydrocarbons', *International Archives of Occupational & Environmental Health*, vol. 71, pp. 187-193.

7424 12998 Anttila, A et al. 1995, 'Cancer Incidence among Finnish Workers Exposed to Halogenated Hydrocarbons', *Journal of Occupational and Environmental Medicine,* vol. 37, no. 7, pp. 797-806.

6995 3273 Armenian, HK et al. 1975, 'Epidemiologic characteristics of patients with prostatic neoplasms', *American Journal of Epidemiology*, vol.102, no. 1, pp. 47-54.

7130 3243 Arnetz, BB et al. 1991, 'Mortality among petrochemical science and engineering employees', *Archives of Environmental Health,* vol. 46, no. 4, pp. 237-248.

7148 3293 Aronson, KJ et al. 1996, 'Occupational risk factors for
7236 16619 prostate cancer: Results from a case-control study in Montreal, Quebec, Canada', *American Journal of Epidemiology* vol. 143, no. 4, pp. 363-373.

7112 3082 Asp, S Riihimaki, V Hernberg, S and Pukkala, E 1994, 'Mortality and cancer morbidity of Finnish Chlorophenoxy herbicide applicators: An 18-year prospective follow-up', *American Journal of Industrial Medici*ne, vol. 26, pp. 243-253.

8025 29527 Austin, H Keil, J Cole, P 1989, 'A prospective follow-up study of cancer mortality in relation to serum DDT', *American Journal of Public Health*, vol. 79, no. 1, pp. 43-46.

8424 29495 Australian Institute of Health & Welfare 1999, *Morbidity of Vietnam Veterans, A study of the health of Australia's Vietnam veteran community - Validation study,* vol. 3, AIHW.

7947 36638 Australian Institute of Health & Welfare 2003, *Cancer incidence study : Australian Veterans of the Korean War*, AIHW Cat. No. PHE 48, Canberra

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6632 25817 Bertazzi, PA et al. 2001, 'Health effects of dioxin exposure: a 20-year mortality study', *American Journal of Epidemiology*, vol. 153, no. 11, pp. 1031-1044.

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7581 *Scandinavian Journal of Work Environmental Health*, vol. 11, pp. 397-407.

7173 3312 Blair, A et al. 1992, 'Clues to cancer etiology from studies of farmers', *Scandinavian Journal of Work Environmental Health,* vol. 18, pp. 209-215.

7358 14763 Blair, A et al. 1998, 'Mortality and cancer incidence of aircraft maintenance workers exposed to trichloroethylene and other organic solvents and chemicals: extended follow up', *Occupational & Environmental Medicine*, vol. 55, no. 3, pp. 161-171.

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6714 33023 Boffetta, P et al. 2001, 'Occupational exposure to diesel
7464 32996 engine emissions and risk of cancer in Swedish men and women', *Cancer Causes & Control*, vol. 12, pp. 365-374.

6712 32994 Boffetta, P Jourenkova, N & Gustavsson, P 1997, 'Cancer risk from occupational and environmental exposure to polycyclic aromatic hydrocarbons', *Cancer Causes & Control*, vol. 8, pp. 444-472.

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APPENDIX B

FForce Item ID	RMA ID / Reference Numbers	Title
-	-	SMRC Information List 2010, pp. 1-124.
8535	-	Repatriation Medical Authority (RMA) 2005, 15 December Covering letter to the 196K Information for SoPs 28 & 29 of 2005, pp. 1-2, with Submissions to the RMA Attachment A, pp. 1-2 and RMA Reference List up to and including investigation #042-4, pp. 1-87.
-	-	Repatriation Medical Authority 2007, Deputy Registrar email of 9 March on further information, Whittemore 22233, Tverdal 26034, Engleland 9479, p. 1 and amended RMA 18/05/2007 Reference List up to and including investigation #042-4, pp.1-87.
-	-	Repatriation Medical Authority 2007, Deputy Registrar email of 20 March on further information, Hammond 6559, Kolonel 3328, Wigle 3025, p. 1 and amended RMA 18/05/2007 Reference List up to and including investigation #042-4, pp.1-87.
-	-	Repatriation Medical Authority 2007, Deputy Registrar email of 20 April on further information, Bako 32045, p. 1.
-	-	Repatriation Medical Authority 2007, Deputy Registrar email of 16 May on further information, US Surgeon General report 2004, p. 1.
-	-	Repatriation Medical Authority 2008, 1 February Covering letter confirming the 196K Information for SoPs 28 & 29 of 2005, pp. 1-4, and RMA Reference List for Investigation #42-4 as at 19 September 2005, pp. 1-83.
-	-	Repatriation Medical Authority 2008, 12 August Covering letter to further information, pp.1-2 with Attachments 1-6 of the further information.

8536	App. A App. B	Repatriation Medical Authority 2008, 19 December Covering letter confirming and sending electronically to the SMRC the 196K Information for SoPs 28 & 29 of 2005, pp. 1-2, with Submissions and Other papers at Appendix A, pp. 1-3 and Appendix B - RMA Reference List for Investigation #42-4 as at 5 September 2005, pp. 1-83.
8496	1.1	Name Provided (and removed under s1961 of the VEA) 1994, Request for Investigation dated 15 August 1994 & RMA letter of reply dated August 1994', pp. 1-3.
8465	1.2	Name Provided (and removed under s1961 of the VEA) 1994, Smoking, Submission to the RMA re with enclosures as below, pp. 1-2.
	1.2a	Lahtonen, R 1985, RMA 3311.
7188	1.2b	Hsing AW, at al 1990, RMA 3310.
7176	1.2c	Hsing AW, at al 1991, RMA 3309.
7197	1.2d	Honda GD, at al 1987, RMA 3308.
	1.2e	Bennett, N no date, RMA 3311.
	1.2f	Kafieris, N undated, 'smoking and other factors'.
	1.2g	Leyden, MJ, undated, 'various risk factors and prostate cancer'.
	1.2h	Kune, GA 1991 and 1992,18 August and 30 April, correspondence identifying studies relevant to smoking.
8464	1.3	Applicant 1, Name Provided (and removed under s1961 of the VEA) 1994, Smoking, submission to the RMA with enclosures as below, pp. 1-3.
7091	1.3a	Dai WS, et al. 1988, RMA 3324.
7101	1.3b	Kipling MD, et al. 1967, RMA 3327.
7078	1.3c	Kolonel L, et al. 1977, RMA 3328.

7099 8100 7216	1.3d	Elghany NA et al. 1990, RMA 3326, 28750, 17239.
6983 7170	1.3e	Schuman LM et al. 1977, RMA 7343, 3244.
7197	1.3f	Honda GD, at al 1987, RMA 3308.
	1.3g	Hayes RB, et al. 1994, RMA 17059.
7089	1.3h	Talamini R, et al. 1993, RMA 3322.
	1.3i	Kahn HA, et al. 1966, RMA 3315.
6994	1.3j	Dorn HF, et al. 1959, RMA 3318.
7088	1.3k	Rogot E, et al. 1980, RMA 3321.
7187	1.3l	Mills PK et al. 1989, RMA 3320.
7188	1.3m	Hsing AW, at al. 1990, RMA 3310.
	1.3n	Hiatt RA, et al. 1994, RMA 3316.
	1.3p	IARC Monographs 1991, vol. 53.
	1.3q	IOM 1993, *Veterans & Agent Orange, Health effects of herbicides used in Vietnam*, National Academy of Science, USA.
8497	1.4	Repatriation Commission 1994, '3 November 'Smoking, Cadmium, Herbicides and other factors, submission to the RMA with enclosures as below', pp. 1-2.
	1.4a	Medline research papers.
13608	1.5	Name Provided (and removed under s1961 of the VEA) 1994, 9 December letter to RMA.
8524	1.6	Name Provided (and removed under s1961 of the VEA) 1994, Sleep deprivation, diet, lack of food, request letter to the RMA', pp. 1-2.

8463	1.7	Applicant 1, Name Provided (and removed under s1961 of the VEA) 1995, Smoking, submission to the RMA with enclosures as below, p. 1.
7078	1.7a	Kolonel L, et al. 1977, RMA 3328.
7101	1.7b	Kipling MD, et al. 1967, RMA 3327.
7099	1.7c	Elghany NA, et al. 1990, RMA 3326.
22299	1.7d	Waalkes MP, & Rehm S, 1994, RMA 3325.
8462	1.8	1995 Fax from DVA with 1994, 'Diet, submission to the RMA attached', pp. 1-9.
7008	1.8a	Wynder, EL et al. 1971, RMA 3269.
	1.8b	Jackliss 1981.
	1.8c	Bosland 1999, RMA 17088.
7089	1.9	Repatriation Commission 1995, 13 March further submission including attachment and reference list.
7095	1.9a	Hsing AW, at al 1993, RMA 7089.
8448	1.10	Name Provided (and removed under s1961 of the VEA) 1995, 29 May submission to RMA.
8514	1.11	Name Provided (and removed under s1961 of the VEA) 1995, 7 May submission to RMA.
8515	1.12	Name Provided (and removed under s1961 of the VEA) 1995, 9 December submission on smoking to RMA.
8489	1.13	Name Provided (and removed under s1961 of the VEA) 1995, 10 January submission to RMA.
13636	1.14	Name Provided (and removed under s1961 of the VEA) 1996, '9 April request for review of SoP95 of 1995 to RMA.
13637	1.15	Name Provided (and removed under s1961 of the VEA) 1996, 9 April further request for review of SoP95 of 1995 to RMA.

8498	1.16	Name Provided (and removed under s1961 of the VEA) 1996, 14 May request for review to RMA.
8517	1.17	Name Provided (and removed under s1961 of the VEA) 1996, 13 June submission to RMA, on exposure to DDT, pp. 1-4.
8516	1.18	Name Provided (and removed under s1961 of the VEA) 1996, 2 May submission to RMA, on smoking, pp. 1-3.
8505	1.19	Name Provided (and removed under s1961 of the VEA) 1996, 19 August request for investigation by RMA, on smoking, pp. 1-31.
8466	1.20	Name Provided (and removed under s1961 of the VEA) 1996, 26 August submission on smoking to RMA, p. 1.
8499	1.21	Name Provided (and removed under s1961 of the VEA) 1996, 28 August request for review to RMA.
8495	1.22	Name Provided (and removed under s1961 of the VEA) 1996, 29 August request for review to RMA.
8491	1.23	Name Provided (and removed under s1961 of the VEA) 1996, 2 September RSL National submission to RMA.
8501	1.24	Name Provided (and removed under s1961 of the VEA) 1996, 25 September submission on smoking to RMA.
8512	1.25	Name Provided (and removed under s1961 of the VEA) 1996, 26 September AVADSC submission on trauma to RMA.
8503	1.26	Name Provided (and removed under s1961 of the VEA) 1996, 1 October submission to RMA.
8504	1.27	Applicant 1, Name Provided (and removed under s1961 of the VEA) 1996, 5 October VVAA NSW B Inc submission to RMA.
7778	1.28	Repatriation Commission 1996, 22 October submission to the RMA.
-	1.29	Name Provided (and removed under s1961 of the VEA) 1996, 20 November request for review of SoP95 of 1995 to RMA.

7779	1.30	Repatriation Commission no date, Submission of SoPs 191 & 192 of 1996 to the RMA.
8450	1.31	Name Provided (and removed under s1961 of the VEA) 1997, 13 June request for review to RMA.
8452	1.32	Repatriation Commission, 1997, 20 October submission to the RMA.
8453	1.33	Name Provided (and removed under s1961 of the VEA) 1997, 28 October submission to RMA.
8473	1.34	Name Provided (and removed under s1961 of the VEA) 1997, 19 December submission from solicitor on behalf of Name Provided (and removed under s1961 of the VEA).
8481	1.35	Name Provided (and removed under s1961 of the VEA) 1998, 21 January VVFSA request for review to RMA.
8471	1.36	Name Provided (and removed under s1961 of the VEA) 1998, 25 February submission to RMA.
8486	1.37	Name Provided (and removed under s1961 of the VEA) 1998, 22 June request for review to RMA.
8490	1.38	Name Provided (and removed under s1961 of the VEA) 1998, 7 September RSL NSW further request for review.
8482	1.39	Name Provided (and removed under s1961 of the VEA) 1998, 22 August request for review to RMA.
8483	1.40	Name Provided (and removed under s1961 of the VEA) 1998, 9 September submission to RMA.
8484	1.41	Name Provided (and removed under s1961 of the VEA) 1998, 10 September letter from Lawyers (ingested arsenic) submission to RMA, pp. 1-4.
8456	1.42	Name Provided (and removed under s1961 of the VEA) 1998, 1 December RAAF Assoc. submission on obesity and smoking to RMA, pp. 1-2.
8487	1.43	Name Provided (and removed under s1961 of the VEA) 1998, 18 December letter from lawyers (ingested arsenic) submission to RMA, pp. 1-2.

8458	1.44	Repatriation Commission, 1998, 1 December submission (herbicides & pesticides) to RMA, pp. 1-23.
	1.45	Name Provided (and removed under s1961 of the VEA) 1999, request for review of SoPs 95 & 96 of 1995 to RMA.
8449	1.46	Name Provided (and removed under s1961 of the VEA) 1999, 21 June submission exposure to DDT to RMA, p. 1.
8500	1.46 Addendum	Name Provided (and removed under s1961 of the VEA) 1999, 21 June Saturation by DDT submission to RMA, pp. 1-12.
5833	1.46	Name Provided (and removed under s1961 of the VEA) F 1999, 21 June Saturation by DDT submission to RMA, book 2 part 2, pp. 1-60.
8525	1.46	Name Provided (and removed under s1961 of the VEA) 1999, 21 June Saturation by DDT submission to RMA, Folio 160-235, pp 1-86.
8522	1.46	Name Provided (and removed under s1961 of the VEA) 1999, 21 June Saturation by DDT', submission to RMA, Folio 75-159, pp. 1-87.
8502	1.46	Name Provided (and removed under s1961 of the VEA) 1999, 21 June Saturation by DDT submission to RMA book 2 part 1, pp. 1-64.
8513	1.46	Name Provided (and removed under s1961 of the VEA)1999, 21 June Saturation by DDT submission to RMA part 1, pp. 1-19.
8478	1.47	Name Provided (and removed under s1961 of the VEA) 1999, 5 July submission on insecticides to RMA, pp. 1-11.
8451	1.48	Name Provided (and removed under s1961 of the VEA) 1999, 9 February submission (contaminated water) to RMA, pp. 1-3.
8459	1.49	Doll, R 1999, 19 October opinion requested (smoking) by RMA, pp. 1-7.
8447	1.50	Colditz, G 1999, 25 October opinion provided (smoking) to RMA, pp. 1-10.

8468	1.51	Dwyer, T 1999, 2 November opinion/submission (smoking) to RMA, pp. 1-3.
8507	1.52	Name Provided (and removed under s1961 of the VEA) 2002, 15 August submission (diet) to RMA, pp. 1-4.
8460	1.52 (2)	Dwyer, AN, 1999, 2 November consensus statement on smoking, pp. 1-4.
8511	1.53	Name Provided (and removed under s1961 of the VEA) 2003 15 April request for review exposure to contaminated waters in Vietnam to RMA, pp. 1-8.
7792	1.54	Name Provided (and removed under s1961 of the VEA) 2002, 22 May submission (diet) to RMA, pp. 1-4.
8510	1.55	Name Provided (and removed under s1961 of the VEA) 2003, 3 June submission on cadmium to RMA, pp. 1-6.
8509	1.56	Name Provided (and removed under s1961 of the VEA) 2003, 29 July Dapto RSL submission (smoking) to RMA, pp. 1-8.
8508	1.57	Name Provided (and removed under s1961 of the VEA) 2003, 12 August submission (smoking) to RMA, p. 1.
8455	1.58	Name Provided (and removed under s1961 of the VEA) 2003, 10 September letter from legal aid NSW (smoking) to RMA, pp. 1-29.
8454	1.59	Applicant 1, Name Provided (and removed under s1961 of the VEA) 2003, 10 September submission (smoking) to RMA, pp. 1-50.
8531	1.60	Name Provided (and removed under s1961 of the VEA) 2003, 10 September submission (diet/nutrition) to RMA, p. 1.
8523	1.61	Name Provided (and removed under s1961 of the VEA) 2003, 10 November request for review exposure to mustard gas to RMA, pp. 1-2.
8527	1.62	Name Provided (and removed under s1961 of the VEA) 2003, 9 November Dapto RSL submission (smoking) to RMA, pp. 1-3.

8521	1.63	Name Provided (and removed under s1961 of the VEA) 2004, 13 February request for review exposure to DDT to RMA, pp. 1-10, RMA letter 2004, February 16, p.1, RMA letter 2004, 23 April, pp. 1-2.
8393	1.64	Name Provided (and removed under s1961 of the VEA) 2004, 24 August RDFWA National office submission exposure whilst spraying herbicides and defoliants to RMA, pp. 1-12.
8528 8529	1.65	Name Provided (and removed under s1961 of the VEA) 2004, 25 August Lismore Legacy request for review on skin cancer by RMA, pp. 1-2, and PUBMED, pp. 1-2.
8493	1.66	Name Provided (and removed under s1961 of the VEA) 2005, 8 August Armed Services request for review exposure to dioxins in Vietnamese waters, to RMA, pp. 1-93.
8530	1.67	Name Provided (and removed under s1961 of the VEA) 2005, 31 August Naval Assoc. (exposure to TCDD), submission to RMA, pp. 1-4.
8480	2.1	Name Provided (and removed under s1961 of the VEA) 1995, 16 January record of meeting between RMA and other specialists, pp. 1-2.
8492	2.2	Name Provided (and removed under s1961 of the VEA) 1995, 17 January record of meeting between RMA and other specialists in relation to cigarette smoking and prostate cancer, pp. 1-13.
-	2.3	Repatriation Commission 1995, 15 September submission to SMRC.
8494	2.4	SMRC, 1995, 22 December Declaration re SoPs 95 & 96 of 1995.
8506	2.5	SMRC, 1995, 22 December Reasons for Decision re SoPs 95 & 96 of 1995, pp. 1-53.
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APPENDIX C

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APPENDIX D

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