



Specialist Medical Review Council

Declaration and Reasons for Decisions

*Section 196W
Veterans' Entitlements Act 1986*

**Re: Statements of Principles
Nos. 89 & 90 of 2011 (Diabetes Mellitus)**

Request for Review Declaration No. 24

DECLARATION

1. In relation to the Repatriation Medical Authority (the RMA) Statements of Principles Nos. 89 and 90 of 2011 concerning diabetes mellitus, made under subsections 196B (2) and (3) of the *Veterans' Entitlements Act 1986* (the VEA), the Specialist Medical Review Council (the Council) under subsection 196W of the VEA:

DECLARES that it is of the view that the sound medical-scientific evidence on which the RMA could have relied to amend either of the Statements of Principles is **insufficient** to include a factor or factors for:

having been on board a vessel and having been exposed to dioxin diluted in water supplied on that vessel, including but not limited to consuming potable water, when the supply had been produced by evaporative distillation of estuarine Vietnamese waters.

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REASONS FOR DECISION

INTRODUCTION TO THE COUNCIL AND ITS FUNCTIONS

2. The Specialist Medical Review Council (the Council) is an independent statutory body established by the VEA. In general terms, upon receipt of a valid application the Council is to review as relevant:
 - the contents of Statement(s) of Principles in respect of a particular kind of injury, disease or death; or
 - a decision of the RMA not to determine a Statement of Principles in respect of a particular kind of injury, disease or death.
3. Again in general terms, in conducting a review, the Council must review all the information that was available to (before) the RMA when it determined, amended, or last amended the Statement(s) of Principles (or decided, or last decided not to determine a Statement of Principles) in respect of a particular kind of injury, disease or death. The Council is constrained to conduct its review by reference to the available information only.¹
4. Fundamental to Statements of Principles, and so to a Council review, is the concept of sound medical-scientific evidence (SMSE), as that term is defined in section 5AB(2) of the VEA, and set out in Appendix A.
5. **Appendix A** sets out further details of:
 - the composition of the Council for this review;
 - the legislative scheme; and
 - the information that was available to (before) the RMA (also listed in Appendix E, Table 2).

THIS REVIEW

6. The Council received an application for review of the contents of Statements of Principles Nos. 89 and 90 of 2011. The Applicant contended that there should be a factor or factors concerning exposure to dioxins through consumption of water (on ships) contaminated by '2,4,5-T (Agent Orange)'². **Appendix B** sets out the details of the Application.
7. The Council accordingly reviewed the sound medical-scientific evidence relevant to the Applicant's contentions as set out by the Council in the scope of review (See also **Appendix C**).

¹ *Vietnam Veterans' Association (NSW Branch) Inc v Specialist Medical Review Council and Anor* (full Federal Court decision) (2002) 72 ALD 378 at paragraph 35 per Branson J.

² 2,4,5-T, along with 2,4-D, is a constituent of the herbicide mixture that was known as 'Agent Orange' during the Vietnam War.

8. **Appendix B** sets out further background to this review.

THE COUNCIL'S PROCESS

9. In conducting a review, the Council identifies from all of the information that was available to (before) the RMA at the relevant times the sound medical-scientific evidence - as that term is defined in section 5AB(2) of the VEA (see [133]) - which in its view 'touches on' (i.e. is relevant to) the issue of whether a particular kind of injury, disease or death (in this review, myeloma) can be related to service with the exposure under consideration.
10. Considering all the relevant information, the Council decides whether or not there is sound medical-scientific evidence that indicates a reasonable hypothesis connecting the particular kind of injury, disease or death to relevant service.^{3 4} In a reasonable hypothesis, the evidence 'points to' as opposed to merely 'leaves open' a link between injury, disease or death and the relevant service. In a reasonable hypothesis, the link is not 'obviously fanciful, impossible, incredible or not tenable or too remote or too tenuous.'⁵
11. If Council is of the opinion that there is a reasonable hypothesis, members then determine, in addition, whether a connection exists to relevant service on the balance of probabilities,⁶ i.e. whether the connection is more probable than not. The balance of probabilities test of association between relevant disease and service is less easily satisfied than in a reasonable hypothesis, so if the balance of probabilities test was satisfied, the reasonable hypothesis test must also be met. If, however, the reasonable hypothesis test was not met, the balance of probabilities test could not be met.
12. In these Reasons the association for both the reasonable hypothesis test (at [10]) and the balance of probabilities test (at [11]) are respectively referred to as the 'relevant association'.
13. Noting that Councillors are appointed to a particular review because of their specialist expertise in the particular condition (in this case, diabetes) and the matters within the scope of the Review, the Council exercises its scientific judgement in weighing the evidence about the relevant association.

³ Relevant service in reasonable hypothesis statements of principles refers to operational, peacekeeping and hazardous service, British nuclear test defence service, and warlike or non-warlike service as those terms are defined in the VEA and the MRCA.

⁴ 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].

⁵ 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].

⁶ Relevant service in balance of probabilities statements of principles 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.

Appendix A sets out further details of the legislative framework for the Review.

SCOPE OF REVIEW AND POOL OF INFORMATION

Scope of Review

14. After due consideration of all submissions oral and written, the Council decided that the final scope of the review would be the same as the proposed scope sent to the Applicant and the Commissions on **4 October 2013**:

having been on board a vessel and having been exposed to dioxin diluted in water supplied on that vessel, including but not limited to consuming potable water, when the supply had been produced by evaporative distillation of estuarine Vietnamese waters.

Pool of Information

15. After due consideration of all submissions oral and written, the Council determined the final pool of information relevant to this review, which was the same as the proposed pool sent to the Applicant and Commissions on **4 October 2013**.
16. **Appendix C** sets out:
- the Council's preliminary and final decisions on the scope of review and on the pool of information; and
 - the steps taken by the Council to discharge its procedural fairness obligations regarding the scope of review and pool of information.

WRITTEN AND COMPLEMENTARY ORAL SUBMISSIONS

17. The Council took into account all the submissions made to it, both written and oral. The Council's summaries of the respective submissions of the Applicant and the Commissions are set out at **Appendix D**.

COUNCIL'S EVALUATION OF THE INFORMATION IN THE POOL

Preliminary comment on diabetes mellitus

18. Statements of Principles Nos. 89 & 90 of 2011 concerning diabetes mellitus define diabetes mellitus as meaning:

a metabolic disorder characterised by hyperglycaemia. This disorder is diagnosed by:

- (i) a fasting plasma glucose concentration of at least 7.0 millimoles per litre; or
- (ii) a venous plasma glucose concentration of at least 11.1 millimoles per litre two hours after ingestion of 75 grams of glucose; or
- (iii) an HbA1c level of at least 6.5%.

The diagnosis of type 2 diabetes mellitus requires two positive laboratory blood tests on separate days, unless the plasma glucose is unequivocally elevated in the presence of acute metabolic decompensation or obvious symptoms.

19. The Council noted that Statement of Principles 89 of 2011 (the **reasonable hypothesis**) contains factors for dioxins, for both onset and worsening of diabetes mellitus. The factors take the following form:

inhaling, ingesting or having cutaneous contact with a chemical agent contaminated by 2,3,7,8-tetrachlorodibenzo-para-dioxin (TCDD), for a cumulative period of at least 500 hours, within a consecutive period of ten years before the clinical onset of diabetes mellitus, where the first exposure occurred at least five years before the clinical onset of diabetes mellitus, and where that exposure has ceased, the clinical onset/worsening of diabetes mellitus occurred within 25 years of cessation;

with the associated definition:

"inhaling, ingesting or having cutaneous contact with a chemical agent contaminated by 2,3,7,8-tetrachlorodibenzo-para-dioxin (TCDD)" means:

- (a) decanting or spraying;
- (b) cleaning or maintaining equipment used to apply;
- (c) being sprayed with;
- (d) handling or sawing timber treated with;
- (e) being in an environment shrouded in dust from timber treated with; or
- (f) using cutting oils contaminated with;

one of the following chemicals:

- (i) 2,4,5-trichlorophenoxyacetic acid;
- (ii) 2,4,5-trichlorophenoxypropionic acid;
- (iii) 2,4,5-trichlorophenol;
- (iv) 2-(2,4,5-trichlorophenoxy)-ethyl 2,2-dichloropropionate;
- (v) o,o-dimethyl-o-(2,4,5-trichlorophenyl)-phosphorothioate;
- (vi) pentachlorophenol;
- (vii) 2,3,4,6-tetrachlorophenol;
- (viii) 2,4,6-trichlorophenol;
- (ix) 1,3,4-trichloro-2-(4-nitrophenoxy)-benzene;
- (x) 2,4-dichloro-1-(4-nitrophenoxy)-benzene; or
- (xi) 2,4-dichloro-1-(3-methoxy-4-nitrophenoxy)-benzene;

20. There are corresponding factors in Instrument **90 of 2011** (the **balance of probabilities** Statement of Principles) that differ only in that the required 'cumulative period' is at least 1000 hours.
21. The Council noted that the existing factors thus include a range of chemicals including 2,4,5-T (a constituent of Agent Orange) that may be contaminated by TCDD and stipulate some further circumstances, beyond the handling and spraying of herbicides, in which exposure to one of those chemicals could have occurred.
22. The Council noted further that the word 'dioxin', refers to a class of chemicals, but the Council understood, in defining the scope, that the dioxin

referred to in the Applicant's submission was 2,3,7,8-tetrachlorodibenzo-para-dioxin (TCDD).

23. Exposure to water contaminated by TCDD is not explicitly covered by the existing factor, hence the applicant's contention.

THE COUNCIL'S EVALUATION OF THE INFORMATION THAT IT CONSIDERED TOUCHED ON THE CONTENTED FACTOR

24. From the information that was available to the RMA at the relevant times, the Council considered all the studies that touched on the scope of review. In considering the matters within the scope of review, the Council closely analysed these studies, both individually and collectively, taking into consideration both quantitative and qualitative evidence in its evaluations.
25. The Council considered that some of the articles in the pool addressed the more general issue of whether dioxins were associated with diabetes. It therefore examined these articles as background to the more specific contention concerning dioxin diluted in water that is in the scope of this review.

Dioxin and Diabetes mellitus

IOM studies

26. The Council examined the series of *Veterans and Agent Orange* reports from the Institute of Medicine (IOM), which provided comprehensive literature reviews and analyses of the evidence for any health outcomes in veterans that might be related to exposure to Agent Orange. These reports have been updated over time, incorporating the evidence in the original reports with any new studies, into the conclusions of each update.

Institute of Medicine (2000). Herbicide/dioxin exposure and type 2 diabetes. *Veterans and Agent Orange*, National Academies Press, Washington, DC. RMA ID 19992

Institute of Medicine (2002). *Veterans and Agent Orange Update 2002*, National Academy Press, Washington, D.C. RMA ID 29493

Institute of Medicine (2009). Committee to review the health effects in Vietnam veterans of exposure to herbicides. *Veterans and Agent Orange Update 2008*, Seventh biennial update. The National Academies Press, Washington DC. RMA ID 56717

Council comment

27. The Council noted that the first of these IOM studies specifically addressed the issue of whether herbicide/dioxin exposure could be related to diabetes

in veterans. The two other studies looked more broadly at potential health effects, including diabetes.

28. The Council noted that there was inconsistent evidence of dose-response across the studies identified in the IOM reports. The Council further noted that these reviews, including the most recent update (2008-2009), concluded that there was only 'limited suggestive evidence' that dioxin contributes to diabetes.
29. These reports did not contain information on potable/distilled water as a cause of diabetes, nor any that dealt with TCDD at much diluted levels of exposure.

Ranch Hand studies

30. The Council examined a number of studies of veterans who had been exposed to herbicides and defoliants during the Vietnam War, in particular the 'Ranch Hand Study', a prospective study launched in 1980 as part of a U.S Government effort to resolve questions of whether there were adverse health effects related to aerial spraying of herbicides. The Study compared Air Force veterans from Operation Ranch Hand (the unit responsible for aerial herbicide spraying in Vietnam from 1962 to 1971) with other Air Force veterans who served in Southeast Asia during the same period but had not been involved with spraying.

Henriksen GL, Ketchum NS, Michalek J, Swaby JA (1997). Serum dioxin and diabetes mellitus in Veterans of Operation Ranch Hand. *Epidemiology*, 8(3): 252-8. RMA IDs 15064 & 14331

Steenland K, Calvert G, Ketchum N, Michalek J (2001). Dioxin and diabetes mellitus: an analysis of the combined NIOSH and Ranch Hand data. *Occupational & Environmental Medicine*, 58(10): 641-8. RMA ID 28532 & 56828

Michalek JE, Pavuk M (2008). Diabetes and cancer in veterans of Operation Ranch Hand after adjustment for calendar period, days of spraying, and time spent in Southeast Asia. *J Occup Environ Med*, 50: 330-40. RMA ID 56845

Council Comments

31. The Council noted that these longitudinal studies concern veterans exposed to herbicides during the Vietnam War. They do not provide evidence on the contended potable water issue.
32. The Council noted that the **Henriksen (1997)** study suggested that dioxin might contribute to diabetes, with a relative risk (RR) of 1.5, for current levels greater than 12 ppt⁷ serum dioxin, given exposure some 20 years earlier.

⁷ ppt = parts per trillion

While the Council considered that these results supported a dioxin-diabetes relationship, doubt remains.

33. The Council considered that the **Steenland et al (2001)** paper was important in terms of the analysis of diabetes in relation to Agent Orange exposure because it attempted to look at both the Ranch Hand and the NIOSH study, another major study of dioxin exposure which was not considered by the RMA in its primary form.⁸
34. The Council noted that the combined NIOSH/Ranch Hand data were contradictory. The Ranch Hand study was positive (though at high doses of >78 ppt serum TCDD) and showed a positive dose-response for diabetes; in contrast, the results of the NIOSH study were negative and showed no evidence of dose-response. When the results were combined there was no statistically significant increase in diabetes (OR, 1.17, 95% CI 0.92 - 1.48)⁹.
35. Given these inconsistencies, the above studies provided only limited support for a dioxin-diabetes link, but again provided no support for any link with the contention regarding contaminated potable water from distillation.

Other Vietnam veteran study

Kang HK, Dalager NA, Needham LL, Patterson DG Jr, et al (2006). Health status of Army Chemical Corps Vietnam veterans who sprayed defoliant in Vietnam. *Am J Ind Med*, 49: 875-84. RMA ID 56849

Council Comment

36. The Council considered the **Kang et al** paper concerning the spraying exposure route. Direct exposure to spraying had a statistically significant OR of 1.5, suggesting a contribution of direct defoliant spraying to incidence of diabetes.
37. The Council considered that this veteran study as well as the Ranch Hand studies were of limited usefulness regarding the contention of this review, due to the different exposure route and other potentially confounding variables.

⁸ The earlier **National Institute for Occupational Safety and Health (NIOSH)**, is cited in Steenland et al (2001) as Calvert G, Sweeney M, Deddens J, et al. An evaluation of diabetes mellitus, serum glucose, and thyroid function among US workers exposed to 2,3,7,8-tetrachlorodibenzo-p-dioxin. *Occup Environ Med* 1999;56:270-6. As the study was not included in the information accessed by the RMA, the Council could not consider the primary study, but could consider the secondary analysis of its data by Steenland et al.

⁹ OR: Odds ratio; CI: Confidence interval

Occupational study

Vena J, Boffetta P, Becher H, Benn T, Bueno-de-Mesquita HB, et al (1998).

Exposure to dioxin and nonneoplastic mortality in the expanded IARC international cohort study of phenoxy herbicide and chlorophenol production workers and sprayers. *Envi Health Pers*, Apr 1998, 106(Suppl 2), 645-653. RMA ID 14332.

Council Comment

38. The Council noted the study by Vena et al analysed exposure to phenoxyacid herbicide and chlorophenol in 36 cohorts followed from 1939 to 1992. The Council noted that there were no statistically significant effects related to diabetes and this meta-analysis found that endocrine mortality was actually reduced.

Population studies

39. The Council examined a Japanese population study and three US articles based on National Health and Nutrition Examination Survey (NHANES) population data:

Uemura H, Arisawa K, Hiyoshi M, Satoh H, et al (2008). Associations of environmental exposure to dioxins with prevalent diabetes among general inhabitants in Japan. *Environ Res*, 108: 63-8. RMA ID 56846

Council comment

40. The Council noted that this Japanese cross-sectional population study found increased prevalence of diabetes in the highest quartile of exposure to dioxins, especially PCBs, PCDDs and PCDFs. There were insufficient data regarding TCDD for the Council to draw any conclusions about it in relation to diabetes.

Lee DH, Lee IK, Song K, Steffes M, et al (2006). A strong dose-response relation between serum concentrations of persistent organic pollutants and diabetes. Results from the National Health and Examination Survey 1999-2002. *Diabetes Care*, 29(7): 1638-44. RMA IDs 56850 & 56575

Lee D-H, Steffes MW, Sjodin A, Jones RS, et al (2010). Low dose of some persistent organic pollutants predicts type 2 diabetes: a nested case-control study. *Environ Health Perspect*, 118(9): 1235-42. RMA ID 58496

41. Six persistent organic pollutants (POPs) were selected, including 1,2,3,4,6,7,8-heptachlorodibenzo-p-dioxin, 1,2,3,4,6,7,8,9-octachlorodibenzo-p-dioxin, because they were detectable in $\geq 80\%$ of participants.
42. The authors found dose-response relations between serum concentrations of the six selected POPs and the prevalence of diabetes.

43. The later study concluded that some POPs may increase diabetes risk at low dose levels, possibly through endocrine disruption.

Everett CJ, Frithsen IL, Diaz VA, Koopman RJ, et al (2007). Association of a polychlorinated dibenzo-p-dioxin, a polychlorinated biphenyl, and DDT with diabetes in the 1999-2002 National Health and Nutrition Examination Study. *Environ Res*, 103: 413-8. RMA ID 56848

44. The authors of this study found that all three compounds examined were significantly associated with diagnosed diabetes.

Council Comment

45. The Council considered the more recent article by **Lee et al (2010)** was of some relevance, but it lacked evidence for an increased risk of diabetes at very low levels of TCDD / dioxin exposure.
46. The three population studies listed above showed mixed results and were specific to other forms of polychlorinated chemicals such as PCB or PCDD which do not necessarily apply to TCDD / dioxin. These findings are not readily extrapolated to the contended association in the current review. Furthermore, these other chemicals were not implicated in the Vietnam War Agent Orange contamination.

Mueller JF, Toms LM, Aylward L (2009). Levels of 2,3,7,8-tetrachlorodibenzo-p-dioxin in Australian Vietnam veterans compared to the Australian population. Final Report to Australian Government Department of Veterans' Affairs, National Research Centre for Environmental Toxicology. RMA ID 573234

Council Comments

47. The Council noted that this study, which the Commissions also described in their submission, was conducted for the Department of Veterans Affairs. Whilst the study attempted to estimate background TCDD levels and exposures experienced by veterans, the overall veteran serum dioxin levels were in a similar range to the ranges estimated in the general population.

COUNCIL'S CONCLUSIONS ON ASSOCIATIONS BETWEEN DIOXINS AND DIABETES

48. The Council noted that the overall association between dioxins and diabetes, in the doses that might be achieved, for example, through spraying of Agent Orange, was not in scope of this review. However, to provide background to the Applicant's contention, the Council carefully considered the articles mentioned above. It concluded that the studies by **Henriksen, Michalek** and the **IOM** reviews (2000, 2002, 2008) supported an association between diabetes and dioxins at high doses.

49. The studies by **Everett et al** (2007), **Lee et al** (2006) & (2010) were supportive of an association between some polychlorinated dibenzodioxins and diabetes, but these studies were not helpful in relation to exposure to the levels of dioxins diluted in drinking water.
50. The articles by **Steenland et al** (2001), **Kang et al** (2006), **Uemura et al** (2008), **Vena et al** (1998) **Mueller** (2009) left open the question of any association between dioxins at high doses and diabetes.
51. The Council's findings on the above studies are consistent with an association between high levels of dioxin exposure and diabetes. Whilst it examined the above studies because of their potential relevance, after further evaluation, the Council did not find in the literature outlined above any data that were directly pertinent to the scope of this review, involving very diluted TCDD in distilled drinking water.

POTABLE WATER (FROM DISTILLATION) AND DIABETES MELLITUS

52. Having looked more broadly at articles that touched on dioxins and diabetes, as background to its analysis, the Council however found very little information that touched directly on the the scope of this review (as set out in paragraph [16]). The most relevant data are discussed below.

Mueller J, Gaus C, Alberts V, Moore M. (2002). Examination of the potential exposure of Royal Australian Navy (RAN) personnel to polychlorinated dibenzodioxins and polychlorinated dibenzofurans via drinking water. A Report to the Department of Veteran Affairs, Australia. The National Research Centre for Environmental Toxicology [NRCET]¹⁰ RMA ID 27791

53. The study was undertaken for the DVA, to investigate why former members of the Royal Australian Navy had the highest elevation in subsequent mortality levels, compared with land and air forces. The sailors were not involved in spraying herbicides during the Vietnam War, but some had been stationed in the Vung Tau waters.
54. The study attempted experiments to ascertain (retrospectively) whether sailors might have been exposed to dioxins through distilled water used in ships during the Vietnam conflict.
55. It examined the co-distillation of organic pollutants such as dioxins along with water under laboratory conditions that attempted to reproduce shipboard distillation processes. Samples of Brisbane River water were also used for testing.

¹⁰ The Article is cited by the RMA as: **The National Research Centre for Environmental Toxicology (ENTOX) [NRCET] (2002)**. Examination of the potential exposure of Royal Australian Navy (RAN) personnel to polychlorinated dibenzodioxins and polychlorinated dibenzofurans via drinking water. A Repo[sic]

56. The study also attempted to calculate water concentrations of dioxins from concentrations found in fish taken from Vietnam waters during the relevant period, using data from a study by **Baughman & Meleson (1973)**¹¹. On this basis it estimated that an average sailor may have had a daily body burden of about 0.4-7ng/day¹² from water plus 0.4-7ng/day from contaminated food.¹³ The authors posited:

..In addition to normal background rates, RAN members may have received exposure that is one to two orders of magnitude above the acceptable intake values and at a level above the observed effect levels in experimental animals.¹⁴

57. However, the authors noted that estimates from fish data had many uncertainties.

58. The study results showed that

- Distillation increased the contaminant concentration. Between 75% and 95% of 2,3,7,8-TCDD was co-distilled with the first 10% of pure or saline water distilled.
- Dioxins tended to co-distil less with increasing molecular mass;
- Co-distillation decreased with increasing levels of suspended solids in the water.

Nevertheless, even at these relatively high levels of suspended solids, TCDD was enriched by almost a factor of 4 in the distillate.¹⁵

59. The study also tested for whether dioxins could be newly synthesised from components of Agent Orange during the evaporative process: the experiments detected no evidence of this occurring.

60. The authors concluded that TCDD, the primary contaminant in Agent Orange, was found to co-distil relatively rapidly and thus would be enriched in the distilled water compared to the source water.

the study clearly demonstrated that if source water is contaminated, co-distillation is a process which can result in the contamination of ship's water supplies with chemicals such as dioxins.¹⁶

61. The study did not attempt to relate potential dioxin exposure to diabetes or any other disease.

¹¹ **Baughman R, Meleson M (1973)**. An analytical method for detecting TCDD (dioxin): Levels of TCDD in samples from Vietnam. *Environ Health Perspect*, 5: 27-35. RMA ID 61194

¹² Ng/day: nanograms per day

¹³ p. 33

¹⁴ p. 36

¹⁵ p. 38

¹⁶ p.6

Council comment

62. The Council noted that both the Applicant and the Commissions in their respective submissions relied on this study. The Council, having examined the study, agreed that it provided some indication that distillation possibly increased concentrations of dioxin.
63. The Council noted that the study was relevant in that it touched on the issue of dilution in water and attempted to estimate dioxin exposures in the Vung Tau harbour during the Vietnam War. However, the Council noted that there were many uncertainties and extrapolations in the data. It drew on data from the **Baughman & Meleson (1973)** study discussed at 56 & 75 (regarding dioxin concentrations measured in fish). Based on the **Batterman et al (1989)** paper (see also 77) the Council considered that the data on fish contamination did not allow accurate estimation of concentrations in the potable water on board ship, because the fish, being bottom feeders, are likely to have had greater concentrations of TCDD than would be found in near surface waters.
64. From the laboratory experiments to estimate concentration of dioxins after the distillation process, the Council further noted that whilst there could be an increase in concentration of the dioxins in the first 10% of the water treated, that concentration might only amount to relatively few parts per trillion.
65. Overall the Council considered that levels of dioxin exposure through the ingestion of potable water remained unknown. The report provided no information on any exposure-disease link.

Institute of Medicine (IOM) (2011). Committee on Blue Water Navy Vietnam Veterans and Agent Orange Exposure; Blue Water Navy Vietnam Veterans and Agent Orange Exposure. National Academies Press - Washington, DC.

66. The US based **IOM committee** was asked to consider whether Blue Water Navy¹⁷ veterans might have been exposed to herbicides used in Vietnam, specifically Agent Orange and its contaminant, TCDD, and whether this exposure could lead to an increased risk of long-term adverse health outcomes.
67. The report aimed to identify:
- potential sources of Agent Orange and its TCDD contaminants in relation to ground troops and Brown Water Navy and Blue Water Navy populations.
 - plausible transport (eg, by soil, water, and air) and routes of exposure (inhalation, dermal contact, and ingestion).
 - toxicologic information to assess any health effects of TCDD

¹⁷ Blue Water Navy refers to deep water vessels; Brown Water Navy to inland waterways.

- plausibility of exposure of those military personnel that did not actually handle the herbicide themselves.
 - any monitoring data on TCDD that had been gathered during or shortly after the Vietnam War;
 - any data on the magnitude of TCDD contamination of Agent Orange
 - epidemiologic studies of health effects seen in Vietnam Navy veterans from search of peer review literature, government and military records, anecdotal reports; etc
68. The **IOM Blue Water Committee** noted that Blue Water and Brown Water Navy personnel were exposed to many chemicals needed to operate and maintain their ships. These other chemicals make attribution of a disease to dioxin exposure very difficult.
69. Moreover, many naval personnel smoked cigarettes, presenting additional disease risks.
70. The **Blue Water Committee** noted and reviewed the Australian study by Mueller et al, discussed at [53]¹⁸.
71. The **Blue Water Committee** was unable to find sufficient data to determine exposure of the deep water navy boats through distillation. It concluded that, given the paucity of monitoring information and the variability and uncertainty in information on the fate and transport of TCDD as it pertains to Vietnam, it was not possible to estimate the likely concentrations of TCDD in marine waters and air at the time of the Blue Water Navy deployment:

Overall, the committee concludes that because of the small number of studies and their limitations, there is no consistent evidence to suggest that Blue Water Navy Vietnam veterans were at higher or lower risk for cancer or other long-term adverse health effects associated with Agent Orange exposure than shore-based veterans, Brown Water Navy veterans, or Vietnam veterans in other branches of service.

...

The committee's judgment is that exposure of Blue Water Navy Vietnam veterans to Agent Orange-associated TCDD cannot reasonably be determined.¹⁹

Council Comment

72. The Council noted that it was not possible to estimate exposure to dioxins in US Navy veterans in Vietnam. The report was unhelpful in determining concentrations of TCDD/dioxins in potable water.

¹⁸ p. 41 of the Blue Water Committee report.

¹⁹ p. 14

73. The Council considered that whilst the report identified that there was some supportive evidence for a role of dioxins, the study did not provide information on any exposure-disease link.
74. Whilst the Council considered that the paper was theoretically relevant to the idea of persisting contamination of water tanks, it did not present evidence on that point.

Baughman R, Meleson M (1973). An analytical method for detecting TCDD (dioxin): Levels of TCDD in samples from Vietnam. *Environ Health Perspect*, 5: 27-35. RMA ID 61194

Council Comment

75. The NRCET study by **Mueller et al (2002)** cited this paper in relation to estimates of exposure to TCDD, which used data from fish. Despite touching on the contention in relation to exposure assessment, the Council considered that the paper did not assist greatly with establishing the relevant exposure levels.
76. This paper was somewhat peripheral, as it did not address diabetes or health outcomes.

Batterman AR, Cook PM, Lodge KB, Lothenbach DB, Butterworth BC (1989). Methodology used for a laboratory determination of relative contributions of water, sediment and food chain routes of uptake for 2,3,7,8-TCDD bioaccumulation by lake trout in Lake Ontario. *Chemosphere* vol. 19 issue 1-6 1989. p. 451-458. RMA ID 61193

77. This study
 - was a long-term laboratory exposure study of lake trout to Lake Ontario sediment and smelt (eaten by trout), designed to investigate the rates of TCDD uptake via water, sediment, and food under simulated Lake Ontario conditions.
 - provided comprehensive bioaccumulation relationships for TCDD.
 - developed innovative methods of preparing sediment, dosing sediment, preparing food and feeding the fish.
 - Results indicated that bioaccumulation of TCDD occurs primarily through the food chain and secondarily through contact with contaminated sediment.
 - The water exposure route, even under simulated equilibrium conditions, and low suspended solids concentrations, did not appear to make a significant contribution to 2,3,7,8-TCDD bioaccumulation.

Council Comment

78. The Council considered that whilst this was an experimental study and did not touch on the contended association with diabetes or any health outcomes, it was useful in that it touched on the issue of measuring exposure to dioxin contamination.
79. The Council considered that the study casts doubt on contamination through water exposure compared to the food chain, which was found to be the primary source of contamination. It indicated against the likelihood of surface water that fed into the distillation process on the ships being contaminated.
80. The Council concluded that the study provided some evidence against the contention relating to contamination in distilled water.

COUNCIL'S SUMMARY OF THE EVIDENCE IN RELATION TO POTABLE WATER AND DIABETES

81. The Council noted that the available literature does not directly address the question in contention.
 - One international review (**IOM Blue Water** report) attempted to address the question of whether sailors in Vung Tau were exposed to significant levels of dioxins in potable water. The only relevant study identified by the Blue Water review was the **Mueller et al** (2002) study. However, the data from the **Mueller et al** were not sufficient for the reviewers to draw conclusions, and the **Blue Water Committee** concluded that there was insufficient evidence.
 - The Council carefully examined the **Mueller** (2002) paper but considered that the study did not address the contended association with diabetes, nor did the paper ascertain what level of dilution of dioxin would have occurred in the distilled potable water (See [65]).
 - The Council identified two primary exposure papers (**Baughman & Meleson, 1973** and **Batterman et al 1989**), which were also incorporated into the evidence from the **Mueller (2002)** and '**Blue Water**' papers. It considered that the **Batterman** study showed that the methods of the **Baughman** fish study were not useful for estimating exposure of the sailors, and did not provide sufficient evidence that the Vung Tau sailors received high levels of exposure. Further, these papers provided no evidence regarding diabetes.

THE COUNCIL'S CONCLUSIONS ON ARTICLES TOUCHING ON THE APPLICANT'S CONTENTIONS

82. Having reviewed the sound medical-scientific evidence, the Council recognised that there was limited scientific evidence of a dioxin-diabetes link for direct exposure to dioxins at high dose levels.
83. The Council weighed up all the sound medical-scientific information in the pool, including by reference to epidemiological principles. It concluded that the sound medical-scientific evidence did not raise a reasonable hypothesis regarding the contended exposure to TCDD through water on ships (as defined in scope at [14]).²⁰ That is, the sound medical-scientific evidence was **insufficient** to amend the Statements of Principles.
84. Diabetes has become a very common disease, and the subject of intense research. Nevertheless, the attribution of diabetes incidence to exposures in potable water goes beyond the data as currently available.
85. The Council considered therefore that any amendment to the Statements of Principles would go beyond the evidence.

DECISION

86. The Council made the declarations set out in **paragraphs 1 and 2** above.

NEW INFORMATION

Council's view on the New Information submitted by the Commissions

87. The Council noted that the Commissions had identified seven additional studies that were unavailable to the RMA at the relevant times. These studies may further weaken the aggregate of evidence in support of the association between dioxins and diabetes. The studies are listed in **Appendix C Table 3**, along with two further new studies noted by the Council.
88. The Council recommends that the RMA notes the new studies presented by the Commissions, in future.

²⁰ See also Appendix C paragraph 22.